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Dietary advice with or without oral nutritional supplements for disease-related malnutrition in adults (Review)

Baldwin C, de van der Schueren MAE, Kruizenga HM, Weekes CE

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Cochrane Database of Systematic Reviews 2021, Issue 12. Art. No.: CD002008.

DOI: [10.1002/14651858.CD002008.pub5](https://doi.org/10.1002/14651858.CD002008.pub5).

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Dietary advice with or without oral nutritional supplements for disease-related malnutrition in adults (Review)

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TABLE OF CONTENTS

ABSTRACT	1
PLAIN LANGUAGE SUMMARY	2
SUMMARY OF FINDINGS	4
BACKGROUND	15
OBJECTIVES	16
METHODS	16
Figure 1.	20
RESULTS	24
Figure 2.	25
Figure 3.	47
Figure 4.	54
Figure 5.	59
Figure 6.	66
Figure 7.	72
DISCUSSION	76
AUTHORS' CONCLUSIONS	80
ACKNOWLEDGEMENTS	81
REFERENCES	83
CHARACTERISTICS OF STUDIES	115
DATA AND ANALYSES	322
Analysis 1.1. Comparison 1: Dietary advice compared with no advice, Outcome 1: Mortality	327
Analysis 1.2. Comparison 1: Dietary advice compared with no advice, Outcome 2: Number of people admitted or readmitted to hospital	328
Analysis 1.3. Comparison 1: Dietary advice compared with no advice, Outcome 3: Length of hospital stay (days)	328
Analysis 1.4. Comparison 1: Dietary advice compared with no advice, Outcome 4: Complications	329
Analysis 1.5. Comparison 1: Dietary advice compared with no advice, Outcome 5: Change in weight (kg)	330
Analysis 1.6. Comparison 1: Dietary advice compared with no advice, Outcome 6: Change in BMI (kg/m ²)	331
Analysis 1.7. Comparison 1: Dietary advice compared with no advice, Outcome 7: Change in fat-free mass (kg)	331
Analysis 1.8. Comparison 1: Dietary advice compared with no advice, Outcome 8: Change in mid-arm circumference (cm)	332
Analysis 1.9. Comparison 1: Dietary advice compared with no advice, Outcome 9: Change in mid-arm muscle circumference (cm)	333
Analysis 1.10. Comparison 1: Dietary advice compared with no advice, Outcome 10: Change in triceps skinfold thickness (mm)	334
Analysis 1.11. Comparison 1: Dietary advice compared with no advice, Outcome 11: Change in energy intake (kcal)	335
Analysis 1.12. Comparison 1: Dietary advice compared with no advice, Outcome 12: Final energy intake (kcal)	335
Analysis 1.13. Comparison 1: Dietary advice compared with no advice, Outcome 13: Change in protein intake (g)	336
Analysis 1.14. Comparison 1: Dietary advice compared with no advice, Outcome 14: Final protein intake (g)	336
Analysis 1.15. Comparison 1: Dietary advice compared with no advice, Outcome 15: Change in grip strength (kg force)	337
Analysis 1.16. Comparison 1: Dietary advice compared with no advice, Outcome 16: Change in global QoL	338
Analysis 1.17. Comparison 1: Dietary advice compared with no advice, Outcome 17: QoL - change in physical function	339
Analysis 1.18. Comparison 1: Dietary advice compared with no advice, Outcome 18: QoL - change in mental function	340
Analysis 1.19. Comparison 1: Dietary advice compared with no advice, Outcome 19: QoL - change in social function	341
Analysis 1.20. Comparison 1: Dietary advice compared with no advice, Outcome 20: QoL - change in cognitive function	342
Analysis 1.21. Comparison 1: Dietary advice compared with no advice, Outcome 21: QoL - change in pain	342
Analysis 1.22. Comparison 1: Dietary advice compared with no advice, Outcome 22: QoL - change in energy/fatigue	343
Analysis 2.1. Comparison 2: Dietary advice compared with nutritional supplements, Outcome 1: Mortality	346
Analysis 2.2. Comparison 2: Dietary advice compared with nutritional supplements, Outcome 2: Number of people admitted or readmitted to hospital	347
Analysis 2.3. Comparison 2: Dietary advice compared with nutritional supplements, Outcome 3: Change in weight (kg)	347
Analysis 2.4. Comparison 2: Dietary advice compared with nutritional supplements, Outcome 4: Change in BMI (kg/m ²)	348
Analysis 2.5. Comparison 2: Dietary advice compared with nutritional supplements, Outcome 5: Change in mid-arm muscle circumference (cm)	348

Analysis 2.6. Comparison 2: Dietary advice compared with nutritional supplements, Outcome 6: Change in mid-arm circumference (cm)	349
Analysis 2.7. Comparison 2: Dietary advice compared with nutritional supplements, Outcome 7: Change in triceps skinfold thickness (mm)	349
Analysis 2.8. Comparison 2: Dietary advice compared with nutritional supplements, Outcome 8: Change in energy intake (kcal)	350
Analysis 2.9. Comparison 2: Dietary advice compared with nutritional supplements, Outcome 9: Change in protein intake (g) ..	350
Analysis 2.10. Comparison 2: Dietary advice compared with nutritional supplements, Outcome 10: Change in grip strength (kg force)	351
Analysis 2.11. Comparison 2: Dietary advice compared with nutritional supplements, Outcome 11: Change in global QoL	352
Analysis 2.12. Comparison 2: Dietary advice compared with nutritional supplements, Outcome 12: QoL - change in physical function	352
Analysis 2.13. Comparison 2: Dietary advice compared with nutritional supplements, Outcome 13: QoL - change in mental function	353
Analysis 2.14. Comparison 2: Dietary advice compared with nutritional supplements, Outcome 14: QoL - change in social function	353
Analysis 2.15. Comparison 2: Dietary advice compared with nutritional supplements, Outcome 15: QoL - change in cognitive function	353
Analysis 2.16. Comparison 2: Dietary advice compared with nutritional supplements, Outcome 16: QoL - change in pain	354
Analysis 2.17. Comparison 2: Dietary advice compared with nutritional supplements, Outcome 17: QoL - change in energy/fatigue	354
Analysis 3.1. Comparison 3: Dietary advice compared with dietary advice plus nutritional supplements, Outcome 1: Mortality ..	358
Analysis 3.2. Comparison 3: Dietary advice compared with dietary advice plus nutritional supplements, Outcome 2: Number of people admitted or readmitted to hospital	359
Analysis 3.3. Comparison 3: Dietary advice compared with dietary advice plus nutritional supplements, Outcome 3: Length of hospital stay (days)	359
Analysis 3.4. Comparison 3: Dietary advice compared with dietary advice plus nutritional supplements, Outcome 4: Complications	360
Analysis 3.5. Comparison 3: Dietary advice compared with dietary advice plus nutritional supplements, Outcome 5: Change in weight (kg)	361
Analysis 3.6. Comparison 3: Dietary advice compared with dietary advice plus nutritional supplements, Outcome 6: Change in BMI (kg/m ²)	362
Analysis 3.7. Comparison 3: Dietary advice compared with dietary advice plus nutritional supplements, Outcome 7: Change in fat free mass (kg)	362
Analysis 3.8. Comparison 3: Dietary advice compared with dietary advice plus nutritional supplements, Outcome 8: Change in mid-arm muscle circumference (cm)	363
Analysis 3.9. Comparison 3: Dietary advice compared with dietary advice plus nutritional supplements, Outcome 9: Change in triceps skinfold thickness (mm)	363
Analysis 3.10. Comparison 3: Dietary advice compared with dietary advice plus nutritional supplements, Outcome 10: Change in energy intake (kcal)	364
Analysis 3.11. Comparison 3: Dietary advice compared with dietary advice plus nutritional supplements, Outcome 11: Final energy intake (kcal/day)	364
Analysis 3.12. Comparison 3: Dietary advice compared with dietary advice plus nutritional supplements, Outcome 12: Change in protein intake (g)	365
Analysis 3.13. Comparison 3: Dietary advice compared with dietary advice plus nutritional supplements, Outcome 13: Final protein intake (g/day)	365
Analysis 3.14. Comparison 3: Dietary advice compared with dietary advice plus nutritional supplements, Outcome 14: Change in grip strength (kg force)	365
Analysis 3.15. Comparison 3: Dietary advice compared with dietary advice plus nutritional supplements, Outcome 15: Change in global QoL	366
Analysis 3.16. Comparison 3: Dietary advice compared with dietary advice plus nutritional supplements, Outcome 16: QoL - change in physical function	366
Analysis 3.17. Comparison 3: Dietary advice compared with dietary advice plus nutritional supplements, Outcome 17: QoL - change in mental function	367
Analysis 3.18. Comparison 3: Dietary advice compared with dietary advice plus nutritional supplements, Outcome 18: QoL - change in social function	367

Analysis 3.19. Comparison 3: Dietary advice compared with dietary advice plus nutritional supplements, Outcome 19: QoL - change in cognitive function	368
Analysis 3.20. Comparison 3: Dietary advice compared with dietary advice plus nutritional supplements, Outcome 20: QoL - change in pain	368
Analysis 3.21. Comparison 3: Dietary advice compared with dietary advice plus nutritional supplements, Outcome 21: QoL - change in energy/fatigue	369
Analysis 4.1. Comparison 4: Dietary advice plus supplements if required compared with no advice, Outcome 1: Mortality	373
Analysis 4.2. Comparison 4: Dietary advice plus supplements if required compared with no advice, Outcome 2: Number of people admitted or readmitted to hospital	374
Analysis 4.3. Comparison 4: Dietary advice plus supplements if required compared with no advice, Outcome 3: Length of hospital stay (days)	375
Analysis 4.4. Comparison 4: Dietary advice plus supplements if required compared with no advice, Outcome 4: Complications ..	375
Analysis 4.5. Comparison 4: Dietary advice plus supplements if required compared with no advice, Outcome 5: Change in weight (kg)	376
Analysis 4.6. Comparison 4: Dietary advice plus supplements if required compared with no advice, Outcome 6: Change in BMI (kg/m ²)	377
Analysis 4.7. Comparison 4: Dietary advice plus supplements if required compared with no advice, Outcome 7: Final BMI (kg/m ²)	377
Analysis 4.8. Comparison 4: Dietary advice plus supplements if required compared with no advice, Outcome 8: Change in fat free mass (kg)	378
Analysis 4.9. Comparison 4: Dietary advice plus supplements if required compared with no advice, Outcome 9: Change in mid-arm circumference (cm)	378
Analysis 4.10. Comparison 4: Dietary advice plus supplements if required compared with no advice, Outcome 10: Change in mid-arm muscle circumference (cm)	379
Analysis 4.11. Comparison 4: Dietary advice plus supplements if required compared with no advice, Outcome 11: Change in triceps skinfold thickness (mm)	379
Analysis 4.12. Comparison 4: Dietary advice plus supplements if required compared with no advice, Outcome 12: Change in energy intake (kcal)	380
Analysis 4.13. Comparison 4: Dietary advice plus supplements if required compared with no advice, Outcome 13: Final energy intake (kcal)	380
Analysis 4.14. Comparison 4: Dietary advice plus supplements if required compared with no advice, Outcome 14: Change in protein intake (g)	381
Analysis 4.15. Comparison 4: Dietary advice plus supplements if required compared with no advice, Outcome 15: Change in grip strength (kg force)	381
Analysis 4.16. Comparison 4: Dietary advice plus supplements if required compared with no advice, Outcome 16: Change in global QoL	382
Analysis 4.17. Comparison 4: Dietary advice plus supplements if required compared with no advice, Outcome 17: Final global QoL	382
Analysis 4.18. Comparison 4: Dietary advice plus supplements if required compared with no advice, Outcome 18: QoL - change in physical function	383
Analysis 4.19. Comparison 4: Dietary advice plus supplements if required compared with no advice, Outcome 19: QoL - change in mental function	383
Analysis 4.20. Comparison 4: Dietary advice plus supplements if required compared with no advice, Outcome 20: QoL - change in social function	384
Analysis 4.21. Comparison 4: Dietary advice plus supplements if required compared with no advice, Outcome 21: QoL - change in cognitive function	384
Analysis 4.22. Comparison 4: Dietary advice plus supplements if required compared with no advice, Outcome 22: QoL - change in pain	384
Analysis 4.23. Comparison 4: Dietary advice plus supplements if required compared with no advice, Outcome 23: QoL - change in energy/fatigue	385
Analysis 5.1. Comparison 5: Dietary advice plus supplements compared with no advice and no supplements, Outcome 1: Mortality	389
Analysis 5.2. Comparison 5: Dietary advice plus supplements compared with no advice and no supplements, Outcome 2: Length of hospital stay (days)	390
Analysis 5.3. Comparison 5: Dietary advice plus supplements compared with no advice and no supplements, Outcome 3: Complications	390

Analysis 5.4. Comparison 5: Dietary advice plus supplements compared with no advice and no supplements, Outcome 4: Change in weight (kg)	391
Analysis 5.5. Comparison 5: Dietary advice plus supplements compared with no advice and no supplements, Outcome 5: Change in fat free mass	391
Analysis 5.6. Comparison 5: Dietary advice plus supplements compared with no advice and no supplements, Outcome 6: Change in BMI (kg/m ²)	392
Analysis 5.7. Comparison 5: Dietary advice plus supplements compared with no advice and no supplements, Outcome 7: Final BMI (kg/m ²)	392
Analysis 5.8. Comparison 5: Dietary advice plus supplements compared with no advice and no supplements, Outcome 8: Change in energy intake (kcal)	393
Analysis 5.9. Comparison 5: Dietary advice plus supplements compared with no advice and no supplements, Outcome 9: Final energy intake (kcal)	393
Analysis 5.10. Comparison 5: Dietary advice plus supplements compared with no advice and no supplements, Outcome 10: Change in protein intake	394
Analysis 5.11. Comparison 5: Dietary advice plus supplements compared with no advice and no supplements, Outcome 11: Final protein intake (g/day)	394
Analysis 5.12. Comparison 5: Dietary advice plus supplements compared with no advice and no supplements, Outcome 12: Change in handgrip strength (kg)	395
Analysis 5.13. Comparison 5: Dietary advice plus supplements compared with no advice and no supplements, Outcome 13: Change in global QoL	395
Analysis 5.14. Comparison 5: Dietary advice plus supplements compared with no advice and no supplements, Outcome 14: QoL - change in physical function	396
Analysis 5.15. Comparison 5: Dietary advice plus supplements compared with no advice and no supplements, Outcome 15: QoL - change in mental function	396
Analysis 5.16. Comparison 5: Dietary advice plus supplements compared with no advice and no supplements, Outcome 16: QoL - change in social function	397
Analysis 5.17. Comparison 5: Dietary advice plus supplements compared with no advice and no supplements, Outcome 17: QoL - change in cognitive function	397
Analysis 5.18. Comparison 5: Dietary advice plus supplements compared with no advice and no supplements, Outcome 18: QoL - change in pain	398
Analysis 5.19. Comparison 5: Dietary advice plus supplements compared with no advice and no supplements, Outcome 19: QoL - change in energy/fatigue	398
ADDITIONAL TABLES	398
APPENDICES	420
WHAT'S NEW	452
HISTORY	452
CONTRIBUTIONS OF AUTHORS	454
DECLARATIONS OF INTEREST	455
SOURCES OF SUPPORT	455
DIFFERENCES BETWEEN PROTOCOL AND REVIEW	455
INDEX TERMS	456

[Intervention Review]

Dietary advice with or without oral nutritional supplements for disease-related malnutrition in adults

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Editorial group: Cochrane Cystic Fibrosis and Genetic Disorders Group.

Publication status and date: Edited (no change to conclusions), published in Issue 12, 2021.

Citation: Baldwin C, de van der Schueren MAE, Kruijenga HM, Weekes CE. Dietary advice with or without oral nutritional supplements for disease-related malnutrition in adults. *Cochrane Database of Systematic Reviews* 2021, Issue 12. Art. No.: CD002008. DOI: [10.1002/14651858.CD002008.pub5](https://doi.org/10.1002/14651858.CD002008.pub5).

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ABSTRACT

Background

Disease-related malnutrition has been reported in 10% to 55% of people in hospital and the community and is associated with significant health and social-care costs. Dietary advice (DA) encouraging consumption of energy- and nutrient-rich foods rather than oral nutritional supplements (ONS) may be an initial treatment.

Objectives

To examine evidence that DA with/without ONS in adults with disease-related malnutrition improves survival, weight, anthropometry and quality of life (QoL).

Search methods

We identified relevant publications from comprehensive electronic database searches and handsearching.

Last search: 01 March 2021.

Selection criteria

Randomised controlled trials (RCTs) of DA with/without ONS in adults with disease-related malnutrition in any healthcare setting compared with no advice, ONS or DA alone.

Data collection and analysis

Two authors independently assessed study eligibility, risk of bias, extracted data and graded evidence.

Main results

We included 94, mostly parallel, RCTs (102 comparisons; 10,284 adults) across many conditions possibly explaining the high heterogeneity. Participants were mostly older people in hospital, residential care and the community, with limited reporting on their sex. Studies lasted from one month to 6.5 years.

DA versus no advice - 24 RCTs (3523 participants)

Most outcomes had low-certainty evidence. There may be little or no effect on mortality after three months, RR 0.87 (95% confidence interval (CI) 0.26 to 2.96), or at later time points. We had no three-month data, but advice may make little or no difference to hospitalisations, or days in hospital after four to six months and up to 12 months. A similar effect was seen for complications at up to three months, MD 0.00 (95% CI -0.32 to 0.32) and between four and six months. Advice may improve weight after three months, MD 0.97 kg (95% CI 0.06 to 1.87) continuing at four to six months and up to 12 months; and may result in a greater gain in fat-free mass (FFM) after 12 months, but not earlier. It may also improve global QoL at up to three months, MD 3.30 (95% CI 1.47 to 5.13), but not later.

DA versus ONS - 12 RCTs (852 participants)

All outcomes had low-certainty evidence. There may be little or no effect on mortality after three months, RR 0.66 (95% CI 0.34 to 1.26), or at later time points. Either intervention may make little or no difference to hospitalisations at three months, RR 0.36 (95% CI 0.04 to 3.24), but ONS may reduce hospitalisations up to six months. There was little or no difference between groups in weight change at three months, MD -0.14 kg (95% CI -2.01 to 1.74), or between four to six months. Advice (one study) may lead to better global QoL scores but only after 12 months. No study reported days in hospital, complications or FFM.

DA versus DA plus ONS - 22 RCTs (1286 participants)

Most outcomes had low-certainty evidence. There may be little or no effect on mortality after three months, RR 0.92 (95% CI 0.47 to 1.80) or at later time points. At three months advice may lead to fewer hospitalisations, RR 1.70 (95% CI 1.04 to 2.77), but not at up to six months. There may be little or no effect on length of hospital stay at up to three months, MD -1.07 (95% CI -4.10 to 1.97). At three months DA plus ONS may lead to fewer complications, RR 0.75 (95% CI 0.56 to 0.99); greater weight gain, MD 1.15 kg (95% CI 0.42 to 1.87); and better global QoL scores, MD 0.33 (95% CI 0.09 to 0.57), but this was not seen at other time points. There was no effect on FFM at three months.

DA plus ONS if required versus no advice or ONS - 31 RCTs (3308 participants)

Evidence was moderate- to low-certainty. There may be little or no effect on mortality at three months, RR 0.82 (95% CI 0.58 to 1.16) or at later time points. Similarly, little or no effect on hospitalisations at three months, RR 0.83 (95% CI 0.59 to 1.15), at four to six months and up to 12 months; on days in hospital at three months, MD -0.12 (95% CI -2.48 to 2.25) or for complications at any time point. At three months, advice plus ONS probably improve weight, MD 1.25 kg (95% CI 0.73 to 1.76) and may improve FFM, 0.82 (95% CI 0.35 to 1.29), but these effects were not seen later. There may be little or no effect of either intervention on global QoL scores at three months, but advice plus ONS may improve scores at up to 12 months.

DA plus ONS versus no advice or ONS - 13 RCTs (1315 participants)

Evidence was low- to very low-certainty. There may be little or no effect on mortality after three months, RR 0.91 (95% CI 0.55 to 1.52) or at later time points. No study reported hospitalisations and there may be little or no effect on days in hospital after three months, MD -1.81 (95% CI -3.65 to 0.04) or six months. Advice plus ONS may lead to fewer complications up to three months, MD 0.42 (95% CI 0.20 to 0.89) (one study). Interventions may make little or no difference to weight at three months, MD 1.08 kg (95% CI -0.17 to 2.33); however, advice plus ONS may improve weight at four to six months and up to 12 months. Interventions may make little or no difference in FFM or global QoL scores at any time point.

Authors' conclusions

We found no evidence of an effect of any intervention on mortality. There may be weight gain with DA and with DA plus ONS in the short term, but the benefits of DA when compared with ONS are uncertain. The size and direction of effect and the length of intervention and follow-up required for benefits to emerge were inconsistent for all other outcomes. There were too few data for many outcomes to allow meaningful conclusions. Studies focusing on both patient-centred and healthcare outcomes are needed to address the questions in this review.

PLAIN LANGUAGE SUMMARY

Advice on diet for adults with malnutrition that is the result of disease

Review question

Can dietary advice with or without oral nutritional supplements (ONS) improve disease-related malnutrition in adults?

Background

Ill people often have a poor appetite or feel sick because of medicines or other treatments and eat less than usual. Eating less over a longer time can cause weight loss, malnutrition, more health problems and death. Healthcare professionals may offer advice about dietary changes to help people to re-establish good eating habits. They might recommend high-protein and high-energy foods so that these people can gain weight and improve their nutrition and general health. It is common for sick people to be offered ONS with or without advice about changing their food intake.

To find the best answer to our review question, we looked for studies that compared five different treatment options: dietary advice compared with no advice; dietary advice compared with ONS; dietary advice plus ONS compared with dietary advice; dietary advice plus ONS if appropriate compared with no dietary advice; and dietary advice plus ONS compared with no dietary advice and no ONS. To make these comparisons fair, we looked for randomised controlled trials (RCTs), where the people taking part had an equal chance (like the flip of a coin) of being in either group that was being compared.

Search date

The evidence is current to: 01 March 2021.

Study characteristics

We found 94 studies (with a total of 10,284 people) that we could include in our review. Although older people have a higher risk of malnutrition, the people in these studies ranged from 17 to over 80 years of age and they were living either at home, in the community, or in hospital. They had a wide range of health conditions, including cancer, dementia and kidney disease. The studies reported on the participants for the length of their hospital stay or in some people in the community for up to six and a half years.

Key results

There is no evidence that any of the treatments affected how long many of the people in the studies lived. They did report some positive changes in energy intake (measured in calories), protein intake, weight, muscle bulk and quality of life. There were some reductions in complications and the length of time spent in hospital. However, there is no clear evidence about which treatment is the most helpful or the time it takes to achieve any benefit. Few studies reported results separately for men and women and so we cannot comment on whether there were any overall differences by sex. No studies recorded information about adverse events (harms) so we cannot offer a summary about possible harms.

More research is needed to work out the best ways to help people who are losing weight because of illness in order to improve their clinical outcomes and quality of life.

Certainty of the evidence

Overall we rated the certainty of the evidence as low for most results, which means that we cannot be confident about the findings we report. There were several reasons for this. Some of the treatment comparisons that we looked at had only a few studies and some of those had small numbers of participants. There were problems with the design of some studies that may have affected the results. Some people knew which treatment they were receiving. We think this may influence the way that they reported some changes, e.g. their energy and protein intake, body weight and quality of life. We think that the way the decision about which group a person went into at the start of the study may have affected the results for some outcomes, e.g. change in weight, change in muscle bulk and mortality.

We needed to see particular results to help us understand whether adults living with disease-related malnutrition can improve their survival, weight and general quality of life if they receive advice about diet with or without ONS. None of the studies reported all of the results that we needed to do this. We were not able to estimate whether participants gain any benefits from the treatments, such as shortening the length of hospital stay, lowering the risk of readmission to hospital or developing complications. The low certainty of evidence, with no evidence in many areas, means we cannot make statements about any benefits and the possible disadvantages of these treatments despite the fact they are being used extensively in clinical practice. We recommend that future studies should be designed to measure these important patient-centred and healthcare outcomes as well as any potential harms.

SUMMARY OF FINDINGS

Summary of findings 1. Dietary advice compared with no advice for disease-related malnutrition in adults

Dietary advice compared with no advice for disease-related malnutrition in adults

Patient or population: adults with disease-related malnutrition

Settings: all healthcare settings

Intervention: dietary advice

Comparison: no advice

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Certainty of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	No advice	Dietary advice				
Mortality Follow-up: up to 3 months	67 per 1000	58 per 1000 (17 to 198)	RR 0.87 (0.26 to 2.96)	574 (7 studies)	⊕⊕⊕⊕ low^{a,b}	The results at all other time points also suggest there may be little or no difference between dietary advice and no advice.
Number of people admitted or readmitted to hospital Follow-up: up to 3 months	See comments.		NA	NA	NA	The results at 4 to 6 months and 12 months and over suggest there may be little or no difference between dietary advice and no advice.
Length of hospital stay (days) Follow-up: up to 3 months	The mean length of hospital stay in the no dietary advice group was 13.5 days.	The mean length of hospital stay in the dietary advice group was 1.10 days lower (1.35 days lower to 0.85 days lower).	NA	148 (1 study)	⊕⊕⊕⊕ low^{c,d}	The results at 4 to 6 months and 12 months and over suggest there may be little or no difference between dietary advice and no advice.

Complications	The mean number of complications in the no dietary advice group was 1.2.	The mean difference in the number of complications in the dietary advice group was 0.00 higher (0.32 lower to 0.32 higher).	NA	148 (1 study)	⊕⊕⊕⊕ low^{c,d}	The results at 4 to 6 months suggest there may be little or no difference between dietary advice and no advice.
Follow-up: up to 3 months						
Change in weight (kg)	The mean change in weight in the no dietary advice group ranged from -2.0 kg to 1.32 kg.	The mean change in weight in the dietary advice group was 0.97 kg higher (0.06 kg higher to 1.87 kg higher).	NA	802 (10 studies)	⊕⊕⊕⊕ low^{e,f}	The results at all other time points also suggest dietary advice may improve weight gain.
Follow-up: up to 3 months						
Change in fat-free mass (kg)	The mean change in fat-free mass in the no dietary advice group was -0.14 kg.	The mean change in fat-free mass in the dietary advice group was 0.29 kg higher (0.11 kg lower to 0.69 kg higher).	NA	98 (2 studies)	⊕⊕⊕⊕ low^{d,g}	The results at 4 to 6 months also suggest there may be little or no difference between dietary advice and no advice. However, results at 12 months and over suggest that dietary advice may increase fat-free mass.
Follow-up: up to 3 months						
Change in global QoL score	The mean change in global QoL score in the no dietary advice group ranged from -19.0 to 2.9.	The mean change in global QoL score in the dietary advice group was 3.30 higher (1.47 higher to 5.13 higher).	NA	421 (5 studies)	⊕⊕⊕⊕ low^{g,h}	The results at all other time points suggest there may be little or no difference between dietary advice and no advice.
Follow-up: up to 3 months						

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% CI) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
CI: confidence interval; **QoL:** quality of life; **RR:** risk ratio.

GRADE Working Group grades of evidence

High certainty: further research is very unlikely to change our confidence in the estimate of effect.

Moderate certainty: further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Low certainty: further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Very low certainty: we are very uncertain about the estimate.

a. Downgraded once due to imprecision caused by low event rates.

b. Downgraded once due to indirectness; the studies included in this outcome look at mortality in different disease groups. Most of the deaths occurred in one study where the disease was cancer of the gastro-intestinal tract and the results may not be applicable across different diseases.

c. Downgraded once due to risk of bias in the single included trial for this outcome particularly across the domains of sequence generation and allocation concealment.

d. Downgraded once due to imprecision caused by small sample size which doesn't meet the optimal information size.

- e. Downgraded once due to indirectness: the studies included in this outcome look at different disease groups and the results of these studies may not be generalisable to other disease groups.
- f. Downgraded once due to heterogeneity: I² value was 88%.
- g. Downgraded once due to risk of bias across several domains but particularly around randomisation and allocation concealment.
- h. Downgraded once due to risk of bias within the included trials from concerns around blinding. Although it is not possible to blind this kind of intervention, knowledge of allocation could affect how participants score themselves with regard to QoL.

Summary of findings 2. Dietary advice compared with oral nutritional supplements for disease-related malnutrition in adults

Dietary advice compared with nutritional ONS for disease-related malnutrition in adults

Patient or population: adults with disease-related malnutrition

Settings: all healthcare settings

Intervention: dietary advice

Comparison: nutritional ONS

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Certainty of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Nutritional ONS	Dietary advice				
Mortality Follow-up: up to 3 months	74 per 1000	49 per 1000 (25 to 93)	RR 0.66 (0.34 to 1.26)	576 (8 studies)	⊕⊕⊕⊖ low^{a,b}	The results at all other time points also suggest there may be little or no difference between dietary advice and nutritional ONS.
Number of people admitted or re-admitted to hospital Follow-up: up to 3 months	115 per 1000	41 per 1000 (5 to 373)	RR: 0.36 (0.04 to 3.24)	50 (1 study)	⊕⊕⊕⊖ low^{a,c}	The results for 4 to 6 months suggest nutritional ONS may reduce the number of people admitted or re-admitted to hospital.
Length of hospital stay (days)	Not reported.		NA	NA	NA	

Complications	Not reported.		NA	NA	NA	
Change in weight (kg) Follow-up: up to 3 months	The mean change in weight in the nutritional ONS group ranged from 0 kg to 3.2 kg.	The mean change in weight in the dietary advice group was 0.14 kg lower (2.01 kg lower to 1.74 kg higher).	NA	517 (9 studies)	⊕⊕○○ lowd,f	The results for 4 to 6 months also suggest there may be little or no difference between the 2 groups.
Change in fat-free mass (kg) Follow-up: up to 3 months	Not reported.		NA	NA	NA	
Change in global QoL score Follow-up: up to 3 months	The mean change in global QoL score in the nutritional ONS group ranged from -0.66 to 20.	The mean change in global QoL score in the dietary advice group was 1.26 higher (0.32 lower to 2.85 higher).	NA	283 (4 studies)	⊕⊕○○ lowd,e	The results for 12 months and over suggest dietary advice may improve global QoL scores. The results at all other time points suggest there may be little or no difference between dietary advice and nutritional ONS.

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% CI) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **ONS:** oral nutritional supplements; **QoL:** quality of life; **RR:** risk ratio.

GRADE Working Group grades of evidence

High certainty: further research is very unlikely to change our confidence in the estimate of effect.

Moderate certainty: further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Low certainty: further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Very low certainty: we are very uncertain about the estimate.

a. Downgraded once due to imprecision caused by low event rates or small sample size or a combination of both.

b. Downgraded once due to indirectness; the studies included in this outcome look at mortality in different disease groups. Most of the deaths occurred in one study where the disease was cancer of the gastro-intestinal tract and the results may not be applicable across different diseases.

c. Downgraded due to indirectness; it is not clear whether the results of this single study would be generalisable to other disease groups.

d. Downgraded once due to indirectness; the studies included in this outcome look at different disease groups and the results of these studies may not be generalisable to other disease groups.

- e. Downgraded once due to risk of bias within the included trials from concerns around blinding. Although it is not possible to blind this kind of intervention, knowledge of allocation could affect how participants score themselves with regard to QoL.
f. Downgraded once due to heterogeneity: I² value was 94%.

Summary of findings 3. Dietary advice compared with dietary advice plus oral nutritional supplements for disease-related malnutrition in adults

Dietary advice compared with dietary advice plus nutritional ONS for disease-related malnutrition in adults

Patient or population: adults with disease-related malnutrition

Settings: all healthcare settings

Intervention: dietary advice plus nutritional ONS

Comparison: dietary advice

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Dietary advice	Dietary advice plus nutritional ONS				
Mortality Follow-up: up to 3 months	74 per 1000	68 per 1000 (35 to 133)	RR 0.92 (0.47 to 1.80)	777 (10 studies)	⊕⊕⊕⊕ low^{a,b}	The results for all other time points also suggest there may be little or no difference between the 2 groups.
Number of people admitted or re-admitted to hospital Follow-up: up to 3 months	283 per 1000	481 per 1000 (294 to 784)	RR 1.70 (1.04 to 2.77)	114 (1 study)	⊕⊕⊕⊕ low^{c,d}	The results for 4 to 6 months suggest there is probably no difference between dietary advice with or without nutritional ONS.
Length of hospital stay (days) Follow-up: up to 3 months	The mean length of hospital stay in the dietary advice group was 17.5 days.	The mean length of hospital stay in the dietary advice plus nutritional ONS group was 1.07 days lower (4.10 days lower to 1.97 days higher).	NA	202 (2 studies)	⊕⊕⊕⊕ low^{c,d}	

Complications	417 per 1000	313 per 1000	RR 0.75 (0.56 to 0.99)	317 (3 studies)	⊕⊕⊕⊕ low^{d,e}	The results for 4 to 6 months suggest there may be little or no difference between the 2 groups.
Follow-up: up to 3 months		(234 to 413)				
Change in weight (kg)	The mean change in weight in the dietary advice group ranged from -5.86 kg to 2.2 kg.	The mean change in weight in the dietary advice plus nutritional ONS group was 1.15 kg higher (0.42 kg higher to 1.87 kg higher).	NA	931 (14 studies)	⊕⊕⊕⊕ low^{a,d}	The results for all other time points suggest there may be little or no difference between the 2 groups.
Follow-up: up to 3 months						
Change in fat-free mass (kg)	The mean change in fat-free mass in the dietary advice group ranged from -0.1 kg to 0.9 kg.	The mean change in fat-free mass in the dietary advice plus nutritional ONS group was 0.10 higher (0.18 lower to 0.39 higher).	NA	187 (3 studies)	⊕⊕⊕⊕ low^{c,d}	
Follow-up: up to 3 months						
Change in global QoL score	The mean change in global QoL score in the dietary advice group ranged from -9.55 to 2.0.	The mean change in global QoL score in the dietary advice plus nutritional ONS group was 0.33 higher (0.09 higher to 0.57 higher).	NA	321 (4 studies)	⊕⊕⊕⊕ low^{d,f}	The results for 4 to 6 months suggest there may be little or no difference between the two groups.
Follow-up: up to 3 months						

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% CI) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **ONS:** oral nutritional supplements; **QoL:** quality of life; **RR:** risk ratio.

GRADE Working Group grades of evidence

High certainty: further research is very unlikely to change our confidence in the estimate of effect.

Moderate certainty: further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Low certainty: further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Very low certainty: we are very uncertain about the estimate.

a. Downgraded once due to risk of bias within the included trials; in 4 out of the 10 trials there were concerns around the randomisation process or allocation concealment, or both. All studies had concerns around blinding of outcome assessment.

b. Downgraded once due to indirectness; the studies included in this outcome look at mortality in different disease groups. Most of the deaths occurred in one study where the disease was cancer of the gastro-intestinal tract and the results may not be applicable across different diseases.

c. Downgraded once due to imprecision caused by small sample size which does not reach the optimum information size.

- d. Downgraded once due to indirectness as it is unclear whether the results are generalisable to other disease groups.
- e. Downgraded once due to inconsistency; there is some heterogeneity in both the magnitude and direction of effect ($I^2 = 58\%$).
- f. Downgraded once due to risk of bias within the included trials from concerns around blinding. Although it is not possible to blind this kind of intervention, knowledge of allocation could affect how participants score themselves with regard to QoL.

Summary of findings 4. Dietary advice plus supplements if required compared with no advice for disease-related malnutrition in adults

Dietary advice plus ONS if required compared with no advice for disease-related malnutrition in adults

Patient or population: adults with disease-related malnutrition

Settings: all healthcare settings

Intervention: dietary advice plus ONS

Comparison: no advice

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	No advice	Dietary advice plus ONS				
Mortality Follow-up: up to 3 months	105 per 1000	86 per 1000 (61 to 122)	RR 0.82 (0.58 to 1.16)	1261 (15 studies)	⊕⊕⊕⊖ low^{a,b}	The results for all other time points also suggest there may be little or no difference between groups.
Number of people admitted or re-admitted to hospital Follow-up: Up to 3 months	385 per 1000	320 per 1000 (227 to 443)	RR 0.83 (0.59 to 1.15)	673 (7 studies)	⊕⊕⊕⊖ moderate^c	The results for all other time points also suggest there may be little or no difference between groups.
Length of hospital stay (days) Follow-up: up to 3 months	The mean length of hospital stay in the no dietary advice group ranged from 2.5 days to 18.6 days.	The mean length of hospital stay in the dietary advice plus ONS group was 0.12 days lower (2.48 days lower to 2.25 days higher).	NA	400 (3 studies)	⊕⊕⊕⊖ low^{c,d}	

Complications	265 per 1000	148 per 1000	RR 0.56 (0.22 to 1.46)	280 (2 studies)	⊕⊕⊕⊕ low^{c,d}	The results for 7 to 12 months also suggest there may be little or no difference between groups
Follow-up: up to 3 months		(58 to 387)				
Change in weight (kg)	The mean change in weight in the no dietary advice group ranged from -4.7 kg to 1.6 kg.	The mean change in weight in the dietary advice plus ONS group was 1.25kg higher (0.73 kg higher to 1.76 kg higher).	NA	1192 (17 studies)	⊕⊕⊕⊕ moderate^c	The results for all other time points suggest there may be little or no difference between groups.
Follow-up: up to 3 months						
Change in fat-free mass (kg)	The mean change in fat-free mass in the no dietary advice group ranged from -1.4 kg to 0.092 kg.	The mean change in fat-free mass in the dietary advice plus ONS group was 0.82 kg higher (0.35 kg higher to 1.29 kg higher).	NA	262 (4 studies)	⊕⊕⊕⊕ low^{c,e}	The results for 4 to 6 months suggest there may be little or no difference between the two groups.
Follow-up: up to 3 months						
Change in global QoL score	The mean change in global QoL score in the no dietary advice group ranged from -12.6 to 62.	The mean change in global QoL score in the dietary advice plus ONS group was 0.15 higher (0.18 lower to 0.48 higher).	NA	389 (7 studies)	⊕⊕⊕⊕ low^{d,f}	The results for 7 to 12 months suggest dietary advice plus ONS may improve global QoL scores.
Follow-up: up to 3 months						

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% CI) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **ONS:** oral nutritional supplements; **QoL:** quality of life; **RR:** risk ratio.

GRADE Working Group grades of evidence

High certainty: further research is very unlikely to change our confidence in the estimate of effect.

Moderate certainty: further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Low certainty: further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Very low certainty: we are very uncertain about the estimate.

a. Downgraded once due to risk of bias within the included trials; in 7 out of the 14 trials there were concerns around the randomisation process or allocation concealment, or both. All studies had concerns around blinding of outcome assessment.

b. Downgraded once due to indirectness; the studies included in this outcome look at mortality in different disease groups. Most of the deaths occurred in one study where the disease was cancer of the gastro-intestinal tract and the results may not be applicable across different diseases.

c. Downgraded once due to indirectness as it is unclear whether the results are generalisable to other disease groups.

- d. Downgraded once due to risk of bias in the included trials for this outcome; there were particular concerns across the domains of randomisation and allocation concealment.
- e. Downgraded once due to small sample size that does not reach the optimum information size.
- f. Downgraded once due to high risk of bias within the included trials from lack of blinding. Although it is not possible to blind for this type of study, we felt that for this outcome the allocation may have an effect on the subjective QoL.

Summary of findings 5. Dietary advice plus supplements compared with no dietary advice plus no supplements for disease-related malnutrition in adults

Dietary advice plus ONS compared with no dietary advice plus no ONS for disease-related malnutrition in adults

Patient or population: adults with disease-related malnutrition

Settings: all healthcare settings

Intervention: dietary advice plus ONS

Comparison: no dietary advice plus no ONS

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	No dietary advice plus no ONS	Dietary advice plus ONS				
Mortality Follow-up: up to 3 months	76 per 1000	69 per 1000 (42 to 116)	RR 0.91 (0.55 to 1.52)	797 (7 studies)	⊕⊕⊕⊕ low^{a,b}	The results for all other time points also suggest there may be little or no difference between groups.
Number of people admitted or re-admitted to hospital Follow-up: up to 3 months	Outcome not reported.		NA	NA	NA	
Length of hospital stay (days)	The mean length of hospital stay in the no dietary advice plus no ONS group was 13.25 days.	The mean length of hospital stay in the dietary advice plus ONS group was 1.81 days lower (3.65 days lower to 0.04 days higher).	NA	258 (2 studies)	⊕⊕⊕⊕ low^{b,c}	The results from a further study at 4 to 6 months also suggest there may be little or no difference between groups

Follow-up: up to 3 months						
Complications	643 per 1000	270 per 1000	RR 0.42 (0.20 to 0.89)	50 (1 study)	⊕⊕⊕⊕	low^{b,c}
Follow-up: up to 3 months		(128 to 572)				
Change in weight (kg)	The mean change in weight in the no dietary advice plus no ONS group ranged from -0.9 kg to 3.4 kg.	The mean change in weight in the dietary advice plus ONS group was 1.08 kg higher (0.17 kg lower to 2.33 kg higher).	NA	620 (8 studies)	⊕⊕⊕⊕	low^{a,b}
Follow-up: up to 3 months						The results for all other time points suggest that dietary advice plus ONS group may increase weight.
Change in fat-free mass (kg)	The mean change in fat-free mass in the no dietary advice plus no ONS group ranged from -1.01 kg to 2.8 kg.	The mean change in fat-free mass in the dietary advice plus ONS group was 0.26 kg higher (0.09 kg lower to 0.62 kg higher).	NA	130 (3 studies)	⊕⊕⊕⊕	very low^{a,b,c}
Follow-up: up to 3 months						The results for all other time points also suggest there may be little or no difference between groups.
Change in global QoL score	The mean change in global QoL score in the no dietary advice plus no ONS group ranged from 1.86 to 25.	The mean change in global QoL score in the dietary advice plus ONS group was 0.32 higher (0.33 lower to 0.96 higher).	NA	357 (4 studies)	⊕⊕⊕⊕	very low^{a,b,c}
Follow-up: up to 3 months						The results for all other time points also suggest there may be little or no difference between groups.

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% CI) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **ONS:** oral nutritional supplements; **QoL:** quality of life; **RR:** risk ratio.

GRADE Working Group grades of evidence

High certainty: further research is very unlikely to change our confidence in the estimate of effect.

Moderate certainty: further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Low certainty: further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Very low certainty: we are very uncertain about the estimate.

a. Downgraded once due to risk of bias within the included trials, particularly across the domains of randomisation or allocation concealment, or both.

b. Downgraded once due to indirectness as it is unclear whether the results are generalisable to different disease groups.

c. Downgraded once due to imprecision from a small sample size which does not meet the optimum information size.

d. Downgraded twice due to risk of bias within the included trials, particularly across the domains of randomisation or allocation concealment, or both; but for this outcome the effect of not being able to blind participants is more significant as knowledge of the allocation may alter the way they perceive their QoL.

BACKGROUND

Description of the condition

Malnutrition can be defined as “a state resulting from lack of intake or uptake of nutrition that leads to altered body composition (decreased fat-free mass) and body cell mass leading to diminished physical and mental function and impaired clinical outcome from disease” (de van der Schueren 2019). Malnutrition can arise from a single cause such as the disease or from a combination of psychological and social conditions which act as co-factors in the development or exacerbation of ill health. The general diagnosis of malnutrition has subgroups of aetiology-based types of malnutrition: disease-related malnutrition with inflammation, disease-related malnutrition without inflammation, and malnutrition or undernutrition without disease (Cederholm 2016). Subclassifications of malnutrition are crucial for the understanding of the related complexities and to plan treatment.

Clinically significant malnutrition consists of nutritional deficits that have serious adverse effects on the treatment and outcome of disease (Cederholm 2016; Jensen 2010). Malnutrition or being at risk of malnutrition is associated with increased morbidity, mortality and increased length of stay in hospital (Kubrak 2007; McWhirter 1994; Naber 1997; Norman 2008a). In addition, in a large cross-sectional study in older people living in Norway, malnutrition was associated with significant reductions in health-related quality of life (HRQoL) assessed by EQ-5D, with impacts in all the five dimensions seen in men and in usual activities and anxiety and depression in women (Kvamme 2011).

Only recently, consensus-based diagnostic criteria were proposed to facilitate recording of the occurrence of malnutrition in adults. These criteria are based on the minimum phenotypic and etiologic criteria of: significant weight loss; or low body mass index (BMI); or low muscle mass and reduced food intake or its assimilation; or inflammation (Cederholm 2019; Jensen 2019).

In practice, malnutrition varies along a spectrum from mild to severe. The difficulties in defining malnutrition are reflected in the variation in reported prevalence which ranges from 9% to 55% (Braunschweig 1999; Elia 2009; Hanger 1999; Kubrak 2007; McWhirter 1994; Norman 2008a; Peake 1998a; Prieto 1996; Watson 1998; Weekes 1998). Although malnutrition is present in individuals from all disease backgrounds, all ages and in all healthcare settings, older people are more likely to be malnourished than younger people. Those over the age of 80 have a five times higher prevalence of malnutrition than those under 50 years old (Age Concern 2006). A recent systematic review of the prevalence of the nutritional risk among older adults varied by country, by method of defining malnutrition risk, and by healthcare setting (Leij-Halfwerk 2019). For hospital, residential care and community settings high malnutrition risk among older adults was prevalent in 28.0% 17.5% and 8.5% of individuals, respectively.

A substantial proportion of disease-related malnutrition occurs and is managed in a community setting. Although the prevalence of malnutrition in the community is lower than in institutions, at any one time the greatest number of malnourished people are living in their own home. Between 5% and 10% of older people are malnourished and malnutrition prevalence rates may increase to

35% in older people receiving home care (Guigoz 1997; McCormack 1997; Schilp 2012).

The management of disease-related malnutrition is likely to be different in areas of food security from its management in poorer parts of the world where there may be less food security, although the mechanisms of any effects seen may be similar. The focus of this review is the management of disease-related malnutrition in high-income countries, where food insecurity is less likely to be an issue for sectors of the population. In this update of our review we have included studies from low- and middle-income countries, where malnutrition was studied in relation to disease. When the term malnutrition is used throughout this review, it is intended to refer to undernutrition and not overnutrition or obesity.

Description of the intervention

Malnutrition is largely unrecognised despite the potentially adverse consequences for individuals and the implications for healthcare resources (Bavelaar 2008; Khalatbari-Soltani 2018; McWhirter 1994). There are no internationally accepted protocols for nutritional intervention in the management of disease-related malnutrition. People who are identified as malnourished in hospital and in the community may be considered for referral to a dietitian. In routine clinical practice the poor nutritional status of many individuals is not recognised and many do not receive any advice (McWhirter 1994; Peake 1998a; Volkert 2010). Dietitians are uniquely qualified to provide appropriate interventions such as diet instruction and intensive nutritional support, but there is no theoretical reason to believe that other health professionals could not give effective dietary advice. The provision of dietary advice is a core dietetic skill, but it is not known whether it is effective at increasing nutrient intake and weight or influencing function and outcome. A range of dietetic strategies is commonly used to promote weight gain and improve the nutritional status of a malnourished individual. These include:

- advice to increase food intake (e.g. increase portion size, add food items in the form of snacks, nourishing drinks, side dishes and desserts);
- advice to modify food constituents to increase the energy density (food fortification);
- the provision of ONS without dietary advice; and
- a combination of advice to increase to food intake and the provision of ONS.

How the intervention might work

We think that the intervention will work by increasing nutritional intake which will then translate to improvements in nutritional status and other outcomes. There is an assumption underpinning the use of interventions to increase nutritional intake that they have equal efficacy, but in practice their use might be influenced by other factors. ONS are usually nutritionally complete, available on prescription and easy to use. However, individuals' willingness to incorporate these frequently sweet-tasting drinks in their daily intake may be adversely influenced by the monotony of taste and sensory-specific satiety. A number of studies highlight problems with the use of ONS and the monitoring of people taking them (Bruce 2003; Gosney 2003; Keele 1997; Munro 1998; Peake 1998b); adherence to ONS has been reported to vary (Hubbard 2012). In addition, ONS are expensive to the healthcare system.

Food is often preferred in the first line management of malnutrition. Food is considered to have practical advantages because it is familiar to patients, can be varied in type, texture and flavour and is cheaper to healthcare providers. However, advice to change aspects of food intake might represent a significant burden to people who are ill and their carers. It is reasonable to presume that any benefits from ONS reflect their functional contribution to an increased nutrient intake (or balance of nutrients). It follows that if a similar increase in nutrient intake can be achieved by dietary means rather than using ONS, it is reasonable to expect similar clinical benefits. However, we do not know which nutrient or combination of nutrients in ONS is responsible for any benefits (protein, energy, vitamins, trace elements) and it may not be possible to modify food intake to produce comparable changes to those achieved with ONS. It is infeasible to replicate interventions because studies of dietary advice rarely report the details of specific foods and combinations of foods used to increase nutrient intake. It is commonly overlooked that individuals may need support from health professionals to implement the necessary behaviour change to achieve an increase in intake, whether from food or ONS. We urge future authors to include a full description of any behaviour change models in their publications, along with any underpinning mechanisms.

Why it is important to do this review

The health and social care costs for people with malnutrition are thought to be three to four times higher than for non-malnourished individuals (Guest 2011), estimated to be GBP 19.6 billion in the UK (Elia 2015), with at least GBP 5 billion of that directly attributed to healthcare costs (Wilson 2013), USD 157 billion in the USA (Snider 2014) and EUR 120 billion in Europe (Ljungqvist 2010). Fuller implementation of the NICE guideline (NICE 2006) and accompanying quality standard (QS24) have been estimated to have the potential to result in cost savings, with effective recognition and treatment of malnutrition and continuity of management across healthcare being key to achieving these goals (Elia 2015). In the UK, National Health Service expenditure on nutritional prescribing is growing. In 2018/19 the cost of nutritional prescribing in primary care was around GBP 358 million of which GBP 150 million (42%) was accounted for by ONS (NHS BSA). Increased awareness of nutrition and active marketing by manufacturers may have contributed to the increased use of ONS. Additional or increased food intake resulting from targeted dietary advice to increase nutritional intake and weight has potential advantages in that it offers greater variety, can be tailored to individual eating habits and additional costs are not met by the health services, although people who are unwell may have some difficulties with shopping and the preparation of food. The increasing costs of ONS in the UK have resulted in enhanced scrutiny of prescribing practices and the encouragement of a 'food first' policy in many areas (NICE 2012).

There is limited evidence to support the hypothesis that food-based interventions and ONS have equal efficacy in managing disease-related malnutrition. Although more than 30 systematic reviews have examined the efficacy of ONS in the management of illness-related malnutrition, there is considerable discordance in the findings for similar outcomes (Baldwin 2021) and there remain uncertainties about whether ONS in routine care can improve outcomes. A retrospective data analysis of the impact of ONS on inpatient outcomes across multiple clinical conditions, including 1.2 million episodes of ONS use, found that ONS was associated

with decreased length of hospital stay, episode cost, and 30-day risk for readmission. Cost savings were impressive, with a return on investment of USD 52.63 in immediate net episode cost savings and USD 2.56 net savings due to averted 30-day readmissions for every USD spent on ONS in the matched sample (Philipson 2013). A serious limitation of this analysis was its retrospective nature and the fact that detailed health and nutrition information was not available.

The evidence for food-based approaches to the management of malnutrition is limited. A systematic review of use of fortified foods and snacks in hospitalised older patients suggested benefits to energy and protein intake, as well as finding good acceptability and evidence of cost-effectiveness (Mills 2018). A recent pooled data-analysis of dietary counselling, ONS, or both in older adults with disease-related malnutrition suggested that dietary counselling combined with ONS was the most effective way to achieve a positive effect on body weight and energy intake (Reinders 2019). No effects were shown, however, for other relevant clinical outcomes. The data in this analysis were from only nine out of 38 eligible studies and should be interpreted with caution. It is widely recommended that improving nutritional intake using foods and beverages is the first step in the process of providing nutritional support and that ONS are a second step in the process which may be appropriate for some people. The evidence base for ONS has been extensively reviewed, whereas that relating to dietary advice given with or without ONS has received relatively little attention. It may be possible to increase oral nutritional intake in a number of different ways and it is important to clarify the role and efficacy of each method as the service, staffing and financial resource implications differ.

OBJECTIVES

To examine the effects of dietary advice alone given by a dietitian or other healthcare professional to adults at nutritional risk of or living with disease-related malnutrition compared with:

1. no advice;
2. the prescription of ONS; or
3. dietary advice ONS.

Also to examine the effects of:

1. dietary advice plus ONS if required compared with no advice and no prescription of ONS; or
2. dietary advice plus ONS compared with no advice and no prescription of ONS.

METHODS

Criteria for considering studies for this review

Types of studies

All randomised controlled trials (RCTs) and quasi-RCTs.

Types of participants

Adults over 16 years of age with disease-related malnutrition or described as at nutritional risk by the study investigator or judged to be at nutritional risk by the review authors due to their clinical condition or clinical treatment or both. We considered studies conducted in all healthcare settings

We excluded studies carried out in pregnant women or people with eating disorders and in conditions of food insufficiency (inadequate availability of food in a whole or part of a country meaning that the population are at risk of famine).

Types of interventions

Dietary advice was defined as instruction in the modification of food intake given with the aim of improving nutritional intake by a dietitian or other healthcare professional; ONS was defined as a whole protein enteral food supplement which is marketed as a clinical product for the management of disease-related malnutrition and taken for any period of time

1. dietary advice compared with no advice;
2. dietary advice compared with ONS;
3. dietary advice compared with dietary advice plus ONS;
4. dietary advice plus ONS if required compared with no advice and no ONS
5. dietary advice and prescription of an ONS compared with no advice and no ONS.

The second comparison includes studies that examined the efficacy of the two different active interventions .

The third comparison includes studies that aimed to explore whether there was additional benefit to giving ONS with dietary advice.

We added a fourth comparison post hoc in response to an additional group of studies that we identified during searching and study identification for the 2004 update. We consider these studies relevant to our review as they examine dietary advice compared with no advice, but the dietary advice includes information on using ONS if considered necessary. In our experience, this style of providing dietary advice most closely reflects how dietary advice is given in practice.

We added the fifth comparison post hoc at the 2021 update and in response to closer scrutiny of the studies of dietary advice plus ONS if required. It became clear that studies for this comparison were falling into two distinct groups. In the first group we saw that ONS were used in addition to dietary advice in only some participants, and this intervention was distinguished by the frequent use of the phrase "if judged appropriate". We identified a second group of studies, where dietary advice and ONS were given to all participants from the start. These two groups comprise the fifth comparison that we have added to this updated review.

We excluded studies of ONS with novel ingredients, e.g. arginine, glutamine and omega-3 fatty acids and elemental and semi-elemental ONS, where the constituents are present in their simplest form. These products are address specialised situations and were judged to be beyond the scope of this review.

Where studies of dietary advice also included escalation of intervention to include enteral and parenteral feeding, studies have only been included if additional feeding was received by 10% or fewer of included participants or if results for participants receiving dietary advice with or without ONS were presented separately.

Types of outcome measures

We have assessed the following primary and secondary outcome measures.

Primary outcomes

1. Mortality
2. Morbidity (assessed by risk of hospital admission or readmission and length of hospital stay and complications)
3. Measures of nutritional status and body composition
 - a. change in weight
 - b. BMI
 - c. fat-free mass (FFM)
 - d. mid-arm circumference (MAC)
 - e. mid-arm muscle circumference (MAMC)
 - f. triceps skinfold thickness (TSF)

Secondary outcomes

1. Nutritional intake before and after the intervention
2. Measures of clinical function (e.g. immune function, cardiac function, respiratory function and other indices of nutritional status)
3. Quality of life (QoL) assessed using validated scales (e.g. EORTC, EQ-5D, SF-36)
4. Cost

Search methods for identification of studies

The authors searched for all relevant published or unpublished studies irrespective of publication status (e.g. abstract or online study report) or language. Full text articles describing the results of RCTs were included in the review.

Electronic searches

The Cochrane Cystic Fibrosis and Genetic Disorders Group's Information Specialist conducted a search of the Group's Trials Register for relevant studies using the following terms: ((diet* OR malnutrition* OR nutrition* OR food* OR feed* OR eat*):TI,KW,AB,MH,EMT) AND ((behavio* OR supplement* OR advice OR advise* OR counsel* OR educat* OR guide OR guidance OR personal* OR program OR programme OR support*):TI,KW,AB,MH,EMT).

The Trials Register is compiled from electronic searches of the Cochrane Central Register of Controlled Trials (CENTRAL) (updated each new issue of the Cochrane Library), weekly searches of MEDLINE, a search of Embase to 1995 and the prospective handsearching of two journals - *Pediatric Pulmonology* and the *Journal of Cystic Fibrosis*. Unpublished work is identified by searching through the abstract books of three major cystic fibrosis conferences: the International Cystic Fibrosis Conference; the European Cystic Fibrosis Conference and the North American Cystic Fibrosis Conference. For full details of all searching activities for the register, please see the relevant sections of the Cystic Fibrosis and Genetic Disorders Group [website](#).

Date of the most recent search of the Group's Trials Register: 03 March 2021.

We also searched the following databases and study registries; please see the appendices for the previous and current search

strategies ([Appendix 1](#); [Appendix 2](#); [Appendix 3](#); [Appendix 4](#); [Appendix 5](#)):

- Cochrane Central Register of Controlled Trials (CENTRAL; 2021, Issue 3) in the Cochrane Library (searched 01 March 2021);
- MEDLINE Ovid (1946 to 10 January 2020);
- Embase Ovid (1974 to 10 January 2020);
- CINAHL EBSCO (Cumulative Index to Nursing and Allied Health Literature; 1982 to 10 January 2020);
- AMED Ovid (Allied and Complementary Medicine; 1985 to 30 June 2005), not searched for this update as authors do not have access;
- National Cancer Institute CancerLit (1999 to 30 June 2005), database no longer available;
- ISI Web of Science (1898 to 10 January 2020);
- Scopus (1823 to 10 January 2020);
- ERIC (searched 1966 to 1998), not searched for this update as authors do not have access;
- Dissertation Abstracts (1861 to July 2000), not searched for this update as authors do not have access;
- US National Institutes of Health Ongoing Trials Register Clinicaltrials.gov (www.clinicaltrials.gov; searched 03 March 2021);
- World Health Organization International Clinical Trials Registry Platform (WHO ICTRP) (apps.who.int/trialsearch; not searched in 2021 as unavailable due to Covid-19).

Searching other resources

We assessed the bibliographies of all retrieved studies and any relevant systematic reviews identified for additional reports of relevant studies. We identified all articles that met the inclusion criteria on [PubMed](#) and using the 'Related articles' feature, we carried out a further search out for additional articles, including newly published articles (Snowball searching).

We identified additional studies from electronic searches carried out by the National Collaborating Centre for Acute Care undertaken in the production of a guideline on nutrition support in adults ([NICE 2006](#)).

We sought unpublished work by contacting experts in clinical nutrition and the membership of the British Dietetic Association in 1999. We contacted the manufacturers of ONS for information on additional studies in 1999. In 1999, we contacted the group of dietitians conducting handsearching of nutrition-based journals to identify RCTs for inclusion in the *Cochrane Library*, before undertaking any additional handsearching.

The authors did not undertake any additional handsearching for the 2021 update.

Data collection and analysis

Selection of studies

Until the update in 2007, one author (CB) reviewed the titles and abstracts from each search on-screen and two authors (CB, TP) obtained the full-text of any potentially relevant studies and assessed these independently against the inclusion criteria. They resolved their differences by discussion and where necessary by consultation with a third author (SL). For the 2007 and 2011

updates, two authors (CB, EW) carried out the study selection. For the 2021 update, four authors (CB, MvdS, HK, EW) reviewed titles and abstracts from searches on-screen, obtained potentially relevant studies and assessed these against the review's inclusion criteria.

The authors recorded abstracts that described the findings of potentially relevant RCTs as 'Studies awaiting classification' to be added once data are available from study investigators or a full-text paper is available.

Data extraction and management

Until the update in 2007 two authors (CB, TP) independently extracted data from all papers obtained. They resolved their differences by discussion and where necessary by consultation with a third author (SL). For the updates in 2007 and 2011, two authors (CB, EW) carried out independent data extraction as for previous updates. For the 2021 update, four authors (CB, MvdS, HK, EW) carried out the data extraction process.

Since the authors sought papers with no restriction on language, they obtained the translation of any relevant non-English papers. They assessed data from inclusion in the study to the end of intervention at the following time points: up to three months; four to six months; seven to 12 months and over 12 months.

For data to be entered into meta-analyses of continuous outcomes (weight, energy intake, etc.), the review authors require sufficient information to allow the derivation of a mean change with standard deviation (SD) for both the intervention and comparison groups; for meta-analyses of dichotomous outcomes (death, hospital admissions) they require the number of participants who experienced the event of interest and the total number in the group. These data have either been available from the paper or the authors have obtained these from the study investigators where possible. Unfortunately for a number of outcomes the review authors have not been able to obtain data in a format that they can enter into a meta-analysis. The review authors performed calculations to obtain the data they required (see [Description of studies](#) for full details).

Six studies reported data for more than one intervention group that met the inclusion criteria for this review or the authors subdivided them according to characteristics of participants. In order to facilitate the inclusion of these data in the meta-analyses, they created duplicate study IDs ([Macia 1991a](#); [Macia 1991b](#); [Macia 1991c](#); [Pedersen 2016a](#); [Pedersen 2016b](#); [Sharma 2002a](#); [Sharma 2002b](#)).

Assessment of risk of bias in included studies

In earlier versions of the review, the review authors assessed the methodological quality of the included studies based on a method described by Schulz ([Schulz 1995](#)). This assessment included an examination of the method of randomisation, whether the study was blinded and whether investigators recorded the number of participants lost to follow-up or excluded from the study.

In the current version of the review, the review authors have assessed the risk of bias for each study for each of the criteria below as high risk of bias, unclear risk of bias or low risk of bias as described in the *Cochrane Handbook for Systematic Reviews of Interventions* ([Higgins 2011](#)). They assessed the generation of the

randomisation sequence and allocation concealment as low risk of bias, unclear risk of bias, or high risk of bias; they recorded the blinding of outcome assessment as reported (low risk of bias), unclear (unclear risk of bias) or not reported (high risk of bias) separately for clinical, functional and nutritional outcomes and as an overall judgement for all outcomes. Other sources of bias that the review authors considered were the reporting of complete

outcome data (accounting for all participants randomised in the study), avoidance of selective reporting of outcome variables and the inclusion of a comparison of baseline variables as well as recording information on any variables not similar at baseline. See 'Risk of bias tables' for details of individual studies ([Characteristics of included studies](#)) ([Figure 1](#)).

Figure 1. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding (performance bias and detection bias): Clinical outcomes	Blinding (performance bias and detection bias): Functional outcomes	Blinding (performance bias and detection bias): Nutritional outcomes	Blinding of participants and personnel (performance bias): All outcomes	Blinding of outcome assessment (detection bias): All outcomes	Incomplete outcome data (attrition bias): All outcomes	Selective reporting (reporting bias)	Other bias
Akpele 2004	?	?	+	?	-	-	?	?	-	+
Alo 2014	+	+	+	?	+	+	+	+	?	?
Anbar 2014	+	+	-	-	-	-	-	+	?	+
Andersson 2017	+	+	+	+	+	-	+	+	?	+
Arnold 1989	?	?	+	?	-	-	?	+	-	+
Baldwin 2011	+	+	+	-	-	-	?	?	+	?
Banks 2016	+	+	+	-	-	-	?	+	?	+
Beattie 2000	+	+	+	?	-	-	?	+	?	?
Beck 2012	+	+	+	-	-	-	-	+	+	+
Beck 2015	+	+	+	-	-	-	?	+	?	+
Berneis 2000	+	?	+	?	?	-	?	?	-	?
Bonilla-Palomas 2016	?	+	+	?	+	-	?	-	+	+
Bourdel-Marchasson 2014	+	+	+	-	-	-	?	+	?	+
Burden 2011	+	+	+	?	-	-	?	+	?	?
Burden 2017	+	+	+	+	+	-	?	-	?	?
Caccialanza 2015	+	?	+	-	-	-	?	-	+	+
Calegari 2011	?	?	+	?	?	-	?	-	?	+
Campbell 2008	+	+	+	-	-	-	?	+	+	?
Cano-Torres 2017	+	?	+	?	+	-	?	+	?	+
Carey 2013	+	?	?	+	+	-	+	+	?	?
Casals 2015	?	?	+	+	+	-	+	+	?	+
Chandra 1985	?	?	+	-	-	-	?	?	-	?
de Luis 2003	+	+	+	-	-	-	?	+	?	+

Figure 1. (Continued)

Chandra 1985	?	?	+	-	-	-	?	?	-	?
de Luis 2003	+	+	+	-	-	-	?	+	?	+
de Sousa 2012	?	?	+	-	-	-	?	+	?	+
Diouf 2016	+	+	?	-	-	-	-	+	+	+
Dixon 1984	?	?	+	-	-	-	?	?	?	?
Endevelt 2011	?	?	+	-	-	-	?	?	+	+
Evans 1987	+	+	+	-	-	-	?	+	?	+
Feldblum 2011	-	-	+	+	+	-	+	-	?	+
Fernandez-Barres 2017	+	+	+	-	-	-	?	+	+	+
Forli 2001	+	?	+	-	-	-	?	+	?	?
Forster 2012	+	+	+	?	-	-	?	+	+	?
Fuenzalida 1990	?	?	+	-	?	-	?	+	?	+
Ganzoni 1994	+	+	+	+	+	-	+	+	?	?
Gonzalez-Espinoza 2005	+	+	+	+	+	-	+	+	?	+
Gray-Donald 1995	?	+	+	+	-	-	?	+	?	?
Gu 2015	-	?	+	?	+	+	+	?	?	+
Hampson 2003	?	+	+	-	-	-	?	+	?	?
Hernandez 2014	+	+	+	?	-	-	?	-	?	?
Holyday 2012	+	?	+	+	?	+	+	?	?	+
Huynh 2015	+	+	+	?	-	-	?	+	+	?
Imes 1988	?	+	+	?	-	-	?	?	?	?
Isenring 2004	+	+	+	-	-	-	?	+	?	+
Jahnavi 2010	?	+	+	?	?	-	?	+	?	+
Jensen 1997	?	+	+	-	-	-	?	-	?	?
Kalnins 2005	-	-	+	-	-	-	?	+	?	?
Kapoor 2017	+	?	+	-	-	-	?	+	?	+
Kendell 1982	?	?	?	?	?	-	?	+	-	?
Kiss 2016	?	?	?	-	-	-	-	+	+	+
Kunvik 2018	+	+	?	?	-	-	?	?	-	+
Le Cornu 2000	?	+	+	-	-	-	?	+	-	+
Locher 2013	?	?	?	?	?	-	?	?	?	?
Lovik 1996	+	+	+	-	-	-	?	+	?	+
Macia 1991a	+	?	+	?	-	-	?	?	?	?
Macia 1991b	+	?	+	?	-	-	?	?	?	?
Macia 1991c	+	?	+	?	-	-	?	?	?	?
Manguso 2005	+	+	+	?	+	-	?	+	?	+
McCarthy 1999	+	+	?	?	-	-	-	-	?	?
Moloney 1983	?	?	+	?	-	-	?	?	?	?
Murphy 1992	-	-	+	-	-	-	?	-	?	?
Neelemaat 2011	+	+	+	-	-	-	?	+	?	+
Norman 2008b	+	+	+	-	-	-	?	+	?	+
Olejko 1984	?	?	+	-	-	-	?	+	-	?
Ollenschlager 1992	?	?	+	?	?	-	?	+	-	+
Ovesen 1993	+	+	+	-	?	-	?	?	?	+
Parsons 2016	+	+	+	-	-	-	?	+	?	?
Paton 2004	+	+	+	?	?	-	?	+	?	+
Payette 2002	?	?	+	+	-	-	?	+	?	+

Figure 1. (Continued)

Paton 2004	+	+	+	?	?	-	?	+	?	+
Payette 2002	?	?	+	+	-	-	?	+	?	+
Pedersen 2016a	+	+	?	+	+	-	+	?	+	+
Pedersen 2016b	+	+	?	+	+	-	+	+	+	+
Persson 2002	+	+	+	?	-	-	?	+	?	+
Persson 2007	?	+	+	-	-	-	?	-	?	?
Pivi 2011	?	?	+	?	+	-	+	+	?	?
Rabeneck 1998	?	?	?	-	-	-	-	+	?	+
Ravasco 2005a	+	+	+	?	?	-	?	+	?	?
Ravasco 2005b	+	+	+	?	?	-	?	+	?	?
Rogers 1992	?	?	+	-	?	-	?	+	?	+
Rydwik 2008	?	?	+	?	-	-	?	+	?	+
Salva 2011	?	?	+	-	+	-	?	+	+	-
Schilp 2013	+	+	+	-	-	-	?	+	+	+
Schwenk 1999	+	+	+	-	-	-	?	+	?	+
Sharma 2002a	?	?	+	-	+	-	?	?	?	-
Sharma 2002b	?	?	+	-	-	-	?	?	-	-
Sharma 2017	+	+	+	+	+	-	+	+	-	+
Silvers 2014	+	+	+	-	-	-	?	-	?	?
Singh 2008	+	+	+	+	+	-	+	+	?	+
Starke 2011	+	?	+	+	-	-	?	+	?	+
Stow 2015	+	+	+	-	-	-	?	?	+	-
Suominen 2015	+	?	+	-	-	-	?	+	-	+
Terp 2018	+	+	+	-	-	-	?	+	+	+
Tu 2013	?	?	?	?	-	-	?	?	-	?
Um 2014	?	?	+	?	?	-	?	+	?	+
Uster 2013	?	?	+	-	-	-	?	+	?	?
Vivanti 2015	+	+	+	-	-	-	?	+	?	?
Weekes 2009	+	+	+	-	-	-	?	+	+	+
Wilson 2001	?	?	+	?	-	-	?	?	-	?
Wong 2004	+	+	+	?	-	-	?	?	?	+
Wyers 2013	+	?	+	+	-	-	?	+	-	+

For a number of studies the review authors have set up duplicate study IDs for analysis purposes, i.e. where they present multiple data sets from a single study within the same comparison (Macia 1991a; Macia 1991b; Macia 1991c; Pedersen 2016a; Pedersen 2016b; Sharma 2002a; Sharma 2002b), below they report on just one of these study IDs in the text but the risk of bias judgements apply to the whole study.

In the original review and updates up until 2007, two authors (CB, TP) independently assessed the methodological quality of each study. For the 2011 and 2021 updates respectively, two authors (CB, EW) and four authors (CB, MvdS, HK, EW) respectively assessed the risk of bias as described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). The authors recorded the results of this assessment in the risk of bias tables for the following domains:

- sequence generation;

- allocation concealment;
- blinding;
- incomplete outcome data;
- selective reporting;
- other potential sources of bias.

The authors additionally scrutinised cluster RCTs for recruitment bias, baseline imbalance, loss of clusters, incorrect analysis, and comparability with individually randomised studies or different types of clusters and recorded the findings under “other potential sources of bias”.

For incomplete outcome data, where it was possible the review authors assessed the attrition rates in the different intervention or control groups and if the difference was at least 20%, they considered this to constitute a high risk of bias.

Measures of treatment effect

For continuous outcomes, such as change in weight, the authors combined the data across studies using a mean difference (MD) and 95% confidence intervals (CIs) (Review Manager 2014). When different measurement scales were used, then the review authors considered whether a meaningful combined analysis was possible, e.g. by using standardised mean difference (SMD). They used the SMD to combine data on the following outcomes:

- Complications — in Group 1 (dietary advice compared with no advice) as different validated tools were used to collect data for this outcome (Analysis 1.4);
- FFM — in Group 1, Group 3 (dietary advice compared with dietary advice plus an ONS) and Group 5 (dietary advice and prescription of an ONS compared with no advice and no ONS) as data on both FFM and body cell mass were combined in the same analysis (Analysis 1.7; Analysis 3.7; Analysis 5.5); and
- QoL for all groups as data were collected using different validated questionnaires (Analysis 1.16; Analysis 1.17; Analysis 1.18; Analysis 1.19; Analysis 1.20; Analysis 1.21; Analysis 1.22; Analysis 2.11; Analysis 2.12; Analysis 2.13; Analysis 2.14; Analysis 2.15; Analysis 2.16; Analysis 2.17; Analysis 3.15; Analysis 3.16; Analysis 3.17; Analysis 3.18; Analysis 3.19; Analysis 3.20; Analysis 3.21; Analysis 4.16; Analysis 4.17; Analysis 4.18; Analysis 4.19; Analysis 4.20; Analysis 4.21; Analysis 4.22; Analysis 4.23; Analysis 5.13; Analysis 5.14; Analysis 5.15; Analysis 5.16; Analysis 5.17; Analysis 5.18; Analysis 5.19).

Cohen's rules have been used to interpret the magnitude of the SMD as follows: small SMD=0.2; medium SMD=0.5; and a large SMD=0.8 as described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011).

For binary outcomes, such as mortality, the authors combined the data from the studies using risk ratios (RR) and 95% CIs.

Unit of analysis issues

Where the review authors identified studies with non-standard designs such as cross-over RCTs and cluster RCTs, they took into account the level at which randomisation occurred. They could not recalculate data taking into account the design effect for cluster RCTs because they did not have reliable information about intra-cluster correlation coefficients for the substantially heterogeneous populations in the included studies. Therefore, where meta-analyses included both parallel and cluster RCTs the authors have taken this into consideration when accounting for any heterogeneity identified. For cross-over studies, they included data in the meta-analyses from baseline to the end of phase 1 of the cross-over. They did not use data from phase 2 of cross-over studies because of the anticipation of substantial carryover effects.

Dealing with missing data

In order to allow an intention-to-treat analysis, the review authors sought data on the number of participants, by allocated treatment group for each outcome, irrespective of adherence to group allocation and whether or not the participant was later thought to be ineligible.

Where the published study reports did not present relevant data, the review authors contacted study investigators for these data.

Where data were available on baseline and follow-up measurements, the review authors calculated the mean change and then imputed SDs from studies judged to be similar for the mean change using a correlation coefficient of 0.8 assuming there was a strong correlation between baseline and follow-up measurements or where calculation was not possible (Higgins 2011).

Assessment of heterogeneity

The authors examined differences between the results of the studies for heterogeneity using the Chi² test, by inspecting the results of the meta-analysis and by using the I² statistic (Higgins 2003). The authors used a P value of less than 0.1 rather than less than 0.05 as evidence of statistical heterogeneity. The I² statistic describes the percentage of total variation across studies that is due to heterogeneity rather than chance (Higgins 2003). The values of I² lie between 0% and 100%, and a simplified categorisation of heterogeneity that the authors used is:

- 0 to 30% — no heterogeneity;
- 30% to 40% — no to moderate heterogeneity;
- 40% to 50% — moderate heterogeneity;
- 50% to 60% — moderate to substantial heterogeneity;
- 60% to 75% — substantial heterogeneity;
- over 75% — considerable heterogeneity.

In all analyses with a heterogeneity of 50% or greater the authors planned to explore the clinical characteristics of studies included in the analysis for an explanation and report on this in the results section.

Assessment of reporting biases

The review authors scrutinised studies to ensure that all the outcome variables stated in the 'Methods' section were presented in the 'Results' section of the published reports. They also compared final papers to published protocols where these were available.

They assessed risk of publication bias and considered that there were sufficient studies (greater than 10) to undertake this for the outcome change in weight at up to three months. Using STATA, they assessed the risk of bias using the asymmetry of the funnel plot, the regression asymmetry test (Egger 1997) and the adjusted rank correlation (Begg 1994).

Data synthesis

The review authors judged that the included studies addressed a range of different participants and interventions, but these were related by a common aim of the intention to improve nutritional intake, therefore, the authors utilised the random-effects model using the Mantel-Haenszel method for all analyses to account for these differences.

Subgroup analysis and investigation of heterogeneity

In order to investigate any heterogeneity where the I² value is greater than 50%, when the review authors are able to include sufficient studies in this review, they planned to conduct subgroup analyses based on clinical judgement of the factors likely to account for differences in outcome within and between groups as follows:

- underlying clinical condition (e.g. cancer, lung disease, gastrointestinal disease);
- age (under 65 years and over 65 years);
- nutritional status at inclusion in the study (percentage of malnourished participants versus participants at risk of malnutrition); and
- study setting (hospital versus community and mixed).

Malnutrition is a multifactorial condition and previous analyses have demonstrated that no one factor is seminal in making a difference to outcomes. For this reason, in the 2021 updated version of this review, the authors did not conduct formal subgroup analyses but attempted to explain any heterogeneity in individual analyses from scrutiny of the clinical characteristics of studies included in the analyses. Most of the included studies did not report on outcomes by sex or gender and so the authors did not undertake any formal analyses by sex.

Sensitivity analysis

When the review authors were able to combine a sufficient number of studies (10 studies or more) (Higgins 2011), they planned to test the robustness of their results based on the risk of bias of the studies, e.g. according to rigour of randomisation method or RCTs versus quasi-RCTs, and the potential impact of including studies where they had imputed SDs.

Summary of findings and assessment of the certainty of the evidence

In a post hoc change to bring this review in line with current (2021) Cochrane guidance, the authors have introduced summary of findings information for the outcomes listed below, where there was at least one study assessing their chosen outcomes.

1. Mortality
2. Length of stay
3. Hospital readmissions

4. Complications
5. Change in weight
6. FFM
7. QoL

For each outcome they have reported the illustrative risk with and without the intervention, magnitude of effect (RR or MD), numbers of studies and participants addressing each outcome and a grade of the overall certainty of the body of evidence using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) with comments (Schunemann 2006). They have created separate tables for each separate comparison they present.

RESULTS

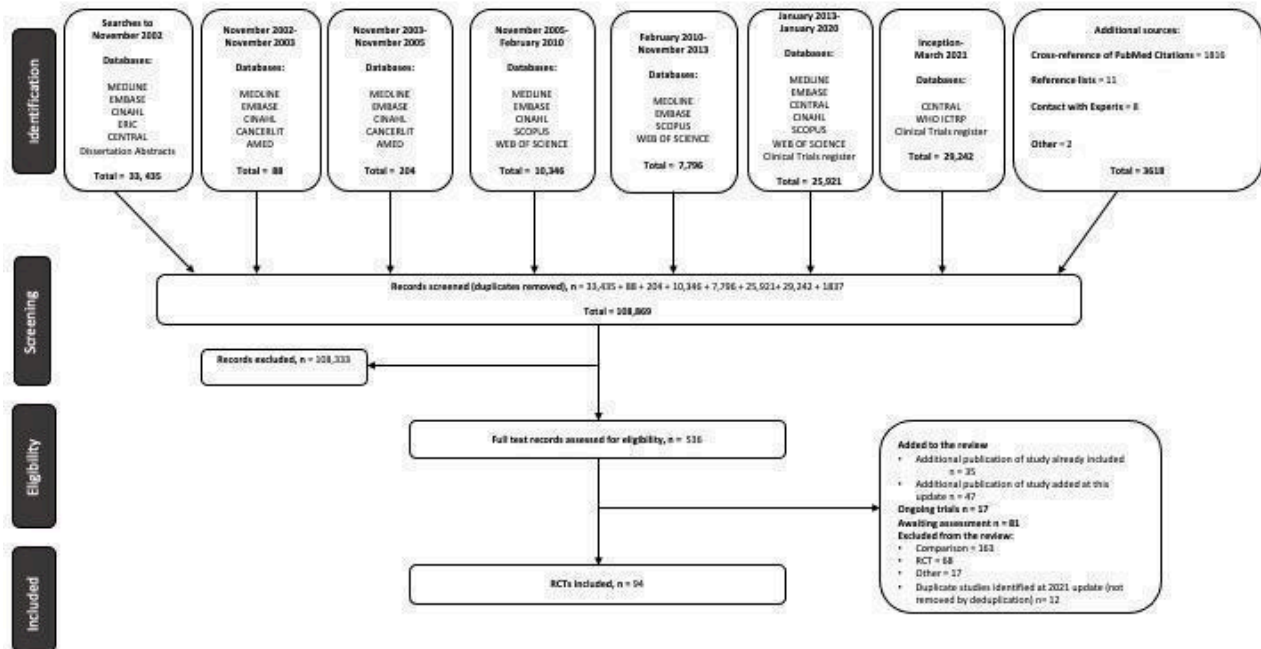
Description of studies

The review authors detail the studies they identified in several tables ([Characteristics of included studies](#); [Characteristics of excluded studies](#); [Characteristics of studies awaiting classification](#); [Characteristics of ongoing studies](#)).

Results of the search

The searches conducted to 2021 identified 536 records which the review authors scrutinised against the inclusion criteria; the process is illustrated in a PRISMA diagram (Figure 2). The authors have included 94 studies (102 comparisons), with 10,284 randomised participants which fulfilled the inclusion criteria for this review (of which 49 studies are new at the 2021 update); they excluded 248 studies ([Characteristics of excluded studies](#)), 81 studies are awaiting classification ([Studies awaiting classification](#)) and they have listed 17 studies potentially relevant to this review as ongoing ([Characteristics of ongoing studies](#)). Searches undertaken for this update identified 35 additional records related to studies already included in the review, mainly clinical study records and conference abstracts, which have been added to the review and 47 additional records related to studies added at this update (Figure 2).

Figure 2.



The review authors have requested additional data on outcomes of interest and on aspects of study quality from 55 study investigators and obtained replies from 45 investigators. For 17 of the studies the investigators were unable to provide the data and information requested (Andersson 2017; Banks 2016; Beck 2015; Berneis 2000; Bourdel-Marchasson 2014; Caccialanza 2015; Carey 2013; Evans 1987; Jensen 1997; Kendell 1982; Murphy 1992; Olejko 1984; Ovesen 1993; Schilp 2013; Sharma 2002a; Silvers 2014; Uster 2013). The review authors did not receive a reply from the investigators of a further nine studies (Arnold 1989; Chandra 1985; Dixon 1984; Macia 1991a; Moloney 1983; Pedersen 2016a; Pedersen 2016b; Rabeneck 1998; Rogers 1992; Wilson 2001).

Six studies reported data for more than one intervention group that met the inclusion criteria for this review or were subdivided according to characteristics of participants. In order to facilitate inclusion of these data in the meta-analyses, duplicate IDs were created as follows (Macia 1991a; Macia 1991b; Macia 1991c; Pedersen 2016a; Pedersen 2016b; Sharma 2002a; Sharma 2002b).

Included studies

Please also see the additional tables which provide summaries of additional clinical outcomes (Table 1), additional functional outcomes (Table 2) and QoL assessments (Table 3) for all included studies across all interventions.

Five studies included comparisons in two parts of the review (Dixon 1984; Pivi 2011; Ravasco 2005a; Ravasco 2005b; Stow 2015) and one study included comparisons in four parts of the review (Baldwin 2011). The participants in the studies were from a variety of clinical backgrounds. The length of intervention varied between studies; 55 (58.6%) of the 94 included studies presented interventions that were given for up to three months, 30 (32%) studies gave the intervention for up to six months and seven (3%) studies gave an

active intervention for seven months or longer. In two of the studies the length of intervention was unclear (Macia 1991a; Tu 2013). The study by Persson appears to describe an intervention that lasts for up to two years (Persson 2002). Data at 3, 6, 12 and 24 months have been used in this review.

28 studies provided data on additional follow-up beyond the intervention for some outcomes for between six months and five years (Arnold 1989; Baldwin 2011; Beck 2012; Beck 2015; Bonilla-Palomas 2016; Bourdel-Marchasson 2014 Burden 2011; Burden 2017; Cano-Torres 2017; de Sousa 2012; Evans 1987; Feldblum 2011; Forster 2012; Holyday 2012; Jahnavi 2010; Kalnins 2005; Le Cornu 2000; Moloney 1983; Neelemaat 2011; Olejko 1984; Paton 2004; Ravasco 2005a; Ravasco 2005b; Rydwick 2008; Starke 2011; Weekes 2009; Wilson 2001; Wyers 2013).

Across the studies, it was originally unclear how grip strength had been measured as the units of measurement were described slightly differently. After consultation with a Professor of Applied Physiology, the review authors have decided that the studies have all reported kg, with some calling it force and others kg force. They have therefore decided to present these data in the analysis with the unit of measurement denoted as kg force.

1. Dietary advice compared with no advice

The review authors identified 24 studies (3523 participants) for this comparison (Alo 2014; Baldwin 2011; Campbell 2008; Cano-Torres 2017; Casals 2015; Dixon 1984; Fernandez-Barres 2017; Forster 2012; Gu 2015; Imes 1988; Kunvik 2018; Locher 2013; Macia 1991a; Manguso 2005; Ollenschlager 1992; Pivi 2011; Ravasco 2005a; Ravasco 2005b; Rydwick 2008; Salva 2011; Stow 2015; Tu 2013; Weekes 2009; Wong 2004), with a paper by Ravasco published in 2012 describing additional follow-up to a median of 6.5 (range 4.9 to 8.1) years from the 2005 study by Ravasco (Ravasco 2005a).

Study design

There were 18 RCTs of parallel design (Baldwin 2011; Campbell 2008; Cano-Torres 2017; Casals 2015; Dixon 1984; Fernandez-Barres 2017; Forster 2012; Imes 1988; Kunvik 2018; Locher 2013; Macia 1991a; Ollenschlager 1992; Pivi 2011; Ravasco 2005a; Ravasco 2005b; Rydwick 2008; Weekes 2009; Wong 2004), two were quasi-RCTs of parallel design (Alo 2014; Gu 2015), one was a cross-over RCT (Manguso 2005), two were cluster-RCTs (Salva 2011; Stow 2015); the review authors were unable to determine the design of one study because there was insufficient detail (Tu 2013). All but one of the included studies were conducted in a single centre; the Baldwin study was multicentre (Baldwin 2011). Studies were globally diverse; the majority (14 out of 24 studies (58%)) were conducted in Europe (Baldwin 2011; Casals 2015; Fernandez-Barres 2017; Forster 2012; Kunvik 2018; Macia 1991a; Manguso 2005; Ollenschlager 1992; Ravasco 2005a; Ravasco 2005b; Rydwick 2008; Salva 2011; Stow 2015; Weekes 2009), three studies were conducted in Asia (Gu 2015; Tu 2013; Wong 2004), three in North America (Dixon 1984; Imes 1988; Locher 2013), two studies in South America (Cano-Torres 2017; Pivi 2011), and one each in Africa (Alo 2014) and Australia (Campbell 2008). The source of funding was reported in 16 studies (Baldwin 2011; Campbell 2008; Casals 2015; Dixon 1984; Fernandez-Barres 2017; Forster 2012; Gu 2015; Imes 1988; Kunvik 2018; Locher 2013; Pivi 2011; Ravasco 2005a; Ravasco 2005b; Salva 2011; Stow 2015; Weekes 2009). Of these, 12 obtained funding from educational or charitable grants and four included some commercial funding. Three studies declared some funding from a company making commercial nutritional products (Forster 2012; Pivi 2011; Stow 2015) and one study was funded by Nestec Ltd. (Salva 2011). The duration of the intervention ranged from the length of hospital stay (Cano-Torres 2017; Gu 2015), up to three months (Baldwin 2011; Campbell 2008; Forster 2012; Locher 2013; Ravasco 2005a; Ravasco 2005b; Rydwick 2008), four to six months (Alo 2014; Casals 2015; Dixon 1984; Fernandez-Barres 2017; Imes 1988; Kunvik 2018; Manguso 2005; Ollenschlager 1992; Pivi 2011; Stow 2015; Weekes 2009; Wong 2004) and 12 months (Salva 2011). Two studies did not report clear information on the length of the intervention (Macia 1991a; Tu 2013). Seven studies included an additional follow-up period beyond the end of the intervention (Baldwin 2011; Cano-Torres 2017; Forster 2012; Ravasco 2005a; Ravasco 2005b; Rydwick 2008; Weekes 2009); these ranged from three months (Forster 2012; Ravasco 2005a; Ravasco 2005b) to a median of 6.5 (range 4.9 to 8.1) years (Ravasco 2005a).

Participants

The largest study included 946 participants (Salva 2011) and the smallest enrolled 19 participants (Dixon 1984).

The majority of studies included older participants with a mean age ranging from 57 years (Cano-Torres 2017) to 76 years (Wong 2004). Three studies included younger adults; the participants in one study had a mean age of 34 to 35 years (Alo 2014) and two studies involved participants as young as 17 years (Imes 1988; Ollenschlager 1992).

20 studies reported the sex of participants; in four of these there were fewer (less than 45%) females than males overall (Baldwin 2011; Campbell 2008; Dixon 1984; Gu 2015) and in two studies this was the case in the intervention group only (Forster 2012; Manguso 2005). In 10 studies there were more (over 55%) females than males (Alo 2014; Cano-Torres 2017; Fernandez-Barres 2017; Kunvik 2018; Locher 2013; Pivi 2011; Ravasco 2005a; Salva 2011; Stow 2015;

Wong 2004); in three of these there were over 82% females (Locher 2013; Stow 2015; Wong 2004). The remaining studies included approximately equal numbers of males and females (45% to 55%). The age of participants was reported in 22 out of 24 studies as either mean (SD) age, median (interquartile (IQR) range), a range or as a single figure (over 75 years in one study (Rydwick 2008)).

The participants in studies had a wide variety of clinical conditions. Six studies were in people with cancer (Baldwin 2011; Dixon 1984; Macia 1991a; Ravasco 2005a; Ravasco 2005b; Tu 2013), five were in older people (Fernandez-Barres 2017; Forster 2012; Locher 2013; Rydwick 2008; Stow 2015), in one of which participants were in residential care (Stow 2015). Three studies enrolled participants from mixed clinical backgrounds (Cano-Torres 2017; Casals 2015; Gu 2015), two were in people with Alzheimer's disease or dementia (Pivi 2011; Salva 2011), one was in people living with HIV infection (Alo 2014), one was in people with Crohn's disease (Imes 1988), one in people at risk of osteoporotic fractures (Wong 2004), one in people with chronic obstructive pulmonary disease (COPD) (Weekes 2009), one in people with liver cirrhosis (Manguso 2005), one in people with chronic kidney disease (Campbell 2008) and one in carers (Kunvik 2018). The study setting varied with three studies beginning the intervention in hospital and continuing it into the community (Cano-Torres 2017; Tu 2013; Wong 2004), two were conducted in hospital only (Gu 2015; Ollenschlager 1992), and the remainder were in outpatients or people living in the community. Three studies involved advice provided to groups of carers and participants via an educational intervention (Fernandez-Barres 2017; Pivi 2011; Salva 2011).

The nutritional status of participants at baseline was assessed in 18 of 24 studies, but the method of assessment varied. Some investigators used validated tools including the SGA, which was used in four studies (Campbell 2008; Ravasco 2005a; Ravasco 2005b; Tu 2013), the Nutrition Risk Score (NRS)- 2002 which was used in two studies (Cano-Torres 2017; Gu 2015), the MNA which was used in three studies (Fernandez-Barres 2017; Kunvik 2018; Salva 2011) and the MUST which was used in two studies (Casals 2015; Stow 2015). The remaining studies assessed nutritional status using combinations of weight loss, BMI and changes in food intake (Alo 2014; Baldwin 2011; Dixon 1984; Locher 2013; Ollenschlager 1992; Rydwick 2008; Weekes 2009). 10 studies reported the BMI of participants at baseline (Alo 2014; Campbell 2008; Cano-Torres 2017; Gu 2015; Kunvik 2018; Manguso 2005; Salva 2011; Stow 2015; Weekes 2009; Wong 2004); the mean BMI was in the normal range in five studies (Alo 2014; Gu 2015; Stow 2015; Weekes 2009; Wong 2004), in the overweight range for four studies (Campbell 2008; Kunvik 2018; Manguso 2005; Salva 2011) and in one study the mean BMI in the intervention (advice) group was in the normal range but participants in the no advice group had a mean BMI in the overweight range (Cano-Torres 2017). Eight studies assessed all participants as malnourished or at nutritional risk (Baldwin 2011; Casals 2015; Dixon 1984; Gu 2015; Ollenschlager 1992; Rydwick 2008; Stow 2015; Weekes 2009), and six studies included some malnourished or at risk participants (Campbell 2008; Kunvik 2018; Locher 2013; Ravasco 2005a; Ravasco 2005b; Salva 2011). The remaining studies did not report how many participants were malnourished.

Interventions

All participants in the intervention group received dietary instruction, but the nature and intensity varied. In 15 out of

24 studies, authors specify that a dietitian delivered the dietary intervention (Baldwin 2011; Campbell 2008; Cano-Torres 2017; Dixon 1984; Imes 1988; Ollenschlager 1992; Ravasco 2005a; Ravasco 2005b; Rydwick 2008; Salva 2011; Stow 2015; Weekes 2009; Wong 2004) or a trained nutritionist (Alo 2014; Kunvik 2018). In three studies nurses gave the intervention (Casals 2015; Dixon 1984; Fernandez-Barres 2017), in one study it was given by doctors from the nutrition and dietetics department (Macia 1991a) and in another study by a postdoctoral researcher (Forster 2012). In three studies the role or occupation of the person delivering the intervention was not stated (Gu 2015; Pivi 2011; Tu 2013). In 14 out of 24 studies, investigators described the intervention as either individualised or personalised (Alo 2014; Campbell 2008; Cano-Torres 2017; Casals 2015; Gu 2015; Imes 1988; Kunvik 2018; Locher 2013; Macia 1991a; Ravasco 2005a; Ravasco 2005b; Rydwick 2008; Tu 2013; Weekes 2009) and one study included an individualised component following group sessions (Fernandez-Barres 2017).

Description of arrangements for follow-up varied with 18 studies incorporating plans for review or monitoring, or both, of participants but the frequency varied from daily follow-up in hospitalised participants with acute leukaemia (Ollenschlager 1992) to three-monthly follow-up in outpatients with Crohn's disease (Imes 1988) and older individuals in residential care (Stow 2015). One study described bi-weekly monitoring (Dixon 1984), three studies used a weekly review (Baldwin 2011; Ravasco 2005a; Ravasco 2005b), three studies monitored on a monthly basis (Alo 2014; Fernandez-Barres 2017; Manguso 2005) and four studies described monitoring and review at varying time intervals throughout the study (Campbell 2008; Casals 2015; Locher 2013; Weekes 2009). Forster stated that investigators conducted follow-up and monitoring at the same interval in both the intervention and control group, but did not report the interval (Forster 2012); and in the study by Wong there was just one additional review following the initial consultation lasting 15 minutes (Wong 2004). Six studies did not describe any plans for review and monitoring (Cano-Torres 2017; Gu 2015; Macia 1991a; Pivi 2011; Tu 2013; Rydwick 2008). One of the studies employed an educational intervention to deliver the dietary advice described a voluntary sign-up system for monitoring (Salva 2011). In one study, follow-up occurred via optional attendance at group discussion and cooking sessions (Kunvik 2018) and in a further study, where the participants received the intervention from case-manager nurses, there was a protocol for monitoring with a decision-tree approach to identify participants who needed referral to a dietitian (Casals 2015).

Outcomes

Not all studies contributed data on all outcomes and data for only some outcomes were available for review authors to enter into the analyses; no study reported on costs. Two studies were unable to contribute data on any outcomes to this review because of how investigators reported data (Dixon 1984; Tu 2013). Additional data were obtained on request from the study investigators or have been derived by imputation (Table 4).

Primary outcomes

Mortality

17 out of 24 studies reported mortality data (Baldwin 2011; Campbell 2008; Cano-Torres 2017; Casals 2015; Dixon 1984; Fernandez-Barres 2017; Imes 1988; Manguso 2005; Ollenschlager 1992; Pivi 2011; Ravasco 2005a; Ravasco 2005b; Rydwick 2008; Salva

2011; Stow 2015; Weekes 2009; Wong 2004); one study reported longer-term follow-up data in a separate paper (Ravasco 2005a). One study did not report mortality by group, so is not included in the analyses (Dixon 1984) and there were no events in five studies (Imes 1988; Manguso 2005; Ravasco 2005a; Ravasco 2005b; Wong 2004).

Morbidity

Investigators used hospital readmissions, length of stay and complications to assess morbidity. Data on the number of people admitted to hospital were available from five studies (Casals 2015; Fernandez-Barres 2017; Imes 1988; Stow 2015; Weekes 2009). However, the study by Casals reported data as mean (SD) admissions per group and mean (SD) days of admission and so the review authors could not combine this with the number of admissions per group data from the other studies. Data on length of hospital stay were available from four studies (Cano-Torres 2017; Casals 2015; Gu 2015; Weekes 2009). Data on complications were available from two studies (Forster 2012; Gu 2015). Complications were self-reported in a symptom diary in one study (Forster 2012) and as a complications score which is part of the NRS-2002 in a further study (Gu 2015). The review authors combined these data using the SMD.

Nutritional status

Data on change in weight were available from 21 studies (Baldwin 2011; Campbell 2008; Casals 2015; Dixon 1984; Fernandez-Barres 2017; Forster 2012; Gu 2015; Imes 1988; Locher 2013; Macia 1991a; Manguso 2005; Ollenschlager 1992; Pivi 2011; Ravasco 2005a; Ravasco 2005b; Rydwick 2008; Salva 2011; Stow 2015; Tu 2013; Weekes 2009; Wong 2004), for change in BMI from 11 studies (Alo 2014; Cano-Torres 2017; Casals 2015; Fernandez-Barres 2017; Forster 2012; Kunvik 2018; Macia 1991a; Pivi 2011; Salva 2011; Stow 2015; Wong 2004), data on change in FFM from three studies (Campbell 2008; Rydwick 2008; Weekes 2009), data on MAC from six studies (Cano-Torres 2017; Forster 2012; Macia 1991a; Pivi 2011; Stow 2015; Weekes 2009), change in MAMC from five studies (Macia 1991a; Manguso 2005; Pivi 2011; Stow 2015; Weekes 2009) and data on change in TSF from six (Forster 2012; Macia 1991a; Manguso 2005; Pivi 2011; Stow 2015; Weekes 2009). The Pivi study reports data as mean and median change with a range; the review authors have not been able to obtain additional data from investigators and the data are not similar enough to other studies for imputation and so are reported narratively (Pivi 2011).

Secondary outcomes

Nutritional outcomes

17 studies provided data on energy intake (Baldwin 2011; Campbell 2008; Fernandez-Barres 2017; Forster 2012; Gu 2015; Imes 1988; Kunvik 2018; Locher 2013; Manguso 2005; Ollenschlager 1992; Ravasco 2005a; Ravasco 2005b; Rydwick 2008; Stow 2015; Tu 2013; Weekes 2009; Wong 2004). Two studies do not report data in a format that allows entry into a meta-analysis (Ollenschlager 1992; Tu 2013); one study reported data as a composite measure (Tu 2013) and the second study reported intake in the intervention group only (Ollenschlager 1992). Furthermore, the Ravasco study reported follow-up data as medians in the 2012 paper (Ravasco 2005a). 12 studies reported the change in energy intake (Baldwin 2011; Campbell 2008; Fernandez-Barres 2017; Forster 2012; Kunvik 2018; Locher 2013; Manguso 2005; Ravasco 2005a; Ravasco 2005b;

Rydwik 2008; Stow 2015; Wong 2004) and three studies analysed final intake values (Gu 2015; Imes 1988; Weekes 2009).

10 studies provided data on the change in protein intake (Campbell 2008; Fernandez-Barres 2017; Forster 2012; Gu 2015; Imes 1988; Kunvik 2018; Manguso 2005; Stow 2015; Weekes 2009; Wong 2004). Manguso reported protein intake as a percentage of energy intake and original data were not available from the author (Manguso 2005). Five studies report the change in protein intake (Fernandez-Barres 2017; Forster 2012; Kunvik 2018; Stow 2015; Wong 2004) and four studies presented final intake values (Campbell 2008; Gu 2015; Imes 1988; Weekes 2009). Ravasco reported the median intake in the 2012 follow-up paper and so these are not included in the meta-analysis (Ravasco 2005a).

Clinical and physical functional outcomes

For the 2021 update, the review authors have summarised the data on handgrip strength in meta-analyses as this is the most frequently reported functional outcome across studies. For this group, two studies provided data on handgrip strength (Stow 2015; Weekes 2009). A summary of other clinical and functional outcomes reported is provided in the additional tables (Table 1; Table 2).

QoL

Seven studies provided data on QoL (Baldwin 2011; Campbell 2008; Casals 2015; Forster 2012; Ravasco 2005a; Ravasco 2005b; Weekes 2009), with one study reporting data collected using both the Short Form-36 (SF-36) and the St George's Respiratory Questionnaire (SGRQ) (Weekes 2009). The review authors have only entered data for global QoL scores into a meta-analysis.

2. Dietary advice compared with ONS

The review authors identified 12 studies (852 participants) for this comparison and obtained additional data from all investigators (Akpele 2004; Baldwin 2011; Gray-Donald 1995; Hernandez 2014; Kalnins 2005; Parsons 2016; Pivi 2011; Ravasco 2005a; Ravasco 2005b; Schwenk 1999; Singh 2008; Stow 2015). The study by Kalnins includes 13 participants, of whom only five are older than 16 years of age; the review authors obtained individual patient data from the lead investigator for inclusion in this review (Kalnins 2005). The 2012 paper by Ravasco described additional study follow-up to a median of 6.5 (range 4.9 to 8.1) years on participants described in an earlier paper (Ravasco 2005a).

Study design

The review authors included 10 RCTs (Akpele 2004; Baldwin 2011; Gray-Donald 1995; Hernandez 2014; Parsons 2016; Pivi 2011; Ravasco 2005a; Ravasco 2005b; Schwenk 1999; Singh 2008), one quasi-RCT (Kalnins 2005), and one was a cluster-RCT (Stow 2015). 11 studies were single-centre and one was multicentre (Baldwin 2011). The majority of studies (seven out of 12 (54%)) were conducted in Europe (Baldwin 2011; Hernandez 2014; Parsons 2016; Ravasco 2005a; Ravasco 2005b; Schwenk 1999; Stow 2015), three were conducted in North America (Akpele 2004; Gray-Donald 1995; Kalnins 2005), one in South America (Pivi 2011) and one in India (Singh 2008). The source of funding was reported in 11 studies (Baldwin 2011; Gray-Donald 1995; Hernandez 2014; Kalnins 2005; Parsons 2016; Pivi 2011; Ravasco 2005a; Ravasco 2005b; Schwenk 1999; Singh 2008; Stow 2015); seven obtained funding from educational or charitable grants, of which three

included some commercial funding or provision of nutritional products from a company making ONS (Baldwin 2011; Pivi 2011; Stow 2015). Companies making nutritional products funded three studies (Kalnins 2005; Parsons 2016; Schwenk 1999).

The duration of the intervention ranged from up to three months (Baldwin 2011; Gray-Donald 1995; Kalnins 2005; Parsons 2016; Ravasco 2005a; Ravasco 2005b; Schwenk 1999; Singh 2008) to four to six months (Akpele 2004; Hernandez 2014; Pivi 2011; Stow 2015). Three studies included an additional follow-up period beyond the end of intervention which varied from three months (Ravasco 2005a; Ravasco 2005b) to 11 months (46 weeks) (Baldwin 2011). Additional follow-up data from one of the studies reported follow up to a median of 6.5 (range 4.9 to 8.1) years (Ravasco 2005a).

Participants

The largest study in this comparison included 176 participants (Baldwin 2011) and the smallest five participants (Kalnins 2005).

In 11 of 12 studies, the age of participants was reported as either mean (SD) age, median (IQR range), a range or as an average without SD or range. Stow did not report age, but the study was conducted in a residential care home, so participants were likely to be in their eighties (Stow 2015). The majority of studies included older participants with a mean (SD) age ranging from 58 (15) years (Ravasco 2005a) to 89.6 (6.9) years (Wong 2004). Three studies involved younger adults (Kalnins 2005; Schwenk 1999; Singh 2008); two studies had participants with a mean age of 28 (10) years to 39.5 (10.2) years (Schwenk 1999; Singh 2008) and the third study included young adults (over 16 years) (Kalnins 2005).

Sex was reported in 10 of 12 studies. In four studies there were fewer females than males overall (less than 45%) (Baldwin 2011; Hernandez 2014; Schwenk 1999; Singh 2008). In the remaining six studies, there were more females than males (over 55%) (Gray-Donald 1995; Kalnins 2005; Parsons 2016; Pivi 2011; Ravasco 2005a; Stow 2015) with two studies including over 85% females (Parsons 2016; Stow 2015) and a third study had solely female participants (Kalnins 2005).

The participants in studies had a wide variety of clinical conditions. Three studies were in people with cancer (Baldwin 2011; Ravasco 2005a; Ravasco 2005b), two in people with chronic kidney disease (Akpele 2004; Hernandez 2014), three were in older people (Gray-Donald 1995; Parsons 2016; Stow 2015), of which two were in older people in residential care (Parsons 2016; Stow 2015), the study by Gray-Donald was in older people living at home. One study was in people with Alzheimer's disease or dementia (Pivi 2011), one was in people living with HIV/AIDS (Schwenk 1999), one was in people with cystic fibrosis (Kalnins 2005) and one in people with chronic pancreatitis (Singh 2008). Most (11 out of 12) studies were in outpatients or people living in the community and one study was in a hospital dialysis unit (Hernandez 2014). One study involved advice provided to groups of carers and participants via an educational intervention (Pivi 2011).

In 12 out of 13 studies, investigators assessed the nutritional status of participants at baseline; the Pivi study did not report the nutritional status of participants at baseline (Pivi 2011). The method of assessment varied. Some investigators used validated tools including the Patient Generated Subjective Global Assessment (PG-SGA) which was used in two studies (Ravasco 2005a; Ravasco 2005b), MNA in one study (Akpele 2004) and

the MUST in two studies (Parsons 2016; Stow 2015). The seven remaining studies used combinations of weight loss and BMI to assess nutritional status (Baldwin 2011; Gray-Donald 1995; Kalnins 2005; Schwenk 1999; Singh 2008), with two studies in people with chronic kidney disease using serum albumin (Akpele 2004; Hernandez 2014). Five studies reported BMI of participants at baseline (Gray-Donald 1995; Hernandez 2014; Schwenk 1999; Singh 2008; Stow 2015); the mean BMI was in the normal range for all groups in two studies (Gray-Donald 1995; Schwenk 1999), in the overweight range in one study (Hernandez 2014) and in the underweight range in one study (Singh 2008). In one study the mean BMI in the dietary counselling group was in the normal range, but participants in the ONS group had a mean BMI in the underweight range (Stow 2015). All participants were assessed as malnourished or at nutritional risk in eight studies (Akpele 2004; Baldwin 2011; Gray-Donald 1995; Kalnins 2005; Parsons 2016; Schwenk 1999; Singh 2008; Stow 2015), and three studies included some malnourished or at risk participants (Hernandez 2014; Ravasco 2005a; Ravasco 2005b). One study did not report on how many participants were malnourished (Pivi 2011).

Interventions

All participants in the intervention groups received either dietary instruction or an ONS but the nature, amount and intensity of support varied. In 11 of 12 studies, the authors specified that the dietary intervention was given by a dietitian and one study did not specify the role or occupation of the person who delivered the training that comprised the dietary instruction (Pivi 2011). Two out of 12 studies described the intervention as either individualised or personalised (Ravasco 2005a; Ravasco 2005b) and one study encouraged nursing staff in the care home to take the preferences of residents into consideration (Stow 2015). Three studies used a specially designed diet sheet to provide information on increasing intake from food (Baldwin 2011; Parsons 2016; Schwenk 1999) and two studies used education sessions to provide dietary information (Hernandez 2014; Pivi 2011). The remaining four studies described encouragement and counselling, but not whether this was standardised or individualised (Akpele 2004; Gray-Donald 1995; Kalnins 2005; Singh 2008). Prescription of ONS varied in terms of the type of supplement used and the amount prescribed. Only two studies failed to specify the amount prescribed, as the prescription was individually tailored to the participants' requirements (Kalnins 2005; Schwenk 1999). The amounts in the remaining studies varied from 360 kcal/day (supplied as two cans of Nepro[®] three days a week during dialysis) in one study (Hernandez 2014) to up to 800 kcal/day (prescribed as one to two cans of Nepro[®] daily) in a further study (Akpele 2004). The majority of studies provided an average of 600 kcal/day from a range of different ONS.

The description of arrangements for follow-up varied, with nine studies incorporating plans for review or monitoring of participants, or both, but the frequency ranged from weekly follow-up (Baldwin 2011; Gray-Donald 1995; Hernandez 2014; Ravasco 2005a; Ravasco 2005b) to three-monthly review of food record charts in people living in residential care (Stow 2015). One study described monitoring at one and three months (Kalnins 2005), another at six weeks (Parsons 2016), and in a further study the monitoring arrangements likely varied by dialysis unit but "dietitians were encouraged to spend extra time each week with their patients reviewing dietary records" (Akpele 2004). Three

studies did not describe any plans for review and monitoring (Pivi 2011; Schwenk 1999; Singh 2008).

Outcomes

Not all studies contributed data on all outcomes and data for only some outcomes were available to enter into the analyses; no study reported on costs. Two studies reported no data relevant to the outcomes of this review, with their primary outcome being change in serum albumin (Akpele 2004; Hernandez 2014). Additional data were obtained on request from the study investigators or have been derived by imputation for some outcomes (Table 5).

Primary outcomes

Mortality

Nine of 12 studies reported mortality data (Baldwin 2011; Gray-Donald 1995; Kalnins 2005; Parsons 2016; Pivi 2011; Ravasco 2005a; Ravasco 2005b; Schwenk 1999; Stow 2015). There were no events in four studies (Kalnins 2005; Ravasco 2005a; Ravasco 2005b; Schwenk 1999).

Morbidity

In this comparison, investigators only assessed morbidity by hospital readmissions and two studies provided data on the number of people admitted to hospital (Schwenk 1999; Stow 2015). While one study mentions collecting data on number of admissions, it does not report the data and the review authors have not been able to contact this investigator (Akpele 2004).

Nutritional status

10 studies provided data on change in weight (Baldwin 2011; Gray-Donald 1995; Kalnins 2005; Parsons 2016; Pivi 2011; Ravasco 2005a; Ravasco 2005b; Schwenk 1999; Singh 2008; Stow 2015), three studies reported change in BMI (Pivi 2011; Singh 2008; Stow 2015), one study provided data on change in FFM (Schwenk 1999), three studies provided data on MAC (Pivi 2011; Singh 2008; Stow 2015), three studies provided data on MAMC (Gray-Donald 1995; Pivi 2011; Stow 2015) and three studies provided data on change in TSF (Gray-Donald 1995; Pivi 2011; Stow 2015). One study reports data as mean and median change with a range and the review authors have not been able to obtain additional data from the study investigators; the data are not similar enough to other studies for imputation and so the review authors report them narratively (Pivi 2011).

Secondary outcomes

Nutritional outcomes

Nine studies provided data on energy intake (Baldwin 2011; Gray-Donald 1995; Kalnins 2005; Parsons 2016; Ravasco 2005a; Ravasco 2005b; Schwenk 1999; Singh 2008; Stow 2015) and six studies on change in protein intake (Parsons 2016; Ravasco 2005a; Ravasco 2005b; Schwenk 1999; Singh 2008; Stow 2015). One study describes the collection of data on energy intake and protein intake, but did not report the results (Akpele 2004). Ravasco reported the 2012 follow-up data for both energy and protein intake as medians which could not be combined in a meta-analysis (Ravasco 2005a).

Clinical and physical functional outcomes

For the 2021 update, the review authors summarised the data on handgrip strength in meta-analyses as this is the most frequently reported functional outcome across studies. Two studies provided data on handgrip strength for this comparison (Gray-Donald 1995; Stow 2015). The review authors have presented a summary of other clinical and functional outcomes reported in the additional tables (Table 1; Table 2).

QoL

Six studies provided data on QoL (Baldwin 2011; Gray-Donald 1995; Parsons 2016; Ravasco 2005a; Ravasco 2005b; Stow 2015); however, Stow did not report the data collected because too few residents completed the assessment. The review authors have entered data for only global QoL scores into a meta-analysis.

3. Dietary advice compared with dietary advice plus ONS

The review authors identified 22 studies (1286 participants) for this comparison (Arnold 1989; Baldwin 2011; Beattie 2000; Burden 2011; Burden 2017; de Luis 2003; de Sousa 2012; Diouf 2016; Dixon 1984; Fuenzalida 1990; Gonzalez-Espinoza 2005; Huynh 2015; Kapoor 2017; Kendell 1982; Le Cornu 2000; McCarthy 1999; Murphy 1992; Norman 2008b; Olejko 1984; Rabeneck 1998; Sharma 2002a; Wilson 2001).

Study design

There were 21 RCTs (Arnold 1989; Baldwin 2011; Beattie 2000; Burden 2011; Burden 2017; de Luis 2003; de Sousa 2012; Diouf 2016; Dixon 1984; Fuenzalida 1990; Gonzalez-Espinoza 2005; Huynh 2015; Kapoor 2017; Kendell 1982; Le Cornu 2000; McCarthy 1999; Norman 2008b; Olejko 1984; Rabeneck 1998; Sharma 2002a; Wilson 2001), and one quasi-RCT (Murphy 1992).

16 studies were conducted in a single centre (Arnold 1989; Beattie 2000; Burden 2011; de Luis 2003; de Sousa 2012; Diouf 2016; Fuenzalida 1990; Gonzalez-Espinoza 2005; Kapoor 2017; Kendell 1982; Le Cornu 2000; McCarthy 1999; Murphy 1992; Norman 2008b; Olejko 1984; Sharma 2002a) and six were multicentre (Baldwin 2011; Burden 2017; Dixon 1984; Huynh 2015; Rabeneck 1998; Wilson 2001). Studies were globally diverse; nine out of 22 were conducted in Europe (Baldwin 2011; Beattie 2000; Burden 2011; Burden 2017; de Luis 2003; de Sousa 2012; Dixon 1984; Le Cornu 2000; Norman 2008b) and nine in North America (Arnold 1989; Fuenzalida 1990; Gonzalez-Espinoza 2005; Kendell 1982; McCarthy 1999; Murphy 1992; Olejko 1984; Rabeneck 1998; Wilson 2001), three studies were conducted in India (Huynh 2015; Kapoor 2017; Sharma 2002a) and one in Africa (Diouf 2016). There were no studies from South America or Australia. The source of funding was declared in 16 studies (Beattie 2000; Burden 2011; Burden 2017; de Sousa 2012; Diouf 2016; Gonzalez-Espinoza 2005; Huynh 2015; Kapoor 2017; Le Cornu 2000; McCarthy 1999; Norman 2008b; Rabeneck 1998; Sharma 2002a; Wilson 2001). Of these five obtained funding from educational or charitable grants (Burden 2011; Burden 2017; Diouf 2016; Gonzalez-Espinoza 2005; Wilson 2001) and one study was reported to be self-funded (Kapoor 2017). Five studies declared funding from a company making commercial nutritional products (Beattie 2000; Huynh 2015; Norman 2008b; Rabeneck 1998; Sharma 2002a), and a further three studies declared that products were provided by the industry (de Sousa 2012; Le Cornu 2000; McCarthy 1999). The duration of intervention ranged from up to three months (Arnold 1989; Baldwin 2011; Beattie 2000; Burden 2011; Burden 2017; de Luis 2003; de Sousa 2012; Diouf 2016; Huynh

2015; Kendell 1982; Le Cornu 2000; McCarthy 1999; Murphy 1992; Norman 2008b; Olejko 1984; Rabeneck 1998; Sharma 2002a), to four to six months (Dixon 1984; Fuenzalida 1990; Gonzalez-Espinoza 2005; Kapoor 2017; Murphy 1992; Wilson 2001). Eight studies included an additional follow-up period beyond the end of the intervention (Arnold 1989; Baldwin 2011; Burden 2011; Burden 2017; de Sousa 2012; Le Cornu 2000; Olejko 1984; Wilson 2001), which ranged from 90 days (de Sousa 2012) to over 12 months (Baldwin 2011). Five studies involved pre-operative or pre-transplant patients awaiting hospital admission (Burden 2011; Burden 2017; Kendell 1982; Le Cornu 2000; Olejko 1984), four were initiated at hospital admission and continued post-discharge (Beattie 2000; Fuenzalida 1990; Huynh 2015; Norman 2008b), and 12 were set in outpatient departments for participants undergoing radiotherapy, chemotherapy, haemodialysis or HIV treatment (Arnold 1989; Baldwin 2011; de Luis 2003; Diouf 2016; Dixon 1984; Gonzalez-Espinoza 2005; Kapoor 2017; McCarthy 1999; Murphy 1992; Rabeneck 1998; Sharma 2002a; Wilson 2001). Although not entirely clear, it seems that only one study was fully completed while the participants were hospitalised (de Sousa 2012).

Participants

The largest study included 212 participants (Huynh 2015) and the smallest nine participants (Fuenzalida 1990).

All studies reported the age of participants as either mean (SD) age, median (IQR range) or as a range. The majority of studies included middle-aged participants with a mean age ranging from 23 years (Olejko 1984) to 79 years (de Sousa 2012).

All studies reported sex. In seven studies there were fewer females than males (less than 45%), with three studies only including males (Fuenzalida 1990; Murphy 1992; Rabeneck 1998). In 13 studies there were more females than males (over 55%) with one study including only females (Kapoor 2017). One study included 50% males and 50% females (Olejko 1984).

The participants in studies had a wide variety of clinical conditions. Five studies were in people with cancer (Arnold 1989; Baldwin 2011; Dixon 1984; Kapoor 2017; McCarthy 1999), five were in people undergoing surgery (pre-operative or post-operative) (Beattie 2000; Burden 2011; Burden 2017; Kendell 1982; Olejko 1984), four were in people living with HIV infection (de Luis 2003; Diouf 2016; Murphy 1992; Rabeneck 1998), one study was in people with COPD (Fuenzalida 1990), one in people with benign gastrointestinal disease (Norman 2008b), one in people with Alzheimer's disease (de Sousa 2012), one in people with end-stage liver disease (Le Cornu 2000), three studies were in people with renal failure (Gonzalez-Espinoza 2005; Sharma 2002a; Wilson 2001) and one in people from various medical and surgical wards (non-cancer) (Huynh 2015).

The nutritional status of participants was assessed at baseline in 21 of 23 studies but the method of assessment varied. Investigators in two studies used the MNA (Beattie 2000, de Sousa 2012), in three studies the SGA (Burden 2011; Gonzalez-Espinoza 2005; Norman 2008b), and a modified SGA in one study (Huynh 2015). One study used both PG-SGA and the MUST (Burden 2017). The remaining studies used weight loss, ideal body weight and BMI or a combination of these to assess nutritional status (Baldwin 2011; de Luis 2003; Dixon 1984; Diouf 2016; Fuenzalida 1990; Kapoor 2017; Kendell 1982; Le Cornu 2000; Murphy 1992; Olejko 1984; Rabeneck

1998; Sharma 2002a; Wilson 2001). Eight studies reported the BMI of participants at baseline; the mean BMI was below 22 in seven out of nine studies (de Sousa 2012; Diouf 2016; Norman 2008b; Olejko 1984; Rabeneck 1998; Sharma 2002a). Values for BMI between 25 and 27 were reported in two studies (Burden 2011; Burden 2017). There were 14 studies which only included malnourished people or individuals who had at least experienced (any) weight loss (Baldwin 2011; de Luis 2003; de Sousa 2012; Dixon 1984; Fuenzalida 1990; Gonzalez-Espinoza 2005; Huynh 2015; Kapoor 2017; Le Cornu 2000; Murphy 1992; Norman 2008b; Rabeneck 1998; Sharma 2017; Wilson 2001), four studies included both well-nourished and malnourished participants (Beattie 2000; Burden 2011; Burden 2017; Diouf 2016). Two studies did not report the proportion of malnourished participants (Arnold 1989; McCarthy 1999) and two studies included well-nourished participants only, who were suspected to become malnourished due to the nature of their disease (orthognathic surgery) (Kendell 1982; Olejko 1984).

Intervention

Participants in both groups received dietary instructions, and participants in the intervention groups also received ONS or other supplements made from local ingredients and judged to be comparable to the use of ONS (Diouf 2016; Gonzalez-Espinoza 2005; Kapoor 2017). The nature and intensity of the dietary advice varied. In four studies, dietary advice consisted of pre-operative written and verbal advice (Burden 2011; Burden 2017; Kendell 1982; Olejko 1984). It remained unclear whether nutritional or dietary advice was individualised or not as no further specifications were given in five studies, which described interventions as routine nutritional management (Beattie 2000), standard dietetic advice (de Sousa 2012), individually-planned hospital diets (Fuenzalida 1990), or individual meal plans (Murphy 1992); in one study authors did not provide details (de Luis 2003). Other studies further specified dietetic advice as intensive nutritional counselling on a weekly basis (Arnold 1989), study dietitians giving verbal and written advice and follow-up at outpatients appointments alongside weekly telephone calls (Baldwin 2011), bi-weekly visits, during which a research nurse gave nutritional counselling (Dixon 1984), nutritional counselling to reach or increase individualized (protein and energy) goals (Gonzalez-Espinoza 2005; Huynh 2015; Le Cornu 2000; Rabeneck 1998; Sharma 2002a; Wilson 2001), 30-minutes dietary counselling sessions (Kapoor 2017), weekly meetings with the research nurse or dietitian to review dietary intake (McCarthy 1999) and standard dietary counselling session (Norman 2008b). In 11 studies, the authors specified that the dietary intervention was delivered by a dietitian or nutritionist (Baldwin 2011; de Sousa 2012; Fuenzalida 1990; Gonzalez-Espinoza 2005; Huynh 2015; Kapoor 2017; McCarthy 1999; Norman 2008b; Olejko 1984; Rabeneck 1998; Wilson 2001). In four studies, the intervention was given by nurses (Dixon 1984) or research assistants (Burden 2011; Burden 2017) or doctors (Diouf 2016). It remains unclear who gave the advice in seven studies (Arnold 1989; Beattie 2000; de Luis 2003; Kendell 1982; Le Cornu 2000; Murphy 1992; Sharma 2002a). In all studies, the focus of the intervention was on consumption of the supplements, which varied from ONS (Arnold 1989; Baldwin 2011; Beattie 2000; Burden 2011; Burden 2017; de Luis 2003; de Sousa 2012; Dixon 1984; Fuenzalida 1990; Huynh 2015; Kendell 1982; Le Cornu 2000; McCarthy 1999; Murphy 1992; Norman 2008b; Olejko 1984; Rabeneck 1998; Sharma 2002a; Wilson 2001) to a mixture of rice and porridge (Diouf 2016), a mixture of different flours (Kapoor 2017) or a dried-egg albumin-based supplement (Gonzalez-Espinoza 2005). The intake of ONS varied from one can

of the supplement (Burden 2017; de Sousa 2012) to approximately 1000 kcal/day (Arnold 1989; Rabeneck 1998) or to 50% of caloric requirements (Kendell 1982; Olejko 1984).

Outcomes

Not all studies contributed data on all outcomes and data were available to enter into the analyses for only some outcomes. Four studies reported no data relevant to the outcomes of this review or data were reported in a format meaning no outcomes could be included in the meta-analyses (Dixon 1984; Kendell 1982; Le Cornu 2000; Olejko 1984). Some additional data were obtained on request from the study authors or have been derived by imputation (Table 6).

Three studies presented data in a format that did not allow us to derive mean change with a SD (Dixon 1984; Kendell 1982; Olejko 1984).

Primary outcomes

Mortality

13 studies reported mortality data (Arnold 1989; Baldwin 2011; Beattie 2000; Burden 2017; de Luis 2003; de Sousa 2012; Diouf 2016; Fuenzalida 1990; Gonzalez-Espinoza 2005; Kapoor 2017; Le Cornu 2000; Murphy 1992; Norman 2008b).

Morbidity

Review authors assessed morbidity by hospital readmissions, length of stay and complications. Two studies provided data on the number of people admitted to hospital (Gonzalez-Espinoza 2005; Norman 2008b). Six studies provided data on the length of hospital stay (Beattie 2000; Burden 2011; Burden 2017; Huynh 2015; Norman 2008b; Wilson 2001). Four studies provided data on complications (Beattie 2000; Burden 2011; Burden 2017; Gonzalez-Espinoza 2005).

Nutritional status

A total of 14 studies reported change in weight (Arnold 1989; Baldwin 2011; Beattie 2000; Burden 2017; de Luis 2003; de Sousa 2012; Diouf 2016; Fuenzalida 1990; Gonzalez-Espinoza 2005; Kapoor 2017; Murphy 1992; Norman 2008b; Rabeneck 1998; Sharma 2002a), five studies reported the change in BMI (de Sousa 2012; Diouf 2016; Huynh 2015; Norman 2008b; Sharma 2002a), three studies reported the change in FFM (de Luis 2003; Diouf 2016; Norman 2008b), three studies reported MAC (de Luis 2003; Kapoor 2017; Murphy 1992), five studies reported MAMC (Beattie 2000; de Luis 2003; de Sousa 2012; Gonzalez-Espinoza 2005; Kapoor 2017), and seven studies reported TSF (Beattie 2000; de Luis 2003; de Sousa 2012; Fuenzalida 1990; Gonzalez-Espinoza 2005; Norman 2008b; Rabeneck 1998).

Secondary outcomes

Nutritional outcomes

Nine studies reported the change in energy intake (Baldwin 2011; Burden 2011; Burden 2017; de Luis 2003; Gonzalez-Espinoza 2005; Huynh 2015; Kapoor 2017; McCarthy 1999; Murphy 1992) and three studies provided data on final energy intake (Arnold 1989; Norman 2008b; Sharma 2002a). Three studies reported data on the change in protein intake (Burden 2017; Huynh 2015; Kapoor 2017) and five studies on final protein intake (Arnold 1989; de Luis 2003; McCarthy 1999; Norman 2008b; Sharma 2002a).

QoL

Five studies reported this outcome; two used the European Organisation for Research and Treatment of Cancer (EORTC) questionnaires (Baldwin 2011, Kapoor 2017), two used the SF-36 (in the study by Norman SF-36 was used to calculate quality-adjusted life years (QALYs) (Norman 2008b; Beattie 2000), and one used a self-developed, non-validated questionnaire (Rabeneck 1998). The review authors only entered data into a meta-analysis for global QoL scores.

Clinical and functional outcomes

For the 2021 update, the review authors have summarised data on handgrip strength in meta-analyses as this is the most frequently reported functional outcome across studies. Six studies provided data on handgrip strength for this comparison (Beattie 2000; Burden 2017; de Sousa 2012; Huynh 2015; Norman 2008b; Rabeneck 1998). The review authors have provided a summary of other clinical and functional outcomes in the additional tables (Table 1; Table 2).

Costs

Only one study reported on costs, using QALYs and incremental cost-effectiveness ratio (ICER) (Norman 2008b).

4. Dietary advice plus ONS, if required, compared with no advice and no ONS

The review authors identified 31 unique studies* (3308 participants) for this comparison (Andersson 2017; Banks 2016; Beck 2012; Beck 2015; Bonilla-Palomas 2016; Bourdel-Marchasson 2014; Caccialanza 2015; Carey 2013; Endevelt 2011; Evans 1987; Feldblum 2011; Forli 2001; Ganzoni 1994; Holyday 2012; Isenring 2004; Jensen 1997; Kiss 2016; Lovik 1996; Moloney 1983; Ovesen 1993; Pedersen 2016a; Pedersen 2016b; Persson 2002; Rogers 1992; Schilp 2013; Sharma 2017; Silvers 2014; Starke 2011; Suominen 2015; Terp 2018; Uster 2013; Vivanti 2015).

*for analysis purposes they have set up a duplicate study ID for the 2016 Pedersen study (Pedersen 2016b).

Study design

All 31 RCTs had a parallel design and most were single-centre studies; two studies were multicentre (Bonilla-Palomas 2016; Bourdel-Marchasson 2014). The majority of studies (n = 20, 63%) were conducted in Europe (Andersson 2017; Baldwin 2011; Beck 2012; Beck 2015; Bonilla-Palomas 2016; Bourdel-Marchasson 2014; Caccialanza 2015; Forli 2001; Ganzoni 1994; Jensen 1997; Lovik 1996; Moloney 1983; Ovesen 1993; Pedersen 2016a; Pedersen 2016b; Persson 2002; Schilp 2013; Suominen 2015; Starke 2011; Terp 2018; Uster 2013), eight in Australia (Banks 2016; Holyday 2012; Isenring 2004; Kiss 2016; Sharma 2017; Silvers 2014; Vivanti 2015), two in North America (Evans 1987; Rogers 1992) and two in Asia (Endevelt 2011; Feldblum 2011). 27 studies reported the source of funding, all obtained funding from educational or charitable grants (Andersson 2017; Banks 2016; Beck 2012; Beck 2015; Bonilla-Palomas 2016; Bourdel-Marchasson 2014; Caccialanza 2015; Carey 2013; Endevelt 2011; Feldblum 2011; Hampson 2003; Holyday 2012; Isenring 2004; Jensen 1997; Kiss 2016; Lovik 1996; Ovesen 1993; Persson 2002; Rogers 1992; Schilp 2013; Silvers 2014; Starke 2011; Suominen 2015; Terp 2018; Uster 2013; Vivanti 2015). Eight studies

declared some funding from a company making commercial nutritional products (Holyday 2012; Isenring 2004; Jensen 1997; Rogers 1992; Starke 2011; Suominen 2015; Uster 2013).

The study setting varied with 22 studies beginning the intervention in hospital and continuing it into the community (Andersson 2017; Beck 2012; Beck 2015; Bonilla-Palomas 2016; Bourdel-Marchasson 2014; Carey 2013; Evans 1987; Feldblum 2011; Forli 2001; Holyday 2012; Isenring 2004; Jensen 1997; Kiss 2016; Pedersen 2016a; Pedersen 2016b; Lovik 1996; Moloney 1983; Ovesen 1993; Persson 2002; Rogers 1992; Sharma 2017; Silvers 2014; Terp 2018), one was conducted in hospital only (Banks 2016) and the remaining eight studies were in outpatients or people living in the community (Caccialanza 2015; Endevelt 2011; Ganzoni 1994; Schilp 2013; Suominen 2015; Starke 2011; Uster 2013; Vivanti 2015).

The duration of intervention ranged from the length of the hospital stay (Banks 2016; Holyday 2012; Starke 2011), one to three months (Andersson 2017; Beck 2012; Beck 2015; Evans 1987; Forli 2001; Isenring 2004; Jensen 1997; Kiss 2016; Pedersen 2016a; Pedersen 2016b; Lovik 1996; Moloney 1983; Sharma 2017; Terp 2018; Uster 2013; Vivanti 2015), four to six months (Bonilla-Palomas 2016; Bourdel-Marchasson 2014; Carey 2013; Endevelt 2011; Feldblum 2011; Ovesen 1993; Rogers 1992; Schilp 2013; Silvers 2014), one year (Caccialanza 2015; Ganzoni 1994; Suominen 2015) and up to two years (Persson 2002). Nine studies included an additional follow-up period beyond the end of the intervention which ranged from three months (Feldblum 2011) to six months (Beck 2012; Beck 2015; Holyday 2012; Starke 2011), 12 months (Bonilla-Palomas 2016; Moloney 1983), two years (Bourdel-Marchasson 2014) and three to five years (Evans 1987).

Participants

The largest study included 336 participants (Bourdel-Marchasson 2014) and the smallest 21 participants relevant to this comparison (Silvers 2014).

All but one study reported the age of participants as either mean (SD) age, median (IQR range) or as a range. The majority of studies included older participants with a mean age ranging from 49 years (Forli 2001) to 87 years (Terp 2018).

Sex was reported in 29 out of 31 studies. In 13 studies there were fewer females than males (less than 45%) (Banks 2016; Caccialanza 2015; Carey 2013; Endevelt 2011; Evans 1987; Isenring 2004; Lovik 1996; Moloney 1983; Ovesen 1993; Persson 2002; Silvers 2014; Terp 2018; Uster 2013), in 11 studies there were more females than males (over 55%) (Andersson 2017; Beck 2012; Beck 2015; Bonilla-Palomas 2016; Feldblum 2011; Holyday 2012; Pedersen 2016a; Pedersen 2016b; Sharma 2017; Schilp 2013; Suominen 2015; Vivanti 2015). Two studies included over 80% males (Isenring 2004; Lovik 1996). The remaining four studies included approximately equal numbers of males and females (45% to 55%) (Bourdel-Marchasson 2014; Forli 2001; Jensen 1997; Kiss 2016).

The participants in studies had a wide variety of clinical conditions. Participants in nine studies were older adults (Beck 2012; Beck 2015; Endevelt 2011; Feldblum 2011; Holyday 2012; Pedersen 2016a; Pedersen 2016b; Schilp 2013; Sharma 2017; Terp 2018), nine studies were in people with cancer (Bourdel-Marchasson 2014; Evans 1987; Isenring 2004; Kiss 2016; Lovik 1996; Moloney 1983; Ovesen 1993; Persson 2002; Silvers 2014), three were in groups with mixed clinical backgrounds (Starke 2011; Uster 2013; Vivanti 2015).

2015), two in people with COPD (Ganzoni 1994; Rogers 1992), two in post-surgical participants (Carey 2013; Jensen 1997), one in people with Alzheimer's disease (Suominen 2015), one was in people undergoing rehabilitation from a wide variety of chronic conditions (Andersson 2017), one was in people with heart failure (Bonilla-Palomas 2016), one was in people with amyloidosis (Caccialanza 2015), one was in people with pressure ulcers (Banks 2016) and one in people undergoing lung transplantation (Forli 2001).

In 28 out of 31 studies, investigators assessed the nutritional status of participants at baseline, but the method of assessment varied. Seven studies used the MNA (Bourdel-Marchasson 2014; Bonilla-Palomas 2016; Endevelt 2011; Feldblum 2011; Holyday 2012; Pedersen 2016a; Suominen 2015), three studies used the SGA (Banks 2016; Carey 2013; Vivanti 2015), three studies used the PG-SGA (Isenring 2004; Kiss 2016; Silvers 2014), six studies used the NRS-2002 (Andersson 2017; Beck 2012; Beck 2015; Starke 2011; Terp 2018; Uster 2013) and one study used the Short Nutritional Assessment Questionnaire 65+ (SNAQ65+) (Schilp 2013). The remainder of studies used combinations of weight loss, ideal body weight and BMI to assess nutritional status (Caccialanza 2015; Evans 1987; Forli 2001; Ovesen 1993; Persson 2002; Rogers 1992). 25 studies reported the BMI of participants at baseline and the mean BMI was in the normal range for all groups (Andersson 2017; Banks 2016; Beck 2012; Beck 2015; Bonilla-Palomas 2016; Bourdel-Marchasson 2014; Caccialanza 2015; Carey 2013; Endevelt 2011; Feldblum 2011; Holyday 2012; Isenring 2004; Kiss 2016; Lovik 1996; Pedersen 2016a; Pedersen 2016b; Schilp 2013; Sharma 2017; Silvers 2014; Starke 2011; Suominen 2015; Uster 2013) and in two studies the baseline BMI was low (Forli 2001; Terp 2018).

Seven studies included only malnourished participants (Bonilla-Palomas 2016; Endevelt 2011; Feldblum 2011; Forli 2001; Holyday 2012; Schilp 2013; Vivanti 2015) (only data of malnourished participants in the Holyday study were included in this review), nine studies included participants assessed as malnourished or at nutritional risk (Andersson 2017; Beck 2012; Beck 2015; Bourdel-Marchasson 2014; Pedersen 2016a; Pedersen 2016b; Persson 2002; Rogers 1992; Sharma 2017; Terp 2018), and 12 studies included well-nourished, malnourished or at risk participants (Banks 2016; Caccialanza 2015; Carey 2013; Evans 1987; Ganzoni 1994; Isenring 2004; Kiss 2016; Ovesen 1993; Silvers 2014; Suominen 2015; Starke 2011; Uster 2013). Three studies did not report how many participants were malnourished (Jensen 1997; Lovik 1996; Moloney 1983).

Interventions

All participants in the intervention group received dietary instruction but the nature and intensity varied. In 25 studies, the authors specified that the dietary intervention was given by a dietitian (Andersson 2017; Banks 2016; Bourdel-Marchasson 2014; Carey 2013; Endevelt 2011; Evans 1987; Feldblum 2011; Forli 2001; Holyday 2012; Isenring 2004; Jensen 1997; Kiss 2016; Lovik 1996; Moloney 1983; Ovesen 1993; Pedersen 2016a; Pedersen 2016b; Persson 2002; Rogers 1992; Schilp 2013; Sharma 2017; Silvers 2014; Suominen 2015; Uster 2013; Vivanti 2015). In two studies a multidisciplinary team of a dietitian, GP and nurse gave the intervention (Beck 2012; Beck 2015), in one study a dietitian and physician (Bonilla-Palomas 2016) and in two studies a dietitian and a nurse (Caccialanza 2015; Terp 2018).

The intervention was described as either individualised or personalised in 28 of 31 studies (Andersson 2017; Banks 2016; Beck 2012; Beck 2015; Bonilla-Palomas 2016; Bourdel-Marchasson 2014; Caccialanza 2015; Carey 2013; Endevelt 2011; Evans 1987; Feldblum 2011; Forli 2001; Holyday 2012; Isenring 2004; Kiss 2016; Lovik 1996; Moloney 1983; Ovesen 1993; Pedersen 2016a; Pedersen 2016b; Persson 2002; Rogers 1992; Schilp 2013; Sharma 2017; Silvers 2014; Suominen 2015; Terp 2018; Uster 2013; Vivanti 2015). Description of arrangements for follow-up varied with 29 studies describing plans for review and monitoring of participants, but the frequency varied from only at admission (Banks 2016) to whenever necessary during six months (Schilp 2013). Seven studies described monthly monitoring (Bonilla-Palomas 2016; Endevelt 2011; Forli 2001; Rogers 1992; Sharma 2017; Uster 2013; Vivanti 2015), 13 studies monitored once per two to three weeks (Andersson 2017; Beck 2012; Beck 2015; Bourdel-Marchasson 2014; Caccialanza 2015; Carey 2013; Feldblum 2011; Isenring 2004; Kiss 2016; Lovik 1996; Moloney 1983; Pedersen 2016a; Pedersen 2016b; Terp 2018) and one study reviewed weekly (Silvers 2014). Follow-up and monitoring were conducted at the same interval in both the intervention and control groups. The remaining studies either did not describe arrangements for review and monitoring or characterised these as when necessary (Evans 1987; Ganzoni 1994; Holyday 2012; Jensen 1997; Persson 2002; Schilp 2013; Starke 2011; Suominen 2015).

Prescription of ONS varied both in terms of the type of supplement used and the amount prescribed. In all studies, ONS were prescribed "when necessary" and participants' personal preferences guided the ONS selection. In five studies, there were fewer than five options in the choice of types of supplement (Evans 1987; Forli 2001; Ganzoni 1994; Jensen 1997; Starke 2011). Seven studies reported the proportion of participants who used ONS (Banks 2016; Beck 2012; Beck 2015; Bourdel-Marchasson 2014; Suominen 2015; Starke 2011; Uster 2013) and varied from 25% (Bourdel-Marchasson 2014) to 88% (Starke 2011). The remaining studies did not report the proportion of participants who used ONS during the study period.

Outcomes

Not all studies contributed data on all outcomes and data were available to enter into the analyses for only some outcomes. One study reported no data relevant to the outcomes of this review or data were reported in a format meaning no outcomes could be included in the meta-analyses (Jensen 1997). Some additional data were obtained on request from the study investigators or have been derived by imputation (Table 7).

Primary outcomes

Mortality

26 studies reported mortality data (Beck 2012; Beck 2015; Bonilla-Palomas 2016; Bourdel-Marchasson 2014; Caccialanza 2015; Carey 2013; Evans 1987; Feldblum 2011; Forli 2001; Ganzoni 1994; Holyday 2012; Isenring 2004; Kiss 2016; Lovik 1996; Moloney 1983; Ovesen 1993; Pedersen 2016a; Persson 2002; Schilp 2013; Sharma 2017; Silvers 2014; Starke 2011; Suominen 2015; Terp 2018, Uster 2013; Vivanti 2015).

Morbidity

Review authors assessed morbidity by hospital readmissions, length of stay and complications. Nine studies provided data on the number of people admitted to hospital (Beck 2012; Beck 2015; Bonilla-Palomas 2016; Bourdel-Marchasson 2014; Holyday 2012; Pedersen 2016a; Pedersen 2016b; Sharma 2017; Starke 2011; Terp 2018). Five studies provided data on the length of hospital stay (Banks 2016; Beck 2012; Holyday 2012; Sharma 2017; Starke 2011). Three studies provided data on complications (Bourdel-Marchasson 2014; Sharma 2017; Starke 2011).

Nutritional status

A total of 24 studies reported data on the change in weight (Andersson 2017; Banks 2016; Beck 2012; Beck 2015; Bourdel-Marchasson 2014; Caccialanza 2015; Carey 2013; Feldblum 2011; Forli 2001; Ganzoni 1994; Holyday 2012; Isenring 2004; Kiss 2016; Lovik 1996; Ovesen 1993; Persson 2002; Rogers 1992; Schilp 2013; Sharma 2017; Silvers 2014; Starke 2011; Terp 2018; Uster 2013; Vivanti 2015), six studies reported data on BMI (Carey 2013; Forli 2001; Persson 2002; Sharma 2002a; Starke 2011; Suominen 2015), four studies reported data on change in FFM (Isenring 2004; Kiss 2016; Ovesen 1993; Schilp 2013), two studies reported data on MAC (Rogers 1992; Sharma 2017), two studies reported data on MAMC (Caccialanza 2015; Sharma 2017) and three studies reported data on TSF (Ovesen 1993; Rogers 1992; Sharma 2017).

Secondary outcomes

Nutritional outcomes

Data on the change in energy intake were available in nine studies (Beck 2012; Beck 2015; Caccialanza 2015; Forli 2001; Isenring 2004; Moloney 1983; Ovesen 1993; Schilp 2013; Uster 2013), and final energy intake from three studies (Carey 2013; Feldblum 2011; Starke 2011). Data on change in protein intake were available in eight studies (Beck 2012; Beck 2015; Isenring 2004; Moloney 1983; Ovesen 1993; Schilp 2013; Suominen 2015; Uster 2013).

Clinical and functional outcomes

For the 2021 update, the review authors have summarised data on handgrip strength in meta-analyses as this is the most frequently reported functional outcome across studies. Nine studies provided data on handgrip strength (Beck 2012; Beck 2015; Carey 2013; Pedersen 2016a; Pedersen 2016b; Rogers 1992; Schilp 2013; Sharma 2017; Terp 2018; Uster 2013). The authors have presented a summary of other clinical and functional outcomes reported in the additional tables (Table 1; Table 2).

QoL

18 studies provided data on QoL (Andersson 2017; Beck 2015; Bourdel-Marchasson 2014; Caccialanza 2015; Carey 2013; Isenring 2004; Jensen 1997; Kiss 2016; Ovesen 1993; Pedersen 2016a; Pedersen 2016b; Rogers 1992; Schilp 2013; Sharma 2017; Silvers 2014; Starke 2011; Suominen 2015; Uster 2013; Vivanti 2015). The review authors have only entered data for the global QoL scores into the meta-analysis.

Costs

Three studies provided data on costs (Beck 2015; Endevelt 2011; Schilp 2013).

5. Dietary advice plus ONS compared with no advice and no ONS

We identified 13 studies (1315 participants) in this comparison (Anbar 2014; Baldwin 2011; Berneis 2000; Calegari 2011; Chandra 1985; Hampson 2003; Jahnavi 2010; Neelemaat 2011; Paton 2004; Payette 2002; Persson 2007; Um 2014; Wyers 2013).

Study design

There were 12 RCTs with a parallel design and one with a cross-over design (Calegari 2011). Six (46%) studies were conducted in Europe (Baldwin 2011; Berneis 2000; Hampson 2003; Neelemaat 2011; Persson 2007; Wyers 2013), three (23%) in Southeast Asia and India (Jahnavi 2010; Paton 2004; Um 2014), two (15%) in Canada (Chandra 1985; Payette 2002) and one each in the Middle East (Anbar 2014) and South America (Calegari 2011). All but two studies reported the source of funding (Anbar 2014; Um 2014). 10 studies obtained funding from educational or charitable grants (Baldwin 2011; Berneis 2000; Calegari 2011; Chandra 1985; Hampson 2003; Jahnavi 2010; Neelemaat 2011; Paton 2004; Persson 2007; Wyers 2013) and five studies declared some funding from companies making commercial nutritional products (Chandra 1985; Paton 2004; Payette 2002; Persson 2007; Wyers 2013).

The study setting varied: one study was conducted in hospital (Anbar 2014); three studies began the intervention in hospital and continued it into the community (Neelemaat 2011; Persson 2007; Wyers 2013); six studies were conducted in outpatients (Baldwin 2011; Berneis 2000; Calegari 2011; Chandra 1985; Paton 2004; Um 2014); and three studies were solely in the community (Hampson 2003; Jahnavi 2010; Payette 2002).

The duration of the intervention ranged from the length of hospital stay (Anbar 2014), one to three months (Baldwin 2011; Berneis 2000; Chandra 1985; Jahnavi 2010; Neelemaat 2011; Paton 2004; Um 2014; Wyers 2013), four to six months (Payette 2002; Persson 2007) and 12 months (Hampson 2003). The cross-over study lasted seven to 12 months; however, we only used data from phase 1, i.e. baseline to three months (Calegari 2011). Five studies included an additional follow-up period beyond the end of the intervention which varied from three months (Wyers 2013), four to six months (Paton 2004), and seven to 12 months (Baldwin 2011; Jahnavi 2010). One study reported survival data up to four years post intervention (Neelemaat 2011).

Participants

The largest study included 210 participants (Neelemaat 2011) and the smallest enrolled 18 participants (Calegari 2011).

In 12 of 13 studies, the age of participants was reported as either mean (SD), median (IQR range), a range with most studies reporting age separately by intervention group. One study did not report age (Berneis 2000). The majority of studies included older participants with a mean (SD) age ranging from 56.4 (15.6) years (Calegari 2011) to 85.0 (6.1) years (Persson 2007). Two studies involved younger adults, with participants having a mean age of 38.4 (19.3) years to 41.0 (14.2) years (Jahnavi 2010; Paton 2004).

Sex was reported in 12 of 13 studies, only one study did not report on this (Persson 2007). In five studies there were fewer females than males overall (less than 45%) (Baldwin 2011; Berneis 2000; Calegari 2011; Jahnavi 2010; Um 2014). In four studies, there were more females than males (over 55%) (Anbar 2014; Neelemaat 2011; Payette 2002; Wyers 2013). One study included approximately

similar numbers of males and females (Paton 2004), one study included only males (Chandra 1985) and another included only females (Hampson 2003).

The participants in studies had a wide variety of clinical conditions. Participants in seven studies were older people, in two studies they had a hip fracture (Anbar 2014; Wyers 2013), in two studies the participants were transitioning from hospital to the community (Neelemaat 2011; Persson 2007), two studies were in older people living in the community (Chandra 1985; Payette 2002), and one study was in older underweight women with osteoporosis (Hampson 2003). Two studies were in people with cancer (Baldwin 2011; Um 2014), two were in people with tuberculosis (Jahnavi 2010; Paton 2004), one was in people with stable HIV infection (Berneis 2000) and one was in people with renal failure on haemodialysis (Calegari 2011).

The nutritional status of participants at baseline was assessed in 11 of 13 studies, but the method of assessment varied. One investigator used a validated tool, the MNA (Wyers 2013) and two studies used weight loss in the previous three to six months (Baldwin 2011; Neelemaat 2011). The remaining eight studies reported the BMI of participants at baseline (Anbar 2014; Calegari 2011; Hampson 2003; Jahnavi 2010; Paton 2004; Payette 2002; Persson 2007; Um 2014); the mean BMI was in the normal range in six studies (Anbar 2014; Calegari 2011; Hampson 2003; Payette 2002; Persson 2007; Um 2014), and in the underweight range for two studies (Jahnavi 2010; Paton 2004). Seven studies assessed all participants as malnourished or at nutritional risk (Baldwin 2011; Chandra 1985; Jahnavi 2010; Neelemaat 2011; Paton 2004; Payette 2002; Persson 2007) and one study included some malnourished or at risk participants (Wyers 2013). One study a BMI below 21 kg/m² or 5% weight loss in six months was an inclusion criterion (Berneis 2000), while in a further study a low BMI was an inclusion criterion (Hampson 2003). The remaining studies did not report how many participants were malnourished or specify malnutrition as an inclusion criteria (Anbar 2014; Calegari 2011; Um 2014).

Interventions

All participants in the intervention group received dietary instruction and ONS, but the nature and intensity of the interventions varied. In nine studies authors reported that a dietitian provided the intervention (Baldwin 2011; Berneis 2000; Calegari 2011; Hampson 2003; Neelemaat 2011; Payette 2002; Persson 2007; Um 2014; Wyers 2013) and in one study Anganwadi workers (i.e. paid, part-time women selected from the community who are trained in various aspects of health, nutrition and child development) gave the intervention (Jahnavi 2010). In three studies the authors did not specify the role or occupation of the person who provided the intervention (Anbar 2014; Chandra 1985; Paton 2004). In all but one study the intervention was tailored to individuals' habitual intake or preferences, or both (Chandra 1985). Two studies did not describe follow-up and review arrangements (Calegari 2011; Chandra 1985) and in two studies follow-up arrangements were unclear (Anbar 2014; Jahnavi 2010). In those studies where follow-up and review arrangements were described these varied considerably; three studies reported that follow-up and review occurred during outpatient visits (Berneis 2000; Hampson 2003; Um 2014) and six studies described a combination of face-to-face sessions in hospital or outpatient visits and phone calls, or a combination of these (Baldwin 2011;

Neelemaat 2011, Paton 2004; Payette 2002; Persson 2007; Wyers 2013).

Outcomes

Not all studies contributed data on all outcomes and data were available to enter into the analyses for only some outcomes. One study reported no data relevant to the outcomes of this review or data were reported in a format meaning no outcomes could be included in the meta-analyses (Chandra 1985). Some additional data were obtained on request from the study authors or have been derived by imputation (Table 8).

Primary outcomes

Mortality

Nine studies reported data on mortality (Anbar 2014; Baldwin 2011; Calegari 2011; Hampson 2003; Jahnavi 2010; Neelemaat 2011; Persson 2007; Um 2014; Wyers 2013).

Morbidity

The review authors assessed morbidity by hospital readmissions, length of stay and complications. No studies in this group reported data on the number of participants admitted to hospital. Three studies reported data on length of hospital stay (Anbar 2014; Neelemaat 2011; Wyers 2013) and one study provided data on complications (Anbar 2014).

Nutritional status

11 studies reported data on weight change (Baldwin 2011; Berneis 2000; Calegari 2011; Hampson 2003; Jahnavi 2010; Neelemaat 2011; Paton 2004; Payette 2002; Persson 2007; Um 2014; Wyers 2013). Four studies reported data on BMI (Calegari 2011; Persson 2007; Um 2014; Wyers 2013), five studies reported data on change in FFM (Berneis 2000; Calegari 2011; Hampson 2003; Neelemaat 2011; Paton 2004), one study reported data on MAC (Wyers 2013), one study reported data on MAMC (Payette 2002) and one study reported data on TSF (Payette 2002).

Secondary outcomes

Nutritional intake

Nine studies reported data on changes in energy intake (Anbar 2014; Baldwin 2011; Berneis 2000; Hampson 2003; Neelemaat 2011; Paton 2004; Payette 2002; Um 2014; Wyers 2013). Only two studies reported on protein intake (Neelemaat 2011; Wyers 2013).

Clinical and functional outcomes

For the 2021 update, the review authors summarised data on handgrip strength in meta-analyses as this is the most frequently reported functional outcome across studies. Four studies provided data on handgrip strength (Jahnavi 2010; Neelemaat 2011; Paton 2004; Persson 2007); and one study reported data graphically which could not be extracted for meta-analysis (Payette 2002). The review authors have provided a summary of other clinical and functional outcomes reported in the additional tables (Table 1; Table 2). One study reported data on the number of post-operative and infectious complications in people with hip fracture (Anbar 2014), one study reported data on the response to influenza vaccine in older people (Chandra 1985) and one study reported data on sputum conversion and treatment completion rates in individuals with tuberculosis

(Jahnvi 2010). One study reported data on the six-minute walk test (Calegari 2011), one study reported data on the timed sit-to-stand test (Jahnvi 2010) and one study reported data on activities of daily living assessed using the Katz score (Persson 2007).

QoL

Nine studies reported QoL data (Baldwin 2011; Berneis 2000; Jahnvi 2010; Neelemaat 2011; Paton 2004; Payette 2002; Persson 2007; Um 2014; Wyers 2013); however, various tools were used and data were reported in different ways, e.g. total QoL scores and different domain scores. Five studies used versions of the Medical Outcomes Study Instrument which is designed as a generic tool for use across different clinical conditions: three studies used versions of the instrument adapted for use with people with HIV infection (Berneis 2000; Jahnvi 2010; Paton 2004) and two studies used the SF-36 (Payette 2002; Persson 2007). Two studies used the three-level EQ-5D in cost-effectiveness analyses (Neelemaat 2011; Wyers 2013). Two studies used QoL tools designed for use in people with cancer; the EORTC (Baldwin 2011; Um 2014) and FAACT (Baldwin 2011).

Costs

Two studies reported cost-effectiveness analyses (Neelemaat 2011; Wyers 2013).

Excluded studies

The review authors excluded a total of 248 studies for the reasons detailed in the tables (*Characteristics of excluded studies*). They excluded 68 studies because after scrutiny they were not RCTs and a further 163 studies because the comparison did not fulfil the inclusion criteria. They excluded 17 studies for other reasons as follows. In eight studies participants were not malnourished or at nutritional risk (Antila 1993; Bauer 1994; Hansra 2017; Jacka 2017; Kiss 2014; Rollo 2020; Sartorelli 2005; Zweers 2020). In one study the majority of participants were children and all participants in the control group were children (Williams 1989a). In one study the routine care arm was not consistent with others in this review (Orell 2019). Four old clinical study records were excluded because there was no evidence of publication (ISRCTN11132850; NCT00136253; NCT00417508; NCT01116947) and one record was excluded because the study was withdrawn after difficulty with recruitment (NCT01190969). In one study there was insufficient information to identify the study (Zhao 1995) and one study has remained unavailable on the journal website or through contact with authors (Margare 2002).

Studies awaiting assessment

Review authors have listed 81 studies as awaiting assessment.

58 studies were listed for the following reasons. 10 studies require translation (Cong 2016; Cui 2017; Jia 2019; Kwon 2004; Liu 2018; Liu 2019; Park 2012; Sui 2020; Zhang 2018b; Zhou 2011). In 47 studies, there was insufficient detail about the intervention to enable a judgement to be made about eligibility for inclusion (Abdelsalam 2019; Banda 2017; Britton 2019; Camere 2016; Cawood 2017; Chewaskulyong 2015; ChiCTR1800014842; ChiCTR-IOR-17013151; Collins 2014; Cramon 2019; CTRI/2012/05/002698; CTRI/2018/10/015882; CTRI/2018/11/016369; Gaitan 2017; Hansen 2020; Hebuterne 2019; Hoekstra 2005; Hubbard 2009; Kalal 2016; Kandel 2014; Kang 2013; Kuhlmann 1999; Lin 2017; Movahed

2020; NCT01171495; NCT02975089; NCT03631537; NCT03632200; NCT03944161; NCT04217564; Norshariza 2018; Otten 2016; Pinto 2021; Qui 2020; RBR-35kjvg; RBR-3shhxs; Salem 2020; Sathiaraj 2020; Shadid 2019; Shatenstein 2017; Stratton 2007; Tharun 2020; Touger Decker 1997 UMIN000032234; Vazquez-Sanchez 2019; Verho 2017; Wu 2018). One clinical study record is eligible for inclusion and is listed as completed online, but no full-text publication has been identified (NCT02051777).

In total, 45 of these 58 studies are described as RCTs. Of the remaining studies, one is a stepped-wedge RCT (Britton 2019), one is described as a two-group study (ChiCTR1800014842), one is described as a controlled study (CTRI/2018/11/016369) and one is described as a prospective clinical study (Lin 2017). One study is described as a randomised study (Abdelsalam 2019), a further study is described as having a randomised factorial design (Banda 2017) and in six studies it is unclear whether participants were randomly allocated (ChiCTR-IOR-17013151; Kuhlmann 1999; Kwon 2004; Park 2012; Shatenstein 2017; UMIN000032234). The smallest study reports on 18 participants (Kuhlmann 1999) and the largest includes 308 participants (Cawood 2017).

The participants in the studies are from a variety of clinical backgrounds; 19 studies are in people with cancer (Britton 2019; Chewaskulyong 2015; Cong 2016; Cui 2017; Hebuterne 2019; Lin 2017; Movahed 2020; NCT03631537; NCT03632200; Norshariza 2018; Park 2012; Pinto 2021; Qui 2020; RBR-35kjvg; RBR-3shhxs; Sathiaraj 2020; Shadid 2019; Sui 2020; Zhang 2018b), 12 in malnourished or frail older people (Cawood 2017; Cramon 2019; Hubbard 2009; Kandel 2014; Kwon 2004; NCT02051777; NCT02975089; NCT03944161; Otten 2016; Vazquez-Sanchez 2019; Verho 2017; Wu 2018), six are in people with renal disease (Abdelsalam 2019; Gaitan 2017; Kuhlmann 1999; Salem 2020; UMIN000032234; Zhou 2011), four are in people with COPD (Camere 2016; Collins 2014; Hoekstra 2005; Jia 2019), three are in people with liver disease (CTRI/2018/11/016369; Kalal 2016; Tharun 2020), three are in older people with Alzheimer's disease or dementia (Liu 2018; Liu 2019; Shatenstein 2017), two in people with diseases of the gastrointestinal tract (ChiCTR1800014842; CTRI/2018/10/015882), two studies are in people hospitalised with a hip fracture (Kang 2013; Stratton 2007), two are in people with tuberculosis (Banda 2017; ChiCTR-IOR-17013151), two are in people with HIV infection (CTRI/2012/05/002698; NCT01171495), one study is in people with multiple sclerosis (NCT04217564) one study is in people with pneumonia (Hansen 2020) and one is in people undergoing denture fitting (Touger Decker 1997).

The remaining 23 studies which are listed as awaiting assessment have been identified as eligible for inclusion in the review, but could not be included at this update (Abdollahi 2019; Cereda 2019; Ha 2010; Hsieh 2019; Jabbour 2019; Limwannata 2021; Loser 2021; Maharshi 2016; Meng 2021; Molassiotis 2021; Nyguyen 2020; Reinders 2020; Sahathevan 2018; Schuetz 2019; Smith 2020; Soderstrom 2020; Sudarsanam 2011; Torbergsen 2019; van der Werf 2020; Wills 2019; Yang 2019; Yang 2020; Zhu 2019). All these studies are described as RCTs. The smallest study reports on 32 participants (Molassiotis 2021) and the largest 2088 participants (Schuetz 2019). The participants are from a variety of clinical backgrounds. Nine studies are in people with cancer (Abdollahi 2019; Cereda 2019; Jabbour 2019; Loser 2021; Meng 2021; Molassiotis 2021; van der Werf 2020; Yang 2020; Zhu 2019), five in older people (Hsieh 2019; Reinders 2020; Smith 2020; Soderstrom

2020; Yang 2019), two are in people with renal disease on replacement therapy (Limwannata 2021; Sahathevan 2018), one in medical inpatients at nutritional risk (Schuetz 2019), one is in people who have suffered an acute stroke (Ha 2010), one is in people with liver cirrhosis (Maharshi 2016), one is in people with COPD (Ngyuyen 2020), one is in people with tuberculosis (Sudarsanam 2011), one is in people hospitalised with a hip fracture (Torbergsen 2019) and one is in people with Amyotrophic Lateral Sclerosis (Wills 2019).

The interventions in these studies varied. Seven studies are of dietary counselling interventions compared with routine care and are eligible for inclusion in Comparison 1 of the review (Abdollahi 2019; Hsieh 2019; Loser 2021; Maharshi 2016; Ngyuyen 2020; Reinders 2020; Wills 2019). One study is of dietary counselling compared with an ONS and is eligible for inclusion in Comparison 2 of the review (Yang 2019). Eight studies are of dietary counselling plus and ONS compared with dietary counselling alone and are eligible for inclusion in Comparison 3 of the review (Cereda 2019; Limwannata 2021; Meng 2021; Sahathevan 2018; Smith 2020; Sudarsanam 2011; Yang 2020; Zhu 2019). Five studies are of dietary counselling interventions plus ONS if required compared with routine care and are eligible for inclusion in Comparison 4 of the review (Ha 2010; Jabbour 2019; Molassiotis 2021; Schuetz 2019; van der Werf 2020). One study is of dietary counselling plus ONS compared with routine care and is eligible for inclusion in Comparison 5 of the review (Torbergsen 2019). One study has four arms dietary counselling, ONS, dietary counselling plus ONS and routine care and can be included in Comparisons 1,2,3 and 5 of the review (Soderstrom 2020).

Ongoing studies

The review authors identified 17 ongoing studies which might be eligible for inclusion in this review in the future; 13 from searches of Clintrials.gov (Munk 2020; NCT02440165; NCT02763904; NCT02892747; NCT03075189; NCT03114202; NCT03191253; NCT03315195; NCT03352388; NCT03519139; NCT03540784; NCT03995303; NCT04628117) and four by searching other databases (ACTRN12612001253897; ChiCTR2000028963; CTRI/2019/05/019387; PACTR201108000303396).

14 of the ongoing studies are RCTs (ACTRN12612001253897; ChiCTR2000028963; Munk 2020; NCT02763904; NCT02892747; NCT03075189; NCT03114202; NCT03191253; NCT03315195; NCT03352388; NCT03519139; NCT03540784; NCT03995303; NCT04628117), one is a multicentre cluster-RCT (NCT02440165), one describes the method as a two-group study with no details of any randomisation (CTRI/2019/05/019387) and the description of the assignment to groups in one study implies it is a quasi-RCT (PACTR201108000303396).

14 studies report their planned recruitment numbers and the smallest study aims to recruit 22 participants (NCT04628117) and the largest 295 participants (NCT02892747).

The participants in the studies are from a variety of clinical backgrounds. Five are in older adults (ACTRN12612001253897; NCT03075189; NCT03352388; NCT03519139; NCT03995303), two are in people with cancer (ChiCTR2000028963; NCT03114202), two are in people undergoing surgery (NCT02440165; NCT03315195), two in people with HIV infection (NCT03191253; PACTR201108000303396), one in hospitalised patients at

nutritional risk (NCT02763904), one in people with cirrhosis, frailty and sarcopenia (CTRI/2019/05/019387), one in people with inflammatory bowel disease (NCT03540784), one in adults with chronic heart failure (NCT02892747), one in people with end-stage kidney disease receiving peritoneal dialysis (NCT04628117) and one in hospitalised patients with mixed clinical conditions (oncology, gastrointestinal and medical patients)(Munk 2020).

The interventions and comparisons in the ongoing studies also varied. Five studies are of dietary counselling interventions compared with routine care and are potentially eligible for inclusion in Comparison 1 of the review (NCT03075189; NCT03114202; NCT03352388; NCT03519139; NCT02892747), five studies are of dietary counselling plus an ONS compared with dietary counselling alone and are potentially eligible for inclusion in Comparison 3 (ACTRN12612001253897; NCT02763904; NCT03315195; NCT04628117; PACTR201108000303396), three studies were of dietary advice with ONS (if required) compared with routine care and potentially eligible for inclusion in Comparison 4 (NCT02440165; NCT03191253; NCT03995303), one study was of dietary advice plus ONS compared with routine care and potentially eligible for inclusion in Comparison 5 (ChiCTR2000028963) and one study was of dietary counselling with ONS, but it was not possible from the study report to determine whether this might be eligible for inclusion in Comparison 4 or 5 (Munk 2020). For two studies it is not possible from the study record to fully evaluate the intervention (CTRI/2019/05/019387; NCT03540784).

Risk of bias in included studies

The review authors used the original Cochrane risk of bias tool to assess the risk of bias in the included studies.

Allocation

Generation of sequence

Dietary advice compared with no advice

There are 24 studies included in this comparison, the review authors judged 14 studies to have a low risk of bias for sequence generation (Alo 2014; Baldwin 2011; Campbell 2008; Cano-Torres 2017; Fernandez-Barres 2017; Forster 2012; Kunvik 2018; Macia 1991a; Manguso 2005; Ravasco 2005a; Ravasco 2005b; Stow 2015; Weekes 2009; Wong 2004). Methods of generation were mainly the use of computer-generated randomisation lists or random number tables. They judged 10 studies to have an unclear risk of bias; in one study the author could not recall how the sequence was generated (Imes 1988) and the remaining nine studies did not report any details of how the sequence was generated (Casals 2015; Dixon 1984; Locher 2013; Ollenschlager 1992; Pivi 2011; Rydwick 2008; Salva 2011; Tu 2013). The review authors judged one study in this comparison to have a high risk of bias as participants were assigned a number based on time of admission and group allocation was dependent on whether the number was odd or even (Gu 2015).

Dietary advice compared with ONS

The review authors judged nine of the 12 studies in this comparison to have a low risk of bias for sequence generation (Baldwin 2011; Gray-Donald 1995; Hernandez 2014; Parsons 2016; Ravasco 2005a; Ravasco 2005b; Schwenk 1999; Singh 2008; Stow 2015). Again, studies mainly used computer-generated sequences or random number tables. A further two studies did not provide any

information regarding sequence generation and were judged to have an unclear risk of bias (Akpele 2004; Pivi 2011). The final study used alternation to randomise participants and is judged to have a high risk of bias (Kalnins 2005).

Dietary advice versus dietary advice plus ONS

The authors judged 11 of the 22 studies in this comparison to have a low risk of bias for sequence generation as the methods used (mostly computer-generated lists and random number tables) were appropriate (Baldwin 2011; Beattie 2000; Burden 2011; Burden 2017; de Luis 2003; Diouf 2016; Gonzalez-Espinoza 2005; Huynh 2015; Kapoor 2017; McCarthy 1999; Norman 2008b). 10 studies did not provide any information on how the sequence was generated and the review authors judged these to have an unclear risk of bias (Arnold 1989; de Sousa 2012; Dixon 1984; Fuenzalida 1990; Kendell 1982; Le Cornu 2000; Olejko 1984; Rabeneck 1998; Sharma 2002a; Wilson 2001). One study used alternation and the review authors judged this to have a high risk of bias for randomisation (Murphy 1992).

Dietary advice plus ONS, if required, compared with no advice and no ONS

The review authors judged 23 out of 31 studies in this comparison to have a low risk of bias for sequence generation as the methods used were appropriate (Andersson 2017; Banks 2016; Beck 2012; Beck 2015; Bourdel-Marchasson 2014; Caccialanza 2015; Carey 2013; Evans 1987; Forli 2001; Ganzoni 1994; Holyday 2012; Isenring 2004; Lovik 1996; Ovesen 1993; Pedersen 2016a; Persson 2002; Schilp 2013; Sharma 2017; Silvers 2014; Starke 2011; Suominen 2015; Terp 2018; Vivanti 2015). Seven studies did not provide sufficient information to make a judgement and had an unclear risk of bias (Bonilla-Palomas 2016; Endevelt 2011; Jensen 1997; Kiss 2016; Moloney 1983; Rogers 1992; Uster 2013). One study allocated participants according to month and ward of hospitalisation and the review authors judged this to have a high risk of bias for the generation of randomisation sequence (Feldblum 2011).

Dietary advice plus ONS compared with no advice and no ONS

Six of the 13 studies in this comparison used appropriate methods of sequence generation and the review authors judged these to have a low risk of bias (Anbar 2014; Baldwin 2011; Berneis 2000; Neelemaat 2011; Paton 2004; Wyers 2013). The remaining seven studies did not provide sufficient information on generation of randomisation sequence and the authors judged them to have an unclear risk of bias (Calegari 2011; Chandra 1985; Hampson 2003; Jahnvi 2010; Payette 2002; Persson 2007; Um 2014).

Allocation concealment

Dietary advice compared with no advice

The authors judged 12 out of the 24 studies in this comparison to have a low risk of bias for this domain as investigators adequately concealed the allocation of participants prior to study start (Baldwin 2011; Campbell 2008; Fernandez-Barres 2017; Forster 2012; Imes 1988; Kunvik 2018; Manguso 2005; Ravasco 2005a; Ravasco 2005b; Stow 2015; Weekes 2009; Wong 2004); 11 studies failed to provide sufficient information on this domain and have an unclear risk of bias (Cano-Torres 2017; Casals 2015; Dixon 1984; Gu 2015; Locher 2013; Macia 1991a; Ollenschlager 1992; Pivi 2011; Rydwick 2008; Salva 2011; Tu 2013). The authors judged one study to have a high risk of bias (Alo 2014).

Dietary advice compared with ONS

The review authors judged eight of the 12 studies in this comparison to have a low risk of bias due to allocation concealment (Baldwin 2011; Gray-Donald 1995; Parsons 2016; Ravasco 2005a; Ravasco 2005b; Schwenk 1999; Singh 2008; Stow 2015). Three studies did not provide sufficient information to allow the authors to make a judgement and have an unclear risk of bias (Akpele 2004; Hernandez 2014; Pivi 2011). The review authors judged one study, which used alternate allocation, to have a high risk of bias due to a lack of allocation concealment (Kalnins 2005).

Dietary advice versus dietary advice plus ONS

The authors judged that 10 of the 22 studies in this comparison sufficiently concealed group allocation and these have a low risk of bias (Baldwin 2011; Beattie 2000; Burden 2011; Burden 2017; de Luis 2003; Diouf 2016; Gonzalez-Espinoza 2005; Huynh 2015; Le Cornu 2000; Norman 2008b). A further 11 studies did not provide information on allocation concealment and have an unclear risk of bias (Arnold 1989; de Sousa 2012; Dixon 1984; Fuenzalida 1990; Kapoor 2017; Kendell 1982; McCarthy 1999; Olejko 1984; Rabeneck 1998; Sharma 2002a; Wilson 2001). One study did not conceal allocation and has a high risk of bias (Murphy 1992).

Dietary advice plus ONS, if required, compared with no advice and no ONS

The review authors judged most of the studies in this comparison (19 out of 31 studies) to have adequately concealed allocation and to have a low risk of bias (Andersson 2017; Banks 2016; Beck 2012; Beck 2015; Bonilla-Palomas 2016; Bourdel-Marchasson 2014; Evans 1987; Ganzoni 1994; Isenring 2004; Jensen 1997; Lovik 1996; Ovesen 1993; Pedersen 2016a; Persson 2002; Schilp 2013; Sharma 2017; Silvers 2014; Terp 2018; Vivanti 2015). There were 11 studies which did not provide sufficient information to allow the review authors to make a judgement and which have an unclear risk of bias (Caccialanza 2015; Carey 2013; Endevelt 2011; Forli 2001; Holyday 2012; Kiss 2016; Moloney 1983; Rogers 1992; Starke 2011; Suominen 2015; Uster 2013). One study did not conceal allocation and has a high risk of bias (Feldblum 2011).

Dietary advice plus ONS compared with no advice and no ONS

Just five of the 13 studies in this comparison had a low risk of bias from allocation concealment (Anbar 2014; Baldwin 2011; Hampson 2003; Neelemaat 2011; Paton 2004). The remaining eight studies did not provide information about allocation concealment and the review authors judged these to have an unclear risk of bias (Berneis 2000; Calegari 2011; Chandra 1985; Jahnvi 2010; Payette 2002; Persson 2007; Um 2014; Wyers 2013).

Blinding

Blinding of assessment of clinical outcomes

Dietary advice compared with no advice

The review authors judged 22 studies in this comparison to have a low risk of bias (Alo 2014; Baldwin 2011; Campbell 2008; Cano-Torres 2017; Casals 2015; Dixon 1984; Fernandez-Barres 2017; Forster 2012; Gu 2015; Imes 1988; Macia 1991a; Manguso 2005; Ollenschlager 1992; Pivi 2011; Ravasco 2005a; Ravasco 2005b; Rydwick 2008; Salva 2011; Stow 2015; Tu 2013; Weekes 2009; Wong 2004). Two of the studies did not assess clinical outcomes and the authors judged these to have an unclear risk of bias (Kunvik 2018; Locher 2013).

Dietary advice compared with ONS

The review authors judged all 12 studies to have a low risk of bias (Akpele 2004; Baldwin 2011; Gray-Donald 1995; Hernandez 2014; Kalnins 2005; Parsons 2016; Pivi 2011; Ravasco 2005a; Ravasco 2005b; Schwenk 1999; Singh 2008; Stow 2015).

Dietary advice versus dietary advice plus ONS

The authors judged 18 of the 22 studies in this comparison to have a low risk of bias (Arnold 1989; Baldwin 2011; Beattie 2000; Burden 2011; Burden 2017; de Luis 2003; de Sousa 2012; Dixon 1984; Fuenzalida 1990; Gonzalez-Espinoza 2005; Huynh 2015; Kapoor 2017; Le Cornu 2000; Murphy 1992; Norman 2008b; Olejko 1984; Sharma 2002a; Wilson 2001). The review authors judged four studies to have an unclear risk of bias: two studies did not report clinical outcomes (Diouf 2016; Kendell 1982) and two studies did not measure clinical outcomes (McCarthy 1999; Rabeneck 1998).

Dietary advice plus ONS, if required, compared with no advice and no ONS

The review authors judged 28 of the 31 studies in this comparison to have a low risk of bias (Andersson 2017; Banks 2016; Beck 2012; Beck 2015; Bonilla-Palomas 2016; Bourdel-Marchasson 2014; Caccialanza 2015; Endevelt 2011; Evans 1987; Feldblum 2011; Forli 2001; Ganzoni 1994; Holyday 2012; Isenring 2004; Jensen 1997; Lovik 1996; Moloney 1983; Ovesen 1993; Persson 2002; Rogers 1992; Schilp 2013; Sharma 2017; Silvers 2014; Starke 2011; Suominen 2015; Terp 2018; Uster 2013; Vivanti 2015). They judged three studies to have an unclear risk of bias as these studies did not measure clinical outcomes (Carey 2013; Kiss 2016; Pedersen 2016a).

Dietary advice plus ONS compared with no advice and no ONS

The review authors judged 12 out of 13 studies in this comparison to have a low risk of bias (Baldwin 2011; Berneis 2000; Calegari 2011; Chandra 1985; Hampson 2003; Jahnavi 2010; Neelemaat 2011; Paton 2004; Payette 2002; Persson 2007; Um 2014; Wyers 2013). In the remaining study the assessment of clinical outcomes (post-operative complications) was not blinded and review authors judged that lack of blinding might have influenced assessment of this outcome; therefore this study was judged to be at high risk of bias (Anbar 2014).

Blinding of assessment of functional outcomes

Dietary advice compared with no advice

The authors judged just one study out of 24 to have a low risk of bias from blinding of functional outcomes (Casals 2015). They judged 15 studies to have an unclear risk of bias (Alo 2014; Cano-Torres 2017; Gu 2015; Imes 1988; Kunvik 2018; Locher 2013; Macia 1991a; Manguso 2005; Ollenschlager 1992; Pivi 2011; Ravasco 2005a; Ravasco 2005b; Rydwik 2008; Tu 2013; Wong 2004) and eight studies to have a high risk of bias from a lack of blinding for functional outcomes (Baldwin 2011; Campbell 2008; Dixon 1984; Fernandez-Barres 2017; Forster 2012; Salva 2011; Stow 2015; Weekes 2009).

Dietary advice compared with ONS

The review authors judged two of the 12 studies in this comparison to have a low risk of bias of blinding of functional outcomes (Gray-Donald 1995; Singh 2008). They judged six studies to have an unclear risk of bias (Akpele 2004; Hernandez 2014; Pivi 2011; Ravasco 2005a; Ravasco 2005b; Schwenk 1999) and four studies to have a high risk of bias because the lack of blinding might

have influenced assessment of functional outcomes (Baldwin 2011; Kalnins 2005; Parsons 2016; Stow 2015).

Dietary advice versus dietary advice plus ONS

The authors judged two out of 22 studies in this comparison to have a low risk of bias for the blinding of functional outcomes (Burden 2017; Gonzalez-Espinoza 2005). They judged seven studies to have an unclear risk of bias (Arnold 1989; Beattie 2000; Burden 2011; Huynh 2015; Kendell 1982; McCarthy 1999; Wilson 2001) and the 13 studies to have a high risk of bias (Baldwin 2011; de Luis 2003; de Sousa 2012; Diouf 2016; Dixon 1984; Fuenzalida 1990; Kapoor 2017; Le Cornu 2000; Murphy 1992; Norman 2008b; Olejko 1984; Rabeneck 1998; Sharma 2002a).

Dietary advice plus ONS, if required, compared with no advice and no ONS

The authors judged eight out of 31 studies to have a low risk of bias for this domain (Andersson 2017; Carey 2013; Feldblum 2011; Ganzoni 1994; Holyday 2012; Pedersen 2016a; Sharma 2017; Starke 2011) and a further four studies to have an unclear risk of bias (Bonilla-Palomas 2016; Moloney 1983; Uster 2013; Vivanti 2015). They judged the remaining 19 studies to have a high risk of bias because the lack of blinding might have influenced assessment of functional outcomes (Banks 2016; Beck 2012; Beck 2015; Bourdel-Marchasson 2014; Caccialanza 2015; Endevelt 2011; Evans 1987; Forli 2001; Isenring 2004; Jensen 1997; Kiss 2016; Lovik 1996; Ovesen 1993; Persson 2002; Rogers 1992; Schilp 2013; Silvers 2014; Suominen 2015; Terp 2018).

Dietary advice plus ONS compared with no advice and no ONS

The authors judged just one of the 13 studies in this comparison to have a low risk of bias for the blinding of functional outcomes (Payette 2002). They judged six studies to have an unclear risk of bias (Berneis 2000; Calegari 2011; Jahnavi 2010; Paton 2004; Um 2014; Wyers 2013) and the six studies to have a high risk of bias (Anbar 2014; Baldwin 2011; Chandra 1985; Hampson 2003; Neelemaat 2011; Persson 2007).

Blinding of assessment of nutritional outcomes

Dietary advice compared with no advice

The authors judged seven out of 24 studies to have a low risk of bias from blinding of nutritional outcomes (Alo 2014; Cano-Torres 2017; Casals 2015; Gu 2015; Manguso 2005; Pivi 2011; Salva 2011). Four studies had an unclear risk of bias (Locher 2013; Ollenschlager 1992; Ravasco 2005a; Ravasco 2005b) and 13 studies had a high risk of bias (Baldwin 2011; Campbell 2008; Dixon 1984; Fernandez-Barres 2017; Forster 2012; Imes 1988; Kunvik 2018; Macia 1991a; Rydwik 2008; Stow 2015; Tu 2013; Weekes 2009; Wong 2004).

Dietary advice compared with ONS

The review authors judged two out of 12 studies to have a low risk of bias from blinding of nutritional outcomes (Pivi 2011; Singh 2008) and two further studies had an unclear risk of bias (Ravasco 2005a; Ravasco 2005b). However, they judged eight studies in this comparison to have a high risk of bias (Akpele 2004; Baldwin 2011; Gray-Donald 1995; Hernandez 2014; Kalnins 2005; Parsons 2016; Schwenk 1999; Stow 2015).

Dietary advice versus dietary advice plus ONS

The authors judged two out of 22 studies in this comparison to have a low risk of bias from blinding of nutritional outcomes (Burden 2017; Gonzalez-Espinoza 2005). Three studies had an unclear risk of bias (Fuenzalida 1990; Kendell 1982; Wilson 2001) and 17 studies had a high risk of bias (Arnold 1989; Baldwin 2011; Beattie 2000; Burden 2011; de Luis 2003; de Sousa 2012; Diouf 2016; Dixon 1984; Huynh 2015; Kapoor 2017; Le Cornu 2000; McCarthy 1999; Murphy 1992; Norman 2008b; Olejko 1984; Rabeneck 1998; Sharma 2002a).

Dietary advice plus ONS, if required, compared with no advice and no ONS

The review authors judged seven out of 31 studies in this comparison to have a low risk of bias from blinding of nutritional outcomes (Andersson 2017; Bonilla-Palomas 2016; Carey 2013; Feldblum 2011; Ganzoni 1994; Pedersen 2016a; Sharma 2017). They judged five studies to have an unclear risk of bias (Holyday 2012; Ovesen 1993; Persson 2002; Rogers 1992; Uster 2013) and 18 studies to have a high risk of bias (Banks 2016; Beck 2012; Beck 2015; Bourdel-Marchasson 2014; Caccialanza 2015; Endevelt 2011; Evans 1987; Forli 2001; Isenring 2004; Jensen 1997; Kiss 2016; Lovik 1996; Moloney 1983; Schilp 2013; Silvers 2014; Starke 2011; Suominen 2015; Terp 2018; Vivanti 2015).

Dietary advice plus ONS compared with no advice and no ONS

No study in this comparison had a low risk of bias from blinding of nutritional outcomes. Six of the 13 studies had an unclear risk of bias (Berneis 2000; Calegari 2011; Jahnavi 2010; Paton 2004; Um 2014; Wyers 2013) and seven had a high risk of bias (Anbar 2014; Baldwin 2011; Chandra 1985; Hampson 2003; Neelemaat 2011; Payette 2002; Persson 2007).

Overall blinding of participants and personnel (performance bias)

Dietary advice compared with no advice

The authors judged 23 out of 24 studies to have an overall high risk of performance bias (Baldwin 2011; Campbell 2008; Cano-Torres 2017; Casals 2015; Dixon 1984; Fernandez-Barres 2017; Forster 2012; Gu 2015; Imes 1988; Kunvik 2018; Locher 2013; Macia 1991a; Manguso 2005; Ollenschlager 1992; Pivi 2011; Ravasco 2005a; Ravasco 2005b; Rydwick 2008; Salva 2011; Stow 2015; Tu 2013; Weekes 2009; Wong 2004). One study had a low risk of performance bias as although the study participants and personnel were not blinded to the group allocation, this is unlikely to have affected the assessment of outcomes (Alo 2014).

Dietary advice compared with ONS

The review authors judged all 12 studies to have an overall high risk of performance bias (Akpele 2004; Baldwin 2011; Gray-Donald 1995; Hernandez 2014; Kalnins 2005; Parsons 2016; Pivi 2011; Ravasco 2005a; Ravasco 2005b; Schwenk 1999; Singh 2008; Stow 2015).

Dietary advice versus dietary advice plus ONS

The review authors judged one study in this comparison to have an overall low risk of performance bias; although group allocation was unblinded, we considered the assessment of outcomes was unlikely to be affected by lack of blinding (Holyday 2012). The authors judged the remaining 21 studies in this comparison to have an overall high risk of performance bias (Arnold 1989; Baldwin 2011; Beattie 2000; Burden 2011; Burden 2017; de Luis 2003; de

Sousa 2012; Diouf 2016; Dixon 1984; Fuenzalida 1990; Gonzalez-Espinoza 2005; Huynh 2015; Kapoor 2017; Kendell 1982; Le Cornu 2000; McCarthy 1999; Murphy 1992; Norman 2008b; Olejko 1984; Rabeneck 1998; Sharma 2002a).

Dietary advice plus ONS, if required, compared with no advice and no ONS

All 31 studies had an overall high risk of performance bias (Andersson 2017; Banks 2016; Beck 2012; Beck 2015; Bonilla-Palomas 2016; Bourdel-Marchasson 2014; Caccialanza 2015; Carey 2013; Endevelt 2011; Evans 1987; Feldblum 2011; Forli 2001; Ganzoni 1994; Holyday 2012; Isenring 2004; Jensen 1997; Kiss 2016; Lovik 1996; Moloney 1983; Ovesen 1993; Pedersen 2016a; Persson 2002; Rogers 1992; Schilp 2013; Sharma 2017; Silvers 2014; Starke 2011; Suominen 2015; Terp 2018; Uster 2013; Vivanti 2015).

Dietary advice plus ONS compared with no advice and no ONS

The review authors judged all 13 studies in this comparison to have an overall high risk of performance bias (Anbar 2014; Baldwin 2011; Berneis 2000; Calegari 2011; Chandra 1985; Hampson 2003; Jahnavi 2010; Neelemaat 2011; Paton 2004; Payette 2002; Persson 2007; Um 2014; Wyers 2013).

Overall blinding of outcome assessors (detection bias)

Dietary advice compared with no advice

The review authors judged three out of 24 studies in this comparison to have an overall low risk of detection bias (Alo 2014; Casals 2015; Pivi 2011); Casals reported the blind assessment of all outcomes (clinical, functional and nutritional) (Casals 2015). The remaining 21 studies had an unclear risk of detection bias (Baldwin 2011; Campbell 2008; Cano-Torres 2017; Dixon 1984; Fernandez-Barres 2017; Forster 2012; Gu 2015; Imes 1988; Kunvik 2018; Locher 2013; Macia 1991a; Manguso 2005; Ollenschlager 1992; Ravasco 2005a; Ravasco 2005b; Rydwick 2008; Salva 2011; Stow 2015; Tu 2013; Weekes 2009; Wong 2004).

Dietary advice compared with ONS

The review authors judged two out of 12 studies in this comparison to have an overall low risk of detection bias (Pivi 2011; Singh 2008) and 10 studies to have an unclear risk of bias (Akpele 2004; Baldwin 2011; Gray-Donald 1995; Hernandez 2014; Kalnins 2005; Parsons 2016; Ravasco 2005a; Ravasco 2005b; Schwenk 1999; Stow 2015).

Dietary advice versus dietary advice plus ONS

The review authors judged two out of 22 studies in this comparison to have an overall low risk of detection bias (Gonzalez-Espinoza 2005; Wilson 2001). They judged 17 studies to have an unclear risk of detection bias (Arnold 1989; Baldwin 2011; Beattie 2000; Burden 2011; Burden 2017; de Luis 2003; de Sousa 2012; Dixon 1984; Fuenzalida 1990; Huynh 2015; Kapoor 2017; Kendell 1982; Le Cornu 2000; Murphy 1992; Norman 2008b; Olejko 1984; Sharma 2002a) and three studies to have a high risk of detection bias (Diouf 2016; McCarthy 1999; Rabeneck 1998).

Dietary advice plus ONS, if required, compared with no advice and no ONS

The review authors judged seven out of 31 studies in this comparison to have an overall low risk of detection bias (Andersson 2017; Carey 2013; Feldblum 2011; Ganzoni 1994; Holyday 2012; Pedersen 2016a; Sharma 2017) and 22 studies to have an unclear

risk of bias (Banks 2016; Beck 2015; Bonilla-Palomas 2016; Bourdel-Marchasson 2014; Caccialanza 2015; Endevelt 2011; Evans 1987; Forli 2001; Isenring 2004; Jensen 1997; Lovik 1996; Moloney 1983; Ovesen 1993; Persson 2002; Rogers 1992; Schilp 2013; Silvers 2014; Starke 2011; Suominen 2015; Terp 2018; Uster 2013; Vivanti 2015). They judged two studies to have a high risk of detection bias (Beck 2012; Kiss 2016).

Dietary advice plus ONS compared with no advice and no ONS

The review authors judged that none of the 13 studies in this comparison had an overall low risk of detection bias. They judged 12 studies to have an overall unclear risk of bias (Baldwin 2011; Berneis 2000; Calegari 2011; Chandra 1985; Hampson 2003; Jahnvi 2010; Neelemaat 2011; Paton 2004; Payette 2002; Persson 2007; Um 2014; Wyers 2013) and one study to have an overall high risk of bias (Anbar 2014).

Incomplete outcome data

Dietary advice compared with no advice

The review authors judged 14 of the 24 studies in this comparison to have a low risk of attrition bias (Alo 2014; Campbell 2008; Cano-Torres 2017; Casals 2015; Fernandez-Barres 2017; Forster 2012; Manguso 2005; Ollenschlager 1992; Pivi 2011; Ravasco 2005a; Ravasco 2005b; Rydwick 2008; Salva 2011; Weekes 2009). In three of these studies, all participants completed the study (Alo 2014; Ravasco 2005a; Ravasco 2005b). In five studies attrition rates were less than 15% with numbers of dropouts equal across groups or reasons for withdrawal given, or both (Casals 2015; Forster 2012; Manguso 2005; Ollenschlager 1992; Pivi 2011). In the remaining six studies attrition rates ranged from 19% to 44%, but again investigators provided reasons for withdrawal and numbers were similar across groups (Campbell 2008; Cano-Torres 2017; Fernandez-Barres 2017; Rydwick 2008; Salva 2011; Weekes 2009).

The review authors judged 10 studies to have an unclear risk of attrition bias (Baldwin 2011; Dixon 1984; Gu 2015; Imes 1988; Kunvik 2018; Locher 2013; Macia 1991a; Stow 2015; Tu 2013; Wong 2004). Three studies did not report attrition rates (Gu 2015; Macia 1991a; Tu 2013). In five studies attrition rates ranged from 9% to 37%, but investigators either provided no information about which group the withdrawals were in (Dixon 1984; Stow 2015) or they specified the groups but failed to provide reasons (Imes 1988) or they did not describe either the groups or the reasons for withdrawal (Locher 2013; Wong 2004). One study reported an attrition rate of 14% with reasons, but investigators reported only on 55 participants with protein intake below 1.2 g/kg body weight per day and did not report on the 24 participants with protein intake over 1.2 g/kg body weight per day (Kunvik 2018). In the final study 2% withdrew (reasons not given) and only 43% were still alive at 12 months, but death rates were similar across groups (Baldwin 2011).

Dietary advice compared with ONS

We included 12 studies (Akpele 2004; Baldwin 2011; Gray-Donald 1995; Hernandez 2014; Kalnins 2005; Parsons 2016; Pivi 2011; Ravasco 2005a; Ravasco 2005b; Schwenk 1999; Singh 2008; Stow 2015).

Nine studies had a low risk of attrition bias (Gray-Donald 1995; Kalnins 2005; Parsons 2016; Pivi 2011; Ravasco 2005a; Ravasco 2005b; Schwenk 1999; Singh 2008; Stow 2015). Two studies lost no participants to follow-up (Ravasco 2005a; Ravasco 2005b). Five

studies had an attrition rate below 15% with similar rates across groups and fully reported reasons for withdrawal (Gray-Donald 1995; Kalnins 2005; Pivi 2011; Schwenk 1999; Singh 2008). Two studies had attrition rates over 15%, but again with similar rates across groups and reasons for withdrawal fully reported (Parsons 2016; Stow 2015).

Two studies were judged to have an unclear risk of bias; one study did not report attrition (Akpele 2004) and in the second while 2% withdrew (reasons not given) and only 43% were still alive at 12 months, death rates were similar across groups (Baldwin 2011).

The remaining study had a high risk of attrition bias with 28% overall attrition, but there was a difference in rates between groups of 10% in the advice group compared to 45% in the supplement group (Hernandez 2014).

Dietary advice versus dietary advice plus ONS

The review authors judged 15 out of the 22 studies in this comparison to have a low risk of bias (Arnold 1989; Beattie 2000; Burden 2011; de Luis 2003; de Sousa 2012; Diouf 2016; Fuenzalida 1990; Gonzalez-Espinoza 2005; Huynh 2015; Kapoor 2017; Kendell 1982; Le Cornu 2000; Norman 2008b; Olejko 1984; Rabeneck 1998). Three studies reported no loss to follow-up (Fuenzalida 1990; Kendell 1982; Olejko 1984). A further seven studies reported an attrition rate below 15% (Arnold 1989; Beattie 2000; Burden 2011; de Luis 2003; de Sousa 2012; Gonzalez-Espinoza 2005; Le Cornu 2000); in one study all the withdrawals were from the control group (de Sousa 2012) and in a second study the attrition rate was 5% in the intervention group and 17.5% in the control group (Le Cornu 2000). Five studies reported attrition rates over 15%, sometimes much higher, but with similar numbers across groups (Diouf 2016; Huynh 2015; Kapoor 2017; Norman 2008b; Rabeneck 1998).

The review authors judged three studies to have an unclear risk of bias; one study reported less than 15% attrition, but did not provide reasons for withdrawals (Sharma 2002a) and in the second while 2% withdrew (reasons not given) and only 43% were still alive at 12 months, death rates were similar across groups (Baldwin 2011). The third study reported an attrition rate of 37%, but did not state which groups these were from (Dixon 1984).

The review authors judged four studies to have a high risk of attrition bias (Burden 2017; McCarthy 1999; Murphy 1992; Wilson 2001). One study reported less than 15% attrition with reasons for how many participants dropped out of which groups, but for some outcome measures data are provided for fewer participants than originally included in the study (Burden 2017). Investigators do not report the reasons why data were missing for these outcomes. One study reported 15% attrition, but gave no details on which group the withdrawals were from (Wilson 2001). Two studies reported high rates of attrition that were not balanced across groups; in one there was an overall rate of 40% with 10% withdrawing from the advice only group and 30% from the advice plus ONS group (McCarthy 1999) and in the second an overall rate of 27% broke down to 45% withdrawals in the advice only group and 9% in the advice plus ONS group (Murphy 1992).

Dietary advice plus ONS, if required, compared with no advice and no ONS

The review authors judged 21 out of the 31 studies included in this comparison to have a low risk of bias (Andersson 2017; Banks

2016; Beck 2012; Beck 2015; Bourdel-Marchasson 2014; Carey 2013; Evans 1987; Forli 2001; Ganzoni 1994; Isenring 2004; Kiss 2016; Lovik 1996; Persson 2002; Rogers 1992; Sharma 2017; Schilp 2013; Starke 2011; Suominen 2015; Terp 2018; Uster 2013; Vivanti 2015). In nine studies, 15% or less dropped out with reasons given and similar numbers across groups (Andersson 2017; Beck 2015; Carey 2013; Forli 2001; Holyday 2012; Isenring 2004; Lovik 1996; Schilp 2013; Starke 2011; Suominen 2015). In two further studies fewer than 3% dropped out, but all were in the control group (Bourdel-Marchasson 2014; Rogers 1992). In six studies attrition rates ranged from 18% to 43%, but numbers were balanced across groups (Banks 2016; Beck 2012; Kiss 2016; Sharma 2017; Terp 2018; Uster 2013). Similarly, two studies reported attrition rates of 45% to 55% but with similar numbers across groups (Ganzoni 1994; Persson 2002). One study reported more than 20% of participants dropped out but gave reasons why (Vivanti 2015). The final low-risk study reported a large number of deaths during the study (87%), but to put this into context, all participants had cancer and the numbers of deaths were approximately equal across groups (Evans 1987).

The review authors judged five studies to have an unclear risk of attrition bias (Endevelt 2011; Holyday 2012; Moloney 1983; Ovesen 1993; Pedersen 2016a). Two of these did not report on attrition (Endevelt 2011; Moloney 1983); in two studies attrition rates ranged from 25% to 35% and while the numbers were similar across groups there were no reasons given for withdrawals (Ovesen 1993; Pedersen 2016a). In the final study there was a low number of dropouts (all due to death), but data on weight change was only available 48% of participants and no information was reported to explain why (Holyday 2012).

The remaining five studies had a high risk of attrition bias (Bonilla-Palomas 2016; Caccialanza 2015; Feldblum 2011; Jensen 1997; Silvers 2014). In one study, mortality in the control group was more than double that in intervention group (Bonilla-Palomas 2016). In the remaining four studies, overall attrition rates ranged from 25.8% to 58%, but were not balanced across groups. In one study an overall rate of 25.8% was calculated from 11.5% in the advice plus ONS group compared to 32% in the no advice or supplements group (Feldblum 2011); in a further study overall attrition of 28.6% broke down to 10% in the advice plus ONS group and 45% in the no advice or ONS group (Silvers 2014). Conversely, Jensen reported 33.5% attrition overall with 50% withdrawals in the advice and ONS group compared to 17% in the no advice or ONS group (Jensen 1997) and finally Caccialanza showed an overall attrition rate of 58% due to 71% in the advice plus ONS group and 46% in the no advice or ONS group (Caccialanza 2015).

Dietary advice plus ONS compared with no advice and no ONS

The review authors judged eight of the 13 studies in this comparison to have a low risk of attrition bias (Anbar 2014; Jahnvi 2010; Hampson 2003; Neelemaat 2011; Paton 2004; Payette 2002; Um 2014; Wyers 2013). The first study reported that all participants completed the study (Anbar 2014). Five studies reported less than 15% attrition and provided reasons for dropouts (Hampson 2003; Jahnvi 2010; Payette 2002; Um 2014; Wyers 2013). The remaining two studies had almost 30% attrition, but provided reasons for this and numbers were similar across groups (Neelemaat 2011; Paton 2004).

Three studies had an unclear risk of bias; one study did not report any information on attrition (Chandra 1985). A further study

had 16% attrition, but did not report which group withdrawals were from (Berneis 2000). Finally, in the Baldwin study, while 2% withdrew (reasons not given) and only 43% were still alive at 12 months, death rates were similar across groups (Baldwin 2011).

Two studies had a high risk of attrition bias (Calegari 2011; Persson 2007). In one study there was 17% attrition, but all from the control group (Calegari 2011); while in the second there was a 50% attrition rate with 43% in the intervention group and 56% in the control group (Persson 2007).

Selective reporting

Dietary advice compared with no advice

Seven out of the 24 studies included in this comparison had a low risk of selective reporting bias; for five studies a protocol was identified and all specified outcomes were reported (Campbell 2008; Fernandez-Barres 2017; Forster 2012; Salva 2011; Stow 2015). For a further two studies there was no published protocol, but a review author was an investigator on the study and provided all requisite data (Baldwin 2011; Weekes 2009).

The review authors judged 14 studies to have an unclear risk of selective reporting bias (Alo 2014; Cano-Torres 2017; Casals 2015; Dixon 1984; Gu 2015; Imes 1988; Locher 2013; Macia 1991a; Manguso 2005; Pivi 2011; Ravasco 2005a; Ravasco 2005b; Rydwick 2008; Wong 2004). They were unable to identify a pre-registered or pre-published protocol for 12 studies; however, in 11 of these studies, all the outcomes described in the methods section were reported in the results (Alo 2014; Cano-Torres 2017; Casals 2015; Gu 2015; Imes 1988; Macia 1991a; Manguso 2005; Pivi 2011; Ravasco 2005a; Ravasco 2005b; Wong 2004). In a further study, all outcomes described in the methods section except one were reported in results (Rydwick 2008). In one study, the review authors identified the study protocol, but one outcome was not reported at all and the available results for the other outcomes only reported at the earlier of two planned time points (Locher 2013).

The remaining three studies had a high risk of selective reporting bias (Kunvik 2018; Ollenschlager 1992; Tu 2013). For one study, review authors identified the pre-registered protocol but not all the main aims of the study were reported (Kunvik 2018). The review authors did not identify the protocols for the remaining two studies; for one study additional data for outcomes were provided by the investigators, but there were still some missing data for some outcomes (Ollenschlager 1992) and in the second study investigators reported outcomes using a composite score and not the original data (Tu 2013).

Dietary advice compared with ONS

The review authors judged two of 12 studies reporting data for this comparison to have a low risk of selective reporting bias (Baldwin 2011; Stow 2015). In one study the pre-registered protocol was identified and all outcomes were reported (Stow 2015). The review authors did not identify a pre-registered protocol for the remaining study, but a review author was an investigator on the study and provided all requisite data (Baldwin 2011).

The review authors judged nine studies to have an unclear risk of selective reporting bias. For eight studies they were not able to identify a pre-registered protocol, but investigators reported in the results section all the outcomes listed in the methods

sections (Gray-Donald 1995; Hernandez 2014; Kalnins 2005; Pivi 2011; Ravasco 2005a; Ravasco 2005b; Schwenk 1999; Singh 2008); for one of these the results were not in an analysable format, but the investigator provided the data (Schwenk 1999). In the remaining study, the review authors identified a protocol, but this only records the primary outcome; other outcomes listed in the methods section of the full paper are reported in results section (Parsons 2016).

The review authors judged one study to have a high risk of bias as they could not identify a study protocol and some outcomes listed in the methods section were not reported in the results section (Akpele 2004).

Dietary advice versus dietary advice plus ONS

The review authors judged three out of 22 studies in this comparison to have a low risk of selective reporting (Baldwin 2011; Diouf 2016; Huynh 2015). For two of these the review authors identified a study protocol and investigators reported all outcome measures (Diouf 2016; Huynh 2015). For the remaining study, the review authors did not identify a protocol, but one of the investigators is a review author and provided all requisite data (Baldwin 2011).

The review authors judged 16 studies to have an unclear risk of selective reporting bias. They did not identify a pre-registered protocol for 15 studies, so they were not able to judge if all outcomes were reported by investigators, although some investigators did provide additional details for some outcomes on request (Arnold 1989; Beattie 2000; Burden 2011; de Luis 2003; de Sousa 2012; Dixon 1984; Fuenzalida 1990; Gonzalez-Espinoza 2005; Kapoor 2017; Le Cornu 2000; McCarthy 1999; Murphy 1992; Norman 2008b; Rabeneck 1998; Sharma 2002a). The review authors identified a published protocol for one study, but it did not report on all pre-specified secondary outcome measures (Burden 2017).

The review authors judged the remaining three studies to have a high risk of bias (Kendell 1982; Olejko 1984; Wilson 2001). One study lacked a published protocol and did not report results for all the outcomes that were listed in the methods section (Wilson 2001), while two further studies reported all outcomes, but only using general narrative statements and no data (these were also not available from the investigators) (Kendell 1982; Olejko 1984).

Dietary advice plus ONS, if required, compared with no advice and no ONS

The review authors deemed eight studies to have a low risk of selective reporting bias as investigators reported all outcomes that were specified in the protocol in the results section (Beck 2012; Bonilla-Palomas 2016; Caccialanza 2015; Endevelt 2011; Kiss 2016; Pedersen 2016a; Schilp 2013; Terp 2018). Investigators for one study reported most outcome measures (some secondary outcomes missing) (Schilp 2013).

Review authors were unable to identify a protocol for 22 studies and judged there to be an unclear risk of selective reporting bias as they were not sure whether investigators reported all planned outcomes (Andersson 2017; Banks 2016; Beck 2015; Bourdel-Marchasson 2014; Carey 2013; Evans 1987; Feldblum 2011; Forli 2001; Ganzoni 1994; Holyday 2012; Isenring 2004; Jensen 1997; Lovik 1996; Moloney 1983; Ovesen 1993; Persson 2002; Rogers 1992; Sharma 2017; Silvers 2014; Starke 2011; Uster 2013; Vivanti 2015).

The review authors judged the remaining study to have a high risk of selective reporting bias (Suominen 2015). While they identified a published protocol for the study, in which all outcomes were reported, the study investigators only provided narrative text and no data were available for the primary outcome (Suominen 2015).

Dietary advice plus ONS compared with no advice and no ONS

The review authors judged one study to have a low risk of selective outcome reporting (Baldwin 2011). This study did not have a published protocol, but one of the investigators is a review author and provided all requisite data (Baldwin 2011).

Nine studies had an unclear risk of selective reporting bias as the review authors did not identify the relevant published protocols (Anbar 2014; Berneis 2000; Calegari 2011; Hampson 2003; Jahnvi 2010; Paton 2004; Payette 2002; Persson 2007; Um 2014); in seven studies the lack of a published protocol meant that review authors were unable to judge if investigators reported all planned outcomes (Anbar 2014; Berneis 2000; Calegari 2011; Hampson 2003; Jahnvi 2010; Payette 2002; Um 2014). In a further two of these studies the data were not always in a format that allowed analysis and some additional data were made available from the investigators (Paton 2004; Persson 2007).

The review authors judged three studies to have a high risk of bias as they identified a protocol, but the investigators did not report all the outcomes (Chandra 1985; Neelemaat 2011; Wyers 2013).

Other potential sources of bias

This domain was mainly assessed on the basis of whether the baseline characteristics revealed any imbalances between the intervention and control groups.

Dietary advice compared with no advice

Investigators reported baseline variables to be similar between the groups in nine of the 24 studies in this comparison and the review authors considered these studies to be at low risk of bias (Alo 2014; Casals 2015; Fernandez-Barres 2017; Kunvik 2018; Manguso 2005; Ollenschlager 1992; Rydwick 2008; Weekes 2009; Wong 2004). One study reported similar baseline characteristics, but was stopped prematurely which led to an overall unclear risk of bias from other sources (Baldwin 2011). One study reported no differences in baseline characteristics, but investigators did not report nutritional status as this was not an inclusion criterion of their study, so the review authors judged this study to have an unclear risk of bias (Pivi 2011).

In seven studies there were differences in the baseline characteristics (Campbell 2008; Cano-Torres 2017; Forster 2012; Gu 2015; Imes 1988; Salva 2011; Stow 2015). In one of the studies, there was additional clustering bias which led to a judgement of a high risk of bias (Stow 2015). Details are presented in the additional tables (Table 9).

Six studies did not supply details of baseline characteristics and the review authors judged all of these to have an unclear risk of bias (Dixon 1984; Locher 2013; Macia 1991a; Ravasco 2005a; Ravasco 2005b; Tu 2013). In two of these studies baseline characteristics were not shown, but one study reported them to be statistically equivalent (Dixon 1984) and the second reported successful balancing for sex and BMI (Locher 2013).

Dietary advice compared with ONS

Reported baseline variables were similar between the groups in four of the 12 studies that compared dietary advice to ONS and the review authors consider three of these studies to be at a low risk of bias (Akpele 2004; Schwenk 1999; Singh 2008). One study reported similar baseline characteristics, but was stopped prematurely which led to an overall unclear risk of bias from other sources (Baldwin 2011). A further study reported no differences in baseline characteristics, but did not report nutritional status as this was not an inclusion criterion of the study, so the review authors judged this study to have an unclear risk of bias (Pivi 2011).

Four studies reported differences between some characteristics of the groups at baseline (Gray-Donald 1995; Hernandez 2014; Parsons 2016; Stow 2015). In one of the studies, there was additional clustering bias which led to a judgement of a high risk of bias (Stow 2015). Details are presented in the additional tables (Table 10).

In three studies investigators provided no details of baseline characteristics and the review authors judged these to have an unclear risk of bias (Kalnins 2005; Ravasco 2005a; Ravasco 2005b).

Dietary advice versus dietary advice plus ONS

Investigators reported baseline variables to be similar between the groups in eight of the 22 studies in this comparison and the review authors consider these studies to be at a low risk of bias (Arnold 1989; Burden 2017; de Luis 2003; de Sousa 2012; Fuenzalida 1990; Gonzalez-Espinoza 2005; Le Cornu 2000; Rabeneck 1998). The review authors note that in one of these studies there were more participants in the intervention group and that at the point of recruitment it was undecided if surgery would be open or laparoscopic; the default used was open-surgery stratum for randomisation, but the groups seem to be well-balanced (Burden 2017).

Eight studies reported differences in baseline characteristics (Beattie 2000; Diouf 2016; Huynh 2015; Kapoor 2017; McCarthy 1999; Murphy 1992; Sharma 2002a; Wilson 2001); these characteristics are presented in the additional tables (Table 11).

The review authors judged six studies to have an unclear risk of bias; one study reported similar baseline characteristics, but was stopped prematurely which led to an overall unclear risk of bias from other sources (Baldwin 2011). Five studies did not present baseline characteristics (Burden 2011; Dixon 1984; Kendell 1982; Norman 2008b; Olejko 1984). While two of these did not detail baseline characteristics, investigators reported these to be similar (Dixon 1984; Norman 2008b); the review authors judged both studies to have an unclear risk as the available information was insufficient to assess whether an important risk of bias exists. One study also measured dietary intake using an unreliable outcome measure and the reported SDs indicated that data for this outcome might be skewed; the review authors judged this study to have an unclear risk of bias overall (Burden 2011).

Dietary advice plus ONS, if required, compared with no advice and no ONS

Baseline variables were similar between the groups in 23 of the 31 studies in this comparison and the review authors considered these studies to have a low risk of bias (Andersson 2017; Banks 2016;

Beck 2012; Beck 2015; Bonilla-Palomas 2016; Bourdel-Marchasson 2014; Caccialanza 2015; Endevelt 2011; Evans 1987; Feldblum 2011; Holyday 2012; Isenring 2004; Kiss 2016; Lovik 1996; Ovesen 1993; Pedersen 2016a; Persson 2002; Rogers 1992; Schilp 2013; Sharma 2017; Starke 2011; Suominen 2015; Terp 2018).

There were differences between some characteristics of the groups at baseline in six studies (Carey 2013; Forli 2001; Jensen 1997; Moloney 1983; Silvers 2014; Uster 2013); these are presented in the additional tables (Table 12).

Two studies did not report details of baseline characteristics and the review authors judged both of these studies to have an unclear risk of bias (Ganzoni 1994; Vivanti 2015).

Dietary advice plus ONS compared with no advice and no ONS

Baseline variables were similar between the groups in seven of the 13 studies that compared data and the review authors considered these studies to have a low risk of bias (Anbar 2014; Calegari 2011; Jahnvi 2010; Neelemaat 2011; Paton 2004; Um 2014; Wyers 2013). One study reported similar baseline characteristics, but was stopped prematurely which led to an overall unclear risk of bias from other sources of bias (Baldwin 2011).

Two studies reported some differences between groups at baseline (Hampson 2003; Payette 2002). Details are presented in the additional tables (Table 13).

Three studies did not report details of baseline characteristics and the review authors judged all of these to have an unclear risk of bias (Berneis 2000; Chandra 1985; Persson 2007). In one study, investigators described the groups as similar in the text, but data are not shown (Persson 2007).

Sensitivity analyses

As no studies were at overall low risk of bias, it was not possible to test the robustness of the results by producing sensitivity analyses exploring the potential impact of study quality.

Effects of interventions

See: **Summary of findings 1** Dietary advice compared with no advice for disease-related malnutrition in adults; **Summary of findings 2** Dietary advice compared with oral nutritional supplements for disease-related malnutrition in adults; **Summary of findings 3** Dietary advice compared with dietary advice plus oral nutritional supplements for disease-related malnutrition in adults; **Summary of findings 4** Dietary advice plus supplements if required compared with no advice for disease-related malnutrition in adults; **Summary of findings 5** Dietary advice plus supplements compared with no dietary advice plus no supplements for disease-related malnutrition in adults

All comparisons

Review authors collected data on a variety of outcome measures encompassing clinical and functional status and QoL. However, because the study investigators used different measures to assess the outcomes or reported the data in such a way that they could not be analysed, it has only been possible to pool some of these data within a meta-analysis. The review authors have summarised the types of data collected and the tools used in the additional tables (Table 1; Table 2; Table 3). They have analysed available data on the

change in handgrip strength and included data on several domains of QoL in the analyses.

In the summary of findings tables, the review authors have graded the certainty of the evidence for pre-defined outcomes (see above) and provided definitions of these gradings ([Summary of findings 1](#); [Summary of findings 2](#); [Summary of findings 3](#); [Summary of findings 4](#); [Summary of findings 5](#)).

The review authors only report results below in the text for time points for which data or information are available. If investigators did not report data or information at a specific time point, then the authors have not included any text.

Group 1 – Dietary advice compared with no advice

The comparison includes 24 studies (3523 randomised participants) ([Alo 2014](#); [Baldwin 2011](#); [Campbell 2008](#); [Cano-Torres 2017](#); [Casals 2015](#); [Dixon 1984](#); [Fernandez-Barres 2017](#); [Forster 2012](#); [Gu 2015](#); [Imes 1988](#); [Kunvik 2018](#); [Locher 2013](#); [Macia 1991a](#); [Manguso 2005](#); [Ollenschlager 1992](#); [Pivi 2011](#); [Ravasco 2005a](#); [Ravasco 2005b](#); [Rydwik 2008](#); [Salva 2011](#); [Stow 2015](#); [Tu 2013](#); [Weekes 2009](#); [Wong 2004](#)), but there were no usable data from two of these studies ([Dixon 1984](#); [Tu 2013](#)). Authors of the 2005 Ravasco study published additional data in 2012 which described additional follow-up to a median of 6.5 (range 4.9 to 8.1) years ([Ravasco 2005a](#); [Ravasco 2012](#)). The study by Macia reports data according to disease site (head and neck, breast and abdominopelvic). The review authors have added these data to the analyses by group for weight, BMI, MAC, MAMC and TSF using different identifiers for head and neck ([Macia 1991a](#)) for breast cancer ([Macia 1991b](#)) and for abdominopelvic cancers ([Macia 1991c](#)).

Please refer to the summary of findings table for the explanations of judgements ([Summary of findings 1](#)). Note that GRADE judgements are for specific outcomes at the three-months time point and are not provided for all outcomes at each time point.

Primary outcome

1. Mortality

Zero to three months

Data were available from seven studies (574 participants) at up to three months ([Baldwin 2011](#); [Campbell 2008](#); [Manguso 2005](#); [Ravasco 2005a](#); [Ravasco 2005b](#); [Rydwik 2008](#); [Stow 2015](#)). There was no difference in mortality between the participants who received dietary advice and those who received no advice, RR 0.87 (95% CI 0.26 to 2.96) (low-certainty evidence). Moderate to substantial heterogeneity was observed ($I^2 = 52%$) ([Analysis 1.1](#)). Removal of one study reduces heterogeneity ($I^2 = 28%$) ([Stow 2015](#)) and there remains no difference in mortality between groups, RR 1.54 (95% CI 0.39 to 6.17). The Stow study is a cluster-RCT and it was not possible to recalculate data taking into consideration the design effect for clusters which might account for the difference between this and other studies in the analysis ([Stow 2015](#)).

Four to six months

Data were available from 10 studies (1028 participants) at the time point from four to six months ([Baldwin 2011](#); [Cano-Torres 2017](#); [Casals 2015](#); [Fernandez-Barres 2017](#); [Imes 1988](#); [Ollenschlager 1992](#); [Pivi 2011](#); [Stow 2015](#); [Weekes 2009](#); [Wong 2004](#)). There was no difference in mortality between the participants who received

dietary advice and those who received no advice, RR 0.88 (95% CI 0.61 to 1.27). There was no heterogeneity ($I^2 = 6%$) ([Analysis 1.1](#)). One study with four intervention groups and a control group reported that overall 23 of 88 (26%) participants died during the four-month study, but mortality is not reported according to group allocation, so it is not possible to include these results in the analysis ([Dixon 1984](#)).

12 months and over

Data were available from five studies (1445 participants) that assessed mortality at 12 months and over ([Baldwin 2011](#); [Fernandez-Barres 2017](#); [Ravasco 2005a](#); [Salva 2011](#); [Weekes 2009](#)). There was no difference in mortality between the participants who received dietary advice and those who received no advice, RR 1.07 (95% CI 0.59 to 1.91), but there was considerable heterogeneity in this analysis ($I^2 = 79%$) ([Analysis 1.1](#)). The authors are unable to explain this heterogeneity as removal of each study individually did not reduce the heterogeneity noticeably.

The review authors did not undertake a combined total analysis as a number of studies report mortality at several time points.

2. Morbidity

a. Hospital admissions

Four studies provided hospital admission data for inclusion in the meta-analysis ([Fernandez-Barres 2017](#); [Imes 1988](#); [Stow 2015](#); [Weekes 2009](#)).

Four to six months

Three studies (259 participants) reported on interventions at between four and six months ([Imes 1988](#); [Stow 2015](#); [Weekes 2009](#)); there was no difference between the two groups, RR 1.33 (95% CI 0.55 to 3.18) but substantial heterogeneity ($I^2 = 75%$) ([Analysis 1.2](#)). Removal of the Stow study reduces heterogeneity ($I^2 = 0%$) and there remains no difference in hospital readmissions between groups, RR 0.86 (95% CI 0.54 to 1.36); the study by Stow is a cluster-RCT and it was not possible to recalculate data taking into consideration the design effect for clusters which might account for the difference between this and other studies in the analysis ([Stow 2015](#)).

12 months and over

Two studies (230 participants) reported on interventions at 12 months and over ([Fernandez-Barres 2017](#); [Weekes 2009](#)). Again there was no difference between the two groups, RR 0.64 (95% CI 0.36 to 1.13) and no heterogeneity ($I^2 = 0%$) ([Analysis 1.2](#)).

One study in 106 hospitalised participants, reported significantly fewer mean (SD) hospital admissions per participant after six months in the group receiving dietary advice compared with the group receiving no advice, 0.25 (0.4) admissions and 0.62 (1.11) admissions respectively ($P = 0.04$) ([Casals 2015](#)). Since investigators reported data as mean (SD) admissions, these could not be combined with data from the other studies reporting this outcome.

b. Length of hospital stay

Four studies provided data on length of hospital stay ([Cano-Torres 2017](#); [Casals 2015](#); [Gu 2015](#); [Weekes 2009](#)).

Zero to three months

Hospital stay was significantly shorter in 148 participants receiving dietary advice compared with no advice at up to three months (Gu 2015), MD -1.10 days (95% CI -1.35 to -0.85) (low-certainty evidence) (Analysis 1.3).

Four to six months

Data were available from three studies at over four and up to six months (Cano-Torres 2017; Casals 2015; Weekes 2009). There was no difference between the two groups, MD 1.93 (95% CI -3.42 to 7.28), but considerable heterogeneity ($I^2 = 81%$) (Analysis 1.3). Removal of one study reduced heterogeneity ($I^2 = 4%$) and length of stay was significantly shorter in the groups receiving no advice compared to the groups receiving advice, MD 4.52 days (95% CI 0.80 to 8.25) (Cano-Torres 2017). The review authors find it difficult to account for the different effect seen in the study by Cano-Torres, as both the Casals and the Cano-Torres studies enrolled hospital inpatients (Cano-Torres 2017; Casals 2015). In the study by Cano-Torres, a dietitian provided the dietary advice and in the study by Casals nurses did so; but in the Weekes study, participants also received dietary advice from a dietitian and yet the effect on length of hospital stay is different.

12 months and over

There was no difference in length of hospital stay in 57 participants receiving dietary advice compared with no advice at 12 months (Weekes 2009), MD -3.00 days (95% CI -11.58 to 5.58) (Analysis 1.3).

The review authors did not undertake a combined analysis as one study reported length of hospital stay at several time points. (Analysis 1.3).

c. Complications

Data on complications were available from two studies (288 participants), but investigators used different tools and so the review authors combined results using the SMD (Forster 2012; Gu 2015).

There were no differences in complications between groups for a study at the three-month time point, SMD 0.00 (95% CI -0.32 to 0.32) (low-certainty evidence) (Gu 2015) or for the second study at six months, SMD -0.21 (95% CI -0.55 to 0.12) (Forster 2012). Analysis of both studies combined showed no difference in complications between the two groups, SMD -0.10 (95% CI -0.34 to 0.13) and no heterogeneity ($I^2 = 0%$). There was no heterogeneity between subgroups ($I^2 = 0%$) (Analysis 1.4).

3. Measures of nutritional status

a. Change in weight

Zero to three months

10 studies (802 participants) reported data on weight change for interventions lasting up to three months (Baldwin 2011; Campbell 2008; Forster 2012; Gu 2015; Locher 2013; Manguso 2005; Ravasco 2005a; Ravasco 2005b; Rydwick 2008; Stow 2015). Groups receiving dietary advice had a significantly greater weight gain compared with groups receiving no advice, MD 0.97 kg (95% CI 0.06 to 1.87) (low-certainty evidence). Heterogeneity was considerable ($I^2 = 88%$). Removal of one study resulted in no weight change

between groups and reduced the heterogeneity to moderate (MD 0.34 kg (95% CI -0.14 to 0.81) (Ravasco 2005a) (Analysis 1.5). It is difficult to explain why the effect size from dietary advice in one study by Ravasco is so much greater than other studies in the group with participants with similar disease backgrounds (Baldwin 2011; Ravasco 2005b). Neither study by Ravasco reported baseline characteristics of participants making comparison across studies difficult; the investigators provided the data included in the meta-analysis.

Four to six months

Six studies (573 participants) reported data on weight change for interventions that lasted from four to six months (Baldwin 2011; Casals 2015; Fernandez-Barres 2017; Stow 2015; Weekes 2009; Wong 2004). Groups receiving dietary advice had a significantly greater weight gain compared with groups receiving no advice, MD 1.61 kg (95% CI 0.09 to 3.13). Heterogeneity was considerable, ($I^2 = 83%$) (Analysis 1.5). The removal of one study resulted in no difference in weight change between groups (Casals 2015) and reduced the heterogeneity to moderate, MD 0.69 kg (95% CI -0.14 to 1.52) (Analysis 1.5). This study was in acutely ill hospitalised participants (Casals 2015), whereas the other studies in this analysis were in participants with chronic conditions living at home or in residential care and the different aetiology of malnutrition might account for the differences seen in effects of interventions.

The study by Pivi reported a higher mean weight change (group body weight range) in participants receiving education on diet compared with a control group, 1.19 kg (54.29 to 50kg) and -2.20 kg (61.87 to 60.65kg) respectively (Pivi 2011).

12 months and over

Five studies (1215 participants) reported data on weight change after 12 months of the intervention (Baldwin 2011; Fernandez-Barres 2017; Macia 1991a; Macia 1991b; Macia 1991c; Salva 2011; Weekes 2009). There was a statistically significant benefit to receiving dietary advice compared with no advice, MD 2.95 kg (95% CI 0.75 to 5.16), heterogeneity was substantial ($I^2 = 70%$). The removal of one study resulted in a significantly greater weight gain in groups receiving dietary advice compared with groups receiving no advice (Salva 2011) and reduced the heterogeneity to zero per cent, MD 3.88 kg (95% CI 2.34 to 5.43) (Analysis 1.5). The study by Salva is a cluster-RCT and it was not possible to recalculate data taking into consideration the design effect for clusters which might account for the difference between this and other studies in the analysis (Salva 2011).

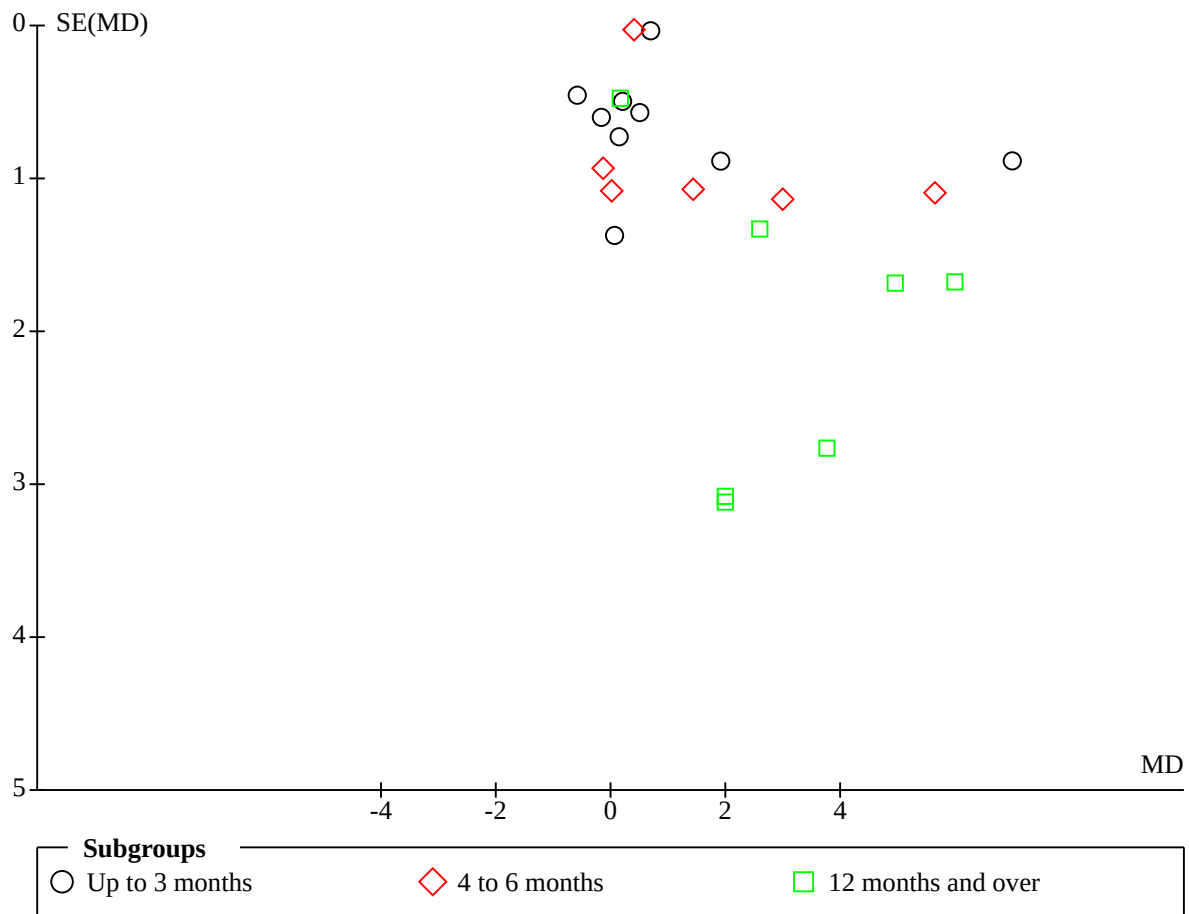
The review authors did not undertake any combined analysis as several studies report data at more than one time point (Analysis 1.5).

Sensitivity analysis

The review authors imputed the SD of weight change for one study reporting data at 12 months and over (Macia 1991a; Macia 1991b; Macia 1991c). There were too few studies in the analysis at this time point to examine the impact of this on the overall result.

The funnel plot examination, the Egger regression asymmetry test and the Begg's adjusted rank correlation suggested no evidence of small study bias ($P = 0.824$ and $P = 0.348$, respectively) (Figure 3).

Figure 3. Funnel plot of comparison: 1 Dietary advice compared with no advice, outcome: 1.5.1 Change in weight (kg).



b. BMI

Zero to three months

Two studies (181 participants) reported the change from baseline in BMI for interventions lasting up to three months (Forster 2012; Stow 2015). There was no difference between groups receiving dietary advice and groups receiving no advice, MD 0.34 kg/m² (95% CI -0.24 to 0.92). Heterogeneity was substantial (I² = 61%) (Analysis 1.6). One study was a cluster-RCT and it was not possible to recalculate data taking into consideration the design effect for clusters which might account for the difference between this and the other study in the analysis (Stow 2015).

Four to six months

Seven studies (596 participants) reported the change from baseline in BMI for interventions lasting from four to six months (Alo 2014; Cano-Torres 2017; Casals 2015; Fernandez-Barres 2017; Kunvik 2018; Stow 2015; Wong 2004). There were no differences between groups receiving dietary advice compared with no advice MD 0.26 kg/m² (95% CI -0.08 to 0.60). Heterogeneity was considerable, (I² = 78%). Removal of one study reduced heterogeneity to moderate (I² = 43%) (Casals 2015), but it is not possible to explain how this study might be different from others in the analysis (Analysis 1.6).

One study reported a higher mean change in BMI (group BMI range) in participants receiving education on diet compared with a control group, 1.19 kg/m² (22.71 to 22.84 kg/m²) and -2.21 kg/m² (24.81 to 24.32kg/m²) respectively (Pivi 2011).

12 months and over

Three studies (1148 participants) reported data on the change in BMI after 12 months of the intervention (Fernandez-Barres 2017; Macia 1991a; Macia 1991b; Macia 1991c; Salva 2011). There was a significant benefit to receiving dietary advice compared with no advice, MD 2.17 kg/m² (95% CI 0.25 to 4.09), but heterogeneity was considerable, (I² = 87%). Removal of each study in the analysis did not reduce the heterogeneity significantly and so it is not possible to explain why the effect sizes differ between studies.

The review authors did not undertake any combined analysis as several studies report data at more than one time point (Analysis 1.6).

c. FFM

In total, three studies (138 participants) reported on this outcome (Campbell 2008; Rydwick 2008; Weekes 2009). One study reported data as body cell mass derived from total body potassium

(Campbell 2008) and two studies calculated FFM from the sum of four skinfolds (Rydwik 2008; Weekes 2009); therefore, the review authors used the SMD to combine data (Analysis 1.7).

Zero to three months

Two studies (98 participants) reported data for the change from baseline in FFM at up to three months (Campbell 2008; Rydwik 2008). There was no difference between groups receiving dietary advice and groups receiving no advice, SMD 0.29 kg (95% CI -0.11 to 0.69) (low-certainty evidence) and there was no heterogeneity ($I^2 = 0\%$) (Analysis 1.7).

Four to six months

One study (40 participants) reported data on the change from baseline in FFM at four to six months (Weekes 2009). There was no difference between groups receiving dietary advice compared with no advice, SMD 0.62 kg (95% CI -0.02 to 1.26) (Analysis 1.7).

12 months and over

The Weekes study (40 participants) also reported data for the change from baseline in FFM at 12 months and over (Weekes 2009) and found a large increase in FFM in groups receiving dietary advice compared with no advice, SMD 0.83 kg (95% CI 0.14 to 1.53) (Analysis 1.7).

The review authors did not undertake any combined analysis as one study reported data at more than one time point (Analysis 1.7).

d. MAC

Zero to three months

Two studies (176 participants) reported the change in MAC at up to three months (Forster 2012; Stow 2015). There was no difference between groups receiving dietary advice and groups receiving no advice, MD 0.23 cm (95% CI -0.61 to 1.07). Heterogeneity was substantial ($I^2 = 62\%$) (Analysis 1.8). The difference between results might be explained by the fact that the Stow study is a cluster-RCT and it was not possible to recalculate the data taking into consideration the design effect for clusters (Stow 2015).

Four to six months

Three studies (120 participants) reported the change in MAC from baseline at four to six months (Cano-Torres 2017; Stow 2015; Weekes 2009). There were no differences between groups receiving dietary advice compared with no advice, MD 0.14 cm (95% CI -0.37 to 0.65). There was no heterogeneity, ($I^2 = 0\%$) (Analysis 1.8).

One study reported a higher mean change in MAC (group MAC range) in participants receiving education on diet compared with a control group, 1.87 cm (24.72 to 25.11cm) and -0.41 cm (26.14 to 26.07cm) respectively (Pivi 2011).

12 months and over

Two studies (126 participants) reported data on change in MAC after 12 months of intervention (Macia 1991a; Macia 1991b; Macia 1991c; Weekes 2009); one of the studies reported data according to site of disease (Macia 1991a; Macia 1991b; Macia 1991c). There was no difference between groups receiving dietary advice compared with

no advice, MD 0.65 cm (95% CI -0.20 to 1.50) and there was no heterogeneity ($I^2 = 0\%$).

The review authors did not undertake any combined analysis as several studies report data at more than one time point (Analysis 1.8).

e. MAMC

Zero to three months

Two studies (109 participants) reported the change from baseline in MAMC at up to three months (Manguso 2005; Stow 2015). There was a significant improvement in MAMC in participants receiving dietary advice, MD 1.05 cm (95% CI 0.71 to 1.39) and no heterogeneity (Analysis 1.9).

Four to six months

Two studies (66 participants) reported the change in MAMC at four to six months (Stow 2015; Weekes 2009). There was a significant increase in MAMC in groups receiving dietary advice compared with no advice, MD 0.56 cm (95% CI 0.07 to 1.04). There was no heterogeneity ($I^2 = 0\%$) (Analysis 1.9).

One study reported a higher mean change in MAMC (group range for MAMC) in participants receiving education on diet compared with a control group, -1.27 cm (20.25 to 19.96 cm) and -0.19 cm (21.21 to 21.60 cm), respectively (Pivi 2011).

12 months and over

Two studies (128 participants) reported data for this outcome at 12 months (Macia 1991a; Macia 1991b; Macia 1991c; Weekes 2009), with one study reporting data according to site of disease (Macia 1991a; Macia 1991b; Macia 1991c). There was no difference in MAMC between groups MD 2.04 cm (95% CI -0.07 to 4.15), but heterogeneity was considerable ($I^2 = 91\%$). The two studies in this analysis include participants from different disease backgrounds, COPD (Weekes 2009) and cancer (Macia 1991a; Macia 1991b; Macia 1991c), and the different aetiology of malnutrition might explain the different effects of intervention. In addition, the review authors derived the data for the Macia study by imputation using an assumed correlation co-efficient of 0.8 and assumptions may have been incorrect resulting in use of incorrect SDs of change (Macia 1991a; Macia 1991b; Macia 1991c).

The review authors did not undertake any combined analysis as several studies report data at more than one time point (Analysis 1.9).

f. TSF

Zero to three months

Three studies (254 participants) reported the change from baseline in TSF at up to three months (Forster 2012; Manguso 2005; Stow 2015). There was a significant reduction in TSF in participants receiving dietary advice compared to groups receiving no advice, MD -0.95 mm (95% CI -1.83 to -0.08) and no heterogeneity (Analysis 1.10).

Four to six months

Two studies (67 participants) reported the change in TSF at four to six months (Stow 2015; Weekes 2009). There were no differences

between groups receiving dietary advice compared with no advice, MD 0.89 mm (95% CI -0.25 to 2.04). There was low heterogeneity ($I^2 = 5\%$) (Analysis 1.10).

One study reported a higher mean change in TSF (group range for TSF) in participants receiving education on diet compared with a control group, 2.32 mm (14.20 to 16.40 mm) and 2.20 mm (15.67 to 15.85 mm), respectively (Pivi 2011).

12 months and over

Two studies (128 participants) reported data on change in TSF after 12 months of intervention (Macia 1991a; Macia 1991b; Macia 1991c; Weekes 2009), with one study reporting data according to site of disease (Macia 1991a; Macia 1991b; Macia 1991c). There was no difference in TSF between groups, MD 1.24 mm (95% CI -0.84 to 3.31) and heterogeneity was moderate ($I^2 = 50\%$).

The review authors did not undertake a combined analysis as several studies report data at more than one time point (Analysis 1.10).

Secondary outcomes

1. Nutritional intake before and after the intervention

a. Change in energy intake

Zero to three months

Nine studies (536 participants) reported changes in energy intake at up to three months (Baldwin 2011; Campbell 2008; Forster 2012; Locher 2013; Manguso 2005; Ravasco 2005a; Ravasco 2005b; Rydwick 2008; Stow 2015). There was no difference between those who received dietary advice and those who received no advice, MD 242.63 kcal (95% CI -40.31 to 525.56), but heterogeneity was considerable ($I^2 = 97\%$) (Analysis 1.11). Removal of each study individually did not reduce the heterogeneity noticeably, so the review authors are unable to explain the high level of heterogeneity.

Four to six months

Three studies (356 participants) measured energy intake in participants receiving dietary advice at four to six months (Fernandez-Barres 2017; Stow 2015; Wong 2004). Results showed a significantly higher energy intake in those receiving dietary advice compared with no advice, MD 97.17 kcal (95% CI 20.22 to 174.12) and heterogeneity was substantial ($I^2 = 61\%$) (Analysis 1.11). Removal of one study reduced heterogeneity to zero ($I^2 = 0\%$) (Stow 2015), and there remained a significantly higher energy intake in groups receiving dietary advice, MD 63.63 kcal (95% CI 55.25 to 72.01). This study is a cluster-RCT and it was not possible to recalculate data taking into consideration the design effect for clusters which might account for the difference between this and other studies in the analysis (Stow 2015).

12 months and over

One study (111 participants) measured energy intake up to 12 months (Fernandez-Barres 2017) and reported no difference between groups, MD 52.00 kcal (95% CI -64.88 to 168.88).

The review authors did not undertake a combined analysis as several studies report data at more than one time point (Analysis 1.11).

b. Final energy intake

Zero to three months

Two studies (276 participants) reported the final energy intake for participants at up to three months (Gu 2015; Imes 1988). There was no difference between those who received dietary advice and those who received no advice, MD -45.91 kcal (95% CI -390.74 to 298.92), but heterogeneity was considerable ($I^2 = 80\%$) (Analysis 1.12). One study was in acutely ill hospital inpatients (Gu 2015) and the second study was in people with Crohn's disease living at home (Imes 1988). The different aetiology of malnutrition in those with acute and chronic disease might account for the differences between these groups as the acute malnutrition might be expected to resolve as the patient gets better and eating return to normal pre-illness levels.

Four to six months

One study (124 participants) measured the final energy intake in participants receiving dietary advice at four to six months (Imes 1988). Investigators reported no difference between those receiving dietary advice compared with no advice, MD -20.00 kcal (95% CI -320.10 to 280.10) (Analysis 1.12).

12 months and over

One study (37 participants) measured the final energy intake after 12 months (Weekes 2009) and reported a significantly higher intake in the group receiving dietary advice compared with the group receiving no advice, MD 194 kcal (95% CI 34.33 to 353.67) (Analysis 1.12).

The review authors did not undertake a combined analysis as several studies report data at more than one time point (Analysis 1.12).

The 2012 paper by Ravasco presented follow-up data and reported median energy intakes after a median follow-up of 6.5 years; the review authors were not able to analyse these in RevMan (Ravasco 2005a). Ravasco reported the median final energy intake was significantly higher in the group receiving dietary advice, 2482 kcal (95% CI 2210 to 2685) than the group receiving no advice 1332 kcal (95% CI 1098 to 1426) (Ravasco 2005a).

c. Change in protein intake

Zero to three months

Five studies (345 participants) reported changes in protein intake at up to three months (Campbell 2008; Ravasco 2005a; Ravasco 2005b; Forster 2012; Stow 2015). Protein intake was significantly higher in those who received dietary advice than those who received no advice, MD 12.50 g (95% CI 2.80 to 22.19), but heterogeneity was considerable ($I^2 = 83\%$). Removal of the two studies by Ravasco and reporting just the results from the remaining two studies reduced the heterogeneity to zero, and there was no difference in protein intake between the groups, MD 3.15 g (95% CI -0.36 to 6.66) (Analysis 1.13). The two Ravasco studies are both in people with cancer (Ravasco 2005a; Ravasco 2005b), whereas the remaining two studies are in older people living at home or in residential care (Forster 2012; Stow 2015). The different clinical background of participants might explain some of the differences in effect size, but it is unlikely to be responsible for all the differences as the final study is in individuals with chronic kidney disease (Campbell

2008), which includes participants with significant illness similar to the Ravasco studies. The studies by Ravasco consistently achieve effects that are substantially different from other similar studies and there is no obvious reason to explain this.

Four to six months

Four studies (356 participants) measured protein intake in participants receiving dietary advice for four to six months (Fernandez-Barres 2017; Kunvik 2018; Stow 2015; Wong 2004) and reported a significantly higher protein intake in those receiving dietary advice compared with no advice, MD 3.02 g (95% CI 2.60 to 3.43); there was no heterogeneity (Analysis 1.13).

12 months and over

One study measured protein intake up to 12 months and reported no difference between groups MD 4.00 g (95% CI -0.51 to 8.51) (Fernandez-Barres 2017).

The review authors did not undertake a combined analysis as several studies report data at more than one time point (Analysis 1.13).

d. Final protein intake

Zero to three months

Four studies (426 participants) reported the final protein intake at up to three months (Campbell 2008; Gu 2015; Imes 1988; Manguso 2005). Final protein intake was significantly higher in those who received dietary advice than those who received no advice, MD 8.29 g (95% CI 1.24 to 15.34), but heterogeneity was considerable ($I^2 = 89%$) (Analysis 1.14). Removal of each study individually did not reduce the heterogeneity noticeably, so we are unable to explain the high level of heterogeneity.

Four to six months

One study (124 participants) measured protein intake in participants receiving dietary advice for six months (Imes 1988). Investigators reported no significant difference between those receiving dietary advice compared with no advice, MD 5.00 g (95% CI -7.32 to 17.32) (Analysis 1.14).

12 months and over

One study (50 participants) measured protein intake at 12 months (Weekes 2009) and reported a significantly higher intake in the group receiving dietary advice compared with the group receiving no advice, MD 11.8 g (95% CI 10.73 to 12.87) (Analysis 1.14).

The 2012 follow-up paper to the Ravasco study reported protein intake after a median follow-up of 6.5 years and found this to be significantly higher in the group receiving dietary advice, 74 g (95% CI 69 to 77) than the group receiving no advice 40 g (95% CI 38 to 42.5) (Ravasco 2005a).

The review authors did not undertake a combined analysis as several studies report data at more than one time point (Analysis 1.14).

2. Measures of functional status

a. Handgrip strength

Zero to three months

One study (24 participants) reported the change in handgrip strength at up to three months (Stow 2015). There was no difference between those receiving dietary advice and those receiving no advice, MD -0.98 kg force (95% CI -3.38 to 1.42) (Analysis 1.15).

Four to six months

Two studies (57 participants) reported on the change in handgrip strength from baseline at four to six months (Stow 2015; Weekes 2009). No difference was observed between the groups, MD -0.86 kg force (95% CI -3.32 to 1.59) and there was substantial heterogeneity ($I^2 = 63%$) (Analysis 1.15). The Stow study is a cluster-RCT and it was not possible to recalculate data taking into consideration the design effect for clusters which might account for the difference between this and the other study in the analysis (Stow 2015).

12 months and over

One study (37 participants) reported on this outcome at 12 months and over (Weekes 2009). There was no difference in handgrip strength between those receiving dietary advice and those receiving no advice, MD 0.30 kg force (95% CI -1.32 to 1.92) (Analysis 1.15).

The review authors did not undertake a combined analysis as several studies report data at more than one time point (Analysis 1.15).

3. QoL

Eight studies reported this outcome; three used the EORTC questionnaires (Baldwin 2011; Ravasco 2005a; Ravasco 2005b), one used the FAACT questionnaire (presented separately in the analysis where data for both questionnaires from the study were available) (Baldwin 2011), three used the SF-12 or SF-36 (Casals 2015; Forster 2012; Weekes 2009), one used the Kidney Disease Quality of Life Short Form (Campbell 2008), one used the Linear Analogue Self-Assessment Questionnaire (Ollenschlager 1992) and one used the SGRQ (Weekes 2009). One study only reported data for the intervention group and so has not been included in any of the analyses (Ollenschlager 1992). A further study reported collecting data on QoL, but does not report any results because of completion of questionnaires by too few participants (Stow 2015).

The review authors have entered data into a meta-analysis for global QoL scores, physical function, mental function, social function, cognitive function, pain and energy or fatigue using the SMD to combine data using different QoL questionnaires.

a. Global QoL

Zero to three months

Five studies (545 participants) reported on change in global QoL scores (Baldwin 2011; Campbell 2008; Forster 2012; Ravasco 2005a; Ravasco 2005b). There was a large improvement in global QoL in groups receiving advice compared with no advice, SMD 3.30 (95% CI 1.47 to 5.13) (low-certainty evidence) but there was considerable heterogeneity ($I^2 = 98%$) (Analysis 1.16). Removal of each study individually did not reduce the heterogeneity noticeably, however

we expect the heterogeneity likely arises from the differences in QoL instruments used, and the differences in clinical backgrounds and care settings. The studies by Ravasco consistently achieve effects that are substantially larger than other similar studies and there is no obvious reason to explain this.

Additionally, one study reported on a second QoL questionnaire (FAACT) (Baldwin 2011); data showed no difference between groups, SMD 0.03 (95% CI -0.32 to 0.38) (Analysis 1.16).

Four to six months

Three studies (278 participants) reported on the change in global QoL scores (Baldwin 2011; Casals 2015; Weekes 2009). One of these used two different QoL questionnaires, but the review authors only report one (SGRQ) here (Weekes 2009); a second study also used two questionnaires and these are presented separately (Baldwin 2011). There was no difference in change in global QoL at four to six months between the groups receiving advice and the groups receiving no advice, SMD 0.52 (95% CI -0.00 to 1.04). There was substantial heterogeneity ($I^2 = 69%$) (Analysis 1.16). Removal of one study reduced heterogeneity ($I^2 = 0%$) (Casals 2015) and there remained no difference in results between groups, SMD 0.24 (95% CI -0.15 to 0.63). This study randomised acutely ill hospitalised participants (Casals 2015), whereas the other studies in this analysis were in individuals with chronic disease; therefore the different disease backgrounds and aetiology of malnutrition might explain some of the differences.

Additionally, one study reported on a second QoL questionnaire (FAACT) (Baldwin 2011); data showed no difference between groups, SMD -0.05 (95% CI -0.52 to 0.42) (Analysis 1.16).

12 months and over

Two studies (97 participants) reported on a change in QoL at 12 months or longer (Ravasco 2005a; Weekes 2009); one of these used two different QoL questionnaires, but review authors report only one (SGRQ) here (Weekes 2009). There was a large improvement in global QoL in groups receiving advice compared with groups receiving no advice, SMD 3.79 (95% CI 0.33 to 7.25); however, there was considerable heterogeneity ($I^2 = 98%$). Removal of one study reduced heterogeneity ($I^2 = 0%$) (Ravasco 2005a) and there remained a large improvement in QoL in the group receiving advice, SMD 0.73 (95% CI 0.24 to 1.21). As in previous analyses, it is difficult to explain the large effect sizes seen in this study, but some of the differences may simply be explained by the different disease background of participants (cancer and COPD) as well as the use of different QoL instruments (Ravasco 2005a).

Review authors did not undertake a combined analysis as several studies reported data at more than one time point.

b. QoL - physical function

Zero to three months

Five studies (429 participants) reported on change in physical function at up to three months (Baldwin 2011; Campbell 2008; Forster 2012; Ravasco 2005a; Ravasco 2005b). There was a large improvement in physical function in groups receiving advice compared with no advice alone, SMD 3.38 (95% CI 1.54 to 5.23). However, there was considerable heterogeneity ($I^2 = 98%$). Removal of two studies reduced heterogeneity ($I^2 = 0%$) (Ravasco 2005a;

Ravasco 2005b), but there was no difference between the groups, SMD -0.03 (95% -0.26 to 0.19). As in previous analyses, it is difficult to explain the large effect sizes seen in the Ravasco studies, but some of the differences may simply be explained by the different disease background of participants (cancer and COPD) as well as the use of different QoL instruments (Analysis 1.17). The studies by Ravasco consistently achieve effects that are substantially larger than other similar studies and there is no obvious reason to explain this.

Four to six months

Two studies (147 participants) reported on change in physical function at six months (Casals 2015; Weekes 2009), one of which used two different QoL questionnaires, which the review authors did not combine (Weekes 2009). There was no difference between the groups receiving advice and the groups receiving no advice, SMD 0.44 (95% CI -0.47 to 1.35) (Analysis 1.17); however, there was considerable heterogeneity between subgroups ($I^2 = 84%$). Differences may be due to the different disease backgrounds and aetiology of malnutrition; one study being in acutely ill hospitalised participants (Casals 2015), whereas the other study in this analysis was in outpatients with COPD (Weekes 2009).

The second QoL questionnaire (SGRQ) reported by Weekes showed no difference between groups, SMD 0.38 (95% CI -0.24 to 1.01) (Analysis 1.17).

12 months and over

One study (35 participants) using two different QoL questionnaires reported change in physical function at 12 months or over (Weekes 2009). There was no difference between the group receiving advice and the group receiving no advice, either with the SF-36, SMD 0.65 (95% CI -0.03 to 1.33) or with the SGRQ, SMD 0.04 (95% CI -0.64 to 0.71) (Analysis 1.17).

Review authors did not undertake a combined analysis as several studies reported data at more than one time point.

c. QoL – mental function

Zero to three months

Five studies (421 participants) reported on change in mental function at up to three months (Baldwin 2011; Campbell 2008; Forster 2012; Ravasco 2005a; Ravasco 2005b). There was a large improvement in mental function in groups receiving advice compared with no advice, SMD 2.99 (95% CI 1.30 to 4.67); however, there was considerable heterogeneity ($I^2 = 98%$) (Analysis 1.18). Removal of two studies reduced heterogeneity ($I^2 = 0%$) (Ravasco 2005a; Ravasco 2005b) and there remained a significant but small to moderate improvement in mental function in the groups receiving advice compared with the groups receiving no advice, SMD 0.36 (95% 0.13 to 0.59). As in previous analyses, it is difficult to explain the large effect sizes seen in the studies by Ravasco, but some of the differences may simply be explained by the different disease background of participants (cancer, kidney disease and older people) as well as the use of different QoL instruments.

Four to six months

Two studies (106 participants) reported on change in physical function at six months (Casals 2015; Weekes 2009). There was no

difference between the groups receiving advice and the groups receiving no advice, SMD 0.49 (95% CI -0.61 to 1.59); however, there was considerable heterogeneity ($I^2 = 89\%$) (Analysis 1.18). One study was in people who were acutely ill and hospitalised (Casals 2015) whereas the other study in this analysis was in outpatients with COPD (Weekes 2009), therefore, the different disease backgrounds and aetiology of malnutrition might explain some of the differences.

12 months and over

One study (35 participants) reported change in mental function at 12 months or over (Weekes 2009). There was no difference between the group receiving advice and the group receiving no advice, SMD -0.64 (95% CI -0.05 to 1.34) (Analysis 1.18).

Review authors did not undertake a combined analysis as one study reported data at more than one time point.

d. QoL – social function

Zero to three months

Five studies (419 participants) reported on change in social function at up to three months (Baldwin 2011; Campbell 2008; Forster 2012; Ravasco 2005a; Ravasco 2005b). There was a large improvement in social function in groups receiving advice compared with no advice, SMD 3.52 (95% CI 1.71 to 5.32); however, there was considerable heterogeneity ($I^2 = 98\%$) (Analysis 1.19). Removal of two studies reduced heterogeneity ($I^2 = 0\%$) (Ravasco 2005a; Ravasco 2005b) and there remained a significant but small to moderate improvement in social function in the groups receiving advice compared with the groups receiving no advice, SMD 0.38 (95% CI 0.15 to 0.61). As in previous analyses, it is difficult to explain the large effect sizes seen in the studies by Ravasco, but some of the differences may simply be explained by the different disease background of participants (cancer, kidney disease and older people) as well as the use of different QoL instruments.

Four to six months

One study (40 participants) using two different QoL questionnaires to report on change in social function at six months (Weekes 2009). There was no difference between the group receiving advice and the group receiving no advice, either with the SF-36 SMD 0.10 (95% CI -0.52 to 0.72) or with the SGRQ, SMD 0.11 (95% CI -0.50 to 0.73) (Analysis 1.19).

12 months and over

One study (34 participants) using two different QoL questionnaires reported change in social function at 12 months or over (Weekes 2009). There was no difference between the group receiving advice and the group receiving no advice using the SF-36, SMD 0.36 (95% CI -0.32 to 1.04); however, results from the SGRQ favoured advice, SMD 1.17 (95% CI 0.44 to 1.91) (Analysis 1.19).

Review authors did not undertake a combined analysis as one study reported data at more than one time point.

e. QoL – cognitive function

Zero to three months

Four studies (287 participants) reported on change in cognitive function at up to three months (Baldwin 2011; Campbell 2008; Ravasco 2005a; Ravasco 2005b). There was a large improvement in cognitive function in groups receiving advice compared with no advice, SMD 3.43 (95% CI 0.79 to 6.07), however, there was considerable heterogeneity ($I^2 = 98\%$) (Analysis 1.20). Removal of each study individually did not reduce the heterogeneity noticeably, however we expect the heterogeneity likely arises from the differences in QoL instruments used, and the differences in clinical backgrounds and care settings. The studies by Ravasco consistently achieve effects that are substantially larger than other similar studies and there is no obvious reason to explain this.

f. QoL – pain

Zero to three months

Four studies (376 participants) reported on change in pain at up to three months (Baldwin 2011; Campbell 2008; Ravasco 2005a; Ravasco 2005b). There was a large reduction in pain in groups receiving advice compared with no advice, SMD -5.48 (95% CI -8.13 to -2.84) (Analysis 1.21); however, there was considerable heterogeneity ($I^2 = 99\%$). Removal of two studies reduced heterogeneity ($I^2 = 29\%$) (Ravasco 2005a; Ravasco 2005b) and there was no difference in pain between the groups receiving advice compared with the groups receiving no advice, SMD -0.15 (95% CI -0.14 to 0.45) ($P = 0.32$). As in previous analyses, it is difficult to explain the large effect sizes seen in the studies by Ravasco, but some of the differences may simply be explained by the different disease background of participants (cancer and older people) as well as the use of different QoL instruments. The studies by Ravasco consistently achieve effects that are substantially larger than other similar studies and there is no obvious reason to explain this.

Four to six months

One study (40 participants) reported on change in pain at six months (Weekes 2009). There was no difference between the group receiving advice and the group receiving no advice, SMD 0.30 (95% CI -0.32 to 0.93) (Analysis 1.21).

12 months and over

One study (34 participants) reported change in pain at 12 months or over (Weekes 2009). There was no difference between the group receiving advice and the group receiving no advice, SMD 0.22 (95% CI -0.46 to 0.90) (Analysis 1.21).

Review authors did not undertake a combined analysis as one study reported data at more than one time point.

g. QoL - energy/fatigue

Zero to three months

Four studies (375 participants) reported on change in energy/fatigue at up to three months (Baldwin 2011; Forster 2012; Ravasco 2005a; Ravasco 2005b). There was a large improvement in energy/fatigue in groups receiving advice compared with no advice, SMD -5.95 (95% CI -8.65 to -3.25) (Analysis 1.22), however, there was considerable heterogeneity ($I^2 = 99\%$). Removal of each study individually did not reduce the heterogeneity noticeably, however we expect the heterogeneity likely arises from the differences in QoL instruments used, and the differences in clinical backgrounds and care settings. The studies by Ravasco consistently achieve

effects that are substantially larger than other similar studies and there is no obvious reason to explain this.

Four to six months

One study (40 participants) reported on change in energy/fatigue at six months (Weekes 2009). There was no difference between the group receiving advice and the group receiving no advice, SMD 0.06 (95% CI -0.56 to 0.69) (Analysis 1.22).

12 months and over

One study (34 participants) reported change in energy/fatigue at 12 months or over (Weekes 2009). There was no difference between the group receiving advice and the group receiving no advice, SMD 0.34 (95% CI -0.33 to 1.01) (Analysis 1.22).

Review authors did not undertake a combined analysis as one study reported data at more than one time point.

4. Cost

The lead investigator on the Weekes study provided unpublished data on cost-effectiveness (Weekes 2009). In this study of outpatients with COPD (59 participants), the total costs and subcategories of costs were not significantly different between the groups at six or 12 months. However, based on bootstrapping of incremental cost-effectiveness ratios (ICERs), the probability for dietary advice being cost-effective for QALYs gained was 93% at 12 months when the willingness to pay was GBP 20,000 per QALY (a conservative ceiling value often used in England) and 90% when the willingness to pay was zero GBP, mainly resulting from the cost savings associated with hospital admissions.

One study reported there was no difference in the mean (SD) costs of hospitalisation in those that received dietary advice, CNY 16,099 (1243) and those that received no advice CNY 17,834 (1823) (Gu 2015).

Group 2 — Dietary advice compared with ONS

This comparison includes 12 studies (852 participants) (Akpele 2004; Baldwin 2011; Gray-Donald 1995; Hernandez 2014; Kalnins 2005; Parsons 2016; Pivi 2011; Ravasco 2005a; Ravasco 2005b; Schwenk 1999; Singh 2008; Stow 2015).

Please refer to the summary of findings table for the explanations of judgements (Summary of findings 2). Note that GRADE judgements are for specific outcomes at the three-months time point and are not provided for all outcomes at each time point.

Primary outcome

1. Mortality

Zero to three months

Eight studies (576 participants) provided data at up to three months (Baldwin 2011; Gray-Donald 1995; Kalnins 2005; Parsons 2016; Ravasco 2005a; Ravasco 2005b; Schwenk 1999; Stow 2015). There was no difference in mortality between the participants who received dietary advice and those who received ONS, RR 0.66 (95% CI 0.34 to 1.26) (low-certainty evidence) (Analysis 2.1). There was no heterogeneity ($I^2 = 0\%$).

Four to six months

Three studies (302 participants) provided data at between four and six months (Baldwin 2011; Pivi 2011; Stow 2015). There was difference in mortality between the participants who received dietary advice and those who received ONS, RR 0.98 (95% CI 0.65 to 1.47). There was no heterogeneity ($I^2 = 0\%$) (Analysis 2.1).

12 months and over

Two studies (256 participants) assessed mortality at 12 months and over (Baldwin 2011; Ravasco 2005a). There was no difference in mortality between the participants who received dietary advice and those who received ONS, RR 0.56 (95% CI 0.15 to 2.06), but there was considerable heterogeneity in this analysis ($I^2 = 80\%$) (Analysis 2.1). Participants in both studies had cancer, but one study was in those receiving palliative treatment (Baldwin 2011), whereas in the second study a higher proportion of individuals had potentially curable disease (Ravasco 2005a).

Review authors did not undertake a combined analysis as a number of studies report mortality at several time points (Analysis 2.1).

2. Morbidity

a. Hospital admissions

Two studies (111 participants) provided data on hospital admissions (Schwenk 1999; Stow 2015). No studies reported data on length of hospital stay or complications.

Zero to three months

At up to three months, there was no difference between the two groups, RR 0.36 (95% CI 0.04 to 3.24) (low-certainty evidence) (Schwenk 1999) (Analysis 2.2).

Four to six months

One study reported at four to six months (Stow 2015) and found that those receiving ONS had significantly fewer hospital admissions than those receiving dietary advice, RR 3.63 (95% CI 1.37 to 9.60) (Analysis 2.2).

A combined analysis of both studies showed significantly fewer hospital admissions in those receiving ONS, RR 2.30 (95% CI 1.02 to 5.15), but substantial heterogeneity ($I^2 = 72\%$) (Analysis 2.2). The two studies were undertaken in different populations, i.e. one studied people with HIV infection (Schwenk 1999) and the second was in older people in residential care (Stow 2015). The two studies used different methodologies; one study was a parallel RCT (Schwenk 1999), whereas the other was a cluster-RCT (Stow 2015).

3. Measures of nutritional status

a. Change in weight

Zero to three months

Nine studies (517 participants) reported the change in weight from baseline at up to three months (Baldwin 2011; Gray-Donald 1995; Kalnins 2005; Parsons 2016; Ravasco 2005a; Ravasco 2005b; Schwenk 1999; Singh 2008; Stow 2015), but one study reported no change in weight with a SD of zero in the group receiving ONS and so the MD for this study was not estimable (Ravasco 2005b). There was no difference between groups receiving dietary advice and groups receiving ONS, MD -0.14 kg (95% CI -2.01 to 1.74) (low-certainty evidence), but heterogeneity was considerable ($I^2 = 94\%$) (Analysis 2.1).

2.3). Removal of one study reduced the heterogeneity to zero (Ravasco 2005a); and the result then showed significantly greater weight gain in the groups receiving ONS, MD -0.81 kg (95% CI -1.37 to -0.24). It is not possible to explain the effect on heterogeneity on removing this study on the basis of differences in clinical condition of the participants. The lead investigator on this study provided these data on request (Ravasco 2005a).

Four to six months

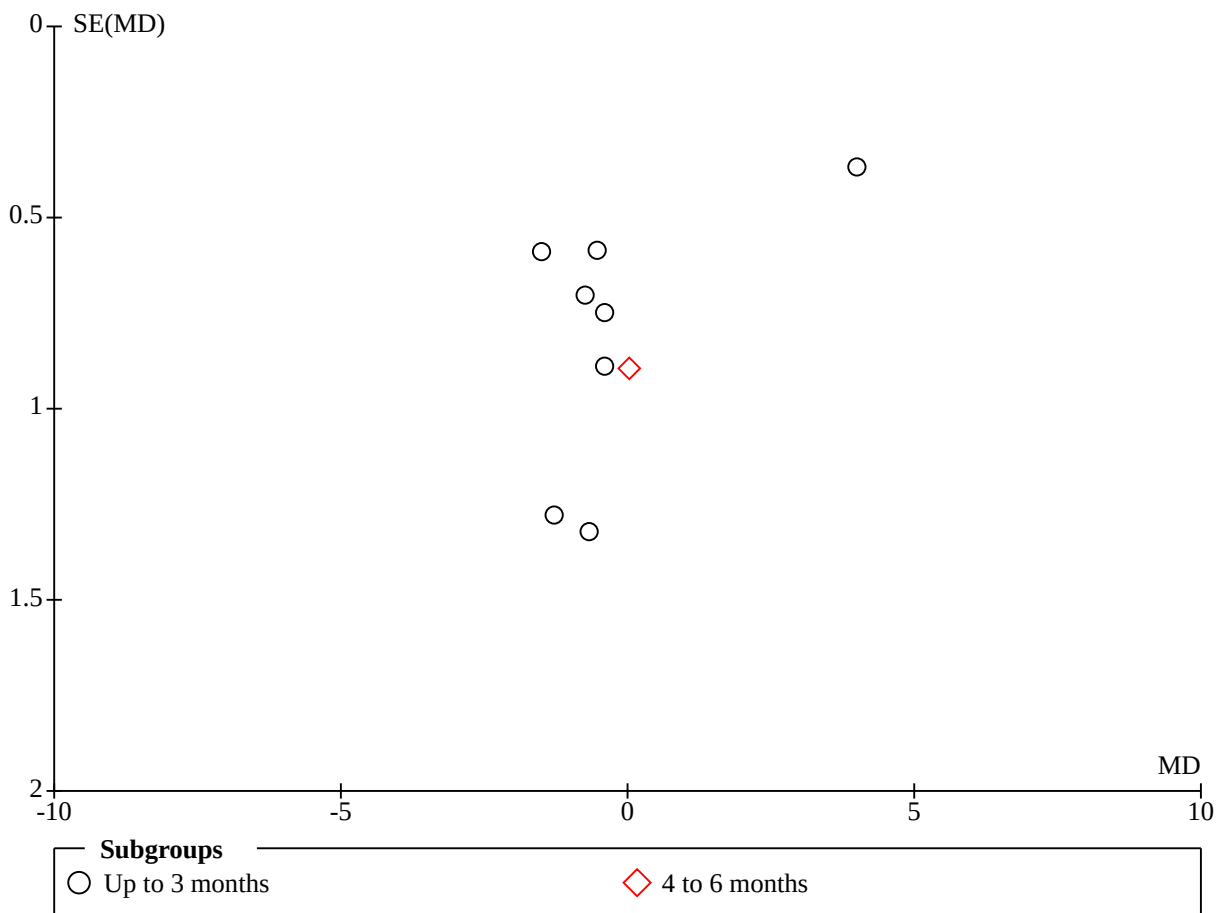
One study (44 participants) reported analysable data on weight change at four to six months (Stow 2015). There was no difference between groups receiving dietary advice compared with ONS, MD 0.03 kg (95% CI -1.72 to 1.78) (Analysis 2.3).

One study reported a lower mean weight change (group range for weight) in participants receiving education on diet compared with participants receiving ONS, 1.19 kg (54.29 to 50 kg) and 6.66 kg (54.70 to 57.93 kg) respectively (Pivi 2011).

Review authors did not undertake a combined analysis as one study reports data at more than one time point (Analysis 2.3).

The funnel plot examination, the Egger regression asymmetry test and the Begg's adjusted rank correlation suggested evidence of significant small study bias (P = 0.049 and P = 0.266, respectively), although there were only eight studies in this analysis, therefore, the test may be invalid (Figure 4).

Figure 4. Funnel plot of comparison: 2 Dietary advice compared with ONS, outcome: 2.3.1 Change in weight (kg).



b. BMI

Zero to three months

Two studies (97 participants) reported the change in BMI from baseline to up to three months (Singh 2008; Stow 2015). There was no difference between groups receiving dietary advice and groups receiving ONS, MD 0.21 kg/m² (95% CI -0.64 to 0.23). There was no heterogeneity (I² = 0%) (Analysis 2.4).

Four to six months

One study (44 participants) reported analysable data for the change in BMI from baseline to four to six months (Stow 2015). There was no difference between groups receiving dietary advice compared with ONS, MD -0.01 kg/m² (95% CI -0.72 to 0.70) (Analysis 2.4).

One study reported a lower mean change in BMI (group range for BMI) in participants receiving education on diet compared with participants receiving ONS, 1.19 kg/m² (22.71 to 22.84 kg/m²) and 6.55 kg/m² (21.66 to 22.98 kg/m²) respectively (Pivi 2011).

Review authors did not undertake a combined analysis as one study reports data at more than one time point ([Analysis 2.4](#)).

c. FFM

One study (50 participants) reported data on change in FFM at up to three months ([Schwenk 1999](#)). After eight weeks of intervention there was no difference in the mean (SD) change in FFM between those receiving dietary advice (3.8% (6.2)) and those receiving ONS (1.6% (4.5)).

d. MAC

Zero to three months

Two studies (91 participants) reported data on change in MAC from baseline to up to three months ([Singh 2008](#); [Stow 2015](#)). There was no difference between groups receiving dietary advice and groups receiving ONS, MD -0.17 cm (95% CI -0.72 to 0.38). There was no heterogeneity ($I^2 = 0\%$) ([Analysis 2.6](#)).

Four to six months

One study (20 participants) reported data on change in MAC from baseline to four to six months ([Stow 2015](#)). There was no difference between groups, MD -0.15 cm (95% CI -4.30 to 4.00) ([Analysis 2.6](#)).

One study reported a lower mean change in MAC (group range for MAC) in participants receiving education on diet compared with participants receiving ONS, 1.87 cm (24.72 to 25.11 cm) and 5.44 cm (23.99 to 25.20 cm), respectively ([Pivi 2011](#)).

Review authors did not undertake a combined analysis as one study reports data at more than one time point ([Analysis 2.6](#)).

e. MAMC

Zero to three months

Two studies (81 participants) reported the change from baseline in MAMC at up to three months ([Gray-Donald 1995](#); [Stow 2015](#)). There was no difference in MAMC between groups, MD 0.43 cm (95% CI -0.36 to 1.22) and no heterogeneity ([Analysis 2.5](#)).

Four to six months

One study (29 participants) reported the change in MAMC from baseline to four to six months ([Stow 2015](#)). There was no difference between groups receiving dietary advice compared with ONS, MD -0.11 cm (95% CI -1.07 to 0.85) ([Analysis 2.5](#)).

One study reported a lower mean change in MAMC (group range for MAMC) in participants receiving education on diet compared with a control group, -1.27 cm (20.25 to 19.96 cm) and 3.43 cm (20.36 to 21.01 cm), respectively ([Pivi 2011](#)).

Review authors did not undertake a combined analysis as one study reports data at more than one time point ([Analysis 2.5](#)).

f. TSF

Zero to three months

Three studies (129 participants) reported the change in TSF from baseline up to three months ([Gray-Donald 1995](#); [Singh 2008](#); [Stow 2015](#)). There was no difference in TSF between groups, MD -0.75 mm (95% CI -1.55 to 0.05) and no heterogeneity ([Analysis 2.7](#)).

Four to six months

One study (17 participants) reported the change from baseline in TSF to four to six months ([Stow 2015](#)). There was no difference between groups receiving dietary advice compared with those receiving ONS, MD -0.99 mm (95% CI -8.96 to 6.98) ([Analysis 2.7](#)).

One study reported a higher mean change in TSF (group range for TSF) in participants receiving education on diet compared with those receiving ONS, 2.32 mm (14.20 to 16.40 mm) and 1.44 mm (11.54 to 13.55 mm), respectively ([Pivi 2011](#)).

Review authors did not undertake a combined analysis as one study reports data at more than one time point ([Analysis 2.7](#)).

Secondary outcomes

1. Nutritional intake before and after the intervention

a. Change in energy intake

Zero to three months

Eight studies (327 participants) reported analysable data for the changes in energy intake at up to three months ([Baldwin 2011](#); [Gray-Donald 1995](#); [Kalnins 2005](#); [Ravasco 2005a](#); [Ravasco 2005b](#); [Schwenk 1999](#); [Singh 2008](#); [Stow 2015](#)). There was no difference between those who received dietary advice and those who received ONS, MD -1.52 kcal (95% CI -206.23 to 203.20), but heterogeneity was considerable ($I^2 = 78\%$) ([Analysis 2.8](#)). Removal of the two studies by Ravasco reduced the heterogeneity ($I^2 = 0\%$), and participants receiving ONS had a significantly higher energy intake than participants receiving dietary advice ([Ravasco 2005a](#); [Ravasco 2005b](#)).

Parsons studied 70 participants in a residential care setting and reported that mean (SE) energy intake was higher in the ONS group (39 participants), than in the dietary advice group (31 participants), 1646 (75) kcal compared to 1223 (94) kcal, but the differences were not statistically significant ([Parsons 2016](#)).

Four to six months

One study (25 participants) reported analysable data for the change in energy intake at six months ([Stow 2015](#)); investigators found no difference between those receiving dietary advice compared with ONS, MD -145.00 kcal (95% CI -598.85 to 308.85) ([Analysis 2.8](#)).

12 months and over

The follow-up paper to the Ravasco study reported that the median energy intake after a median follow-up of 6.5 years was significantly higher in the group receiving dietary advice, 2482 kcal (95% CI 2210 to 2685) than in the group receiving ONS, 1335 kcal (95% CI 1150 to 1569) ([Ravasco 2005a](#)) ([Analysis 2.8](#)).

Review authors did not undertake a combined analysis as one study reports data at more than one time point ([Analysis 2.8](#)).

b. Change in protein intake

Zero to three months

Five studies (221 participants) reported the change from baseline in protein intake at up to three months ([Parsons 2016](#); [Ravasco 2005a](#); [Ravasco 2005b](#); [Singh 2008](#); [Stow 2015](#)). There was a statistically higher increase in protein intake in the ONS group compared to the

dietary advice group, MD -13.09 g (95% CI -19.23 to -6.96), with no heterogeneity ($I^2 = 0\%$) (Analysis 2.9).

Four to six months

Only one study (25 participants) provided analysable data for the change in protein intake at four to six months (Stow 2015) and reported a significantly higher protein intake in the ONS group compared with the dietary advice group, MD -6.00 g (95% CI -9.91 to -2.09) (Analysis 2.9).

12 months and over

Ravasco (63 participants) reported that participants' median protein intake after a median follow-up of 6.5 years was significantly higher in the dietary advice group (74 g (95% CI 69 to 77)), than in the ONS group (42 g (95% CI 39 to 44)) (Ravasco 2005a) (Analysis 2.9).

Review authors did not undertake a combined analysis as one study reports data at more than one time point (Analysis 2.9).

2. Measures of functional status

a. Handgrip strength

Zero to three months

Two studies (69 participants) provided data for change in handgrip strength at up to three months (Gray-Donald 1995; Stow 2015) and found no difference between those receiving dietary advice and those receiving ONS, MD 0.32 kg force (95% CI -1.10 to 1.74) with no heterogeneity (Analysis 2.10).

Four to six months

One study (17 participants) provided data on the change in grip strength from baseline to between four and six months (Stow 2015). No difference was observed between the groups, MD -0.07 kg force (95% CI -2.35 to 2.21) (Analysis 2.10).

Review authors did not undertake a combined analysis as one study reports data at more than one time point (Analysis 2.10).

3. QoL

Five studies reported on this outcome; three used the EORTC questionnaires (Baldwin 2011; Ravasco 2005a; Ravasco 2005b), one used the FAACT questionnaire (Baldwin 2011), one used the EQ-5D (Parsons 2016) and one used the General Perceived Health Questionnaire (Gray-Donald 1995). Another study reports collecting data on QoL, but does not report any results because of completion by too few participants (Stow 2015).

The review authors have entered data into meta-analyses for global QoL scores, physical function, mental function, social function, cognitive function, pain and energy/fatigue using the SMD to combine data using different QoL questionnaires.

a. Global QoL

Zero to three months

Four studies (290 participants) reported on change in global QoL scores (Baldwin 2011; Gray-Donald 1995; Ravasco 2005a; Ravasco 2005b). There was no difference in global QoL between groups receiving advice compared with groups receiving ONS, SMD 1.26 (95% CI -0.32 to 2.85) (low-certainty evidence). There was

considerable heterogeneity ($I^2 = 97\%$) (Analysis 2.11). Removal of two studies (Ravasco 2005a; Ravasco 2005b) reduced heterogeneity ($I^2 = 0\%$) and there remained no difference between the groups, SMD -0.12 (95% CI -0.43 to 0.19). When assessing changes in global QoL, it is difficult to explain the effect sizes three to four times larger in the studies by Ravasco than in other studies using EORTC QLQ-C30 to report outcomes in people with cancer (King 1996; Ravasco 2005a; Ravasco 2005b). The studies by Ravasco consistently achieve effects that are substantially larger than other similar studies and there is no obvious reason to explain this.

One study (68 participants) additionally reported QoL using FAACT (Baldwin 2011) and found no difference between groups, SMD -0.04 (95% CI -0.40 to 0.31) (Analysis 2.11).

Four to six months

One study (68 participants), using two different QoL questionnaires, reported on change in global QoL scores (Baldwin 2011). There was no difference in change in global QoL at four to six months between the group receiving advice and the group receiving ONS, either with the EORTC, SMD 0.07 (95% CI -0.43 to 0.57) or with FAACT, SMD -0.15 (95% CI -0.63 to 0.33) (Analysis 2.11).

12 months and over

One study (63 participants) reported on change in QoL at 12 months or more (Ravasco 2005a). There was a large improvement in global QoL in groups receiving advice compared with groups receiving ONS, SMD 10.68 (95% CI 8.69 to 12.67) (Analysis 2.11).

Review authors did not undertake a combined analysis as studies reported data at more than one time point.

b. QoL – physical function

Zero to three months

Three studies (236 participants) reported on change in physical function at up to three months (Baldwin 2011; Ravasco 2005a; Ravasco 2005b). There was no difference in physical function between groups receiving advice compared with groups receiving ONS, SMD 2.41 (95% CI -0.79 to 5.61) (Analysis 2.12). However, there was considerable heterogeneity ($I^2 = 98\%$). Removal of one study reduced heterogeneity ($I^2 = 0\%$) (Baldwin 2011), leaving only the two studies by Ravasco in the analysis (Ravasco 2005a; Ravasco 2005b). Since the review authors have some concerns about the effect sizes reported in these studies i.e. three to four times larger than those reported in other studies in people with cancer using EORTC QLQ-C30 (King 1996), they feel it is prudent not to report an overall effect at this time.

c. QoL – mental function

Zero to three months

Three studies (232 participants) reported on change in mental function at up to three months (Baldwin 2011; Ravasco 2005a; Ravasco 2005b). There was no difference in mental function between groups receiving advice compared with groups receiving ONS, SMD 3.45 (95% CI -0.24 to 7.15) (Analysis 2.13). However, there was considerable heterogeneity ($I^2 = 98\%$). Removal of each study individually did not reduce the heterogeneity noticeably; however, the review authors expect the heterogeneity reflects the use of different QoL instruments and the differences in clinical

backgrounds and care settings. Since they have some concerns about the effect sizes reported in these studies i.e. three to four times larger than those reported in comparable studies in people with cancer using EORTC QLQ-C30 (King 1996), they feel it is prudent not to report an overall effect at this time.

d. QoL – social function

Zero to three months

Three studies (232 participants) reported on change in social function at up to three months (Baldwin 2011; Ravasco 2005a; Ravasco 2005b). There was no difference in social function between groups receiving advice compared with groups receiving ONS, SMD 3.13 (95% CI -0.21 to 6.48) (Analysis 2.14). However, there was considerable heterogeneity ($I^2 = 98%$). Removal of one study reduced heterogeneity ($I^2 = 13%$) (Baldwin 2011), leaving only the two studies by Ravasco in the analysis (Ravasco 2005a; Ravasco 2005b). Since the review authors have some concerns about the effect sizes reported in these studies i.e. three to four times larger than those reported in other studies in people with cancer using EORTC QLQ-C30 (King 1996), they feel it is prudent not to report an overall effect at this time.

e. QoL – cognitive function

Zero to three months

Three studies (234 participants) reported on change in cognitive function at up to three months (Baldwin 2011; Ravasco 2005a; Ravasco 2005b). There was a large improvement in cognitive function in groups receiving advice compared with groups receiving ONS, SMD 4.23 (95% CI 0.05 to 8.42) (Analysis 2.15), however, there was considerable heterogeneity ($I^2 = 99%$). Removal of each study individually did not reduce the heterogeneity noticeably, however, we expect the heterogeneity reflects the differences in QoL instruments used, and the differences in clinical backgrounds and care settings. Since the review authors have some concerns about the effect sizes reported in these studies i.e. three to four times larger than those reported in other studies in people with cancer using EORTC QLQ-C30 (King 1996), they feel it is prudent not to report an overall effect at this time.

f. QoL - pain

Zero to three months

Three studies (236 participants) reported on change in pain at up to three months (Baldwin 2011; Ravasco 2005a; Ravasco 2005b). There was no difference in pain between groups receiving advice compared with groups receiving ONS, SMD -5.42 (95% CI -11.40 to 0.56) (Analysis 2.16). However, there was considerable heterogeneity ($I^2 = 99%$). Removal of each study individually did not reduce the heterogeneity noticeably, however, we expect the heterogeneity reflects the differences in QoL instruments used, and the differences in clinical backgrounds and care settings. Since the review authors have some concern about the effect sizes reported in these studies i.e. three to four times larger than those reported in other studies in people with cancer using EORTC QLQ-C30 (King 1996), they feel it is prudent not to report an overall effect at this time.

g. QoL – energy/fatigue

Zero to three months

Three studies (232 participants) reported on change in energy/fatigue at up to three months (Baldwin 2011; Ravasco 2005a; Ravasco 2005b). There was no difference in energy/fatigue between groups receiving advice compared with groups receiving ONS, SMD -8.41 (95% CI -18.21 to 1.39) (Analysis 2.17). However, there was considerable heterogeneity ($I^2 = 99%$). Removal of each study individually did not reduce the heterogeneity noticeably; however, the review authors expect the heterogeneity reflects the differences in QoL instruments used, and the differences in clinical backgrounds and care settings. Since they have some concern about the effect sizes reported in these studies i.e. three to four times larger than those reported in other studies in people with cancer using EORTC QLQ-C30 (King 1996), they feel it is prudent not to report an overall effect at this time.

4. Cost

None of the studies in this comparison reported cost data.

Group 3 – Dietary advice compared with dietary advice plus ONS

This comparison includes 22 studies (1498 participants) (Arnold 1989; Baldwin 2011; Beattie 2000; Burden 2011; Burden 2017; de Luis 2003; de Sousa 2012; Diouf 2016; Dixon 1984; Fuenzalida 1990; Gonzalez-Espinoza 2005; Huynh 2015; Kapoor 2017; Kendell 1982; Le Cornu 2000; McCarthy 1999; Murphy 1992; Norman 2008b; Olejko 1984; Rabeneck 1998; Sharma 2002a; Wilson 2001). There were no usable data for three of these studies (Dixon 1984; Kendell 1982; Olejko 1984).

Please refer to the summary of findings table for the explanations of judgements (Summary of findings 3). Note that GRADE judgements are for specific outcomes at the three-months time point and are not provided for all outcomes at each time point.

Primary outcome

1. Mortality

13 studies reported mortality data (Arnold 1989; Baldwin 2011; Beattie 2000; Burden 2017; de Luis 2003; de Sousa 2012; Diouf 2016; Fuenzalida 1990; Gonzalez-Espinoza 2005; Kapoor 2017; Le Cornu 2000; Murphy 1992; Norman 2008b).

Zero to three months

Data were available from 10 studies (777 participants) at up to three months (Arnold 1989; Baldwin 2011; Beattie 2000; Burden 2017; de Luis 2003; de Sousa 2012; Diouf 2016; Fuenzalida 1990; Kapoor 2017; Norman 2008b). There was no difference in mortality between the participants who received dietary advice plus ONS versus participants who received dietary advice only, RR 0.92 (95% CI 0.47 to 1.80) (low-certainty evidence). There was no heterogeneity ($I^2 = 29%$) (Analysis 3.1). Four studies (285 participants) reported no deaths (Beattie 2000; de Luis 2003; Fuenzalida 1990; Norman 2008b).

Four to six months

Five studies (373 participants) provided data at the time point from four to six months (Baldwin 2011; Gonzalez-Espinoza 2005; Kapoor 2017; Le Cornu 2000; Murphy 1992). There was no difference in mortality between the dietary advice plus ONS group compared to the dietary advice only group, RR 1.03 (95% CI 0.53 to 2.00). There was moderate heterogeneity ($I^2 = 38%$) (Analysis 3.1).

Seven to 12 months

Only one study (176 participants) reported mortality at seven to 12 months (Baldwin 2011), RR 0.96 (95% CI 0.58 to 1.58) (Analysis 3.1).

Review authors did not undertake a combined analysis as two studies report data at more than one time point.

2. Morbidity

a. Hospital admissions

Two studies reported hospital admission data (Gonzalez-Espinoza 2005; Norman 2008b).

Zero to three months

One study (114 participants) reported on hospital readmissions between zero and three months (Norman 2008b). The group receiving dietary advice plus ONS had a significantly lower number of readmissions compared to the dietary advice only group, RR 1.70 (95% CI 1.04 to 2.77) (low-certainty evidence) (Analysis 3.2).

Four to six months

One study (28 participants) reported on hospital readmissions between four and six months (Gonzalez-Espinoza 2005). There was no difference between the two groups, RR 0.84 (95% CI 0.50 to 1.42) (Analysis 3.2).

Analysis of both studies combined showed no difference in hospital admissions between the two groups, RR 1.20 (95% CI 0.58-2.48).

Heterogeneity between subgroups was substantial ($I^2 = 75%$). Heterogeneity may be explained by the difference in number of participants in the studies; one study included more than 100 participants (Norman 2008b) and the second study less than 30 (Gonzalez-Espinoza 2005). Disease background was comparable between the groups (non-malignant disease), as was nutritional status (both confirmed by SGA).

b. Length of hospital stay

Zero to three months

Data on length of hospital stay were available for analysis from two studies (202 participants) at up to three months (Beattie 2000; Norman 2008b). There was no difference in the length of hospital stay in the group receiving dietary advice plus ONS compared with the dietary advice alone group, MD -1.07 days (95% CI -4.10 to 1.97) (low-certainty evidence) (Analysis 3.3). There was no heterogeneity ($I^2 = 0%$).

An additional three studies reported data on length of hospital stay, but could not be included in the meta-analysis (Burden 2011; Burden 2017; Huynh 2015). The first study reported no difference in median length of stay in pre-operative participants with colorectal cancer receiving dietary advice plus ONS compared with dietary advice alone; 13.5 versus 14.0 days respectively (Burden 2011). The second study also reported no difference in median (IQR) length of stay in pre-operative participants with colorectal cancer receiving dietary advice plus ONS compared with dietary advice alone; 7.0 days (4.0 to 10.5) versus 7.0 days (4.0 to 10.0) respectively, ($P = 0.630$) (Burden 2017). The third study reported was no difference in median (IQR) length of stay in a mixed population of participants on discharge from hospital receiving dietary advice plus ONS

compared with dietary advice alone; 4.0 days (3.0 to 6.0) versus 4.5 days (3.0 to 7.0) respectively, ($P = 0.1694$) (Huynh 2015).

Seven to 12 months

One study (46 participants) in people on haemodialysis reported data on the total number of days of hospitalisation at up to nine months (Wilson 2001). Those receiving dietary advice plus ONS were hospitalised for 71 days and those receiving dietary advice alone were hospitalised for 107 days.

c. Complications

Data on the number of participants with complications were available from four studies (Beattie 2000; Burden 2011; Burden 2017; Gonzalez-Espinoza 2005).

Zero to three months

Three studies reported data on complications at up to three months (Beattie 2000; Burden 2011; Burden 2017). There were significantly fewer complications in groups receiving dietary advice plus ONS versus dietary advice alone, RR 0.75 (95% CI 0.56 to 0.99) (low-certainty evidence); however, heterogeneity was moderate to substantial ($I^2 = 58%$) (Analysis 3.4). Removal of one study reduced heterogeneity to zero (Burden 2011) and groups receiving dietary advice plus ONS had significantly fewer complications than groups receiving dietary advice alone, RR 0.57 (95% CI 0.38 to 0.84). We have not been able to explain the reason for heterogeneity.

Four to six months

One study (28 participants) provided data on the number of participants with complications (Gonzalez-Espinoza 2005). There was no difference in the incidence of peritonitis in individuals with renal disease receiving continuous ambulatory peritoneal dialysis (CAPD) between groups receiving dietary advice plus ONS and dietary advice alone, RR 1.92 (95% CI 0.57 to 6.54) (Analysis 3.4).

There was moderate to substantial heterogeneity between subgroups ($I^2 = 54%$). Analysis of all studies combined showed no differences in complications between the two groups, RR 0.79 (95% CI 0.60-1.05); (Analysis 3.4).

3. Measures of nutritional status

a. Change in weight

Data on weight change were available in 15 studies (Arnold 1989; Baldwin 2011; Beattie 2000; Burden 2017; de Luis 2003; de Sousa 2012; Diouf 2016; Fuenzalida 1990; Gonzalez-Espinoza 2005; Huynh 2015; Kapoor 2017; Murphy 1992; Norman 2008b; Rabeneck 1998; Sharma 2002a).

Zero to three months

At this time point, 14 studies (931 participants) reported on weight change (Arnold 1989; Baldwin 2011; Beattie 2000; Burden 2017; de Luis 2003; de Sousa 2012; Diouf 2016; Fuenzalida 1990; Huynh 2015; Kapoor 2017; Norman 2008b; Rabeneck 1998; Sharma 2002a; Sharma 2002b). Weight change was significantly higher in the groups receiving dietary advice plus ONS compared with dietary advice alone, MD 1.15 kg (95% CI 0.42 to 1.87) (low-certainty evidence) with substantial heterogeneity ($I^2 = 71%$) (Analysis 3.5). Removal of three studies reduced heterogeneity ($I^2 = 0%$) (Beattie 2000; Diouf 2016; Kapoor 2017) and there was significantly greater

weight gain in the groups receiving dietary advice plus ONS, MD 0.52 (95% CI 0.16 to 0.88). We have not been able to explain the reason for heterogeneity.

Four to six months

Four studies (209 participants) reported data on weight change between four and six months (Baldwin 2011; Gonzalez-Espinoza 2005; Kapoor 2017; Murphy 1992). There was no difference between the two groups, MD 2.27 kg (95% CI -0.44 to 4.98) and considerable heterogeneity ($I^2 = 76%$) (Analysis 3.5). One study stood out of the others with very positive results (Kapoor 2017). This study was different from the other studies as it was performed in India in 63 participants with cancer undergoing palliative treatment; these participants had very low body weight and very low baseline intakes. The intervention product was a macronutrient and flour mixture that could be used to make bread, this being quite different from ONS to be taken in addition to other meals. The review authors assume that the participants in this study had greater potential to improve their nutritional status, given their poor nutritional status at the start of the study, while, in addition, the product may have fulfilled basic nutritional needs (Kapoor 2017). After removing this study from the analysis, the differences between groups were smaller, but there remained no significant difference between

groups, MD 0.67 kg (95% CI -0.79 to 2.13) and no heterogeneity ($I^2 = 0%$).

Seven to 12 months

One study (31 participants) reported on weight change between seven and 12 months (Baldwin 2011). There was no difference between the two groups, MD 0.14 kg (95% CI -4.24 to 4.52) (Analysis 3.5).

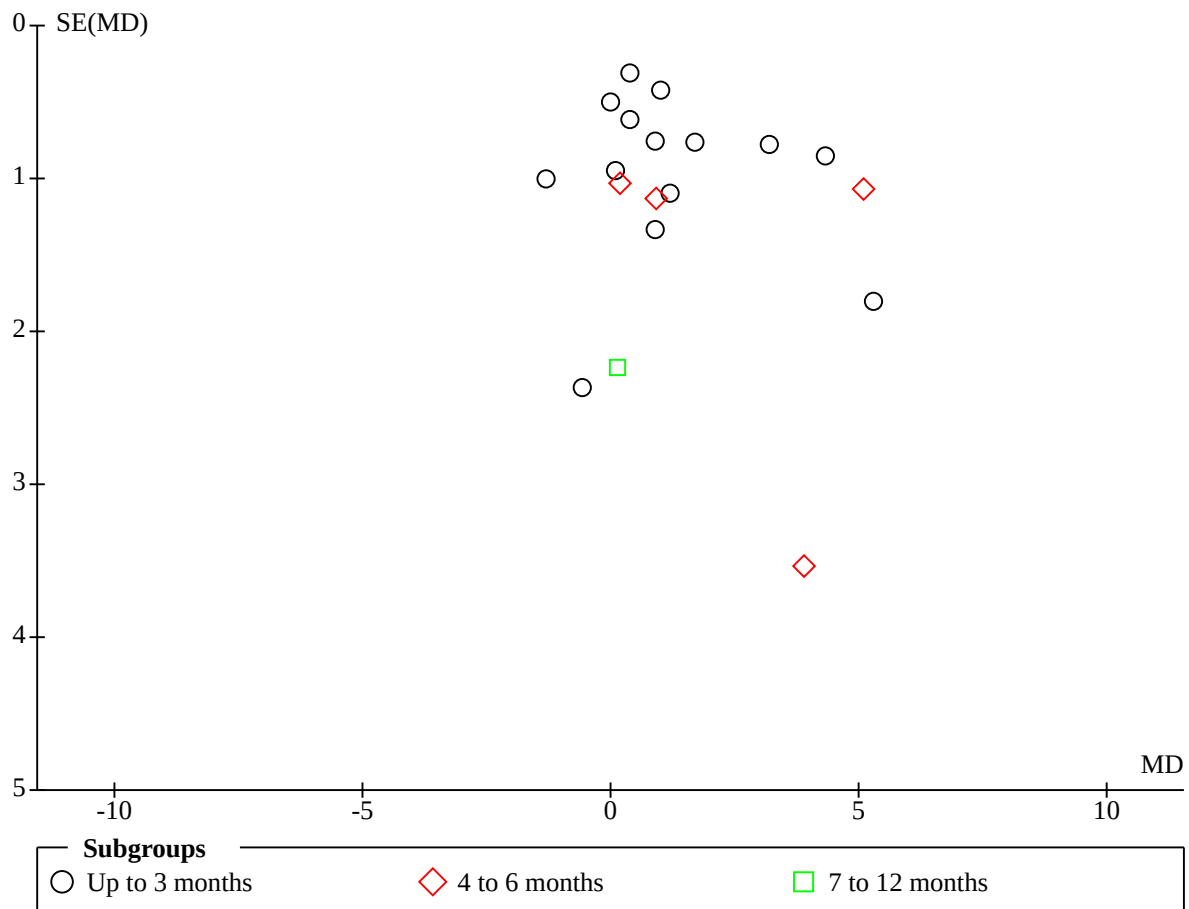
Review authors did not undertake a combined analysis as two studies report data at more than one time point.

Sensitivity analysis

The SD of weight change was imputed for three studies at up to three months (Arnold 1989; Fuenzalida 1990; Sharma 2002a; Sharma 2002b). The removal of these studies from the analysis had no impact on the results, MD 1.48 kg (95% CI 0.65 to 2.32) and heterogeneity remained substantial ($I^2 = 77%$).

The funnel plot examination, the Egger regression asymmetry test and the Begg's adjusted rank correlation suggested no evidence of small study bias ($P = 0.245$ and $P = 0.511$ respectively) (Figure 5).

Figure 5. Funnel plot of comparison 3: dietary advice plus ONS compared with dietary advice alone. Outcome 3.5.1 change in weight (kg)



b. BMI

Six studies (seven data sets) reported data on the change in BMI (de Sousa 2012; Diouf 2016; Gonzalez-Espinoza 2005; Huynh 2015; Norman 2008b; Sharma 2002a; Sharma 2002b).

Zero to three months

Five studies (six data sets; 350 participants) reported on this outcome between zero and three months (de Sousa 2012; Diouf 2016; Huynh 2015; Norman 2008b; Sharma 2002a; Sharma 2002b). There was no difference in the change in BMI between groups receiving dietary advice plus ONS and groups receiving dietary advice alone, MD 0.50 kg/m² (95% CI -0.30 to 1.33) with considerable heterogeneity ($I^2 = 95%$) (Analysis 3.6). Studies took place in a wide variety of different clinical conditions, settings and age ranges and removal of any single study did not alter heterogeneity.

Four to six months

One study (18 participants) in people on continuous ambulatory peritoneal dialysis reported on the change in BMI at four to six months (Gonzalez-Espinoza 2005). There was no difference between the group receiving dietary advice and ONS and those receiving advice alone, MD -0.10 (95% CI -0.47 to 0.27).

There was moderate heterogeneity between subgroups ($I^2 = 44.4%$). Analysis of all studies combined showed no differences in change in BMI between the two groups, MD 0.42 (95% CI -0.31 to 1.16). Heterogeneity was considerable ($I^2 = 95%$).

c. FFM

Zero to three months

Three studies (187 participants) reported on change in FFM at up to three months and data have been combined using the SM (de Luis 2003; Diouf 2016; Norman 2008b). There was no difference between the two groups, SMD 0.10 kg (95% CI -0.18 to 0.39) (low-certainty evidence) with no heterogeneity ($I^2 = 0%$) (Analysis 3.7).

d. MAC

This outcome was reported in three studies (de Luis 2003; Kapoor 2017; Murphy 1992); however, the data were not presented in a format that was amenable to meta-analysis.

In 70 participants living with HIV infection, there was no difference in change in MAC between the groups receiving dietary advice plus ONS and dietary advice alone; mean change -0.1 cm versus -0.7 cm, respectively (de Luis 2003). In a further study of people with HIV infection ($n = 16$), there was no difference in change in MAC between the groups receiving dietary advice plus ONS and dietary advice alone, mean change 1.3 cm versus 1.2 cm, respectively (Murphy 1992). In 15 participants with cancer cachexia undergoing palliative care in India, there was a statistically significant reduction in MAC in the group receiving dietary advice alone ($P = 0.006$), but investigators did not report data relating to the 17 participants who received dietary advice plus ONS (Kapoor 2017).

e. MAMC

Data on MAMC were available from five studies (Beattie 2000; de Luis 2003; de Sousa 2012; Gonzalez-Espinoza 2005; Kapoor 2017).

Zero to three months

Four studies (241 participants) reported on change in MAMC up to three months (Beattie 2000; de Luis 2003; de Sousa 2012; Kapoor 2017). There was a significantly greater improvement in MAMC in groups receiving dietary advice plus ONS compared with dietary advice alone, MD 0.78 cm (95% CI 0.37-1.18), with zero to moderate heterogeneity ($I^2 = 37%$) (Analysis 3.8).

Four to six months

Two studies (60 participants) reported on change in MAMC between four and six months (Gonzalez-Espinoza 2005; Kapoor 2017). There was no difference between the groups, MD 1.20 cm (95% CI -0.63 to 3.03), with considerable heterogeneity ($I^2 = 74%$) (Gonzalez-Espinoza 2005; Kapoor 2017) (Analysis 3.8). The heterogeneity most likely reflects the two very different populations; participants with renal disease receiving CAPD and participants with cancer cachexia receiving palliative care.

The review authors did not undertake a combined analysis as one study reported data at more than one time point.

c. TSF

Seven studies reported data on TSF (Beattie 2000; de Luis 2003; de Sousa 2012; Fuenzalida 1990; Gonzalez-Espinoza 2005; Norman 2008b; Rabeneck 1998).

Zero to three months

Six studies (393 participants) reported on the change in TSF up to three months (Beattie 2000; de Luis 2003; de Sousa 2012; Fuenzalida 1990; Norman 2008b; Rabeneck 1998). While analysis showed a beneficial effect in favour of dietary advice and ONS, MD 1.06 mm (95% CI 0.14 to 1.97), heterogeneity was considerable ($I^2 = 78%$) (Analysis 3.9). Removal of any single study did not reduce heterogeneity. There was a wide variation in the clinical backgrounds of participant populations.

Four to six months

One study in 28 renal patients receiving CAPD reported data at four to six months (Gonzalez-Espinoza 2005). There was no difference in TSF between the group receiving dietary advice plus ONS and the group receiving dietary advice alone, mean change 1.6 mm versus 0.5 mm respectively.

Secondary outcomes

1. Nutritional intake before and after the intervention

a. Change in energy intake

Data on change in energy intake was available in nine studies (Baldwin 2011; Burden 2011; Burden 2017; de Luis 2003; Gonzalez-Espinoza 2005; Huynh 2015; Kapoor 2017; McCarthy 1999; Murphy 1992).

Zero to three months

Seven studies (464 participants) reported on change in energy intake between zero and three months (Baldwin 2011; Burden 2011; Burden 2017; de Luis 2003; Huynh 2015; Kapoor 2017; McCarthy 1999). There was a significantly greater increase in energy intake

in groups receiving dietary advice plus ONS, MD 344.46, (95% CI 164.21 to 524.71). Heterogeneity was moderate to substantial ($I^2 = 59\%$). Removal of one study in participants receiving perioperative supplementation reduced heterogeneity to zero (Burden 2011), while the effect of dietary advice plus ONS continued to result in significantly greater energy intake than dietary advice alone MD 284.75 kcal (95% CI 163.02 to 406.49). Investigators collected data on energy intake using unstructured dietary recalls and the lack of accuracy of this method might have contributed to large SD of change and suggests that data were skewed.

Four to six months

Three studies (75 participants) reported on change in energy intake between four and six months (Gonzalez-Espinoza 2005; Kapoor 2017; Murphy 1992). The group receiving dietary advice and ONS had a significantly greater energy intake than the group receiving dietary advice alone, MD 362.75 kcal (95% CI 128.53 to 596.97) and no heterogeneity ($I^2 = 0\%$) (Analysis 3.10).

The review authors did not undertake a combined analysis as several studies report data at more than one time point.

b. Final energy intake

Three studies reported data on final energy intake (Arnold 1989; Norman 2008b; Sharma 2002a; Sharma 2002b).

Zero to three months

Data were available from all three studies (140 participants) at up to three months, final energy intake was significantly higher in groups receiving dietary advice and ONS compared with dietary advice alone, MD 303.81 (95% CI 110.58 to 497.03), but heterogeneity was substantial ($I^2 = 84\%$). Studies took place in a wide variety of different clinical conditions, settings and age ranges and removal of any single study did not alter heterogeneity.

c. Change in protein intake

Data on change in protein intake was available in three studies (Burden 2017; Huynh 2015; Kapoor 2017).

Zero to three months

Three studies (230 participants) reported on change in protein intake between zero and three months (Burden 2017; Huynh 2015; Kapoor 2017). There was a statistically significant difference between the two groups, MD 12.21 (95% CI 6.39 to 18.03) and no heterogeneity ($I^2 = 0\%$) (Analysis 3.12).

Four to six months

One study (32 participants) reported on change in protein intake between four and six months (Kapoor 2017). There was a significantly greater increase in protein intake in the group receiving dietary advice plus ONS compared with dietary advice alone, MD 16.20 g (95% CI 4.83 to 27.57) (Analysis 3.12).

The review authors did not undertake a combined analysis as one study reported data at more than one time point.

d. Final protein intake

Five studies provided data on final protein intake (Arnold 1989; de Luis 2003; McCarthy 1999; Norman 2008b; Sharma 2002a; Sharma 2002b).

Zero to three months

Data were available from all five studies (299 participants) at up to three months, final protein intake was significantly higher in groups receiving dietary advice and ONS compared with dietary advice alone, MD 11.76 g (95% CI 5.59 to 17.93), but heterogeneity was substantial ($I^2 = 81\%$). Studies took place in a wide variety of different clinical conditions, settings and age ranges and removal of any single study did not alter heterogeneity.

2. Measures of functional status

a. Handgrip strength

Data on change in handgrip strength were available from six studies (Beattie 2000; Burden 2017; de Sousa 2012; Huynh 2015; Norman 2008b; Rabeneck 1998).

Zero to three months

All six studies (537 participants) reported on change in handgrip strength between zero and three months (Beattie 2000; Burden 2017; de Sousa 2012; Huynh 2015; Norman 2008b; Rabeneck 1998). There was no difference between the two groups, MD 1.07 kg force (95% CI -0.22 to 2.37) and considerable heterogeneity ($I^2 = 82\%$) (Analysis 3.14). Studies took place in a wide variety of different clinical conditions, settings and age ranges and removal of any single study did not alter heterogeneity.

3. QoL

Five studies reported this outcome; two used the EORTC questionnaires (Baldwin 2011; Kapoor 2017), one used the FAACT questionnaire (Baldwin 2011) and in two used the SF-36 (in the Norman study SF-36 was used to calculate quality-adjusted life years (QALYs)) (Norman 2008b; Beattie 2000), and one used a self-developed, non-validated 30-item QoL questionnaire designed specifically for the study (Rabeneck 1998).

The review authors have entered data into the meta-analyses for global QoL scores, physical function, mental function, social function, cognitive function, pain and energy/fatigue using the SMD to combine data using different QoL questionnaires.

a. Global QoL

Zero to three months

Four studies (334 participants) reported on change in global QoL scores (Baldwin 2011, Kapoor 2017, Norman 2008b; Rabeneck 1998). There was a small to moderate improvement in global QoL in groups receiving advice plus ONS compared with advice alone, SMD 0.33 (95% CI 0.09 to 0.57) (low-certainty evidence). There was zero to moderate heterogeneity ($I^2 = 13\%$) (Analysis 3.15).

One study (113 participants) additionally reported QoL using a second questionnaire (FAACT) (Baldwin 2011) and found no difference between groups, SMD -0.02 (95% CI -0.39 to 0.35) (Analysis 3.15).

Four to six months

Two studies (94 participants) reported on change in global QoL scores (Baldwin 2011, Kapoor 2017). There was no difference between the two groups, SMD 0.35 (95% CI -0.55 to 1.24) but there was substantial heterogeneity ($I^2 = 75\%$) (Analysis 3.15). Both studies were in people with cancer undergoing palliative care and the sample sizes were comparable. However, the studies were conducted in different parts of the world, UK (Baldwin 2011) and India (Kapoor 2017). The differences in the results might reflect cultural and national differences in response to QoL questions.

One study (62 participants) additionally reported QoL using a second questionnaire (FAACT) (Baldwin 2011) and found no difference between groups, SMD -0.40 (95% CI -0.90 to 0.10) (Analysis 3.15).

The review authors did not undertake a combined analysis as one study reported data at more than one time point.

b. QoL – physical function

Zero to three months

Four studies (324 participants) reported on change in physical function at up to three months (Baldwin 2011; Beattie 2000; Kapoor 2017; Norman 2008b). There was a moderate improvement in physical function in groups receiving advice plus ONS compared with advice alone, SMD 0.52 (95% CI 0.08 to 0.95) (Analysis 3.16). However, there was substantial heterogeneity ($I^2 = 72\%$). Removal of one study reduced heterogeneity ($I^2 = 0\%$) (Baldwin 2011) and a moderate to large effect remained, SMD 0.74 (95% CI 0.47 to 1.02). Both studies were in people with cancer undergoing palliative care and the sample sizes were comparable. However, the studies were conducted in different parts of the world, UK (Baldwin 2011) and India (Kapoor 2017). The differences in the results might reflect cultural and national differences in response to QoL questions.

Four to six months

One study (32 participants) reported on change in physical function at six months (Kapoor 2017). There was no difference between the group receiving advice plus ONS and the group receiving advice alone, SMD 0.08 (95% CI -0.62 to 0.77) (Analysis 3.16).

The review authors did not undertake a combined analysis as two studies reported data at more than one time point.

c. QoL - mental function

Zero to three months

Four studies (316 participants) reported on change in mental function at up to three months (Baldwin 2011; Beattie 2000; Kapoor 2017; Norman 2008b). There was no difference between the group receiving advice plus ONS and the group receiving advice alone, SMD 0.29 (95% CI -0.25 to 0.83) (Analysis 3.17); however, there was considerable heterogeneity ($I^2 = 82\%$). Removal of one study reduced heterogeneity to zero to moderate ($I^2 = 35\%$) (Baldwin 2011) and there was a moderate improvement in mental function in groups receiving advice plus ONS compared with advice alone, SMD 0.55 (95% CI 0.21 to 0.89). It is difficult to explain how the removal of this study affected heterogeneity as the participants were similar to those in the Indian study (Kapoor 2017) in that they were patients with cancer receiving palliative chemotherapy and the sample sizes were comparable. However, the studies were conducted in different parts of the world, UK (Baldwin 2011) and India (Kapoor 2017).

The differences in the results might reflect cultural and national differences in response to QoL questions.

Four to six months

One study (32 participants) reported on change in physical function at six months (Kapoor 2017). There was no difference between the group receiving advice plus ONS and the group receiving advice alone, SMD 0.27 (95% CI -0.42 to 0.97) (Analysis 3.17).

The review authors did not undertake a combined analysis as one study reported data at more than one time point.

d. QoL – social function

Zero to three months

Three studies (214 participants) reported on change in social function at up to three months (Baldwin 2011; Kapoor 2017; Norman 2008b). There was no difference between the groups receiving advice plus ONS and the groups receiving advice alone, SMD 0.06 (95% CI -0.33 to 0.45) (Analysis 3.18). Heterogeneity was moderate ($I^2 = 49\%$).

Four to six months

One study (32 participants) reported on change in social function at six months (Kapoor 2017). The group receiving advice plus ONS had a large improvement in social function compared with the group receiving advice alone, SMD 0.87 (95% CI 0.14 to 1.60) (Analysis 3.18).

The review authors did not undertake a combined analysis as one study reported data at more than one time point.

e. QoL – cognitive function

Zero to three months

Two studies (137 participants) reported on change in cognitive function (Baldwin 2011; Kapoor 2017). There was no difference between the groups receiving advice plus ONS and the groups receiving advice alone, SMD 0.11 (95% CI -0.23 to 0.45) with no heterogeneity ($I^2 = 0\%$) (Analysis 3.19).

Four to six months

One study (32 participants) reported on change in social function at six months (Kapoor 2017). There was no difference between the group receiving advice plus ONS and the group receiving advice alone, SMD 0.40 (95% CI -0.30 to 1.10) (Analysis 3.19).

Review authors did not undertake a combined analysis as one study reported data at more than one time point.

f. QoL – pain

Zero to three months

Three studies (219 participants) reported on change in pain at up to three months (Baldwin 2011; Kapoor 2017; Norman 2008b). There was no difference between the groups receiving advice plus ONS and the groups receiving advice alone, SMD -0.07 (95% CI -0.36 to 0.23) with no heterogeneity ($I^2 = 14\%$) (Analysis 3.20).

Four to six months

One study (32 participants) reported on change in pain at six months (Kapoor 2017). There was no difference between the group receiving advice plus ONS and the group receiving advice alone, SMD 0.13 (95% CI -0.57 to 0.82) (Analysis 3.20).

The review authors did not undertake a combined analysis as one study reported data at more than one time point.

g. QoL – energy/fatigue

Zero to three months

Three studies (218 participants) reported on change in energy/fatigue at up to three months (Baldwin 2011; Kapoor 2017; Norman 2008b). There was no difference between the groups receiving advice plus ONS and the groups receiving advice alone, SMD -0.16 (95% CI -0.84 to 0.51) however, there was considerable heterogeneity ($I^2 = 83%$) (Analysis 3.21). Removal of one study reduced heterogeneity to zero (Kapoor 2017) and there remained no difference between groups in energy/fatigue, SMD 0.21 (95% CI -0.09 to 0.50) ($P = 0.17$) (Analysis 3.21). It is difficult to explain how the studies by Kapoor and Baldwin differ. Both studies were in people with cancer undergoing palliative care and the sample sizes were comparable. However, the studies were conducted in different parts of the world, UK (Baldwin 2011) and India (Kapoor 2017). The differences in the results might reflect cultural and national differences in response to QoL questions.

Four to six months

One study (32 participants) reported on change in pain at six months (Kapoor 2017). There was no difference between the group receiving advice plus ONS and the group receiving advice alone, SMD -0.31 (95% CI -1.10 to 0.38) (Analysis 3.21).

The review authors did not undertake a combined analysis as one study reported data at more than one time point.

4. Cost

Only one study carried out in Germany (101 participants) reported on cost-effectiveness (Norman 2008b). Investigators concluded that the intervention was cost-effective according to international benchmarks. After three months, the mean (SD) health status utilities were significantly higher in the intervention group than in the control group, 0.731 (0.015) compared to 0.671 (0.016) ($P = 0.028$). The intervention was associated with significantly higher costs, the ICER was EUR 9497 and EUR 12,099 per additional QALY, respectively, but deemed cost-effective according to international thresholds (under EUR 50,000 per QALY).

Group 4 – Dietary advice plus ONS if required compared with no advice and no ONS

This comparison includes 31 studies (32 data sets; 3308 participants) (Andersson 2017; Banks 2016; Beck 2012; Beck 2015; Bonilla-Palomas 2016; Bourdel-Marchasson 2014; Caccialanza 2015; Carey 2013; Endevelt 2011; Evans 1987; Feldblum 2011; Forli 2001; Ganzoni 1994; Holyday 2012; Isenring 2004; Jensen 1997; Kiss 2016; Lovik 1996; Moloney 1983; Ovesen 1993; Pedersen 2016a; Pedersen 2016b; Persson 2002; Rogers 1992; Schilp 2013; Sharma 2017; Silvers 2014; Starke 2011; Suominen 2015; Terp 2018; Uster 2013; Vivanti 2015). There were no usable data for one of these studies (Jensen 1997).

Please refer to the summary of findings table for the explanations of judgements (Summary of findings 4). Note that GRADE judgements are for specific outcomes at the three-months time point and are not provided for all outcomes at each time point.

Primary outcome

1. Mortality

Mortality data were available from 26 studies (Beck 2012; Beck 2015; Bonilla-Palomas 2016; Bourdel-Marchasson 2014; Caccialanza 2015; Carey 2013; Evans 1987; Feldblum 2011; Forli 2001; Ganzoni 1994; Holyday 2012; Isenring 2004; Kiss 2016; Lovik 1996; Moloney 1983; Ovesen 1993; Pedersen 2016a; Persson 2002; Schilp 2013; Sharma 2017; Silvers 2014; Starke 2011; Suominen 2015; Terp 2018; Uster 2013; Vivanti 2015).

Zero to three months

Data were available from 15 studies (1261 participants) at up to three months (Beck 2015; Caccialanza 2015; Carey 2013; Forli 2001; Holyday 2012; Isenring 2004; Kiss 2016; Lovik 1996; Pedersen 2016a; Persson 2002; Schilp 2013; Sharma 2017; Terp 2018; Uster 2013; Vivanti 2015). There was no difference in mortality between the participants who received dietary advice plus ONS if required and those who received usual care, RR 0.82 (95% CI 0.58 to 1.16) (low-certainty evidence). There was no heterogeneity ($I^2 = 0%$) (Analysis 4.1).

Four to six months

Data were available from 10 studies (1140 participants) at the time point from four to six months (Beck 2012; Beck 2015; Feldblum 2011; Ovesen 1993; Persson 2002; Silvers 2014; Starke 2011; Suominen 2015; Terp 2018; Uster 2013). There was no difference in mortality between the participants receiving dietary advice plus ONS if required and those receiving no advice or ONS, RR 1.03 (95% CI 0.69 to 1.55). There was no heterogeneity ($I^2 = 21%$) (Analysis 4.1).

Seven to 12 months

Data were available from six studies (851 participants) at this time point (Bonilla-Palomas 2016; Bourdel-Marchasson 2014; Caccialanza 2015; Ganzoni 1994; Moloney 1983; Persson 2002). There was no difference in mortality between those receiving dietary advice plus ONS if required and those receiving no advice or ONS, RR 0.87 (95% CI 0.63 to 1.19). There was substantial heterogeneity ($I^2 = 64%$) (Analysis 4.1). Removal of one study in individuals with heart failure reduced heterogeneity to approaching moderate (Bonilla-Palomas 2016), RR 0.98 (95% CI 0.77 to 1.24) ($I^2 = 35%$). Due to the number and variety of clinical conditions in this analysis, it is not possible to explain the heterogeneity.

12 months and over

Data were available from five studies (900 participants) at 12 months and over (Bourdel-Marchasson 2014; Caccialanza 2015; Evans 1987; Persson 2002; Sharma 2017). There was no difference in mortality between those receiving dietary advice plus ONS if required and those receiving no advice or ONS, RR 0.93 (95% CI 0.81 to 1.08). There was moderate heterogeneity ($I^2 = 44%$) (Analysis 4.1).

The review authors did not undertake a combined analysis as a number of studies report data at more than one time point.

2. Morbidity

a. Hospital admissions

Hospital admission data were available from nine studies (Beck 2012; Beck 2015; Bonilla-Palomas 2016; Bourdel-Marchasson 2014; Holyday 2012; Pedersen 2016a; Pedersen 2016b; Sharma 2017; Starke 2011; Terp 2018).

Zero to three months

Six studies (673 participants) reported on hospital readmissions at up to three months (Beck 2012; Beck 2015; Holyday 2012; Pedersen 2016a; Pedersen 2016b; Sharma 2017; Terp 2018). There was no difference between those receiving dietary advice plus ONS if required and those receiving no advice or ONS, RR 0.83 (95% CI 0.59 to 1.15) and moderate to substantial heterogeneity ($I^2 = 58%$) (moderate-certainty evidence) (Analysis 4.2). Removal of two studies reduced heterogeneity ($I^2 = 0%$) (Beck 2012; Terp 2018) and resulted in a significant reduction in readmissions in the groups receiving dietary advice plus ONS if required, RR 0.67 (95% CI 0.52 to 0.86). In these two studies, in contrast to the others, there were more readmissions in the intervention group than in the control group (Beck 2012; Terp 2018). It is difficult to explain this difference since all studies were performed in an older population and had a sufficient sample size.

Four to six months

Five studies (456 participants) reported on hospital readmissions between four and six months (Beck 2012; Beck 2015; Holyday 2012; Sharma 2017; Starke 2011). There was no difference between those receiving dietary advice plus ONS if required and those receiving no advice or ONS, RR 0.79 (95% CI 0.58 to 1.03) and moderate to substantial heterogeneity ($I^2 = 55%$) (Analysis 4.2). Removal of one study reduced heterogeneity ($I^2 = 25%$) (Beck 2012) and resulted in a significant reduction in readmissions in the groups receiving dietary advice plus ONS if required, RR 0.71 (95% CI 0.53 to 0.94). In this study, in contrast to the others, there were more readmissions in the intervention group than in the control group (Beck 2012). It is difficult to explain this difference since all studies were performed in an older population and had a sufficient sample size.

Seven to 12 months

Two studies (456 participants) reported on hospital readmissions between four and six months (Bonilla-Palomas 2016; Bourdel-Marchasson 2014). There was no difference in hospital admissions between the participants who received dietary advice plus ONS if required and those who received usual care, RR 0.52 (95% CI 0.18 to 1.55) and high heterogeneity ($I^2 = 83%$) (Analysis 4.2). This heterogeneity might be explained by the different clinical backgrounds (participants with heart failure and participants with cancer).

The review authors did not undertake a combined analysis as a number of studies report data at more than one time point

b. Length of hospital stay

Data on the length of hospital stay were available from five studies (Banks 2016; Beck 2012; Holyday 2012; Sharma 2017; Starke 2011).

Zero to three months

Data on the length of hospital stay to enter into meta-analysis were available from three studies (400 participants) (Beck 2012; Holyday 2012; Starke 2011). There was no difference in length of hospital stay in participants receiving dietary advice plus ONS if required compared with no advice or ONS, MD -0.12 days (95% CI -2.48 to 2.45) (low-certainty evidence) (Analysis 4.3). There was low heterogeneity ($I^2 = 2%$).

An additional two studies reported data on the length of hospital stay in a format that authors could not include in the meta-analysis (Banks 2016; Sharma 2017). In people with pressure ulcers there was no difference in median (IQR) length of stay between the group receiving dietary advice plus ONS if required compared with no advice or ONS; 14.5 days (6.2 to 23.5) versus 14.0 days (10 to 31), respectively (Banks 2016). There was a significantly shorter median (IQR) length of stay in older acute medical patients receiving dietary advice plus ONS if required compared with no advice or ONS; 5.0 days (3.0 to 8.4) versus 8.8 days (4.1 to 13.9), respectively, ($P = 0.007$) (Sharma 2017).

c. Complications

Data on the number of participants with complications were available from three studies (Bourdel-Marchasson 2014; Sharma 2017; Starke 2011).

Zero to three months

Data were available from two studies (280 participants) at up to three months (Sharma 2017; Starke 2011). There were no differences in complications between those receiving dietary advice plus ONS if required and those receiving no advice or ONS, RR 0.56 (95% CI 0.22 to 1.46) (low-certainty evidence) with substantial heterogeneity ($I^2 = 64%$) (Analysis 4.4). Participants in both studies were older acute medical patients and it is not possible to explain the heterogeneity.

Seven to 12 months

Data were available from one study (336 participants) (Bourdel-Marchasson 2014). There were no differences in complications between those receiving dietary advice plus ONS if required and those receiving no advice or ONS, RR 0.88 (95% CI 0.35 to 2.22) (Analysis 4.4).

Analysis of all studies combined showed no difference in complications between those receiving dietary advice plus ONS if required and those receiving no advice or ONS, RR 0.68 (95% CI 0.40 to 1.18) with no heterogeneity ($I^2 = 32%$). There was no heterogeneity between subgroups ($I^2 = 0%$) (Analysis 4.4).

3. Measures of nutritional status

a. Change in weight

Data on weight change were available from 24 studies (Andersson 2017; Banks 2016; Beck 2012; Beck 2015; Bourdel-Marchasson 2014; Caccialanza 2015; Carey 2013; Feldblum 2011; Forli 2001; Ganzoni 1994; Holyday 2012; Isenring 2004; Kiss 2016; Lovik 1996; Ovesen 1993; Persson 2002; Rogers 1992; Schilp 2013; Sharma 2017; Silvers 2014; Starke 2011; Terp 2018; Uster 2013; Vivanti 2015).

Zero to three months

17 studies (1192 participants) reported on weight change at up to three months (Andersson 2017; Banks 2016; Beck 2012; Beck 2015;

Carey 2013; Forli 2001; Holyday 2012; Isenring 2004; Kiss 2016; Lovik 1996; Persson 2002; Schilp 2013; Sharma 2017; Starke 2011; Terp 2018; Uster 2013; Vivanti 2015). Weight gain was greater in groups receiving dietary advice plus ONS if required compared with no advice and no ONS, MD 1.25 kg (95% CI 0.73 to 1.76) (moderate-certainty evidence) and there was moderate heterogeneity ($I^2 = 44\%$) (Analysis 4.5).

Four to six months

10 studies (961 participants) reported on weight change after four to six months (Beck 2012; Bourdel-Marchasson 2014; Carey 2013; Feldblum 2011; Ovesen 1993; Persson 2002; Rogers 1992; Schilp 2013; Silvers 2014; Uster 2013). There was no difference between those receiving dietary advice plus ONS if required and those receiving no advice or ONS, MD 0.58 kg (95% CI -0.30 to 1.45) with substantial heterogeneity ($I^2 = 61\%$) (Analysis 4.5). Removal of two studies reduced heterogeneity ($I^2 = 28\%$) (Silvers 2014; Uster 2013) and there was a significantly greater weight gain in the groups receiving advice plus ONS if required compared with those that received no advice or ONS, MD 0.63 (95% CI 0.02 to 1.24). One study was underpowered with a high risk of attrition bias due to a higher mortality rate in the control group (Silvers 2014). Investigators from one study provided original data which, on closer inspection, appeared to be skewed by the inclusion of a participant in the intervention group who lost more than 20 kg body weight (Uster 2013).

Seven to 12 months

Two studies (107 participants) reported on weight change between seven and 12 months (Caccialanza 2015; Persson 2002). There was no difference between the two groups, MD 0.94 kg (95% CI -0.35 to 2.23) ($P = 0.15$) and no heterogeneity ($I^2 = 0\%$) (Analysis 4.5).

12 months and over

Two studies (77 participants) reported on weight change from baseline up to 12 months and over (Ganzoni 1994; Persson 2002). There was no difference between the two groups, MD 2.17 kg (95% CI -1.20 to 5.54) and moderate heterogeneity ($I^2 = 44\%$) (Analysis 4.5).

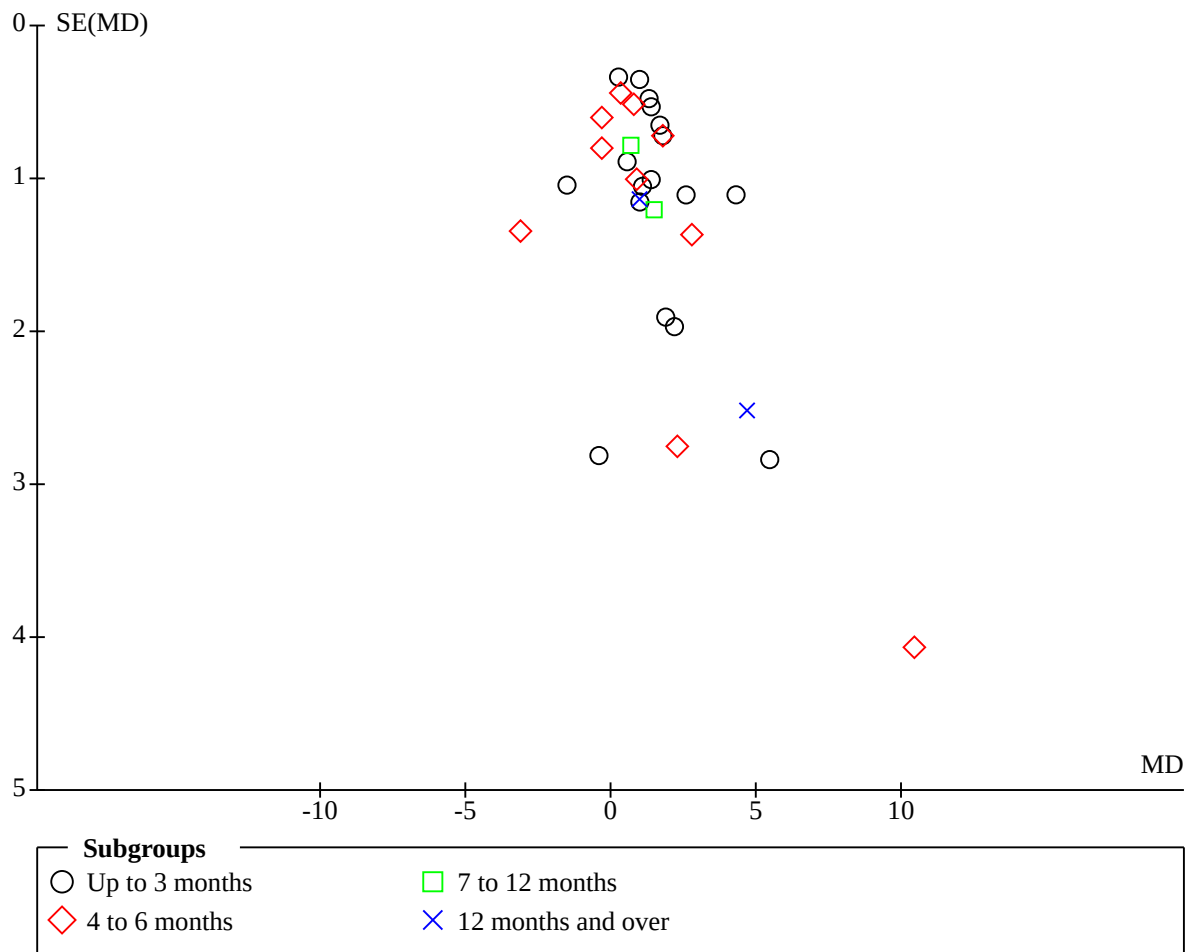
The review authors did not undertake a combined analysis as several studies report data at more than one time point (Analysis 4.5).

Sensitivity analysis

The review authors imputed the SD of weight change for one study reporting data at four to six months (Rogers 1992). Removal of this study from the analysis had no impact on the results, MD 0.41 kg (95% CI -0.47 to 1.28) and heterogeneity remained moderate to substantial, ($I^2 = 60\%$).

The funnel plot examination, the Egger regression asymmetry test and the Begg's adjusted rank correlation suggested no evidence of small study bias ($P = 0.133$ and $P = 0.303$ respectively) (Figure 6).

Figure 6. Funnel plot of comparison 4: dietary advice plus ONS if required compared with no advice and no ONS. Outcome 4.5.1 change in weight (kg)



b. BMI

Four studies report data on change in BMI (Carey 2013; Persson 2002; Sharma 2017; Suominen 2015).

Zero to three months

Two studies (130 participants) reported the change in BMI from baseline for interventions lasting up to three months (Carey 2013; Sharma 2017). The increase in BMI was significantly greater in those receiving dietary advice and ONS if required compared with no advice or ONS, MD 0.72 kg/m² (95% CI 0.06 to 1.37). There was no heterogeneity (I² = 0%) (Analysis 4.6).

Four to six months

One study (27 participants) reported the change in BMI from baseline for interventions lasting from four to six months (Carey 2013). There was no difference between groups receiving dietary advice and ONS if required compared with no advice or ONS, MD 0.80 kg/m² (95% CI -1.12 to 2.72) (Analysis 4.6).

Seven to 12 months

One study (78 participants) reported data on the change in BMI after 12 months of intervention (Suominen 2015). There was no difference between the group receiving dietary advice and ONS if required compared with no advice or ONS, MD -0.10 kg/m² (95% CI -0.61 to 0.41) (Analysis 4.6). In one study BMI increased in the intervention group at 12 months from 25.4 to 25.8 kg/m² and at 24 months from 25.4 to 26.0 kg/m² (Persson 2002). No data were reported for the control group.

Review authors did not undertake a combined analysis as one study reported data at more than one time point (Analysis 4.6).

Two studies report data on final values for BMI (Forli 2001; Starke 2011).

Zero to three months

Two studies (169 participants) reported final BMI measurements for interventions lasting up to three months (Forli 2001; Starke 2011). The final BMI was significantly greater in those receiving dietary advice and ONS if required compared with no advice or ONS, MD 1.19 kg/m² (95% CI 0.18 to 2.20). There was no heterogeneity (I² = 0%) (Analysis 4.7).

c. FFM

Data on change in FFM was available from four studies (Isenring 2004; Kiss 2016; Ovesen 1993; Schilp 2013).

Zero to three months

Four studies (262 participants) reported on change in FFM at up to three months (Isenring 2004; Kiss 2016; Ovesen 1993; Schilp 2013). There was a significantly greater change in FFM in the groups receiving dietary advice plus ONS if required compared with no advice or ONS, MD 0.82 kg (95% CI 0.35 to 1.29) (low-certainty evidence) but with substantial heterogeneity ($I^2 = 73%$) (Analysis 4.8). Removal of one study reduced heterogeneity ($I^2 = 18%$) (Isenring 2004) and there was no difference between groups in FFM, MD 0.34 kg (95% CI -0.23 to 0.91). The SD of change was imputed for this study from two other studies in this group, but it is possible the assumptions were incorrect.

Four to six months

Two studies (184 participants) reported on the change in FFM between four and six months (Ovesen 1993; Schilp 2013). There was no difference between the two groups, MD 0.15 kg (95% CI -0.52 to 0.82) and moderate heterogeneity ($I^2 = 42%$) (Analysis 4.8).

The review authors did not undertake a combined analysis as two studies report data at more than one time point.

d. MAC

Two studies report data on change in MAC (Rogers 1992; Sharma 2017).

Zero to three months

One study (103 participants) reported data on change in MAC from baseline to three months (Sharma 2017). There was no difference between groups receiving dietary advice and ONS if required and groups receiving no advice or ONS, MD 0.13 cm (95% CI -0.68 to 0.94) (Analysis 4.9).

Four to six months

One study (27 participants) reported data on change in MAC from baseline to four months (Rogers 1992). There was no difference between groups, MD 0.30 cm (95% CI -0.84 to 1.44) (Analysis 4.9).

There was no heterogeneity between subgroups ($I^2 = 0%$). In a combined analysis there was no difference in change in MAC between groups, MD 0.19 (95% CI -0.47 to 0.85) with no heterogeneity ($I^2 = 0%$) (Analysis 4.9).

e. MAMC

Two studies report data on change in MAMC (Caccialanza 2015; Sharma 2017).

Zero to three months

One study (103 participants) reported the change from baseline in MAMC to three months (Sharma 2017). There was no difference in MAMC between groups, MD -0.14 cm (95% CI -0.71 to 0.43) (Analysis 4.10).

Seven to 12 months

One study (144 participants) reported the change in MAMC from baseline to seven to 12 months (Caccialanza 2015). There was no difference between groups receiving dietary advice plus ONS if required compared with no advice or ONS, MD 0.60 cm (95% CI -0.17 to 1.37) (Analysis 4.10).

There was moderate to substantial heterogeneity between subgroups ($I^2 = 56.7%$). In a combined analysis there was no difference in change in MAMC between groups, MD 0.18 (95% CI -0.54 to 0.90) with moderate to substantial heterogeneity ($I^2 = 57%$). The studies recruited participants with very different clinical backgrounds (acute medical older people and individuals with chronic amyloidosis) and investigators measured the outcome at very different time points (up to three months and at 12 months).

f. TSF

Three studies reported data on change in TSF (Ovesen 1993; Rogers 1992; Sharma 2017).

Zero to three months

Only one study (103 participants) contributed data on change in TSF following an intervention lasting up to three months (Sharma 2017). There was no difference between groups receiving dietary advice plus ONS if required compared with no advice or ONS, MD 0.89 mm (95% CI -1.15 to 2.93) (Analysis 4.11).

Four to six months

Two studies (132 participants) contributed data on change in TSF following an intervention lasting four to six months (Ovesen 1993; Rogers 1992). There was no difference between groups receiving dietary advice plus ONS if required compared with no advice or ONS, MD 0.60 mm (95% CI -0.57 to 1.77) with no heterogeneity ($I^2 = 0%$) (Analysis 4.11).

There was no heterogeneity between subgroups ($I^2 = 0%$). In a combined analysis there was no difference in change in TSF between groups, MD 0.67 mm (95% CI -0.34 to 1.69) with no heterogeneity ($I^2 = 0%$).

Secondary outcomes

1. Nutritional intake before and after the intervention

a. Change in energy intake

Data on change in energy intake was available from eight studies (Beck 2012; Beck 2015; Forli 2001; Isenring 2004; Moloney 1983; Ovesen 1993; Schilp 2013; Uster 2013).

Zero to three months

Eight studies (645 participants) reported on the change in energy intake up to three months (Beck 2012; Beck 2015; Forli 2001; Isenring 2004; Moloney 1983; Ovesen 1993; Schilp 2013; Uster 2013). There was a significantly greater improvement in energy intake in the groups receiving dietary advice plus ONS if required compared with no advice or ONS, MD 147.01 kcal/day, 95% CI 21.55 to 272.47 kcal with moderate to substantial heterogeneity ($I^2 = 58%$) (Analysis 4.12). Removal of one study reduced heterogeneity to zero (Moloney 1983) and the difference in change in energy intake remained statistically significant in favour of the groups receiving dietary advice plus ONS if required, MD 222.89 kcal/day (95% CI 142.67 to 303.11). This is the only study in this group where energy intake

decreased in both groups; however, it is not possible to explain why the results of this study differ from those undertaken in a similar population, i.e. people with cancer receiving radiotherapy (Isenring 2004; Ovesen 1993; Uster 2013).

Four to six months

Three studies (290 participants) reported on change in energy intake between four and six months (Ovesen 1993; Schilp 2013; Uster 2013). There was no difference between groups receiving dietary advice plus ONS if required compared with no advice or ONS, MD 50.31 kcal/day (95% CI -154.15 to 254.76) and zero to moderate heterogeneity ($I^2 = 39%$) (Analysis 4.12). One study in 336 older people with cancer receiving chemotherapy reported an increase in energy intake between visits 1 and 2 in both groups, but the change was significantly higher ($P < 0.01$) in the group receiving dietary advice plus ONS if required (intervention 328 kcal/day; control 132 kcal/day) (Bourdel-Marchasson 2014). In a study of older people living in the community ($n = 68$), after six months the intervention group (dietary advice plus ONS if required) showed a significant improvement in dietary intake compared with the control group (no advice or ONS) (Endevelt 2011).

Seven to 12 months

A study of 144 outpatients with amyloidosis reported that dietary advice and ONS if required significantly improved total daily energy intake compared with no advice and no ONS, OR 2.18 (95% CI 1.04 to 4.57) (Caccialanza 2015).

The review authors did not undertake a combined analysis as three studies report data at more than one time point.

b. Final energy intake

Three studies reported final energy intake (Carey 2013; Feldblum 2011; Starke 2011).

Zero to three months

Three studies (327 participants) reported final energy intake at up to three months (Carey 2013; Feldblum 2011; Starke 2011). There was no difference between groups receiving dietary advice plus ONS if required and those receiving no advice or ONS, MD 215.17 kcal/day (95% CI -55.09 to 485.43) with considerable heterogeneity ($I^2 = 83%$). Removal of one study reduced heterogeneity ($I^2 = 12%$) (Starke 2011) and there remained no difference between the two groups, MD 109.58 kcal/day (95% CI -71.29 to 290.44). All three studies were conducted in similar populations (hospitalised older people); however, in one study the duration of the intervention was for the length of hospital stay only (two to three weeks) (Starke 2011), whereas the intervention continued for three to six months after hospital discharge in the other two studies (Carey 2013; Feldblum 2011).

Four to six months

Two studies (195 participants) reported final energy intake at up to three months (Carey 2013; Feldblum 2011). There was no difference between groups receiving dietary advice plus ONS if required and those receiving no advice or ONS, MD -8.62 kcal/day (95% CI -154.63 to 137.39) with no heterogeneity ($I^2 = 0%$).

No combined analysis was undertaken as several studies reported data at more than one time point.

c. Change in protein intake

Data on change in protein intake were available in eight studies (Beck 2012; Beck 2015; Isenring 2004; Moloney 1983; Ovesen 1993; Schilp 2013; Suominen 2015; Uster 2013).

Zero to three months

Seven studies (610 participants) reported on the change in protein intake up to three months (Beck 2012; Beck 2015; Isenring 2004; Moloney 1983; Ovesen 1993; Schilp 2013; Uster 2013). There was a significantly higher intake in the between groups receiving dietary advice plus ONS if required compared with no advice or ONS, MD 7.76 g/day, 95% CI 0.47 to 15.05 with considerable heterogeneity ($I^2 = 79%$) (Analysis 4.14). Removal of two studies reduced heterogeneity to zero (Moloney 1983; Uster 2013) and there was a significantly higher protein intake in groups receiving dietary advice and ONS if required, MD 13.04 g/day (95% CI 9.65 to 16.43). In these two studies protein intake decreased in both groups in contrast with the other studies. It is not possible to explain why the results of these studies differ from the others conducted in similar populations, i.e. individuals with cancer receiving radiotherapy (Isenring 2004; Ovesen 1993).

Four to six months

Three studies (290 participants) reported on the change in protein intake between four and six months (Ovesen 1993; Schilp 2013; Uster 2013). There was no difference between groups receiving dietary advice plus ONS if required compared with no advice or ONS, MD 3.10 g/day (95% CI -7.41 to 13.61) and substantial heterogeneity ($I^2 = 60%$) (Analysis 4.14). Removal of one study reduced heterogeneity to zero (Uster 2013) and protein intake was significantly greater in groups receiving advice plus ONS if required, MD 8.31 g/day (95% CI 1.33 to 15.30). In contrast to the other studies, in this study the increase in protein intake was higher in the control group (Uster 2013).

12 months and over

Only one study (78 participants) contributed data on the change in protein intake between baseline and 12 months and over (Suominen 2015); there was no difference between groups receiving dietary advice plus ONS if required compared with no advice or ONS, MD 5.60 g (95% CI -3.00 to 14.20) (Analysis 4.14).

Review authors did not undertake a combined analysis as several studies report data at more than one time point.

2. Measures of functional status

Data on change in handgrip strength was available in nine studies (Beck 2012; Beck 2015; Carey 2013; Pedersen 2016a; Pedersen 2016b; Rogers 1992; Schilp 2013; Sharma 2017; Terp 2018; Uster 2013).

Zero to three months

Eight studies (801 participants) reported the change in handgrip strength at up to three months (Beck 2012; Beck 2015; Carey 2013; Pedersen 2016a; Pedersen 2016b; Schilp 2013; Sharma 2017; Terp 2018; Uster 2013). There was no difference between groups receiving dietary advice plus ONS if required compared with no advice or ONS, MD 0.18 kg (95% CI -0.36 to 0.72) and no heterogeneity ($I^2 = 0%$) (Analysis 4.15).

Four to six months

Three studies (224 participants) reported analysable data for the change in handgrip strength between four and six months (Carey 2013; Schilp 2013; Uster 2013). There was no difference between groups receiving dietary advice plus ONS if required compared with no advice or ONS, MD 0.28 kg (95% CI -1.02 to 1.59) with no heterogeneity ($I^2 = 0\%$) (Analysis 4.15).

The review authors did not undertake a combined analysis as several studies report data at more than one time point.

A further study of 17 outpatients with COPD reported a significantly greater increase in handgrip strength in the group receiving dietary advice and ONS if required compared with no advice, 5.5 kg versus -6.0 kg ($P = 0.01$) (Rogers 1992).

3. QoL

There were 18 studies (19 data sets) which assessed QoL, but used a variety of QoL instruments (Andersson 2017; Beck 2015; Bourdel-Marchasson 2014; Caccialanza 2015; Carey 2013; Isenring 2004; Jensen 1997; Kiss 2016; Ovesen 1993; Pedersen 2016a; Pedersen 2016b; Rogers 1992; Schilp 2013; Sharma 2017; Silvers 2014; Starke 2011; Suominen 2015; Uster 2013; Vivanti 2015). Five studies used the EQ-5D (Andersson 2017; Beck 2015; Schilp 2013; Sharma 2017; Vivanti 2015) and four studies used the EORTC questionnaire (Bourdel-Marchasson 2014; Carey 2013; Isenring 2004; Uster 2013). One study used both the EQ-5D and EORTC-C-30 (Silvers 2014), three studies (four data sets) used the SF-36 (Caccialanza 2015; Pedersen 2016a; Pedersen 2016b; Starke 2011), two studies used the QoL Index (Jensen 1997; Ovesen 1993), one study used FACT-L (Kiss 2016), one study used the Sickness Impact Profile (Rogers 1992) and one study used the HR-QoL (Suominen 2015).

Review authors entered data into the meta-analyses for global QoL scores, physical function, mental function, social function, cognitive function, pain and energy/fatigue using the SMD to combine data using different QoL questionnaires.

a. Global QoL

Zero to three months

Seven studies (389 participants) reported on change in global QoL scores (Beck 2015; Carey 2013; Isenring 2004; Kiss 2016; Persson 2002; Sharma 2017; Vivanti 2015). There was no difference in global QoL between groups receiving advice plus ONS if required compared with no advice and no ONS, SMD 0.15 (95% CI -0.18 to 0.48) (low-certainty evidence) with moderate to substantial heterogeneity ($I^2 = 57\%$) (Analysis 4.16). Removal of one study reduced heterogeneity ($I^2 = 39\%$) (Isenring 2004) and there remained no effect of intervention on global QoL, SMD 0.05 (95% CI -0.25 to 0.35). All studies took place in a variety of different clinical conditions, settings and age ranges, but it is not possible to explain how the removal of this study affected heterogeneity as the participants in the Isenring study were similar to those in the Persson study (Isenring 2004; Persson 2002).

Four to six months

Two studies (156 participants) reported on change in global QoL scores (Carey 2013; Schilp 2013). There was no difference between groups receiving dietary advice plus ONS if required compared

with no advice or ONS, SMD 0.04 (95% CI -0.28 to 0.36) with no heterogeneity ($I^2 = 0\%$) (Analysis 4.16).

Seven to 12 months

One study (78 participants) reported on change in global QoL at up to 12 months (Suominen 2015) and the group receiving advice plus ONS if required had a small improvement in global QoL compared with the group receiving no advice and no ONS, SMD 0.60 (95% CI 0.14 to 1.05) (Analysis 4.16).

The review authors did not undertake a combined analysis as one study reported data at more than one time point.

b. QoL – physical function

Zero to three months

Five studies (458 participants) reported on change in physical function at up to three months (Isenring 2004; Kiss 2016; Pedersen 2016a; Persson 2002; Schilp 2013). There was no difference in change in physical function between groups receiving dietary advice plus ONS if required compared with no advice or ONS, SMD 0.02 (95% CI -0.22 to 0.25) with zero to moderate heterogeneity ($I^2 = 31\%$) (Analysis 4.18).

Four to six months

Two studies (147 participants) reported on change in physical function at six months (Kiss 2016; Schilp 2013). There was no difference between the groups receiving advice plus ONS if required and the groups receiving no advice and no ONS, SMD -0.08 (95% CI -0.40 to 0.25) with no heterogeneity ($I^2 = 0\%$) (Analysis 4.18).

Seven to 12 months

One study (144 participants) reported on change in physical function at up to 12 months (Caccialanza 2015). There was no difference between the group receiving advice plus ONS if required and the group receiving no advice and no ONS, SMD 0.02 (95% CI -0.31 to 0.35) (Analysis 4.18).

The review authors did not undertake a combined analysis as one study reported data at more than one time point.

c. QoL – mental function

Zero to three months

Four studies (435 participants) reported on change in mental function at up to three months (Isenring 2004; Pedersen 2016a; Persson 2002; Schilp 2013). Groups receiving advice plus ONS if required had a small improvement in mental function compared with groups receiving no advice and no ONS, SMD 0.29 (95% CI 0.10 to 0.48) with no heterogeneity ($I^2 = 0\%$) (Analysis 4.19).

Four to six months

One study (123 participants) reported on change in mental function at six months (Schilp 2013). The group receiving advice plus ONS if required had a small to moderate improvement in mental function compared with the group receiving no advice and no ONS, SMD 0.42 (95% CI 0.07 to 0.78) (Analysis 4.19).

Seven to 12 months

One study (144 participants) reported on change in mental function at up to 12 months (Caccialanza 2015). The group receiving advice plus ONS if required had a small to moderate improvement in mental function compared with the group receiving no advice and no ONS, SMD 0.46 (95% CI 0.13 to 0.79) (Analysis 4.19).

The review authors did not undertake a combined analysis as one study reported data at more than one time point.

d. QoL - social function

Zero to three months

Two studies (156 participants) reported on change in social function at up to three months (Isenring 2004; Persson 2002). There was no difference between the groups receiving advice plus ONS if required and the groups receiving no advice and no ONS, SMD 0.02 (95% CI -0.35 to 0.40) with no heterogeneity ($I^2 = 27%$) (Analysis 4.20).

e. QoL – cognitive function

Zero to three months

Two studies (156 participants) reported on change in cognitive function at up to three months (Isenring 2004; Persson 2002). There was no difference between the groups receiving advice plus ONS if required and the groups receiving no advice and no ONS, SMD 0.35 (95% CI -0.23 to 0.92) with substantial heterogeneity ($I^2 = 66%$) (Analysis 4.21). It is not possible to explain the heterogeneity between these two studies since the populations were similar and they used the same QoL tool.

f. QoL – pain

Zero to three months

Two studies (156 participants) reported on change in pain at up to three months (Isenring 2004; Persson 2002). There was no difference between the groups receiving advice plus ONS if required and the groups receiving no advice and no ONS, SMD -0.48 (95% CI -1.03 to 0.07) with substantial heterogeneity ($I^2 = 62%$) (Analysis 4.22). It is not possible to explain the heterogeneity between these two studies since the populations were similar and they used the same QoL tool.

g. QoL – energy/fatigue

Zero to three months

Two studies (155 participants) reported on change in energy/fatigue at up to three months (Isenring 2004; Persson 2002). There was no difference between the groups receiving advice plus ONS if required and the groups receiving no advice and no ONS, SMD -0.58 (95% CI -1.61 to 0.46) with considerable heterogeneity ($I^2 = 89%$) (Analysis 4.23). It is not possible to explain the heterogeneity between these two studies since the populations were similar and they used the same QoL tool.

4. Cost

Zero to three months

One study (71 participants) estimated that the cost for the discharge liaison team plus a dietitian and ONS if required in the intervention group ($n = 34$) as being EUR 9416 compared to EUR 1150 just for the discharge liaison team with no dietitian and no

ONS in the control group ($n = 37$) (Beck 2015). The estimated cost of hospitalisations was EUR 92,020 in the intervention group and EUR 220,025 in the control group; cost savings added up to EUR 3048 per participant in the intervention group.

Four to six months

Two studies reported at this time point (Endevelt 2011; Schilp 2013). The Endevelt study (68 participants) reported that the costs of visits by a primary care physician were significantly lower in the intervention group; investigators also reported a trend of decreased cost in hospital admissions and prescribed medications but these differences did not reach statistical significance (Endevelt 2011). The Schilp study (146 participants) reported that dietetic treatment in undernourished older adults living in the community was not cost-effective compared with usual care (Schilp 2013).

Group 5 – Dietary advice with ONS compared with no advice and no ONS

This comparison 13 studies (1315 participants) (Anbar 2014; Baldwin 2011; Berneis 2000; Calegari 2011; Chandra 1985; Hampson 2003; Jahnavi 2010; Neelemaat 2011; Paton 2004; Payette 2002; Persson 2007; Um 2014; Wyers 2013).

Please refer to the summary of findings table for the explanations of judgements (Summary of findings 5). Note that GRADE judgements are for specific outcomes at the three-months time point and are not provided for all outcomes at each time point.

Primary outcome

1. Mortality

Mortality data were available from nine studies (Anbar 2014; Baldwin 2011; Calegari 2011; Hampson 2003; Jahnavi 2010; Neelemaat 2011; Persson 2007; Um 2014; Wyers 2013).

Zero to three months

Data were available from seven studies (797 participants) at up to three months (Anbar 2014; Baldwin 2011; Calegari 2011; Jahnavi 2010; Neelemaat 2011; Um 2014; Wyers 2013). There was no difference in mortality between the dietary advice with ONS group and the no advice and no ONS group, RR 0.91 (95% CI 0.55 to 1.52) (low-certainty evidence). No heterogeneity was evident ($I^2 = 0%$) (Analysis 5.1).

Four to six months

Data were available from four studies (650 participants) at this time point (Baldwin 2011; Neelemaat 2011; Persson 2007; Wyers 2013). There was no difference in mortality between the dietary advice with ONS group and the no advice and no ONS group, RR 0.85 (95% CI 0.62 to 1.17). There was no heterogeneity ($I^2 = 0%$) (Analysis 5.1).

Seven to 12 months

Data were available from three studies (461 participants) at the time point from seven to 12 months (Baldwin 2011; Hampson 2003; Neelemaat 2011). There was no difference in mortality between the dietary advice with ONS group and the no advice and no ONS group, RR 0.99 (95% CI 0.76 to 1.29). There was low heterogeneity ($I^2 = 13%$) (Analysis 5.1).

12 months and over

Data were available from three studies (542 participants) at the time point of 12 months and over (Baldwin 2011; Neelemaat 2011; Wyers 2013). There was no difference in mortality between the dietary advice with ONS group and the no advice and no ONS group, RR 1.07 (95% CI 0.96 to 1.20). There was no heterogeneity ($I^2 = 0\%$) (Analysis 5.1).

The review authors did not undertake a combined analysis as a number of studies report data at more than one time point.

2. Morbidity

b. Length of hospital stay

Three studies reported data on the length of hospital stay (Anbar 2014; Neelemaat 2011; Wyers 2013).

Zero to three months

Data were available from two studies (258 participants) on the length of hospital stay at up to three months (Anbar 2014; Neelemaat 2011). There was no difference in length of hospital stay between the dietary advice with ONS group and the no advice and no ONS group, MD -1.81 days (95% CI -3.65 to 0.04) (low-certainty evidence). There was no heterogeneity ($I^2 = 0\%$) (Analysis 5.2).

Four to six months

Data were available from one study (147 participants) on the length of hospital stay at four to six months (Wyers 2013). There was no difference in length of hospital stay between the dietary advice with ONS group and the no advice and no ONS group, MD 1.10 days (95% CI -12.46 to 14.66) (Analysis 5.2).

There was no heterogeneity between subgroups ($I^2 = 0\%$). In a combined analysis there was no difference in the length of hospital stay between groups, MD -1.75 days (95% CI -3.58 to 0.08) with no heterogeneity ($I^2 = 0\%$) (Analysis 5.2).

c. Complications

Data on complications were available from one study (Anbar 2014).

Zero to three months

One study (50 participants) reported on complications at up to three months (Anbar 2014). There were significantly fewer complications in the group receiving advice plus ONS compared with the group receiving no advice or ONS, RR 0.42 (95% CI 0.20 to 0.89) (low-certainty evidence) (Analysis 5.3).

3. Measures of nutritional status

a. Change in weight

Data on weight change were available in 11 studies (Baldwin 2011; Berneis 2000; Calegari 2011; Hampson 2003; Jahnavi 2010; Neelemaat 2011; Paton 2004; Payette 2002; Persson 2007; Um 2014; Wyers 2013).

Zero to three months

Eight studies (620 participants) reported on weight change at up to three months (Baldwin 2011; Berneis 2000; Jahnavi 2010;

Neelemaat 2011; Payette 2002; Persson 2007; Um 2014; Wyers 2013). There was no difference in weight change between the dietary advice with ONS group and the no advice and no ONS group, MD 1.08 kg (95% CI -0.17 to 2.33) (low-certainty evidence) and considerable heterogeneity ($I^2 = 80\%$) (Analysis 5.4). Removal of two studies removed heterogeneity ($I^2 = 1\%$) (Calegari 2011; Um 2014) and there was significantly greater weight gain the groups receiving dietary advice plus ONS compared with the groups receiving no advice and no ONS, MD 2.02 kg (95% CI 1.46 to 2.57). In these two studies weight gain was greater in the control group than in the group receiving dietary advice and ONS. It is difficult to explain this difference since it contrasts with the results of other studies in similar populations (Baldwin 2011). The review authors note that they imputed the SD for change in both these studies.

Four to six months

Five studies (450 participants) reported on weight change between four and six months (Baldwin 2011; Paton 2004; Payette 2002; Persson 2007; Wyers 2013). There was a significantly greater weight gain in the dietary advice with ONS group compared with the no advice and no ONS group, MD 1.88 kg (95% CI 0.90 to 2.87) and substantial heterogeneity ($I^2 = 54\%$) (Analysis 5.4). Heterogeneity might be explained by a greater increase in weight in one study (Persson 2007). Removing this study still results in a significant increase in weight, MD 1.47 kg (95% CI 0.88 to 2.06), but with no heterogeneity ($I^2 = 0\%$). Persson included older participants admitted onto acute elderly care and trauma wards (Persson 2007). A further study also included older participants, but these participants were living in the community (Payette 2002). Two studies were in participants with cancer and tuberculosis respectively (Baldwin 2011; Paton 2004) and the final study was in older people admitted for surgery for a hip fracture (Wyers 2013). It is likely that at baseline participants in the study by Persson were in a more acute situation, but had a better recovery once this passed (Persson 2007).

Seven to 12 months

Two studies (110 participants) reported data on weight change at this time point (Baldwin 2011; Hampson 2003). There was a significantly greater weight gain in the dietary advice with ONS group than the no advice and no ONS group, MD 2.60 kg (95% CI 1.42 to 3.78) and no heterogeneity ($I^2 = 0\%$) (Analysis 5.4).

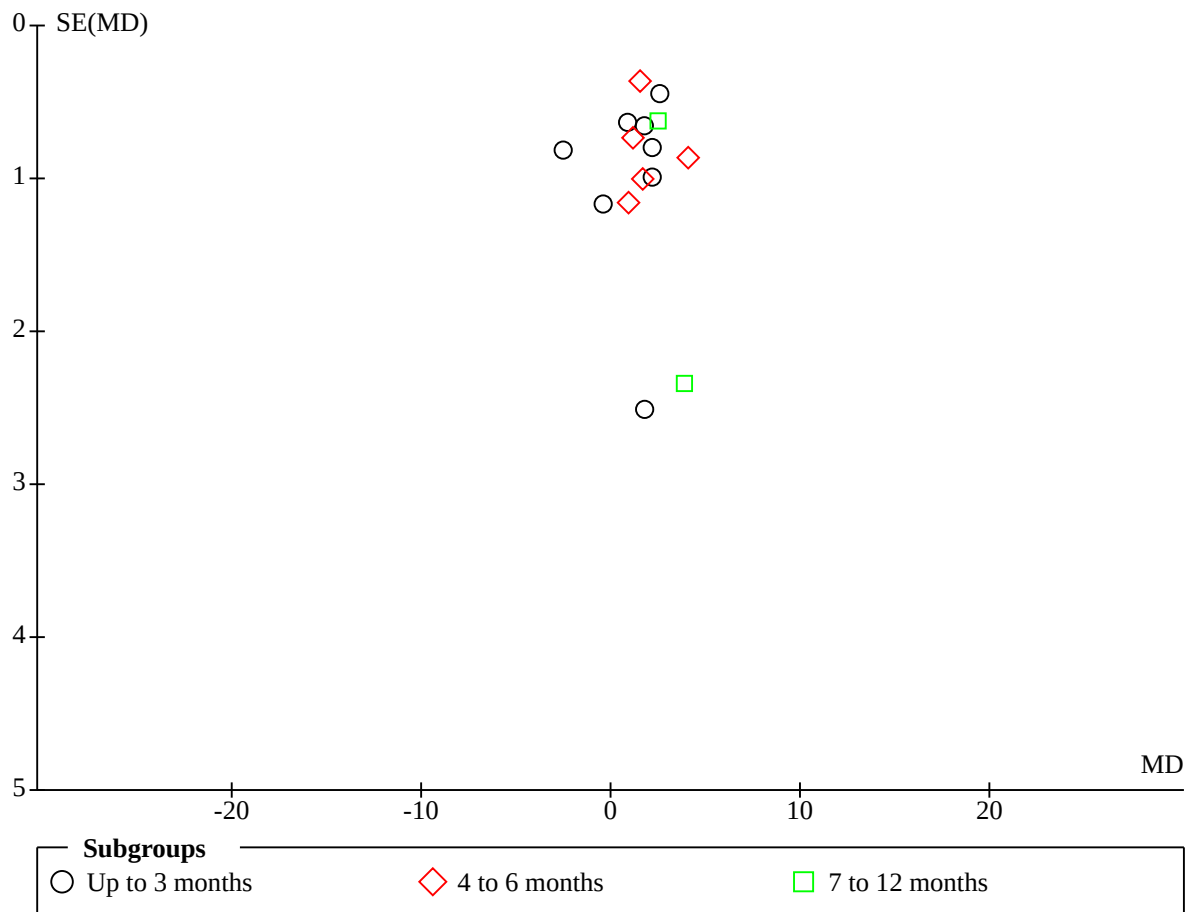
The review authors did not undertake a combined analysis as several studies provided data at more than one time point.

Sensitivity analysis

The review authors imputed the SD of weight change for three studies (Berneis 2000; Calegari 2011; Um 2014). There were too few studies in the analysis at this time point to examine the impact of this on the overall result.

Funnel plot examination, the Egger regression asymmetry test and the Begg's adjusted rank correlation suggested no evidence of small study bias ($P = 0.377$ and $P = 0.386$ respectively) although there were only eight studies in this analysis therefore the test may be invalid (Figure 7).

Figure 7. Funnel plot of comparison 5: dietary advice plus ONS compared with no advice and no ONS. Outcome 5.4.1 change in weight (kg)



b. BMI

Data on the change in BMI were available from four studies (Calegari 2011; Persson 2007; Um 2014; Wyers 2013).

Zero to three months

One study (137 participants) reported data on change in BMI at up to three months (Wyers 2013). There was a significantly greater increase in BMI in the dietary advice plus ONS group compared with the no advice and no ONS group, MD 0.66 kg/m² (95% CI 0.19 to 1.13) (Analysis 5.6).

A second study (15 participants) in people on haemodialysis reported the change in BMI was significantly greater in the no advice and no ONS group (0.6 kg/m²) compared to the dietary advice plus ONS group (0.37 kg/m²) (Calegari 2011). Similarly, a further study (87 participants) of people with cancer receiving radiotherapy also reported a greater change in BMI in the no advice and no ONS group (1.1 kg/m²) compared with the dietary advice plus ONS group (0.2 kg/m²) (Um 2014).

Four to six months

Data on change in BMI were available to enter into a meta-analysis from one study (131 participants) between four and six months

(Wyers 2013). There was no difference in change in BMI between the dietary advice plus ONS group and the no advice and no ONS group, MD 0.44 kg/m² (95% CI -0.09 to 0.98). A study of older people at discharge from hospital (108 participants) reported that the change in BMI was greater in the dietary advice plus ONS group (0.3 kg/m²) compared with the no advice and no ONS group (-0.7 kg/m²) (P < 0.001) (Persson 2007).

The review authors did not undertake a combined analysis as the included study provided data at more than one time point.

Data on final values for BMI were available from four studies (Calegari 2011; Persson 2007; Um 2014; Wyers 2013).

Zero to three months

Three studies (254 participants) reported data on final BMI at up to three months (Calegari 2011; Um 2014; Wyers 2013). There was no difference in final BMI between the dietary advice plus ONS groups compared with the no advice and no ONS groups, MD 0.64 kg/m² (95% CI -0.76 to 2.04) with moderate heterogeneity (I² = 46%) (Analysis 5.7).

Four to six months

Two studies (242 participants) reported data on final BMI between four and six months (Persson 2007; Wyers 2013). There was no difference in final BMI between the groups receiving dietary advice plus ONS and the groups receiving no advice and no ONS, MD 0.71 kg/m² (95% CI -0.45 to 1.87) with moderate heterogeneity ($I^2 = 40\%$) (Analysis 5.7).

The review authors did not undertake a combined analysis as one study provided data at more than one time point.

c. FFM

Data on change in FFM were available from five studies and the review authors combined these in a meta-analysis using the SMD because the data consisted of estimates of FFM using different methods (Berneis 2000; Calegari 2011; Hampson 2003; Neelemaat 2011; Paton 2004).

Zero to three months

Three studies (130 participants) reported on the change in FFM at up to three months (Calegari 2011; Neelemaat 2011; Paton 2004). There was no difference in the change in FFM between the dietary advice with ONS group and the no advice and no ONS group, SMD 0.26 kg (95% CI -0.09 to 0.62) (very low-certainty evidence) and no heterogeneity ($I^2 = 0\%$) (Analysis 5.5). In a study of 15 people with HIV infection, mean (SD) FFM as a % of total body weight increased in the dietary advice plus ONS group from 83.5% (1.8) to 86.3% (1.7) ($P < 0.05$), but there was no change in FFM in the no advice and no ONS group (Berneis 2000).

Four to six months

One study (26 participants) reported on the change in FFM at six months (Paton 2004). There was no difference between the dietary advice with ONS groups and the no advice and no ONS groups, SMD 0.21 kg (95% CI -0.57 to 0.99) (Analysis 5.5).

Seven to 12 months

A further study (71 participants) reported the change in FFM at 12 months (Hampson 2003). There was no difference between the dietary advice with ONS groups and the no advice and no ONS groups, SMD 0.29 kg (95% CI -0.18 to 0.75) (Analysis 5.5).

The review authors did not undertake a combined analysis as one study provided data at more than one time point.

d. MAC

One study (152 participants) which recruited frail older people after hip fracture provided data for the change in MAC (Wyers 2013).

Zero to three months

The study reported no difference in change in MAC at three months between the dietary advice plus ONS group and the no advice and no ONS group, MD 0.01 cm (95% CI -0.75 to 0.76) (Wyers 2013).

Four to six months

After six months there was no difference in change in MAC between the dietary advice plus ONS group and the no advice and no ONS group, MD 0.38 cm (95% CI -0.33 to 1.10) (Wyers 2013).

e. MAMC

One study (83 participants) of frail older people living at home reported on the change in MAMC, but presented data in narrative as no SDs of change were available (Payette 2002).

Four to six months

There was no difference in the mean (SD) change in MAMC at four months between the dietary advice plus ONS group (from 21.0 (2.4) cm at baseline to 21.0 (2.0) cm at four months, change = 0.0 cm) and the no advice and no ONS group (from 21.3 (2.0) cm at baseline to 21.1 (2.5) cm at four months, change = -0.2 cm) (Payette 2002).

f. TSF

Data on change in TSF were available from one study (83 participants) of frail older people living at home (Payette 2002), but the review authors present the data in narrative. While the mean (SD) is reported at baseline and at the end of the intervention, the change data has no SD available.

Four to six months

Data on TSF were available from one study (83 participants) in older people living in the community (Payette 2002). There was a greater increase in TSF in the dietary advice and ONS group (reported as mean (SD)), from 13.5 (5.3) mm at baseline to 14.4 (5.6) mm at 16 weeks (the end of intervention) (change = 0.9 mm) compared with the no advice and no ONS group which increased from 13.3 (6.5) mm at baseline to 13.6 (6.6) mm at 16 weeks (change = 0.3 mm).

Secondary outcomes

1. Nutritional intake before and after the intervention

a. Change in energy intake

Data on change in energy intake were available from seven studies (Baldwin 2011; Berneis 2000; Hampson 2003; Neelemaat 2011; Paton 2004; Payette 2002; Wyers 2013).

Zero to three months

Five studies (347 participants) reported on the change in energy intake at up to three months (Baldwin 2011; Berneis 2000; Neelemaat 2011; Paton 2004; Wyers 2013). There was a significantly higher energy intake in the groups receiving dietary advice and ONS compared with the no advice and no ONS group, MD 319.78 kcal/day (95% CI 152.83 to 486.73). Moderate heterogeneity was evident ($I^2 = 50\%$) (Analysis 5.8).

Four to six months

Three studies (244 participants) reported on the change in energy intake between four and six months (Paton 2004; Payette 2002; Wyers 2013). There was a significantly greater intake in the groups receiving dietary advice plus ONS compared with the groups receiving no advice and no ONS, MD 239.83 kcal/day (95% CI 38.74 to 440.92) and moderate to substantial heterogeneity ($I^2 = 54\%$) (Analysis 5.8). Removal of one study reduced heterogeneity ($I^2 = 0\%$) (Wyers 2013) and the effect remained significant, MD 318.79 kcal/day (95% CI 179.93 to 457.64). Heterogeneity might be explained by the fact that in two studies the participants were recovering from an acute illness (Paton 2004; Payette 2002), while in the third study the participants were frail, older people living at home (Wyers 2013).

Seven to 12 months

One study (63 participants) reported data on the change in energy intake at up to 12 months (Hampson 2003). There was a significantly greater energy intake in the dietary advice and ONS group and the no advice and no ONS group, MD 464.00 kcal/day (95% CI 270.07 to 657.93) (Analysis 5.8).

The review authors did not undertake a combined analysis as two studies report data at more than one time point.

b. Final energy intake

Data on final energy intake were available from three studies (Anbar 2014; Berneis 2000; Um 2014).

Zero to three months

All three studies (152 participants) reported data at up to three months (Anbar 2014; Berneis 2000; Um 2014). The dietary advice and ONS groups had a significantly higher energy intake compared with the no advice and no ONS groups, MD 399.11 kcal/day (95% CI 123.00 to 675.22) with considerable heterogeneity ($I^2 = 76%$) (Analysis 5.9). Removal of one study reduced heterogeneity ($I^2 = 25%$) (Berneis 2000) and the effect remained statistically significant, MD 281.16 kcal/day (95% CI 111.55 to 450.76). Heterogeneity is likely explained by the different disease backgrounds (older participants compared with younger adults with HIV infection) and small study sample sizes.

c. Change in protein intake

Data on the change in protein intake were available from two studies (Neelemaat 2011; Wyers 2013).

Zero to three months

Both studies (285 participants) reported on the change in protein intake at up to three months (Neelemaat 2011; Wyers 2013). There was no difference between the dietary advice and ONS group and the no advice and no ONS group, MD 7.14 g/day (95% CI -0.46 to 14.74) with no heterogeneity ($I^2 = 25%$) (Analysis 5.10).

Four to six months

Only one study (135 participants) reported the change in protein intake at six months (Wyers 2013). There was no difference in protein intake between the dietary advice and ONS group and the no advice and no ONS group, MD 0.92 g/day (95% CI -8.93 to 10.76) (Analysis 5.10).

The review authors did not undertake a combined analysis as one study reported data at more than one time point.

d. Final protein intake

Data on final protein intake were available from four studies (Anbar 2014; Berneis 2000; Hampson 2003; Um 2014).

Zero to three months

Three studies (152 participants) reported data at up to three months (Anbar 2014; Berneis 2000; Um 2014). The dietary advice and ONS group had a significantly higher final protein intake than the no dietary advice and no ONS group, MD 18.15 g/day (95% CI 9.37 to 26.93) with no heterogeneity ($I^2 = 17%$).

Seven to 12 months

Data were available from one study (71 participants) at this time point (Hampson 2003). The dietary advice and ONS group had a significantly higher final protein intake than the no dietary advice and no ONS group, MD 17.00 g/day (95% CI 7.18 to 26.82).

There was no heterogeneity between subgroups ($I^2 = 0%$). In an analysis of all studies combined, the dietary advice and ONS groups had a significantly higher final protein intake than the no dietary advice and no ONS groups, MD 17.67 g/day (95% CI 11.80 to 23.55) with no heterogeneity ($I^2 = 0%$) (Analysis 5.11).

2. Measures of functional status

a. Handgrip strength

Data on change in handgrip strength were available from six studies (Jahnavi 2010; Neelemaat 2011; Paton 2004; Payette 2002; Persson 2007; Wyers 2013).

Zero to three months

Three studies (244 participants) reported data for analysis on the change in handgrip strength at up to three months (Jahnavi 2010; Neelemaat 2011; Paton 2004). There was no difference between the dietary advice and ONS group and the no advice and no ONS group, MD 0.99 kg force (95% CI -0.42 to 2.40) with moderate heterogeneity ($I^2 = 49%$) (Analysis 5.12). In a further study of frail older people after hip fracture (152 participants), there was no difference in change in handgrip strength at three months between the dietary advice plus ONS group and the no advice and no ONS group, MD 0.13 kg force (95% CI -1.35 to 1.62) (Wyers 2013).

Four to six months

Three studies (200 participants) reported data for analysis on the change in handgrip strength between four and six months (Paton 2004; Payette 2002; Persson 2007). There was no statistically significant difference between the dietary advice and ONS group and the no advice and no ONS groups, MD 0.72 kg force (95% CI -0.88 to 2.31) and no heterogeneity ($I^2 = 10%$) (Analysis 5.12). In a further study of frail older people after hip fracture (152 participants), there was no difference in change in handgrip strength at six months between the dietary advice plus ONS group and the no advice and no ONS group, MD 0.12 kg force (95% CI -1.63 to 1.86) (Wyers 2013).

The review authors did not undertake a combined analysis as one study reported data at more than one time point.

3. QoL

The 10 studies reporting data on QoL used a variety of different tools and reported data in different ways e.g. total QoL scores and different domain scores (Baldwin 2011; Berneis 2000; Calegari 2011; Jahnavi 2010; Neelemaat 2011; Paton 2004; Payette 2002; Persson 2007; Um 2014; Wyers 2013).

Two studies used the EORTC questionnaire (Baldwin 2011; Um 2014), one used the FAACT (Baldwin 2011), four used the SF-36 (Calegari 2011; Jahnavi 2010; Payette 2002; Persson 2007), one used the SF-12 (Neelemaat 2011), two used the EuroQol-5D (Neelemaat 2011; Wyers 2013) and one used the Medical Outcomes Instrument adapted for use in people with HIV (Berneis 2000).

The review authors entered data into meta-analyses for global QoL scores, physical function, mental function, social function, cognitive function, pain and energy/fatigue using the SMD to combine data using different QoL questionnaires.

a. Global QoL

Zero to three months

Four studies (367 participants) reported on change in global QoL (Baldwin 2011; Jahn timer 2010; Paton 2004; Wyers 2013). There was no difference in the change in global QoL between the dietary advice plus ONS group compared with the no advice or ONS group, SMD 0.32 (95% CI -0.33 to 0.96) (very low-certainty evidence) and there was considerable heterogeneity ($I^2 = 88%$) (Analysis 5.13). Removal of one study reduced heterogeneity to zero (Jahn timer 2010) but there remained no difference in global QoL between the two groups, SMD -0.04 (95% CI -0.29 to 0.20). Although the intent of intervention was the same for all studies, they took place in a variety of different populations, countries and healthcare systems and used different QoL tools and one or more of these factors likely explains the observed heterogeneity.

One study (117 participants) reporting global QoL using FAACT also found no difference between groups (Baldwin 2011), SMD 0.01 (95% CI -0.35 to 0.38) (Analysis 5.13).

Four to six months

Three studies (214 participants) reported on change in global QoL scores (Baldwin 2011; Paton 2004; Wyers 2013). There was no difference in global QoL between the dietary advice and ONS group and the no advice and no ONS groups, SMD 0.04 (95% CI -0.24 to 0.31) with no heterogeneity ($I^2 = 0%$) (Analysis 5.13).

One study (64 participants) reporting global QoL using FAACT also found no difference between groups (Baldwin 2011), SMD -0.30 (95% CI -0.80 to 0.19) (Analysis 5.13).

The review authors did not undertake a combined analysis as one study reported data at more than one time point.

b. QoL – physical function

Zero to three months

Three studies (242 participants) reported on change in physical function at up to three months (Baldwin 2011; Jahn timer 2010; Paton 2004). There was no difference in change in physical function between the dietary advice plus ONS group compared with no advice or ONS group, SMD 0.37 (95% CI -0.11 to 0.84); however, there was substantial heterogeneity ($I^2 = 67%$) (Analysis 5.14). Removal of one study reduced heterogeneity to zero (Baldwin 2011) and dietary advice and ONS groups had a moderate improvement in physical function compared with the no advice and no ONS groups, SMD 0.58 (95% CI 0.23 to 0.93). Although the intent of intervention was the same for all studies, they took place in a variety of different populations, countries and healthcare systems and used different QoL tools and one or more of these factors likely explains the observed heterogeneity.

Four to six months

Two studies (90 participants) reported on change in physical function at six months (Paton 2004; Persson 2007). The dietary

advice and ONS groups had a moderate to large improvement in physical function compared with the no advice and no ONS groups, SMD 0.63 (95% CI 0.18 to 1.09) with no heterogeneity ($I^2 = 11%$).

The review authors did not undertake a combined analysis as two studies reported data at more than one time point.

c. QoL – mental function

Zero to three months

Three studies (239 participants) reported on change in mental function at up to three months (Baldwin 2011; Jahn timer 2010; Paton 2004). There was no difference in change in mental function between the dietary advice plus ONS groups compared with the no advice or ONS groups, SMD 0.39 (95% CI -0.16 to 0.93); however, there was considerable heterogeneity ($I^2 = 75%$) (Analysis 5.15). Removal of one study reduced heterogeneity to zero (Jahn timer 2010) and there remained no difference between the two groups, SMD 0.12 (95% CI -0.21 to 0.46). Although the studies all shared the same objectives, they were undertaken in a variety of different populations, countries and healthcare systems and used different QoL tools and one or more of these factors likely explains the observed heterogeneity.

Four to six months

Two studies (90 participants) reported on change in mental function at six months (Paton 2004; Persson 2007). There was no difference in change in mental function between the dietary advice plus ONS group compared with the no advice or ONS group, SMD 0.04 (95% CI -0.38 to 0.45) with no heterogeneity ($I^2 = 0%$).

The review authors did not undertake a combined analysis as two studies reported data at more than one time point.

d. QoL – social function

Zero to three months

Three studies (235 participants) reported on change in social function at up to three months (Baldwin 2011, Jahn timer 2010; Paton 2004). The dietary advice plus ONS group had a small to moderate improvement in social function compared with the no advice and no ONS group, SMD 0.47 (95% CI 0.02 to 0.91) with substantial heterogeneity, ($I^2 = 62%$) (Analysis 5.16). Removal of one study reduced heterogeneity to zero (Baldwin 2011) and the effect remained significant with the dietary advice plus ONS group showing a small improvement in social function compared with the no advice and no ONS group, SMD 0.71 (95% CI 0.36 to 1.06). Although the objective was the same for all studies, they took place in a variety of different populations, countries and healthcare systems and used different QoL tools and one or more of these factors likely explains the observed heterogeneity.

Four to six months

One study (36 participants) reported on change in social function at six months (Paton 2004). There was no difference in change in social function between the dietary advice plus ONS group compared with the no advice or ONS group, SMD 0.40 (95% CI -0.26 to 1.06) (Analysis 5.16).

The review authors did not undertake a combined analysis as one study reported data at more than one time point.

e. QoL – cognitive function

Zero to three months

Two studies (141 participants) reported on change in cognitive function (Baldwin 2011; Paton 2004). There was no difference between the groups receiving advice plus ONS and the groups receiving advice alone, SMD 0.21 (95% CI -0.13 to 0.54) with no heterogeneity ($I^2 = 0\%$) (Analysis 5.17).

Four to six months

One study (36 participants) reported on change in cognitive function at six months (Paton 2004). There was no difference in change in cognitive function between the dietary advice plus ONS group compared with the no advice or ONS group, SMD 0.29 (95% CI -0.37 to 0.95) (Analysis 5.17).

The review authors did not undertake a combined analysis as one study reported data at more than one time point.

f. QoL – pain

Zero to three months

Three studies (238 participants) reported on change in pain scores at up to three months (Baldwin 2011; Jahnavi 2010; Paton 2004). There was no difference between the dietary advice plus ONS groups and the no advice and no ONS groups, SMD 0.46 (95% CI -0.24 to 1.16) with considerable heterogeneity ($I^2 = 85\%$) (Analysis 5.18). Removal of one study reduced heterogeneity to zero (Jahnavi 2010) and there remained no difference in the change in pain scores between the two groups, SMD 0.08 (95% CI -0.25 to 0.42). Although the objective was the same for all studies, they took place in a variety of different populations, countries and healthcare systems and used different QoL tools and one or more of these factors likely explains the observed heterogeneity.

Four to six months

One study (36 participants) reported no difference in the change in pain scores at six months between the dietary advice plus ONS group compared with the no advice or ONS group, SMD 0.28 (95% CI -0.37 to 0.94) (Paton 2004) (Analysis 5.18).

The review authors did not undertake a combined analysis as one study reported data at more than one time point.

g. QoL – energy or fatigue

Zero to three months

Three studies (238 participants) reported on change in energy or fatigue at up to three months (Baldwin 2011, Jahnavi 2010; Paton 2004). There was no difference between the dietary advice plus ONS group and the no advice and no ONS groups, SMD 0.46 (95% CI -0.24 to 1.16) with no heterogeneity, ($I^2 = 20\%$) (Analysis 5.19).

Four to six months

One study (36 participants) reported no difference in change in energy or fatigue between the dietary advice plus ONS group compared with the no advice or ONS group, SMD -0.01 (95% CI -0.66 to 0.64) (Paton 2004) (Analysis 5.19).

The review authors did not undertake a combined analysis as one study reported data at more than one time point.

4. Cost

Two studies reported cost-effectiveness analyses (Neelemaat 2011; Wyers 2013).

One study (210 participants, 105 in each group) showed that after three months there were no differences in costs between groups (Neelemaat 2011). Cost-effectiveness for QALYs and physical activities could not be demonstrated because there was no effect on QoL and physical activity. For functional limitations investigators reported a 0.95 probability that the intervention is cost-effective in comparison with usual care for ceiling ratios over EUR 6500.

A second study (152 participants) showed that the mean costs of the nutritional intervention were EUR 613 (Wyers 2013). Total costs and subcategories of costs were not significantly different between groups. Based on bootstrapping of ICERs, the nutritional intervention was likely to be cost-effective for weight as measured over the three-month intervention period, regardless of nutritional status at baseline. When assessing QALYs, the probability for the nutritional intervention being cost-effective was relatively low, except in people aged below 75 years.

DISCUSSION

This update is the third substantial update of the original review (Baldwin 2001) and the review now includes 94 studies and 10,284 participants.

The results of the 2021 update confirm the results from the previous versions. In general, dietary advice, with or without ONS, elicited an improvement in energy intake, and to a lesser extent protein intake, and an increase in weight. Results were most positive for the first three months and attenuated at later time points. It is important to note that in the majority of studies (59%) included in this review the intervention lasted for three months and the majority of benefits observed also occurred in the first three months but in the absence of agreed cut-offs for recognition of clinically meaningful benefits it is difficult to draw conclusions on their clinical significance. For the smaller number of studies reporting longer intervention and follow-up (32% for four to six months and 3% for seven to 12 months or more), there was insufficient evidence to draw conclusions on any benefits. To date there is insufficient information to determine whether three months is the optimal length of intervention of this kind and indeed whether it represents a realistic goal in clinical practice.

This Cochrane Review includes nutritional, clinical, functional, economic and patient-centred outcomes. The authors found some evidence for improvements in nutritional intake and body weight; however, the evidence for estimates of body composition and physical function such as MAMC, FFM, TSF thickness and grip strength was lacking as few studies reported these outcomes. It can be questioned whether these parameters are as sensitive to improved dietary intake as weight, especially when the changes in weight are only small (in this review the observed MDs in weight were around 1 kg with CIs indicating all differences were less than 2 kg). The majority of participants in this review were older people and understanding of the molecular and cellular mechanisms involved in the recovery of physical function in this group is unclear

(Munk 2016). It has been demonstrated that recovery of habitual strength and physical function in healthy people after exposure to semi-starvation took more than six months (Keys 1950). It is possible that the length of intervention and follow-up in studies in this review was too short to capture changes to these outcomes

For the first time, the review authors have included QoL scores in this review, with no consistency in effect for either global scores or individual domain scores. QoL measures are intended to measure what really matters to the patient. It has been shown that self-assessed health status may be an even more powerful predictor of mortality and morbidity than many objective measures of health (DeSalvo 2006; Dominick 2002). QoL measures are increasingly used to assess the effectiveness of interventions because they are thought to reflect how patients feel in addition to objective outcomes such as mortality. Whilst it might be hoped that improved nutrition resulted in improvements to patient-centred outcomes such as participation in family life, reduced reliance on formal and informal carers and activities of daily living, studies mostly failed to measure these types of outcomes or used a range of different tools making comparisons difficult to draw. A better QoL is associated with less use of medical services, and with decreased healthcare costs (Ferris 2009). The studies included in this review mostly used generic QoL measures to provide an assessment of an individual's overall health. This allows comparison between different health conditions which is in contrast to disease-specific QoL measures that have the advantage of being able to detect changes specific to the impact of treatment of a particular disease, but prevents comparisons across different patient groups. QoL measures may involve scores for separate domains (e.g. pain, energy or fatigue, social functioning, cognitive functioning, physical functioning) or combine different domains into a composite score. In the studies included in this review there was inconsistent reporting of domain or composite scores at different time points, which may partially explain the lack of consistency in findings. A disadvantage of the general QoL scales is that usually there is no weighting of the importance of the separate domains. Also, factors seemingly important to a patient, e.g. financial security or ability to work are often not incorporated in the QoL scales (Carr 2001).

Temel showed that intensive supportive care (without nutrition) improved QoL and clinical outcomes in people with advanced lung cancer and raised the suggestion that attention, frequent visits and early treatment of symptoms may be as important as the intervention itself (Temel 2010). In the studies in this review it was not always possible to distinguish between benefits resulting from the nutritional intervention, or the improved level of care.

With regard to clinically relevant endpoints, this Cochrane Review does not provide consistent evidence for positive effects of dietary advice, with or without ONS, on mortality, complications, length of stay or readmissions. As this review assessed adults with disease-related malnutrition, it must be accepted that a nutritional intervention is only one of multiple interventions, that may affect clinical outcomes. This is particularly relevant when considering people with cachexia, or for whom inflammation is a key contributor to their disease-related malnutrition, such that treatment of the underlying disease or inflammation is critical to an improvement in clinical outcomes. It must, therefore, be questioned whether it is realistic to expect that optimal treatment

of malnutrition by nutritional interventions alone would improve clinical outcomes.

There was statistical and clinical heterogeneity across all studies contributing to the findings of this Cochrane Review, apart from the effects on mortality. The review authors combined studies for each intervention and therefore the findings of this review must be interpreted with caution. The possibility that the effects of interventions vary according to factors which it has not been possible to identify must be borne in mind, since the authors cannot assume that the effects of different interventions will be the same in all clinical groups, care settings and participants of different ages. Until there are more homogenous studies in different patient groups, the review authors can not fully evaluate the effects of dietary advice given with or without ONS in individuals and patient populations.

In conclusion, although this Cochrane Review has summarised the findings of 94 separate studies of dietary advice there remains a lack of good-quality evidence for all reported outcomes and in particular there is a need for more evidence of the effects of dietary advice on clinically-relevant endpoints, patient-centred outcomes and cost-effectiveness.

Summary of main results

The aim of this review was to assess whether adults with disease-related malnutrition (or at risk of malnutrition) can improve their survival, weight, and general health-related QoL if they receive dietary advice and ONS. The review authors identified 94 studies (10,284 participants) which included a heterogeneous group of participants from a variety of healthcare settings and represented five different intervention types. All studies were at risk of bias for one or more elements, statistical heterogeneity was frequently high and the certainty of evidence was low for the majority of analyses. The review authors undertook pooled analyses by intervention for the outcomes specified and explained heterogeneity where possible when the I^2 statistic exceeded 50%.

Dietary advice compared with no advice (usual diet)

The review includes 24 studies comparing dietary advice with no dietary advice, but not all studies contributed data on all outcomes and data were available to enter into the meta-analyses for only some outcomes. Except for mortality, few studies provided data for inclusion in these analyses.

There was no effect of dietary advice observed on the review's primary outcomes of mortality and two estimates of morbidity (hospital readmissions and complications). There was low-certainty evidence from one study of significantly shorter hospitalisation in people receiving dietary advice (Analysis 1.3). For all time points there was low-certainty evidence of an effect on weight change, but this did not translate into consistent improvements in other measures of body composition. One study with data at the 12-month time point reported a significant improvement in FFM (low-certainty evidence; Analysis 1.7); and data demonstrated an increase in MAMC at up to three months and at four to six months (Analysis 1.8) in addition to a decrease in TSF measurements at up to three months (Analysis 1.10). There was inconsistent evidence for an effect of dietary advice on energy and protein intake (Analysis 1.11; Analysis 1.12; Analysis 1.13; Analysis 1.14). There was no effect of dietary advice observed on handgrip strength at any time point (Analysis 1.15), but there was evidence

of an improvement in global QoL scores at up to three months (five studies) and at 12 months and over (two studies; low-certainty evidence; [Analysis 1.16](#)). There was no effect seen on cost.

Dietary advice compared with ONS

The review includes 12 studies comparing dietary advice with ONS, but not all studies contributed data on all outcomes and data were available to enter into the meta-analyses for only some outcomes.

The review authors observed no effect on mortality at any time point. There was no difference between groups in the number of hospital admissions at three months (low-certainty evidence); however there were fewer hospital admissions in one study at four to six months in the group receiving ONS ([Analysis 2.2](#)). No data were reported on the effects of intervention on complications and length of hospital stay. There were no differences between groups in weight change (low-certainty evidence) or changes in body composition. However, there was evidence of higher energy intake (six studies) and protein intake (five studies) in groups receiving ONS after three months, which persisted to four to six months for protein ([Analysis 2.8](#); [Analysis 2.9](#)). One study with an extended follow-up (median 6.5 years) reported higher energy and protein intakes in the dietary advice group ([Ravasco 2005a](#)). Similarly, there was no difference in handgrip strength or in global QoL score between groups at three months, but significantly better global QoL scores from one study at 12 months and over in the group receiving dietary advice (low-certainty evidence; [Analysis 2.11](#)). No studies assessed cost-effectiveness.

Dietary advice compared with dietary advice plus ONS

The review includes 22 studies comparing dietary advice with dietary advice plus ONS, but not all studies contributed data on all outcomes and data were available to enter into the meta-analyses for only some outcomes.

As for previous comparisons, there was no difference between groups in mortality at any time point. There was no difference between groups in length of hospital stay at up to three months (low-certainty evidence; [Analysis 3.3](#)); however, in the group receiving dietary advice alone there were fewer hospital admissions at that time point (low-certainty evidence; [Analysis 3.2](#)). There was low-certainty evidence of fewer complications in the groups receiving dietary advice plus ONS at up to three months (three studies); however, there were no differences at other time points ([Analysis 3.4](#)). There was low-certainty evidence of a greater improvement in weight in the group receiving dietary advice plus ONS up to three months, but there was no difference in weight beyond three months ([Analysis 3.5](#)) and minimal evidence of any impact on changes in body composition ([Analysis 3.7](#); [Analysis 3.8](#); [Analysis 3.9](#)). There was evidence of higher energy intake (six studies) and protein intake (three studies) in the groups receiving dietary advice plus ONS at up to three months (three studies) and four to six months (one study) ([Analysis 3.10](#); [Analysis 3.12](#)). Again, there was no difference in handgrip strength ([Analysis 3.14](#)). There was low-certainty evidence of an improvement in global QoL in the group receiving dietary advice plus ONS at up to three months (four studies) and no difference at other time points ([Analysis 3.15](#)). Data from one study suggested that dietary advice plus an ONS was cost-effective up to three months ([Norman 2008b](#)).

Dietary advice plus ONS if required compared with no advice and no ONS

The review includes 31 studies comparing dietary advice plus ONS if required with no advice and no ONS, but not all studies contributed data on all outcomes and data were available to enter into the meta-analyses for only some outcomes.

There was no difference between groups for clinical outcomes (mortality, hospital readmissions, length of hospital stay and complications) (moderate to low-certainty evidence; [Analysis 4.2](#); [Analysis 4.3](#); [Analysis 4.4](#)). There were improvements in weight and FFM in the groups receiving dietary advice plus ONS at up to three months (moderate-certainty evidence, [Analysis 4.5](#); low-certainty evidence, [Analysis 4.8](#)), but there were no differences at other time points or for other measures of body composition ([Analysis 4.9](#); [Analysis 4.10](#); [Analysis 4.11](#)). At three months, there was evidence of an increase in energy intake (eight studies) and protein intake (seven studies) ([Analysis 4.12](#); [Analysis 4.14](#)). At four to six months there was no difference in energy intake (three studies), but there was a higher protein intake in groups receiving dietary advice plus ONS (three studies) ([Analysis 4.12](#); [Analysis 4.14](#)). The review authors found no difference in handgrip strength at any time point. There was no difference in global QoL up to six months, but there was greater improvement in global QoL scores at seven to 12 months in the groups receiving dietary advice plus ONS if required (low-certainty evidence; [Analysis 4.16](#)). One study with data at up to three months demonstrated cost savings associated with dietary advice and ONS if required compared with no advice and no ONS. Two studies with data up to six months showed no difference in cost-effectiveness between groups ([Endevelt 2011](#); [Schilp 2013](#)).

Dietary advice and ONS compared with no advice and no ONS

The review includes 13 studies comparing dietary advice plus ONS with no advice and no ONS, but not all studies contributed data on all outcomes and data were available to enter into the meta-analyses for only some outcomes.

There was no difference in mortality between groups at any time point ([Analysis 5.1](#)). There were no data on hospital readmissions and low-certainty evidence of no difference in length of hospital stay at up to three months or four to six months ([Analysis 5.2](#)). There were significantly fewer complications in the groups receiving dietary advice plus ONS at up to three months (one study), but data were not reported at other time points (low-certainty evidence; [Analysis 5.3](#)). There was no difference in weight change at up to three months (low-certainty evidence), however, there was an improvement in weight in the groups receiving dietary advice plus ONS at all other time points (eight studies; [Analysis 5.4](#)). There were no changes in measures of body composition (FFM, MAMC, TSF) (very low-certainty evidence, [Analysis 5.5](#)). There was evidence of an increase in energy intake (five studies) and protein intake (three studies) in groups receiving dietary advice plus ONS at up to three months and at seven to 12 months (one study each) ([Analysis 5.8](#); [Analysis 5.10](#)). Energy intake was also improved in the group receiving dietary advice plus ONS at four to six months (three studies; [Analysis 5.8](#)). There was no difference in handgrip strength at any time point ([Analysis 5.12](#)). There was very low-certainty evidence of no difference between the two groups in global QoL scores at any time point (four studies; [Analysis 5.13](#)). Intervention with dietary advice and ONS was probably cost-

effective for functional limitations after three months (Neelemaat 2011) and likely to be cost-effective for weight (Wyers 2013).

Overall completeness and applicability of evidence

There was statistical and clinical heterogeneity across all groups of studies in this review. The review authors addressed this statistically by using a random-effects model for all the analyses presented in the review. Where heterogeneity was moderate or high ($I^2 \geq 50\%$), they removed the studies one by one to allow examination of their effect on heterogeneity. When the authors derived a homogeneous effect, they attempted to identify the characteristics of studies that might have contributed to the heterogeneity. The authors made their decisions to remove studies on statistical grounds and these may not necessarily be clinically justified. The heterogeneity could be explained by a number of factors including clinical condition, stage and disease severity of the participants, healthcare setting, frequency and intensity of intervention and other yet to be identified factors. The identified studies represented a wide range of clinical conditions, but the numbers of participants with any one condition were small with the possible exception of studies conducted in those with cancer and in older people. Even amongst these groups of studies, there was wide variation in co-morbidities in older people and site, stage and treatment modality in people with cancer. In the majority of included studies the mean age of participants was over 65 years, but a wide age range was represented overall. The majority of studies were conducted in outpatients or community, a smaller number involved individuals who spent some time in hospital.

The review authors assume that the mode, duration and the intensity of the intervention may have influenced the effects, but due to lack of reporting of relevant data they were unable to undertake further analyses to explore their assumptions. Whilst all of these studies included some type of dietary advice, the investigators rarely fully described the nature, intensity and content of the intervention. Furthermore, health literacy of participants may have influenced their understanding of information or their experience of attempting to implement it. Interpretation of dietary advice differed hugely amongst studies. In some, investigators provided the participants with a written leaflet, while in others they used face-to-face or telephone contact, or a combination of both. In many cases the review authors were unable to identify how (written or verbal), how often and by whom the dietary advice was delivered. Studies also varied in amount and timing of contact (frequency and intensity) from one meeting at the start of the study through to bi-weekly meetings over a period of months. Sometimes a trained dietitian or nutritionist gave the dietary advice, but sometimes it was a nurse, a doctor, a research assistant, or a community worker. In addition, investigators rarely reported the details of the experience and training of the healthcare worker giving the advice.

In the majority of studies, the intervention lasted for three months. To date there is insufficient information to determine whether this is the optimal length of intervention of this kind and indeed whether it represents a realistic goal in clinical practice. These variations are reflected in clinical practice, where these interventions might consist of only one or two visits by a dietitian to an inpatient through to regular repeated dietetic outpatient visits in people with long-term disease, e.g. renal failure or COPD. A shorter and less intensive intervention is often seen as more feasible in clinical practice, but we do not know

about its effectiveness in comparison to a longer, more intensive intervention. Whilst it may seem that a longer, more intensive dietary intervention might be more effective, in the absence of formal cost-effectiveness analyses it is not possible to say whether these are more effective than shorter and less intensive interventions. However, in all studies there was a consistent aim of improving nutritional intake with the goal of minimising weight loss or promoting weight gain. Dietitians receive referrals to provide nutritional support to individuals from a variety of clinical backgrounds in different healthcare settings. It is not possible from the findings of this review to be specific about the effect size that can be achieved in any one patient group and indeed it is likely that the effect size will vary according to all the above variables. This review suggests that it is possible to achieve an increase in energy intake and weight gain with dietary advice with or without ONS and in some cases the increase in weight gain may be accompanied by beneficial changes in body composition. However, it remains to be determined whether these improvements in weight and body composition translate consistently into clinical benefits and patient-related outcomes.

Quality of the evidence

The certainty of evidence in this review is low for the majority of analyses (Summary of findings 1; Summary of findings 2; Summary of findings 3; Summary of findings 4; Summary of findings 5), with only studies of dietary advice plus supplements if required compared with no advice having some moderate-certainty evidence (Summary of findings 4). The main issues were the high risk of bias due to a lack of blinding of outcome assessors, selection bias resulting from failures in the randomisation process and some studies were downgraded because of differences in baseline characteristics between groups. Furthermore, only two of the 94 included studies were able to adequately blind participants and personnel to the intervention (Alo 2014; Holyday 2012). Whilst this is a considerable source of potential bias, it is important to bear in mind that it is difficult to conceive of an adequate placebo for dietary advice. It is impossible to prevent some participants in the control arm from seeking other sources of dietary advice which act as confounders. Whilst dietary advice can be compared with usual care, this has varied enormously in terms of quality and duration between studies; and in fact was rarely defined or fully described. Furthermore, only one study reported the behaviour change model underpinning their intervention (Locher 2013). Whilst in theory it might be possible to design a study where outcome assessment may be blinded, this was not the case in many of the included studies and a possible reason for this is inadequate funding for this type of research.

Potential biases in the review process

The protocol for this review specified three comparison groups. An additional group was added after the first searches conducted in 1999 when review authors identified a comparison that they had not anticipated and most closely represented actual dietetic practice. Since they included this comparison in the first version of the review the potential for bias at this stage is minimal. The authors included a fifth comparison in the 2021 update of this review, as they identified many studies in which investigators provided dietary advice with ONS to all participants, rather than 'if judged to be appropriate'. The addition of the two extra groups are logical and consistent with changes in routine clinical practice. The addition of the fifth group at a later stage in the review process

means that the review authors cannot rule out the possibility that they have missed studies that might have been identified from earlier searches. After the inclusion of this comparison, they scrutinised the list of studies excluded from earlier searches again and they might also have identified additional studies through the Snowball searching process.

The original search strategy for this review and the current update was comprehensive in that eight databases were searched including databases other than the most commonly used (Avenell 2001); there was no language restriction on papers retrieved and two review authors have selected studies independently. From the 2021 update, the authors have also included searches of the online database Clinicaltrials.gov and WHO ICTRP to identify ongoing studies and recently finished studies that may not yet have been published (Appendix 5). The review authors did not undertake any formal handsearching and searching of the grey literature was not possible because of time constraints.

Using the asymmetry of the funnel plot, the Egger's test and the Begg's test suggested no evidence of small study bias for four out of five comparisons. There was evidence of significant small study bias in the comparison of dietary advice with ONS; however, it is worth noting that since there were only eight studies in the analysis the test may be invalid. Interestingly, 22 of the 80 studies that are listed as 'Awaiting classification' would be eligible for inclusion in this group; these are currently listed as such because they are reported in abstract form only and the review authors have not been able to obtain data and full details of interventions to enter into the analysis. An additional 23 full-text publications have been identified as eligible for inclusion in final searches, but it has not been possible to include these in the 2021 update because of time constraints.

Agreements and disagreements with other studies or reviews

The review authors are unaware of any other systematic reviews that have addressed the potential benefits of dietary advice given with or without ONS as comprehensively as this one. Two recent syntheses have addressed ONS interventions in different healthcare settings (Feinberg 2017; Reinders 2019) and one large RCT has evaluated the impact of individualised dietary advice with ONS, enteral or parenteral nutrition if required in hospitalised patients (Schuetz 2019).

Reinders presented a pooled analysis of individual patient data in older adults across a range of healthcare settings and suggested that dietary counselling with ONS results in a significant increase in energy intake and that dietary counselling with or without ONS results in significant benefits to weight gain; with dietary counselling combined with ONS seeming to be more effective (Reinders 2019). Drawbacks to this review are that individual patient data from only nine out of 38 eligible studies provided data for analysis; therefore it remains unknown whether the results are representative. Nonetheless, Reinders' results are in agreement with this Cochrane Review in so far as the review authors found beneficial effects on weight from dietary advice given with or without ONS over usual diet. They also found improvements in energy and protein intake in groups receiving dietary advice with or without ONS; however, the timing of the improvements varied. In both the review by Reinders and in this Cochrane Review there are a number of limitations to the

evidence. In both reviews, the data for each of these outcomes are drawn from a limited number of studies and may not be representative of the real effect had data been available from all studies.

In a systematic review of nutritional support in hospitalised patients there was no effect of a general nutrition intervention (defined as aiming to increase normal food consumption and including, but not limited to, dietary counselling) on weight or BMI (Feinberg 2017). These findings are in contrast to those in this Cochrane Review, but this review includes studies across care settings and the studies have not been analysed according to care setting.

Since the completion of this updated Cochrane Review, a large RCT in hospitalised patients has been published (Schuetz 2019). In this study, 2088 participants were randomised to receive protocol-guided individualised nutritional support provided by a dietitian or standard hospital food for the duration of hospital stay. By 30 days those in the intervention group reported significant improvements to energy and protein intake compared to those in the control group and experienced significantly fewer adverse outcomes (infections, major complications, major cardiovascular disease event, respiratory failure, acute kidney failure), lower mortality, a significant improvement in QoL and a significantly reduced decline in functional status. These findings are in partial agreement with this Cochrane Review. The improvements in energy and protein intake concur with the review's findings and the review authors found improvement to clinical and functional outcomes for some comparisons; however, they found no effect on mortality. This is an important RCT because it is adequately-powered, outcomes were assessed blinded to group allocation and it reflects current clinical practice. It is difficult to fully assess whether the RCT's findings are in agreement with those of this Cochrane Review as the RCT was limited to one healthcare setting and this review spans all care settings.

AUTHORS' CONCLUSIONS

Implications for practice

This Cochrane Review has summarised the findings of 94 separate studies and found largely low-certainty evidence (but individual gradings ranged from moderate to very low) to suggest that dietary advice given with or without oral nutritional supplements (ONS) may improve nutritional intake, weight, and quality of life in some adults with disease-related malnutrition or at nutritional risk. The results were inconsistent and there were no clear trends related to which intervention might be the most beneficial or the length time needed for the intervention to be effective.

This review found no evidence for a beneficial effect of dietary advice on mortality and little evidence of benefit to clinical and functional outcomes. Furthermore, there was very little evidence regarding cost benefits. For many outcomes there were too few data to draw firm conclusions. There is no reason for these interventions not to be made available to adults who have experienced weight loss that is secondary to disease. However, in the context of shared decision-making discussions, it is currently not possible to specify any benefits that individuals or their families might reasonably expect.

Implications for research

In this review there was moderate to very low-certainty evidence that dietary advice given with or without nutritional ONS may improve nutritional intake, weight, and quality of life in some people with disease-related malnutrition or at nutritional risk. The results were inconsistent and there were no clear trends related to which intervention might be the most beneficial or the length time needed for the intervention to be effective. The review authors found no evidence for a beneficial effect of dietary advice on mortality and limited evidence of benefit to clinical and functional outcomes. There were almost no data on cost-effectiveness. The heterogeneity of findings may result from variation in the interventions themselves, the healthcare settings, patient populations and the underlying mechanisms by which the intervention might operate. Any future randomised controlled trials (RCTs) and well-designed non-RCTs should consider the following points.

Population

Research is needed in populations:

- homogeneous for severity of malnutrition at study inclusion, defined using standard assessment tools;
- with a shared aetiology of the underlying malnutrition and which groups similar participants, where possible;
- with a range of clinical conditions where the stage and treatment intent of the condition are as homogeneous as possible and clearly described; and
- in a range of community, health and social care settings.

Intervention

Interventions in this review were extremely varied in terms of nature, intensity, length of intervention, healthcare professional involved and their level of expertise whilst all being considered as dietary advice with or without ONS. A more consistent approach is required to define and describe different dietary interventions for nutritionally vulnerable individuals. The healthcare background of people delivering interventions should be fully described as well as their relevant expertise in nutrition. Interventions should be underpinned by a behaviour change model and this should be valid and appropriate to the aims of the intervention and fully described.

Comparison

It is widely accepted that participants in the control groups should be offered an intervention. However, both active and other interventions should be standardised across studies and fully specified as for the interventions.

Outcomes

There are three key points in relation to assessment of outcomes:

- outcomes should be measured using tools that have been validated in the relevant population;
- outcomes should be measured at consistent time points that reflect the realities of clinical practice eg. 30-day mortality or hospital readmissions; and
- outcomes should be assessed by assessors blinded to group allocation.

We suggest the following relevant outcomes.

- Clinical
 - Mortality
 - Measures of morbidity, e.g. length of hospital stay, complications
- Nutritional
 - Weight and change in body composition
 - Dietary intake
- Functional
 - Functional changes which are relevant to the population under consideration, e.g. Barthel Index, activities of daily living (ADL) scores, handgrip strength
- Patient-centred outcomes
 - Quality of life
 - Patient satisfaction
 - Patient experience
- Cost effectiveness
- Adherence to both food-based and ONS interventions
- Adverse events

The most pressing research priority is to strengthen the evidence base for clinical practice. If further syntheses are undertaken in this area, it might be more meaningful to follow the principles of realist reviews which might inform which interventions are more likely to be beneficial in which patient groups and under which conditions (Pawson 2005).

ACKNOWLEDGEMENTS

We acknowledge the valuable input from Professor Stuart Logan and Dr Tessa Parsons in the development of the protocol and the full review and also with updating the review until January 2007, when they stepped down from the review team.

We are grateful to the following authors who have provided additional data and information for the included studies:

Dr Chihurumanya Alo, Ebonyi State University, Nigeria
 Dr Joanna Andersson, Klinikk Bærum Sykehus, Gjøttum, Norway
 Dr. Abou Badiane, Laboratoire de Nutrition, Université Cheikh Anta Kiop Dakar, Senegal
 Dr. Christine Baldwin, King's College, London, UK
 Professor Peter Ballmer, Kantonsspital, Winterthur, Switzerland
 Dr Merrilyn Banks, Royal Brisbane & Woman's Hospital, Herston, Australia
 Dr Alison Beattie, Ninewells Hospital, Dundee, UK
 Dr Anne Marie Beck, Herlev hospital, Herlev, Denmark
 Dr Isabelle Bourdel-Marchasson, Hospital Xavier Arnoz, Bordeaux, France
 Dr Brandli, Surcher Hohenklinik Wald, Lausanne, Switzerland
 Dr Sorrel Burden, University of Manchester, Manchester, UK
 Dr Sharon Carey, Royal Prince Alfred Hospital, Sydney, Australia
 Dr Katrina Campbell, King's College, London, UK
 Professor T Cederholm, Uppsala University Hospital, Uppsala, Sweden
 Dr Silvia Fernandez-Barres, Universitat Rovira I Virgili (URV), Tarragona, Spain
 Dr R Fonseca, Dean of School of Dental Medicine, Michigan, USA
 Dr Liv Forli, Rikshospitalet, Oslo, Norway
 Dr Liliana Gonzalez-Espinoza, Hospital de Especialidades, Tamaulipas, Mexico
 Dr Margaret Holyday, Prince of Wales Hospital, Sydney, Australia

Dr Catherine Huggins, Monash University, Clayton, Victoria, Australia
Dr D.T.T Huynh, Abbott Nutrition, Singapore, Singapore
Sharleen Imes, University of Alberta, Alberta, Canada
Dr Elizabeth Isenring, Flinders University, Adelaide, Australia
Dr Per Ole Iversen, University of Oslo, Denmark
Dr Martin Jensen, Denmark
Daina Kalnins, The Hospital for Sick Children, Toronto, Canada
Dr. Neha Kapoor, The All India Institute of Medical Sciences, New Delhi, India
Professor Ulrich Keller, University Hospital, Basel, Switzerland
Dr Nicole Kiss, Deakin University, Victoria, Australia
Dr Hinke Kruizenga, Amsterdam UMC, location VUmc, Amsterdam, the Netherlands
Dr Susanna Kunvik, The Social Services & Healthcare Centre of Pori, Finland
Dr Julie L Locher, University of Alabama, Birmingham, USA
Astrid Lovik, Oslo University Hospital, Oslo, Norway
Dr Daniel de Luis, Hospital Universitario Rio Hortega, Valladolid, Spain
Dr Francesco Manguso, Federico II University of Naples, Naples, Italy
Kathleen Mayer, Ross Laboratories, Columbus, USA
Professor Donna McCarthy, University of Wisconsin Hospitals, Madison, USA
Joseph Murphy, Ottawa Hospital, Ottawa, Canada
Professor Kristina Norman, Charité, , UK Berlin, Germany
Dr Guenter Ollenschlager, Cologne, Germany
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Dr Thomas Petty, Presbyterian St. Luke's Hospitals, Chicago, USA
Dr Paula Ravasco, Santa Maria University Hospital, Lisbon, Portugal
Dr Robert Rogers, University of Pittsburgh, Pittsburgh, USA

Dr Elizabeth Rydwik, Karolinska Institutet, Solna, Sweden
Dr Achim Schwenk, St Georges Hospital, London, UK
Dr Luis E. Simental-Mendia, Mexican Social Security Institute, Durango, Mexico
Dr Pierre Singer, Rabin Medical Center, Israel
Dr Siddharth Singh, All India Institute of Medical Sciences, New Delhi, India
Dr Ruth Stow, Birmingham City University, Birmingham, UK
Dr Merja Suominen, University of Helsinki, Helsinki, Finland
Dr Marian van Bokhorst de van der Schuren on behalf of Dr Floor Neelemaat VU Medical Center, The Netherlands
Dr Angela Vivanti, University of Queensland, Brisbane, Australia
Dr Lena Vogt, Kantonsspital, Winterthur, Switzerland
Dr Liz Williams, University of Sheffield, Sheffield, UK
Dr Samuel Y Wong, Prince of Wales Hospital, Hong Kong, Hong Kong
Dr Caroline Wyers, VieCuri Medical Center, The Netherlands
Judith van Zwiene - Pot Msc, Amsterdam UMC, location VUmc, Amsterdam, the Netherlands
Additionally we are grateful to Professor Marinos Elia, Institute of Human Nutrition, Southampton General Hospital, UK for his expert advice and guidance on clinical nutrition for this review. Also to Reinhard Wentz, Dipl. Bibl., Campus Library Manager, Imperial College London, UK and Nick Woolley, Information Specialist King's College, University of London, UK for their help with developing the search strategy and Mr Alex Cheok, King's College London, UK for translation of a paper included in the review.

Many thanks to The Systematic Review Training Unit who provided support, funded by the London Regional Health Authority.

This project was supported by the National Institute for Health Research, via Cochrane Infrastructure funding to the Cochrane Cystic Fibrosis and Genetic Disorders Group. The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the Systematic Reviews Programme, NIHR, NHS or the Department of Health.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES
Characteristics of included studies [ordered by study ID]

Akpele 2004
Study characteristics

Methods	Pilot RCT. Duration: mean 7.5 months (longest follow-up 14 months). Location: USA.
Participants	Inclusion criteria: adults (> 18 years), receiving haemodialysis three times weekly for a minimum of 6 months, serum albumin < 3.5g/dL, MNA score < 23.5. Exclusion criteria: co-morbidities or medical illness that reduced life expectancy to less than 6 months. Number randomised: 40; attrition: none described. Diagnosis: CKD receiving haemodialysis. Age (mean): dietary advice group 61.5 years; supplement group 66.6 years. Gender split: not reported. Nutritional status: serum albumin <3.5g/dL, MNA score <23.5.
Interventions	Intervention (intervention group 1): participants received <i>dietary advice</i> in the form of intensive dietary counselling. Intervention (intervention group 2): participants received <i>ONS</i> in the form of 1 - 2 cans of Nepro daily in addition to usual diet.
Outcomes	Rate of change of serum albumin.
Publication details	Language: English. Funding: not declared. Publication status: peer-reviewed journal.
Notes	No outcomes usable for this review reported.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Insufficient information/detail. Quote: "subjects were randomised".
Allocation concealment (selection bias)	Unclear risk	Insufficient information/detail. Quote: "subjects were randomised".
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	Not described but unlikely that assessment of clinical outcomes would be influenced by lack of blinding.
Blinding (performance bias and detection bias) Functional outcomes	Unclear risk	No functional outcomes assessed.
Blinding (performance bias and detection bias)	High risk	Not reported but likely that assessment of nutritional outcomes would be influenced by lack of blinding.

Akpele 2004 (Continued)

Nutritional outcomes

Blinding of participants and personnel (performance bias) All outcomes	High risk	Not described and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes were influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not described and likely that assessment of some outcomes would be influenced by lack of blinding.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No attrition reported.
Selective reporting (reporting bias)	High risk	No protocol identified. Some outcomes described in the methods not reported (nutritional intake, hospital admissions, missed treatments and weight).
Other bias	Low risk	Baseline characteristics compared and Chi ² tests used for difference. No statistically significant differences between groups.

Alo 2014
Study characteristics

Methods	<p>RCT ("quasi randomised" - no further details).</p> <p>Parallel design with 2 arms.</p> <p>Duration: intervention and follow-up: 6 months.</p> <p>Location: Nigeria.</p>
Participants	<p>Inclusion criteria: diagnosed with HIV and receiving HAART, providing consent, resident with Abakaliki town (Nigeria), without opportunistic infection.</p> <p>Exclusion criteria: pregnancy.</p> <p>Number randomised: 84 (intervention group 42, control group 42); attrition: not described.</p> <p>Gender split: 26 (31%) males, 58 (69%) females.</p> <p>Age: mean (SD) years: intervention group 33.8 (7.7) years; control group 35.3 (10.2) years.</p> <p>Nutritional status: BMI (kg/m²) at baseline: intervention group 23.1 in males and 21.9 in females; control group 23.3 in males and 20.3 females.</p>
Interventions	<p>Intervention: participants received <i>dietary advice</i> in the form of dietary counselling and individualised food prescriptions based on locally available food and counselling on food hygiene. Prescription based on easily available and affordable foods, to contain all food groups and assessment of requirements.</p> <p>Control: participants received <i>no dietary advice</i> but the details were not described.</p>
Outcomes	BMI, haemoglobin.
Publication details	<p>Language: English.</p> <p>Funding: none declared.</p>

A10 2014 (Continued)

Publication status: peer reviewed journal.

Notes	Emailed authors for details of how randomisation carried out, any attrition, mean change in BMI and weight data.	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	<p>Study described as quasi-experimental. No information on random sequence generation in the paper.</p> <p>Quote: "Participants were selected using a simple random sampling technique and were then randomized"</p> <p>Additional information from authors Quote: "Two nurses representing the intervention group and the control group respectively picked patients enrolment numbers from the ballot bag. All the patients enrolment numbers picked by the nurse representing intervention group automatically became the intervention group and the same with the control group." Therefore judged as low risk.</p>
Allocation concealment (selection bias)	Low risk	No information on allocation concealment in the paper. Information provided by authors indicated that 'drawing lots' was used, therefore judged as high risk.
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	Not described but assessment of clinical outcomes unlikely to be influenced by lack of blinding.
Blinding (performance bias and detection bias) Functional outcomes	Unclear risk	No functional outcomes assessed.
Blinding (performance bias and detection bias) Nutritional outcomes	Low risk	Not described but only BMI assessed which is unlikely to be influenced by lack of blinding.
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Not described and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is unlikely that assessment of outcomes was influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Not described but unlikely that assessment of the 2 outcomes reported would be influenced by lack of blinding.
Incomplete outcome data (attrition bias) All outcomes	Low risk	<p>No attrition, (information provided by authors).</p> <p>Quote: "We did not record any attrition by death or withdrawal from study or lost to follow up. Patients were ambulatory patients and so not chronically ill. There was available grant to trace lost to follow up patients to their homes by treatment supporters, so it was easy to follow up patients even when they did not come to clinic on their monthly appointments".</p>
Selective reporting (reporting bias)	Unclear risk	No protocol identified. All outcomes described in the methods reported in the results.

Alo 2014 (Continued)

Other bias	Unclear risk	Baseline characteristics compared (gender, age and BMI). No differences noted between groups. No comparison of stage of disease and treatment characteristics which might have had an impact on the outcomes of interest.
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Anbar 2014
Study characteristics

Methods	<p>Prospective RCT (unblinded).</p> <p>Parallel design.</p> <p>Duration: data collected up to 14 days or discharge (including pre-op period).</p> <p>Location: single centre (Petah Tikva, Israel).</p>
Participants	<p>Inclusion criteria: aged > 65 years and admitted within 48 hours of injury to an orthogeriatric unit following hip fracture; orthopedic surgery considered the treatment of choice.</p> <p>Exclusion criteria: presented to hospital > 48 hours after injury, receiving steroids and/or immunosuppression therapy; presence of active oncologic disease, multiple fractures, diagnosed dementia or in the event that participants required supplemental nasal oxygen which precludes the measurement of REE.</p> <p>Number randomised: 50 participants: intervention group n = 22; control group n = 28.</p> <p>Gender split: intervention group 6 (27%) male and 16 (73%) female; control group 11 (39%) male and 17 (61%) female.</p> <p>Age: mean (SD) intervention group 82.3 (6.1) years; control group 83.7 (6.4) years.</p> <p>Nutritional status: BMI, mean (SD): intervention group 25.2 (3.2) kg/m²; control group 24.7 (4.4) kg/m².</p>
Interventions	<p>Intervention: participants received <i>dietary advice plus ONS</i> in the form of a hospital-prepared diet plus ONS (355 kcal/237 mL and 13.5 g protein or 237 kcal/237 mL and 9.9 g protein/237 mL), adjusted to meet energy goals which were determined by repeated resting energy expenditure measurements using indirect calorimetry; participants, family and caregivers educated regarding the importance of nutritional support and more attention was given to personal food preferences.</p> <p>Control: participants received <i>no dietary advice and no ONS</i> in the form of usual hospital food (standard or texture adapted) and a fixed dose of oral nutritional supplement if already prescribed prior to hospitalisation.</p>
Outcomes	<p>Primary outcomes</p> <p>Postoperative complications (i.e. surgical, infectious, cardio-vascular, gastro-intestinal, deep vein thrombosis and new pressure sores).</p> <p>Length of hospital stay.</p> <p>Secondary outcomes</p> <p>Energy intake.</p> <p>Calculated energy balance.</p>
Publication details	<p>Language: English.</p> <p>Funding: not stated.</p>

Anbar 2014 (Continued)

Publication status: peer-reviewed journal.

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: Randomisation was performed using a concealed, computer-generated program.
Allocation concealment (selection bias)	Low risk	Quote: use of a consecutively numbered opaque envelope.
Blinding (performance bias and detection bias) Clinical outcomes	High risk	Quote: Patients were examined daily by the research nurse and attending physician for the presence of postoperative complications.
Blinding (performance bias and detection bias) Functional outcomes	High risk	Not blinded and lack of blinding might have affected assessment of outcomes.
Blinding (performance bias and detection bias) Nutritional outcomes	High risk	Quote: The nutrient intake of each patient was monitored by the research team on a daily basis.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not blinded and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Some outcome assessors were aware of group allocation and this might have affected assessment of some outcomes.
Incomplete outcome data (attrition bias) All outcomes	Low risk	All participants completed the study with no drop-outs.
Selective reporting (reporting bias)	Unclear risk	No study protocol identified, thus unable to judge whether all planned outcomes were reported.
Other bias	Low risk	Baseline characteristics were similar in both groups.

Andersson 2017
Study characteristics

Methods	Open-label RCT. Parallel design with 2 arms. Duration: 3 months. Location: Oslo, Norway.
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Andersson 2017 (Continued)

Participants	<p>Inclusion criteria: resident in the capital Oslo or the nearby municipalities of Asker or Bærum, able to communicate in Norwegian and to provide written informed consent.</p> <p>Exclusion criteria: lack of rehabilitation potential (decided by the treating physician), duration of stay < 10 days or > 30 days at Godthaab Health and Rehabilitation Institution, not planned to return home after their stay, expected survival < 1 year, and refusal to participate.</p> <p>Number randomised: 100 adults (with musculoskeletal disorders, cancer, lymphedema, cardiovascular disease, chronic pulmonary disease, stroke or neurodegenerative diseases) admitted to Godthaab Health and Rehabilitation Institution.</p> <p>Gender split: 28 men and 72 women.</p> <p>Age: mean (SD) intervention group 75.2 (7.8) years, control group 75.5 (9.4) years.</p> <p>Nutritional status: undernourished or at risk of disease-related malnutrition (scored > 3 on NRS-2002).</p>
Interventions	<p>Intervention: participants received <i>dietary advice plus ONS if required</i> in the form of an individual nutritional plan (developed by a clinical nutritionist in collaboration with the participant) with documentation of nutritional status, nutrient requirements, and nutrient intake. Nutritional plan: information on swallowing function, bowel function, appetite, food preferences, and personal habits such as eating patterns, dietary intake, and estimated energy and protein requirements according to national guidelines*. The swallowing function, bowel function, appetite, food preferences, and personal habits were self-reported by the participants. Participants received repetition (and individual adjustments if needed) of this counselling during 3 telephone calls of 0.5 h duration at 1, 7 and 10 weeks after discharge and at 1 home visit (1 h duration) 4 weeks after discharge.</p> <p>Control: participants received <i>no dietary advice and no ONS</i> in the form of no specific nutritional advice at the time of discharge.</p> <p>Both groups received the same standard care including general advice on nutrition during their stay at the rehabilitation centre.</p> <p><u>* Guidelines</u></p> <p>Energy:</p> <ul style="list-style-type: none"> - bedridden participants: 29 kcal/kg per day; - ambulatory participants: 33 kcal/kg per day; - participants in recovery phase: 40 kcal/kg per day; - age > 70 years: reduce by 10%; - overweight (BMI > 25 kg/m²): reduce by 10%. <p>Protein:</p> <ul style="list-style-type: none"> - healthy participants: 0.8-1.5 g/kg per day; - with disease: 1.5 - 2.0 g/kg per day.
Outcomes	<p>Body weight*, QoL EQ-5D (only sub-scores), appetite (DRAQ), self-perceived state of health (VAS; scores 0 - 100).</p>
Publication details	<p>Language: English.</p> <p>Funding: Throne Holst Foundation and The Directorate of Health, Norway.</p> <p>Publication status: peer-reviewed journal.</p>

Andersson 2017 (Continued)

Notes Few of the participants were undernourished (NRS 2002 score > 4); whereas most of them had a NRS 2002 score of 3 or 4, thus being at risk of disease-related malnutrition. The data for weight change and change in EQ 5D were obtained from the author.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "The randomization was performed by a person not involved in the study with the software program www.randomization.com."
Allocation concealment (selection bias)	Low risk	Numbered sealed opaque envelopes were used.
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	Quote: the assessors of the study outcomes were blinded to the allocation.
Blinding (performance bias and detection bias) Functional outcomes	Low risk	Quote: the assessors of the study outcomes were blinded to the allocation.
Blinding (performance bias and detection bias) Nutritional outcomes	Low risk	Quote: the assessors of the study outcomes were blinded to the allocation.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not blinded and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: the assessors of the study outcomes were blinded to the allocation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	15/100 (15%) (intervention group: 6; control group: 9) were lost to follow-up at 3 months due to death (n = 1), too tired (n = 3) and no reason was given (n = 11).
Selective reporting (reporting bias)	Unclear risk	No study protocol identified, thus unable to judge whether all planned outcomes were reported.
Other bias	Low risk	Baseline variables stated, groups similar at baseline.

Arnold 1989
Study characteristics

Methods	RCT. Parallel design with 2 arms. Duration: 6 months, intervention to 10 weeks and follow-up to 6 months for some outcomes. Location: single centre in the USA.
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Arnold 1989 (Continued)

Participants	<p>Inclusion: living at home, planned to receive potentially curative radiotherapy for cancers of head and neck</p> <p>Exclusion: both chemotherapy and radiotherapy planned for treatment</p> <p>Number randomised: 50 adults.</p> <p>Gender split: 29 males and 21 females.</p> <p>Age: 34 - 88 years.</p> <p>Nutritional status: mean weight in treatment and comparison groups was 1 - 2 kg below usual weight at study entry.</p>
Interventions	<p>Intervention: participants (n = 23) received <i>dietary advice and ONS</i> in the form of intensive dietary counselling and the prescription of nutritional supplements to provide an additional 960 - 1080 kcal/day.</p> <p>Control: participants (n = 27) received <i>dietary advice alone</i> in the form of intensive dietary counselling.</p>
Outcomes	Survival*, number having a complete response to therapy, radiation side-effects, tumour status, body weight*, serum albumin, transferrin, change in dietary energy*, protein intake.
Publication details	<p>Language: English.</p> <p>Funding: not mentioned.</p> <p>Publication status: peer-reviewed journal.</p>

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Described as randomised, but no details of method.
Allocation concealment (selection bias)	Unclear risk	No details of method of allocation concealment.
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	The trial was unblinded. However, this is unlikely to influence clinical outcomes.
Blinding (performance bias and detection bias) Functional outcomes	Unclear risk	No functional outcomes reported.
Blinding (performance bias and detection bias) Nutritional outcomes	High risk	The trial was unblinded. Nutritional outcomes could have been influenced by lack of blinding.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not blinded and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding
Blinding of outcome assessment (detection bias)	Unclear risk	Judged to be unclear, as low risk for clinical outcomes and high risk for nutritional outcomes.

Arnold 1989 (Continued)

All outcomes

Incomplete outcome data (attrition bias) All outcomes	Low risk	No withdrawals. 3 (6%) deaths in the dietary counselling and supplement group, no deaths in the control group.
Selective reporting (reporting bias)	High risk	No study protocol identified, thus unable to judge whether all planned outcomes were reported. Data on mortality obtained from the paper. Data on weight change obtained by extrapolation from Figure 3. Energy intake data presented in a figure with no SDs or SEs, therefore risk of bias. No response received from author to request for data.
Other bias	Low risk	Baseline variables stated, groups similar at baseline.

Baldwin 2011
Study characteristics

Methods	<p>RCT.</p> <p>Design: 2 x 2 factorial trial.</p> <p>Duration: 12 months; intervention 6 weeks and follow-up to 12 months.</p> <p>Location: started with a single centre in the UK; ended with 6 centres (5 UK and 1 Australia).</p>
Participants	<p>Inclusion: adults with histologically proven, metastatic or locally advanced tumours of the GI tract, non-small lung cancer or mesothelioma with weight loss in the previous 3 months and planned to undergo palliative chemotherapy.</p> <p>Exclusion: unable or unwilling to provide consent, had a clinical condition precluding oral nutrition, were unable to tolerate milk or it was considered that they should receive immediate enteral or parenteral nutrition.</p> <p>Number randomised: 358 adults (group 1, n = 96; group 2, n = 90; group 3, n = 86; group 4, n = 86).</p> <p>Gender split: 256 males and 102 women.</p> <p>Age: median (range) 66 (24 - 88 years).</p> <p>Disease status: locally advanced or metastatic cancers of the gastrointestinal tract (n = 277) or non-small-cell lung cancer or mesothelioma. All participants had lost weight at the start of the trial (mean (SD) 9.8% (6%) in lung participants and 11.2% (6.4%) GI participants).</p> <p>Nutritional status: any amount of weight loss in the previous 3 months.</p> <p>153 participants were alive at 12 months:</p> <p>No intervention group: 47 deaths and 2 withdrawals. Dietary advice group: 52 deaths and 2 withdrawals. Nutritional supplements group: 55 deaths and 2 withdrawals. Dietary advice and supplements group: 44 deaths and 1 withdrawal.</p>
Interventions	<p>Control: (trial group 1) participants received <i>no dietary advice and no ONS</i> in the form of no additional intervention.</p> <p>Intervention: (trial group 2) participants received <i>dietary advice</i> in the form of standardised dietary counselling and an information booklet to increase intake by 600 kcal/day</p> <p>Intervention: (trial group 3) participants received <i>ONS</i> in the form of an oral nutritional supplement providing 588 kcal/day.</p>

Baldwin 2011 (Continued)

Intervention: (Trial group 4) participants received *dietary advice and ONS* in the form of standardised dietary counselling and an information booklet to increase intake by 600 kcal/day and an oral nutritional supplement providing 588 kcal/d.

Outcomes	Survival*, QoL*, weight*, handgrip strength*, energy intake*.
Publication details	<p>Language: English.</p> <p>Funding: Henry Smith Charity and The Special Trustees Chelsea and Westminster Hospital, London.</p> <p>Publication status: peer-reviewed journal.</p>
Notes	<p>Trial was stopped prematurely on advice of the independent data monitoring committee.</p> <p>Data, specified per group, were received from the authors. Data on handgrip strength were not normally distributed and so have not been included in the meta-analyses. Both FFACT and EORTC QoL data were provided. For meta-analyses we only used the EORTC QoL data.</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation was performed by an independent trials centre using a computer-generated list. Participants were stratified for performance status and site of disease.
Allocation concealment (selection bias)	Low risk	Group allocation was concealed until participants had signed consent to participate.
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	The outcome assessors were not blinded but unlikely that these outcomes would be influenced by lack of blinding.
Blinding (performance bias and detection bias) Functional outcomes	High risk	The outcome assessors were not blinded.
Blinding (performance bias and detection bias) Nutritional outcomes	High risk	The outcome assessors were not blinded and assessment of some nutritional outcomes might be influenced by lack of blinding.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not blinded and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Judged to be unclear because low risk for clinical outcomes and high risk for functional and nutritional outcomes.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	<p>153/358 (43%) participants were alive at 12 months:</p> <p>No intervention group: 49 (51 %) including 47 deaths.</p> <p>Dietary advice group: 54 (60 %) including 52 deaths.</p> <p>Nutritional supplements group: 57 (66 %) including 55 deaths.</p> <p>Dietary advice and supplements group: 45 (52 %) including 44 deaths.</p>

Baldwin 2011 (Continued)

7 (2 %) participants withdrew but reasons for withdrawal were not reported.

Selective reporting (reporting bias)	Low risk	No published protocol but the trial principal investigator is one of the review authors. The data on survival, weight, QoL and grip strength were not presented by group and not fully reported in the paper, therefore original data have been provided by the authors for this review. The numbers of participants completing assessment of energy intake was only 31 of 358 and so these data should be interpreted with caution. Data on grip strength were judged to be unsafe because of difficulties carrying out this assessment according to standard protocols and so are not included.
Other bias	Unclear risk	Baseline characteristics for the 4 groups were similar. Trial was stopped prematurely on advice of the independent data monitoring committee. Unclear how this may have influenced results.

Banks 2016
Study characteristics

Methods	<p>Pilot RCT.</p> <p>Parallel design with 2 arms.</p> <p>Duration: during hospital admission, follow up on day 5, 10, 15, 22 and then weekly or until discharge.</p> <p>Location: a tertiary referral hospital in Brisbane, Australia.</p>
Participants	<p>Inclusion criteria: participants with a stage II–IV pressure ulcers (PU), either existing on admission or acquired during admission.</p> <p>Exclusion criteria: unable to receive nutrition support via the enteral route (on parenteral nutrition); inappropriate for intensive nutrition support (receiving palliative care or medically deteriorating); unable to follow nutrition support advice (cognitively impaired, language barriers); previously enrolled in the study.</p> <p>Number randomised: 50 adults.</p> <p>Gender split: intervention group 14 males, 11 females; control group 19 males; 6 females.</p> <p>Age: mean (SD): intervention group 62.3 (20.7) years; control group 65.8 (15.8) years.</p> <p>Nutritional status: assessed by SGA; intervention group - well nourished n = 5, mild to moderate malnutrition n = 13, severe malnutrition n = 7; control group - well nourished n = 4, mild to moderate malnutrition n = 15, severe malnutrition n = 6.</p>
Interventions	<p>All participants received evidence-based PU care according to local hospital practices.</p> <p>Intervention: participants received <i>dietary advice plus ONS if required</i> in the form of intensive individualised nutritional care provided by a research dietitian including a high protein/energy diet and/or supplements aimed at meeting estimated nutritional requirements of 1.2g protein/kg body weight/day and 30 kcal/kg per day and the prescription of a 'wound healing' nutritional formula, enriched with arginine, vitamin C and zinc; participants offered the choice of 2 different brands of the supplement based on their preference and prescription based on recommended daily dosage by manufacturer. It was expected that participants would be reviewed by the research dietitian at least 3 times/week.</p> <p>Control: participants received <i>no dietary advice and no ONS</i> in the form of standard nutritional care provided by the clinical team which usually included a dietitian and may have included a standard hospital diet or high protein/energy diet and/or nutritional supplements and/or enteral tube feeding.</p>

Banks 2016 (Continued)

Outcomes PU change, from baseline, in score (PUSH) and area (measured using Visitrak system), adequacy of intake of protein and calories, length of stay to heal or discharge, participant outcome (early discharge, PU healed, PU worsened, discharged not healed).

Publication details **Language:** English.
Funding: by a grant from the Queensland Health, Health Practitioner Research Scheme.
Publication status: peer reviewed journal.

Notes The data for weight change data were obtained from the author. Weight change was over any time within the study period, not just the end of the study, but was at least 1 week.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: After recruitment, a computer-generated randomised list was used to determine the group allocation sequence. Randomisation was stratified by PU stage (stage II or stage III and IV) to ensure equal representation of PU severity across groups. Where more than one PU existed, the highest stage PU was chosen as the primary PU for data collection purposes.
Allocation concealment (selection bias)	Low risk	Allocation was performed by telephoning an independent researcher.
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	The trial was unblinded. However, this is unlikely to influence clinical outcomes.
Blinding (performance bias and detection bias) Functional outcomes	High risk	The trial was unblinded. Functional outcomes could have been influenced by lack of blinding.
Blinding (performance bias and detection bias) Nutritional outcomes	High risk	The trial was unblinded. Nutritional outcomes could have been influenced by lack of blinding.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not blinded and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Judged to be unclear because low risk for clinical outcomes and high risk for functional and nutritional outcomes.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Attrition: (36% overall) intervention group 10/25 (40%); control group 8/25 (32%) due to early discharge. No differences in the baseline characteristics between the measured and lost to follow-up groups.
Selective reporting (reporting bias)	Unclear risk	No study protocol identified, thus unable to judge whether all planned outcomes were reported. Only the PUSH tool score and the PU area change was reported in detail. Data on weight change were obtained from the author. Data on energy and protein intake were not in a format suitable for this review, and were not provided by the author.

Banks 2016 (Continued)

Other bias	Low risk	Groups were comparable at baseline.
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Beattie 2000
Study characteristics

Methods	<p>RCT.</p> <p>Parallel design with 2 arms.</p> <p>Duration: 10 weeks.</p> <p>Location: single centre in the UK.</p>
Participants	<p>Inclusion criteria: adults resuming oral food intake after surgery with BMI < 20 kg/m², TSF or MAMC < 15th percentile or > 5% weight loss. All participants had an MNA score 20 or less.</p> <p>Exclusion criteria: requiring parenteral nutrition, pregnant or lactating, with terminal illness, decompensated liver or renal disease.</p> <p>Number randomised: 101 adults (both men and women).</p> <p>Gender split: 41 females, 60 males.</p> <p>Age: mean (SD); intervention group 54.4 (19.4) years; control group 62.4 (10.9) years.</p> <p>Nutritional status: on inclusion to study defined as mild (BMI ≤20 kg/m²), moderate (BMI ≤18 kg/m²), severe (BMI ≤16 kg/m²) normal (BMI 20-25 kg/m²), overweight (BMI ≥25 kg/m²); intervention group severe 1, moderate 5, mild 29, normal 13, overweight 4; control group severe 2, moderate 9, mild 19, normal 16, overweight 3. nb. participants with normal or overweight BMI had weight loss ≥5% at inclusion.</p>
Interventions	<p>Intervention: participants received <i>dietary advice and ONS</i> in the form of routine nutritional management and 400 mL of a 1.5 kcal/mL nutritional supplement.</p> <p>Control: participants received <i>dietary advice alone</i> in the form of routine nutritional management.</p>
Outcomes	Survival*, weight*, BMI*, MAMC*, TSF*, handgrip strength*, complication rate, wound infection, chest infection, antibiotic use, QoL.
Publication details	<p>Language: English.</p> <p>Funding: this study was funded by Abbott Laboratories.</p> <p>Publication status: peer-reviewed journal.</p>
Notes	Routine nutritional management provided by more than one dietitian and not described in the paper. Information on quality obtained from authors. Information on QoL not added to meta-analyses as only scores for physical and mental QoL were provided in the manuscript - global QoL missing.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation was performed using a computer-generated list of random numbers.
Allocation concealment (selection bias)	Low risk	The allocation was not concealed physically but the list of numbers was not consulted until the participant was recruited.

Beattie 2000 (Continued)

Blinding (performance bias and detection bias) Clinical outcomes	Low risk	The paper states that assessors were not blinded to treatment. However, it unlikely that morbidity is influenced by lack of blinding.
Blinding (performance bias and detection bias) Functional outcomes	Unclear risk	No functional outcomes reported.
Blinding (performance bias and detection bias) Nutritional outcomes	High risk	The paper states that assessors were not blinded to treatment. Nutritional status and QoL outcomes can be influenced by assessors knowing group allocations.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not blinded and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Judged to be unclear because low risk for clinical outcomes and high risk for nutritional and QoL outcomes.
Incomplete outcome data (attrition bias) All outcomes	Low risk	8/101 (8%) attrition, 3 drop outs in intervention group (advice plus supplements) (transferred to intensive care unit n = 1, required artificial nutritional support n = 2) and 5 dropouts in control group (routine nutritional management group) (lost to follow-up n = 2, required artificial nutritional support n = 3).
Selective reporting (reporting bias)	Unclear risk	No study protocol identified, thus unable to judge whether all planned outcomes were reported. Data for analysis were extracted from the paper. Additional information on study quality obtained from authors. QoL data were not complete, only physical and mental health data provided
Other bias	Unclear risk	Baseline variables provided, but groups not similar - group receiving advice plus supplements was younger by almost 10 years than the advice only group. Routine nutritional management provided by more than one dietitian and not described in the paper.

Beck 2012
Study characteristics

Methods	<p>RCT.</p> <p>Parallel design with 2 arms.</p> <p>Duration: 8 weeks intervention with 26 weeks follow-up.</p> <p>Location: University Hospital of Herlev in Denmark (but participants drawn from 3 municipalities).</p>
Participants	<p>Inclusion criteria: identified as at nutritional risk according to the level 1 screen NRS 2002; were 65+ years of age, living in three municipalities (Herlev, Roedovre or Gladsaxe), hospitalised for a minimum of 2 days in the geriatric medicine wards of the University Hospital of Herlev.</p> <p>Exclusion criteria: suffered from senile dementia or terminal disease; could not understand the Danish language; resident in nursing homes; or unable to or willing to give informed consent.</p> <p>Number randomised: 152 elderly participants (over 65 years of age) randomised, 124 completed study.</p>

Beck 2012 (Continued)

Gender split: intervention group 54 females (74%) and 19 males (26%); control group 57 females (72%) and 22 males (28%).

Age: data not reported (all greater than 65 years).

Nutritional status: all at nutritional risk assessed using NRS 2002.

Interventions	<p>Intervention: participants received <i>dietary advice plus ONS if required</i> in the form of comprehensive nutritional assessment by a dietitian, followed by 3 home visits with individualised nutritional counselling by a registered dietitian complemented with 3 follow-up visits conducted by the GP.</p> <p>Control: participants received <i>no dietary advice and no ONS</i> in the form of 3 follow-up visits by GPs alone.</p>	
Outcomes	<p>Primary outcome: risk of readmissions*.</p> <p>Secondary outcomes: functional status (hand grip strength*, chair stand, mobility, disability and tiredness in daily activities, rehabilitation capacity), nutritional status (weight*, BMI, energy* and protein intake*), need of social services (home care, home nursing, meals-on-wheels) and mortality*.</p>	
Publication details	<p>Language: English.</p> <p>Funding: grants from the Health Insurance Foundation, the Tryg Foundation and the General Practitioners' Foundation for Development of General Practice. These are all non-commercial and had no role in study design, or in the collection, analysis, interpretation and publication of the data. TDC provided cell phones for scientific research assistants and registered dietitians and, as the others, had no role in study design, or in the collection, analysis, interpretation and publication of data.</p> <p>Publication status: peer-reviewed journal.</p>	
Notes		
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote from paper: "Participants were randomized at discharge. Each allocation using generated random numbers was written on paper and concealed in a serially numbered, opaque envelope. The scientific research assistants opened the next envelope after recruiting each participant and then contacted the GP and, if relevant, the registered dietitians. Hence the scientific research assistants, who collected the outcome data, knew which group a participant was in. The principal investigator was the only one blinded for the intervention". Randomisation ratio not described.
Allocation concealment (selection bias)	Low risk	Quote from paper: "Each allocation using generated random numbers was written on paper and concealed in a serially numbered, opaque envelope."
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	Comment: Not blinded. Scientific research assistants were aware of group assignment. Outcome not likely influenced by lack of blinding.
Blinding (performance bias and detection bias) Functional outcomes	High risk	Comment: Not blinded. Hence the scientific research assistants, who collected the outcome data, knew which group a participant was in. Outcomes could have been influenced by lack of blinding.
Blinding (performance bias and detection bias) Nutritional outcomes	High risk	Comment: Not blinded. Hence the scientific research assistants, who collected the outcome data, knew which group a participant was in. Outcomes could have been influenced by lack of blinding.

Beck 2012 (Continued)

Blinding of participants and personnel (performance bias) All outcomes	High risk	Not blinded and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Not blinded, most of the outcomes were functional and nutrition parameters; knowing the group allocation could have influenced outcome assessment.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Comment: 34/152 (22%) attrition. Withdrawals were balanced across groups: 18 (23%) in control group, and 16 (22%) in intervention group. Otherwise no missing data. It was even possible to obtain follow-up data from some of those who withdrew.
Selective reporting (reporting bias)	Low risk	Study protocol identified Clintrials.gov. All specified outcomes reported.
Other bias	Low risk	Comment: baseline characteristics were similar between groups.

Beck 2015
Study characteristics

Methods	<p>RCT.</p> <p>Parallel design with 2 arms.</p> <p>Duration: 12 weeks, follow-up at 6 months.</p> <p>Location: single centre in Denmark.</p>
Participants	<p>Inclusion criteria: > 70 years of age, hospitalised at the wards of Geriatric Medicine and Orthopaedic Surgery, at nutritional risk according to the level 2 screening in NRS 2002 and planned to be discharged to their private home assisted by the discharge Liaison-Team.</p> <p>Exclusion criteria: dementia or terminal disease, impaired renal function (GFR < 30 mL/min/1.73 m²), unable to understand the Danish language, nursing homes or rehabilitation homes, incapable of performing hand-grip test, planning a weight-reducing diet, no informed consent.</p> <p>Number randomised: 71 adults.</p> <p>Gender split: 23 males, 48 females.</p> <p>Age: data not reported (all greater than 70 years).</p> <p>Nutritional status: all at nutritional risk assessed using NRS 2002.</p>
Interventions	<p>Intervention: participants received <i>dietary advice plus ONS if required</i> in the form of visits from the Liaison-Team in cooperation with a dietician (who made 3 home visits over a period of 12 weeks).</p> <p>Control: participants received <i>no dietary advice and no ONS</i> in the form of visits from the Liaison-Team without dietician.</p>
Outcomes	<p>Nutritional status (weight*, and dietary intake*), muscle strength (hand-grip strength*, chair stand), functional status (mobility, and activities of daily living), QoL (EQ-5D), use of social services, rehospitalisation and mortality*, costs.</p>

Beck 2015 (Continued)

The economic analysis of time spent by the dietitian, use of oral nutritional supplements and number of hospitalisation days was described by Pohju et al (2016).

Publication details

Language: English.

Funding: a grant from the Danish Regions and the Danish Health Cartel.

Publication status: peer-reviewed journal.

Notes

Outcomes were presented as median change scores in the article. In the review we used the mean change scores which were provided by the authors.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: Simple randomisation was used, i.e. each allocation was written on paper, concealed in an opaque envelope. The opaque envelopes were gathered in a jar from which the patients drew a lot after recruitment.
Allocation concealment (selection bias)	Low risk	Quote: ... each allocation was written on paper, concealed in an opaque envelope. The opaque envelopes were gathered in a jar from which the patients drew a lot after recruitment.
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	The study was unblinded. However, this is unlikely to influence clinical outcomes.
Blinding (performance bias and detection bias) Functional outcomes	High risk	The study was unblinded. Functional outcomes could have been influenced by lack of blinding.
Blinding (performance bias and detection bias) Nutritional outcomes	High risk	The study was unblinded. Nutritional outcomes could have been influenced by lack of blinding.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not blinded and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Judged to be unclear because low risk for clinical outcomes and high risk for functional and nutritional outcomes.
Incomplete outcome data (attrition bias) All outcomes	Low risk	A total of 63 (89%) participants completed the second data collection; 8 participants died (2 (6%) in the intervention group and 6 (16%) in the control group).
Selective reporting (reporting bias)	Unclear risk	No study protocol identified, thus unable to judge whether all planned outcomes were reported.
Other bias	Low risk	Baseline characteristics were similar between groups.

Berneis 2000
Study characteristics

Methods	<p>RCT.</p> <p>Parallel design with 2 arms.</p> <p>Duration: 12 weeks.</p> <p>Location: Basel, Switzerland.</p>
Participants	<p>Inclusion criteria: adults with HIV infection and weight loss 5% or more in 6 months or BMI < 21 or CD4 cell count < 500/mm³ in a stable condition without acute infectious complications.</p> <p>Exclusion criteria: not specified.</p> <p>Number randomised: 18 adults but 3 not included because of non-adherence and severe disease complications, so 15 participants.</p> <p>Gender split: 14 males and 1 female.</p> <p>Age: not reported.</p> <p>Nutritional status: not reported</p>
Interventions	<p>Intervention: participants (n = 8) received <i>dietary advice and ONS</i> in the form of dietary advice and nutritional supplements (target unspecified).</p> <p>Control: participants (n = 7) received <i>no dietary advice and no ONS</i> in the form of no nutritional therapy.</p>
Outcomes	Weight*, lean and fat mass, macronutrient intake, energy intake*, immune function, QoL.
Publication details	<p>Language: English.</p> <p>Funding: grant from the Swiss Federal Office of Health (Grant no 94–7189), Novartis Nutrition (Bern, Switzerland), and the Swiss National Science Foundation.</p> <p>Publication status: peer-reviewed journal.</p>
Notes	Additional data and information on quality requested from authors. Received a reply to say information no longer available.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Information from author states that randomisation performed by pharmacy using a random number generator.
Allocation concealment (selection bias)	Unclear risk	The author could not supply details about allocation concealment.
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	Although not specifically mentioned, the trial must have been unblinded due to the nature of the intervention. However, this is unlikely to influence clinical outcomes.
Blinding (performance bias and detection bias) Functional outcomes	Unclear risk	The trial was unblinded. Functional outcomes could have been influenced by lack of blinding.
Blinding (performance bias and detection bias)	Unclear risk	The trial was unblinded. Nutritional outcomes could have been influenced by lack of blinding.

Berneis 2000 (Continued)
 Nutritional outcomes

Blinding of participants and personnel (performance bias) All outcomes	High risk	Not blinded and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Judged to be unclear because low risk for clinical outcomes and high risk for functional and nutritional outcomes.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Original group consisted of 18 participants, but 3 (17%) not included because of non-adherence and severe disease complications. Author unable to provide details of which groups the drop-outs were in.
Selective reporting (reporting bias)	High risk	No study protocol identified, thus unable to judge whether all planned outcomes were reported. Outcomes were reported, as mean change at baseline and end of follow-up therefore change scores were calculated and SDs imputed.
Other bias	Unclear risk	Baseline variables not stated, don't know if groups similar at baseline.

Bonilla-Palomas 2016
Study characteristics

Methods	<p>RCT.</p> <p>Parallel design with 2 arms.</p> <p>Duration: intervention began at hospital admission and lasted 6 months, follow-up to a maximum of 12 months.</p> <p>Location: multicentre (2 centres) in Spain.</p>
Participants	<p>Inclusion criteria: adults with acute heart failure (whether chronic and uncompensated or of new onset), in a state of malnutrition (score on the MNA < 17 points).</p> <p>Exclusion criteria: pregnancy, chronic renal failure in dialysis, already receiving nutritional treatment, concomitant disease with life expectancy < 1 year regardless of heart failure itself, participation in other clinical trials, surgery or percutaneous coronary intervention during hospital stay to correct the cause of acute heart failure, clinical status meaning it is impossible to perform the nutritional assessment as established in the study protocol, lack of consent for such procedures.</p> <p>Number randomised: 120 participants.</p> <p>Gender split: 45 males and 75 females.</p> <p>Age: mean (SD) 79.2 (7) years.</p> <p>Nutritional status: all malnourished (MNA < 17 points).</p>
Interventions	<p>Intervention: participants received <i>dietary advice plus ONS if required</i> in the form of heart failure treatment with follow-up by cardiologist combined with an individualized nutritional intervention performed by a physician specialist in nutrition assisted by a nutritionist and based on diet optimisation, specific recommendations and nutritional supplement prescriptions in cases in which nutritional goals were not reached; supplements chosen according to the requirements and co-morbidities of the participant.</p>

Bonilla-Palomas 2016 (Continued)

Control: participants received *no dietary advice and no ONS* in the form of standard heart failure treatment with follow-up by cardiologist.

Outcomes	A composite of all-cause death or readmission for worsening of heart failure, weight, nutritional intake.
Publication details	<p>Language: English.</p> <p>Funding: Spanish Society of Cardiology as a Project of the Spanish Society of Cardiology for Clinical Research in Cardiology.</p> <p>Publication status: peer-reviewed journal.</p>
Notes	The design paper states that a sample size of 182 participants is needed; in the paper reporting study outcomes only 120 participants were included.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Using a simple randomization process, 120 patients were assigned to the control or intervention group. The randomization sequence has been generated and deposited in the secretariat of the Internal Medicine Department of Hospital Juan de la Cruz". There was no description of how the randomisation sequence was generated e.g. computer-generated or random number tables.
Allocation concealment (selection bias)	Low risk	Quote: "A randomization sequence has been generated and deposited in the secretariat of the Internal Medicine Department of Hospital Juan de la Cruz. The investigators are in contact with the staff of the secretariat by telephone".
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	The study was unblinded. However, this is unlikely to influence mortality rate and readmissions.
Blinding (performance bias and detection bias) Functional outcomes	Unclear risk	No data on functional outcomes collected.
Blinding (performance bias and detection bias) Nutritional outcomes	Low risk	The study was unblinded. Nutritional outcomes could have been influenced by lack of blinding.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not blinded and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Judged to be unclear because low risk for clinical outcomes and high risk for nutritional outcomes.
Incomplete outcome data (attrition bias) All outcomes	High risk	Attrition was only caused by mortality (47% in the control group and 20% in the intervention group).
Selective reporting (reporting bias)	Low risk	All outcomes described in the protocol article are reported.
Other bias	Low risk	Baseline characteristics are similar between groups.

Bourdel-Marchasson 2014
Study characteristics

Methods	<p>RCT.</p> <p>Parallel design with 2 arms.</p> <p>Duration: interviews were performed 6 times during the chemotherapy sessions for 3 to 6 months with two-year follow-up.</p> <p>Location: multicentre in France.</p>
Participants	<p>Inclusion criteria: aged 70 years or older and being treated with chemotherapy for solid tumour, at risk of malnutrition (MNA < 17 or > 23.5).</p> <p>Exclusion criteria: Karnofsky index < 50%, under chemotherapy process.</p> <p>Number randomised: 336 participants (randomised 341, dropouts 5).</p> <p>Gender split: 51% males, 49% females.</p> <p>Age: mean (SD), intervention group 77.7 (5.2) years; control group 78.3 (4.7) years.</p> <p>Nutritional status: all at risk of malnutrition (MNA < 17 or > 23.5)</p>
Interventions	<p>Intervention: participants received <i>dietary advice plus ONS if required</i> in the form of dietary counselling (face-to-face discussion targeting the main nutritional symptoms) to achieve an energy intake of 30 kcal/kg body weight/day and 1.2 g protein/kg/day.</p> <p>Control: participants received <i>no dietary advice and no ONS</i> in the form of usual nutritional care routinely given in the cancer treatment settings with no restrictions for dietary advice, oral supplements or prescription of artificial nutrition.</p>
Outcomes	<p>Primary outcome: 1-year mortality.</p> <p>Secondary outcomes: 2-year mortality, toxicities and chemotherapy outcomes, weight change, nutritional intake, prescription of enteral and parenteral nutrition, hospitalisation for reasons other than chemotherapy, QoL (EORTC-C30) , MNA, ADL, IADL, MMS and GDS.</p>
Publication details	<p>Language: English.</p> <p>Funding: supported by the National Hospital Program of Clinical Research (Programme Hospitalier de Recherche Clinique 2006) (46%), La Ligue contre le cancer (52%) and AMGEN (2%) and sponsored by the university hospital of Bordeaux (CHU Bordeaux). The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.</p> <p>Publication status: peer-reviewed journal.</p>
Notes	<p>Quote: "The trial was stopped before completion of the planned inclusions. However, it is unlikely that the lack of an observed effect of intervention is due to lack of power. In the whole sample, a trend of an increase in two-year mortality in the intervention group was seen. However, even if we had reached the planned sample size, such mortality rates in both arms would not have provided a significant difference in survival. This absence of effect on mortality and other outcomes was not due to unbalanced characteristics of patients between groups according to cancer disease, chemotherapy or nutritional baseline assessment."</p>
Risk of bias	
Bias	Authors' judgement Support for judgement

Bourdel-Marchasson 2014 (Continued)

Random sequence generation (selection bias)	Low risk	The randomisation list was prepared by the clinical trial unit biostatistician. Randomization was centralized by internet, with a 1:1 ratio, stratified by recruitment centre.
Allocation concealment (selection bias)	Low risk	Randomisation was centralized by internet and the randomization list stored by the clinical trial unit biostatistician.
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	The trial was unblinded. However, this is unlikely to influence clinical outcomes.
Blinding (performance bias and detection bias) Functional outcomes	High risk	The trial was unblinded. Functional outcomes could have been influenced by lack of blinding.
Blinding (performance bias and detection bias) Nutritional outcomes	High risk	The trial was unblinded. Nutritional outcomes could have been influenced by lack of blinding.
Blinding of participants and personnel (performance bias) All outcomes	High risk	None of the staff in cancer treatment centres were aware of the content of the nutritional intervention. Patients were unblinded to group assignment. It is possible that assessment of some outcomes was influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Judged to be unclear because low risk for clinical outcomes and high risk for functional and nutritional outcomes.
Incomplete outcome data (attrition bias) All outcomes	Low risk	341 were randomised, 336 were analyzed. Attrition n = 5 (less than 1%) (1 consent withdrawal, 4 with exclusion criteria) all in the control group.
Selective reporting (reporting bias)	Unclear risk	Protocol identified Clinicaltrials NCT00459589. Some secondary outcomes not reported (function, QoL, MNA and some biochemical outcomes).
Other bias	Low risk	Baseline characteristics presented and groups were similar. Study was stopped early. However, it is unlikely that the lack of an observed effect of intervention is due to lack of power.

Burden 2011
Study characteristics

Methods	<p>RCT.</p> <p>Parallel design with 2 arms.</p> <p>Duration: pre-operative intervention (mean (range, SD) time to surgery was 37 (7 – 371 days, 54.7 days); participants followed up until 3 months after operation.</p> <p>Location: single centre in the UK.</p>
Participants	<p>Inclusion criteria: diagnosed with colorectal cancer and scheduled for surgery with pre-operative weight loss > 1 kg/3 - 6 months.</p> <p>Exclusion criteria: pregnant, enrolled in another trial, unable to give informed consent, had an inoperable tumour.</p>

Burden 2011 (Continued)

Number randomised: 125 participants (intervention group n = 59 (analysed n = 54), control group n = 66 (analysed n = 62)).

Gender split: intervention group 63% male; control group 61% male.

Age: mean (SD), intervention group 64.5 (13.9) years; control group 65.3 (2.7) years.

Nutritional status: 83 (71%) participants had lost weight in 3 – 6 months preceding surgery; the % of usual body weight lost was in the range 1% – 31% (mean (SD) 5.8% (6.5%)).

Interventions	<p>Intervention: participants received <i>dietary advice and ONS</i> in the form of 400 mL of oral supplement and dietary advice (consisting of increasing energy and protein from food, based on an information leaflet*).</p> <p>Control: participants received <i>dietary advice alone</i> in the form of dietary advice as described above.</p> <p>*The author explained: "The leaflet was Build yourself up: for patients undergoing surgical procedures". It included the eat well plate, foods to include in your diet going through the food groups, There was a section on increasing energy and protein content of the diet. At the end it included high calorie snacks. Dietary counselling was not provided in the sense of dietetic practice i.e. assessment of habitual intake and tailored advice. The research assistant talked the patient through the written leaflet. So this advice was usual care as it is usually given out in pre-op clinics by clinic nurses".</p>
Outcomes	<p>Primary outcome: number of post-operative complications.</p> <p>Secondary outcomes: use of postoperative antibiotics, length of hospital stay, energy and protein intake, complications, grip strength.</p>
Publication details	<p>Language: English.</p> <p>Funding: NHS fellowship award and Central Manchester foundation trust small awards.</p> <p>Publication status: peer-reviewed journal.</p>
Notes	<p>Of the 54 participants randomised to the treatment group, 50 completed a diary to record compliance to the intervention (2 full cartons of supplement daily). It was reported that 36 (72%) of participants managed 100% of the intervention, 8 (16%) managed 50% (at least 1 carton daily) and 6 (12%) managed < 25% of the intervention.</p> <p>The author provided change scores for energy intake and protein intake on our request.</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Numeral sequence of random blocks generated by independent statistician.
Allocation concealment (selection bias)	Low risk	Sequentially numbered brown opaque envelopes.
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	Incomplete blinding, personnel blinded, participants not blinded. It is unlikely that post-op complications is influenced by lack of blinding.
Blinding (performance bias and detection bias) Functional outcomes	Unclear risk	Functional outcomes were not measured in this study.
Blinding (performance bias and detection bias)	High risk	It is possible that there is bias associated with dietary intake recorded by 24 h recall because participants were unblinded.

Burden 2011 (Continued)

Nutritional outcomes

Blinding of participants and personnel (performance bias) All outcomes	High risk	Incomplete blinding, personnel blinded, participants not blinded. It is possible that assessment of some outcomes was influenced by lack of blinding
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Judged to be unclear because low risk for clinical outcomes and high risk for nutritional outcomes.
Incomplete outcome data (attrition bias) All outcomes	Low risk	5 of 54 (9%) in the intervention group and 4 of 62 (6%) in the control group did not have surgery so were excluded from the analysis.
Selective reporting (reporting bias)	Unclear risk	No study protocol identified, thus unable to judge whether all planned outcomes were reported. Data on change in grip strength were not reported.
Other bias	Unclear risk	Baseline characteristics were compared and were broadly similar in the two groups. Dietary intake was measured by unstructured dietary recalls; this method is not very reliable. The SD of the mean change in energy intake was twice as high as the mean change, indicating a skewed distribution.

Burden 2017
Study characteristics

Methods	<p>RCT.</p> <p>Parallel design with 2 arms.</p> <p>Duration: oral nutritional supplements were administered from diagnosis to the day preceding surgery for a minimum of 5 days.</p> <p>Location: multicentre study in the UK.</p>
Participants	<p>Inclusion criteria: diagnosis of colorectal cancer, scheduled for surgery with pre-operative weight loss > 1 kg/3 – 6 months.</p> <p>Exclusion criteria: pregnant, had a pacemaker, already taking a similar ONS, with insulin dependent diabetes</p> <p>Number randomised: 101 participants (intervention group n = 55; control group n = 46).</p> <p>Gender split: intervention 64% male, control 70% male.</p> <p>Age: mean (SD) intervention group 70.5 (11.7) years; control group 68.9 (11.5) years.</p> <p>Nutritional status: median (IQR) % weight loss, intervention 4.9 kg (2.2 - 8.8); control 6.8 kg (3.4 - 12.1)</p>
Interventions	<p>Intervention: participants received <i>dietary advice and ONS</i> in the form of 250 mL/day oral nutritional supplements (10.1 KJ and protein 0.096 g/mL) and dietary advice.</p> <p>Control: participants received <i>dietary advice alone</i> in the form of dietary advice.</p>
Outcomes	<p>Primary outcome: 1 or more surgical site infection or chest infection.</p>

Burden 2017 (Continued)

Secondary outcomes: % weight loss, total complications, and body composition measurements.

Publication details

Language: English.

Funding: Macmillan Cancer Support and British Dietetic Association.

Publication status: peer-reviewed journal.

Notes

Non-normally distributed data are displayed as median and IQRs. In this format, the data are not in a format sufficient for meta-analyses.

Data on handgrip strength are reported as mean (SD) and thus included in meta-analyses.

On request, change scores of weight, kcal intake, and protein intake were obtained from the author, and included in the meta-analyses.

Outcomes are reported at 2 time-points, preoperatively and post-operatively. As the intervention was given preoperatively only, we have chosen to only report the preoperative outcome measures in this review.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	The participants were randomly allocated on a 1:1 ratio by using blocks of two ensuring equal numbers in each group. Allocation was stratified according to tumour site (rectal versus colon) and surgical approaches (open versus laparoscopic). 4 lists of random numbers were produced by a statistician, and an independent researcher set up the randomization procedure for each of the strata.
Allocation concealment (selection bias)	Low risk	Sequentially-numbered opaque sealed envelopes were used, which allowed block randomization sequence allocation to be implemented and ensured sequence allocation concealment.
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	Described as single blind. For the purposes of blinding, control participants were given sealed cardboard boxes of identical weight and appearance as the supplement group at the time of group allocation. These boxes contained bottled water in 125 mL bottles. Thus research team was blind to the intervention, but the participants were not.
Blinding (performance bias and detection bias) Functional outcomes	Low risk	Described as single blind. For the purposes of blinding, control participants were given sealed cardboard boxes of identical weight and appearance as the supplement group at the time of group allocation. These boxes contained bottled water in 125 mL bottles. Thus the research team was blind to the intervention, but the participants were not.
Blinding (performance bias and detection bias) Nutritional outcomes	Low risk	Described as single blind. For the purposes of blinding, control participants were given sealed cardboard boxes of identical weight and appearance as the supplement group at the time of group allocation. These boxes contained bottled water in 125 mL bottles. Thus research team was blind to the intervention, but the participants were not.
Blinding of participants and personnel (performance bias) All outcomes	High risk	The research team was blind to the intervention, but the participants were not. It is possible that assessment of some outcomes was influenced by lack of blinding
Blinding of outcome assessment (detection bias)	Unclear risk	The research team was blind to the intervention, but the participants were not.

Burden 2017 (Continued)

All outcomes

Incomplete outcome data (attrition bias) All outcomes	High risk	<p>1 of 55 (2%) in the intervention group died; 6 of 46 (13%) in the control group failed to complete (4 died, 1 participant withdrew from the control group and 1 further participant from the control group was excluded from the analysis).</p> <p>For the outcome measures: handgrip strength, % weight loss, PG-SGA, energy intake and protein intake data are provided for fewer participants than originally included. The reasons why data were missing for these outcomes is not reported.</p>
Selective reporting (reporting bias)	Unclear risk	<p>Study protocol identified. All outcomes reported apart from hospital readmissions and quality of life (secondary outcomes). Many outcomes reported as median and IQR, thus not in a format sufficient for meta-analysis.</p>
Other bias	Unclear risk	<p>Baseline variables reported. Overall, there were more participants in the intervention group (n = 55) than in the control group (n = 46). At the point of recruiting participants, if it was undecided if surgery was open or laparoscopic, the default used was open-surgery stratum for randomization. The two arms of the trial were well-matched with similar proportions of participants within each stratum, site of cancer, and type of operation (laparoscopic or open).</p>

Caccialanza 2015
Study characteristics

Methods	<p>RCT.</p> <p>Parallel design with 2 arms.</p> <p>Duration: 12 months.</p> <p>Location: single centre in Italy.</p>
Participants	<p>Inclusion criteria: amyloidosis adult outpatients who were treatment naïve and able to provide written informed consent.</p> <p>Exclusion criteria: indication to autologous stem cell transplantation, in need of starting or ongoing dialysis or ongoing artificial nutrition, presence of ascites or relevant peripheral oedema.</p> <p>Number randomised: 144 participants; intervention n = 72, control n = 72.</p> <p>Gender split: intervention group 62% male; control group 60% male.</p> <p>Age: mean (SD) intervention 65.4 (10.5) years; control 64.8 (9.7) years.</p> <p>Nutritional status: BMI at baseline, mean (SD): intervention group 24.6 (3.3) and control group 25.4 (4.1).</p> <p>Unintentional weight loss, median (IQR): intervention group 3.0 (0.0 – 6.0) kg and control group 4.0 (0.3 – 7.0) kg.</p>
Interventions	<p>Intervention: participants received <i>dietary advice plus ONS if required</i> in the form of personalized dietary prescription (modelled on personal eating patterns and preferences, to satisfy estimated protein-calorie requirements* and based primarily on the use of regular foods; oral nutrition supplements were prescribed when necessary) plus dietetic advice from a registered dietitian every 3 weeks by telephone and every 3 months face-to-face.</p> <p>Control: participants received <i>no dietary advice and no ONS</i> in the form of written general nutritional advice aimed at maintaining or recovering body weight, participants were allowed to ad libitum food</p>

Caccialanza 2015 (Continued)

intake, without fixed prescription of oral nutritional supplements; if participants had questions concerning nutrition, they were advised by the Amyloidosis Center's attending physician or the nurses, but not by the professional dietitian.

*Energy requirements: Harris-Benedict equation x 1.5, protein requirements 1.1 g/kg of actual body weight in case of normal kidney function; in the presence of kidney involvement, adjustments were performed according to available guidelines and laboratory data.

Outcomes	Body weight*, MAMC, energy intake (% of participants reaching requirements), QoL (SF-36, only subscales), mortality*.
Publication details	<p>Language: English.</p> <p>Funding: the Fondazione IRCCS Policlinico San Matteo (Pavia, Italy) and partly supported by grants from "Associazione Italiana per la Ricerca sul Cancro - Special Program Molecular Clinical Oncology 5 per mille" (grant n. 9965) and Cariplo Foundation (grant no. 2013-0964).</p> <p>Publication status: peer-reviewed journal.</p>
Notes	Not all participants were malnourished at baseline. QoL data could not be used because only subscales were reported.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: a computer-generated randomization list (randomized blocks) was used. Accordingly, eligible participants were randomized (1:1) to either the nutritional counselling (NC) or usual care (UC) group."
Allocation concealment (selection bias)	Unclear risk	Not described.
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	Stated as open-label, meaning that both researchers and participants know which treatment is being administered. However, this is unlikely to influence mortality rate.
Blinding (performance bias and detection bias) Functional outcomes	High risk	Stated as open-label, meaning that both researchers and participants know which treatment is being administered. Functional outcomes could have been influenced by lack of blinding.
Blinding (performance bias and detection bias) Nutritional outcomes	High risk	Stated as open-label, meaning that both researchers and participants know which treatment is being administered. Nutritional outcomes could have been influenced by lack of blinding.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not blinded and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Judged to be unclear because low risk for clinical outcomes and high risk for functional and nutritional outcomes.
Incomplete outcome data (attrition bias) All outcomes	High risk	Overall attrition 84/144 (58%) participants; intervention group 51/72 (71%), control group 33/72 (46%), therefore amounts judged to be unbalanced between groups. High mortality rates due to complexity of the group.

Caccialanza 2015 (Continued)

Assessed at 3 months: intervention n = 56, control n = 47.

Assessed at 12 months: intervention n = 39, control n = 21.

41 did not attend the first follow-up visit at 3 months (intervention group n = 16, control group n = 25).

Most drop outs were caused by death: intervention n = 20, control n = 33.

Selective reporting (reporting bias)	Low risk	Protocol identified Clintrials NCT02055534 all planned outcomes were reported.
Other bias	Low risk	Baseline characteristics were similar between groups.

Calegari 2011
Study characteristics

Methods	<p>RCT.</p> <p>Duration: 2 phases (separated by a 1 month wash-out). Phase 1: 3-month intervention compared with control. Phase 2: Control group also received the intervention.</p> <p>Only data from Phase 1 included.</p> <p>Location: single centre study in Porto Alegre, Brazil.</p>
Participants	<p>Inclusion criteria: on haemodialysis.</p> <p>Exclusion criteria: clinically unstable, with infectious or inflammatory diseases, neoplasias, scheduled for transplant or death before inclusion in the study.</p> <p>Number randomised: 18 participants; intervention group n = 9, control group n = 9. Attrition: 15 (83%) completed the first phase. 2 participants died and 1 moved to peritoneal dialysis, all from control group.</p> <p>Gender split: 15 (83%) males, 3 (17%) females.</p> <p>Age: mean (SD) and range 56.4 (15.6) years, 26 years to 88 years.</p> <p>Nutritional status: BMI, mean (SD): intervention group 22.3 (2.3) kg/m², control group 20.9 (2.1) kg/m².</p>
Interventions	<p>Intervention: participants received <i>dietary advice plus ONS</i> in the form of oral nutritional supplementation (355 kcal, 53% carbohydrates, 10 g of proteins, 15 g of lipids, 257 mg of calcium, 271 mg of phosphorus, 313 mg of potassium, and 106 mg of sodium) during each haemodialysis session for 3 months; supplementation was offered to participants in the period between the beginning and mid-dialysis. In addition, they were provided with special attention, such as nutritional guidance, family counselling, and dental assessment.</p> <p>Control: participants received <i>no dietary advice and no ONS</i> in the form of "routine nutritional guidance".</p>
Outcomes	<p>Nutritional status (dry weight, BMI, SGA); body composition (MAC, MAMA, lean mass, fat mass), QoL (SF-36 domain scores); functional status (6-minute walking test).</p>
Publication details	<p>Language: English.</p> <p>Funding: Instituto de Doenças Renais provided ingredients for the intervention formula.</p> <p>Publication status: peer-reviewed journal.</p>

Calegari 2011 (Continued)

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not described.
Allocation concealment (selection bias)	Unclear risk	Not described.
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	Not described but mortality unlikely to be influenced by lack of blinding.
Blinding (performance bias and detection bias) Functional outcomes	Unclear risk	Not described and likely to be influenced by lack of blinding.
Blinding (performance bias and detection bias) Nutritional outcomes	Unclear risk	Not described and likely to be influenced by lack of blinding.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not blinded and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	It is not stated whether the outcome assessors were blinded and some outcome assessment might be influenced by lack of blinding.
Incomplete outcome data (attrition bias) All outcomes	High risk	Attrition data fully reported, however, reasons were unbalanced between groups: 3/18 (17 %) in did not complete the first phase: intervention group 0/9 (0 %) and control group 3/9 (33 %); of these 2/9 (22 %) died and 1/9 (11 %) moved to peritoneal dialysis.
Selective reporting (reporting bias)	Unclear risk	No protocol identified. All outcomes mentioned in the methods are reported.
Other bias	Low risk	Intervention and control groups were similar at baseline.

Campbell 2008
Study characteristics

Methods	RCT. Parallel design with 2 arms. Duration: 12 weeks. Location: Australia.
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Campbell 2008 (Continued)

Participants	<p>Inclusion criteria: adults with stage 4 chronic kidney disease, not previously seen by a dietitian, not expected to require renal replacement therapy within 6 months.</p> <p>Exclusion criteria: not specified.</p> <p>Number randomised: 62 participants randomised, 56 participants started study, 50 participants completed the study.</p> <p>Gender split: (at baseline) males n = 34, females n = 22.</p> <p>Age: mean (SD) intervention group 69.5 (11.7) years; control group 70.9 (11.6) years.</p> <p>Nutritional status: (assessed using SGA) intervention group 24% malnourished (SGA B); control group 11% malnourished (SGA B).</p>	
Interventions	<p>Intervention: participants (n = 24) received <i>dietary advice</i> in the form of dietary counselling to increase energy intake, maintain protein intake and information on appropriate nutritional choices for people with renal disease.</p> <p>Control: participants (n = 26) received <i>no dietary advice</i> in the form of usual care (generic information on nutrition).</p>	
Outcomes	Dietary intake*, body weight*, nutritional status (SGA), body composition (total body potassium), survival * biochemistry.	
Publication details	<p>Language: English.</p> <p>Funding: Royal Brisbane and Women's Hospital Foundation seeding grant, Queensland University of technology PG Research Award and an Institute of Health and Biomedical Innovation Research Scholarship.</p> <p>Publication status: peer-reviewed journal.</p>	
Notes		
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated number sequence.
Allocation concealment (selection bias)	Low risk	Described as concealed to recruiting officer until after baseline assessment.
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	It is not stated whether the outcome assessors were blinded but unlikely that these outcomes would be influenced by lack of blinding.
Blinding (performance bias and detection bias) Functional outcomes	High risk	Not stated and likely that some of these outcomes might have been influenced by lack of blinding.
Blinding (performance bias and detection bias) Nutritional outcomes	High risk	Not stated and likely that some of these outcomes might have been influenced by lack of blinding.
Blinding of participants and personnel (performance bias)	High risk	Not blinded and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding.

Campbell 2008 (Continued)

All outcomes

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	It is not stated whether the outcome assessors were blinded and some outcome assessment might be influenced by lack of blinding.
Incomplete outcome data (attrition bias) All outcomes	Low risk	62 participants randomised in the study, attrition fully described with reasons: attrition 12 (I: 8/32(27%); C:4/30(13%): 6 participants did not receive the intervention; 6 did not complete (4 deaths (all in the intervention group) and 2 participants received dialysis).
Selective reporting (reporting bias)	Low risk	Protocol identified on ANZCTR database. All specified outcomes reported. Data on mortality, change in weight, energy and protein intake, body cell mass and QoL were used in this review. The data are reported in the paper but the weight and body cell mass data are presented as a mean (SD) at baseline and at 12 weeks and therefore the mean change with SD has been obtained from the authors. The energy intake data reported in kJ/kg, and protein as g/kg, therefore mean change (SD) obtained from the author.
Other bias	Unclear risk	Baseline variables stated, groups similar at baseline apart from amounts of malnutrition (see above) and it is unclear what influence this might have had on outcomes assessed.

Cano-Torres 2017
Study characteristics

Methods	<p>RCT.</p> <p>Parallel design with 2 arms.</p> <p>Duration: intervention given for duration of hospital stay; follow-up for 6 months (data collection at 2, 4, 6 months).</p> <p>Location: Mexico.</p>
Participants	<p>Inclusion criteria: adults over 20 years of age with malnutrition admitted to Dept. Internal Medicine.</p> <p>Exclusion criteria: expected length of stay less than 48h, disturbance of consciousness, psychiatric disease, pregnant or breastfeeding, chronic kidney disease, parenteral or enteral nutrition, needing ventilation, liver disease, CVD alcohol-related disease, malignancy.</p> <p>Number randomised: 55 participants (intervention group n = 28, control group n = 27). Attrition: total n = 7 (intervention group n = 2, control group n = 5).</p> <p>Gender split: 22 (40%) males, 33 (60%) females.</p> <p>Age: mean (SD) 57.1 (20.7) years.</p> <p>Diagnoses: various, intervention group 61.5% chronic disease; control group 59% chronic disease.</p> <p>Nutritional status: BMI (kg/m²) at baseline: intervention group 24.7 (7.7) and control group 27.3(8.8).</p> <p>NRS score, mean (SD): intervention group 4.1 (0.8) and control group 4.2 (1.2).</p>
Interventions	<p>Intervention: participants received <i>dietary advice</i> in the form of an individualised nutrition plan from a clinical dietitian provided daily including, estimation of energy and protein requirements, motivation to adhere to diet, assessment of intake, nutritional counselling.</p>

Cano-Torres 2017 (Continued)

Control group: participants received *no dietary advice* in the form of standard nutritional management in the hospital.

Outcomes	Length of stay, mortality, BMI, arm circumference.
Publication details	<p>Language: English.</p> <p>Funding: none declared.</p> <p>Publication status: peer-reviewed journal.</p>
Notes	Email to authors, allocation concealment, confirm that length of stay and BMI are expressed as mean(SD)? mean change for BMI and arm circumference.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "patients were randomly allocated (using a list of random numbers generated by computer)".
Allocation concealment (selection bias)	Unclear risk	Judged as unclear because insufficient information about how group allocation was concealed from participants.
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	It is not stated whether the outcome assessors were blinded to group allocation but unlikely that these outcomes would be influenced by lack of blinding.
Blinding (performance bias and detection bias) Functional outcomes	Unclear risk	No functional outcomes assessed.
Blinding (performance bias and detection bias) Nutritional outcomes	Low risk	Not described but nutritional intake not assessed and other nutritional outcomes unlikely to be influenced by lack of blinding.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not blinded and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	It is not stated whether the outcome assessors were blinded and some outcome assessment might be influenced by lack of blinding.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Attrition fully described with reasons. 7 (intervention group n = 2/28 (7%) (1 death and 1 withdrawal), control group n = 5/27 (19%) (5 deaths)) drop outs out of 55 participants.
Selective reporting (reporting bias)	Unclear risk	<p>No protocol identified. The stated outcomes of the study are mortality and length of stay and both of these are reported.</p> <p>A number of additional outcomes are also reported but not referred to explicitly in the methods, therefore judged as unclear risk of bias.</p>
Other bias	Low risk	At baseline the control group had a lower haemoglobin level than the intervention group - 10.2 (2.3) g/dL compared to 12.3 (2.7) g/dL; otherwise groups well-balanced for all characteristics.

Cano-Torres 2017 (Continued)

This has been judged to be unlikely to affect the outcomes of interest.

Carey 2013
Study characteristics

Methods	<p>RCT.</p> <p>Duration: 6 months.</p> <p>Location: Sydney, Australia</p>
Participants	<p>Inclusion criteria: adults with major upper GI surgery with Roux-en-y reconstructive surgery, defined as a gastrectomy (total or partial), esophagectomy or pancreoduodenectomy.</p> <p>Exclusion criteria: known active disease, pyloric preserving surgery, inability to consent or living more than 2 hours from the centre.</p> <p>Number randomised: 27 participants (intervention group n = 14 and control group n = 13).</p> <p>Gender split: 21 males, 6 females.</p> <p>Age: mean (SD) intervention group 65 (11) years, control group 66 (7) years.</p> <p>Nutritional status: assessed by SGA, intervention group status A n = 4, B n = 7, C n = 3; control group status A n = 6, B n = 6, C n = 1.</p> <p>*SGA A (well nourished), B (mild to moderate malnutrition), C (severe malnutrition)</p>
Interventions	<p>Intervention: participants received <i>dietary advice plus ONS if required</i> in the form of 45-minute dietary education session* from the ward dietitian prior to discharge from hospital (usual care) followed up with regular phone review by the clinical dietitian every 2 weeks 6 months and face-to-face follow-up when deemed appropriate by the dietitian to discuss current weight and oral dietary intake (assessed by patient report and individualized nutritional counselling to improve intakes as required) and GI symptoms (such as reflux, bloating/wind, anorexia, early satiety, vomiting and bowel habits with advice to alleviate the symptoms provided) with additional written advice and oral or enteral nutrition supplementation provided as necessary.</p> <p>Control group: participants received <i>no dietary advice and no ONS</i> in the form of 45-minute dietary education session* from the ward dietitian prior to discharge from hospital (usual care), discharged with the ward dietitian's contact details but no dietitian follow-up was arranged.</p> <p>* Education included written information and advice regarding the use of oral nutritional supplements if appropriate.</p>
Outcomes	<p>Weight, triceps skinfold, MAMC, mid-arm muscle mass, hand-grip strength, SGA, dietary intake, QoL (EORTC QLQ-C30), GI symptoms (Gastro Intestinal Symptom Rating Scale)</p>
Publication details	<p>Language: English.</p> <p>Funding: not stated.</p> <p>Publication status: peer-reviewed journal.</p>
Notes	<p>Not all participants were malnourished according to the SGA.</p>
Risk of bias	
Bias	<p>Authors' judgement Support for judgement</p>

Carey 2013 (Continued)

Random sequence generation (selection bias)	Low risk	Quote: Randomization consisted of a pre-determined randomization table.
Allocation concealment (selection bias)	Unclear risk	Not reported.
Blinding (performance bias and detection bias) Clinical outcomes	Unclear risk	Not measured.
Blinding (performance bias and detection bias) Functional outcomes	Low risk	Quote: The research dietitian performed nutritional assessment and data collection for all patients, and was blinded to the group allocations.
Blinding (performance bias and detection bias) Nutritional outcomes	Low risk	Quote: The research dietitian performed nutritional assessment and data collection for all patients, and was blinded to the group allocations.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not blinded and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: The research dietitian performed nutritional assessment and data collection for all patients, and was blinded to the group allocations.
Incomplete outcome data (attrition bias) All outcomes	Low risk	In both groups, 1 participant was lost to follow-up because of moving and death.
Selective reporting (reporting bias)	Unclear risk	No study protocol identified, thus unable to judge whether all planned outcomes were reported.
Other bias	Unclear risk	Participants in the intervention groups weighed 66.6 kg, compared to participants in the control group 82.7 kg $P=0.022$, and also BMI, arm muscle circumference were less (non-significant) and pre-operative weight loss was higher (non-significant).

Casals 2015
Study characteristics

Methods	<p>RCT.</p> <p>Duration: intervention and follow-up 6 months.</p> <p>Location: Spain.</p>
Participants	<p>Inclusion criteria: hospitalised, medium/high risk of malnutrition (MUST), over 18 years of age, willing to participate, resident in the healthcare district.</p> <p>Exclusion criteria: treatment with oral food supplements, enteral or parenteral nutrition during admission, chemotherapy or radiotherapy during admission, presence of malabsorption.</p> <p>Number randomised: 106 participants randomised (intervention group $n = 52$, control group $n = 54$). Attrition: 13 participants dropped out (intervention group $n = 6$, control group $n = 7$).</p>

Casals 2015 (Continued)

Diagnosis: mixed clinical conditions.

Gender split: 53 (50%) males, 53 (50%) females.

Age: mean (SD) intervention group 73 (13) years; control group 73 (12) years.

Nutritional status: all at medium/high risk (MUST) mean (SD) score: intervention group 2.6 (1.27) and control group 2.4 (1.27).

Interventions	<p>Intervention: participants received <i>dietary advice</i> in the form of individualised nutritional counselling provided by case manager nurses which began in hospital and continued at home; review and monitoring varied according to whether participants were at medium or high risk.</p> <p>Control: participants received <i>no dietary advice</i> in the form of standard hospital discharge procedures (report to community team and follow-up phone call).</p>
Outcomes	BMI, number of participants at medium/high risk, biochemical measures (total protein, albumin, cholesterol, total lymphocytes), hospital readmissions, length of stay, QoL (SF-12), functional independence (Barthel), satisfaction (CSQ-8).
Publication details	<p>Language: English.</p> <p>Funding: Andalucian Government.</p> <p>Publication status: peer-reviewed journal.</p>
Notes	Email authors, detail of randomisation.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not described. Quote: "once the patient had been included, they were randomised"
Allocation concealment (selection bias)	Unclear risk	Not described.
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	Quote: "to minimize potential biases, the final assessment and data analysis were performed by professionals other than those who conducted the intervention and follow-up". Judged low risk because blinding unlikely to affect clinical outcomes
Blinding (performance bias and detection bias) Functional outcomes	Low risk	Quote: "to minimize potential biases, the final assessment and data analysis were performed by professionals other than those who conducted the intervention and follow-up". Judged as low risk.
Blinding (performance bias and detection bias) Nutritional outcomes	Low risk	Quote: "to minimize potential biases, the final assessment and data analysis were performed by professionals other than those who conducted the intervention and follow-up". Judged as low risk because outcome assessment blinded.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not blinded and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding.

Casals 2015 (Continued)

Blinding of outcome assessment (detection bias) All outcomes	Low risk	Final assessment and analyses performed blinded to group allocation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Attrition fully described with reasons. 13 out of 106 participants dropped out. (intervention group: 6/52 (12%) all deaths; control group: 7/54 (13%) 6 deaths and 1 loss to follow-up).
Selective reporting (reporting bias)	Unclear risk	No protocol identified. All outcomes mentioned in the methods are reported.
Other bias	Low risk	Groups well balanced at baseline for all characteristics.

Chandra 1985
Study characteristics

Methods	RCT. Duration: 4 weeks. Location: Newfoundland, Canada	
Participants	Inclusion criteria: elderly men with clinical and biochemical parameters suggesting malnutrition. Exclusion criteria: not specified. Number randomised: 30 participants (intervention group n = 15, control group n = 15). Gender split: all male Age: range 70 - 84 years. Nutritional status: not reported.	
Interventions	Intervention: participants received <i>dietary advice and ONS</i> in the form of dietary advice and supplements. Control: participants received <i>no dietary advice and no ONS</i> in the form of no intervention.	
Outcomes	Weight*, TSF*, biochemistry.	
Publication details	Language: English. Funding: not declared. Publication status: peer-reviewed journal.	

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No details.

Chandra 1985 (Continued)

Allocation concealment (selection bias)	Unclear risk	No details.
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	It is not stated whether the trial was blinded or not, but the nature of the intervention suggest that the trial was unblinded. However, this is unlikely to influence biochemistry outcomes.
Blinding (performance bias and detection bias) Functional outcomes	High risk	It is not stated whether the trial was blinded or not. Functional outcomes could have been influenced by lack of blinding.
Blinding (performance bias and detection bias) Nutritional outcomes	High risk	It is not stated whether the trial was blinded or not. Nutritional outcomes could have been influenced by lack of blinding.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not described and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Judged to be unclear because low risk for clinical outcomes and high risk for functional and nutritional outcomes.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information on attrition.
Selective reporting (reporting bias)	High risk	No study protocol identified. Not all outcome data reported. Data presented on change in weight and TSF and pre-albumin for the intervention group only. No data extracted and no response to request for data from the author.
Other bias	Unclear risk	Baseline characteristics not stated.

de Luis 2003

Study characteristics

Methods	<p>RCT.</p> <p>Parallel design with 2 arms. Duration: 3 months.</p> <p>Location: single centre in Spain.</p>
Participants	<p>Inclusion criteria: adults with HIV infection, absence of chronic fever, digestive conditions, drug consumption that might affect nutritional intake, with normal renal and hepatic function and 5% or more weight loss in previous 6 months.</p> <p>Exclusion criteria: not specified.</p> <p>Number randomised: 70 participants, 6 participants withdrew between randomisation and baseline (intervention group n = 33, control group n = 33).</p> <p>Gender split: intervention group 71.4% males, control group 82.8 % males.</p> <p>Age: mean (SD) intervention group 37.5 (11) years, control group 39.9 (9) years.</p>

de Luis 2003 (Continued)

Nutritional status: not reported.

Interventions	<p>Intervention: participants received <i>dietary advice and ONS</i> in the form of dietary advice to increase energy and protein intake and 3 x 250 mL supplement (Ensure).</p> <p>Control: participants received <i>dietary advice alone</i> in the form of dietary advice to increase energy and protein intake.</p>
Outcomes	Survival*, weight*, BMI*, TSF*, MUAC*, energy intake*, immune function, cardiac function.
Publication details	<p>Language: Spanish.</p> <p>Funding: not reported.</p> <p>Publication status: peer-reviewed journal.</p>
Notes	Additional data and information on quality obtained from authors.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Information from the author indicated that a random number series was used to generate a sequence.
Allocation concealment (selection bias)	Low risk	Information from the author indicated that sealed envelopes were used to conceal allocation.
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	The study was unblinded. The trial was unblinded. However, this is unlikely to influence clinical outcomes.
Blinding (performance bias and detection bias) Functional outcomes	High risk	Information from the author indicated that outcome assessment was not blinded.
Blinding (performance bias and detection bias) Nutritional outcomes	High risk	Information from the author indicated that outcome assessment was not blinded.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not blinded and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Judged to be unclear, as low risk for clinical outcomes and high risk for functional and nutritional outcomes.
Incomplete outcome data (attrition bias) All outcomes	Low risk	4 participants (2 in each group) withdrew as they relocated due to work commitments
Selective reporting (reporting bias)	Unclear risk	No study protocol identified, thus unable to judge whether all planned outcomes were reported. Outcomes reported not all in a format usable for meta-analysis. Change in weight, TSF, MAMC and energy intake are reported as mean (SD) at baseline and end of intervention. Mean change (SD) obtained from authors.

de Luis 2003 (Continued)

Other bias	Low risk	Baseline variables stated, groups similar at baseline.
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de Sousa 2012
Study characteristics

Methods	RCT. Parallel design with 2 arms. Duration: 3 weeks intervention when ONS were stopped, with follow-up to 90 days Location: single centre in Portugal (Geriatric Unit of a Psychiatric Hospital in Porto (Hospital Magalhães Lemos)).	
Participants	Inclusion criteria: aged 60 years and older admitted to hospital with recently diagnosed probable mild Alzheimer disease on the basis of the Diagnostic Statistics Disorders- IV and International Classification of Diseases criteria, who presented weight loss higher than 5% of body weight in the previous year. Exclusion criteria: having severe acute illness, receiving terminal care, cancer, receiving enteral or par-enteral nutrition, receiving dietary advice or ONS in the previous month. Number randomised: 35 participants. Gender split: 9 males, 26 females. Age: mean (SD) intervention group 79.4 (6.9) years; control group 78.4 (5.2) years. Nutritional status: mean (SD) MNA score, intervention 11.6 (3.8); control 13 (1.8).	
Interventions	Intervention: participants received <i>dietary advice and ONS</i> in the form of standard dietetic advice (usual care) with once daily 200 mL high protein energy-dense liquid oral nutritional supplement. Control: participants received <i>dietary advice alone</i> in the form of standard dietetic advice (usual care).	
Outcomes	MNA (score), weight (kg), BMI, TSF (mm), MAMC (cm), Albumin (%), total protein (g/dL), total cholesterol (mg/dL), vitamin B12 (pg/mL), folic acid (ng/mL), MMSE (score), clock-drawing test (score), Barthel index (score).	
Publication details	Language: English. Funding: no funding, products were provided by Novartis. Publication status: peer-reviewed journal.	
Notes		
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Insufficient information about the sequence generation.
Allocation concealment (selection bias)	Unclear risk	Insufficient information about the allocation concealment.
Blinding (performance bias and detection bias)	Low risk	The trial was unblinded. However, this is unlikely to influence clinical outcomes.

de Sousa 2012 (Continued)

Clinical outcomes

Blinding (performance bias and detection bias) Functional outcomes	High risk	No blinding. This may have influenced functional outcomes.
Blinding (performance bias and detection bias) Nutritional outcomes	High risk	No blinding. This may have influenced nutritional outcomes.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not blinded and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Judged to be unclear as low risk for clinical outcomes and high risk for functional and nutritional outcomes.
Incomplete outcome data (attrition bias) All outcomes	Low risk	2 of 17 (11%) participants in the control group died and were excluded from the analyses.
Selective reporting (reporting bias)	Unclear risk	No study protocol identified, thus unable to judge whether all planned outcomes were reported.
Other bias	Low risk	Groups were comparable at baseline.

Diouf 2016
Study characteristics

Methods	<p>RCT.</p> <p>Parallel design with 2 arms.</p> <p>Duration: intervention during hospitalisation and then 9 weeks following discharge.</p> <p>Location: single centre in Senegal.</p>
Participants	<p>Inclusion criteria: people living with HIV/AIDS (any stage, taking or not-taking antiretroviral treatment).</p> <p>Exclusion criteria: psychiatric illness, diabetes, physical disability, unable to eat.</p> <p>Number randomised: 65 participants (intervention group n = 32, control group n = 33).</p> <p>Gender split: 32% males, 68% females.</p> <p>Age: mean (SD) intervention 40 (12) years; control 42 (12) years.</p> <p>Nutritional status: severe malnutrition (BMI < 16 kg/m²): intervention group n = 34% and control group n = 24%.</p>
Interventions	<p>Intervention: participants received <i>dietary advice and ONS</i> in the form of standard hospital diet supplemented with supplement of 200 g/day* plus dietary counselling to improve diet at home (after discharge); supplementation was continued for 9 weeks at home.</p>

Diouf 2016 (Continued)

Control: participants received *dietary advice alone* in the form of standard hospital diet alone plus dietary counselling to improve diet at home (after discharge).

*200 g of supplement made up of 100 g ready to use food mixed with 100 g of rice porridge. Ready to use food is composed of peanut butter and skimmed milk powder fortified with a vitamin-mineral complex commercialised by Nutriset. The rice porridge (9.1 g rice flour per 100 mL water) was prepared ex-temporaneously, mixed with the ready to use food and served immediately.

Outcomes	<p>Body weight, fat-free mass, % body fat, dietary intake.</p> <p>Individual dietary intakes were measured and compared to the Recommended Dietary Allowances. Body composition was determined using Bio-Impedance Analysis.</p>
Publication details	<p>Language: English.</p> <p>Funding: Universite Cheikh Anta Dio de Dakar, Senegal. UNICEF Senegal provided the products.</p> <p>Publication status: peer-reviewed journal.</p>
Notes	<p>Both well-nourished and malnourished participants were included.</p> <p>At our request, authors provided change scores for weight, fat-free mass and body fat.</p> <p>Energy and protein intakes were only measured during 7 consecutive days in 10 randomly selected participants from each group during hospitalization; therefore results on nutritional intake are not presented in this review.</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	The randomisation and assignment to group was performed by the senior researcher using a computer-generated random number list (EPI INFO 6.0; Centers for Disease Control and Prevention, Atlanta).
Allocation concealment (selection bias)	Low risk	The randomisation and assignment to group was performed by the senior researcher using a computer-generated random number list (EPI INFO 6.0; Centers for Disease Control and Prevention, Atlanta).
Blinding (performance bias and detection bias) Clinical outcomes	Unclear risk	No clinical outcomes reported.
Blinding (performance bias and detection bias) Functional outcomes	High risk	The study was unblinded. Functional outcomes could have been influenced by lack of blinding.
Blinding (performance bias and detection bias) Nutritional outcomes	High risk	The study was unblinded. Nutritional outcomes could have been influenced by lack of blinding.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not blinded and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	High risk	The study was unblinded. Outcomes could have been influenced by lack of blinding.

Diouf 2016 (Continued)

Incomplete outcome data (attrition bias) All outcomes	Low risk	<p>High drop-out rates, but same numbers of dropouts across both groups (intervention group n = 12, control group n = 16).</p> <p>During hospitalisation, 6 participants died in the intervention group and 8 in the control group so 51 completed this stage (intervention group n = 26, control group n = 25).</p> <p>After 9 weeks of home monitoring, 6 participants dropped out of the intervention group (3 participants withdrew and 3 died) and 8 dropped out of the control group (4 participants lost to follow-up and 4 died).</p> <p>Final analysis of 37 participants, 20 in intervention group and 17 in control group.</p>
Selective reporting (reporting bias)	Low risk	Study protocol identified; all outcomes reported.
Other bias	Low risk	<p>Trend towards less females, lower CD4 counts and lower Hb (all non-significant) in the intervention group.</p> <p>Nutritional intake from the standard hospital diet was comparable between groups.</p>

Dixon 1984
Study characteristics

Methods	<p>RCT.</p> <p>Parallel design with 4 arms.</p> <p>Duration: 4 months.</p> <p>Location: USA.</p>
Participants	<p>Inclusion criteria: adults with more than 5% weight loss in previous 2 months or persistent change to eating habits or problems interfering with eating, undergoing palliative treatment or chemotherapy for cancer affecting a variety of sites (main sites colorectal (27%) lymphoma (16%).</p> <p>Exclusion criteria: people with breast cancer.</p> <p>Number randomised: 88 participants, 63% of participants completed (23 deaths and 10 dropouts, groups not specified).</p> <p>Gender split: 50 males and 38 females.</p> <p>Age: mean (SD) 59.6 (13.7) years.</p> <p>Nutritional status: mean (SD) number of problems interfering with eating 6.6 (3.4); mean (SD) number of changes to eating patterns 1.6 (1.3).</p>
Interventions	<p>Intervention group 1 participants (n = 9) received <i>dietary advice and ONS</i> in the form of nutritional counselling and a range of nutritional supplements.</p> <p>Intervention group 2 (n = 14): nutritional counselling, nutritional supplements and relaxation training.</p> <p>Intervention group 3 (n = 13): nutritional counselling and relaxation training.</p> <p>Intervention group 4 participants (n = 9) received <i>dietary advice alone</i> in the form of nutritional counselling during bi-weekly visits.</p>

Dixon 1984 (Continued)

Control group participants (n = 10) received *no dietary advice and no ONS* in the form of no home visits.

Intervention groups 1 and 4 and the control group were included in the review.

Outcomes	Survival*, body weight*, TSF*, MAMC*, performance status (Karnofsky scale), subjective evaluation of helpfulness.
Publication details	<p>Language: English.</p> <p>Funding: PHS grant 5R18 CA22619.</p> <p>Publication status: peer-reviewed journal.</p>
Notes	<p>Data from 2 interventions used.</p> <p>1. nutritional counselling versus no dietary advice; and</p> <p>2. nutritional counselling versus nutritional counselling and nutritional supplements.</p> <p>Nutritional counselling provided by nurses</p> <p>No data usable for analysis because data are presented as mean change from desirable weight and change from standard for TSF and analysed using ANOVA. No response received from author.</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Described as randomised, method not stated.
Allocation concealment (selection bias)	Unclear risk	Method not stated.
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	It is not stated whether the outcome assessors were blinded but unlikely that these outcomes would be influenced by lack of blinding.
Blinding (performance bias and detection bias) Functional outcomes	High risk	The trial was unblinded. Functional outcomes could have been influenced by lack of blinding.
Blinding (performance bias and detection bias) Nutritional outcomes	High risk	The trial was unblinded. Nutritional outcomes could have been influenced by lack of blinding.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not blinded and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Judged to be unclear, as low risk for clinical outcomes and high risk for functional and nutritional outcomes.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	63% of participants completed the study. 23 deaths and 10 dropouts, groups not specified therefore insufficient information to judge risk of bias.

Dixon 1984 (Continued)

Selective reporting (reporting bias)	Unclear risk	No study protocol identified, thus unable to judge whether all planned outcomes were reported. All outcomes mentioned in the methods reported. No data usable for analysis because data are presented as mean change from desirable weight and change from standard for TSF and analysed using ANOVA. No response received from author.
Other bias	Unclear risk	Baseline variables not shown, but reported to be statistically equivalent, therefore, insufficient information to make a judgement.

Endevelt 2011
Study characteristics

Methods	<p>RCT.</p> <p>Parallel design with 3 arms.</p> <p>Duration: 6 months.</p> <p>Location: Haifa, Israel</p>
Participants	<p>Inclusion criteria: adults aged 75 and older, community dwelling at nutritional risk ((serum cholesterol below 160 mg/dL or serum albumin below 3.5 mg/dL or total lymphocyte count of less than 1800) AND (MNA-sf below 10 or more than 10% weight loss in 6 months)).</p> <p>Exclusion criteria: diagnosis of cancer or liver disease, clinical depression, cognitive impairment (MMSE < 23) and inability or unwillingness to sign and informed consent.</p> <p>Number randomised: 127 people agreed to participate, 68 participants randomised but 59 people not randomised due to communication and language difficulties or unwillingness to have home visits by a dietitian. Total cohort, n = 127; Group 1, n = 59; Group 2, n = 35; Group 3, n = 33.</p> <p>Gender split: Group 1, 24 male, 35 female; Group 2, 13 male, 22 female; Group 3, 12 male, 21 female.</p> <p>Age: mean (SD) Group 1, 84.5 (5.6) years; Group 2, 84.2 (6.0) years; Group 3, 84.7 (4.7) years.</p> <p>Nutritional status: mean (SD) BMI: Group 1, 27.4 (5.2) kg/m²; Group 2, 27.3 (5.0) kg/m²; Group 3, 27.0 (5.2) kg/m².</p>
Interventions	<p>Intervention group 1: participants received <i>dietary advice plus ONS if required</i> in the form of dietetic intervention treatment where each participant had 5 meetings with the clinic dietitian in their homes over a period of 6 months (baseline, 2 weeks, 1 month, 2 months, 6 months); the intensity varied according to the severity of the undernutrition and the content of the meetings was protocolled.</p> <p>Intervention group 2: advice by the primary care physician and a booklet on nutrition.</p> <p>Intervention group 3: participants received <i>no dietary advice and no ONS</i> in the form of standard care.</p>
Outcomes	MNA, food frequency questionnaire (vitamins, minerals, protein), biochemical measurements, health care costs*, cognition (MMSE), depression (GDS-sf), ADL (Barthel).
Publication details	<p>Language: English.</p> <p>Funding: grant from the National Institute for Health Policy Israel (NIHP).</p> <p>Publication status: peer-reviewed journal.</p>
Notes	The sample size of intervention group 2 was too small according to the sample size calculation.

Endevelt 2011 (Continued)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The procedure of randomisation was not reported. From the 127 individuals who agreed to participate, only 68 participants were randomised to either dietetic intervention or medical intervention. The other 59 individuals were not included in the randomisation process due to communication and language difficulties or unwillingness to have home visits by a dietitian.
Allocation concealment (selection bias)	Unclear risk	Not reported.
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	However, this is unlikely to influence clinical outcomes.
Blinding (performance bias and detection bias) Functional outcomes	High risk	Assessments were performed by trained interviewers. Details on blinding are not reported. The design suggests that the study was unblinded. Functional outcomes could have been influenced by lack of blinding.
Blinding (performance bias and detection bias) Nutritional outcomes	High risk	Assessments were performed by trained interviewers. Details on blinding are not reported. The design suggests that the study was unblinded. Nutritional outcomes could have been influenced by lack of blinding.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not described and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Judged to be unclear because low risk for clinical outcomes and high risk for functional and nutritional outcomes.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Not reported.
Selective reporting (reporting bias)	Low risk	Study protocol identified Clintrials NCT00316966. All specified endpoints reported but not all endpoints were reported in a way that made them usable for meta-analysis.
Other bias	Low risk	Baseline characteristics were similar, except for a trend for higher education in group 1.

Evans 1987
Study characteristics

Methods	RCT. Parallel design with 3 arms. Duration: 12 weeks (all outcomes) and follow-up between 3 and 5 years for survival.
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Evans 1987 (Continued)

Location: Toronto, Canada

Participants	<p>Inclusion criteria: adults receiving chemotherapy for advanced colorectal and non-small-cell lung cancer.</p> <p>Exclusion criteria: obstruction of the superior vena cava, CNS metastases or chronic systemic illness</p> <p>Number randomised: 180 participants, 156 deaths in the 3 study groups.</p> <p>Gender split: 109 males, 71 females.</p> <p>Age: range intervention group 23 - 79 years; control group 33 - 78 years.</p> <p>Nutritional status: more than 5% weight loss at study entry; 46% of participants.</p>
Interventions	<p>Intervention 1: participants (n = 51) received <i>dietary advice plus ONS if required</i> in the form of nutritional counselling to achieve a target caloric intake (using supplements if required).</p> <p>Intervention 2 (n = 60): nutritional counselling to achieve target caloric intake but including 25% of calories as protein (using food and protein supplements) plus a supplement of zinc and magnesium.</p> <p>Control: participants (n = 69) received <i>no dietary advice and no ONS</i> in the form of <i>ad lib</i> food intake.</p>
Outcomes	Body weight, energy intake, mortality*, tumour response to chemotherapy.
Publication details	<p>Language: English.</p> <p>Funding: not declared.</p> <p>Publication status: peer-reviewed journal.</p>
Notes	<p>Data from only the first intervention group and the control group (120 participants) will be used:</p> <ol style="list-style-type: none"> 1. nutritional counselling to achieve target caloric intake 2. ad lib food intake.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation was performed using a central office. Participants were stratified and randomisation blocked.
Allocation concealment (selection bias)	Low risk	Allocation was concealed by using a central office.
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	<p>Although not mentioned, the trial was likely unblinded, due to the nature of the intervention. However, this is unlikely to influence clinical outcomes</p> <p>Judged to be unclear because low risk for clinical outcomes and high risk for functional and nutritional outcomes</p>
Blinding (performance bias and detection bias) Functional outcomes	High risk	We assume the trial was unblinded. Functional outcomes could have been influenced by lack of blinding.
Blinding (performance bias and detection bias) Nutritional outcomes	High risk	We assume the trial was unblinded. Nutritional outcomes could have been influenced by lack of blinding.

Evans 1987 (Continued)

Blinding of participants and personnel (performance bias) All outcomes	High risk	Follow-up assessments were performed by the study dietitian either in person or by telephone. We assume this was not blinded and it is likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Judged to be unclear because low risk for clinical outcomes and high risk for functional and nutritional outcomes.
Incomplete outcome data (attrition bias) All outcomes	Low risk	156 deaths in the 3 study groups: 88 due to lung cancer and 68 due to colorectal cancer; 94/111 (85%) in both intervention groups combined and 62/69 (90%) in the control group.
Selective reporting (reporting bias)	Unclear risk	No study protocol identified, thus unable to judge whether all planned outcomes were reported. Data presented as median % change and therefore not in a usable format and author unable to supply data.
Other bias	Low risk	Baseline variables stated, groups similar at baseline.

Feldblum 2011
Study characteristics

Methods	<p>RCT.</p> <p>Parallel design with 3 arms.</p> <p>Duration: 6 months intervention and 3 months follow-up.</p> <p>Location: Israel.</p>
Participants	<p>Inclusion criteria: adults aged 65 and older admitted to internal medicine department with a positive malnutrition screening score (MNA-sf or > 10% weight loss in 6 months).</p> <p>Exclusion criteria: a current diagnosis of cancer, cognitive impairment (MMSE score < 23), an inability to be interviewed, language difficulties, or an unwillingness to provide informed consent.</p> <p>Number randomised: 259 participants.</p> <p>Gender split: 113 males, 146 females.</p> <p>Age: mean (SD) intervention 1, 75.3 (5.8) years; intervention 2, 75.2 (5.6) years; control 75.1(5.8) years.</p> <p>Nutritional status: mean (SD) MNA score, intervention 1, 19.3 (2.3); intervention 2, 19.7 (2.3); control 19.4 (2.9).</p>
Interventions	<p>Intervention 1: participants received <i>dietary advice plus ONS if required</i> in the form of individualised nutritional treatment from a dietitian in the hospital and 3 home visits (1 week, 1 month and 1 month after discharge).</p> <p>Intervention 2: participants received <i>no dietary advice and no ONS</i> in the form of 1 meeting with a dietitian in the hospital.</p> <p>Control: participants received <i>no dietary advice and no ONS</i> in the form of standard care.</p> <p>Groups 2 and 3 were combined into a single group that served as the control group in the analysis.</p>

Feldblum 2011 (Continued)

Outcomes MNA, weight, albumin, total lymphocyte count, haemoglobin, transferrin, total cholesterol, nutritional intake (energy, carbohydrate, fat, protein), ADL (Barthel Index), depression (GDS), cognition (MMSE), mortality.

Publication details **Language:** English.

Funding: the Israel National Institute for Health Policy and Health Services Research.

Publication status: peer-reviewed journal.

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	The intervention groups were allocated according to month and ward of hospitalization, with an equal proportion of winter and summer months being maintained. In each month, the internal medicine departments were randomly assigned a treatment group.
Allocation concealment (selection bias)	High risk	Not concealed. Participants who were admitted to these departments were given the assigned treatment of that month.
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	Trained interviewers blinded to treatment group allocation performed the measurements.
Blinding (performance bias and detection bias) Functional outcomes	Low risk	Trained interviewers blinded to treatment group allocation performed the measurements.
Blinding (performance bias and detection bias) Nutritional outcomes	Low risk	Trained interviewers blinded to treatment group allocation performed the measurements.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not blinded and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Trained interviewers blinded to treatment group allocation performed the measurements.
Incomplete outcome data (attrition bias) All outcomes	High risk	The overall dropout rate (people who refused the 6-month visit) was 25.8%. The main causes for withdrawal were subjective health deterioration and 'not feeling good'. The attrition was not balanced between groups (intervention group: 11.5% and control group: 32%)
Selective reporting (reporting bias)	Unclear risk	No study protocol identified, thus unable to judge whether all planned outcomes were reported.
Other bias	Low risk	Baseline results were similar between groups, except from educational level. This was lower in the control group.

Fernandez-Barres 2017
Study characteristics

Methods	<p>RCT.</p> <p>Duration: 12 months.</p> <p>Location: multicentre in Spain.</p>
Participants	<p>Inclusion criteria: participation in Home Care Program, over 65 years, MNA score 17 - 23.5, difficulty performing ADLs.</p> <p>Exclusion criteria: MNA score outside the range specified, enteral feed, severe dysphagia, serious illness that progresses to malnutrition, taking vitamin or mineral supplements.</p> <p>Diagnosis: older people receiving Home Care.</p> <p>Number randomised: 173 (intervention group n = 101, control group n = 72). Attrition fully described, intervention group 30/101 (38%), control group 24/72 (33%).</p> <p>Gender split: 32% male, 68% female.</p> <p>Age: mean (SD): intervention group 84.3 (6.7) years; control group 85.4 (7.6) years.</p> <p>Nutritional status: BMI mean (SD): intervention group 27 (5) kg/m²; control group 26.9 (6.3) kg/m².</p>
Interventions	<p>Intervention group: participants received <i>dietary advice</i> in the form of individual and group sessions for carers and further individual dietary monitoring of participants in the presence of caregivers.</p> <p>Control group: participants received <i>no dietary advice</i> in the form of routine care from nurses and doctors.</p>
Outcomes	<p>Mortality, MNA (3 dimensions), weight, BMI, MUAC, calf circumference, food intake (12 groups), biochemical status, dependency (Barthel), cognitive function (Pfeiffers test), mood (Yesavage Depression scale).</p> <p>Caregiver knowledge also assessed.</p>
Publication details	<p>Language: English.</p> <p>Funding: Instituto Salud, Madrid & Generalitat de Catalunya, Barcelona.</p> <p>Publication status: peer-reviewed journal.</p>

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	<p>Quote: "Subjects were classified randomly, individually and stratified by Primary Health Care Centre. From a common database subjects were computer-assigned to the intervention group and non-intervention group."</p> <p>Judgement: implies computer used to facilitate random assignment, but poorly described.</p>
Allocation concealment (selection bias)	Low risk	<p>Judgement: implies computer used to allocate groups, but poorly described.</p>

Fernandez-Barres 2017 (Continued)

Blinding (performance bias and detection bias) Clinical outcomes	Low risk	<p>Quote: "participants, nurses and researchers were not blinded because of the practical impossibilities" but unlikely that assessment of clinical outcomes would be influenced by lack of blinding.</p> <p>Quote: Lab technicians analysing biochemical parameters were blinded to group assignment but these outcomes are not included in the review.</p>
Blinding (performance bias and detection bias) Functional outcomes	High risk	<p>Quote: "participants, nurses and researchers were not blinded because of the practical impossibilities", and it is likely that assessment of this outcome would be influenced by lack of blinding.</p>
Blinding (performance bias and detection bias) Nutritional outcomes	High risk	<p>Quote: "participants, nurses and researchers were not blinded because of the practical impossibilities", and it is likely that assessment of this outcome would be influenced by lack of blinding.</p>
Blinding of participants and personnel (performance bias) All outcomes	High risk	<p>Not blinded and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding.</p>
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	<p>No blinding for the majority of outcomes assessed and likely that assessment of some outcomes would be influenced by lack of blinding.</p>
Incomplete outcome data (attrition bias) All outcomes	Low risk	<p>Fully described. Intervention group 30/101(38%); control group 24/72 (33%).</p> <p>Reasons: mortality n = 12 (intervention group n = 10, control group n = 2), withdrew n = 7 (intervention group n = 1, control group n = 6), institutionalisation or hospitalisation n = 9 (intervention group n = 5, control group n = 4).</p>
Selective reporting (reporting bias)	Low risk	<p>Protocol identified on Clinicaltrials.gov. All primary outcomes described in the protocol are reported and several secondary outcomes. Continuous data reported as mean at baseline and end of intervention. Mean change requested from the author.</p>
Other bias	Low risk	<p>Groups well balanced at baseline for all characteristics.</p>

Forli 2001
Study characteristics

Methods	<p>RCT.</p> <p>Parallel design with 2 arms.</p> <p>Duration: 10 - 18 days.</p> <p>Location: Norway.</p>
Participants	<p>Inclusion criteria: adults with end-stage lung disease awaiting transplantation; all participants malnourished defined as BMI < 18.7 kg/m².</p> <p>Exclusion criteria: people with cystic fibrosis, pulmonary hypertension or with BMI over 25 kg.m².</p> <p>Number randomised: 37 participants; intervention group, n = 20; control group, n = 22. Attrition: 2 participants withdrew from each group.</p> <p>Gender split: 18 males, 19 females.</p>

Forli 2001 (Continued)

Age: mean (range) intervention group, 49 (44 - 53) years; control group, 48 (44 - 52) years.

Nutritional status: mean (95% CI) BMI intervention group, 17.5 (16.8 - 18.3) kg/m²; control group, 17.0 (16.1 - 17.9) kg/m².

Interventions	<p>Intervention: participants received <i>dietary advice plus ONS if required</i> in the form of dietary advice to take an energy-rich diet and supplements if wanted.</p> <p>Control: participants received <i>no dietary advice and no ONS</i> in the form of normal hospital diet.</p>
Outcomes	Survival*, weight*, BMI, TSF*, MAMC*, MUAC*, respiratory function*.
Publication details	<p>Language: English.</p> <p>Funding: not declared.</p> <p>Publication status: peer-reviewed journal.</p>
Notes	Additional data and information on quality obtained from authors.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Described in the paper as using random number tables.
Allocation concealment (selection bias)	Unclear risk	Allocation concealment is not described.
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	Stated in the paper as assessed blind to intervention group. Quote: None of the investigators who performed the measurements was aware of the group allocation, apart from the dietitian who, for practical reasons, was responsible for assessments of dietary intake, allocation of dietary counselling, measurements of weight, skinfold and hand grip strength. When food records prior to the first hospital stay were made, everyone was blinded to group affiliation.
Blinding (performance bias and detection bias) Functional outcomes	High risk	All assessments of nutritional status performed by the study dietitian who was not blinded to intervention group.
Blinding (performance bias and detection bias) Nutritional outcomes	High risk	All assessments of nutritional status performed by the study dietitian who was not blinded to intervention group.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not blinded and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Judged to be unclear because low risk for clinical and functional outcomes and high risk for nutritional outcomes.
Incomplete outcome data (attrition bias) All outcomes	Low risk	2 participants withdrew from each group, the reasons for withdrawals are clearly stated.
Selective reporting (reporting bias)	Unclear risk	No study protocol identified. Data not reported for clinical and functional outcomes (secondary outcomes), but stated as not significantly different. Data on

Forli 2001 (Continued)

weight reported as median change with no SD, therefore mean change (SD) obtained from author. Data on energy intake reported as median intake KJ/kg therefore obtained from authors.

Other bias	Unclear risk	Baseline variables given, but one assessment of lung function was significantly different.
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Forster 2012
Study characteristics

Methods	<p>RCT.</p> <p>Parallel design with 3 treatment arms.</p> <p>Duration: total 6 months - intervention 3 months and follow-up 3 months.</p> <p>Location: UK.</p>
Participants	<p>Inclusion criteria: adults aged 65 - 85 years, living in the community, no history of hospitalisation in the previous year, self-reported daily fruit and vegetable intake less than 3 portions.</p> <p>Exclusion criteria: use of micronutrient or fish oil supplements in the last 3 months, active GI disease, malabsorption, previous gastric surgery, BMI < 18 kg/m², psychiatric illness, unable to understand, ID-DM or illness known to influence immune status.</p> <p>Diagnosis: chronic diseases mean (SD) 2.6 (1.6), prescribed medications 4 (2.9).</p> <p>Number randomised: 217 participants randomised (intervention group 1, n = 73; intervention group 2, n = 73; control group, n = 71). Attrition: total 8 (intervention group 1, n = 1; intervention group 2, n = 3; control group, n = 4).</p> <p>Gender split: intervention group 1, 57.5% males; intervention group 2, 45.2% males; control group, 43.7% males.</p> <p>Age: mean (SD) intervention group 1, 72.5 (5) years; intervention group 2, 72.6 (5.2) years; control group, 72.6 (5.5) years.</p> <p>Nutritional status: BMI mean (SD), intervention group 2, 8.0 (4.4) kg/m²; control group, 29.2 (5.7) kg/m².</p>
Interventions	<p>Intervention 1: participants received <i>dietary advice</i> in the form of provision of a selection of foods designed to meet individualised prescription to include 5 portions fruit and vegetables per day, whole grain bread, fish 2x weekly and nuts at least once a week.</p> <p>Intervention 2: micronutrient supplement.</p> <p>Control: participants received <i>no dietary advice</i> in the form of placebo micronutrient supplement and no dietary advice.</p>
Outcomes	<p>Self-reported infections (symptom diary), nutritional biochemistry, dietary intake, weight, BMI, MAC, TSF, QoL (SF-36), GDS.</p>
Publication details	<p>Language: English.</p> <p>Funding: UK Food Standards Agency and some funding to one author from Nutricia.</p> <p>Publication status: peer-reviewed journal.</p>

Forster 2012 (Continued)

Notes Intervention group 1 and control used in the review.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "computer-generated block randomization was used". Stratified according to age.
Allocation concealment (selection bias)	Low risk	Quote: "a distant email randomization service was used to assign treatment group & study number".
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	Only one clinical outcome (self-reported infections); judged to have adequate blinding. Quote: "study physician who was blinded to randomisation" interpreted information provided in the symptom diaries. The principal investigator, lab staff and statistician were blinded to group allocation.
Blinding (performance bias and detection bias) Functional outcomes	Unclear risk	Functional outcomes: QoL and GDS. Insufficient information on how these data were collected but likely that they could be influenced by lack of blinding.
Blinding (performance bias and detection bias) Nutritional outcomes	High risk	No information available on who measured nutritional outcomes, dietary intake, weight, BMI, MAC, TSF but likely that lack of blinding could have influenced assessment of some.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants aware of the intervention and possible for participants in other groups to obtain the intervention. Quote: Partial blinding achieved with micronutrient supplement but not possible to blind participants or study researchers to dietary intervention. It is possible that assessment of some outcomes was influenced by lack of blinding
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information available on who measured nutritional outcomes, dietary intake, weight, BMI, MAC, TSF, therefore not possible to make a judgement. Quote: "the researcher responsible for implementation of the intervention was aware of treatment allocation but laboratory personnel, principal investigators and trial statistician were all blinded to participants identity and group allocation until completion of analyses".
Incomplete outcome data (attrition bias) All outcomes	Low risk	Fully reported. 5 participants withdrew, 1/73 (0.01%) from the advice group and 4/71 (0.06%) from the no advice group.
Selective reporting (reporting bias)	Low risk	Reported outcomes checked against the protocol. All outcomes other than immune function included in this paper. Author contacted for more information. Response indicated that immune function outcomes will be reported in a separate paper.
Other bias	Unclear risk	At baseline intervention group 1 (food group) had a significantly higher alcohol intake than the micronutrient group or control group, otherwise groups were well balanced for all characteristics. Judged as unclear because it is not possible to judge the impact that this might have had on the outcomes assessed

Fuenzalida 1990
Study characteristics

Methods	<p>RCT.</p> <p>Parallel design with 2 treatment arms.</p> <p>Duration: 42 days total (21 days in hospital and 21 days at home).</p> <p>Location: single centre in the USA.</p>
Participants	<p>Inclusion criteria: adults with COPD with FEV₁ 30% - 50% of predicted and more than 5% weight loss, mean (SD) % IBW at study entry 78.5% (9.6%).</p> <p>Exclusion criteria: not living in the area of the study, medical problems confounding thier nutritional or lung status, home oxygen therapy, cancer, use of oral corticosteroids, alcoholism, previous lobectomy, dementia, azotemia, CVD, liver disease, nonambulatory, chemotherapy use, interstitial lung disease, pneumonia in the past month, diabetes, malabsorption, use of ONS, and intestinal resection.</p> <p>Number randomised: 9 participants (intervention group, n = 4, control group, n = 5).</p> <p>Gender split: all males.</p> <p>Age: mean (SD) 62.4 (5.6) years.</p> <p>Nutritional status: per cent (SD) loss of usual weight in previous year 8.3 (1.54) %.</p>
Interventions	<p>Intervention: participants received <i>dietary advice and ONS</i> in the form of individually planned diet and 1080 kcal of a nutritional supplement.</p> <p>Control: participants received <i>dietary advice alone</i> in the form of individualised diet planned by dietitian to provide 100% of recommended daily intake.</p>
Outcomes	<p>Survival*, weight*, BMI*, TSF*, MAMC*, MUAC*, energy intake*, measures of pulmonary function (FEV₁*), measures of immune function.</p>
Publication details	<p>Language: English.</p> <p>Funding: grant from the National Institute of Arthritis, Metabolism, Kidney and Digestive Diseases and grant from the National Institutes of Health.</p> <p>Publication status: peer-reviewed journal.</p>

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Described as randomised but method not stated.
Allocation concealment (selection bias)	Unclear risk	Method not stated.
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	Not reported, but must have been an unblinded trial due to the nature of the intervention. However, this is unlikely to have influenced clinical outcomes.
Blinding (performance bias and detection bias) Functional outcomes	High risk	Not reported, but must have been an unblinded trial due to the nature of the intervention. Functional outcomes could have been influenced by lack of blinding.

Fuenzalida 1990 (Continued)

Blinding (performance bias and detection bias) Nutritional outcomes	Unclear risk	Not reported, but must have been an unblinded trial due to the nature of the intervention. Nutritional outcomes could have been influenced by lack of blinding.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not described and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Judged to be unclear as low risk for clinical outcomes and high risk for functional and nutritional outcomes.
Incomplete outcome data (attrition bias) All outcomes	Low risk	No losses occurred during the study.
Selective reporting (reporting bias)	Unclear risk	No study protocol identified, thus unable to judge whether all planned outcomes were reported. Outcomes reported not in a format suitable for direct entry into a meta-analysis. Data in the paper on weight have been used to derive mean change (SD). Information on study quality obtained from authors.
Other bias	Low risk	Baseline variables given, groups similar at baseline.

Ganzoni 1994
Study characteristics

Methods	<p>RCT.</p> <p>Parallel design with 2 treatment arms.</p> <p>Duration: 12 months.</p> <p>Location: Germany.</p>
Participants	<p>Inclusion criteria: adults with COPD.</p> <p>Exclusion criteria: not reported/translated.</p> <p>Number randomised: 29 participants (intervention group, n = 15, control group, n = 14). 20 participants completed the study, there were 5 deaths (3 in the intervention group and 2 in the control group), 3 participants could not be followed up at 12 months and 1 participant did not have a baseline assessment completed (information provided by author).</p> <p>Gender split: not reported/translated.</p> <p>Age: average age 66 years.</p> <p>Nutritional status: body weight: average 52 kg (range 38 - 68 kg); lung function (FEV₁): average 0.81 (range 0.4 - 1.51).</p>
Interventions	<p>Intervention: participants (n = 15) received <i>dietary advice plus ONS if required</i> in the form of nutritional counselling to use a high-calorie diet using a variety of methods including nutritional supplements if required.</p> <p>Control: participants (n = 14) received <i>no dietary advice and no ONS</i> in the form of no individual nutritional counselling. Participants may have attended a group session where diet was discussed.</p>

Ganzoni 1994 (Continued)

Outcomes	Body weight*, 4-site skinfold measurements (summed), survival*, energy intake*, respiratory function (FEV ₁ * and 6-minute walking distance).	
Publication details	Language: German. Funding: not declared. Publication status: peer-reviewed journal.	
Notes	Additional data and information on quality obtained from authors.	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Information obtained from author, randomisation performed using a table of random numbers.
Allocation concealment (selection bias)	Low risk	Information from the author, a person not involved in the study administered the random allocation.
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	Information obtained from author confirmed blind assessment of outcomes.
Blinding (performance bias and detection bias) Functional outcomes	Low risk	Information obtained from author confirmed blind assessment of outcomes.
Blinding (performance bias and detection bias) Nutritional outcomes	Low risk	Information obtained from author confirmed blind assessment of outcomes.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not described and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	All outcome assessments were blinded.
Incomplete outcome data (attrition bias) All outcomes	Low risk	20 participants completed the study, there were 5 deaths, 3 in the intervention group and 2 in the control group and an additional 4 participants had missing assessment information.
Selective reporting (reporting bias)	Unclear risk	No study protocol identified, thus unable to judge whether all planned outcomes were reported. Outcomes reported but not in a format suitable for entry into meta-analysis. Data on mortality obtained from the author as the detail in the paper was unclear. Data on mean change for weight are reported without a SD and therefore the original data have been obtained from the authors. Data on energy intake are reported as mean and range with no SD at baseline and end of follow-up. Data requested from authors but no detail available.
Other bias	Unclear risk	Baseline variables not given, and not known if groups similar at baseline.

Gonzalez-Espinoza 2005
Study characteristics

Methods	<p>RCT.</p> <p>Parallel design with 2 treatment arms.</p> <p>Duration: 6 months.</p> <p>Location: single centre in Mexico.</p>
Participants	<p>Inclusion criteria: adults receiving continuous peritoneal dialysis for at least 1 month.</p> <p>Exclusion criteria: peritonitis within 6 weeks of the study, allergy to egg albumin, decompensated heart failure, nephrotic syndrome, liver disease, malabsorption, cancer or AIDS.</p> <p>Number randomised: 30 participants. 28 in final study group (intervention group n = 13; control group n = 15), as 2 participants not included in the intervention group because of a deterioration in health.</p> <p>Gender split: 19 males and 9 females.</p> <p>Age: mean (SD) intervention group 45.7 (14.4) years; control group 47.6 (17.4) years.</p> <p>Nutritional status: all participants malnourished according to SGA.</p>
Interventions	<p>Intervention group: participants received <i>dietary advice and ONS</i> in the form of nutritional counselling plus a dried egg-albumin-based supplement added to milk or sprinkled on food.</p> <p>Control group: participants received <i>dietary advice alone</i> in the form of nutritional counselling alone.</p>
Outcomes	Survival, weight*, energy intake* BMI, MAMC*, TSF* hospital admission.
Publication details	<p>Language: English.</p> <p>Funding: partially funded by a grant from Laboratorios Pisa, SA de CV, Guadalajara, Mexico.</p> <p>Publication status: peer-reviewed journal.</p>
Notes	Information on nutritional supplement from www.inovaalimentos.com/#Ultrashock

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random numbers table.
Allocation concealment (selection bias)	Low risk	Performed by a person external to the study once the individual had provided informed consent.
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	Information from author, outcomes assessed blinded to intervention.
Blinding (performance bias and detection bias) Functional outcomes	Low risk	Information from author, outcomes assessed blinded to intervention.
Blinding (performance bias and detection bias) Nutritional outcomes	Low risk	Information from author, outcomes assessed blinded to intervention.

Gonzalez-Espinoza 2005 (Continued)

Blinding of participants and personnel (performance bias) All outcomes	High risk	Not blinded and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Information from author, outcomes assessed blinded to intervention.
Incomplete outcome data (attrition bias) All outcomes	Low risk	2 of 15 participants in the dietary advice and supplements group were not included in the analysis because of deterioration in health.
Selective reporting (reporting bias)	Unclear risk	No study protocol identified, thus unable to judge whether all planned outcomes were reported. Outcomes reported not in a format suitable for entry into meta-analysis. Data on change in weight, energy intake, TSF and MAMC are presented as mean (SD) at baseline and at end of intervention. Data on mean change (SD) from baseline were obtained from the authors for weight, energy and MAMC. SDs for change in TSF were imputed. Data on hospital admissions obtained from the authors.
Other bias	Low risk	Baseline characteristics reported, groups similar at baseline.

Gray-Donald 1995
Study characteristics

Methods	<p>RCT.</p> <p>Parallel design with 2 treatment arms.</p> <p>Duration: 12 weeks.</p> <p>Location: Canada.</p>
Participants	<p>Inclusion criteria: elderly people living at home at nutritional risk (defined as the presence of 2 of the following conditions) (i) involuntary weight loss of over 5% in last month, over 7.5% in last 3 months, over 10% in last 6 months and (ii) BMI < 27 or BMI < 24.</p> <p>Exclusion criteria: receiving palliative care, alcoholic, cancer, with any illness requiring a therapeutic diet not compatible with nutritional supplementation.</p> <p>Number randomised: 50 participants (intervention group, n = 25; control group, n = 25). 4 deaths, 3 in the intervention group and 1 in the control group.</p> <p>Gender split: intervention group 26% males; control group 33% males.</p> <p>Age: mean 78 years.</p> <p>Nutritional status: BMI mean (SD), intervention group 19 (3) kg/m²; control group 19 (3) kg/m².</p>
Interventions	<p>Intervention (group 1): participants received <i>ONS</i> in the form of weekly visits from a dietitian and 2 x 235 mL of a nutritional supplement.</p> <p>Intervention (group 2): participants received <i>dietary advice</i> in the form of weekly visits from a dietitian with dietary counselling.</p>

Gray-Donald 1995 (Continued)

Outcomes Survival*, body weight*, MAMC*, MUAC skinfold (triceps*, subscapular, suprailliac), energy intake*, handgrip strength*, perception of health, general well-being score, number of falls.

Publication details **Language:** English.

Funding: National Health Research & Development Program, Health Canada.

Publication status: peer-reviewed journal.

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "separate randomization lists were prepared for each group by a person outside the study". Insufficient information on how sequence was generated.
Allocation concealment (selection bias)	Low risk	Information from author indicates that sealed envelopes were used.
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	Clinical outcomes assessed blinded to group allocation. Quote: "the other research dietitian, who was unaware of the subject's treatment, completed measurements of functional and health status outcomes.
Blinding (performance bias and detection bias) Functional outcomes	Low risk	Functional outcomes assessed blinded to group allocation. Quote: "the other research dietitian, who was unaware of the subject's treatment, completed measurements of functional and health status outcomes.
Blinding (performance bias and detection bias) Nutritional outcomes	High risk	Quote: "one research dietitian was responsible for recruitment, collection of baseline data and follow-up nutritional data". Assessment not blinded to group allocation and might have been influenced by lack of blinding.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not blinded and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Some outcomes collected without blinding of group allocation and lack of blinding might have affected the assessment of these outcomes.
Incomplete outcome data (attrition bias) All outcomes	Low risk	4 deaths, 3/25 (12%) in the supplement group and 1/25 (4%) in the dietary counselling group. Fully reported with reasons and similar between groups.
Selective reporting (reporting bias)	Unclear risk	No protocol identified. All outcomes specified in the methods reported and data on mortality, change in weight, TSF, MAMC were extracted from the paper. Data on energy intake are presented as mean change in daily intake averaged over 3 months, therefore mean change (SD) from baseline to 3 months has been obtained from the authors. Data on grip strength are presented as a mean (SD) at baseline and at end of intervention, therefore mean change (SD) obtained from the author.
Other bias	Unclear risk	Baseline variables given, participants reporting a good appetite was significantly better in advice group than supplement group.

Gu 2015
Study characteristics

Methods	<p>Quasi-RCT.</p> <p>Parallel design with 2 treatment arms.</p> <p>Duration: length of hospitalisation.</p> <p>Location: China.</p>
Participants	<p>Inclusion criteria: aged 18 - 80 years, able to give consent, hospitalised for longer than 5 days.</p> <p>Exclusion criteria: severe liver and kidney disease, expected life expectancy of > 1 month, receiving enteral or parenteral nutrition.</p> <p>Diagnosis: mixed clinical backgrounds.</p> <p>Number randomised: 148 participants (intervention group, n = 73; control group, n = 75); no attrition reported.</p> <p>Gender split: 92 (62%) males, 56 (38%) females.</p> <p>Age: mean (SD) total cohort 63.6 (13.7) years; intervention group 64.6 (1.5) years; control group 62.7 (1.6) years.</p> <p>Nutritional status: all at nutritional risk assessed by NRS-2002.</p>
Interventions	<p>Intervention group: participants received <i>dietary advice</i> in the form of regular care and treatment plus individualised nutritional support*.</p> <p>Control group: participants received <i>no dietary advice</i> in the form of regular care and treatment.</p> <p>*Requirements assessed using Harris Benedict formula, intake below 75% of requirements for energy and protein resulted in 3 different dietary interventions to promote increased food intake (education, tailoring of food provision to meet individual preferences and provision of snacks).</p>
Outcomes	<p>Energy and protein intake (total intake and % achieving requirements), weight, complications (infectious and severe), length of stay, cost (hospital expenses).</p>
Publication details	<p>Language: Chinese.</p> <p>Funding: The State's scientific advancement program (Wenzhou State Science & Technology Programme fund (Y20120030)).</p> <p>Publication status: peer-reviewed journal.</p>
Notes	<p>Translation completed.</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Quote: "Patients at nutritional risk on hospital admission were assigned a number based on time of admission. Patients with odd numbers were placed in the control group; patients with even numbers were placed in the intervention group."
Allocation concealment (selection bias)	Unclear risk	Insufficient information to make a judgement.

Gu 2015 (Continued)

		Quote: "the researchers/risk assessors were blinded and had no knowledge of the arrangement of patient's numbers"
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	Blinding of study personnel implied. Quote: "the researchers/risk assessors were blinded and had no knowledge of the arrangement of patient's numbers". This outcome is unlikely to be affected by blinding.
Blinding (performance bias and detection bias) Functional outcomes	Unclear risk	Functional outcomes not measured.
Blinding (performance bias and detection bias) Nutritional outcomes	Low risk	Food intake assessed by dietary recall and blinding of study personnel implied. Judged to be unclear, as awareness of group allocation and study aims might influence how the participants recall intake. Quote: "the researchers/risk assessors were blinded and had no knowledge of the arrangement of patient's numbers".
Blinding of participants and personnel (performance bias) All outcomes	High risk	Blinding of personnel implied but because this is a dietary intervention it is not possible to blind participants. It is possible that assessment of some outcomes was influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Blinding of outcome assessment. Quote: "the researchers/risk assessors were blinded and had no knowledge of the arrangement of patient's numbers".
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No attrition reported, therefore insufficient information to make a judgement.
Selective reporting (reporting bias)	Unclear risk	No protocol identified. All outcomes discussed in the methods section are fully reported in the results.
Other bias	Low risk	Baseline characteristics compared and groups similar for all elements with the exception of gender. More males than females included but this is unlikely to affect the outcomes assessed.

Hampson 2003
Study characteristics

Methods	<p>RCT.</p> <p>Parallel design with 2 treatment arms.</p> <p>Duration: 12 months.</p> <p>Location: UK.</p>
Participants	<p>Inclusion criteria: adult women with osteoporosis at the femoral neck and or total hip and a low BMI (≤ 21 kg/m²).</p> <p>Exclusion criteria: evidence of any progressive wasting disease, severe renal impairment, cardiorespiratory disease, endocrine disease, drug therapy known to interfere with bone metabolism.</p>

Hampson 2003 (Continued)

Number randomised: 71 participants (intervention group, n = 36; control group, n = 35). 6 participants withdrew from the study (5 in the intervention group and 1 in control group).

Gender split: all female.

Age: mean (SD) intervention group 76 (4.2) years; control group 76.7 (5.7) years.

Nutritional status: BMI mean (SD), intervention group 19.9 (1.9) kg/m²; control group 20.7 (1.8) kg/m².

Interventions	<p>Intervention group: participants received <i>dietary advice and ONS</i> in the form of dietary advice to increase intake and 2x 200mL supplement (Nutricia) plus 1 g calcium and 800 units cholecalciferol.</p> <p>Control group: participants received <i>no dietary advice and no ONS</i> in the form of no dietary advice plus 1 g calcium and 800 units cholecalciferol.</p>
Outcomes	Survival*, weight*, bone mineral density, fat mass, lean mass, energy intake*.
Publication details	<p>Language: English.</p> <p>Funding: the medical charity Action Research. Nutricia Clinical Care, Nutricia Ltd and Shire Pharmaceuticals Ltd provided the nutritional and calcium/vitamin D supplements.</p> <p>Publication status: peer-reviewed journal.</p>
Notes	Additional data on outcomes requested from author.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Random sequence generated in a department external to the study (Department of Public Health).
Allocation concealment (selection bias)	Low risk	Sealed envelopes.
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	Not stated, but we assume the trial was unblinded given the nature of the intervention. However, this is unlikely to influence clinical outcomes
Blinding (performance bias and detection bias) Functional outcomes	High risk	Not stated, but we assume the trial was unblinded. Functional outcomes could have been influenced by lack of blinding.
Blinding (performance bias and detection bias) Nutritional outcomes	High risk	Not stated, but we assume the trial was unblinded. Nutritional outcomes could have been influenced by lack of blinding.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not described and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Judged to be unclear because low risk for clinical outcomes and high risk for functional and nutritional outcomes.
Incomplete outcome data (attrition bias) All outcomes	Low risk	6/71 (8%) participants did not complete the study; 5/36 (14%) in the dietary advice and supplement group and 2/35 (6%) in the control group.

Hampson 2003 (Continued)

Selective reporting (reporting bias)	Unclear risk	No study protocol identified, thus unable to judge whether all planned outcomes were reported. Outcomes reported not in a format suitable for entry into meta-analysis. Data on energy intake reported as mean (SD) for groups at baseline and end of intervention, therefore mean change data obtained from the authors. Data on weight change reported as % change. Data requested from authors but not received.
Other bias	Unclear risk	Baseline variables given, treatment group were significantly lighter and had lower fat mass than the control group.

Hernandez 2014
Study characteristics

Methods	<p>RCT.</p> <p>Parallel design with 2 treatment arms.</p> <p>Duration: 4 months (intervention and follow-up).</p> <p>Location: Spain.</p>
Participants	<p>Inclusion criteria: over 18 years of age, receiving haemodialysis for more than 6 months, stable haemodynamic condition.</p> <p>Exclusion criteria: transfer to another haemodialysis unit, renal drug therapy that would interfere with plasma metabolite concerns, cognitive impairment or psychiatric disorder, active inflammatory or infectious disease, pregnancy or hospitalisation.</p> <p>Diagnosis: end-stage kidney failure, undergoing haemodialysis.</p> <p>Number randomised: 120 randomised (intervention group, n = 60; control group, n = 60). Attrition: 33 (28%) participants, 87 participants completed.</p> <p>Gender split: (for the 87 completing the study) intervention group 37 males and 17 females; control group 20 males and 13 females.</p> <p>Age: mean (SD) intervention group 70 (2) years; control group 72 (2) years.</p> <p>Nutritional status: (assessed as % with serum albumin below 3.5 g/dL) intervention group, n = 31 (57%); control group, n = 19 (57%).</p>
Interventions	<p>Intervention (intervention group 1): participants received <i>dietary advice</i> in the form of 12-session education program (weekly for 2 months and fortnightly for the next 2 months) on a range of nutrition topics inline with National Kidney Foundation guidelines.</p> <p>Control (intervention group 2): participants received <i>ONS</i> in the form of 470 mL Nepro taking during dialysis or at home if full amount not tolerated.</p>
Outcomes	Biochemical (large range of serum biochemistry), % malnourished (albumin status), nutrition knowledge.
Publication details	<p>Language: English.</p> <p>Funding: grant from the Catholic University of Murcia (a member of the private Fresenius Medical Care Clinic).</p> <p>Publication status: peer-reviewed journal.</p>

Hernandez 2014 (Continued)

Notes No data reported on outcomes of interest for this review.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: randomization was performed through a computer-generated number sequence.
Allocation concealment (selection bias)	Low risk	Quote: the number sequence was concealed from the researchers until after baseline assessment.
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	Not described but unlikely that assessment of clinical outcomes would be influenced by lack of blinding.
Blinding (performance bias and detection bias) Functional outcomes	Unclear risk	Not described but no functional outcomes assessed.
Blinding (performance bias and detection bias) Nutritional outcomes	High risk	Not described and likely that assessment of some nutritional outcomes would be influenced by lack of blinding.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not described and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not described and likely that assessment of some outcomes would be influenced by lack of blinding.
Incomplete outcome data (attrition bias) All outcomes	High risk	Attrition fully reported. 33 (28%) participants dropped out of the study; 6 (10%) of 60 in the dietary advice group and 27 (45%) of 60 in the ONS group. Significantly more participants withdrew from the ONS group (n = 20 (33%)) compared with the dietary advice group (n = 0) because of unwillingness to continue with the study, and the imbalance might have influenced outcome assessment.
Selective reporting (reporting bias)	Unclear risk	No protocol identified. All outcomes discussed in the methods section are fully reported in the results.
Other bias	Unclear risk	Baseline characteristics compared between groups remaining in the study. Statistically significant differences between total serum protein and creatinine (significantly higher in supplement group). No significant differences for knowledge or serum biochemistry between those who remained in the study and those that dropped out. The influence of these differences on outcomes unclear.

Holyday 2012
Study characteristics

Methods RCT.

Holyday 2012 (Continued)

Parallel design with 2 treatment arms.

Duration: follow-up at the end of admission to acute geriatric medicine ward (at least 72 hours) up to 6 months following discharge.

Location: single centre in Australia (acute geriatric medicine wards of the Prince of Wales Hospital, Sydney).

Participants	<p>Inclusion criteria: adults admitted to acute geriatric medicine wards by a geriatrician with an expected length of stay of at least 72 hours.</p> <p>Exclusion criteria: expected length of stay less than 72 hours, palliative treatment, not able to be nutritionally assessed, already seen by a dietitian.</p> <p>Number randomised: 143 individuals were screened and randomised.</p> <p>Gender split: 61 males and 82 females.</p> <p>Age: mean (SD) intervention group 83.7 (0.8) years; control group 83.4 (0.9) years.</p> <p>Nutritional status: intervention group MNA well-nourished n = 12, MNA at risk of malnutrition n = 47, MNA malnourished n = 12; control group MNA well-nourished n = 12, MNA at risk of malnutrition n = 40, MNA malnourished n = 20.</p>
Interventions	<p>Intervention: participants received <i>dietary advice plus ONS if required</i> in the form of individually tailored hospital meals (with texture modification and fortification), nutrition supplements, assistance with meals by ward-based staff, education of individuals and their carers, referral to other health professionals for discharge planning.</p> <p>Control: participants received <i>no dietary advice and no ONS</i> in the form of usual nutritional care: the dietitian on the ward was not informed on the screening outcome.</p>
Outcomes	1 month and 6 months emergency frequency, readmissions, weight change during admission, in-hospital death.
Publication details	<p>Language: English.</p> <p>Funding: The Gut Foundation (Randwick, Australia); Pharmatel Fresenius Kabi Pty Ltd provided an unrestricted research grant to support this study. They had no other involvement in the work.</p> <p>Publication status: peer-reviewed journal.</p>
Notes	Only the data of the malnourished group were included in this review.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote from paper: Patients were randomly allocated using a computerised random number generator.
Allocation concealment (selection bias)	Unclear risk	Screening and randomisation was performed by the research dietitian. It is unclear whether the dietitian had access to the randomisation list.
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	All data were extracted from the hospital charts. The medical personnel was blinded.
Blinding (performance bias and detection bias) Functional outcomes	Low risk	All data were extracted from the hospital charts. The medical personnel was blinded.

Holyday 2012 (Continued)

Blinding (performance bias and detection bias) Nutritional outcomes	Unclear risk	Not measured.
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Dietitian and participants were aware of the intervention but this is unlikely to have influenced assessment of outcomes
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Outcomes were extracted from the hospital charts.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	There was 1 death in the control group and 4 in the intervention group. Weight change was only obtained for 69 (48%) participants and no information was reported to explain why, therefore judged as unclear risk of bias.
Selective reporting (reporting bias)	Unclear risk	No study protocol identified, thus unable to judge whether all planned outcomes were reported.
Other bias	Low risk	All baseline characteristics were similar in both group. The percentage of malnourished patients was 28% in the control group and 17% in the intervention group.

Huynh 2015
Study characteristics

Methods	<p>Prospective RCT.</p> <p>Parallel design.</p> <p>Duration: 12 weeks.</p> <p>Location: multicentre trial at 9 private and 4 public hospitals across India.</p>
Participants	<p>Inclusion criteria: aged ≥ 18 years, males and non-pregnant, non-lactating females, admitted within 36 hours to either the medical or the surgical wards, and who were diagnosed with moderate or severe malnutrition based on the modified SGA.</p> <p>Exclusion criteria: active tuberculosis, acute hepatitis, HIV infection, diabetes, dementia, brain metastases, active malignancy, severe renal or liver failure, burn injury,, clinically significant ascites, oedema, eating disorders or psychological condition interfering with nutritional intake, taking progesterone, steroids or growth hormone.</p> <p>Diagnosis groups: neurological disorders, respiratory medicine, cardiovascular medicine, gastrointestinal disorders, genitourinary and haematological, trauma and orthopaedic diseases, various internal medicine (infection, malaria), others.</p> <p>Number randomised: 212 adults.</p> <p>Gender split: intervention group 57% males, control group 55% males.</p> <p>Age: mean (SD) age intervention group 40.9 (19.6) years; control group 39.0 (16.4) years.</p> <p>Nutritional status: all but 4 participants were moderately or severely malnourished according to modified SGA. These 4 were randomised according to ITT principles, and allocated to intervention group (n = 1) or control group (n = 3).</p>

Huynh 2015 (Continued)

Interventions	<p>Intervention: participants received <i>dietary advice and ONS</i> in the form of 3 sessions of dietary counselling (administered at baseline, weeks 4 and 8) plus 2 servings of oral nutritional supplement per day for 12 weeks.</p> <p>Control: participants received <i>dietary advice alone</i> in the form of 3 sessions of dietary counselling (administered at baseline, weeks 4 and 8).</p> <p>Dietary counselling was provided to both groups by hospital dietitians who were trained in using a standardised methodology. In each dietary counselling session, energy and nutritional requirements were calculated for each group to achieve their individualised energy goals. The dietitians instructed the participants on the methods for improving their nutritional intake using home foods for the control group and home foods in conjunction with oral nutritional supplement for the intervention group. At hospital discharge and follow-up visits at weeks 4 and 8, participants in the control group were given instructions on consuming small frequent meals and using protein rich foods and a high-energy food-source. In addition to being advised on using home foods in meal preparation, participants in the intervention group were instructed to consume the oral nutritional supplement between meals.</p>	
Outcomes	<p>Primary outcome: change in weight over 12 weeks.</p> <p>Secondary outcomes: change in BMI, modified SGA score, pre-albumin, albumin, haemoglobin, total protein and C-reactive protein over 12 weeks, change in dietary intake (energy intake and macronutrient intake) and functionality using handgrip strength.</p>	
Publication details	<p>Language: English.</p> <p>Funding: Abbott Nutrition provided funding for the study and was responsible for the study design, monitoring, data analysis, manuscript preparation and submission.</p> <p>Publication status: peer-reviewed journal.</p>	
Notes	<p>Outcomes are reported at 4 weeks, 8 weeks and 12 weeks. For meta-analysis, only the 12 weeks outcomes were used.</p> <p>The authors were contacted to provide change data for weight, BMI, dietary intake and grip strength</p>	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Eligible patients were randomised in a 1:1 ratio to the control or oral nutritional supplement group. Sealed envelopes containing the patient group assignment were prepared from randomisation schedules generated by Abbott Nutrition for each site."
Allocation concealment (selection bias)	Low risk	Quote: "As eligible patients were enrolled, they were assigned a subject number sequentially starting with the first envelope."
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	Unknown whether the study was blinded or not. Nevertheless, this is unlikely to influence biochemical parameters.
Blinding (performance bias and detection bias) Functional outcomes	Unclear risk	Quote: "Anthropometric measurements were performed by study staff trained in standardised methods of conducting the measurements." It is unknown whether these persons were aware of group allocation.
Blinding (performance bias and detection bias) Nutritional outcomes	High risk	The study was unblinded. Nutritional outcomes could have been influenced by lack of blinding.

Huynh 2015 (Continued)

Blinding of participants and personnel (performance bias) All outcomes	High risk	Not blinded and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Judged to be unclear because low risk for clinical outcomes and unclear or high risk for functional and nutritional outcomes.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Screened and randomised n = 212, allocated to each group n = 106, withdrew consent n = 5 (intervention n = 2, control n = 3), not completed n = 54 (intervention n = 30, control n = 24) - most important reasons: lost to follow-up, withdrew consent. No differences between groups.
Selective reporting (reporting bias)	Low risk	Study protocol identified; all relevant outcomes reported.
Other bias	Unclear risk	Baseline characteristics comparable between the two groups, except for weight (mean (SD)) intervention group 46 (9.6) kg, control 48.5 (10.5) kg).

Imes 1988
Study characteristics

Methods	<p>RCT.</p> <p>Parallel design with 2 treatment arms.</p> <p>Duration: 6 months.</p> <p>Location: Canada.</p>
Participants	<p>Inclusion criteria: adults with Crohn's disease.</p> <p>Exclusion criteria: pregnancy, receiving parenteral nutrition, living too far from the hospital and age under 18 years or over 70 years.</p> <p>Number randomised: 137 participants (intervention group, n = 67; control group, n = 70).</p> <p>Gender split: 62 males and 75 females.</p> <p>Age: range, 17.5 - 71.0 years.</p> <p>Disease status: CDAI, mean (SD) (range): 110 (96) (0 - 463). Concomitant medication: prednisolone n = 42%, salazopyrin n = 45% or vitamin supplements n = 50% and with active and inactive disease included.</p> <p>Nutritional status: mean (SD) % ideal body weight, intervention group 103 (20); control group 105 (17).</p>
Interventions	<p>Intervention: participants received <i>dietary advice</i> in the form of monthly dietary counselling sessions aiming to achieve the 'Canadian Recommended Dietary Allowances'.</p> <p>Control: participants received <i>no dietary advice</i> in the form of no dietary intervention.</p>
Outcomes	<p>Energy* and protein intake, vitamin and mineral intake, assessments of clinical condition, survival*, MAMC*, MUAC*, TSF*, hospital admissions*.</p>
Publication details	<p>Language: English.</p> <p>Funding: MSI Foundation and Alberta Heritage Foundation for Medical Research.</p>

Imes 1988 (Continued)

Publication status: peer-reviewed journal.

Notes Additional outcomes and longer follow-up reported in separate papers.
 Additional data and information on quality obtained from author.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Author cannot recall how the sequence was generated therefore insufficient information to make a judgement.
Allocation concealment (selection bias)	Low risk	Sealed envelopes.
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	Blinded assessment of clinical outcomes.
Blinding (performance bias and detection bias) Functional outcomes	Unclear risk	No functional assessments made.
Blinding (performance bias and detection bias) Nutritional outcomes	High risk	Assessment of nutritional outcomes not blinded and lack of blinding likely to influence assessment of some outcomes.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not blinded and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	The outcome assessors were not blinded for assessment of nutritional status and lack of blinding might influence the outcome of the assessment.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Information obtained from the author. 137 participants randomised, 125 completed 6 months of study, 8/67 (12%) drop-outs in the dietary advice group and 4/70 (6%) in the no dietary advice group. There were no deaths. Reasons for drop-outs not reported therefore judged to be unclear.
Selective reporting (reporting bias)	Unclear risk	No protocol identified. Data on mortality and hospital admissions could not be extracted from the papers and have been obtained from author. Additional outcomes and longer follow-up reported in separate papers.
Other bias	Unclear risk	Baseline variables given, advice group were younger and had a lower CDAI than the no advice group which might have influenced the outcomes.

Isenring 2004
Study characteristics

Methods RCT.
 Parallel design with 2 treatment arms.
Duration: 12 weeks.

Isenring 2004 (Continued)

Location: Australia.

Participants	<p>Inclusion criteria: adults receiving radiotherapy for cancers of head and neck (88%) or abdomen (12%).</p> <p>Exclusion criteria: under 18 years, hospitalised for 5 days or more, receiving enteral or parenteral nutrition.</p> <p>Number randomised: 60 participants (intervention group, n = 29; control group, n = 31). Attrition: 6 participants were lost to follow-up (4 from the intervention group). 5 participants from the control group requested referral to a dietitian.</p> <p>Gender split: 51 males and 9 females.</p> <p>Age: mean (SD) 61.9 (14) years.</p> <p>Nutritional status: at baseline 65% of participants were well-nourished and 35% malnourished (PG-SGA).</p>
Interventions	<p>Intervention: participants received <i>dietary advice plus ONS if required</i> in the form of individualised intensive nutritional counselling and nutritional supplements if appropriate.</p> <p>Control: participants received <i>no dietary advice and no ONS</i> in the form of a standard nutrition booklet and participants could request referral to a dietitian.</p>
Outcomes	Survival*, weight*, grip strength*, fat-free mass (BIA), QoL, change in PG-SGA score, energy intake*.
Publication details	<p>Language: English.</p> <p>Funding: Wesley Research Institute. Abbot Australia and Mead Johnson supplied the product.</p> <p>Publication status: peer-reviewed journal.</p>
Notes	Additional data and information on quality obtained from authors.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Details provided by the author, a random number table.
Allocation concealment (selection bias)	Low risk	Details provided by the author, sealed opaque envelopes.
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	The study was assumed to be unblinded. However, this is unlikely to influence clinical outcomes
Blinding (performance bias and detection bias) Functional outcomes	High risk	The study was assumed to be unblinded. Functional outcomes could have been influenced by lack of blinding.
Blinding (performance bias and detection bias) Nutritional outcomes	High risk	The study was assumed to be unblinded. Nutritional outcomes could have been influenced by lack of blinding.
Blinding of participants and personnel (performance bias)	High risk	Not described and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding

Isenring 2004 (Continued)

All outcomes

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Judged to be unclear because unclear risk for clinical, functional and nutritional outcomes.
Incomplete outcome data (attrition bias) All outcomes	Low risk	6 participants were lost to follow-up, details not given in the paper but provided by the author on request. 4 deaths (2 in the intervention group and 2 in the control group) and 2 others lost to follow-up in the intervention group (1 as a result of deterioration in condition and 1 because participant discontinued treatment and withdrew from the study).
Selective reporting (reporting bias)	Unclear risk	No study protocol identified, thus unable to judge whether all planned outcomes were reported. Outcomes reported in text and figures but not in a format usable for meta-analysis. Data on mortality and mean change (SD) for weight and energy intake obtained from authors.
Other bias	Low risk	Baseline variables given, groups similar at baseline.

Jahnavi 2010
Study characteristics

Methods	<p>RCT (randomised 1:1)</p> <p>Parallel design with 2 treatment arms.</p> <p>Duration: 3 months</p> <p>Location: multicentre, 30 community-based government-sponsored childcare centres in 16 villages in Andra Pradesh, India.</p>
Participants	<p>Inclusion criteria: male and female, aged 18 - 65 years, evidence of active tuberculosis, evidence of wasting (BMI < 20 kg/m²), started on Directly Observed Treatment Short Course (DOTS) within the past 2 weeks.</p> <p>Exclusion criteria: diabetes, positive human-immunodeficiency antibody test or other severe underlying diseases.</p> <p>Number randomised: 100 participants.</p> <p>Gender split: intervention group 36 males, 14 females; control group 38 males, 12 females.</p> <p>Age: mean (SD) intervention group 41 (14.2) years; control group 39.5 (14.3) years.</p> <p>Nutritional status: BMI mean (SD), intervention group 17.1 (2.8) kg/m²; control group 17.9 (2.1) kg/m².</p>
Interventions	<p>Intervention: participants received <i>dietary advice and ONS</i> in the form of target intake calculated as 35kcal/kg/day at baseline, importance of meeting the target was explained to the patient. After 24 hour recall, advice was provided to meet this requirement + dietary plan + supplements (i.e. sweet balls every day - 600kcal). Sweet balls had to be consumed in the presence of Anganwadi workers.</p> <p>Control: participants received <i>no dietary advice and no ONS</i> in the form of no dietary plan and no supplements, given general advice and instructed to increase food intake.</p>
Outcomes	Weight*, quality of life (SF-36), functional status (handgrip)*; timed sit to stand test; bacterial conversion rate.
Publication details	Language: English.

Jahnavi 2010 (Continued)

Funding: Padova University, Italy.

Publication status: peer-reviewed journal.

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: The randomisation was 1:1 for the two groups and was performed by randomly shuffling the envelopes that contained the study codes.
Allocation concealment (selection bias)	Low risk	Study codes were concealed in envelopes.
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	No blinding described however clinical outcome (sero-conversion) unlikely to be affected by lack of blinding.
Blinding (performance bias and detection bias) Functional outcomes	Unclear risk	No blinding described but functional outcome could be influenced by lack of blinding.
Blinding (performance bias and detection bias) Nutritional outcomes	Unclear risk	No blinding described but nutritional outcome could be influenced by lack of blinding.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not described and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No blinding described and assessment of functional and nutritional outcomes could be influenced by lack of blinding.
Incomplete outcome data (attrition bias) All outcomes	Low risk	2/100 (2 %) died (intervention group n = 0 (0%); control group n = 2 (4 %)).
Selective reporting (reporting bias)	Unclear risk	No protocol identified. All outcomes mentioned in the methods are reported.
Other bias	Low risk	Baseline data reported and no differences between groups.

Jensen 1997
Study characteristics

Methods	RCT. Parallel design with 2 treatment arms. Duration: 110 days. Location: Denmark.
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Jensen 1997 (Continued)

Participants	<p>Inclusion criteria: adults < 75 years.</p> <p>Exclusion criteria: not stated but individuals with diabetes and disseminated cancer were excluded.</p> <p>Diagnosis: post-surgery for operable colon/rectum cancer n = 50, diverticulitis n = 15, ulcer n = 5 and other n = 17.</p> <p>Number randomised: 87 participants (intervention group, n = 40; control group, n = 47). Attrition: 28 dropouts (20 intervention group and 8 in control group).</p> <p>Gender split: 42 males and 45 females.</p> <p>Age: elective surgery intervention group 60 (12) years, control group 53 (14) years; acute surgery intervention group 53 (12) years, control group 74 (7) years.</p> <p>Nutritional status: unclear.</p>
Interventions	<p>Intervention: participants received <i>dietary advice plus ONS if required</i> in the form of dietary counselling to improve nutritional intake and aiming for a protein intake of 1.5 g/kg using oral nutritional supplements if required.</p> <p>Control: participants received <i>no dietary advice and no ONS</i> in the form of no nutritional advice.</p>
Outcomes	Weight *, body composition (DEXA), energy intake*, appetite, fatigue assessments, handgrip strength*, work capacity, respiratory function*, QoL (not global).
Publication details	<p>Language: English.</p> <p>Funding: the Health Insurance Foundation, the Danish Cancer Society, Onkologisk Forskningsfond and a European Society of Parenteral and Enteral Nutrition Fellowship donated by Abbott.</p> <p>Publication status: peer-reviewed journal.</p>
Notes	Additional data awaited from authors. QoL could not be included because only subscores were available.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No details of sequence generation reported. Randomisation was stratified.
Allocation concealment (selection bias)	Low risk	Sealed envelopes.
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	The study was unblinded. However, this is unlikely to influence clinical outcomes. The paper states that the surgeon was blinded to intervention group.
Blinding (performance bias and detection bias) Functional outcomes	High risk	The study was unblinded. Functional outcomes could have been influenced by lack of blinding
Blinding (performance bias and detection bias) Nutritional outcomes	High risk	The trial was unblinded. Nutritional outcomes could have been influenced by lack of blinding
Blinding of participants and personnel (performance bias)	High risk	Not blinded and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding.

Dietary advice with or without oral nutritional supplements for disease-related malnutrition in adults (Review)

188

Jensen 1997 (Continued)

All outcomes

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Judged to be unclear because low risk for clinical outcomes and high risk for functional and nutritional outcomes
Incomplete outcome data (attrition bias) All outcomes	High risk	28 dropouts (20 (50%) dietary advice group and 8 (17%) in no advice group). Numbers of withdrawals not balanced between groups and reasons for withdrawals not given in paper and not provided by authors on request.
Selective reporting (reporting bias)	Unclear risk	No study protocol identified, thus unable to judge whether all planned outcomes were reported. Outcomes not in a format usable for meta analysis, energy intake data presented as kcal/kg and weight change data described in text as mean at baseline and end of follow-up. Additional data on mean change (SD) for weight and energy intake requested from authors but not provided.
Other bias	Unclear risk	Baseline variables given, control group (no advice) were significantly older and heavier than the treatment (advice plus supplements if required) group.

Kalnins 2005
Study characteristics

Methods	Quasi-RCT. Parallel design with 2 treatment arms. Duration: 6 months (intervention for 3 months and follow-up to 6 months). Location: Canada.
Participants	Inclusion criteria: adults and children with CF, under 90% weight for height or 5% reduction in weight for height over 3 months. Exclusion criteria: CF-related diabetes, with a gastrostomy tube CF-associated liver disease, FEV1 < 30%, oxygen dependence, already receiving routine ONS. Number randomised: 13 participants overall but mixed population of children and adults. Data obtained from authors on participants > 16 years of age (intervention group n = 2, control group n = 3). Attrition: No dropouts from the 5 adults. Gender split: not reported for the 5 adults included. Age: mean (SD) 27.4 (8.4) years. Nutritional status: not reported for the 5 adults included.
Interventions	Intervention (intervention group 1): participants received <i>dietary advice</i> in the form of dietary counselling to increase food intake by 20% of predicted requirements. Intervention (intervention group 2): participants received <i>ONS</i> in the form of a nutritional supplement to increase energy intake by 20% of predicted requirements.
Outcomes	Survival*, z scores for weight* and height, weight for height, pulmonary function*, energy* intake, REE, faecal balance studies.
Publication details	Language: English. Funding: Mead Johnson Canada.

Kalnins 2005 (Continued)

Publication status: peer-reviewed journal.

Notes Small trial of supplementation in a mixed population of children and adults with CF. Data obtained from the author on results for adults only.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Quasi-randomised using cards with advice or supplement written on them. The participant selected a card blind. Then the next participant randomised received the other intervention group.
Allocation concealment (selection bias)	High risk	Investigators used alternate allocation.
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	No blind assessment but unlikely that assessment of clinical outcomes would be influenced by lack of blinding.
Blinding (performance bias and detection bias) Functional outcomes	High risk	No blind assessment and likely that assessment of some functional outcomes would be influenced by lack of blinding.
Blinding (performance bias and detection bias) Nutritional outcomes	High risk	No blind assessment and likely that some nutritional outcomes would be influenced by lack of blinding.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not blinded and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Outcomes were not assessed blinded to group allocation and it is likely that assessment of some outcomes would be influenced by lack of blinding.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Reported 2 dropouts, 1 in each group. Study was of mixed ages, information obtained from authors indicated that dropouts were children and not adults, therefore no dropouts amongst the 5 adults included in this review.
Selective reporting (reporting bias)	Unclear risk	No protocol identified. This paper reports outcomes for adults and children combined. Details of mean change (SD) weight and energy intake for the 5 adults have been obtained from the authors.
Other bias	Unclear risk	Baseline variables not given, unsure if groups similar at baseline.

Kapoor 2017
Study characteristics

Methods RCT.
 Parallel design with 2 treatment arms.
Duration: 6 months.

Kapoor 2017 (Continued)

Location: single centre in India.

Participants

Inclusion criteria: adult women with cancer attending palliative clinics, with symptoms of cachexia, weight loss of more than 5% from pre-treatment weight, BMI < 20 kg/m² along with haemoglobin level < 12 g/dL, and energy intake of < 1500 kcal/d.

Exclusion criteria: GI tract disorders, on anabolic steroids, taking synthetic oral nutritional supplements, life expectancy less than 3 months.

Number randomised: 123 adult women with advanced cancer were screened for eligibility. 63 participants randomised (intervention group n = 30; control group n = 33). Attrition: 39 participants lost to follow-up (intervention group n = 13; control group n = 18).

Gender split: all female

Age: mean (SD) intervention 44 (13.2) years; control 47.8 (14.7) years.

Nutritional status: not reported.

Interventions

Intervention group: participants received *dietary advice and ONS* in the form of 30 minutes nutritional counselling* per fortnightly visit by a qualified nutritionist plus 100 g of IAtta (by RG)**, to be consumed in addition to their daily dietary intake.

Control group: participants received *dietary advice alone* in the form of 30 minutes nutritional counselling* per fortnightly visit by a qualified nutritionist.

*Participants were advised to increase the frequency of homemade meals, and the consumption of energy- and protein-dense food products was encouraged during these sessions. Depending on the physical status of the participants, low levels of physical activity (walking and/or stairs) and participation in household activities was encouraged.

**Each 100 g pack of IAtta contained a mixture of roasted bengal gram flour, roasted barley flour, roasted soybean flour, flaxseed powder, and dried Amaranthus spinosus powder. Each pack was labelled with use by date and batch number. The caregiver was advised to make unleavened flat breads (chapatis) by adding spices from the dispensed IAtta pack and to discard leftover supplement at the end of the day. On average 3 flat breads could be prepared from each pack, which provides approximately 400 kcal. Each 400 kcal consists of 50% daily protein requirement, 75% daily fat requirement, and 30% to 50% of iron, calcium, and vitamin A as part of an Indian sedentary woman's recommended dietary allowance.

Outcomes

Anthropometric measures (body weight, MUAC, sum of four skin folds), nutritional status (PG-SGA), dietary intake (one-on-one interview sessions between the nutritionist and the participant, 2-day 24-hour dietary recall data and the Indian Migrant Study Food Frequency Questionnaire for portion size estimation, daily energy, carbohydrate, protein, and fat intake), physical activity levels (Indian Migrant Study Physical Activity Questionnaire, metabolic equivalent unit), QoL (EORTC-QLQ-C30).

Adherence to dietary supplement was recorded.

Anthropometric measurements, dietary intake, physical activity level and quality of life parameters were assessed at baseline, after 3 months, and at the end of 6 months.

Publication details

Language: English

Funding: the study was self-funded

Publication status: peer-reviewed journal

Notes

The author provided change scores for body weight, MUAC, energy intake and protein intake for inclusion in this review. Energy intake and protein were measured in two different ways, by dietary recall and by FFQ. We used the data collected by dietary recall.

Kapoor 2017 (Continued)

The clinical trial record seems to be for this study, although the full text by Kapoor indicates that the clinical trial number is NCT 02350855, so this does not match. I think the trial number listed in the manuscript might be an error.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: Eligible patients were asked for consent and enrolled in the study. They were allocated study codes, and a randomization sheet was generated by using nQuery software (7.0 version) by RG
Allocation concealment (selection bias)	Unclear risk	Quote: Eligible patients were asked for consent and enrolled in the study. They were allocated study codes, and a randomization sheet was generated by using nQuery software (7.0 version) by RG. Unclear whether the person recruiting the participants could foresee which group the next participant would be in.
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	Quote: The patients in control groups were unaware of the IAtta intervention in the other group. Although the study was not a blinded study, it is unlike that the outcome was influenced by lack of blinding, as participants were unaware of the interventions in the other group
Blinding (performance bias and detection bias) Functional outcomes	High risk	NK performed recruitment and measurements, but was aware of group assignment. Functional outcomes could have been influenced by lack of blinding
Blinding (performance bias and detection bias) Nutritional outcomes	High risk	NK performed recruitment and measurements, but was aware of group assignment. Nutritional outcomes could have been influenced by lack of blinding
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not blinded and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Judged to be unclear because low risk for clinical outcomes and high risk for functional and nutritional outcomes
Incomplete outcome data (attrition bias) All outcomes	Low risk	63 participants were included; 13 of 30 (43%) in the intervention group and 18 of 33 (55%) in the control group were lost to follow-up (intervention group n = 13, control group n = 18) because of travelling difficulties, financial causes, being bedridden and death.
Selective reporting (reporting bias)	Unclear risk	Study protocol identified; some relevant data not reported i.e. mid arm circumference and skinfold thickness measurements
Other bias	Low risk	There were differences in baseline characteristics for body fat, energy intake, protein intake, PG-SGA score and several QoL scores. Baseline parameters - body weight, body fat, MUAC, energy intake, physical activity level, global health quality of life, and fatigue domain - were adjusted to observe the overall difference between the groups using a generalized estimating equation.

Kendell 1982
Study characteristics

Methods	<p>RCT.</p> <p>Parallel design with 2 treatment arms.</p> <p>Duration: 6 weeks.</p> <p>Location: single centre in the USA.</p>
Participants	<p>Inclusion criteria: adults awaiting elective orthognathic surgery.</p> <p>Exclusion criteria: not specified.</p> <p>Number randomised: 24 participants (intervention group n = 12; control group n = 12). Attrition: 100% follow-up.</p> <p>Gender split: 5 males and 19 females.</p> <p>Age: mean (SD) 25 (8.1) years.</p> <p>Nutritional status: 12 out of 24 participants had a weight below IBW at inclusion.</p>
Interventions	<p>Intervention group: participants received <i>dietary advice and ONS</i> in the form of dietary instruction and an oral nutritional supplement (1.5 kcal/mL) to provide 50% of calculated energy requirements.</p> <p>Control group: participants received <i>dietary advice alone</i> in the form of dietary instruction given verbally and in writing.</p>
Outcomes	<p>Survival*, body weight*, MAUC, MAMC*, TSF*, serum chemistry and creatinine height index, macro and micronutrient intake, length of hospital stay.</p>
Publication details	<p>Language: English</p> <p>Funding:</p> <p>Publication status: peer-reviewed journal</p>
Notes	<p>Data not available from authors.</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Described as randomised, method not reported.
Allocation concealment (selection bias)	Unclear risk	Method not reported.
Blinding (performance bias and detection bias) Clinical outcomes	Unclear risk	Not reported.
Blinding (performance bias and detection bias) Functional outcomes	Unclear risk	Not reported
Blinding (performance bias and detection bias) Nutritional outcomes	Unclear risk	Not reported.

Kendell 1982 (Continued)

Blinding of participants and personnel (performance bias) All outcomes	High risk	Not described and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	100% follow-up.
Selective reporting (reporting bias)	High risk	All outcomes reported but using general statements e.g. 'at each time interval, there were no statistically significant differences in body weight, MAC, TSF and creatinine height index between the experimental and control groups'. Data presented in table as % deficit and data not available from the authors, therefore risk of bias due to partial reporting.
Other bias	Unclear risk	Baseline variables not given, no information available from authors, not sure if groups similar at baseline.

Kiss 2016
Study characteristics

Methods	<p>Pilot RCT.</p> <p>Parallel design with 2 treatment arms.</p> <p>Duration: 3 months following completion of radiation therapy.</p> <p>Location: Australia.</p>
Participants	<p>Inclusion criteria: adults undergoing radical (chemo) radiation therapy for a primary diagnosis of non-small cell lung cancer or small cell lung cancer.</p> <p>Exclusion criteria: palliative intent radiation therapy, induction chemotherapy (with the exception of people with small cell lung cancer in which this is standard care), small peripheral tumours or no mediastinal disease, hyperfractionated radiation therapy, non-English speaking, or cognitive impairment or psychiatric illness.</p> <p>Number randomised: 24 participants. Attrition: overall attrition was 37%.</p> <p>Gender split: 12 males and 12 females.</p> <p>Age: mean (SD) intervention group 62.6 (12.8) years; control group 64.3 (12.0) years.</p> <p>Nutritional status: (PG-SGA) intervention group well-nourished n = 7, moderately malnourished n = 5; control group well-nourished n = 6, moderately malnourished n = 6.</p> <p>BMI, mean (SD): 27.8 (7.7).</p>
Interventions	<p>Intervention: participants received <i>dietary advice plus ONS if required</i> in the form of intensive, individualized dietary counselling tailored to manage participants' specific symptoms and accommodate food preferences and social circumstances so as to meet nutritional requirements and maintain nutritional status. Dietary counselling was provided 1 week prior to radiation therapy, weekly during radiation therapy, and fortnightly for 6 weeks post-therapy. The intervention was delivered by three dietitians, in person during treatment and over the phone during pre-treatment and post-treatment.</p>

Kiss 2016 (Continued)

Control: participants received *no dietary advice and no ONS* in the form of standard care of the centre at that time, consisting of assessment and review by a dietitian fortnightly during radiation therapy and at 4 weeks post therapy including symptom assessments, weight changes and dietary intake, and provision of dietary counselling. However, this differed from the intervention group in that they were not structured or defined.

Outcomes	PG-SGA score at 4 weeks post-radiation therapy, weight, fat-free mass, fatigue, functional status, and global QoL. Outcomes measured at week 1 and end of radiotherapy and 4 weeks and 3 months following completion of radiation therapy.
Publication details	Language: English. Funding: PhD scholarship from the Victorian Cancer Agency. Publication status: peer-reviewed journal.
Notes	Not all participants were malnourished according to the SGA. Additional data on weight change was provided by the authors.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No information.
Allocation concealment (selection bias)	Unclear risk	No information.
Blinding (performance bias and detection bias) Clinical outcomes	Unclear risk	Not measured.
Blinding (performance bias and detection bias) Functional outcomes	High risk	Outcome measures were determined by the research dietitian who was not blinded.
Blinding (performance bias and detection bias) Nutritional outcomes	High risk	Outcome measures were determined by the research dietitian who was not blinded.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not blinded and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding
Blinding of outcome assessment (detection bias) All outcomes	High risk	Outcome measures were determined by the research dietitian who was not blinded.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Overall attrition was 37%, equally distributed between groups, mostly due to disease progression and inability to contact the participant.
Selective reporting (reporting bias)	Low risk	Study protocol identified ANZCTR ACTRN12612000180819 and all planned outcomes were reported.

Kiss 2016 (Continued)

Other bias	Low risk	Baseline characteristics similar between groups.
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Kunvik 2018
Study characteristics

Methods	<p>RCT.</p> <p>Duration: 6 months (data collection at baseline and 6 months).</p> <p>Location: Finland.</p>
Participants	<p>Inclusion criteria: caregivers, age > 65 years, living at home, normal cognition (MMSE < 25 geriatric assessment).</p> <p>Exclusion criteria: non-specified.</p> <p>Number randomised: 79 (intervention group, n = 28, control group, n = 27). Attrition: 10/79 (18%) intervention group n = 6, control group n = 4 (data reported on 55 participants with protein intake < 1.2 g/kg BW/d. 24 participants therefore not included in this analysis).</p> <p>Gender split: 45.5% male.</p> <p>Age: mean (SD) years 73.5 (6.0) years.</p> <p>Nutritional status: assessed using MNA, 85.5% good nutritional status (> 23.5, 12.7% at risk (MNA 17 - 23.5), 1.8% malnourished (< 17 points).</p>
Interventions	<p>Intervention: participants received <i>dietary advice</i> in the form of a nutritional care plan from nutritionist plus group discussion and cooking classes((provided by the nutritionist) plus booklet.</p> <p>Control: participants received <i>no dietary advice</i> in the form of a booklet plus usual care community care as needed.</p>
Outcomes	Energy and protein intake, BMI, usefulness and satisfaction with intervention.
Publication details	<p>Language: English.</p> <p>Funding: National Institute for Health and Welfare (THL) Finland.</p> <p>Publication status: unpublished (but submitted manuscript).</p>
Notes	Email to authors to confirm study numbers and request data for change in protein intake in g and change in BMI per group.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	<p>Adequate randomisation.</p> <p>Quote: "a computer-generated, blocked randomization list".</p>
Allocation concealment (selection bias)	Low risk	<p>Adequate allocation concealment.</p> <p>Quote: "a person unrelated to the investigation and unfamiliar with the procedure performed the randomisation" "a person unrelated to the investigation and unfamiliar with the procedure performed the randomisation".</p>

Kunvik 2018 (Continued)

Blinding (performance bias and detection bias) Clinical outcomes	Unclear risk	Blinding not described but no clinical outcomes assessed.
Blinding (performance bias and detection bias) Functional outcomes	Unclear risk	Blinding not described but no functional outcomes assessed.
Blinding (performance bias and detection bias) Nutritional outcomes	High risk	Blinding not described. BMI and nutritional intake assessed. Judged to be high risk as nutritional intake assessment might be influenced by lack of blinding.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not blinded and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not described and likely that assessment of some outcomes would be influenced by lack of blinding.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	<p>10 out of 79 (intervention group n = 6 out of 35 (17%); control group n = 4 out of 35 (11%) participants withdrew. Reasons reported (for 9 participants the caring role ended and 1 other reasons).</p> <p>Data reported only on 55 participants with protein intake below 1.2 g/kg body weight per day. Judged to be unclear because the data from the 24 participants with protein intake over 1.2 g/kg body weight per day not reported and so not possible to judge the impact of this decision.</p>
Selective reporting (reporting bias)	High risk	Protocol identified and indicates 4 aims, including data collection on QoL, well-being, coping and effect of nutritional status of caregivers on those receiving care. This manuscript reports nutritional intake and BMI of caregivers only and judged to be evidence of selective reporting or reporting of findings in multiple manuscripts.
Other bias	Low risk	Baseline characteristics compared and similar for all elements.

Le Cornu 2000
Study characteristics

Methods	<p>RCT.</p> <p>Parallel design with 2 treatment arms.</p> <p>Duration: variable (from pre-transplant assessment to liver transplant).</p> <p>Location: single centre in the UK.</p>
Participants	<p>Inclusion criteria: adults with end-stage liver disease accepted for orthotopic liver transplantation, MAMC below 25th percentile.</p> <p>Exclusion criteria: MAMC greater than 25th percentile, fulminant or subacute hepatic failure or malignant disease, requiring acute transplantation, fluid restriction < 500 mL/day, re-grafts, multiple organ grafts or celiac disease.</p> <p>Number randomised: 82 participants (intervention group, n = 42; control group, n = 40).</p>

Le Cornu 2000 (Continued)

Gender split: 83% males, 27% females.

Age: range 24 - 68 years.

Nutritional status: median (range) MAMC (cm) intervention 22.15 (17.6 - 26.2); control 23.2 (17.2 - 26.8).

Interventions

Intervention: participants received *dietary advice and ONS* in the form of a supplement of a calorie-dense enteral feed taken daily (in addition to standard dietary advice) until transplantation.

Control: participants received *dietary advice alone* in the form of standard dietetic advice.

Standard dietary advice consisted of a dietary recall after which patients were advised on how to adapt their usual dietary intake to increase energy intake and achieve or maintain a moderate protein intake.

Outcomes

Nutritional status (upper arm anthropometric measurements and handgrip strength), dietary intake was calculated from 5-day food diaries.

Post-transplant: 30-day mortality, 6-month mortality, length of stay in ICU, time spent on ventilator, septic complications, major non-infectious complications, frequency and severity of rejections.

Publication details

Language: English.

Funding: no funding, products were supplied by Nutricia.

Publication status: peer-reviewed journal.

Notes

Authors report that, for the supplemented group, there was a statistically significant increase in MAC, grip strength and MAMC between trial entry and the appointment nearest transplant or death. For the control group, there was also a statistically significant improvement in MAC and MAMC, but no change in grip strength. We emailed the authors to ask for the data, but they replied that they do not have the data anymore.

Dietary intake was only measured in a few 10 randomly selected (5 in each group) participants.

Dietary intake increased from 1840 kcal at entry to the trial to 2395 kcal at transplant in 5 randomly selected participants in the supplemented group and from 2473 tot 2718 in 5 participants in the control group. Data on dietary intake not entered in the review due to small numbers.

Authors report pre-transplant mortality, post-transplant mortality, and total mortality. As the primary goal of the study was to study the effects of nutritional support on mortality, we report combined mortality.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not mentioned.
Allocation concealment (selection bias)	Low risk	Randomisation was done by using sealed envelopes selected by a person other than the trial coordinator.
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	The study was unblinded, but is unlikely that this will have influenced primary endpoints such as mortality.
Blinding (performance bias and detection bias) Functional outcomes	High risk	The study was unblinded, functional outcomes could have been influenced by lack of blinding.

Le Cornu 2000 (Continued)

Blinding (performance bias and detection bias) Nutritional outcomes	High risk	The study was unblinded, nutritional outcomes could have been influenced by lack of blinding.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not blinded and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Judged to be unclear because low risk for clinical outcomes and high risk for functional and nutritional outcomes.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Mortality (primary outcome) was n = 7 (17.5%) in the control group and n = 2 (5%) in the intervention group. Reasons for death are clearly described.
Selective reporting (reporting bias)	High risk	No study protocol identified, thus unable to judge whether all planned outcomes were reported. Unable to interpret outcomes, as results were presented as global description. Quote: "when all diagnoses were considered together, most of the biochemical parameters measured at the appointment before transplantation or death were similar for the two groups" (except for serum phosphate). Outcome data are missing; although described as improvement this can not be verified as no data are given in the manuscript.
Other bias	Low risk	Similar baseline characteristics at inclusion in the study.

Locher 2013
Study characteristics

Methods	<p>RCT (stratified by gender and BMI).</p> <p>Duration: 60 days.</p> <p>Location: USA.</p>
Participants	<p>Inclusion: older adults receiving Medicare home health services, > 65 years, homebound, able to communicate, living in a private residence, experiencing either an acute or chronic illness, undereating.</p> <p>Exclusion: cognitive impairment (< 8/10 Short Portable MSQ), terminal illness, cancer diagnosis within past 5 years, end-stage renal disease, tube feed, dependence on ventilator.</p> <p>Diagnosis: acute or chronic illness.</p> <p>Number randomised: 40 participants, but 34 included in analyses (intervention group n = 18, control group n = 16). Attrition: 6/40 but reasons not described.</p> <p>Gender split: 6/34 (18%) male, 28/34 (82%) female.</p> <p>Age: mean (SD) years 81.4 (8.2).</p> <p>Nutritional status: 15.2% BMI < 18.5.</p>
Interventions	<p>Intervention: participants received <i>dietary advice</i> in the form of B-NICE (behavioural nutrition intervention), self management education approaches to guide participants and carers to improve caloric intake.</p>

Locher 2013 (Continued)

Control: participants received *no dietary advice* in the form of standard care.

Outcomes	Body weight, caloric intake.
Publication details	<p>Language: English.</p> <p>Funding: National Institutes of Health/National Institute on Aging.</p> <p>Publication status: peer-reviewed journal.</p>

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	<p>Quote: "randomly assigned...using stratified blocked randomisation".</p> <p>Judgement, insufficient information on method of randomisation.</p>
Allocation concealment (selection bias)	Unclear risk	Not described.
Blinding (performance bias and detection bias) Clinical outcomes	Unclear risk	No clinical outcomes assessed.
Blinding (performance bias and detection bias) Functional outcomes	Unclear risk	No functional outcomes assessed.
Blinding (performance bias and detection bias) Nutritional outcomes	Unclear risk	<p>Quote: "research interviewers collecting outcomes data were blinded to group assignment". Absence of performance blinding might have influenced assessment of nutritional intake.</p>
Blinding of participants and personnel (performance bias) All outcomes	High risk	<p>Quote: "This was a social behavioural intervention therefore not possible to blind participants or study personnel to group assignment." Not blinded and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding</p>
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Knowledge of group allocation might have influenced collection of food intake data, therefore some outcome assessment might have been influenced by absence of performance bias.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	"40 participants randomised and 34 included in the analyses". Group allocation and reasons for attrition not described therefore insufficient information to make a judgement.
Selective reporting (reporting bias)	Unclear risk	Published protocol identified. Planned outcomes, energy intake and weight at 60 days and 6 months, and fidelity outcomes. Only data at 60 days reported and fidelity outcomes not reported. Outcome data are reported without SDs, therefore data requested from authors.
Other bias	Unclear risk	Baseline characteristics not presented but in the text "the randomisation schedule was successful in balancing for both gender and BMI". Judged as unclear because insufficient information on all characteristics likely to influence differences in outcomes.

Lovik 1996
Study characteristics

Methods	<p>RCT.</p> <p>Parallel design with 2 treatment arms.</p> <p>Duration: 6 weeks.</p> <p>Location: Norway.</p>
Participants	<p>Inclusion criteria: adults who had received radiotherapy for cancers of head and neck.</p> <p>Exclusion criteria: serious liver or kidney disease, other cancers, diseases presumed to affect nutritional status, poor ability to cooperate or poor general condition.</p> <p>Number randomised: 52 participants (intervention group, n = 28; control group, n = 24). Attrition: 3 deaths (group not reported, analysed 49 participants).</p> <p>Gender split: 40 males, 9 females.</p> <p>Age: range 34 - 86 years.</p> <p>Nutritional status: at study entry unclear, 10% reported weight loss and BMI ranged from 18 - 37kg/m².</p>
Interventions	<p>Intervention: participants received <i>dietary advice plus ONS if required</i> in the form of intensive dietary instruction from a dietitian including advice to use nutritional supplements if required.</p> <p>Control: participants received <i>no dietary advice and no ONS</i> in the form of a standard information sheet "for patients receiving radiation therapy for cancer" providing information on all aspects of treatment and including advice to eat a nutritious diet.</p>
Outcomes	<p>Body weight*, BMI, TSF, MAMC, MUAC, energy intake*, survival*, serum chemistry, albumin and transferrin.</p>
Publication details	<p>Language: Norwegian.</p> <p>Funding: Meddinova's Research Fund.</p> <p>Publication status: peer-reviewed journal.</p>
Notes	<p>Additional data and information on quality obtained from authors.</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Details from author, sequence generation using a random number list.
Allocation concealment (selection bias)	Low risk	Sequentially numbered sealed opaque envelopes.
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	The study was assumed to be unblinded. However, this is unlikely to influence clinical outcomes.
Blinding (performance bias and detection bias)	High risk	The study was assumed to be unblinded. Functional outcomes could have been influenced by lack of blinding.

Lovik 1996 (Continued)

Functional outcomes

Blinding (performance bias and detection bias) Nutritional outcomes	High risk	The study was assumed to be unblinded. Nutritional outcomes could have been influenced by lack of blinding.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not described and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Judged to be unclear because low risk for clinical outcomes and high risk for functional and nutritional outcomes.
Incomplete outcome data (attrition bias) All outcomes	Low risk	3 deaths, group not reported. All participants were analysed.
Selective reporting (reporting bias)	Unclear risk	No study protocol identified, thus unable to judge whether all planned outcomes were reported. Data on change in weight extracted from the paper, but clarification needed for mortality data. Data on TSF, MAMC presented as number of participants with values below 85% of the normal limit and so not included. Data on energy intake is expressed according to expected intake, therefore not usable.
Other bias	Low risk	Baseline variables given, groups similar at baseline.

Macia 1991a
Study characteristics

Methods	<p>RCT.</p> <p>Parallel design with 2 treatment arms.</p> <p>Duration: not reported.</p> <p>Location: Spain.</p>
Participants	<p>Inclusion criteria: adults receiving radiotherapy for cancers of head and neck, breast and abdominopelvic area.</p> <p>Exclusion criteria: Karnofsky score < 50, previous diet therapy for diabetes, hypercholesterolemia or other conditions.</p> <p>Number randomised: 92 participants (intervention group, n = 30; control group, n = 62). Numbers of withdrawals and deaths not reported.</p> <p>Gender split: not reported.</p> <p>Age: not reported.</p> <p>Nutritional status: unclear.</p>
Interventions	<p>Intervention: participants received <i>dietary advice</i> in the form of dietary instructions on appropriate alimentation during radiotherapy given verbally and in writing.</p>

Macia 1991a (Continued)

Control: participants received *no dietary advice* in the form of ad lib food intake and no dietary instruction.

Outcomes	Weight*, TSF*, MAUC*, MAMC*, BMI*, total protein, albumin, transferrin, total lymphocyte count, iron, cholesterol, triglycerides, clinical observations.
Publication details	<p>Language: English.</p> <p>Funding: none declared.</p> <p>Publication status: peer-reviewed journal.</p>
Notes	<p>Dietary advice given by doctors from nutrition and dietetic unit.</p> <p>The ID Macia 1991a has been used to identify the head and neck cancer group.</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Used coin toss to randomise participants.
Allocation concealment (selection bias)	Unclear risk	No details provided however unlikely that lack of concealment would influence group allocation.
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	Paper states that clinical variables were assessed by doctors unaware of group allocation.
Blinding (performance bias and detection bias) Functional outcomes	Unclear risk	No functional outcomes assessed.
Blinding (performance bias and detection bias) Nutritional outcomes	High risk	Not stated and likely that lack of blinding would influence the assessment of some nutritional outcomes.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not blinded and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not described for all outcomes and absence of blinding of some outcomes might influence the results.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Numbers of withdrawals and deaths not reported.
Selective reporting (reporting bias)	Unclear risk	No protocol identified. All outcomes in the methods reported but as mean change at baseline and end of follow-up according to site of tumour therefore change scores were calculated and SDs imputed. No response received from author to requests for data.
Other bias	Unclear risk	Baseline variables not reported, not sure if groups similar at baseline.

Macia 1991b
Study characteristics

Methods	<p>RCT.</p> <p>Parallel design with 2 treatment arms.</p> <p>Duration: not reported.</p> <p>Location: Spain.</p>
Participants	<p>Inclusion criteria: adults receiving radiotherapy for cancers of head and neck, breast and abdominopelvic area.</p> <p>Exclusion criteria: Karnofsky score < 50, previous diet therapy for diabetes, hypercholesterolemia or other conditions.</p> <p>Number randomised: 92 participants (intervention group, n = 30; control group, n = 62). Numbers of withdrawals and deaths not reported.</p> <p>Gender split: not reported.</p> <p>Age: not reported.</p> <p>Nutritional status: unclear.</p>
Interventions	<p>Intervention: participants received <i>dietary advice</i> in the form of dietary instructions on appropriate alimentation during radiotherapy given verbally and in writing.</p> <p>Control: participants received <i>no dietary advice</i> in the form of ad lib food intake and no dietary instruction.</p>
Outcomes	<p>Weight*, TSF*, MAUC*, MAMC*, BMI*, total protein, albumin, transferrin, total lymphocyte count, iron, cholesterol, triglycerides, clinical observations.</p>
Publication details	<p>Language: English.</p> <p>Funding: none declared.</p> <p>Publication status: peer-reviewed journal.</p>
Notes	<p>Dietary advice given by doctors from nutrition and dietetic unit.</p> <p>The ID Macia 1991b has been used to identify the breast cancer group.</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Used coin toss to randomise participants.
Allocation concealment (selection bias)	Unclear risk	No details provided however unlikely that lack of concealment would influence group allocation.
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	Paper states that clinical variables were assessed by doctors unaware of group allocation.
Blinding (performance bias and detection bias)	Unclear risk	No functional outcomes assessed.

Macia 1991b (Continued)
 Functional outcomes

Blinding (performance bias and detection bias) Nutritional outcomes	High risk	Not stated and likely that lack of blinding would influence the assessment of some nutritional outcomes.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not blinded and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not described for all outcomes and absence of blinding of some outcomes might influence the results.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Numbers of withdrawals and deaths not reported.
Selective reporting (reporting bias)	Unclear risk	No protocol identified. All outcomes in the methods reported but as mean change at baseline and end of follow-up according to site of tumour therefore change scores were calculated and SDs imputed. No response received from author to requests for data.
Other bias	Unclear risk	Baseline variables not reported, not sure if groups similar at baseline.

Macia 1991c
Study characteristics

Methods	<p>RCT.</p> <p>Parallel design with 2 treatment arms.</p> <p>Duration: not reported.</p> <p>Location: Spain.</p>
Participants	<p>Inclusion criteria: adults receiving radiotherapy for cancers of head and neck, breast and abdominopelvic area.</p> <p>Exclusion criteria: Karnofsky score < 50, previous diet therapy for diabetes, hypercholesterolemia or other conditions.</p> <p>Number randomised: 92 participants (intervention group, n = 30; control group, n = 62). Numbers of withdrawals and deaths not reported.</p> <p>Gender split: not reported.</p> <p>Age: not reported.</p> <p>Nutritional status: unclear.</p>
Interventions	<p>Intervention: participants received <i>dietary advice</i> in the form of dietary instructions on appropriate alimentation during radiotherapy given verbally and in writing.</p> <p>Control: participants received <i>no dietary advice</i> in the form of ad lib food intake and no dietary instruction.</p>

Macia 1991c (Continued)

Outcomes	Weight*, TSF*, MAUC*, MAMC*, BMI*, total protein, albumin, transferrin, total lymphocyte count, iron, cholesterol, triglycerides, clinical observations.
Publication details	Language: English. Funding: none declared. Publication status: peer-reviewed journal.
Notes	Dietary advice given by doctors from nutrition and dietetic unit. The ID Macia 1991c has been used to identify the abdominopelvic cancer group.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Used coin toss to randomise participants.
Allocation concealment (selection bias)	Unclear risk	No details provided however unlikely that lack of concealment would influence group allocation.
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	Paper states that clinical variables were assessed by doctors unaware of group allocation.
Blinding (performance bias and detection bias) Functional outcomes	Unclear risk	No functional outcomes assessed.
Blinding (performance bias and detection bias) Nutritional outcomes	High risk	Not stated and likely that lack of blinding would influence the assessment of some nutritional outcomes.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not blinded and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not described for all outcomes and absence of blinding of some outcomes might influence the results.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Numbers of withdrawals and deaths not reported.
Selective reporting (reporting bias)	Unclear risk	No protocol identified. All outcomes in the methods reported but as mean change at baseline and end of follow-up according to site of tumour therefore change scores were calculated and SDs imputed. No response received from author to requests for data.
Other bias	Unclear risk	Baseline variables not reported, not sure if groups similar at baseline.

Manguso 2005
Study characteristics

Methods	<p>RCT.</p> <p>Cross-over design with 2 treatment arms.</p> <p>Duration: 6 months in total but only results from the first 3 months will be considered.</p> <p>Location: Naples, Italy.</p>
Participants	<p>Inclusion criteria: adults admitted to a specialist unit for the management of liver cirrhosis (Child A or B class).</p> <p>Exclusion criteria: HBV infection, autoimmune liver disease, drug or alcohol use, hepatocellular carcinoma, HIV infection, liver transplantation, impaired renal function, sepsis, or thyroid dysfunction, following specific diets, ascites and in current or previous treatment with albumin.</p> <p>Number randomised: 90 participants (intervention group, n = 45; control group, n = 45). Attrition: 3 withdrawals, but information from authors, no deaths.</p> <p>Gender split: 52 males and 38 females.</p> <p>Age: mean (IQR) 60 (9) years.</p> <p>Nutritional status: Mean (SD) BMI, intervention 27.8 (2.1) kg/m²; control 28.5 (3.2) kg/m².</p>
Interventions	<p>Intervention: participants received <i>dietary advice</i> in the form of a controlled diet consisting of specific prescription for macronutrients and calcium.</p> <p>Control: participants received <i>no dietary advice</i> in the form of spontaneous diet.</p>
Outcomes	Survival*, weight*, MAMC*, TSF*, energy intake*, Childs Score, biochemistry profile.
Publication details	<p>Language: English.</p> <p>Funding: none declared.</p> <p>Publication status: peer-reviewed journal.</p>
Notes	Weight may be inappropriate in analysis due to possible presence of ascites.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated sequence.
Allocation concealment (selection bias)	Low risk	Sequentially-numbered opaque sealed envelopes.
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	Blinding not described but assessment of mortality unlikely to be influenced by lack of blinding.
Blinding (performance bias and detection bias) Functional outcomes	Unclear risk	None measured.
Blinding (performance bias and detection bias)	Low risk	Information from author, the assessor was blinded to intervention group.

Manguso 2005 (Continued)

Nutritional outcomes

Blinding of participants and personnel (performance bias) All outcomes	High risk	Not blinded and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	The main outcomes assessed were nutritional intake and body composition and information from the author indicated that these were assessed by a researcher blinded to the intervention. Judged unclear as lack of blinding of performance might have influenced nutritional intake.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Information from author: no deaths occurred in the study, 1/45 participant withdrew from the dietary advice group and 2/45 from the no intervention group. 3 additional participants not included because they developed ascites.
Selective reporting (reporting bias)	Unclear risk	No protocol identified. Results on all outcomes specified in the methods reported but as mean (SD) at baseline and end of intervention. Mean change (SD) for weight, energy intake, TSF and MAMC and additional information obtained from authors.
Other bias	Low risk	Baseline characteristics comparable between groups.

McCarthy 1999
Study characteristics

Methods	<p>RCT.</p> <p>Parallel design with 2 arms.</p> <p>Duration: 4 weeks.</p> <p>Location: single centre in the USA.</p>
Participants	<p>Inclusion criteria: adults beginning a first course of curative radiotherapy for stage 1 or 2 cancer.</p> <p>Exclusion criteria: head and neck cancer.</p> <p>Number randomised: 40 participants (intervention group, n = 19; control group, n = 18). Attrition: 32 completed the 4-week data collection period, 8 participants dropped out, 6 in the intervention group and 2 in the control group.</p> <p>Gender split: 23 males, 9 females.</p> <p>Age: mean (SD) intervention group 59.6 (9.6) years; control group 55.6 (14) years.</p> <p>Nutritional status: unclear.</p>
Interventions	<p>Intervention: participants received <i>dietary advice and ONS</i> in the form of weekly nutritional counselling to maintain recommended dietary intake of calories and protein plus 8 oz of 1.0 kcal/mL nutritional supplement.</p> <p>Control: participants received <i>dietary advice alone</i> in the form of weekly nutritional counselling.</p>
Outcomes	Energy intake*.
Publication details	<p>Language: English.</p> <p>Funding: Mead Johnson and Abbott provided some of the nutritional supplements.</p>

McCarthy 1999 (Continued)

Publication status: peer-reviewed journal.

Notes Data obtained from authors.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Coin toss used to randomise participants.
Allocation concealment (selection bias)	Low risk	Not reported but unlikely to have been influenced.
Blinding (performance bias and detection bias) Clinical outcomes	Unclear risk	None measured.
Blinding (performance bias and detection bias) Functional outcomes	Unclear risk	None measured.
Blinding (performance bias and detection bias) Nutritional outcomes	High risk	Paper states that assessments were made by the nurse and dietitian that implemented the intervention. Outcomes may have been influenced by knowing groups assignment.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not blinded and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Paper states that assessments were made by the nurse and dietitian that implemented the intervention. Outcomes may have been influenced by knowing groups assignment.
Incomplete outcome data (attrition bias) All outcomes	High risk	8 participants lost to follow-up, 6 of 20 (30%) in the experimental group (disliked the supplements) and 2 of 20 (10%) in the control group. These 8 were not analysed.
Selective reporting (reporting bias)	Unclear risk	No study protocol identified, thus unable to judge whether all planned outcomes were reported. Outcomes reported are presented in a figure and so not in a format usable for meta-analysis. Mean change (SD) in energy intake obtained from authors.
Other bias	Unclear risk	Baseline variables given, the supplement group weighed less and received less radiotherapy.

Moloney 1983
Study characteristics

Methods RCT.

Parallel design with 2 treatment arms.

Duration: unclear, intervention given for 3 weeks, survival reported to 1 year; outcomes reported at different time points.

Moloney 1983 (Continued)

Location: Ireland.

Participants	<p>Inclusion criteria: consecutive adults with cancer (various sites) undergoing radiotherapy.</p> <p>Exclusion criteria: clinically poor and considered unethical to withhold adjunctive feeding.</p> <p>Number randomised: 84 participants (intervention group, n = 42; control group, n = 42). Attrition: no information.</p> <p>Gender split: 50 males and 34 females.</p> <p>Age: mean intervention group 63 years; control group 55 years.</p> <p>Nutritional status: no information given.</p>
Interventions	<p>Intervention: participants received <i>dietary advice plus ONS if required</i> in the form of dietary counselling and supplements.</p> <p>Control: participants received <i>no dietary advice and no ONS</i> in the form of no advice.</p>
Outcomes	Survival*, energy intake*, macronutrient and micronutrient intake.
Publication details	<p>Language: English.</p> <p>Funding: not declared.</p> <p>Publication status: peer-reviewed journal.</p>
Notes	Data for survival given at 9 months for dietary advice and supplement group and at 11 months for no advice group.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Described as randomised, but method not stated.
Allocation concealment (selection bias)	Unclear risk	Method not stated.
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	The study was assumed to be unblinded. However, this is unlikely to influence clinical outcomes.
Blinding (performance bias and detection bias) Functional outcomes	Unclear risk	Not measured.
Blinding (performance bias and detection bias) Nutritional outcomes	High risk	The study was unblinded. Nutritional outcomes could have been influenced by lack of blinding.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not blinded and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding
Blinding of outcome assessment (detection bias)	Unclear risk	Judged to be unclear because low risk for clinical outcomes and high risk for functional and nutritional outcomes.

Moloney 1983 (Continued)

All outcomes

Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information on attrition.
Selective reporting (reporting bias)	Unclear risk	No study protocol identified, thus unable to judge whether all planned outcomes were reported. Mortality data obtained from the paper. Data on change in energy intake is expressed as mean (SD) at baseline and end of intervention, therefore change scores were calculated and SDs imputed. No response received from author.
Other bias	Unclear risk	Baseline variables given, treatment group were older.

Murphy 1992
Study characteristics

Methods	Quasi-RCT. Parallel design with 2 treatment arms. Duration: 16 weeks. Location: single centre in Canada.
Participants	Inclusion criteria: adults with HIV infection who had involuntary weight loss of more than 5%. Exclusion criteria: impaired phagia or gut function or previous dietary counselling from a dietitian. Number randomised: 22 participants (intervention group, n = 11; control group, n = 11). Attrition: 6 dropouts, 1 in the intervention group and 5 in the control group. Gender split: all males. Age: mean (SD) 37.3 (6.7) years. Nutritional status: mean(SD) % weight loss, intervention 10.1 (4.3) %; control 10.7 (3.0) %.
Interventions	Intervention: participants received <i>dietary advice and ONS</i> in the form of dietary counselling verbally and in writing to consume a calculated amount of energy and protein per day and 2x 235 mL of a supplement (1.5 kcal/mL). Control: participants received <i>dietary advice alone</i> in the form of dietary counselling verbally and in writing to consume a calculated amount of energy and protein per day.
Outcomes	Survival*, body weight*, BMI*, MUAC*, serum albumin, energy* and protein intake.
Publication details	Language: English. Funding: nothing mentioned. Publication status: peer-reviewed journal.
Notes	Outcomes not assessed blind. Additional data and information on quality obtained from authors.

Risk of bias

Murphy 1992 (Continued)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Participants were selected consecutively as they presented with weight loss (alternate allocation). No details of the group for the first participant.
Allocation concealment (selection bias)	High risk	Investigators used alternate allocation.
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	The study was unblinded. However, this is unlikely to influence clinical outcomes.
Blinding (performance bias and detection bias) Functional outcomes	High risk	The study was unblinded. Functional outcomes could have been influenced by lack of blinding.
Blinding (performance bias and detection bias) Nutritional outcomes	High risk	The study was unblinded. Nutritional outcomes could have been influenced by lack of blinding.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not blinded and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Judged to be unclear because low risk for clinical outcomes and high risk for functional and nutritional outcomes.
Incomplete outcome data (attrition bias) All outcomes	High risk	6 dropouts, 5 (45%) in the dietary counselling group and 1 (9%) in the dietary counselling and supplement group. 5 dropouts because of subsequent GI disease, and 1 due to self exclusion. Significantly more participants dropped out from the dietary counselling group compared with counselling plus supplement group and the imbalance might have influenced outcome assessment.
Selective reporting (reporting bias)	Unclear risk	No protocol identified. All specified outcomes reported but continuous variables presented as mean (SD) at baseline and end of intervention. Mean change with SDs for weight has been imputed. Data on change in energy intake are presented with precise P values and so mean change (SD) obtained by calculation. Additional data and information on quality obtained from authors.
Other bias	Unclear risk	Baseline variables given, dietary counselling group weighed 5 kg less than the dietary counselling group and supplement group.

Neelemaat 2011
Study characteristics

Methods	RCT. Parallel design with 2 treatment arms. Duration: 3 months post hospital discharge.
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Neelemaat 2011 (Continued)

Location: single centre (University Medical Centre) in Amsterdam, The Netherlands.

Participants	<p>Inclusion criteria: malnourished elderly adults (> 60 years) admitted to hospital, expected length of stay > 2 days. Malnourished (5% unintentional weight loss 3/12 OR 10% unintentional weight loss 6/12, BMI < 20 kg/m²).</p> <p>Exclusion criteria: senile dementia, could not understand Dutch language, not willing or able to give consent, already received nutritional support.</p> <p>Number randomised: 210 (intervention group, n = 105, control group, n = 105). Attrition: intervention group n = 30 (16 withdrew and 14 died), control group n = 30 (19 withdrew and 11 died).</p> <p>Gender split: intervention group 56% female, 44% male; control group 60% female, 40% male.</p> <p>Age: mean (SD) years, intervention group 74.6 (9.7); control group 74.4 (9.3).</p> <p>Nutritional status: all malnourished as above.</p>	
Interventions	<p>Intervention: participants received <i>dietary advice and ONS</i> in the form of energy and protein enriched diet, 2 x oral nutritional supplements (Nutridrink, Nutricia: expected increase in intake of 600 kcal/day and 24 g protein/day during the entire study period), 400 IE vitamin D3, 500 mg calcium (Calci-Chew D3, Nycomed) per day during the entire study period, telephone counselling by a dietitian to give advice and to stimulate compliance (every other week after discharge, 6 in total).</p> <p>Control: participants received <i>no dietary advice and no ONS</i> in the form of usual care i.e. nutritional support only on prescription by their treating physician, which means that in general they did not receive post-discharge nutritional support.</p>	
Outcomes	<p>Primary outcomes: changes in activities of daily living (functional limitations, LASA Functional Limitation Questionnaire and LASA Physical Activity Questionnaire); functional status (Short Physical Performance Battery) and muscle strength (handgrip strength)*.</p> <p>Secondary outcomes: changes in body weight*, body composition (measured by Bioelectro-impedance analysis).</p>	
Publication details	<p>Language: English.</p> <p>Funding: The Netherlands Organisation for Health Research and Development.</p> <p>Publication status: peer-reviewed journal.</p>	
Notes	<p>Data included from 2 subsequent publications (Neelemaat 2012 and Neelemaat 2017).</p>	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "A computerised random number generator was used to assign patients in blocks of 10 to the intervention or control groups.
Allocation concealment (selection bias)	Low risk	Quote: "...opened a consecutively numbered opaque envelope containing the patients' group assignment".
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	Not described but unlikely to affect assessment of clinical outcomes.
Blinding (performance bias and detection bias) Functional outcomes	High risk	Not described and lack of blinding might have influenced the assessment of some functional outcomes.

Neelemaat 2011 (Continued)

Blinding (performance bias and detection bias) Nutritional outcomes	High risk	Not described and lack of blinding might have influenced the assessment of some nutritional outcomes.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not blinded and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding of outcome assessment not described and lack of blinding might have influenced the assessment of some outcomes.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Attrition fully reported and reasons similar in each group: 60/210 (29%). Intervention group 30/105 (29%); control group 30/105 (29%).
Selective reporting (reporting bias)	Unclear risk	Study protocol identified. (http://www.trialregister.nl (candidate number 1660, NTR number NTR476, ISRCTN ISRCTN29617677, date ISRCTN created 27 Jan 2006). Most outcomes specified in the protocol were reported. Complication rate is not reported in any of the three publications identified.
Other bias	Low risk	Baseline characteristics were similar in both groups.

Norman 2008b
Study characteristics

Methods	<p>RCT.</p> <p>Parallel design with 2 treatment arms.</p> <p>Duration: 3 months from hospital discharge.</p> <p>Location: single centre in Germany.</p>
Participants	<p>Inclusion criteria: adults with benign gastrointestinal disorders admitted to hospital and classified as malnourished according to SGA criteria.</p> <p>Exclusion criteria: malignant disease, renal insufficiency (serum creatinine 41.3mg/dl), and life expectancy < 3 months or age < 18 years.</p> <p><u>2008:</u></p> <p>Number randomised: 101 participants (intervention group, n = 48, control group, n = 48). Attrition: 21 dropouts, 10 intervention group (withdrew before baseline) and 11 lost to follow-up in the control group.</p> <p>Gender split: not stated.</p> <p>Age: mean (SD), intervention group 52.2 (16.5) years; control group 53.6 (16.8) years.</p> <p>Nutritional status: all malnourished according to SGA (grade B or C).</p> <p><u>2011:</u></p> <p>Number randomised: 160 participants, 114 completed the study (intervention group, n = 60; control group, n = 54).</p> <p>Gender split: 57 males, 57 females.</p>

Norman 2008b (Continued)

Age: mean (SD) total cohort 50.6 (16.1) years.

Nutritional status: all malnourished according to SGA (grade B or C).

Interventions	<p>Intervention: participants received <i>dietary advice and ONS</i> in the form of dietary counselling from a dietician to increase energy and protein intake from food and up to 3 x 200 mL Fresubin protein energy drinks.</p> <p>Control: participants received <i>dietary advice alone</i> in the form of dietary counselling to increase energy and protein intake from food.</p>
Outcomes	<p><u>2008:</u> Energy intake*, weight*, height, BMI*, TSF*, MUAC*, body composition (BIA), handgrip strength*, length of stay, number of readmissions*, number of prescribed drugs on discharge, peak expiratory flow.</p> <p><u>2011:</u> QoL, cost.</p>
Publication details	<p>Language: English.</p> <p>Funding: grant from Fresenius Kabi, Bad Homburg.</p> <p>Publication status: peer-reviewed journal.</p>
Notes	<p>A first study was published in 2008; new data were published in 2011.</p> <p>Quality-adjusted life years were calculated by adopting the area under the curve method.</p> <p>QoL was assessed with Short-Form (SF)-36 Health Survey and SF-36 values were transformed into health-status utilities.</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Participants were randomised according to a computer-generated randomisation list kept by a co-worker not involved in the study.
Allocation concealment (selection bias)	Low risk	Central allocation, web-based by a co-worker not involved in the study.
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	Not reported, in the 2008 paper the main outcome was number of readmissions. It is unlikely that this may have been influenced by knowing the group allocation.
Blinding (performance bias and detection bias) Functional outcomes	High risk	Although not reported, intervention participants received supplements and control participants did not. Functional outcomes could have been influenced by lack of blinding.
Blinding (performance bias and detection bias) Nutritional outcomes	High risk	Although not reported, intervention participants received supplements and control participants did not. Nutritional outcomes could have been influenced by lack of blinding.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not described and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Judged to be unclear because low risk for clinical outcomes and high risk for functional and nutritional outcomes.

Norman 2008b (Continued)

Incomplete outcome data (attrition bias) All outcomes	Low risk	<p><u>2008</u>: 21 dropouts: Dietary counselling and supplement group: 10 withdrew before baseline; Dietary counselling alone: 11 lost to follow-up.</p> <p>Also, in the dietary counselling and supplement group 8 known to not take the supplement, but included in the ITT analysis.</p> <p>In the dietary counselling group, 4 reported consuming nutritional supplements during the study period.</p> <p><u>2011</u>: 160 participants were recruited for the study, of which 120 completed the study.</p> <p>Dietary counselling and supplement group: 12 withdrew before the start, 8 lost to follow-up.</p> <p>Dietary counselling alone: 20 lost to follow-up, 6 did not complete SF 36 QoL questionnaires.</p> <p>ITT analyses for 60 participants in intervention group and 54 participants in control group.</p>
Selective reporting (reporting bias)	Unclear risk	<p>No study protocol identified, thus unable to judge whether all planned outcomes were reported. Data on mean change (SD) for weight and grip strength were extracted from the paper. Data on TSF and MUAC were not presented but were assessed and so have been obtained from author. Details of hospital admissions are not reported clearly and therefore have been clarified with the authors.</p> <p>For the 2011 manuscript 6 participants did not complete SF36 correctly and all were assigned to the control group.</p>
Other bias	Low risk	Baseline characteristics described in text as not different and data given for some variables.

Olejko 1984
Study characteristics

Methods	<p>RCT.</p> <p>Parallel design with 3 treatment arms.</p> <p>Duration: 6 weeks.</p> <p>Location: single centre in the USA.</p>
Participants	<p>Inclusion criteria: adults awaiting elective orthognathic surgery.</p> <p>Exclusion criteria: not specified.</p> <p>Number randomised: 24 participants (intervention group 1, n = 8; intervention group 2, n = 8; control group, n = 8). 100% follow-up.</p> <p>Gender split: 12 males, 12 females.</p> <p>Age: mean (SD), 22.8 (6.1) years.</p> <p>Nutritional status: 12 of 24 participants had a weight below IBW at study inclusion. Mean BMI can be calculated from individual participant data (mean BMI 22).</p>

Olejko 1984 (Continued)

Interventions	<p>Intervention (intervention group 1): participants received <i>dietary advice and ONS</i> in the form of dietary instruction and an oral nutritional supplement (1.5 kcal/mL) to provide 50% of energy requirements.</p> <p>Intervention (intervention group 2): participants received <i>dietary advice and ONS</i> in the form of dietary instruction, an oral nutritional supplement (1.5 kcal/mL) to provide 50% of energy requirements and a nutritional supplement to take preoperatively.</p> <p>Control: participants received <i>dietary advice alone</i> in the form of dietary instruction given verbally and in writing.</p>	
Outcomes	Survival*, body weight*, MUAC*, MAMC*, TSF*, serum chemistry and creatinine height index, macro and micronutrient intake.	
Publication details	<p>Language: English.</p> <p>Funding: not reported.</p> <p>Publication status: peer-reviewed journal.</p>	
Notes		
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Described as randomised, method not reported.
Allocation concealment (selection bias)	Unclear risk	Method not reported.
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	Not reported, but the nature of the study suggests that the study was unblinded. However, it is unlikely that knowing groups assignment would have influenced clinical outcomes.
Blinding (performance bias and detection bias) Functional outcomes	High risk	Not reported, but the nature of the study suggests that the study was unblinded. Functional outcomes could have been influenced by lack of blinding.
Blinding (performance bias and detection bias) Nutritional outcomes	High risk	Not reported, but the nature of the study suggests that the study was unblinded. Nutritional outcomes could have been influenced by lack of blinding.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not blinded and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Judged to be unclear because of low risk for clinical outcomes and high risk for functional and nutritional outcomes.
Incomplete outcome data (attrition bias) All outcomes	Low risk	100% follow-up.
Selective reporting (reporting bias)	High risk	No study protocol identified, thus unable to judge whether all planned outcomes were reported. All outcomes were reported but using general state-

Olejko 1984 (Continued)

ments about change rather than numerical presentation e.g. 'the pre-load group reported an average weight gain of 3.1% during the one month pre-operative period, which was significantly greater ($P < 0.05$) than that of the other two groups'. No data are available from the authors therefore unclear risk of bias due to partial reporting.

Other bias	Unclear risk	Baseline variables not given, not sure if groups similar at baseline.
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Ollenschlager 1992
Study characteristics

Methods	RCT. Parallel design with 2 treatment arms. Duration: mean of 25.5 weeks. Location: Germany.
Participants	Inclusion criteria: adults undergoing chemotherapy for acute leukaemia who had undesired weight loss $> 5\%$ or weight $90\% < IBW$. Exclusion criteria: metabolic diseases, renal or liver insufficiency, the need for artificial nutrition. Number randomised: 29 participants (intervention group, $n = 15$; control group, $n = 16$). Attrition: 2 deaths in the intervention group. Gender split: not possible to work out from the information provided. Age: aged 17 - 59 years. Nutritional status: not possible to work out from the information provided.
Interventions	Intervention: participants received <i>dietary advice</i> in the form of daily dietary instruction and modification of diet. Control: participants received <i>no dietary advice</i> in the form of ad libitum intake.
Outcomes	Weight*, survival*, number of complete remissions and days temperature >38.5 C, nutrient intake (intervention gp only) *, subjective well-being (intervention gp only).
Publication details	Language: English. Funding: none declared. Publication status: peer-reviewed journal.
Notes	Data given for mean study period. Data on nutrient intake and subjective well-being only collected for intervention group so not used. Additional data and information obtained from authors.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Described as randomised, method not stated.

Ollenschlager 1992 (Continued)

Allocation concealment (selection bias)	Unclear risk	Method not stated.
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	Blinding not described but assessment of mortality unlikely to be influenced by lack of blinding.
Blinding (performance bias and detection bias) Functional outcomes	Unclear risk	Not stated.
Blinding (performance bias and detection bias) Nutritional outcomes	Unclear risk	Not stated.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not described and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No blinding described and likely that lack of blinding might influence assessment of some outcomes.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Fully described with reasons. (2/15 deaths in the dietary advice group, 0/16 deaths in the routine care group; 2 participants in the dietary advice group excluded from the analysis because only 1 weight obtained in week 1).
Selective reporting (reporting bias)	High risk	No protocol identified. Data given for mean study period. Data on nutrient intake and subjective well-being only collected for intervention group so not used. Data on weight change presented as % of ideal body weight, mean change (SD) not available from authors and so not included in the review. Additional data on mortality and information on some outcomes obtained from authors.
Other bias	Low risk	Baseline variables given, groups similar at baseline.

Ovesen 1993
Study characteristics

Methods	RCT. Parallel design with 2 treatment arms. Duration: 5 months. Location: Denmark.
Participants	Inclusion criteria: adults receiving chemotherapy for small-cell lung cancer, ovarian cancer or breast cancer.

Ovesen 1993 (Continued)

Exclusion criteria: prior chemotherapy, current or planned hormonal therapy, major surgery within the last month, present of ascites, oedema, malabsorption or other diseases that necessitated dietary intervention, CNS metastases.

Number randomised: 137 participants (intervention group, n = 74; control group, n = 63). Attrition: 30 deaths, 20 in the intervention group and 10 in the control group; 19 withdrawals, 9 in the intervention group and 10 in the control group.

Gender split: 75% males and 25% females.

Age: combined range 22 - 80 years.

Nutritional status: 50% of participants malnourished at study entry defined as > 5% weight loss in the previous 3 months.

Interventions	<p>Intervention: participants received <i>dietary advice plus ONS if required</i> in the form of dietary instruction given 2x monthly to exceed the Nordic recommended allowances using supplements if indicated.</p> <p>Control: participants received <i>no dietary advice and no ONS</i> in the form of no dietary advice.</p>
Outcomes	Survival*, weight*, TSF, MAMC, MUAC, energy intake*, FFM*, QoL*, tumour response.
Publication details	<p>Language: English.</p> <p>Funding: the Danish Cancer Society.</p> <p>Publication status: peer-reviewed journal.</p>

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Sequence generation was reported as using a table of random numbers.
Allocation concealment (selection bias)	Low risk	Allocation concealment was reported as using sealed opaque envelopes.
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	The study was assumed to be unblinded. However, this is unlikely to influence clinical outcomes.
Blinding (performance bias and detection bias) Functional outcomes	High risk	The study was unblinded. Functional outcomes could have been influenced by lack of blinding.
Blinding (performance bias and detection bias) Nutritional outcomes	Unclear risk	The study was unblinded. Nutritional outcomes could have been influenced by lack of blinding.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not blinded and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Judged to be unclear because low risk for clinical outcomes and high risk for functional and nutritional outcomes.

Ovesen 1993 (Continued)

Incomplete outcome data (attrition bias) All outcomes	Unclear risk	30 deaths: 20 in the dietary advice group and 10 in the no advice group. 19 withdrawals: 9 in the dietary advice group and 10 in the no advice group. Amounts similar between groups but no reasons given.
Selective reporting (reporting bias)	Unclear risk	No study protocol identified, thus unable to judge whether all planned outcomes were reported. outcomes reported at baseline and monthly to five months after the intervention. The data on mortality (up to 1400 days ~ 3.8 years) at interim time-points is unclear and it has not been possible to clarify with authors, therefore only data from baseline to 5 months have been used in meta-analysis.
Other bias	Low risk	Baseline variables given, groups similar at baseline.

Parsons 2016
Study characteristics

Methods	<p>RCT.</p> <p>Parallel design with two treatment arms.</p> <p>Duration: 12 weeks.</p> <p>Location: UK.</p>
Participants	<p>Inclusion criteria: care home resident, > 50 years of age, medium/high risk of malnutrition (MUST), able to give consent and able to eat and drink safely with adequate cognitive function (not tested, judgement of nursing staff or info in medical notes).</p> <p>Exclusion criteria: receiving enteral or parenteral feeding or oral nutritional supplements (or in the 4 weeks prior to the study), chronic kidney disease requiring dialysis, liver failure, malignancy, receiving palliative care for terminal illness.</p> <p>Diagnosis: multiple problems, 45% nursing care, 55% residential care.</p> <p>Number randomised: 104 participants. Attrition: 34 of 104 (33%) (intervention group, n = 20; control group, n = 14).</p> <p>Gender split: 145 males, 86% females.</p> <p>Age: mean (SD) 88.5 (7.9) years.</p> <p>Nutritional status: assessed using MUST, 46% medium risk, 54% high risk.</p>
Interventions	<p>Intervention (intervention group 1): participants received <i>ONS</i> in the form of a specially designed diet sheet encouraging intake of high energy foods, drinks and snacks.</p> <p>Intervention (intervention group 2): participants received <i>dietary advice</i> in the form of access to a range of oral nutritional supplements to take ad lib according to choice and guidance to staff and participants on using ONS. Target intake 600 kcal/day.</p> <p>Both interventions discussed at baseline and week 6 by dietitian.</p>
Outcomes	Recorded at baseline, 6 & 12 weeks; malnutrition risk (MUST), QoL (EQ5D), dietary intake (24 h recall), appetite on VAS. Mortality also recorded.
Publication details	<p>Language: English.</p> <p>Funding: educational grant from Nutricia.</p>

Parsons 2016 (Continued)

Publication status: peer-reviewed journal.

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: undertaken independently of the researchers using random number tables produced by EXCEL. Codes were generated prior to commencement of the trial.
Allocation concealment (selection bias)	Low risk	Quote: ..using opaque, sealed envelopes labelled with the random numbers containing the designated interventions.
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	Not reported beyond inclusion into the trial, but unlikely that assessment of clinical outcomes would be influenced by lack of blinding.
Blinding (performance bias and detection bias) Functional outcomes	High risk	Not reported beyond inclusion into the trial, and likely that assessment of functional outcomes would be influenced by lack of blinding. Quote: "at the point of randomisation, both the residents and researchers were blinded to the designated intervention".
Blinding (performance bias and detection bias) Nutritional outcomes	High risk	Not reported beyond inclusion into the trial, and likely that assessment of clinical outcomes would be influenced by lack of blinding. Quote: "at the point of randomisation, both the residents and researchers were blinded to the designated intervention".
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not blinded and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported and likely that assessment of some outcomes would be influenced by lack of blinding.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Attrition fully reported. 34/104 (33%) participants lost to follow-up (dietary advice group n = 20/51 (39 %), including 4 deaths; ONS group n = 14/53 (26 %), including 2 deaths). Reasons similar for both groups and mainly related to decline in health or memory.
Selective reporting (reporting bias)	Unclear risk	Protocol published on Clinical Trial Registry which records only the primary outcome of QoL. All other outcomes mentioned in the methods are reported in the results but data for quality of life, energy and protein intake reported as baseline value (SD) for the combined group and end value (SD) for the group allocation. Data have been requested from authors.
Other bias	Unclear risk	Baseline characteristics compared between groups and no significant differences other than the visual analogue score component of EQ5D. VAS scores significantly higher at baseline in the comparison group receiving ONS and unclear what influence this would have on outcomes.

Paton 2004

Study characteristics

Methods	<p>RCT.</p> <p>Parallel design with 2 treatment arms.</p> <p>Duration: 24 weeks (intervention for 6 or 12 weeks and follow-up to 24 weeks).</p> <p>Location: single centre (Hospital-based TB Control Unit, Singapore).</p>
Participants	<p>Inclusion criteria: males and females aged 18 - 69 years old, evidence of active tuberculosis (symptoms of fever or cough + sputum smear - acid-fast bacilli or chest x-ray), evidence of wasting (BMI < 20 kg/m²), started on combination antituberculous chemotherapy within the previous 2 weeks.</p> <p>Exclusion criteria: diabetes mellitus, severe underlying disease, concomitant corticosteroid or immunosuppressive therapy, positive HIV test or considered at risk of HIV infection, past history of non-compliance to tuberculosis therapy, unable to tolerate conventional treatment, required inpatient treatment for their disease.</p> <p>Number randomised: 36 participants (intervention group, n = 15; control group, n = 13). Attrition: 10 participants lost to follow-up (4 in intervention group and 6 in control group).</p> <p>Gender split: intervention group 8 (47%) males and 11 (53%) females; control group 8 (42%) males and 9 (58%) females.</p> <p>Age: mean (SD), intervention group 39.5 (14.3) years; control group 38.4 (19.3) years.</p> <p>Nutritional status: mean(SD) BMI, intervention 16.7 (1.5) kg/m²; control 17.9 (1.9) kg/m².</p>
Interventions	<p>Intervention: participants received <i>dietary advice and ONS</i> in the form of advice to increase intake, aim 35 kcal/kg body weight/day; high energy oral nutritional supplements (2 - 3 packets/day), contacted by telephone to assess progress, target of 35 kcal/kg and explained why important to meet, also phoned at 2 - 3 weeks, 6 weeks and 12 weeks.</p> <p>Control: participants received <i>no dietary advice and no ONS</i> in the form of general advice to address any major dietary imbalance identified, instructed to increase intake as they could but no specific instructions.</p>
Outcomes	Weight*, BMI, body composition (DEXA)*, energy intake*, grip strength*, QoL, physical function (sit-to-stand test).
Publication details	<p>Language: English.</p> <p>Funding: none detailed.</p> <p>Publication status: peer-reviewed journal.</p>
Notes	Additional data requested from author.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: sequence generated by a member of staff not otherwise involved in the study.
Allocation concealment (selection bias)	Low risk	Described as shuffling of sealed opaque envelopes.
Blinding (performance bias and detection bias)	Low risk	Not stated but assessment of mortality unlikely to be affected by lack of blinding.

Paton 2004 (Continued)

Clinical outcomes

Blinding (performance bias and detection bias) Functional outcomes	Unclear risk	Not stated but assessment of functional outcomes may have been affected by lack of blinding.
Blinding (performance bias and detection bias) Nutritional outcomes	Unclear risk	Not stated but assessment of nutritional outcomes may have been affected by lack of blinding.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not described and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not stated and assessment of some outcomes may have been affected by lack of blinding.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Attrition fully reported and reasons balanced between groups. 10/36 (28%) participants lost to follow-up at participants' request, 4/19 (21%) in dietary advice and supplement group and 6/17 (35%) in dietary advice group.
Selective reporting (reporting bias)	Unclear risk	No protocol identified. All specified outcomes reported but some in unusable format. Data on change in energy intake was presented in the text and not suitable for entry into meta-analysis therefore obtained from author. Other data were extracted from the paper although 'n' for weight and grip strength were clarified with the authors.
Other bias	Low risk	Baseline variables given, groups similar at baseline.

Payette 2002
Study characteristics

Methods	<p>RCT.</p> <p>Parallel design with 2 treatment arms.</p> <p>Duration: 16 weeks.</p> <p>Location: multicentre at 7 local community service centres, Quebec, Canada.</p>
Participants	<p>Inclusion criteria: older adults (aged > 65 years) who were at high nutritional risk (unintentional weight loss > 5% in previous month, > 7.5% in previous 3 months or > 10% in previous 6 months AND BMI < 27 OR BMI < 24), orientated to time and place.</p> <p>Exclusion criteria: palliative care, alcoholic, active cancer or illness requiring a therapeutic diet incompatible with oral nutritional supplements.</p> <p>Number randomised: 83 (intervention group, n = 41; control group, n = 42). Attrition: 5 participants refused the assignment and declined participation before the start of the study (intervention group n = 1, control group n = 4); 1 participant (intervention group) was lost to follow-up due to cancer diagnosis.</p> <p>Gender split: intervention group 12 (29%) male, 29 (71%) female; control group 12 (29%) male, 30 (71%) female.</p> <p>Age: mean (SD) years, intervention group 81.6 (7.5), control group 78.6 (6.1).</p>

Payette 2002 (Continued)

Nutritional status: mean (SD) BMI, intervention 20.1 (2.7) kg/m²; control 20.1 (3.0) kg/m².

Interventions	<p>Intervention: participants received <i>dietary advice and ONS</i> in the form of 2 x 235 mL/day oral nutritional supplements (Ensure or Ensure Plus, Abbott Laboratories), clearly instructed not to replace their usual meals with the drinks, encouraged to use oral nutritional supplements to supplement diet; contacted by phone every 2 weeks by a dietitian and given nutritional counselling and encouragement to improve their food and supplement intake.</p> <p>Control: participants received <i>no dietary advice and no ONS</i> in the form of no nutritional treatment and no oral nutritional supplements, visited each month and, to control for any effect of greater attention to 1 group, were given a small gift.</p>
Outcomes	Energy intake, body weight, handgrip strength, AMC.
Publication details	<p>Language: English.</p> <p>Funding: none detailed.</p> <p>Publication status: peer-reviewed journal.</p>
Notes	Author contacted to request change data.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not described.
Allocation concealment (selection bias)	Unclear risk	Not described.
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	2 research dietitians collected data: 1 was responsible for recruitment and collection of baseline and follow-up nutritional data and the other (blinded to participants' treatment) completed measurements of functional and health status.
Blinding (performance bias and detection bias) Functional outcomes	Low risk	See comment above.
Blinding (performance bias and detection bias) Nutritional outcomes	High risk	See comment above.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not described and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Assessment of some outcomes may have been influenced by lack of blinding.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Attrition fully reported and reasons balanced between groups. 6/89 (7%); intervention group 2/43 (5%) and control group 4/46 (9%).

Payette 2002 (Continued)

Selective reporting (reporting bias)	Unclear risk	No protocol identified.
Other bias	Low risk	Baseline characteristics presented in Table 1. Study groups similar at baseline. Although control group was significantly younger than intervention group (mean (SD) age 78.6 (6.1) versus 81.6 (7.5) years respectively) this is unlikely to affect outcomes.

Pedersen 2016a
Study characteristics

Methods	<p>RCT.</p> <p>Parallel design with 2 intervention groups and 1 control group.</p> <p>Duration: 8 weeks (randomization took place upon discharge from hospital and follow-up interventions lasted 8 weeks).</p> <p>Location: single centre in Denmark.</p>
Participants	<p>Inclusion criteria: malnourished or at risk of malnutrition, 75 years and older, living independently and alone in the area served by the hospital, able to speak the Danish language, and to communicate over the telephone.</p> <p>Exclusion criteria: nursing home residents, terminal illnesses or cognitive impairment.</p> <p>Number randomised: 208 participants (intervention group 1, n = 73; intervention group 2, n = 68; control group, n = 67).</p> <p>Gender split: intervention group 1, 57% females; intervention group 2, 51% females; control group, 65% females.</p> <p>Age: mean 86.1 years.</p> <p>Nutritional status: mean (SD) MNA score, intervention 1 17.1 (3.2); intervention 2 17.3 (3.7); control 17.0 (3.9).</p>
Interventions	<p>Intervention (group 1): participants received <i>dietary advice plus ONS if required</i> in the form of standard care during hospital stay followed by nutritional counselling* during home visits (45 min duration) by a clinical dietician at 1, 2 and 4 weeks post hospital discharge.</p> <p>Intervention (group 2): participants received <i>dietary advice plus ONS if required</i> in the form of standard care during hospital stay followed by nutritional counselling via telephone consultations (15 min duration) by a clinical dietician at 1, 2 and 4 weeks post hospital discharge.</p> <p>Control: participants received <i>no dietary advice and no ONS</i> in the form of standard care during hospital stay and no follow-up care from the hospital after discharge.</p> <p>*based on nutritional needs identified during the hospital stay, and tailored to the individual's preferences and circumstances; since reduced appetite and low food intake had become normal, the intervention focused on nutritional and meal behaviour that improve appetite and increase nutritional intake.</p> <p>The counselling sessions were attended by the participant's home carer, who holds a key position in supporting the participant on a daily basis.</p>
Outcomes	<p>Primary outcome: change in ADL (Barthel-100 score) at discharge and 8 weeks later.</p>

Pedersen 2016a (Continued)

Secondary outcomes: change in physical performance (handgrip strength*, 30-sec. chair stand test, CAS), QoL and depression measurements (SF-36 (not global), Depression List, Geriatric Depression Score), and Avlund mobility-tiredness score (Mob-T).

Publication details	<p>Language: English.</p> <p>Funding: not declared.</p> <p>Publication status: peer-reviewed journal.</p>
Notes	<p>This study is a duplicate of Pederson 2016b. The study has 2 intervention arms and a single control group. Therefore the number of participants in the control group is divided by 2. This study ID describes the data of intervention group 'home visit' versus control, whereas Pederson 2016b describes 'telephone counselling' versus control.</p> <p>The primary aim of the study was to compare the effects of 2 nutritional follow-up intervention strategies (home visit and telephone consultation) with no follow-up, with regard to preventing short-term deterioration in ADL, and the second, to compare the effect of the interventions on physical function, health-related QoL, and emotional health.</p> <p>QoL data could not be used because only subscores were reported.</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation executed electronically via the web-based, clinical-trial- support-system, 'TrialPartner' (Public Health and Quality Improvement, Central Denmark Region). This central computer program used permuted block-sizes and stratified the randomisation according to nutritional status.
Allocation concealment (selection bias)	Low risk	Randomisation took place upon discharge and was executed electronically via the web-based, clinical-trial- support-system, 'TrialPartner' (Public Health and Quality Improvement, Central Denmark Region). This central computer program used permuted block-sizes and stratified the randomisation according to nutritional status.
Blinding (performance bias and detection bias) Clinical outcomes	Unclear risk	Not measured.
Blinding (performance bias and detection bias) Functional outcomes	Low risk	<p>Owing to the nature of the interventions, it was not possible to blind the participants to the intervention.</p> <p>The principal investigator obtained baseline characteristics before randomisation, and was not in contact with the participants after that.</p> <p>The research assistant who conducted the baseline and follow-up measurements (week 0 and week 8) was not informed of the results of the randomisation, but it cannot be ruled out that the participants may have mentioned their assignment.</p>
Blinding (performance bias and detection bias) Nutritional outcomes	Low risk	<p>Owing to the nature of the interventions, it was not possible to blind the participants to the intervention.</p> <p>The principal investigator obtained baseline characteristics before randomisation, and was not in contact with the participants after that.</p> <p>The research assistant who conducted the baseline and follow-up measurements (week 0 and week 8) was not informed of the results of the randomisation.</p>

Pedersen 2016a (Continued)

		tion, but it cannot be ruled out that the participants may have mentioned their assignment.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not blinded and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding
Blinding of outcome assessment (detection bias) All outcomes	Low risk	The research assistant who conducted the baseline and follow-up measurements (week 0 and week 8) was not informed of the results of the randomisation, but it cannot be ruled out that the participants may have mentioned their assignment.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	At 8 weeks after discharge, 157/208 (75%) completed the follow-up (home visit n = 52, telephone consultation n = 51, and control group n = 54). Drop-outs (25%) were equally divided across groups but the reasons for drop-out not mentioned.
Selective reporting (reporting bias)	Low risk	The study protocol was published in 2015 (Journal of Ageing Research & Clinical Practice) with primary outcome: ADL and secondary outcomes: physical performance (handgrip strength, chair stand), QoL, depression measurements, and tiredness score. All specified outcomes reported in 2 papers
Other bias	Low risk	Baseline characteristics given and similar between groups

Pedersen 2016b
Study characteristics

Methods	<p>RCT.</p> <p>Parallel design with 2 intervention groups and 1 control group.</p> <p>Duration: 8 weeks (randomization took place upon discharge from hospital and follow-up interventions lasted 8 weeks).</p> <p>Location: single centre in Denmark.</p>
Participants	<p>Inclusion criteria: malnourished or at risk of malnutrition, 75 years and older, living independently and alone in the area served by the hospital, able to speak the Danish language, and to communicate over the telephone.</p> <p>Exclusion criteria: nursing home residents, terminal illnesses or cognitive impairment.</p> <p>Number randomised: 208 participants (intervention group 1, n = 73; intervention group 2, n = 68; control group, n = 67).</p> <p>Gender split: intervention group 1, 57% females; intervention group 2, 51% females; control group, 65% females.</p> <p>Age: mean 86.1 years.</p> <p>Nutritional status: mean (SD) MNA score, intervention group 1 17.1 (3.2); intervention group 2 17.3(3.7); control group 17.0 (3.9).</p>
Interventions	<p>Intervention group 1: participants received <i>dietary advice plus ONS if required</i> in the form of standard care during hospital stay followed by nutritional counselling* during home visits (45 min duration) by a clinical dietician at 1, 2 and 4 weeks post hospital discharge.</p>

Pedersen 2016b (Continued)

Intervention group 2: participants received *dietary advice plus ONS if required* in the form of standard care during hospital stay followed by nutritional counselling via telephone consultations (15 min duration) by a clinical dietician at 1, 2 and 4 weeks post hospital discharge.

Control group: participants received *no dietary advice and no ONS* in the form of standard care during hospital stay and no follow-up care from the hospital after discharge.

*based on nutritional needs identified during the hospital stay, and tailored to the individual's preferences and circumstances; since reduced appetite and low food intake had become normal, the intervention focused on nutritional and meal behaviour that improve appetite and increase nutritional intake.

The counselling sessions were attended by the participant's home carer, who holds a key position in supporting the participant on a daily basis.

Outcomes	<p>Primary outcome: change in ADL (Barthel-100 score) at discharge and 8 weeks later.</p> <p>Secondary outcomes: change in physical performance (handgrip strength*, 30-sec. chair stand test, CAS), QoL and depression measurements (SF-36, Depression List, Geriatric Depression Score), and Avlund mobility-tiredness score (Mob-T).</p>	
Publication details	<p>Language: English.</p> <p>Funding: not declared.</p> <p>Publication status: peer-reviewed journal.</p>	
Notes	<p>This study is a duplicate of Pederson 2016a. The study has 2 intervention arms and a single control group. Therefore the number of participants in the control group is divided by 2. This study ID describes the data of intervention group 'telephone counselling' versus control, whereas Pederson 2016a describes 'home visits' versus control.</p> <p>The primary aim of the study was to compare the effects of 2 nutritional follow-up intervention strategies (home visit and telephone consultation) with no follow-up, with regard to preventing short-term deterioration in ADL, and the second, to compare the effect of the interventions on physical function, health-related QoL, and emotional health.</p> <p>QoL data could not be used because only subscores were reported.</p>	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation executed electronically via the web-based, clinical-trial- support-system, 'TrialPartner' (Public Health and Quality Improvement, Central Denmark Region). This central computer program used permuted block-sizes and stratified the randomisation according to nutritional status.
Allocation concealment (selection bias)	Low risk	Randomisation took place upon discharge and was executed electronically via the web-based, clinical-trial- support-system, 'TrialPartner' (Public Health and Quality Improvement, Central Denmark Region). This central computer program used permuted block-sizes and stratified the randomisation according to nutritional status.
Blinding (performance bias and detection bias) Clinical outcomes	Unclear risk	Not measured.
Blinding (performance bias and detection bias) Functional outcomes	Low risk	Owing to the nature of the interventions, it was not possible to blind the participants to the intervention.

Pedersen 2016b (Continued)

		<p>The principal investigator obtained baseline characteristics before randomisation, and was not in contact with the participants after that.</p> <p>The research assistant who conducted the baseline and follow-up measurements (week 0 and week 8) was not informed of the results of the randomisation, but it cannot be ruled out that the participants may have mentioned their assignment.</p>
Blinding (performance bias and detection bias) Nutritional outcomes	Low risk	<p>Owing to the nature of the interventions, it was not possible to blind the participants to the intervention.</p> <p>The principal investigator obtained baseline characteristics before randomisation, and was not in contact with the participants after that.</p> <p>The research assistant who conducted the baseline and follow-up measurements (week 0 and week 8) was not informed of the results of the randomisation, but it cannot be ruled out that the participants may have mentioned their assignment.</p>
Blinding of participants and personnel (performance bias) All outcomes	High risk	<p>Not blinded and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding.</p>
Blinding of outcome assessment (detection bias) All outcomes	Low risk	<p>The research assistant who conducted the baseline and follow-up measurements (week 0 and week 8) was not informed of the results of the randomisation, but it cannot be ruled out that the participants may have mentioned their assignment.</p>
Incomplete outcome data (attrition bias) All outcomes	Low risk	<p>At 8 weeks after discharge, 157/208 (75%) completed the follow-up (home visit n = 52, telephone consultation n = 51, and control group n = 54). Drop-outs (25%) were equally divided across groups but the reasons for drop-out not mentioned.</p>
Selective reporting (reporting bias)	Low risk	<p>The study protocol was published in 2015 (Journal of Ageing Research & Clinical Practice) with primary outcome: ADL and secondary outcomes: physical performance (handgrip strength, chair stand), QoL, depression measurements, and tiredness score.</p>
Other bias	Low risk	<p>Baseline characteristics given and similar between groups</p>

Persson 2002
Study characteristics

Methods	<p>RCT.</p> <p>Parallel design with 2 treatment arms.</p> <p>Duration: 24 months.</p> <p>Location: Sweden.</p>
Participants	<p>Inclusion criteria: adults who were newly diagnosed with colorectal or gastric cancer.</p> <p>Exclusion criteria: requiring constant hospital care (Karnofsky score < 40), with an earlier cancer diagnosis or those who did not speak or understand Swedish.</p> <p>Number randomised: 142 participants but 5 dropouts immediately after randomisation (intervention group, n = 3; control group, n = 2) so 137 participants included (intervention group, n = 67; con-</p>

Persson 2002 (Continued)

trol group, n = 70). Attrition: at 24 months there were 74 drop outs (intervention group, n = 33; control group, n = 41).

Gender split: 63% males, 37% females.

Age: range 42 - 89 years.

Nutritional status: number with weight loss, intervention 52/67; control 48/70.

Interventions	Intervention: participants received <i>dietary advice plus ONS if required</i> in the form of nutritional counselling to increase food intake to Nordic Nutrition Recommendations and a prescription for nutritional supplements if wanted.	
	Control: participants received <i>no dietary advice and no ONS</i> in the form of standard care.	
Outcomes	Survival*, weight*, BMI*, energy intake*.	
Publication details	Language: English.	
	Funding: the Swedish Cancer Society.	
	Publication status: peer-reviewed journal.	
Notes		
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Information from the author, random sequence generated on computer by independent centre.
Allocation concealment (selection bias)	Low risk	Information from the author, allocation performed by independent centre, allocation concealed until participant recruited.
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	Not stated but unlikely to affect assessment of clinical outcomes.
Blinding (performance bias and detection bias) Functional outcomes	Unclear risk	Not stated and lack of blinding likely to influence assessment of some functional outcomes
Blinding (performance bias and detection bias) Nutritional outcomes	High risk	Not stated and lack of blinding likely to influence assessment of some nutritional outcomes.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not described and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not described and lack of blinding might have influenced assessment of some outcomes.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Information from author: 137 participants randomised in the study, at 24 months there were 74 drop outs (intervention group: 25 deaths, 5 withdrawals and 3 exclusions; control group: 26 deaths, 14 withdrawals and 1 exclusion). Amounts and reasons similar between groups.

Persson 2002 (Continued)

Selective reporting (reporting bias)	Unclear risk	No study protocol identified, thus unable to judge whether all planned outcomes were reported. The data on mortality is unclear in the paper. The data on weight change is presented partly in text and partly in figures and not suitable for direct entry into meta-analysis. The data on energy intake is presented as % recommendations. All data included in the review has been obtained from the author including data at 4 time-points.
Other bias	Low risk	Baseline variables given, groups similar at baseline.

Persson 2007
Study characteristics

Methods	RCT. Parallel design with 2 treatment arms. Duration: median 4.3 months, range 3.6 - 6.9 months. Location: Sweden.	
Participants	Inclusion criteria: elderly people admitted to hospital for trauma or acute illness, at risk of malnutrition defined by MNA score < 10. Exclusion criteria: malignant disorders, terminal illness or with severe cognitive dysfunction. Number randomised: 108 participants (intervention group, n = 51; control group, n = 57). Attrition: 54 dropouts. Gender split: not reported. Age: mean (SD), intervention group 85 (5.9) years, control group 85 (6.1) years. Nutritional status: mean (SD) BMI, intervention 19.8 (1.9); control 20.6 (3.0).	
Interventions	Intervention: participants received <i>dietary advice and ONS</i> in the form of individualised counselling to increase food intake, plus a nutritional supplement and a multivitamin supplement. Control: participants received <i>no dietary advice and no ONS</i> in the form of brief written dietary advice.	
Outcomes	Weight *, BMI*, handgrip strength*, energy intake*, activities of daily living, cognitive function, peak expiratory flow, QoL.	
Publication details	Language: English. Funding: the Swedish Research Council, Karolinska Institutet and by grants from S. Persson Family Foundation and Sempers Foods AB. Publication status: peer-reviewed journal.	
Notes		
Risk of bias		
Bias	Authors' judgement	Support for judgement

Persson 2007 (Continued)

Random sequence generation (selection bias)	Unclear risk	Quote: randomisation performed by drawing files from a sealed box.
Allocation concealment (selection bias)	Low risk	Quote: randomisation performed by drawing files from a sealed box.
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	Not blinded but clinical outcomes unlikely to be influenced by lack of blinding
Blinding (performance bias and detection bias) Functional outcomes	High risk	Not blinded but functional outcomes may have been affected by lack of blinding.
Blinding (performance bias and detection bias) Nutritional outcomes	High risk	Not blinded but nutritional outcomes may have been affected by lack of blinding.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not blinded and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not blinded and some outcomes likely to have been affected by lack of blinding.
Incomplete outcome data (attrition bias) All outcomes	High risk	ITT analysis using data obtained at inclusion carried forward and used at follow-up for those who were still alive but not examined. Treated as protocol analysis also included. Attrition fully reported. 54 (50%) participants did not complete the study; 22/51 (43%) in the intervention group and 32/57 (56%) in the control group including 6/51 (12%) deaths in the intervention group and 12/57 (21%) deaths in the control group. The remaining participants withdrew consent or declined follow-up; 8 participants in the control group had the intervention prescribed during the study. The high attrition rate and imbalance between groups might have influenced outcome assessment.
Selective reporting (reporting bias)	Unclear risk	No study protocol identified, thus unable to judge whether all planned outcomes were reported. Outcomes reported but not in a format suitable for meta-analysis. Data on change in weight and handgrip strength are presented as mean (SD) at the start and end of the intervention and have therefore been obtained from authors. Data on mortality extracted from the paper.
Other bias	Unclear risk	Stated in text that baseline characteristics not different but data not shown.

Pivi 2011
Study characteristics

Methods	RCT. Parallel design. Duration: 6 months.
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Pivi 2011 (Continued)

Location: Brazil.

Participants	<p>Inclusion criteria: > 65 years old with probable Alzheimer's disease.</p> <p>Exclusion criteria: other forms of dementia; receiving tube feeding; diabetes or renal disease;</p> <p>Diagnosis: Alzheimer's disease.</p> <p>Number randomised: 90 (intervention groups, dietary advice n = 29 and oral nutritional supplements n = 30; control group, n = 31). Attrition: fully described - dietary advice group: 4/29 (14%); oral nutritional supplements group: 4/30 (13%); control group: 4/31 (13%).</p> <p>Gender split: (32%) male, (68%) female.</p> <p>Age: mean (SD) 75.2 years.</p> <p>Nutritional status: not reported.</p>
Interventions	<p>Intervention (intervention group 1): participants received <i>dietary advice</i> in the form of 10x classroom interactive education program delivered to caregivers and participants.</p> <p>Intervention (intervention group 2): participants received <i>ONS</i> in the form of oral nutritional supplements twice daily for 6 months.</p> <p>Control: participants received <i>no dietary advice</i> in the form of monthly assessments with no intervention.</p>
Outcomes	Mortality; weight; BMI; arm circumference and MAMC; TSF thickness; total protein; total lymphocyte count.
Publication details	<p>Language: English.</p> <p>Funding: commercial / non-commercial funding - Ministry of Education; Abbott Laboratories.</p> <p>Publication status: peer-reviewed journal.</p>

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "subjects were randomised into three groups.....". Judged as insufficient information.
Allocation concealment (selection bias)	Unclear risk	Not described.
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	Blinding not described but assessment of mortality unlikely to be influenced by lack of blinding.
Blinding (performance bias and detection bias) Functional outcomes	Unclear risk	No functional outcomes assessed.
Blinding (performance bias and detection bias) Nutritional outcomes	Low risk	Blinding not described and assessment of nutritional status unlikely to be influenced by lack of blinding. Nutritional intake not assessed.

Pivi 2011 (Continued)

Blinding of participants and personnel (performance bias) All outcomes	High risk	Not described and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Not described but unlikely that the outcomes assessed would be influenced by lack of blinding.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Fully described and similar amounts in each group. Overall 13% attrition. Dietary advice: 4/29 (14%); oral nutritional supplements group: 4/30 (13%); control group: 4/31 (13%).
Selective reporting (reporting bias)	Unclear risk	No protocol identified. All outcomes described in the methods reported but not possible to judge overall.
Other bias	Unclear risk	Baseline characteristics compared and no differences between groups but nutritional status not an inclusion and not reported at baseline, therefore not possible to judge the influence of baseline nutritional status on outcomes.

Rabeneck 1998
Study characteristics

Methods	<p>RCT.</p> <p>Parallel design with 2 treatment arms.</p> <p>Duration: 6 weeks.</p> <p>Location: multicentre trial in the USA.</p>
Participants	<p>Inclusion criteria: adults with HIV infection who were < 90% ideal weight or who had > 10% weight loss in previous 6 months.</p> <p>Exclusion criteria: dysphagia, severe diarrhoea, cytomegalovirus, or mycobacterium avium complex infection, suspected untreated infection, or a diagnosis of infection or hospitalisation within the previous 2 weeks.</p> <p>Number randomised: 118 participants (intervention group, n = 50; control group, n = 52). Attrition: 28 dropouts (intervention group, n = 16; control group, n = 12).</p> <p>Gender split: all males.</p> <p>Age: mean (SD), intervention group 39.3 (8.8) years; control group 41.1 (9.7) years.</p> <p>Nutritional status: mean (SD) BMI, intervention 20.6 (3.0) kg/m²; control 21.0 (2.6) kg/m².</p>
Interventions	<p>Intervention: participants received <i>dietary advice and ONS</i> in the form of nutritional counselling to achieve target and an oral nutritional supplement.</p> <p>Control: participants received <i>dietary advice alone</i> in the form of nutritional counselling to achieve specific energy target.</p>
Outcomes	<p>Weight*, MUAC*, skinfold measurements at all sites*, body composition (BIA)*, grip strength*, cognitive function, QoL, energy intake*.</p>
Publication details	<p>Language: English.</p>

Rabeneck 1998 (Continued)

Funding: the study was supported by Mead Johnson.

Publication status: peer-reviewed journal.

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Described as randomised, but method not stated.
Allocation concealment (selection bias)	Unclear risk	Method not reported.
Blinding (performance bias and detection bias) Clinical outcomes	Unclear risk	No objective clinical outcomes measured.
Blinding (performance bias and detection bias) Functional outcomes	High risk	The study was unblinded. Functional outcomes could have been influenced by lack of blinding.
Blinding (performance bias and detection bias) Nutritional outcomes	High risk	The study was unblinded. Nutritional outcomes could have been influenced by lack of blinding.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not blinded and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding
Blinding of outcome assessment (detection bias) All outcomes	High risk	The study was unblinded. Functional and nutritional outcomes could have been influenced by lack of blinding
Incomplete outcome data (attrition bias) All outcomes	Low risk	16 dropouts in intervention group (dietary counselling and supplements) and 12 dropouts in control group (dietary counselling); reasons for dropouts reported for the 19 participants who failed to complete at least 4 weeks of the 6-week treatment period.
Selective reporting (reporting bias)	Unclear risk	No study protocol identified, thus unable to judge whether all planned outcomes were reported. Specified outcomes extracted from paper. No data obtained from the author.
Other bias	Low risk	Baseline variables given, groups similar at baseline.

Ravasco 2005a
Study characteristics

Methods	RCT. Parallel design with 3 arms. Duration: 42 days intervention plus 3 months follow-up.
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Ravasco 2005a (Continued)

Location: Portugal.

Participants	<p>Inclusion criteria: adults with colorectal cancer undergoing radiotherapy.</p> <p>Exclusion criteria: renal disease or diabetes.</p> <p>Number randomised: 111 participants (intervention group 1, n = 37; intervention group 2, n = 37; control group, n = 37). Attrition: no participants lost to follow-up.</p> <p>Gender split: 66 males and 45 females.</p> <p>Age: mean (SD) 58 (15) years.</p> <p>Nutritional status: at baseline 42/111 participants were 'malnourished' (identified by PG-SGA); 15 in Intervention group 1, 14 in Group 2, 13 in Group 3).</p>
Interventions	<p>Intervention (intervention group 1): participants received <i>dietary advice</i> in the form of individualised dietary counselling to achieve calculated energy and protein requirements.</p> <p>Intervention (intervention group 2): participants received <i>ONS</i> in the form of 2x 200 mL cans of nutritional supplement.</p> <p>Control group: participants received <i>no dietary advice</i> in the form ad libitum food intake.</p>
Outcomes	Survival*, weight*, energy intake*, protein intake, symptom-induced morbidity, QoL.
Publication details	<p>Language: English.</p> <p>Funding: Nucleo Regional do Sul da Liga Portuguesa contra o Cancro-Terry Fox Foundation.</p> <p>Publication status: peer-reviewed journal.</p>
Notes	<p>Data will be used in 2 parts of the review dietary advice versus no advice and dietary advice versus nutritional supplements.</p> <p>Additional data and information obtained from authors.</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated random numbers.
Allocation concealment (selection bias)	Low risk	Sequentially numbered sealed opaque envelopes.
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	Blinding not described but assessment of mortality unlikely to be influenced by lack of blinding
Blinding (performance bias and detection bias) Functional outcomes	Unclear risk	Not stated and likely that some outcomes might be influenced by lack of blinding.
Blinding (performance bias and detection bias) Nutritional outcomes	Unclear risk	Not stated and likely that some outcomes might be influenced by lack of blinding.

Ravasco 2005a (Continued)

Blinding of participants and personnel (performance bias) All outcomes	High risk	Not described and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No blinding described and likely that lack of blinding might influence assessment of some outcomes.
Incomplete outcome data (attrition bias) All outcomes	Low risk	No participants lost to follow-up. Author confirmed that no deaths occurred in the 3-month study.
Selective reporting (reporting bias)	Unclear risk	No protocol identified. All specified outcomes reported in text and figures but not in a format or sufficient detail to make them usable for meta-analysis. Much of the data reported as medians (IQR). Additional data on mean change (SD) for weight, energy intake and QOL obtained from author.
Other bias	Unclear risk	Baseline variables not given, not sure if groups similar at baseline.

Ravasco 2005b
Study characteristics

Methods	<p>RCT.</p> <p>Parallel design with 3 arms.</p> <p>Duration: 42 days intervention plus 3 months follow-up.</p> <p>Location: Portugal.</p>
Participants	<p>Inclusion criteria: adults receiving radiotherapy for head and neck cancer.</p> <p>Exclusion criteria: renal disease or diabetes.</p> <p>Number randomised: 75 participants (intervention group 1, n = 25; intervention group 2, n = 25; control group, n = 25). Attrition: no participants lost to follow-up.</p> <p>Gender split: 60 males, 15 females.</p> <p>Age: mean (range) 60 years (36 - 79 years).</p> <p>Nutritional status: at baseline 45/75 participants were 'malnourished' (identified by PG-SGA); intervention group 1, n = 16; intervention group 2, n = 14; control group, n = 15).</p>
Interventions	<p>Intervention (intervention group 1): participants received <i>dietary advice</i> in the form of individualised dietary counselling to achieve calculated energy and protein requirements.</p> <p>Intervention (intervention group 2): participants received <i>ONS</i> in the form of 2x 200 mL cans of nutritional supplement.</p> <p>Control group: participants received <i>no dietary advice</i> in the form ad libitum food intake.</p>
Outcomes	Survival*, weight*, energy intake*, nutritional status (PG-SGA), symptom-induced morbidity, QoL.
Publication details	<p>Language: English.</p> <p>Funding: Nucleo Regional do Sul da Liga Portuguesa contra o Cancro-Terry Fox Foundationn.</p>

Ravasco 2005b (Continued)

Publication status: peer-reviewed journal.

Notes Data will be used in 2 parts of the review dietary advice versus no advice and dietary advice versus nutritional supplements.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Block randomisation using computer-generated random assignments.
Allocation concealment (selection bias)	Low risk	Concealed in numbered opaque envelopes.
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	Blinding not described but assessment of mortality unlikely to be influenced by lack of blinding.
Blinding (performance bias and detection bias) Functional outcomes	Unclear risk	Not stated and likely that some outcomes might be influenced by lack of blinding.
Blinding (performance bias and detection bias) Nutritional outcomes	Unclear risk	Not stated and likely that some outcomes might be influenced by lack of blinding.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not described and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No blinding described and likely that lack of blinding might influence assessment of some outcomes.
Incomplete outcome data (attrition bias) All outcomes	Low risk	No participants lost to follow-up. Author confirmed that no deaths occurred in the 3-month study.
Selective reporting (reporting bias)	Unclear risk	No protocol identified. All specified outcomes reported in text and figures but not in a format or sufficient detail to make them usable for meta-analysis. Much of the data reported as medians (IQR). Additional data on mean change (SD) for weight, energy intake and QoL obtained from author.
Other bias	Unclear risk	Baseline variables not given, not sure if groups similar at baseline.

Rogers 1992
Study characteristics

Methods RCT.
 Parallel design with 2 arms.
Duration: 4 months.

Rogers 1992 (Continued)

Location: USA.

Participants	<p>Inclusion criteria: adults with COPD and weight < 90% of IBW and FEV₁/FVC < 0.6.</p> <p>Exclusion criteria: recent (within 8 weeks) exacerbation of COPD, diabetes, thyroid dysfunction, mal-absorption, alcoholism, myopathic disease or neoplastic disease, received nutritional supplements in the previous 3 months, corpulmonale, congestive heart failure.</p> <p>Number randomised: 28 participants (intervention group, n = 15; control group, n = 12). Attrition: 1 withdrawal in the control (no advice) group.</p> <p>Gender split: not reported.</p> <p>Age: mean (SE), 62 (2.0) years.</p> <p>Nutritional status: mean (SE) % IBW, intervention 77.8 (1.6) %; control 78.6 (2.0) %.</p>
Interventions	<p>Intervention: participants received <i>dietary advice plus ONS if required</i> in the form of nutritional counselling to achieve a balanced meal plan plus supplements as needed; advice provided during 4-week inpatient phase and then at each outpatient visit.</p> <p>Control: participants received <i>no dietary advice and no ONS</i> in the form of no dietary advice.</p>
Outcomes	Weight*, TSF*, MUAC*, grip strength*, respiratory function*, QoL* (Sickness Impact Profile (SIP)).
Publication details	<p>Language: English.</p> <p>Funding: the National Heart, Lung and Blood Institute, the American Lung Association of Southwestern Pennsylvania, Clinical Research Unit of Presbyterian-University Hospital and Ross Laboratories.</p> <p>Publication status: peer-reviewed journal.</p>
Notes	Additional data and information awaited from authors. No data on QoL was presented, only that the difference was not significant.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Described as randomised, method not stated.
Allocation concealment (selection bias)	Unclear risk	Method not stated.
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	The study was unblinded. However, this is unlikely to influence clinical outcomes.
Blinding (performance bias and detection bias) Functional outcomes	High risk	The study was unblinded. Functional outcomes could have been influenced by lack of blinding.
Blinding (performance bias and detection bias) Nutritional outcomes	Unclear risk	No nutritional outcomes reported.
Blinding of participants and personnel (performance bias)	High risk	Not blinded and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding

Rogers 1992 (Continued)

All outcomes

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Judged to be unclear, as low risk for clinical outcomes and high risk for functional outcomes.
Incomplete outcome data (attrition bias) All outcomes	Low risk	1 withdrawal in the no advice group. Reason not given.
Selective reporting (reporting bias)	Unclear risk	No study protocol identified, thus unable to judge whether all planned outcomes were reported. All specified outcomes were reported in a format not suitable for entry into meta-analysis. Change in weight, TSF, MAMC and hand-grip strength are reported as mean (SD) at the start and end of intervention with a P value. No data obtained from authors therefore mean change (SD) derived using data in the paper.
Other bias	Low risk	Baseline variables given, groups similar at baseline.

Rydwik 2008
Study characteristics

Methods	<p>RCT.</p> <p>Parallel design with 4 arms.</p> <p>Duration: 12 weeks intervention, and a further 6 months follow-up.</p> <p>Location: Sweden.</p>
Participants	<p>Inclusion criteria: frail adults, aged over 75 years with unintentional weight loss > 5% or BMI < 20 kg/m² (or both) and low physical activity level.</p> <p>Exclusion criteria: under 75 years, BMI > 30 kg/m², non-walkers, people with recent cardiac problems requiring hospital care, recent hip fracture or surgery with previous 6 months, CVA within the previous 2 years, score below 7 points on the SF-MMSE or institutionalisation.</p> <p>Diagnosis: older people living in the community.</p> <p>Number randomised: 96 participants (intervention group 1, n = 25; intervention group 2, n = 25; intervention group 3, n = 23; control group, n = 23). Attrition: 32 dropouts (intervention group 1, n = 7; intervention group 2, n = 11; intervention group 3, n = 4; control group, n = 10).</p> <p>Gender split: 38/96 (40%) males, 58/96 (60%) females.</p> <p>Age: mean (SD) years intervention group 1, 83.1 (4.5); intervention group 2, 83.1 (4); intervention group 3, 83.5 (3.7); control group, 82.9 (4).</p> <p>Nutritional status: BMI kg/m² intervention group 1, 21.8 (3.4); intervention group 2, 21.9 (3.8); intervention group 3, 21.9 (3.8); control group, 21.6 (3.6).</p>
Interventions	<p>Intervention 1: participants received <i>dietary advice</i> in the form of dietary counselling to increase energy intake.</p> <p>Intervention 2: dietary counselling plus exercise training.</p> <p>Intervention 3: exercise training alone.</p>

Rydwik 2008 (Continued)

Control group: participants received *no dietary advice* in the form of general physical training advice (30 min per day) and general diet advice (3x main courses and 2 - 3 in-between meal snacks daily).

Outcomes	Weight*, TSF*, fat free mass, energy intake*, muscle strength, physical performance (balance, time-to-up-and-go, walking speed, chair to stand etc), self-efficacy.
Publication details	<p>Language: English.</p> <p>Funding: none declared.</p> <p>Publication status: peer-reviewed journal.</p>
Notes	Data on dietary counselling group and control group will be used.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	<p>Quote: "subjects were randomised consecutively in batches.....The randomisation procedure was conducted in an open manner".</p> <p>Insufficient information to make a judgement.</p>
Allocation concealment (selection bias)	Unclear risk	Not described.
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	Blinding not described but assessment of mortality unlikely to be influenced by lack of blinding.
Blinding (performance bias and detection bias) Functional outcomes	Unclear risk	No functional outcomes assessed.
Blinding (performance bias and detection bias) Nutritional outcomes	High risk	Not stated and likely that some outcomes might be influenced by lack of blinding.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not described and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No blinding described and likely that lack of blinding might influence assessment of some outcomes.
Incomplete outcome data (attrition bias) All outcomes	Low risk	<p>Fully described 32/96 (33%) dropouts overall: 7/25 (28%) in the dietary counselling group, 11/25 in the dietary counselling plus exercise, 4/23 in the exercise alone group and 10/23 (43%) in the control group.</p> <p>Judged as low risk because amount of attrition imbalanced between intervention groups (dietary counselling 28% versus control 43%) but the difference not greater than 20%.</p>
Selective reporting (reporting bias)	Unclear risk	No protocol identified. All specified outcomes reported apart from TSF. The data were requested from the authors but unavailable. Data on mean change in weight and energy intake were reported without SD and so have been obtained from the author.

Rydwik 2008 (Continued)

Other bias	Low risk	Baseline variables given, groups similar at baseline.
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Salva 2011
Study characteristics

Methods	Cluster RCT. Duration: 12 months. Location: Spain.
Participants	Inclusion criteria: diagnosis of mild-moderate dementia; MMSE < 26; living at home; ambulatory with identified caregiver. Exclusion criteria: MMSE > 26; residents in an institution; nasogastric feeding; terminal care; already participating in a nutrition intervention study. Diagnosis: dementia (SSM IV criteria). Number randomised: 946 (intervention group, n = 448; control group, n = 498). Attrition: fully described; intervention group 4/29 (14%), control group 4/31 (13%). Gender split: 302/646 (32%) male, 644/946 (68%) female. Age: mean (SD) years 79 (7.3). Nutritional status: MNA (intervention group 7.8% malnourished and 51.5% at risk; control group 2.8% malnourished and 34.5% at risk).
Interventions	Intervention: participants received <i>dietary advice</i> in the form of standardised protocol for feeding and nutrition delivered as education to caregivers, participants and relatives; Control: participants received <i>no dietary advice</i> in the form of usual care (detail not described).
Outcomes	Activities of daily living; MNA; caregiver burden scale; nutritional status (weight, MAC, calf circumference); cognitive function (MMSE, Clinical Dementia Rating scale, Eating Behaviour Scale, neuropsychiatric inventory questionnaire, depression, instrumental activities of daily living, healthcare costs, caregiver burden (Zarit scale), mortality.
Publication details	Language: English. Funding: commercial funding - Nestec Limited. Publication status: peer-reviewed journal.

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote from paper: "The unit of randomisation was the medical centres..." Comment: insufficient detail of the method provided.
Allocation concealment (selection bias)	Unclear risk	Not described.

Salva 2011 (Continued)

Blinding (performance bias and detection bias) Clinical outcomes	Low risk	Not described but judged to be low risk as assessment of clinical outcomes is unlikely to be influenced by lack of blinding.
Blinding (performance bias and detection bias) Functional outcomes	High risk	Not described but judged to be high risk as assessment of some functional outcomes is likely to be influenced by lack of blinding.
Blinding (performance bias and detection bias) Nutritional outcomes	Low risk	Not described but judged to be low risk as no nutritional intake outcomes assessed.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not described and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not described and likely that some outcomes might be influenced by lack of blinding of assessment.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Number of participants lost to follow-up/deaths/dropouts fully described: intervention group 155/448(35%) (43 deaths,7 lost to follow-up, dropouts 105); control group 135/498 (27%) (29 deaths,5 lost to follow-up, dropouts 101). Attrition high but numbers and reasons similar in each group.
Selective reporting (reporting bias)	Low risk	Published protocol identified. All outcomes fully reported.
Other bias	High risk	Baseline characteristics were compared. The intervention group were frailer at baseline (MMSE score Clinical Dementia Rating score, NPI-Q score and activities of daily living score and had a higher caregiver burden (Zarit scale). More participants in the intervention group were malnourished or at risk of being malnourished intervention group 7.8% malnourished and 51.5% at risk; control group 2.8% malnourished and 34.5% at risk. All of these factors have the potential to influence outcomes assessed. Assessment of risk of bias in cluster-randomised trials (1) Recruitment bias: no (2) Baseline imbalance: frail status (3) Loss of clusters: no (4) Incorrect analysis: no (5) Comparability with individually randomised trials / different types of clusters: different types of clusters

Schilp 2013
Study characteristics

Methods	RCT. Parallel design with 2 arms.
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Schilp 2013 (Continued)

Duration: 6 months.

Location: the Netherlands.

Participants	<p>Inclusion criteria: adults aged > 65 years, home-dwelling, non-institutionalized, undernourished (SNAQ⁶⁵⁺).</p> <p>Exclusion criteria: MMSE < 18, unable to stand on the weighing scale.</p> <p>Number randomised: 146 participants (intervention group, n = 72; control group, n = 74). Attrition: 127 participants completed the 6 months examination: intervention group, n = 62 (86 %); control group, n = 65 (88 %). The reasons for dropout were withdrawal (intervention group n = 5; control group n = 6), death (intervention group n = 3; control group n = 0) and health problems (intervention group n = 2; control group n = 3).</p> <p>Gender split: 52 males, 94 females.</p> <p>Age: mean (SD), intervention 80.6 (7.5) years; control 80.5 (7.5) years.</p> <p>Nutritional status: n (%) meeting SNAQ criteria for undernutrition, intervention weight loss \geq 4 kg/6 months 23(32), MUAC < 25 cm 35 (49), both 14 (19); control weight loss \geq 4 kg/6 months 26 (35), MUAC < 25 cm 37 (50), both 11 (15).</p>
Interventions	<p>Intervention: participants received <i>dietary advice plus ONS if required</i> in the form of dietary counselling from a team of 18 qualified trained dietitians, aiming to achieve adequate protein and energy intake, preferably by regular foods and beverages.</p> <p>Control: participants received <i>no dietary advice and no ONS</i> in the form of usual care, no referral to a dietitian but provided with a standard brochure of the Netherlands Nutrition Centre with general information about healthy eating habits.</p>
Outcomes	<p>Body weight*, physical performance, handgrip strength*, energy intake*, protein intake*, fat-free mass* as costs* were assessed at baseline, after 3 months and 6 months and QoL* after 6 months.</p>
Publication details	<p>Language: English.</p> <p>Funding: the Ministry of Health, Welfare and Sports of the Netherlands.</p> <p>Publication status: peer-reviewed journal.</p>
Notes	<p>To avoid bias of potential prescription of vitamin D as part of the dietetic treatment, all participants were prescribed a combined calcium (1000 mg calcium carbonate) plus vitamin D (800 IU cholecalciferol) supplement by their general practitioner if this was not already used.</p> <p>Analyses were derived from GEE; mean changes were re-calculated from the data set by one of researchers of the group.</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: Block randomisation by the primary investigator within 1 day of baseline examination using the website www.randomization.com . Participants recruited at an outpatient clinic department were randomised with a separate scheme, because they were expected to be more severely undernourished.
Allocation concealment (selection bias)	Low risk	Random allocation to either the intervention group or the control group was individually performed in blocks of 4 and 6 by using the website www.randomization.com

Schilp 2013 (Continued)

Blinding (performance bias and detection bias) Clinical outcomes	Low risk	The study was unblinded. However, this is unlikely to influence clinical outcomes.
Blinding (performance bias and detection bias) Functional outcomes	High risk	Quote: Participants, researcher and research assistants were no longer blinded for the intervention assignment from this point [=after randomization].
Blinding (performance bias and detection bias) Nutritional outcomes	High risk	Quote: Participants, researcher and research assistants were no longer blinded for the intervention assignment from this point [=after randomisation].
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not blinded and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Judged to be unclear, as low risk for clinical outcomes and high risk for functional and nutritional outcomes.
Incomplete outcome data (attrition bias) All outcomes	Low risk	After 3 months 8 participants in the intervention group and 9 participants in the control group were lost to follow-up (withdrawn, health problems or death), after months another 2 participants in the intervention group (withdrawn, health problems) and 0 participants in the control group were lost to follow-up.
Selective reporting (reporting bias)	Low risk	Protocol identified Dutch Trial Register NTR 1808, all planned outcomes with the exception of the secondary outcomes MUAC and supplementation with calcium and vitamin D were reported.
Other bias	Low risk	Baseline characteristics were similar between groups and there were no statistically significant differences in baseline characteristics between participants who discontinued early and study completers.

Schwenk 1999
Study characteristics

Methods	<p>RCT.</p> <p>Parallel design with 2 arms.</p> <p>Duration: 8 weeks.</p> <p>Location: Germany.</p>
Participants	<p>Inclusion criteria: HIV positive adults who had lost > 5% of usual weight or who were actively losing weight, > 3% in last month.</p> <p>Exclusion criteria: unable to swallow usual food, severe lactose intolerance, prescription of any ONS, nutritional counselling, hormonal or appetite stimulants, enteral or parenteral nutrition during the previous 3 months.</p> <p>Number randomised: 50 participants (intervention group, n = 26; control group, n = 24). Attrition: 5 drop outs (intervention group, n = 2; control group, n = 3).</p> <p>Gender split: 47 males, 3 females.</p>

Schwenk 1999 (Continued)

Age: mean (SD) intervention group 39.4 (9.2) years; control group 39.5 (10.2) years).

Nutritional status: mean (SD) BMI, intervention group 1 19.6 (2.3) kg/m²; intervention group 2 19.9 (2.1) kg/m².

Interventions	<p>Intervention (intervention group 1): participants received <i>ONS</i> in the form of oral nutritional supplements (0.6 - 1.5 kcal/mL) to increase energy intake by 600 kcal.</p> <p>Intervention (intervention group 2): participants received <i>dietary advice</i> in the form of dietary counselling to increase food intake by 600 kcal using household food items.</p>
Outcomes	Survival*, change in body cell mass and change in weight*, change in energy intake*, hospital admissions*, Cost-effectiveness planes and cost-effectiveness acceptability curves, QALYs.
Publication details	<p>Language: English.</p> <p>Funding: Nestle Clinical Nutrition, Germany.</p> <p>Publication status: peer-reviewed journal.</p>
Notes	Additional data and information obtained from authors.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Information from author, block randomisation derived using random numbers.
Allocation concealment (selection bias)	Low risk	Sealed envelopes prepared by a person not involved in the study.
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	Information from author indicates that the study was not blinded but unlikely that lack of blinding would influence assessment of clinical outcomes.
Blinding (performance bias and detection bias) Functional outcomes	High risk	Information from author indicates that the study was not blinded and likely that lack of blinding would influence assessment of functional outcomes.
Blinding (performance bias and detection bias) Nutritional outcomes	High risk	Information from author indicates that the study was not blinded and likely that lack of blinding would influence assessment of nutritional outcomes.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not blinded and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Incomplete blinding and likely that assessment of some outcomes could be influenced by lack of blinding.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Fully reported and similar in each group. 3/24 (12%) dropouts in control (dietary counselling) group and 2/26 (8%) dropouts in intervention (supplement) group. Reasons for drop out were opportunistic infections n = 4 and change of residence n = 1.

Schwenk 1999 (Continued)

Selective reporting (reporting bias)	Unclear risk	No protocol identified. All specified outcomes reported but data were not in a form usable for meta analysis. Data on weight change were reported as % change in area under the curve and data on energy intake was reported as mean calories per kg, therefore mean change (SD) obtained from authors. Data on number of hospital admissions confirmed with the author.
Other bias	Low risk	Baseline variables given, groups similar at baseline.

Sharma 2002a
Study characteristics

Methods	<p>RCT.</p> <p>Parallel group with 3 arms.</p> <p>Duration: 1 month.</p> <p>Location: single centre in India.</p>
Participants	<p>Inclusion criteria: adults with renal disease receiving maintenance dialysis 3x weekly for more than 1 month, BMI < 20 kg/m², and serum albumin < 4.0 g/dL.</p> <p>Exclusion criteria: diabetes, presence of intercurrent illness.</p> <p>Number randomised: 47 participants (intervention group 1, n = 10; intervention group 2, n = 16; control group, n = 14 control). Attrition: 40 participants analysed; 7 dropouts (intervention groups n = 5; control group n = 2).</p> <p>Gender split: 35 males, 5 females.</p> <p>Age: mean intervention group 1 (commercial supplement) 29.6 years; intervention group 2 (home blend) 32.7 years; control group 31.9 years.</p> <p>Nutritional status: mean (SD) BMI, intervention 1, 17.9 (1.3) kg/m²; intervention 2, 17.2 (1.9) kg/m² control 17.1 (1.9) kg/m².</p>
Interventions	<p>Intervention (group 1): participants received <i>dietary advice and ONS</i> in the form of dietary counselling to increase intake in line with current recommendations for renal disease plus 300 mL of commercial supplement (500 kcal, 15 g protein).</p> <p>Intervention (group 2): participants received <i>dietary advice and ONS</i> in the form of dietary counselling to increase intake in line with current recommendations for renal disease plus 300 mL of home-produced blend providing similar kcal and protein.</p> <p>Control: participants received <i>dietary advice alone</i> in the form of dietary counselling to increase intake but in line with current recommendations for renal disease.</p>
Outcomes	Weight*, biochemistry, energy intake*, protein intake*, appetite, Karnofski index, supplementation acceptability questionnaire.
Publication details	<p>Language: English.</p> <p>Funding: the study was supported by Baxter and by a hospital fund.</p> <p>Publication status: peer-reviewed journal.</p>
Notes	This study is a duplicate of Sharma 2002b. The study has 2 intervention arms and a single control group. Therefore the number of participants in the control group is divided by 2. This study ID describes the data of intervention group 'home blend' versus control, whereas Sharma 2002b describes 'com-

Sharma 2002a (Continued)

mercial supplement' versus control. Study is eligible for inclusion on the basis of the intervention; however, due to the high number of control participants that crossed over to the intervention, data cannot be included without further analysis.

Participants were randomised 1:2 into control and intervention, and in turn the experimental group was randomised to receive the commercial nutritional supplement or home-prepared supplement blend.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No details given.
Allocation concealment (selection bias)	Unclear risk	No details given.
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	Is unlikely that biochemistry measurements were influenced by knowing the group allocation.
Blinding (performance bias and detection bias) Functional outcomes	High risk	The study was unblinded. Functional outcomes could have been influenced by lack of blinding.
Blinding (performance bias and detection bias) Nutritional outcomes	Low risk	The study was unblinded. Nutritional outcomes could have been influenced by lack of blinding.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not blinded and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Judged to be unclear because low risk for clinical outcomes and high risk for functional and nutritional outcomes.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	7 dropouts; 5 of 26 (19%) in the intervention group and 2 of 14 (14%) in the control group. Reasons not given.
Selective reporting (reporting bias)	Unclear risk	No study protocol identified, thus unable to judge whether all planned outcomes were reported. Data not all in usable format and not available from author, therefore mean change (SD) has been derived by calculation from the data in Table 2.
Other bias	High risk	Baseline data only presented on participants that completed the study (n = 40). 5 participants crossed over from the control to the supplement group.

Sharma 2002b
Study characteristics

Sharma 2002b (Continued)

Methods	<p>RCT.</p> <p>Parallel group with 3 arms. Duration: 1 month.</p> <p>Location: single centre in India.</p>
Participants	<p>Inclusion criteria: adults with renal disease receiving maintenance dialysis x3 weekly for more than 1 month, BMI < 20 kg/m², and serum albumin < 4.0 g/dL.</p> <p>Exclusion criteria: diabetes, presence of intercurrent illness.</p> <p>Number randomised: 47 participants (intervention group 1, n = 10; intervention group 2, n = 16; control group, n = 14 control). Attrition: 40 participants analysed; 7 dropouts (intervention groups n = 5; control group n = 2).</p> <p>Gender split: 35 males, 5 females.</p> <p>Age: mean intervention group 1 (commercial supplement) 29.6 years; intervention group 2 (home blend) 32.7 years; control group 31.9 years.</p> <p>Nutritional status: mean (SD) BMI, intervention 1, 17.9 (1.3) kg/m²; intervention 2, 17.2 (1.9) kg/m² control 17.1 (1.9) kg/m².</p> <p>Nutritional status: all participants had a BMI < 20 kg/m² and serum albumin < 4.0 g/dL.</p>
Interventions	<p>Intervention (group 1): participants received <i>dietary advice and ONS</i> in the form of dietary counselling to increase intake in line with current recommendations for renal disease plus 300 mL of commercial supplement (500 kcal, 15 g protein).</p> <p>Intervention (group 2): participants received <i>dietary advice and ONS</i> in the form of dietary counselling to increase intake in line with current recommendations for renal disease plus 300 mL of home-produced blend providing similar kcal and protein.</p> <p>Control: participants received <i>dietary advice alone</i> in the form of dietary counselling to increase intake but in line with current recommendations for renal disease.</p>
Outcomes	Weight*, biochemistry, energy intake*, protein intake*, appetite, Karnofski index, supplementation acceptability questionnaire.
Publication details	<p>Language: English.</p> <p>Funding: the study was supported by Baxter and by a hospital fund.</p> <p>Publication status: peer-reviewed journal.</p>
Notes	<p>This study is a duplicate of Sharma 2002a. The study has 2 intervention arms and a single control group. Therefore the number of participants in the control group is divided by 2. This study ID describes the data of intervention group 'commercial supplement' versus control, whereas Sharma 2000a describes 'home blend' versus control. Study is eligible for inclusion on the basis of the intervention; however, due to the high number of control participants that crossed over to the intervention, data cannot be included without further analysis.</p> <p>Participants were randomised 1:2 into control and intervention, and in turn the experimental group was randomised to receive the commercial nutritional supplement or home-prepared supplement blend.</p>
Risk of bias	
Bias	Authors' judgement Support for judgement

Sharma 2002b (Continued)

Random sequence generation (selection bias)	Unclear risk	No details given.
Allocation concealment (selection bias)	Unclear risk	No details given.
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	Is is unlike that biochemistry measured were influenced by knowing the group allocation.
Blinding (performance bias and detection bias) Functional outcomes	High risk	The trial was unblinded. Functional outcomes could have been influenced by lack of blinding.
Blinding (performance bias and detection bias) Nutritional outcomes	High risk	The trial was unblinded. Nutritional outcomes could have been influenced by lack of blinding.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not blinded and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Judged to be unclear because low risk for clinical outcomes and high risk for functional and nutritional outcomes.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	7 dropouts; 5 of 26 (19%) in the intervention group and 2 of 14 (14%) in the control group. Reasons not given.
Selective reporting (reporting bias)	High risk	No study protocol identified, thus unable to judge whether all planned outcomes were reported. Data not all in usable format and not available from author, therefore mean change (SD) has been derived by calculation from the data in Table 2.
Other bias	High risk	Baseline data only presented on participants that completed the study (n = 40). 5 participants crossed over from the control to the supplement group.

Sharma 2017
Study characteristics

Methods	<p>RCT.</p> <p>Parallel design with 2 arms.</p> <p>Duration: 3 months.</p> <p>Location: single centre in Australia.</p>
Participants	<p>Inclusion criteria: 60 years and over presenting to the General Medicine Department of the Flinders Medical Centre between November 2014 and June 2016, malnourished according to PG-SGA (classes B or C).</p>

Sharma 2017 (Continued)

Exclusion criteria: receiving palliative care, resident in rural areas, indigenous Australians, non-English speaking and unable to give informed consent.

Number randomised: 148 participants (intervention group, n = 78; control group, n = 70). Attrition: 103 analysed (intervention group, n = 57; control group, n = 46), 45 lost to follow-up (intervention group, n = 21; control group, n = 24).

Gender split: intervention group 29.7% males, control group 32.9% males.

Age: mean (range), intervention group 82.0 (80.0 - 83.9), control group 81.6 (79.5 - 83.6).

Nutritional status: n (%) PG-SGA score, intervention PG-SGA B 67 (90.5), PG-SGA C 7 (9.5); control PG-SGA B 60 (87), PG-SGA C 9 (13).

Interventions	<p>Intervention: participants received <i>dietary advice plus ONS if required</i> in the form of individualized nutrition care plan plus monthly post-discharge telehealth follow-up.</p> <p>Control: participants received <i>no dietary advice and no ONS</i> in the form of intervention only upon referral by their treating clinicians.</p>
Outcomes	Length of stay, skinfolds*, MUAC*, grip strength* complications, QoL (EQ-5D)*, mortality*, readmission rate*, nutritional status by PG-SGA score.
Publication details	<p>Language: English.</p> <p>Funding: not declared.</p> <p>Publication status: peer-reviewed journal.</p>

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: An independent biostatistician prepared the randomisation schedule using random blocks of 8; treatment allocations were randomly permuted and balanced within blocks.
Allocation concealment (selection bias)	Low risk	Quote: After obtaining written informed consent, the researcher contacted central office to open these sealed envelopes to allocate participants to either control or intervention groups.
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	Quote: After group allocation the participants and the ward dietitian, who provided nutrition intervention, were not blinded to group allocation but the research dietitian who conducted the final outcome assessment was blinded to participants' group allocation. In addition, the research person overseeing data entry and the biostatistician were blinded.
Blinding (performance bias and detection bias) Functional outcomes	Low risk	Quote: After group allocation the participants and the ward dietitian, who provided nutrition intervention, were not blinded to group allocation but the research dietitian who conducted the final outcome assessment was blinded to participants' group allocation. In addition, the research person overseeing data entry and the biostatistician were blinded.
Blinding (performance bias and detection bias) Nutritional outcomes	Low risk	Quote: After group allocation the participants and the ward dietitian, who provided nutrition intervention, were not blinded to group allocation but the research dietitian who conducted the final outcome assessment was blinded to participants' group allocation. In addition, the research person overseeing data entry and the biostatistician were blinded.

Sharma 2017 (Continued)

Blinding of participants and personnel (performance bias) All outcomes	High risk	Not blinded and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Outcomes were assessed by a research dietitian who was blinded to group allocation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	148 participants randomised (intervention group n = 78; control group n = 70), complete data were available for analysis for 103 participants (intervention group n = 57; control group n = 46 participants). The main reasons for participants being lost to follow-up were loss of contact n = 7 (intervention group n = 1; control group n = 6), consent withdrawal n = 12 (intervention group n = 8; control group n = 4) and death n = 26 (intervention group n = 12; control group n = 14). Numbers and reasons similar between groups
Selective reporting (reporting bias)	High risk	No study protocol identified, thus unable to judge whether all planned outcomes were reported.
Other bias	Low risk	Baseline characteristics similar between groups, with both groups having a higher number of females, the majority of participants residing at home pre-admission, a similar number of co-morbidities, and similar Charlson Co-morbidity Index and other baseline characteristics. There was no difference in the severity of malnutrition at baseline.

Silvers 2014
Study characteristics

Methods	<p>RCT (pilot study).</p> <p>Parallel design with 2 arms.</p> <p>Duration: 6 months.</p> <p>Location: Australia.</p>
Participants	<p>Inclusion criteria: histologically proven new diagnosis of primary oesophageal or stomach cancer, due to undergo surgery and/or chemotherapy, aged 19 years and over.</p> <p>Exclusion criteria: recurrent disease or physical, cognitive, language or emotional problems that would prevent participation, treatment was planned at another health care facility.</p> <p>Number randomised: 21 participants (intervention group, n = 10; control group, n = 11). Attrition: 6 deaths (intervention group, n = 1; control group, n = 5).</p> <p>Gender split: intervention group 50% males, control group 64% males.</p> <p>Age: mean (SD) intervention group 72 (12) years; control group 64 (14) years.</p> <p>Nutritional status: mean (SD) BMI: intervention group 28 (6) kg/m², control group 26 (5) kg/m².</p>
Interventions	<p>Intervention group: participants received <i>dietary advice plus ONS if required</i> in the form of intensive nutritional counselling commenced immediately after diagnosis via weekly telephone call by a research dietitian (nutritional assessment and advice using a tailored, symptom-directed treatment approach) with face-to-face interviews scheduled if the participant was attending the hospital; weight,</p>

Silvers 2014 (Continued)

nutrition-impact symptoms and oral intake monitored and oral nutritional supplements supplied if clinically indicated.

Control group: participants received *no dietary advice and no ONS* in the form of no planned dietetic input until participants admitted for surgery or chemotherapy leading to an anticipated delay of approximately 6 - 10 weeks before initial contact with a dietitian; contact with the dietitian only if nursing or medical staff made a referral.

Outcomes	<p>Primary outcome: health-related QoL*.</p> <p>Secondary outcomes: change in weight*, and patient-generated SGA.</p>	
Publication details	<p>Language: English.</p> <p>Funding: Southern Melbourne Integrated Cancer Service (SMICS).</p> <p>Publication status: peer-reviewed journal.</p>	
Notes	Additional data on weight change were obtained from the authors	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	The allocation sequence was constructed using a computer random number generator. Randomisation was stratified by diagnosis (oesophageal or stomach cancer).
Allocation concealment (selection bias)	Low risk	The method of concealment was through use of opaque, consecutively numbered, sealed envelopes with the group allocation written on a piece of paper inside.
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	The study was unblinded. However, this is unlikely to influence clinical outcomes.
Blinding (performance bias and detection bias) Functional outcomes	High risk	The study was unblinded. Functional outcomes could have been influenced by lack of blinding.
Blinding (performance bias and detection bias) Nutritional outcomes	High risk	The study was unblinded. Nutritional outcomes could have been influenced by lack of blinding.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not blinded and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Judged to be unclear, as low risk for clinical outcomes and high risk for nutritional outcomes.
Incomplete outcome data (attrition bias) All outcomes	High risk	Missing outcome data unbalanced in numbers across intervention groups; 5 (45%) deaths in control group, 1(10%) death in intervention group.
Selective reporting (reporting bias)	Unclear risk	No study protocol identified, thus unable to judge whether all planned outcomes were reported.

Silvers 2014 (Continued)

Other bias	Unclear risk	Participants in the intervention group tended to be older and have a higher BMI.
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Singh 2008
Study characteristics

Methods	RCT. Parallel design with 2 arms. Duration: 3 months. Location: India.
Participants	Inclusion criteria: adults with chronic pancreatitis and undernourished, BMI < 18.5 kg/m ² or > 10% weight loss in previous 6 months. Exclusion criteria: clinically apparent steatorrhoea, pancreatic cancer, biliary obstruction, undergoing endoscopic or surgical therapy, uncontrolled diabetes, acute exacerbation of pancreatitis, large pseudocysts, currently consuming alcohol, opioid addicts, comorbid conditions eg. chronic liver disease. Number randomised: 60 participants (intervention group, n = 31; intervention group 2, n = 29). Attrition: 6 dropouts (intervention group, n = 4; intervention group 2, n = 2). Gender split: 50 males, 10 females. Age: mean (SD), intervention group 1, 28 (10) years; intervention group 2, 32 (10) years. Nutritional status: mean (SD) BMI: intervention group 1, 16.7 (1.6) kg/m ² , intervention group 2, 17.2 (1.7) kg/m ² .
Interventions	Intervention (intervention group 1): participants received <i>ONS</i> in the form of a nutritional supplement enriched with medium chain triglycerides to meet predicted energy requirements. Intervention (intervention group 2): participants received <i>dietary advice</i> in the form of dietary advice from a dietitian to meet predicted energy requirements.
Outcomes	BMI*, weight* TSF*, MAMC*, energy and protein intake, nitrogen balance, faecal fat, pain score.
Publication details	Language: English. Funding: Indian Council for Medical Research. Publication status: peer-reviewed journal.
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated random number list.
Allocation concealment (selection bias)	Low risk	Carried out by individual not otherwise involved in the study.

Singh 2008 (Continued)

Blinding (performance bias and detection bias) Clinical outcomes	Low risk	Outcome assessment blinded to treatment.
Blinding (performance bias and detection bias) Functional outcomes	Low risk	Outcome assessment blinded to treatment.
Blinding (performance bias and detection bias) Nutritional outcomes	Low risk	Outcome assessment blinded to treatment.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not blinded and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding
Blinding of outcome assessment (detection bias) All outcomes	Low risk	All outcome assessment was assessed blinded to group allocation. Quote: "the person assessing outcome was blinded to the treatment the patient was receiving".
Incomplete outcome data (attrition bias) All outcomes	Low risk	Fully reported and similar between groups: 4/31 (13%) intervention group at 1.5 months, 2/29 (7%) control group at 1.5 months. But all included in the final analysis.
Selective reporting (reporting bias)	Unclear risk	No protocol identified. All outcomes reported but not in a format usable for meta analysis. Data on change in weight, TSF, MAC and energy intake were reported as mean (SD) at baseline and mean (SD) at end of intervention, therefore mean change (SD) obtained from authors.
Other bias	Low risk	Baseline variables given, groups similar at baseline.

Starke 2011
Study characteristics

Methods	<p>RCT.</p> <p>Parallel design with 2 arms.</p> <p>Duration: intervention 5 days to maximum 28 days, follow-up for 6 months.</p> <p>Location: Switzerland.</p>
Participants	<p>Inclusion criteria: adults consecutively admitted to the general medical ward at "Kantonsspital Liestal" hospital at nutritional risk using the NRS-2002 questionnaire (NRS score 3 or above; participants with a score below 3 were re-evaluated weekly during hospitalisation and asked to participate if a nutritional risk developed).</p> <p>Exclusion criteria: no informed consent, terminal condition, expected stay less than 5 days (judged by physician), previous participation in this study, participant on starvation, on parenteral nutrition, and/or being on dialysis.</p> <p>Number randomised: 132 participants (intervention group, n = 66; control group, n = 66). Protocol violations: 8 participants in each groups. Data analysed, based in ITT analyses, all 132 participants.</p>

Starke 2011 (Continued)

Gender split: not reported.

Age: mean (SD) intervention group 70 (16) years; control group 75 (11) years.

Nutritional status: mean (SD) BMI, intervention group 24.6 (5.3) kg/m², control group 24.1 (4.9) kg/m².

Interventions

Intervention: participants received *dietary advice plus ONS if required* in the form of individual nutritional care to meet the daily energetic requirement*, including a detailed nutritional assessment, individual food supply, fortification of meals with maltodextrin, rapeseed oil, cream and/or protein powder, in-between snacks and oral nutritional supplements. Complications influencing feeding (e.g. nausea) were reported to the ward physician and treatment was optimised (e.g. medication). If less than 75% of the portion (i.e. served food at one meal with known energy/protein content) was consumed, energy and protein intake was compensated on a daily basis by either oral nutritional supplements (Nestlé Nutrition) or in-between meals.

Control: participants received *no dietary advice and no ONS* in the form of standard nutritional care, including the prescription of oral nutritional supplements and nutritional therapy prescribed by the physician independently of this study and according to the routine ward management.

*daily energetic requirement according to the individual total energy expenditure (calculated from resting energy expenditure corrected by an individual factor for physical activity level and disease (stress factor, SF12); protein intake was set at 1.0 g/kg body weight.

Outcomes

Primary outcomes: average daily energy* and protein* intake.

Secondary outcomes: change in body weight* during hospitalisation, number of complications, number of antibiotic therapies due to infectious complications, length of hospital stay*, QoL* Short Form 36 Questions Score, hospital readmission* (after 6 months), mortality* (hospital and 6 months after discharge), compliance with oral nutrition standard supplement consumption and plasma concentrations of 25-OH-D3, ascorbic acid and glutathione.

Publication details

Language: English.

Funding: no financial or personal interest in any company/organisation sponsoring the study (JS, HS, PS). JS received grants from the Exchange Organisation StudEx/ Switzerland and the German Academic Exchange Service (DAAD)/ Germany at different time intervals during the study. Further study support was received by Nestlé Nutrition/Switzerland for biochemical analyses. None of the mentioned organisations and enterprises participated in protocol preparation, analysis nor interpretation of data, writing the manuscript and publication matters. RM received grants for clinical studies and education from Nestlé.

Publication status: peer-reviewed journal.

Notes

The aim of the present study was to develop and evaluate a routinely manageable concept for an improved nutritional care of malnourished hospitalised patients.

Some results are only described in the text, but no data given. The corresponding author was contacted and asked to provide change scores energy intake and protein, but he answered that he could not provide these data.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: computer-generated randomization.
Allocation concealment (selection bias)	Unclear risk	Comment: Not described.

Starke 2011 (Continued)

Blinding (performance bias and detection bias) Clinical outcomes	Low risk	Quote: except energy and protein intake, all outcome data were blinded in terms of that physicians and nurses who were responsible for the outcome did not have access to group allocation.
Blinding (performance bias and detection bias) Functional outcomes	Low risk	Quote: except energy and protein intake, all outcome data were blinded in terms of that physicians and nurses who were responsible for the outcome did not have access to group allocation.
Blinding (performance bias and detection bias) Nutritional outcomes	High risk	Quote: except energy and protein intake, all outcome data were blinded in terms of that physicians and nurses who were responsible for the outcome did not have access to group allocation.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not blinded and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Judged to be unclear, as low risk for clinical and functional outcomes but high risk for nutritional outcomes.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Discharged or death before minimum intervention period occurred in 8 participants in each group. 1 participant in each group was excluded from ITT analyses due to withdrawal or death. Numbers and reasons for attrition balanced between groups.
Selective reporting (reporting bias)	Unclear risk	No study protocol identified, thus unable to judge whether all planned outcomes were reported. Protocol violations.
Other bias	Low risk	Baseline parameters were comparable between groups.

Stow 2015
Study characteristics

Methods	<p>RCT (feasibility study).</p> <p>Cluster randomised.</p> <p>Duration: 6 months.</p> <p>Location: UK.</p>
Participants	<p>Inclusion criteria: MUST score > 1, able to eat and drink, registered with a GP and eligible for treatment by the UK National Health Service, living in residential care home.</p> <p>Exclusion criteria: receiving enteral or parenteral nutrition, receiving nutritional support (advice or oral nutritional supplements), known eating disorder or condition not compatible with receiving the intervention, non-native English speaker, lacking capacity.</p> <p>Number randomised: 93 participants (intervention group 1, n = 29; intervention group 2, n = 32; control group, n = 32). Attrition: 63 of 93 residents (36%).</p> <p>Gender split: 20 males, 73 females.</p> <p>Age: mean (SD) years not reported.</p> <p>Nutritional status: 50/91 (55%) high nutritional risk, 41/91 (45%) medium nutritional risk (MUST)*.</p>

Stow 2015 (Continued)

Interventions	<p>Intervention (intervention group 1): participants received <i>ONS</i> in the form of standard care* plus 2x liquid oral nutritional supplements providing 600 kcal, 24 g protein daily.</p> <p>Intervention (intervention group 2): participants received <i>dietary advice</i> in the form of face-to-face instruction from the primary researcher to increase intake by approximately 600 kcal and 20 - 25g protein daily.</p> <p>Control: participants received <i>no dietary advice and no ONS</i> in the form of standard care* plus instructions to care and catering staff on increasing residents' daily intake by 600 kcal, 20 - 25g protein per day.</p> <p>*provision of a calorie-dense diet, small frequent, energy-enriched meals in a family-style dining room with prompting and assistance.</p>	
Outcomes	Nutritional intake, weight, BMI, handgrip strength, MUAC, TSF, VAS, QoL (EQ-5D, CO-OP).	
Publication details	<p>Language: English.</p> <p>Funding: undertaken by an MRes student funded by NIHR Clinical Academic Training Programme for AHPs.</p> <p>Publication status: peer-reviewed journal.</p>	
Notes		
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: sequence was generated using a computer-generated random number list. Homes were randomised once eligible residents had been identified.
Allocation concealment (selection bias)	Low risk	Quote: sequence was generated using a computer-generated random number list. Homes were randomised once eligible residents had been identified.
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	No blinding, but unlikely that assessment of clinical outcomes would be influenced by lack of blinding.
Blinding (performance bias and detection bias) Functional outcomes	High risk	<p>No blinding, and likely that assessment of functional outcomes would be influenced by lack of blinding.</p> <p>Quote: 1 primary researcher communicated intervention allocation ... and conducted outcome assessments. It was therefore impossible to blind the researcher to intervention.</p>
Blinding (performance bias and detection bias) Nutritional outcomes	High risk	<p>No blinding, and likely that assessment of nutritional outcomes would be influenced by lack of blinding.</p> <p>Quote: 1 primary researcher communicated intervention allocation...and conducting outcome assessments. It was therefore impossible to blind the researcher to intervention.</p>
Blinding of participants and personnel (performance bias) All outcomes	High risk	<p>Quote: residents were recruited prior to random allocation of care homes to the treatment/control arms. Individual residents were not told of the care home intervention assignment. ...due to the nature of the interventions, ... it was not possible to blind the staff delivering them.</p> <p>Judgement, incomplete blinding and lack of blinding likely to have influenced outcome assessments.</p>

Stow 2015 (Continued)

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	<p>Researcher collected all data; it was impossible to blind the researcher to group.</p> <p>No blinding and lack of blinding might have influenced the assessment of some outcomes.</p>
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	<p>Attrition amount fully reported but group allocation unclear. 63/93 (36%) participants completed the study. 23 deaths, 6 in the control (dietary advice) group, 6 in the intervention (supplement) group and 11 in the routine care group (information provided by author). Numbers and reasons for withdrawal reported but not according to group allocation.</p>
Selective reporting (reporting bias)	Low risk	<p>Protocol published on Current Controlled Clinical Trials. All outcomes specified reported or commented on, e.g. qualitative outcomes to be reported in a separate paper and QoL not analysed because of completion by too few residents.</p>
Other bias	High risk	<p>Baseline characteristics presented, the group receiving the control (food-based intervention) were heavier than the intervention (supplement) group and had a higher energy, protein and fluid intake at baseline as well as a higher EQ5D VAS score. Judged to be likely that these differences would influence outcome assessment.</p> <p>Assessment of risk of bias in cluster-randomised trials</p> <p>(1) Recruitment bias: yes (care home residents recruited after recruitment of care homes)</p> <p>(2) Baseline imbalance: weight, energy, protein & fluid intake, QoL (detail above)</p> <p>(3) Loss of clusters: no</p> <p>(4) Incorrect analysis: ? (feasibility trial and so not carried out for analyses in this paper, but planned for subsequent trial)</p> <p>(5) Comparability with individually randomised trials / different types of clusters: inclusion in meta-analyses results in heterogeneity for some outcomes</p>

Suominen 2015

Study characteristics

Methods	<p>RCT.</p> <p>Parallel design with 2 arms.</p> <p>Duration: 1 year.</p> <p>Location: Finland.</p>
Participants	<p>Inclusion criteria: individuals with Alzheimer's disease living with a spouse, aged > 64 years, able to reach the study place by taxi, able to stand on a scale, resident in the Helsinki metropolitan area, absence of terminal disease, an estimated life expectancy of at least half a year (confirmed by medical records).</p> <p>Exclusion criteria: not mentioned.</p> <p>Number randomised: 99 couples (intervention group, n = 50; control group, n = 49). Attrition: 78 couples completed the study (intervention group, n = 40; control group, n = 38).</p>

Suominen 2015 (Continued)

Gender split: 31% males, 69% females.

Age: mean (SD), intervention 78.2 years; control 76.8 (5.9) years.

Nutritional status: assessed by MNA. Intervention % with score < 17: 0%; 17 - 23.5: 43%; > 23.5: 57%. Control % with score < 17: 0%; 17 - 23.5: 37%; > 23.5: 63%.

Interventions	<p>Intervention: participants received <i>dietary advice plus ONS if required</i> in the form of tailored nutritional guidance on the basis of the food diaries, results of weight measurement, home visits and discussions with the participants and their caregivers held every 3 months; oral nutritional supplements provided according to participants' needs.</p> <p>Control: participants received <i>no dietary advice and no ONS</i> in the form of a written guide on nutrition of older people.</p>
Outcomes	<p>Primary outcome: change in weight* of individuals with Alzheimer's disease.</p> <p>Secondary outcomes: changes in protein intake* and other nutrients, health-related QoL* and rate of falls.</p>
Publication details	<p>Language: English.</p> <p>Funding: support from Finland's Slot Machine Association (RAY) and Nutricia provided the protein supplements. The funders had no role in the design, analysis or interpretation of data or in writing, reporting or deciding whether to submit this article for publication. The authors are independent researchers unassociated with the funders.</p> <p>Publication status: peer-reviewed journal.</p>
Notes	<p>Study aimed to examine the effect of tailored nutritional guidance on nutrition, health-related QoL and falls in people with Alzheimer disease.</p> <p>The authors report no change in weight between the groups, however they cannot provide the data. They also emailed that they collected data on energy intake, but these were not reported in the manuscript and were not received from the authors either.</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Participating couples were randomly allocated according to a computer-generated, blocked randomisation list. The block size was six, and the randomisation took place between August 2010 and January 2011. A person unrelated to the investigation and unfamiliar with the procedure performed the randomisation.
Allocation concealment (selection bias)	Unclear risk	Quote: A person unrelated to the investigation and unfamiliar with the procedure performed the randomisation. It remains unclear how, and at which time-point this was done.
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	It is unlikely that participants were unaware of group assignment. Thus assume that the trial was unblinded. However, this is unlikely to influence clinical outcomes.
Blinding (performance bias and detection bias) Functional outcomes	High risk	The trial was unblinded. Functional outcomes could have been influenced by lack of blinding.
Blinding (performance bias and detection bias)	High risk	The study was unblinded. Nutritional outcomes could have been influenced by lack of blinding.

Suominen 2015 (Continued)

Nutritional outcomes

Blinding of participants and personnel (performance bias) All outcomes	High risk	Not described and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Judged to be unclear, as low risk for clinical outcomes and high risk for functional and nutritional outcomes.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Out of 99 participating couples, 78 completed the study (intervention group n = 40; control group n = 38). Reasons for drop out are well-explained (moving to another city, moving to long-term care, death, food records not received).
Selective reporting (reporting bias)	High risk	The data for change in weight (primary outcome) are not available. Authors only report that there were no differences. As data are not available, this is judged as high risk. The study protocol is available, Jyvakorpi SK, Trials 2012, and all outcomes are reported in different papers.
Other bias	Low risk	Baseline characteristics were similar between groups.

Terp 2018
Study characteristics

Methods	<p>RCT.</p> <p>Parallel design with 2 arms.</p> <p>Duration: 3 months.</p> <p>Location: Denmark.</p>
Participants	<p>Inclusion criteria: geriatric patients in a university hospital and in the primary healthcare sector in Copenhagen, > 65 years, at nutritional risk at admission (NRS-2002), BMI < 20.5 kg/m² and/or weight loss within the last three months and/or a reduced dietary intake in the previous week and/or severely ill).</p> <p>Exclusion criteria: terminal illness, active cancer diagnosis, permanently living in a nursing home, and not willing or able to give an informed consent.</p> <p>Number randomised: 144 participants.</p> <p>Gender split: 32 males, 112 females.</p> <p>Age: mean (SD), intervention group 87 (6) years; control group 88 (6) years.</p> <p>Nutritional status: mean (SD) BMI, intervention group 19.6 (2.0) kg/m²; control group 19.7 (2.8) kg/m².</p>
Interventions	<p>Intervention: participants received <i>dietary advice plus ONS if required</i> in the form of an individual dietary plan, based on everyday food, if relevant combined with oral nutritional supplements, by a dietitian for each participant including advice on nutritional intake after discharge. After discharge, participants received a prescription for oral nutritional supplements, funded by the participants and 3 follow-up visits conducted by a district nurse or a healthcare assistant were scheduled at 1, 4, and 8 weeks after discharge.</p>

Terp 2018 (Continued)

Control: participants received *no dietary advice and no ONS* in the form of usual care i.e. weekly monitoring of nutritional status. The nursing staff completed the screening for nutrition risk at admission and the clinical dietician was involved in the process if the participant had specific needs and gave dietary advice and prepared a dietary plan for nutrition intake while they were hospitalized. At discharge, any nutritional problems were documented in the discharge summary, but no follow-up on those who were at nutritional risk was planned.

Outcomes	Change in body weight*, Barthel Index, handgrip strength* and self-rated health from baseline (discharge) to 3 months after discharge, readmission*, and mortality* (90 and 120 days).	
Publication details	<p>Language: English.</p> <p>Funding: work was supported by the Capital Region of Denmark.</p> <p>Publication status: peer-reviewed journal.</p>	
Notes		
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: Randomization was performed using a computer-generated randomization table. An equal distribution among intervention and control was achieved by blocks.
Allocation concealment (selection bias)	Low risk	Quote: The treatment allocation was written and stored in sequentially numbered opaque envelopes and was opened by a study personnel immediately after the participant had given informed consent. The randomization was performed before collection of baseline data.
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	Comment: Not blinded, clinical outcomes were unlikely to have been influenced by lack of blinding.
Blinding (performance bias and detection bias) Functional outcomes	High risk	Comment: Not blinded, functional outcomes could have been influenced by lack of blinding.
Blinding (performance bias and detection bias) Nutritional outcomes	High risk	Comment: Not blinded, nutritional outcomes could have been influenced by lack of blinding.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not blinded and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Judged to be unclear because low risk for clinical outcomes and high risk for functional and nutritional outcomes.
Incomplete outcome data (attrition bias) All outcomes	Low risk	A total of 103 (72%) participants completed the 2nd data collection; 21 participants died (12 in the intervention group and 9 in the control group); 8 participants withdrew (4 in the intervention group and 4 in the control group); 12 participants were unable to participate (6 in the intervention group and 6 in the control group). Numbers and reasons for attrition balanced between groups.

Terp 2018 (Continued)

Selective reporting (reporting bias)	Low risk	Study protocol identified CliniclTrials NCT03131856 all planned outcomes were reported.
Other bias	Low risk	Baseline characteristics were similar between groups.

Tu 2013
Study characteristics

Methods	<p>RCT.</p> <p>Parallel design with 2 arms.</p> <p>Duration: not clear.</p> <p>Location: Taiwan.</p>
Participants	<p>Inclusion criteria: cancer patients on discharge from hospital.</p> <p>Exclusion criteria: multiple types of cancer, metastases, over 80 years of age.</p> <p>Diagnosis: cancer (breast 30%, colon 34.8%, other 35.2%).</p> <p>Number randomised: 537 participants (intervention group, n = 279; control group, n = 258). Attrition: not reported.</p> <p>Gender split: not reported.</p> <p>Age: mean (SD) 64.2 (10.3) years.</p> <p>Nutritional status: assessed using SGA, but difficult to ascertain baseline status.</p>
Interventions	<p>Intervention group: participants received <i>dietary advice</i> in the form of on average 30 minutes of nutrition counselling and meal planning during the 1st week post discharge.</p> <p>Control group: participants received <i>no dietary advice</i> in the form of no nutrition counselling or meal planning.</p>
Outcomes	<p>SGA, weight, food intake.</p> <p>Analysed as composites: weight loss < 5% in 1 month + food intake > 75% of usual = "pass"; weight loss > 5% + food intake < 75% of usual = "fail".</p>
Publication details	<p>Language: English.</p> <p>Funding: none declared.</p> <p>Publication status: peer-reviewed journal.</p>
Notes	<p>Numerous questions about this study in terms of risk of bias and data. No response from authors.</p> <p>At present the method of data presentation means that it is not possible to extract data on any outcomes.</p>
Risk of bias	
Bias	Authors' judgement Support for judgement

Tu 2013 (Continued)

Random sequence generation (selection bias)	Unclear risk	Quote: patients... were randomly divided into experimental and control groups. Insufficient information to make a judgement.
Allocation concealment (selection bias)	Unclear risk	Quote: patients... were randomly divided into experimental and control groups. Insufficient information to make a judgement.
Blinding (performance bias and detection bias) Clinical outcomes	Unclear risk	No clinical outcomes assessed.
Blinding (performance bias and detection bias) Functional outcomes	Unclear risk	No functional outcomes assessed.
Blinding (performance bias and detection bias) Nutritional outcomes	High risk	Not described and likely that assessment of some outcomes would be affected by lack of blinding.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not described and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No blinding described and likely that lack of blinding might influence assessment of some outcomes.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Not described.
Selective reporting (reporting bias)	High risk	No protocol identified. The 3 outcomes specified are reported, but only as a composite score used to assess arbitrary cut-offs 'pass' and 'fail'. No original data presented.
Other bias	Unclear risk	Baseline characteristics not presented or described.

Um 2014
Study characteristics

Methods	RCT. Parallel design with 2 arms. Duration: duration of radiotherapy (3 weeks) with 1 month follow-up. Location: single centre, hospital-based radiotherapy unit, Seoul, South Korea.
Participants	Inclusion criteria: individuals (> 15 years of age) with cancer of the head and neck, thorax or abdomen whose treatment plan included radiotherapy over 3 weeks. Exclusion criteria: people who had received nutrition counselling within 3 months, age > 80 years, poor tolerance of radiotherapy.

Um 2014 (Continued)

Number randomised: 87 participants recruited (intervention group, n = 44; control group, n = 43). Attrition: 3 participants died (intervention group, n = 1; control group, n = 2).

Gender split: intervention group 33 males (75%), 11 females (25%); control group 23 males (53%), 20 females (47%).

Age: mean (SD) intervention group males 58.3 (11.8) years, females 56.8 (20.5) years; control group males 64.0 (11.4) years, 58.8 (11.8) years females.

Nutritional status: BMI, mean (SD): intervention group 24.1 (2.6) kg/m² males, 23.8 (4.1) kg/m² females; control group 24.7 (2.7) kg/m² males, 22.7 (2.6) kg/m² females.

Interventions	<p>Intervention: participants received <i>dietary advice and ONS</i> in the form of intensive nutrition intervention following the standard protocol of the Academy of Nutrition and Dietetics for the duration of radiotherapy; information offered "to help them achieve adequate energy and protein intake"; 3 nutritional counselling sessions of 15 - 30 minutes each (1) educated to meet goals using "a standard formula from the hospital" (2) educational materials provided to help minimise radiotherapy-related side effects (3) calorie-dense foods or quick, easy cooking ideas provided and individualised to each participant's environment. Educational materials and recipe suggestions for incorporating various antioxidant foods were provided. Started within 4 days of starting radiotherapy and repeated weekly or every other week during radiotherapy.</p> <p>Control: participants received <i>no dietary advice and no ONS</i> in the form of one routine 20 minute education session by a dietitian within 4 days of starting radiotherapy, plus samples of an oral nutritional supplement and a cancer survival booklet.</p>	
Outcomes	Nutritional status (PG-SGA scores, weight*, BMI), dietary intake (energy* and protein*), QoL (EORTC-QLQ-C30)*, laboratory results.	
Publication details	<p>Language: English.</p> <p>Funding: not stated.</p> <p>Publication status: peer-reviewed journal.</p>	
Notes		
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Patients were randomly placed into either nutritional intervention or control groups".
Allocation concealment (selection bias)	Unclear risk	Not described.
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	Unlikely to be blinded but assessment of mortality unlikely to be affected by lack of blinding.
Blinding (performance bias and detection bias) Functional outcomes	Unclear risk	Unlikely to be blinded but assessment of functional outcomes likely to be affected by lack of blinding.
Blinding (performance bias and detection bias) Nutritional outcomes	Unclear risk	Unlikely to be blinded but assessment of nutritional outcomes likely to be affected by lack of blinding.

Um 2014 (Continued)

Blinding of participants and personnel (performance bias) All outcomes	High risk	Not described and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Assessment of some outcomes may have been influenced by the lack of blinding.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Attrition fully reported. 3 participants (3.5%) died; 1/44 (2%) in the intervention group and 2/43 (5%) in the control group.
Selective reporting (reporting bias)	Unclear risk	Protocol not identified.
Other bias	Low risk	Baseline characteristics described and intervention and control groups similar at baseline.

Uster 2013
Study characteristics

Methods	<p>RCT.</p> <p>Parallel design with 2 arms.</p> <p>Duration: 3 months.</p> <p>Location: Switzerland.</p>
Participants	<p>Inclusion criteria: adult cancer outpatients, undernourished or at high risk for undernutrition by the NRS 2002 tool.</p> <p>Exclusion criteria: estimated survival < 6 months (as judged by the treating physician), on enteral tube feeding or parenteral nutrition, ongoing nutritional counselling or interventions (e.g. intake of oral nutritional supplements), adjuvant chemotherapy, impaired cognition and inability to give consent.</p> <p>Number randomised: 58 participants (intervention group, n = 30; control group, n = 28). Attrition n = 29 (intervention group, n = 15; control group, n = 14).</p> <p>Gender split: 46 males, 12 females.</p> <p>Age: mean (SD), intervention group 66.2 (8.9) years; control group 63.8 (13.3) years.</p> <p>Nutritional status: mean (SD) BMI, intervention group 23.1 (2.4) kg/m², control group 22.6 (2.8) kg/m².</p>
Interventions	<p>Intervention: participants received <i>dietary advice plus ONS if required</i> in the form of standardized individual nutritional therapy, including counselling by a dietitian, food fortification, and oral nutritional supplements if required.</p> <p>Control: participants received <i>no dietary advice and no ONS</i> in the form of standard care without specific nutritional intervention or fixed prescription of oral nutritional supplements; if participants had questions concerning nutrition, they were advised by the cancer centre's attending physician or the nurses but not by professional dietitians.</p>
Outcomes	<p>Dietary intake (3-day dietary record)*, nutritional status (body weight)*, physical functioning* (performance status, handgrip strength) and QoL (EORTC-C30)*.</p>

Uster 2013 (Continued)

Publication details

Language: English.

Funding: grant from the Krebsliga Schweiz (Swiss Cancer Foundation), Nestle Healthcare Medical Nutrition (Vevey, Switzerland) contributed to the funding of the study.

Publication status: peer-reviewed journal.

Notes

The authors provided additional change scores for weight, energy intake, protein and handgrip strength. Additional change scores for QoL not available at the moment but will become available later, therefore final scores and SD for QoL read from the graphs. Due to a low recruitment of patients, the study was terminated after 2.5 years. A sample size of 200 participants (100 per arm) was calculated, 67 participants were included.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not reported.
Allocation concealment (selection bias)	Unclear risk	Not reported.
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	The description of the study strongly suggests it was unblinded and that both participants and the treating dietitian were aware of group allocation. Unclear who performed the clinical or functional outcome measures. However, knowing group allocation is unlikely to influence clinical outcomes.
Blinding (performance bias and detection bias) Functional outcomes	High risk	The study was unblinded. Functional outcomes could have been influenced by lack of blinding.
Blinding (performance bias and detection bias) Nutritional outcomes	High risk	The study was unblinded. Nutritional outcomes could have been influenced by lack of blinding.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not described and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Judged to be unclear, as low risk for clinical outcomes and high risk for nutritional outcomes.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Due to a low recruitment of participants, the study was terminated after 2.5 years. A sample size of 200 participants (100 per arm) was calculated, 67 participants were included. Attrition n = 29 (intervention group n = 15; control group n = 14), 16 (8 in each group) of these participants died.
Selective reporting (reporting bias)	Unclear risk	No study protocol identified, thus unable to judge whether all planned outcomes were reported.
Other bias	Unclear risk	The tumour types were comparable in the two groups, except for head and neck cancer, which happened to be randomised only the intervention group. The performance status in the intervention group was significantly lower than in the usual care group.

Vivanti 2015
Study characteristics

Methods	<p>RCT.</p> <p>Parallel design with 2 arms.</p> <p>Duration: starting at the emergency department with follow-up at 12 weeks.</p> <p>Location: Australia.</p>
Participants	<p>Inclusion criteria: malnourished adults (MST, confirmed with SGA) aged 60 years or over, presenting to the emergency department.</p> <p>Exclusion criteria: unable to provide informed consent, triage category 1 (highest priority), already receiving dietetic care, admitted from a healthcare facility (including nursing home).</p> <p>Number randomised: 24 participants (intervention group, n = 10, control group, n = 14). Attrition: 5 participants (intervention group, n = 1; control group, n = 4).</p> <p>Gender split: 10 males, 14 females.</p> <p>Age: mean (SD) 79.0 (7.7) years.</p> <p>Nutritional status: assessed using the MST and confirmed with SGA, 21/24 (88 %) participants diagnosed with malnutrition.</p>
Interventions	<p>Intervention: participants received <i>dietary advice plus ONS if required</i> in the form of individualised dietary counselling at baseline when nutrition goals and strategies were made in collaboration with the dietitian in the emergency department following standard medical nutrition therapy practice; follow-up at a minimum of weeks 4 and 8, by telephone review or home visit or both. Strategies included both food-based advice and use of ONS depending on the needs of the patient*.</p> <p>Control: participants received <i>no dietary advice and no ONS</i> in the form of regular treatment through community hospital interface programme nursing staff and community support.</p>
Outcomes	Weight change, length of stay, QoL (EQ-5D), depression, further decline in nutritional status, number of falls (self-recorded).
Publication details	<p>Language: English.</p> <p>Funding: Queensland Health allied health grants.</p> <p>Publication status: peer-reviewed journal.</p>
Notes	*information on nutrition strategies obtained from the authors.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	A statistician-generated randomised sequence.
Allocation concealment (selection bias)	Low risk	Sealed in sequentially numbered opaque envelopes.
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	The intervention group received usual care + individualised dietary care. This suggests that both treating dietitians and participants were aware of group allocation. The emergency department dietitian provided dietary counselling

Vivanti 2015 (Continued)

to the participants in the intervention groups and performed the following follow-up measurements in both groups: malnutrition screening tool and subjective global assessment. Data on death, malnutrition diagnosis, number of presentations to the emergency department, days of unplanned hospital admissions and pressure ulcers were recorded from health information management and emergency department information systems. Clinical outcomes were unlikely to be influenced by knowing group assignment.

Blinding (performance bias and detection bias) Functional outcomes	High risk	Blinding of assessment of depression not described and the outcome might have been influenced by lack of blinding.
Blinding (performance bias and detection bias) Nutritional outcomes	High risk	Not blinded and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants and the treating dietitian were aware of group assignment.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Judged to be unclear, as low risk for clinical outcomes and high risk for nutritional outcomes.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Attrition: intervention group n = 1; control group n = 4, due to withdrawal and death.
Selective reporting (reporting bias)	Unclear risk	No study protocol identified, thus unable to judge whether all planned outcomes were reported.
Other bias	Unclear risk	No description of baseline characteristics.

Weekes 2009
Study characteristics

Methods	<p>RCT.</p> <p>Parallel design with 2 arms.</p> <p>Duration: 12 months (6 months intervention and follow-up to 12 months).</p> <p>Location: UK.</p>
Participants	<p>Inclusion criteria: adult outpatients with COPD and at risk of malnutrition using a validated nutritional screening tool.</p> <p>Exclusion criteria: conditions likely to compromise nutritional status further (diabetes, disseminated malignancy, congestive cardiac failure and untreated thyroid disease).</p> <p>Number randomised: 66 participants; but only 59 at baseline assessment (intervention group n = 31; control group n = 28). Attrition: 37 participants completed (7 deaths; 15 participants withdrew mainly because of deteriorating health).</p> <p>Gender split: (at baseline n = 59), 30 males, 29 females.</p>

Weekes 2009 (Continued)

Age: mean (range): 69 (47 - 85) years for 37 participants completing the study; 69.1 (46 - 89) years for 22 withdrawals.

Nutritional status: mean (SD) BMI, intervention 19.9 (1.4) kg/m²; control 19.5 (1.9) kg/m². Mean (SD) unintentional change from usual weight, intervention -8.0 (5.2) kg; control -9.2 (6.2) kg.

Interventions	<p>Intervention: participants received <i>dietary advice</i> in the form of dietary counselling to increase intake and advice on food fortification.</p> <p>Control: participants received <i>no dietary advice</i> in the form of usual care consisting of a leaflet.</p>
Outcomes	Survival*, weight*, fat-free mass, fat mass, triceps skinfold*, MAC*, MAMC*, handgrip strength*, energy intake*, cost*, respiratory function, respiratory muscle function, QoL.
Publication details	<p>Language: English.</p> <p>Funding: Research Training Fellowship London Regional NHS Executive & Guy's and St Thomas' Hospital Charitable Foundation.</p> <p>Publication status: peer-reviewed journal.</p>
Notes	Some data have been obtained from the author.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated randomisation sequence.
Allocation concealment (selection bias)	Low risk	Sealed opaque envelopes.
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	All assessments made by the lead investigator who was not blinded to group allocation, but clinical assessments unlikely to be influenced by lack of blinding.
Blinding (performance bias and detection bias) Functional outcomes	High risk	All assessments made by the lead investigator who was not blinded to group allocation and some assessments of physical function might have been influenced by lack of blinding.
Blinding (performance bias and detection bias) Nutritional outcomes	High risk	All assessments made by the lead investigator who was not blinded to group allocation and assessments of nutritional intake might have been influenced by lack of blinding.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not blinded and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No blinding described and likely that lack of blinding might influence assessment of some outcomes.
Incomplete outcome data (attrition bias) All outcomes	Low risk	66 randomised, 59 at baseline and 37 completed study. Attrition: intervention group 16/36 (44%); control group 13/30 (43%). 7 deaths - 4 in the intervention group and 3 in the control group. 15 participants withdrew during the study, reasons fully reported; 11% dropped out before baseline assessment.

Weekes 2009 (Continued)

Attrition high but numbers and reasons similar in each group.

Selective reporting (reporting bias)	Low risk	No protocol identified but study author also an author of this review. All specified outcomes reported, but not as mean change (SD) at 6 months (end of intervention) for the outcomes of interest therefore additional data and information obtained from the author.
Other bias	Low risk	Baseline characteristics reported and no differences between groups.

Wilson 2001
Study characteristics

Methods	<p>RCT.</p> <p>Parallel design with 2 arms.</p> <p>Duration: 9 months (6 months treatment and 3 months follow-up).</p> <p>Location: multicentre in the USA.</p>
Participants	<p>Inclusion criteria: adults with hypoalbuminaemia (serum albumin 3.5 - 3.7 g/dL) receiving haemodialysis. An additional group is included with severe hypoalbuminaemia (serum albumin 2.5 - 3.4 g/dL) who received intervention according to current practice.</p> <p>Exclusion criteria: < 18 years or > 80 years of age, hospitalisation for longer than 1 week in the past 3 months, major surgery or sepsis in the past 3 months, urea reduction ratio less than 65% for 2 of the past 3 months, unintentional weight loss > 10% in the past 6 months, HIV infection, malignancy, use of appetite stimulant medication, on haemodialysis for less than 3 months.</p> <p>Number randomised: 32 participants (intervention group, n = 16; control group, n = 16). Attrition: 5 participants were not included in the analysis but details of the group allocation are unclear.</p> <p>Gender split: intervention group 39% males, 61% females; control group 14% males, 86% females.</p> <p>Age: mean (SD) intervention group 64 (10) years; control group 58 (8.6) years.</p> <p>Nutritional status: not reported.</p>
Interventions	<p>Intervention: participants received <i>dietary advice and ONS</i> in the form of dietary counselling to increase energy and protein intakes and 1 - 2 cans of supplement (250 calories per serving).</p> <p>Control: participants received <i>dietary advice alone</i> in the form of dietary counselling to increase energy and protein intake.</p>
Outcomes	Time to nutritional repletion, number of days spent in hospital*.
Publication details	<p>Language: English.</p> <p>Funding: grant from the council on renal nutrition from the National Kidney Foundation.</p> <p>Publication status: peer-reviewed journal.</p>
Notes	No usable data from this study.

Risk of bias

Bias	Authors' judgement	Support for judgement
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Wilson 2001 (Continued)

Random sequence generation (selection bias)	Unclear risk	Described as randomised, but method not stated.
Allocation concealment (selection bias)	Unclear risk	Not stated.
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	Not stated, but it is unlikely that knowing group allocation would influence number of days spent in hospital.
Blinding (performance bias and detection bias) Functional outcomes	Unclear risk	Not measured.
Blinding (performance bias and detection bias) Nutritional outcomes	High risk	Not blinded and lack of blinding may have influenced assessment of achieving nutritional repletion.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not blinded and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Assessment of some outcomes may have been influenced by lack of blinding.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	5 participants were not included in the analysis but details of the group allocation is unclear, therefore risk of bias.
Selective reporting (reporting bias)	High risk	No study protocol identified, thus unable to judge whether all planned outcomes were reported. The methods section of the paper states that height, weight and weight history and serum albumin are collected at baseline, The results section reports % achieving nutritional repletion defined by improvement in serum albumin and length of hospital stay but no data on weight change. No response received from authors.
Other bias	Unclear risk	Baseline variables given, the dietary counselling and supplement group were significantly older than the dietary group, therefore risk of bias.

Wong 2004
Study characteristics

Methods	RCT. Parallel design with 2 arms. Duration: 4 months. Location: Hong Kong.
Participants	Inclusion criteria: adults presenting with osteoporotic fractures. Exclusion criteria: not described.

Wong 2004 (Continued)

Number randomised: 189 participants (intervention group, n = 73; control group, n = 77). Attrition: 39 participants lost to follow-up (intervention group, n = 18; control group, n = 21).

Gender split: intervention group 18% males, 82% females; control group, 15% males, 85% females.

Age: mean (SD), intervention group 75.8 (9.5) years; control group 73.8 (11.6) years.

Nutritional status: no details of numbers malnourished. BMI, mean (SD): intervention 22.6 (3.9) kg/m²; control 22.6 (3.5) kg/m².

Interventions	<p>Intervention: participants received <i>dietary advice</i> in the form of tailored dietary advice with recipes and specific goals for energy, protein and calcium plus 500 mg calcium and anti-resorptive agent.</p> <p>Control: participants received <i>no dietary advice</i> in the form of no advice plus 500 mg calcium and anti-resorptive agent.</p>
Outcomes	Mortality*, weight*, BMI*, energy intake* protein intake*.
Publication details	<p>Language: English.</p> <p>Funding: none declared.</p> <p>Publication status: peer-reviewed journal.</p>
Notes	Additional data and information requested from authors.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Information from author indicated that a computer-generated list of random numbers was used.
Allocation concealment (selection bias)	Low risk	Information from author indicated that allocation concealment was achieved by an independent person managing this aspect of the trial.
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	Not described but judged to be low risk as assessment of clinical outcomes is unlikely to be influenced by lack of blinding.
Blinding (performance bias and detection bias) Functional outcomes	Unclear risk	No functional outcomes assessed.
Blinding (performance bias and detection bias) Nutritional outcomes	High risk	Not described but judged to be high risk as assessment of some nutritional outcomes is likely to be influenced by lack of blinding.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not described and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not described and likely that assessment of some outcomes would be affected by lack of blinding.

Wong 2004 (Continued)

Incomplete outcome data (attrition bias) All outcomes	Unclear risk	39 participants lost to follow-up. 18/73 (25%) in the intervention group and 21/77 (27%) in the control group but reasons not given, therefore insufficient information to make a judgement.
Selective reporting (reporting bias)	Unclear risk	No protocol identified. All outcomes mentioned in methods reported. Mortality data confirmed with authors. Additional information on study quality obtained from authors. Lack of protocol means insufficient information to make a judgement.
Other bias	Low risk	Baseline variables given, groups similar at baseline.

Wyers 2013
Study characteristics

Methods	<p>RCT.</p> <p>Parallel design with two treatment arms.</p> <p>Duration: 3 months.</p> <p>Location: multicentre in Maastricht, Heerlen and Sittard, The Netherlands.</p>
Participants	<p>Inclusion criteria: adults (> 55 years) admitted for surgical treatment of hip fracture.</p> <p>Exclusion criteria: pathological/periprosthetic fracture, disease of bone metabolism, estimated life expectancy < 1 year, oral nutritional supplements before hospital admission, unable to speak Dutch, outside region or bedridden by fracture, dementia or cognitively impaired (Abbreviated Mental Test score < 7).</p> <p>Number randomised: 152 participants: intervention group, n = 73; control group, n = 79. Attrition: 7 participants died (intervention group, n = 3; control group, n = 4), 7 participants withdrew (intervention group, n = 3; control group, n = 4).</p> <p>Gender split: intervention female 54, male 19; control female 54, male 25.</p> <p>Age: mean(SEM), intervention 77 (1.2) years; control 76 (1.1) years.</p> <p>Nutritional status: assessed by MNA, intervention number (%) with no malnutrition 46 (63), number at risk of malnutrition 27 (37); control number (%) with no malnutrition 41 (52), number at risk of malnutrition 38 (48).</p>
Interventions	<p>Intervention: participants received <i>dietary advice and ONS</i> in the form of frequent dietary counselling (2x during hospital stay and 3x at home (1, 2 and 6 weeks after discharge) plus calls at home at 3, 4, 5, 8 and 10 weeks after discharge) and consumption of 2x oral nutritional supplement each day (Cubitan, Nutricia: providing 500 kcal and 40 g protein per 500 mL) for 3 months.</p> <p>Control: participants received <i>no dietary advice and no ONS</i> in the form of usual care i.e. oral nutritional supplements only if doctor provided them (13%) and 28% received dietetic counselling.</p>
Outcomes	Weight, QALYs (EQ-5D-3L), cost (Euros).
Publication details	<p>Language: English.</p> <p>Funding: The Netherlands Organisation for Health Research and Development; oral nutritional supplements provided by Nutricia Advanced Medical Nutrition (Danone Research, Wageningen, The Netherlands).</p>

Wyers 2013 (Continued)

Publication status: peer-reviewed journal.

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: randomized according to a concealed computer-generated random-number sequence list after pre-stratification for hospital, gender and age (55 - 74 years versus 75 years and above) with an allocation ratio of 1:1.
Allocation concealment (selection bias)	Unclear risk	Blinded for the researcher, according to a computer generated random-number sequence list
Blinding (performance bias and detection bias) Clinical outcomes	Low risk	Study dietitian was not blinded but assessment of mortality unlikely to be affected.
Blinding (performance bias and detection bias) Functional outcomes	Low risk	The study did not address functional outcomes.
Blinding (performance bias and detection bias) Nutritional outcomes	High risk	Study dietitian was not blinded. Assessment of weight may have been influenced by lack of blinding.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not blinded and likely that researchers and participants were aware of group allocation as this was a nutritional intervention. It is possible that assessment of some outcomes was influenced by lack of blinding
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Assessment of some outcomes likely to be affected by lack of blinding.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Attrition fully reported and reasons were similar for both groups. There were 4/73 (5.5%) deaths in the intervention group and 3/79 (4%) in the control group. 3/73 (4%) withdrew from the intervention group and 4/79 (5%) withdrew from the control group.
Selective reporting (reporting bias)	High risk	Published protocol identified (Wyers et al 2010); however, not all stated outcomes have been reported.
Other bias	Low risk	Baseline characteristics reported and groups similar at baseline.

* outcomes included in this review if data usable

ADL: activities of daily living

ANZCTR: Australia and New Zealand Clinical Trials Registry

BASDEC: brief assessment schedule depression cards

BIA: bioelectric impedance analysis

BMI: body mass index

CDAI: Crohn's disease activity index

CF: cystic fibrosis

COPD: chronic obstructive pulmonary disease

CVD: cardiovascular disease

DEXA: dual energy X-ray absorptiometry

DRAQ: Disease-Related Appetite Questionnaire

EORTC: European Organisation for Research and Treatment of Cancer

FAACT: Functional Assessment of Anorexia/Cachexia Therapy

FEV₁: forced expiratory volume in 1 second

FVC: forced vital capacity

GDS: geriatric depression score

GEE: generalized estimating equation

GFR: glomerular filtration rate

GI: gastro-intestinal

Hb: haemoglobin

HIV: human immunodeficiency virus

IADL: instrumental activities of daily living

IBW: ideal body weight

IDDM: insulin-dependent diabetes mellitus

IQR: interquartile range

ITT: intention-to-treat

MAC: mid-arm circumference

MAMA: mid-arm muscle area

MAMC: mid-arm muscle circumference

MCT: medium chain triglycerides

MMSE: mini mental state examination

MNA: mini nutritional assessment

MUAC: mid-upper arm circumference

NRS: nutritional risk screening

PG-SGA: patient-generated subjective global assessment

PU: pressure ulcer

PUSH: Pressure Ulcer Scale for Healing

QALY: quality adjusted life year

QoL: quality of life

RCT: randomised controlled trial

REE: resting energy expenditure

SD: standard deviation

SE: standard error

SGA: subjective global assessment

SNAQ⁶⁵⁺: short nutritional assessment questionnaire for home living older persons

TIBC: total iron binding capacity

TSF: triceps skinfold thickness

VAS: visual analogue score

vs: versus

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
ACTRN12613000518763	Not a RCT. This is a prospective observational study of usual nutritional management in malnourished adults in rural Australia.
Ahnfeldt-Mollerup 2015	Comparison does not meet inclusion criteria: no dietary counselling.
Aleman-Mateo 2014	Comparison does not meet inclusion criteria: no dietary counselling.
Amlogu 2016	Comparison does not meet inclusion criteria: this is a public health intervention, not a health care intervention.
Antila 1993	The included participants are well-nourished and advice is given to maintain normal nutritional status.
Apovian 2017	Comparison does not meet the inclusion criteria: the intervention is readymade home delivered meals and no dietary counselling component

Study	Reason for exclusion
Arija 2012	Comparison does not meet inclusion criteria: no dietary counselling.
Arnarson 2013	Comparison does not meet inclusion criteria: no dietary counselling.
Arutiunov 2009	Not a RCT: this was an observational study and therefore did not meet the inclusion criteria of randomised controlled trial design.
Bachmann 1998	Not a randomised controlled trial.
Badia 2015	Comparison does not meet inclusion criteria: multifactorial intervention.
Baradzina 2013	Comparison does not meet inclusion criteria: multifactorial intervention.
Bauer 1994	Not disease-related malnutrition and not adults, participants are adolescent weight lifters.
Beange 1995	Not a randomised controlled trial, no control group, the 88 participants were "chosen" from 550 residents.
Beck 2008	Comparison does not meet the inclusion criteria: the intervention was nutrition plus exercise compared with a control group receiving neither.
Beck 2016	Comparison does not meet inclusion criteria, the intervention is multidisciplinary and therefore not possible to assess the contribution of the dietetic component alone.
Beddhu 2015	Not a randomised controlled trial; this is an observational study.
Beelen 2017a	Comparison does not meet the inclusion criteria: the intervention is provision of protein-enriched foods with no dietary counselling
Beelen 2017b	Not a RCT: this is a pilot feasibility study of incorporation of protein-enriched foods into the diet
Bello 2019	The comparison does not meet the inclusion criteria. The intervention is not focused on managing malnutrition but seems to have a health promotion focus and therefore seems more consistent with a public health intervention rather than clinical nutrition.
Benzekri 2019	Comparison does not meet the inclusion criteria. This study compares a basket of local foods with a ready to use therapeutic food and there is no mention of dietary advice.
Bernoth 2014	Not a randomised controlled trial; this is a qualitative study.
Bhattacharjee 2015	Not a randomised controlled trial; this is a prospective observational study.
Bills 1993	Not a randomised controlled trial, a questionnaire survey of nutritional practices in a nursing home.
Bolton 1990	Not a randomised controlled trial, but a palatability study of nutritional supplements.
Bories 1994	Not a randomised controlled trial.
Botella-Carretero 2008	Comparison does not meet inclusion criteria, this is a 3-arm trial which compares 2 different oral nutritional supplements with routine care.
Botella-Carretero 2010	Comparison does not meet the inclusion criteria: this is a study of ONS versus usual care with no dietary counselling
Boulos 2016	Not a randomised controlled trial; this is a cross-sectional study.

Study	Reason for exclusion
Bozzetti 1998	Not a randomised controlled trial, a letter with no data.
Braunschweig 2015	Comparison does not meet inclusion criteria: no dietary counselling.
Bugge 1997	Not a randomised controlled trial.
Bunout 1989	Comparison does not meet inclusion criteria, this trial compares an enhanced calorie- and protein-based diet plus a specialized nutritional supplement with a standard hospital diet.
Burger 1993	Not a randomised controlled trial, a 6-month prospective follow-up of nutritional counselling in malnourished individuals with HIV infection.
Buys 2017	Comparison does not meet the inclusion criteria; the intervention is home-delivered meals and not dietary advice.
Caccialanza 2006	Not a randomised controlled trial.
Caetano 2017	Not a randomised controlled trial. This is a 2-group study with no indication of how participants were selected for groups
Capozzi 2012	Comparison does not meet the inclusion criteria: this is a study of nutritional intervention combined with physical activity and so not possible to determine the effect of nutritional intervention alone.
Carlos Candido 2016	Not a randomised controlled trial; This study is published in Portuguese and was translated using Google translate. It is a cross-sectional study of diet and nutritional status in older healthy Portuguese attending a gym.
Carlsson 2005	Comparison does not meet inclusion criteria, this is a 3-arm trial comparing an oral nutritional supplement with an oral nutritional supplement plus nandrolone (appetite stimulant) with routine care.
Cereda 2018	Comparison does not meet inclusion criteria: use of immunomodulating oral nutritional supplements.
Charlton 2012	Not a randomised controlled trial: this is a retrospective analysis
Chen 2017	Not a randomised controlled trial: this is a pre-test/post-test study.
Chew 2021	Comparison does not meet the inclusion criteria. The intervention includes an ONS with beta-hydroxy-beta-methylbutyrate which is a novel ingredient and therefore excluded.
ChiCTR1900020807	Comparison does not meet the inclusion criteria. The intervention is enteral feeding and not dietary advice.
ChiCTR1900021167	Comparison does not meet inclusion criteria. The intervention is a nutritious formula food versus no formula food with no mention of dietary advice. This looks more like an ONS supplementation study.
ChiCTR-INR-17012826	Comparison does not meet the inclusion criteria. The intervention includes an ONS with a novel ingredient HMB.
Choi 2013	Not a randomised controlled trial; this is a cross-sectional study.
Della Valle 2018	Not a RCT, this is a one group observational study.

Study	Reason for exclusion
DeLuis 2010	Comparison does not meet the inclusion criteria: this is a study of a standard ONS versus an n-3 fatty acid enriched ONS with no dietary counselling
Demeny 2015	Not a randomised controlled trial; this is a questionnaire-based survey of practice.
Deutz 2016	Comparison does not meet the inclusion criteria; the intervention is an oral nutritional supplement with beta-hydroxy-beta methylbutyrate versus placebo.
De Waele 2015	Comparison does not meet inclusion criteria: participants in the control group (usual care) also received intensive, personalized nutritional counselling by an oncology dietitian and this does not fit our definition of 'no supplementation, usual diet'.
Ding 2016	Comparison does not meet inclusion criteria; the intervention is a comprehensive intervention including dietary advice, symptom management and psychological support.
Dizon 2016	Comparison does not meet inclusion criteria: the intervention was dietary counselling plus high-protein meal boxes versus low-energy and low-protein meal boxes.
Dorner 2013	Comparison does not meet inclusion criteria: dietary counselling is combined with exercise, therefore not possible to examine the effects of dietary care alone.
DRKS00016661	Comparison does not meet the inclusion criteria. From the trial report this seems to be an ONS versus placebo study.
Duncan 2006	Comparison does not meet inclusion criteria, the intervention is help with eating from a dietetic assistant compared with routine care.
Dupuis 2017	Comparison does not meet inclusion criteria: the intervention is about training protocols for nutritional management rather than specifically dietary advice.
Efthimiou 1988	Comparison does not meet inclusion criteria, this is a 3-arm trial which compares an oral nutritional supplement with routine care. The 3rd group are individuals that are normally nourished and receiving usual diet.
Ekratzadeh 2015	Comparison does not meet the inclusion criteria. This is a study of dietary advice versus an anti-inflammatory diet. No routine care arm.
Elbanna 1996	Not a randomised controlled trial, comparison of preoperative nutritional support in 2 groups, but the control group are purposively recruited before the intervention group.
Elkort 1981	Comparison does not meet inclusion criteria, comparison of an oral nutritional supplement with routine care, both groups are given encouragement to eat a balanced diet which was considered not to constitute dietary advice.
Elmstaahl 1987	Comparison does not meet inclusion criteria, this study has 3 arms comparing 3 different oral nutritional supplements.
Eneroeth 1997	Not a randomised controlled trial and comparison does not meet inclusion criteria. This study compares supplementary nutrition, which can consist of an oral nutritional supplement, enteral or parenteral feeding with hospital food.
Engel 1995	Not a randomised controlled trial.
Evans 2013	Comparison does not meet the inclusion criteria: this is a study of supplementation with FutureLife porridge versus usual care with no dietary counselling

Study	Reason for exclusion
Faber 2015	Comparison does not meet inclusion criteria: use of immunomodulating oral nutritional supplement which is outside the scope of this review.
Faccio 2021	Comparison does not meet the inclusion criteria. The ONS includes novel ingredients, leucine and zinc IMMAX for nutritional recovery.
Fietkau 2013	Comparison does not meet the inclusion criteria: this is a study of a standard ONS with a disease-specific ONS with no dietary counselling
Flynn 1987	Comparison does not meet inclusion criteria, this study compares individualised nutritional counselling to an oral nutritional supplement with standard nutritional.
Forli 2006	Not a randomised controlled trial.
Franzoni 1996	Not a randomised controlled trial.
Gil Gregorio 2003	Comparison does not meet inclusion criteria: oral nutritional supplements with no dietary advice.
Glimelius 1992	Not a randomised controlled trial, an historical control group was used.
Gomez Sanchez 2010	Comparison does not meet the inclusion criteria: this is a study of an immune-enhancing ONS versus usual care with no dietary counselling
Gurgun 2013	Comparison does not meet the inclusion criteria: Participants received an exercise intervention in addition to dietary interventions (dietary advice +ONS) versus exercise versus routine care and so it is not possible to isolate the effects of dietary counselling.
Hamirudin 2017	Not a randomised controlled trial; this is a one group prospective study with no comparison group.
Hammersley 2015	Not a randomised controlled trial; this is an observational study with a multi-component intervention.
Hansra 2017	The participants do not have illness-related malnutrition. The intervention is dietary counseling to manage weight gain.
Hashmi 2016	Comparison does not meet inclusion criteria: no dietary counselling
Hatsu 2014	Not a randomised controlled trial and comparison does not meet inclusion criteria: no dietary counselling.
Hayashi 2014	Not a randomised controlled trial; this is a matched case-controlled study. Comparison does not meet inclusion criteria: no dietary counselling.
Heberer 1984	Comparison does not meet the inclusion criteria: this is a study of parenteral nutrition.
Henquin 1989	Not a randomised controlled trial.
Hickson 2004	Comparison does not meet inclusion criteria, the intervention is help with eating from a dietetic assistant compared with routine care.
Hogan 1997	Not a randomised controlled trial.
Holder 2003	Not a randomised controlled trial, a review article.
Huisman 2012	Comparison does not meet the inclusion criteria: this is a study of preventative nutritional support where participants were monitored and received the intervention if weight loss >5% developed.

Study	Reason for exclusion
	Not comparable with other studies in the review were intervention is initiated at the start of the study.
Hulsewe 1997	Not a randomised controlled trial, a discussion of perioperative nutritional interventions.
Huppertz 2020	The comparison does not meet the inclusion criteria. The comparison in this trial will be between a pre-thickened ONS and an ONS thickened using conventional additives.
Idilman 2009	Comparison does not meet inclusion criteria, this is a retrospective review of nutrition intervention and outcomes in individuals with alcoholic liver disease.
Ingadottir 2019	Comparison does not meet inclusion criteria, the intervention is snacks which were provided versus ONS with no mention of dietary advice.
Ireton 1995	Not a randomised controlled trial, an observational study.
ISRCTN11132850	Other: It looks like this trial was completed and is relevant to comparison 3 but we can't find evidence of publication. Excluded because of lack of information.
ISRCTN56882109	Comparison does not meet the inclusion criteria. This is a trial of a specialised ONS Renilon 7.5 vs standard treatment in people with end stage renal disease
Jacka 2017	Participants are not malnourished or at risk of malnutrition.
Jamieson 1997	Not a randomised controlled trial, a retrospective audit.
Jancey 2017	Comparison does not meet the inclusion criteria; the intervention group receive dietary counselling plus physical activity advice.
Jang 2018	Comparison does not meet the inclusion criteria, the intervention is multicomponent (including nutritional supplementation) with no dietary advice.
Jie 2009	Comparison does not meet inclusion criteria, this study compares enteral and parenteral feeding.
Johnson 1993	Not a randomised controlled trial and comparison does not meet inclusion criteria, this is a comparison of oral nutritional supplements with no nutritional supplement. Both groups follow their usual diet, therefore there is no counselling component.
Kang 2016	Comparison does not meet the inclusion criteria. Although the abstract mentions individualised counselling, the authors have confirmed that they received enteral and parenteral nutrition.
Karavetian 2016	Comparison does not meet the inclusion criteria. This is a study of individualised education versus usual care, but the education relates to the management of hypophosphataemia.
Keller 1995	Not a randomised controlled trial, a retrospective survey of outcomes in malnourished and normally nourished participants.
Kirkil 2012	Comparison does not meet the inclusion criteria: this is a study of immune enhancing enteral and parenteral nutrition with no dietary counselling
Kiss 2014	Malnourished individuals were excluded and both the intervention and control group received nutritional support.
Knowles 1988	Comparison does not meet inclusion criteria, a comparison of an oral nutritional supplement with no nutritional supplement.

Study	Reason for exclusion
Kondrup 1998	Not a randomised controlled trial, a retrospective survey of outcomes in malnourished individuals.
Kong 2018	Comparison does not meet the inclusion criteria. This is an ONS versus no ONS study and there is no dietary advice.
Krasnoff 2006	Comparison does not meet inclusion criteria, a comparison of nutritional counselling plus exercise compared with routine care.
Kristensen 2020	Comparison does not meet the inclusion criteria. The intervention is multidisciplinary and so it is not possible to determine whether any benefits relate to the nutritional intervention.
Kruizenga 2005	Not a randomised controlled trial, a controlled study using historical controls.
La Torre 2018	Comparison does not meet the inclusion criteria, it is focussed on achieving a healthy lifestyle and not on improving nutritional intake in nutritionally vulnerable patients.
Lee 2013	Comparison does not meet the inclusion criteria: this is a study of ONS versus usual care with no dietary counselling
Lee 2016	Comparison does not meet the inclusion criteria; a comparison of oral nutritional supplements with no oral nutritional supplements.
Leedo 2017	Comparison does not meet the inclusion criteria; the intervention consisted of meals and snacks but no dietary counselling.
Lehtisalo 2017	Comparison does not meet the inclusion criteria; this is a multi-component intervention consisting of a dietary component, physical activity, cognitive training and metabolic and cardiovascular management.
Lejeune 2005	Comparison does not meet inclusion criteria, a comparison of dietary advice to achieve weight loss in moderately overweight individuals.
Leslie 2013	Comparison does not meet the inclusion criteria: this is a study of dietary fortification versus usual care with no dietary counselling
Levine 1982	Comparison does not meet inclusion criteria, comparison of standard diet with parenteral nutrition.
Li 2017	Comparison does not meet the inclusion criteria; the intervention is enteral nutrition
Lipschitz 1985	Not a randomised controlled trial.
Lonbro 2013	Not a randomised controlled trial: this is a retrospective data analysis
Luppino 2015	Not a randomised controlled trial. This is a two group study with a group receiving an intervention and a matched historical control group
Lynch 1983	Not a randomised controlled trial, a prospective study of an oral carbohydrate supplement.
Manders 2009	Comparison does not meet inclusion criteria, this is a study of oral nutritional supplements compared with no nutritional supplement.
Margare 2002	This paper was identified during searching but the full manuscript has remained unavailable on the journal website for a number of years. The study was excluded at the 2018/9 update as it was judged unlikely that the paper will be identified.

Study	Reason for exclusion
Maurya 2019	This is not a RCT it is a two group observational study with no random allocation to groups.
Mazzuca 2019	Comparison does not meet the inclusion criteria. This is an ONS versus no ONS study and there is no dietary advice.
McCarter 2018	Comparison does not meet the inclusion criteria: the intervention is an enhanced management protocol and not specifically dietary counselling.
McCormack 2013	Comparison does not meet the inclusion criteria: this is a study of two different ONS containing beta-alanine with no dietary counselling
McWhirter 1996	Comparison does not meet the inclusion criteria: this is a study of oral versus naso-gastric supplementation.
Mendenhall 1993	Comparison does not meet inclusion criteria, comparison of a nutritional supplement with a placebo nutritional supplement.
Mendenhall 1995	Comparison does not meet inclusion criteria, this study compares hospital diet plus an oral nutritional supplement and a vitamin and mineral supplement with hospital diet plus a vitamin and mineral supplement plus a placebo nutritional supplement.
Monnin 1993	Not a randomised controlled trial, a report of the findings from a questionnaire on nutritional counselling in breast cancer.
Montoya 2014	Not a randomised controlled trial. Following translation, this is a quasi-experimental study, the control arm recruited first and then the intervention group.
Morasutti 2012	Not a randomised controlled trial; this is a 2-group study, where the control group is historic control.
Munck 1998	Not a randomised controlled trial, a review of dietary counselling.
Munk 2014	Comparison does not meet the inclusion criteria: this is a study of fortified additional hospital dishes versus usual care with no dietary counselling
Myint 2013	Comparison does not meet the inclusion criteria: this is a study of ONS versus usual care with no dietary counselling
NCT00136253	Other: This looks relevant (?comparison 1) but we can't find evidence of it being published. There is a retrospective study of nutritional intervention by the primary investigator Sehgal AR and an RCT but of clinical barriers. Excluded because of insufficient information.
NCT00417508	Other: This looks like a group 3 study but there is no evidence of publication either from the trial report or doing and author and title search. Excluded because of lack of information.
NCT00769652	Other: This trial looks relevant to include in comparison 1 or 4 but there is no evidence of publication. Excluded because of lack of information.
NCT01116947	Comparison does not meet the inclusion criteria. All participants receive dietary counselling and the intervention is Fosrenol versus a conventional phosphate binder.
NCT01190969	The trial seems to be relevant for inclusion in comparison 2 but on Clinical Trials is listed as withdrawn because of difficulty recruiting.
NCT02681601	Comparison does not meet the inclusion criteria. The intervention is dietary advice plus an oral nutritional supplement which contains omega-3 fatty acids.

Study	Reason for exclusion
NCT03488511	Comparison does not meet the inclusion criteria. The intervention is home-delivered meals versus routine care and there is no dietary advice.
NCT03649698	Comparison does not meet the inclusion criteria. The intervention is supplementation with a protein powder, there is no dietary advice.
NCT03741283	Comparison does not meet the inclusion criteria. The intervention is multimodal and it would not be possible to determine whether any benefits were related to the nutritional components.
NCT03774953	Comparison does not meet the inclusion criteria. This is a trial of a protein supplement versus no supplement with no dietary advice.
NCT03792711	Comparison does not meet inclusion criteria. The intervention is dietary advice versus ONS but the ONS contains a novel ingredient (β -hydroxy- β -methylbutyrate) which is excluded.
NCT03807310	Comparison does not meet the inclusion criteria. This is lifestyle counselling plus a novel ONS versus lifestyle counselling and an isocaloric ONS.
NCT03924089	Comparison does not meet the inclusion criteria, the intervention is dietary advice versus ONS, but the ONS contains novel ingredients (probiotics) which are excluded.
NCT04027413	Comparison does not meet the inclusion criteria. The intervention is exercise plus an ONS versus exercise plus a placebo ONS with no dietary advice.
NCT04036825	Comparison does not meet the inclusion criteria, the intervention is a liquid ONS versus a placebo ONS with no dietary advice.
NCT04109495	Comparison does not meet the inclusion criteria. The intervention is a Smartphone App which provides feedback on intake. There is no dietary advice component.
NCT04175769	Comparison does not meet the inclusion criteria. The intervention involves capsules containing a novel ingredient (fish oils) and there is no dietary advice.
NCT04218253	Comparison does not meet the inclusion criteria. The intervention includes an oral nutritional supplement that contains branched chain amino acids which is judged to be a novel ingredient.
Neidich 1985	Not a randomised controlled trial, the intervention is a high-nitrogen food supplement and the participants are mainly children.
Newmark 1981	Not a randomised controlled trial.
Neyman 1996	Not a randomised controlled trial and comparison does not meet inclusion criteria. This study compares outcomes in participants in a congregate-site meals programme with people not participating in the programme.
Ng 2015	Comparison does not meet inclusion criteria: no dietary counselling.
Nijs 2006	The comparison does not meet the inclusion criteria, this study compares family-style dining versus traditional dining.
NTR6713	The personalised dietary advice is given to improve healthy eating and not to manage illness-related malnutrition
NTR7506	Comparison does not meet the inclusion criteria. The intervention is ONS versus routine care. There is no dietary advice.

Study	Reason for exclusion
Nyamathi 2018	Comparison does not meet the inclusion criteria. The food-based intervention is given with a health promotion focus rather than to manage a clinical problem.
Nykanen 2014	Comparison does not meet the inclusion criteria, this is a multi-component intervention and therefore not possible to assess the individual contribution of the nutrition component.
Nykanen 2018	Comparison does not meet the inclusion criteria. The intervention is a local berry-based supplement and there is no dietary advice.
Olofsson 2007	Comparison does not meet the inclusion criteria: the intervention included many aspects of medical care in addition to a nutritional intervention that may have accounted for any reported benefits.
Ommundsen 2017	Comparison does not meet the inclusion criteria. The intervention is geriatric assessment including nutrition and tailored management versus usual care and so it would not be possible to separate the effects of nutrition.
Openbrier 1984	Not a randomised controlled trial, this is a prospective evaluation of nutritional intervention in malnourished participants with emphysema.
Orell 2019	The routine care arm is not consistent with other studies in the review. The intervention is an individualised nutritional intervention but the comparison arm is on-demand nutritional counselling (requested by the managing clinician).
Otsuki 2020	The comparison does not meet the inclusion criteria. Although participants received individual dietary counselling there is an escalation of intervention to enteral feeding and around 20% of participants received enteral feeding.
Ottery 1996	Not a randomised controlled trial, a description of improvements following nutritional intervention.
Ottestad 2017	Comparison does not meet the inclusion criteria: participants received a protein-enriched milk drink or an isocaloric carbohydrate drink so no dietary advice component.
Palar 2015	Comparison does not meet the inclusion criteria. The food-based intervention is given in the context of public health and not a healthcare context
Parrott 2006	The comparison does not meet the inclusion criteria, this study compares a snack-type supplement provided to people with Alzheimer's disease in a nursing home which is not the same as dietary advice.
Patel 1998	Not a randomised controlled trial and comparison does not meet inclusion criteria; it examines the efficacy of dietary advice to avoid weight gain.
Paulsen 2020	Comparison does not meet the inclusion criteria. The intervention is a computerised decision support system to enhance nutritional intake and not individualised dietary advice.
Pedersen 2005	Not a randomised controlled trial, this is a quasi-experimental study of nurse-facilitated patient involvement in care.
Penalva 2009	Comparison does not meet the inclusion criteria: this is a RCT of oral nutritional supplements versus "oral cooking supplements". Following translation, there is no mention of the use of dietary advice.
Pietersma 2003	Comparison does not meet inclusion criteria, a comparison of individual selection of 1 meal a day from the food cart compared with receiving the usual plated meal.

Study	Reason for exclusion
Planas 2005	Comparison does not meet inclusion criteria, comparison of 2 groups both receiving dietary advice and supplements but the target energy intake varied between the groups.
Plank 2008	Comparison does not meet the inclusion criteria, comparison of oral nutritional supplements with no nutritional supplements.
Poulsen 2014	Comparison does not meet inclusion criteria: use of immunomodulating oral nutritional supplements.
PrayGod 2012	Comparison does not meet the inclusion criteria: this is a study of nutritionally-enriched biscuits versus usual care with no dietary counselling
Rabinovitch 2006	Not a randomised controlled trial, a re-analysis of data.
Rasmussen 2006	Not a randomised controlled trial and comparison does not meet inclusion criteria, as the intervention does not aim to increase nutritional intake.
Reinders 2018	Not a RCT. This is a systematic review with pooled analysis.
Rizk 2017	Comparison does not meet the inclusion criteria. This is a study of a trained dedicated dietitian versus hospital dietitian in managing patients with renal disease.
Rollo 2020	Participants are not malnourished, they are relatively young people on a university campus.
Roussel 2016	Comparison does not meet the inclusion criteria, around 20% of participants in each group received enteral feeding
Rozenryt 2010	Comparison does not meet the inclusion criteria: this is a study of ONS versus usual care with no dietary counselling
Rüfenacht 2010	Comparison does not meet inclusion criteria; comparison of hospital diet plus oral nutritional supplement with dietary counselling plus oral nutritional supplement as required.
Salas-Salvado 2005	Comparison does not meet the inclusion criteria: the comparison is unclear but appears to be dietary advice plus provision of puree diet and inclusion of a snack-type supplement based on natural lypolysed food compared with dietary advice plus provision of a puree diet.
Sankhaanurak 2021	Comparison does not meet the inclusion criteria. All participants received nutrition counselling and were then randomised to a simplified protein counting tool versus control.
Sartorelli 2005	Participants do not have illness-related malnutrition. The intervention relates to promotion of healthy eating rather than management of malnutrition.
Saudny-Unterberger 1997	Comparison does not meet inclusion criteria, comparison of hospital diet and a supplement or extra food with hospital diet only. No dietary counselling.
Shamoto 2020	Comparison does not meet the inclusion criteria. The intervention is a multidisciplinary comprehensive care and so not possible to isolate the effects of dietary advice.
Shan 2001	Comparison does not meet the inclusion criteria. The intervention is described as parenteral nutrition or no parenteral nutrition.
Simmons 2008	Comparison does not meet the inclusion criteria: this is a study of feeding assistance versus usual care with no dietary counselling. Potential for bias in participant selection because to be eligible for inclusion, the nursing home residents had to demonstrate that they were responsive to one of the feeding assistance interventions.

Study	Reason for exclusion
Simmons 2010	Comparison does not meet the inclusion criteria: this is a study of ONS versus snacks versus usual care with no dietary counselling
Skaarud 2016	Comparison does not meet the inclusion criteria: information from the authors indicates that all patients in the intervention group received tube feeding.
Skaarud 2018	Comparison does not meet the inclusion criteria. A high proportion of participants receive an escalation of intervention to enteral nutrition.
Smoliner 2008	Comparison does not meet the inclusion criteria, comparison of the provision of fortified food with routine care in a nursing home which does not meet the definition of dietary advice.
Sohrabi 2016	Comparison does not meet the inclusion criteria: comparison of an oral nutritional supplement with and without a vitamin E supplement and there is no dietary advice.
Solerte 2008	Comparison does not meet inclusion criteria, comparison of an amino acid mixture with a placebo.
Solomon 1978	Comparison does not meet inclusion criteria, comparison of a combination of pre-operative and post-operative diets including a hypo-caloric, carbohydrate-free, protein-containing diet with normal diet.
Somanchi 2011	Not a randomised controlled trial; this is a 2-arm non-randomised study with the two wards "being chosen at random".
Sridar 1994	Not a randomised controlled trial, a prospective study of 12 individuals with COPD after nutritional intervention.
Stack 1996	Not a randomised controlled trial, a prospective, descriptive trial with no control group.
Stark 1990	Comparison does not meet inclusion criteria, all participants were children.
Stevenson 2019	Comparison does not meet the inclusion criteria. The dietary advice given relates to the management of renal disease rather than to improve nutritional intake.
Stewart 2017	Comparison does not meet the inclusion criteria: this is a protocol for a trial of nutritional intervention combined with physical activity.
Suzuki 2019	The dietary advice given in this study is based on healthy eating rather than an intervention to increase energy, protein and nutrient intake.
Swaminathan 2010	This is a cluster intervention study but the method of assignment of clusters is not described and there is no mention of randomisation to clusters.
Swanenburg 2007	Comparison does not meet inclusion criteria, comparison of exercise plus an oral nutritional supplement with no exercise and no supplement.
Tandon 1984	Comparison does not meet the inclusion criteria. The intervention is enteral feeding versus standard oral diet
Tatsumi 2009	Comparison does not meet the inclusion criteria, the intervention is "Hochuekkito" which is a herbal medicine.
Taylor 2006	Comparison does not meet the inclusion criteria, comparison of meal frequency (5 meals versus 3 meals) on nutritional outcomes.

Study	Reason for exclusion
Trabal 2010	Comparison does not meet the inclusion criteria; the oral nutritional supplement used is an immuno-nutrition supplement which is outside of the scope of this review.
Turic 1998	Comparison does not meet the inclusion criteria, intervention involves the provision of a nutritional supplement or snacks to nursing home residents which does not meet the definition of dietary advice.
Turnock 2013	Comparison does not meet the inclusion criteria: this is a study of an immune-enhancing ONS versus standard ONS with no dietary counselling
Unosson 1992	Comparison does not meet inclusion criteria, the intervention is hospital diet plus a nutritional supplement compared with hospital diet.
van Beers 2020	Comparison does not meet the inclusion criteria. The intervention is dietary counselling plus ONS versus no counselling and a placebo but the ONS contains a novel ingredients.
van Blarigan 2020	Participants and comparison don't meet the inclusion criteria. The participants are people with CRC but who have completed treatment and have stable disease. The intervention is a healthy eating intervention. The study is not about illness-related malnutrition.
van den Berg 2010	Comparison does not meet inclusion criteria: participants in the control group (usual care) also received intensive, personalized nutritional counselling by a nurse and this does not fit our definition of 'no supplementation, usual diet'.
van den Heuvel 2017	Comparison does not meet the inclusion criteria. The intervention consists of supplementation with eggs, there is no dietary counselling.
van der Meij 2010	Comparison does not meet the inclusion criteria: this is a study of an immune-enhancing ONS versus standard ONS with no dietary counselling
van der Pols-Vijlbrief 2017	Comparison does not meet inclusion criteria; the study had a multifactorial approach in which participants could choose which problem they wanted to address, meaning that dietary counselling was not the primary intervention and also a number of participants in the intervention group did not choose dietary counselling as the main approach and thus never received any dietary counselling or advice.
Vargas 1995	Comparison does not meet inclusion criteria, 4 arms comparing different combination of nutritional supplements and training.
Vazquez Martinez 2015	Not a randomised trial; on translation, this seems to be an editorial.
Volkert 1996	Comparison does not meet inclusion criteria, the intervention is hospital diet plus a nutritional supplement compared with hospital diet.
Watson 2008	Comparison does not meet the inclusion criteria: the intervention consists of both dietetic and educational and psychological motivation; it would be difficult to attribute any reported benefits to nutrition alone.
Williams 1989a	Participants were mainly children with some adults; no participants over 16 years of age in control group therefore no comparison group.
Williams 1989b	Comparison does not meet inclusion criteria, the intervention is hospital diet plus a nutritional supplement compared with hospital diet.
Woo 1994	Comparison does not meet inclusion criteria, the intervention is hospital diet plus a nutritional supplement compared with hospital diet.

Study	Reason for exclusion
Wouters-Wessling 2005	Comparison does not meet the inclusion criteria, comparison of a nutritional supplement with routine care.
Wright 2008	Not a randomised trial, a prospective observational study with retrospective control group examining feeding assistance to increase intake.
Wu 2020	The comparison does not meet the inclusion criteria. The intervention is not a dietary intervention but seems to be exercises for the oral cavity and oral hygiene in nutritionally at risk participants.
Xie 2017	Comparison does not meet inclusion criteria: participants in the control group (usual care) also received intensive, personalized nutritional counselling and this does not fit our definition of 'no supplementation, usual diet'.
Yoneda 1992a	Comparison does not meet inclusion criteria, a report on the clinical course of individuals with asthma.
Yoneda 1992b	Comparison does not meet inclusion criteria, Japanese study that appears to be an intervention to reduce psychological stress in individuals with respiratory disease.
Yuvaraj 2016	Comparison does not include dietary advice; a comparison of an oral nutritional supplement with "kitchen feeding" implying the provision of additional food.
Zhang 2018a	Comparison does not meet the inclusion criteria. The intervention is described as prephylactic enteral nutrition powder formula. There is no mention of dietary advice and no description of whether the formula is taken orally or via a tube.
Zhao 1995	Other: This reference might be incorrect. Is there a journal 'parenteral and enteral nutrition'. I have checked JPEN and this paper is not there. Nothing identified on title and author search. Excluded because of insufficient information.
Zweers 2020	The majority (95%) of participants are not malnourished, therefore this is not illness-related malnutrition.

HMB: beta-hydroxy-beta-methylbutyrate

ONS: oral nutritional supplement

Characteristics of studies awaiting classification *[ordered by study ID]*

[Abdelsalam 2019](#)

Methods	Randomised study
Participants	100 adults with end stage renal disease on hemodialysis.
Interventions	"nutritional support educational program"
Outcomes	SGA score, anthropometry, nutritional knowledge
Notes	Currently published in an abstract only and insufficient details of the intervention to evaluate eligibility. Assess against inclusion criteria when a full-text publication is available.

Abdollahi 2019

Methods	RCT
Participants	150 women with breast cancer receiving chemotherapy.
Interventions	Nutrition education by a dietitian to reduce the severity of side-effects of treatment.
Outcomes	Primary: chemotherapy induced nausea, vomiting and diarrhoea. Secondary: weight, constipation, reflux, dyspepsia, anorexia, gastritis and chest pain.
Notes	This published study seems to be relevant to include in comparison 1.

Banda 2017

Methods	Randomised factorial design.
Participants	81 patients with tuberculosis.
Interventions	"Multivitamin and/or high calorie versus control".
Outcomes	Weight change, BMI, performance status, treatment success.
Notes	Currently published as an abstract only. It is impossible to fully evaluate eligibility from the details available. Assess once a full-text publication is available.

Britton 2019

Methods	A stepped-wedge RCT.
Participants	307 participants with head and neck cancer undergoing chemoradiation or radiotherapy with curative intent.
Interventions	A motivational interviewing and cognitive behavioural therapy-based intervention delivered by oncology dietitians to support usual dietetic management.
Outcomes	Primary outcome: nutritional status at the end of treatment using PG-SGA. Secondary outcomes: SGA, percentage weight loss, weight loss >10%, depression, treatment interruptions, unplanned hospital admission, QoL.
Notes	This study looks eligible for inclusion but further details needed of the nature of the dietetic intervention to determine comparison group.

Camere 2016

Methods	RCT.
Participants	95 participants with chronic obstructive pulmonary disease with or at risk of malnutrition.
Interventions	Personalised dietary advice versus oral nutritional ONS for 3 months.

Camere 2016 *(Continued)*

Outcomes	Nutritional status (BMI, weight, FFMI), numbers improving nutritional status, lung function (FEV1), handgrip strength, exercise endurance.
Notes	Full paper not published. Available as an abstract only. This seems to meet the inclusion criteria for comparison 2 of the review but needs full assessment once the final paper is available.

Cawood 2017

Methods	RCT.
Participants	308 older people (over 50 years) attending GP services and at risk of malnutrition according to MUST.
Interventions	Dietary advice and low volume oral nutritional supplement versus dietary advice alone.
Outcomes	Total food intake (macronutrient and micronutrient intake).
Notes	Full paper not published. Available as an abstract only. This seems to meet the inclusion criteria for comparison 3 of the review but needs full assessment once the final paper is available.

Cereda 2019

Methods	RCT.
Participants	166 participants with advanced cancer and malnutrition undergoing chemotherapy.
Interventions	Individualised nutritional counselling with 1 - 2 cans of whey protein ONS versus individualised nutritional counselling alone.
Outcomes	Primary outcome: change in phase angle at 3 months. Secondary outcomes: change in phase angle at 1 month, change in standardized phase angle, FFMI, body weight, muscle strength, treatment toxicities.
Notes	Consider for inclusion in comparison 3 of the review (dietary advice versus dietary advice + ONS).

Chewaskulyong 2015

Methods	RCT.
Participants	50 people with locally advanced unresectable or metastatic cancer undergoing chemotherapy.
Interventions	Dietary counselling versus routine care.
Outcomes	Weight, BMI, PG-SGA score, QoL, energy intake, chemotherapy outcome and biochemistry.
Notes	Full paper not published. Available as an abstract only. This seems to meet the inclusion criteria for comparison 1 of the review but needs full assessment once the final paper is available.

ChiCTR1800014842

Methods	2-group trial (likely RCT but not specified)
Participants	Individuals with intra-abdominal infection.
Interventions	Nutrition management versus routine treatment.
Outcomes	Clinical outcome after treatment, post-op complications, inflammatory markers, immunologic function, APACHE II score, SOFA score, NUTRIC score.
Notes	It is not possible to determine from the description in the abstract what nutritional management entails to determine eligibility. Assess once a full-text publication is available.

ChiCTR-IOR-17013151

Methods	Not specified.
Participants	Outpatients with tuberculosis.
Interventions	"dietary intervention versus dietary intervention plus ONS".
Outcomes	Malnutrition risk (NRS-2002) weight, arm muscle circumference, TSF, albumin, prealbumin, transferrin, haemoglobin, total lymphocyte count, 25-hydroxy vitamin D status.
Notes	The WHO International Register was not available at the time of scrutiny. There are insufficient details in the trial report to understand what the intervention is. This needs to be evaluated once there is a full text paper.

Collins 2014

Methods	RCT.
Participants	200 clinically stable outpatients with chronic obstructive pulmonary disease at risk of malnutrition (MUST).
Interventions	Oral nutritional ONS versus dietary advice.
Outcomes	Global QoL (St George's Respiratory Questionnaire), handgrip strength, weight, nutritional intake.
Notes	Full paper not published. Available as an abstract only. This seems to meet the inclusion criteria for comparison 2 of the review but needs full assessment once the final paper is available.

Cong 2016

Methods	RCT.
Participants	80 participants with oesophageal cancer undergoing radiotherapy.
Interventions	Nutritional counseling combined with oral nutritional supplements (Ensource) versus nutritional counselling alone.

Cong 2016 (Continued)

Outcomes	Energy intake, nutritional status, incidence of complications.
Notes	This paper is in Chinese and needs translation to allow full assessment. It looks to be eligible for inclusion in comparison 3 (dietary advice +ONS versus dietary advice alone).

Cramon 2019

Methods	RCT.
Participants	40 hospitalised geriatric participants (over 65 years of age).
Interventions	Individualised nutritional intervention consisting of dietary counselling and a nutrition plan at hospital discharge + 2 home visits.
Outcomes	30-day hospital admissions/re-admission rate, percent of energy and protein target achieved, ADL, handgrip strength and QoL.
Notes	This is currently published as an abstract. The full-text paper needs to be evaluated once available to determine the comparison group (1, 4 or 5).

CTRI/2012/05/002698

Methods	RCT.
Participants	People with HIV infection beginning anti-retroviral therapy.
Interventions	Oral protein supplementation (16 gm/day for 6 months) versus nutritional counselling "according to 6 modules" for a period of 6 months versus a combination of nutritional counselling and oral protein supplementation (16 gm/day) for a period of 6 months.
Outcomes	Nutritional status, immunological status, dietary profile, clinical status, mortality, QoL.
Notes	The International Trial Register was not functioning at the time of assessment. We need to see the full trial record to identify the authors and to identify a full-text publication. A title search and trial ID search do not yield anything obvious.

CTRI/2018/10/015882

Methods	RCT.
Participants	Participants with gastrointestinal disease planned for surgery.
Interventions	Preoperative nutrition based on nutritional status plus 50 g of soya protein versus preoperative nutrition only.
Outcomes	Not specified.
Notes	The details of the preoperative nutrition and soya protein supplement need to be evaluated once there is a full-text publication to determine whether this study meets the inclusion criteria. It could meet the criteria for comparison 3.

CTRI/2018/11/016369

Methods	Controlled trial.
Participants	Patients diagnosed with CHILD B & C chronic liver disease.
Interventions	Telephonic reinforcement of nutritional counselling vs. standard care with no telephonic counselling.
Outcomes	Primary outcome: reduction in mortality. Secondary outcomes: improvement of sarcopenia, reduction of upper GI bleed, reduction hepatorenal syndrome, reduction of hepatic encephalopathy.
Notes	Full trial record not available. This trial needs assessment against the inclusion criteria when a full-text publication is available.

Cui 2017

Methods	Single-blind RCT.
Participants	25 people with gastric cancer (postoperative and receiving neo-adjuvant chemotherapy).
Interventions	Dietary advice and oral nutritional ONS versus personalised dietary advice.
Outcomes	BMI, haemoglobin, prealbumin, albumin, gastrointestinal function score, QoL.
Notes	This study is in Chinese. Limited translation indicated that it meets the inclusion criteria for Group 3. Full translation awaited.

Gaitan 2017

Methods	RCT.
Participants	100 participants with chronic renal failure and protein- energy wasting on haemodialysis.
Interventions	Nutritional counselling to meet daily requirements versus ONS.
Outcomes	BMI, weight, serum cholesterol, serum albumin and handgrip strength.
Notes	Currently published as an abstract only but looks eligible for inclusion in comparison 3 (dietary advice versus ONS). Once a full-text publication is available evaluate against the inclusion criteria.

Ha 2010

Methods	RCT.
Participants	170 participants with acute stroke.
Interventions	Individualised nutritional care (including ONS and enteral feeding) versus routine care.

Ha 2010 (Continued)

Outcomes	<p>Primary outcome: % of participants with weight loss.</p> <p>Secondary outcomes: QoL, handgrip strength, length of stay.</p>
Notes	17 of 170 participants receive enteral feeding. This study should be considered for inclusion in comparison 4 of the review (dietary advice plus ONS versus routine care).

Hansen 2020

Methods	RCT.
Participants	Participants over 65 years with community-acquired pneumonia.
Interventions	Individualised nutrition guidance and oral supplementation versus standard care.
Outcomes	Weight, FFM, handgrip strength, QoL, ADL.
Notes	Currently available as an abstract only. It looks to be eligible for inclusion in comparison 5 (dietary advice plus ONS versus routine care but needs to be assessed once a full-text publication is available).

Hebuterne 2019

Methods	Multicentre RCT.
Participants	173 participants with metastatic colorectal cancer receiving chemotherapy.
Interventions	Early & active individualised dietary counselling by a dietitian with ONS and enteral & parenteral feeding prescribed according to guidelines versus no dietary counselling.
Outcomes	<p>Primary outcome: grade ≥ 3 toxicity.</p> <p>Secondary outcomes: treatment delay, weight.</p>
Notes	Currently available as an abstract only. Full details of the intervention needed as well as numbers of participants going on to receive EN and PN needed to judge eligibility.

Hoekstra 2005

Methods	Pilot RCT.
Participants	30 participants with COPD.
Interventions	An individual nutritional intervention carried out by a dietitian versus standard nutritional advice from a pulmonologist and 3x 125 mL of an ONS.
Outcomes	FFMI, QoL, compliance.
Notes	This seems to be published as an abstract only. A full-text publication is needed to assess fully but looks to meet the inclusion criteria for comparison 2 (dietary advice versus ONS).

Hoekstra 2005 (Continued)

Also seems to be published in Aktuelle Ernährungsmedizin 2005;30-24.

Hsieh 2019

Methods	RCT (4-arm).
Participants	319 frail or pre-frail older adults attending outpatient clinics at Miaoli General Hospital, Taiwan.
Interventions	Interventions were exercise, nutrition intervention, exercise+nutrition intervention and control. The nutritional intervention consisted of advice based around the Taiwanese Food Guide six food groups to maintain a desirable body weight plus a food supplement of 25 g of skim milk powder and 10 g of mixed nuts.
Outcomes	Primary outcome: frailty score, handgrip strength, gait speed, physical activity. Secondary outcomes: physical performance, mental health status. Dietary compliance
Notes	Two groups relevant to include in comparison 1 (nutrition intervention versus control).

Hubbard 2009

Methods	RCT.
Participants	45 community-based older adults at risk of malnutrition (MUST).
Interventions	400 kcal/d from an oral nutritional supplement (Calogen Extra) or dietary advice.
Outcomes	Energy and nutrient intake, appetite, acceptability, tolerance, compliance with supplementation.
Notes	Full paper not published. Available as an abstract only. This seems to meet the inclusion criteria for comparison 2 of the review but needs full assessment once the final paper is available.

Jabbour 2019

Methods	RCT.
Participants	46 adults admitted to the bone marrow transplantation unit (Beirut).
Interventions	At hospital discharge dietary advice tailored to individual requirements plus ONS if required versus no tailored advice. Both groups were advised on food safety guidelines.
Outcomes	Nutritional status, dietary intake, body composition, muscle strength.
Notes	This seems to be relevant for inclusion in comparison 4 (dietary advice plus ONS if required versus no dietary advice).

Jia 2019

Methods	RCT.
Participants	160 participants with COPD.
Interventions	Nutritional support versus usual medical care.
Outcomes	Lung function, nutritional index, blood gas index, length of stay.
Notes	This study is published in Chinese and needs translation before the details of the nutritional intervention can be assessed against the inclusion criteria.

Kalal 2016

Methods	RCT
Participants	104 malnourished individuals with alcoholic liver cirrhosis.
Interventions	Standard nutritional counselling versus nutritional counselling and ONS.
Outcomes	Nutritional, clinical and biochemical status.
Notes	Published as an abstract only but looks to be eligible for inclusion in comparison 3. Evaluate against the inclusion criteria once a full-text publication is available.

Kandel 2014

Methods	RCT.
Participants	Frail adults.
Interventions	Dietary intervention versus dietary intervention and Nordic walking training versus dietary counselling for 8 weeks.
Outcomes	Gait speed, handgrip strength, frailty score.
Notes	Full paper not published. Available as an abstract only. This seems to meet the inclusion criteria for comparison 3 of the review but needs full assessment once the final paper is available. Contact with the senior author failed to clarify questions about the intervention groups.

Kang 2013

Methods	RCT.
Participants	60 hospitalised adults aged over 65 years following surgery for hip fracture.
Interventions	Dietary counselling and oral nutritional ONS + trace element supplement for 2 weeks postoperatively versus usual care.
Outcomes	Change in MNA score, energy and protein intake, handgrip strength.

Kang 2013 (Continued)

Notes	Full paper not published. Available as an abstract only. This seems to meet the inclusion criteria for comparison 1 of the review but needs full assessment once the final paper is available.
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Kuhlmann 1999

Methods	To be determined, participants were "assigned to three groups".
Participants	18 participants with renal disease on maintenance haemodialysis.
Interventions	45 kcal/kg/d and 1.5 g protein /kg/d versus 35 kcal/kg/d and 1.2 g protein /kg/d versus spontaneous intake. Participants in the first 2 groups received food supplements at appropriate dosing to reach the target intake.
Outcomes	Nutritional intake, compliance, tolerance, weight, serum albumin, pre-albumin, cholesterol.
Notes	Full-text paper not available. Further details of the intervention needed including whether dietary counselling was used to implement the intervention.

Kwon 2004

Methods	Not clear from the abstract.
Participants	Urban dwelling older women in Korea.
Interventions	Weekly home-visit nutrition education by a dietitian.
Outcomes	Nutritional knowledge, attitude, and dietary habits, nutrient intake, anthropometric and biochemical status.
Notes	This article is in Japanese and not possible to assess fully against the inclusion criteria. It looks as if the intervention might be a healthy eating intervention but translation needed to determine eligibility.

Limwannata 2021

Methods	RCT.
Participants	80 participants with renal disease receiving haemodialysis.
Interventions	Nutrition counselling plus ONS (ONCE Dialyze) versus nutrition counselling plus ONS (NEPRO) versus nutrition counselling alone.
Outcomes	Nutritional status, body composition, serum albumin and pre-albumin.
Notes	This looks eligible for inclusion in comparison 3 (dietary advice plus ONS versus dietary advice alone).

Lin 2017

Methods	Prospective clinical trial.
Participants	110 adults with colorectal cancer undergoing chemotherapy.
Interventions	Individualised nutritional support (education, encouragement and recipes) and " <i>afterwards doctors administered parenteral or enteral nutrition at 70-80% of requirements</i> " versus normal diet.
Outcomes	Body weight, serum albumin and prealbumin.
Notes	The description of the intervention is confusing in that it describes recipes but also indicates that the doctors administered enteral and parenteral nutrition. Clarification has been sought from authors but no reply received.

Liu 2018

Methods	RCT.
Participants	170 hospitalised patients with Alzheimer's disease.
Interventions	Nurse-led intensive nutritional intervention compared with routine nutritional management.
Outcomes	Nutritional risk (NRS-2002) and QoL.
Notes	The full-text article is in Chinese and so needs translation to determine the detail of the nutritional intervention and eligibility.

Liu 2019

Methods	RCT.
Participants	101 older hospital inpatients with Alzheimer's disease.
Interventions	"nutritional support based on clinical nursing pathway" versus routine nutritional management.
Outcomes	Nutritional risk (NRS-2002) and QoL.
Notes	This article is in Chinese and needs translation to enable judgement about eligibility. **note this seems to be very similar to Liu 2018. Evaluate the two studies together**

Looser 2021

Methods	RCT.
Participants	61 participants with squamous cell carcinoma of the head and neck referred for adjuvant or definitive treatment with curative intent.
Interventions	Individualised nutritional counselling from a dietitian with individualised recommendations versus no nutritional counselling.
Outcomes	Primary outcome: amount of malnutrition (assessed using a range of tools).

Looser 2021 *(Continued)*

Secondary outcomes: therapy-related side-effects, biochemical status.

Notes	This study meets the inclusion criteria for comparison 1 (dietary advice versus no advice).
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Maharshi 2016

Methods	RCT.
Participants	120 participants with cirrhosis and minimal hepatic encephalopathy.
Interventions	Nutritional education to achieve energy and protein targets +2 g salt/day versus routine diet +2g salt/d.
Outcomes	Primary outcomes: improvement or worsening of minimal hepatic encephalopathy, QoL. Secondary outcomes: nutritional status, change in Child-Turcotte-Pugh score, change in Model for End-Stage Liver disease score, change in critical flicker frequency, arterial ammonia, development of HE, hospital admission, complications, death.
Notes	This looks relevant to include in comparison 1 (dietary advice versus no advice).

Meng 2021

Methods	RCT.
Participants	353 adults post surgery for (i) gastric cancer and at nutritional risk. Participants with (ii) colorectal cancer, (iii) head and neck cancer included in related clinical trial reports.
Interventions	Dietary advice and oral intake of Nutren Optimum versus dietary advice alone.
Outcomes	Nutritional outcomes, prevalence of sarcopenia, tolerance to chemotherapy, 90-day readmission, QoL.
Notes	This group of trials listed in the WHO International register all look the same in terms of intervention but involve participants with different sites of cancer. Two trials are now published and look to be relevant to comparison 3 (dietary advice plus ONS versus dietary advice alone).

Molassiotis 2021

Methods	Pilot RCT.
Participants	Adults with advanced cancer and family care-givers.
Interventions	A family-centred individualised nutritional intervention plus ONS if required versus usual care.
Outcomes	Feasibility outcomes: recruitment, consent rate, retention rate, acceptability of assessment tools. Nutritional intake, PG-SGA, QoL, self-efficacy, carer distress, anxiety and depression.
Notes	This looks eligible for inclusion in comparison 4 (dietary advice plus ONS if required versus usual care).

Movahed 2020

Methods	RCT.
Participants	100 participants with oesophageal cancer.
Interventions	Medical Nutrition Therapy consisting of an individualised plan with dietary education, escalation to use of ONS, enteral or parenteral feeding if participants failed to meet requirements versus general nutrition advice (possible to receive ONS, enteral and parenteral nutrition if prescribed by oncologists).
Outcomes	PG-SGA, anthropometry, body composition, dietary intake, biochemical status, nutrition-related complications.
Notes	More details are needed of the numbers of participants receiving enteral and parenteral feeding in order to determine eligibility.

NCT01171495

Methods	RCT
Participants	120 people with HIV who are asymptomatic and anti-retroviral therapy naive.
Interventions	Dietary counselling + multivitamin + ONS versus dietary counselling + multivitamin.
Outcomes	Nutritional status, BMI, clinical status, immune function and antioxidant status.
Notes	This looks relevant to include, possibly in comparison 3 (dietary advice plus ONS versus dietary advice alone) and is listed as completed but no full-text paper identified. If a full-text publication is identified assess against the inclusion criteria.

NCT02051777

Methods	RCT.
Participants	120 adults (> 50 years) at nutritional risk and living in the community.
Interventions	Dietary advice plus ONS1 versus dietary advice plus ONS2 versus dietary advice alone.
Outcomes	Nutrient intake.
Notes	Listed as completed on Clinical Trials but no publication identified. Contact the sponsor Nutricia for further details.

NCT02975089

Methods	RCT.
Participants	40 frail older adults.

NCT02975089 (Continued)

Interventions	Multiple nutrients supplementations versus multiple nutrients plus isolated soy protein supplementation versus individualized nutrition education with designed dishware for balanced diet as well as food supplementations (mixed nuts and milk powder) versus no intervention.
Outcomes	Primary outcomes: change in nutritional intake. Secondary outcomes: frailty score, geriatric depression score, nutritional status, urinary nitrogen and creatinine.
Notes	Currently available as a clinical trial record only and impossible to fully assess the intervention for eligibility. Assess against the inclusion criteria once a full-text paper is available.

NCT03631537

Methods	RCT.
Participants	200 participants with advanced cancer receiving chemotherapy.
Interventions	Nutritional intervention from the nutrition support team including patient education, dietary supplements and parenteral solutions versus clinicians deciding how and whether to give nutritional support.
Outcomes	Treatment toxicities, number of chemotherapy cycles completed, progression-free survival, adverse events.
Notes	Only available as a clinical trial record and not possible to evaluate eligibility. Once a full-text publication is available the intervention should be examined against the inclusion criteria.

NCT03632200

Methods	RCT.
Participants	60 participants with head and neck cancer undergoing surgery.
Interventions	Individualised dietetic consultation post operatively for six months versus routine care.
Outcomes	Primary outcome: nutritional status (weight change). Secondary outcome: PG-SGA score.
Notes	Full details of the dietetic consultation needed to allow assessment against inclusion criteria. Assess for eligibility once there is a full-text publication.

NCT03944161

Methods	RCT.
Participants	Participants with malnutrition.
Interventions	ONS versus nutrition advice from the clinician.

NCT03944161 (Continued)

Outcomes	BMI, change in nutritional status, number with malnutrition, QoL, strength and endurance, number of hospital admissions, number of consultations with clinician.
Notes	From the trial record this looks to be relevant to comparison 2. I note that the advice is not described as dietary counselling but nutrition advice from a clinician and so will need to be evaluated once the full study is published.

NCT04217564

Methods	RCT.
Participants	120 participants with multiple sclerosis.
Interventions	Nutritional counselling versus no nutritional counselling.
Outcomes	Primary outcomes: change in QoL, change in nutritional status. Secondary outcome: change in disease progression.
Notes	The intervention and nutritional status of participants needs assessment against the inclusion criteria once a full-text publication is available. It is not possible to determine the content and goals of the nutritional counselling from the clinical trial record.

Norshariza 2018

Methods	RCT.
Participants	40 outpatients with head and neck cancer undergoing radiotherapy.
Interventions	Dietary counselling from a dietitian plus ONS versus dietary counselling from a dietitian.
Outcomes	Nutritional outcomes (weight change, BMI, body composition, dietary intake, biochemical status), functional outcomes (handgrip strength), side effects of treatment.
Notes	This is currently published as an abstract of The Asian Congress of Nutrition and there is a clinical trials record that seems to relate to the same study. The trial was registered in September 2016 with a projected completion of September 2018. There is no full-text publication identified other than Neoh 2020 which is not an RCT but a prospective observational study. From the trial report it looks to be relevant to include in comparison 3 (dietary advice plus ONS versus dietary advice alone) but needs assessment against further information.

Nyguyen 2020

Methods	RCT.
Participants	120 malnourished individuals with COPD.
Interventions	Tailored nutritional counselling versus routine care (a booklet).
Outcomes	Nutritional intake, change in body weight, nutritional status, SGA score, muscle strength, QoL.

Nyguyen 2020 *(Continued)*

Notes	This study meets the inclusion criteria for comparison 1 (dietary advice versus routine care).
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Otten 2016

Methods	RCT.
Participants	71 frail older adults with malnutrition (MNA).
Interventions	Dietary counselling versus oral nutritional ONS for 3 months.
Outcomes	Mobility (TUG), handgrip strength, knee extension, QoL (EQ-VAS), functional limitations (LASA).
Notes	Full paper not published. Available as an abstract only. This seems to meet the inclusion criteria for comparison 2 of the review but needs full assessment once the final paper is available.

Park 2012

Methods	Comparison of 2 groups (unclear whether participants were randomly allocated to groups).
Participants	40 people with colorectal cancer receiving chemotherapy.
Interventions	Individualised nutrition counselling versus control group who received counselling after completion of data collection.
Outcomes	Energy and protein intake, weight, serum albumin.
Notes	This paper is in Korean and it has not been possible to obtain a translation to date.

Pinto 2021

Methods	RCT.
Participants	80 patients post surgery for oesophagectomy for cancer.
Interventions	Individualised nutrition counselling plus ONS if patients failed to achieve 75% of estimated energy requirements versus standard care.
Outcomes	Primary outcomes: dyspnoea, appetite loss and Global QoL after 1 month. Secondary outcomes: eating, dyspnoea, and Global QoL after 3 months.
Notes	This study looks eligible for inclusion in comparison 4 (dietary advice plus ONS if required versus routine care). Note escalation of intervention to enteral feeding. Check numbers receiving enteral feeding to determine eligibility.

Qui 2020

Methods	RCT.
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Qui 2020 (Continued)

Participants	96 participants with oesophageal cancer receiving concurrent chemotherapy.
Interventions	Whole course nutritional intervention developed by a dietitian and oncologist which could include ONS, enteral and parenteral feeding versus routine care.
Outcomes	Nutritional risk (NRS-2002), nutritional status, nutritional intake, biochemical status, QoL, psychological condition, complications, completion of therapy, efficacy of intervention, length of stay and costs.
Notes	It is not possible to determine from the paper the number of patients that received enteral and parenteral feeding. This needs to be evaluated to determine eligibility for inclusion.

RBR-35kjvg

Methods	RCT.
Participants	Patients with head and neck cancer receiving radiotherapy.
Interventions	Intensive nutritional counselling versus routine care.
Outcomes	Primary outcomes: change in nutritional status, QoL. Secondary outcomes: PG-SGA, food intake, FFM, complications, hospital admissions, treatment interruptions.
Notes	The full trial record is not available. This trial needs to be assessed against the inclusion criteria following full-text publication.

RBR-3shhxs

Methods	RCT.
Participants	62 participants with breast cancer planned to receive neoadjuvant chemotherapy.
Interventions	"dietary guidelines regarding her intervention group".
Outcomes	Primary outcome: QoL. Secondary outcomes: nutritional intake, biochemical status, anthropometry, PG-SGA, treatment toxicity.
Notes	Not currently possible to access the trial registry and so information from the abstract only. This looks relevant to include but the intervention needs to be assessed against the inclusion criteria once more information are available.

Reinders 2020

Methods	RCT.
Participants	264 community dwelling older adults (>65 years) with an habitual low protein intake.

Reinders 2020 *(Continued)*

Interventions	Personalised dietary advice to increase protein intake to 1.2 kg/body weight/day using regular foods and protein-enriched products versus personalised dietary advice to increase protein intake to 1.2 kg/body weight/day plus exercise versus no intervention. All groups receive a standard brochure about healthy eating.
Outcomes	Primary outcome: change in walk time (400 m walk test). Secondary outcomes: Change in dietary intake, prevalence of malnutrition, physical performance, mobility limitations, muscle strength, body weight, body composition, frailty status, QoL, health-care costs.
Notes	This looks like it can be included in comparison 1 (dietary advice versus no advice).

Sahathevan 2018

Methods	RCT.
Participants	126 participants receiving peritoneal dialysis.
Interventions	Dietary counselling and 2x 15 g sachets of a whey protein supplement versus dietary counselling alone.
Outcomes	Anthropometry, body composition, biochemical assessment, dietary intake and appetite, nutritional status, QoL and handgrip strength.
Notes	Full-text publication available. Consider for inclusion in comparison 3 (dietary advice versus dietary advice + ONS).

Salem 2020

Methods	RCT.
Participants	100 participants receiving haemodialysis.
Interventions	Nutrition education including tailored dietary counselling from a renal dietitian versus usual care.
Outcomes	Nutritional intake (diet history), malnutrition inflammation score, anthropometry and biochemical status.
Notes	Published as an abstract only. It is not possible to fully assess the eligibility of the nutrition education. Assess against inclusion criteria once a full-text publication is available.

Sathiaraj 2020

Methods	Pilot RCT.
Participants	103 participants with cancer receiving chemotherapy.
Interventions	Nutrition interventions using the Nutrition Care Process.
Outcomes	Primary outcome: change in fatigue.

Sathiaraj 2020 (Continued)

Secondary outcomes: change in nutritional status, BMI, body weight, depression.

Notes	Published as a conference abstract only and not possible to fully evaluate the nutrition intervention. Assess against the inclusion criteria once a full-text publication is available.
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Schuetz 2019

Methods	RCT.
Participants	2088 medical patients who were in hospital and at nutritional risk.
Interventions	Protocol-guided individualised nutritional support to reach protein and calorie goals versus standard hospital food.
Outcomes	Primary endpoint: any adverse clinical outcome (all-cause mortality), admission to intensive care, non-elective hospital readmission, major complications and decline in functional status at 30 days.
Notes	This study meets the inclusion criteria for comparison 4 (dietary advice plus ONS if required versus routine care).

Shadid 2019

Methods	RCT.
Participants	60 participants with histologically proven squamous cell carcinoma for treatment with radical radiotherapy or radical concurrent chemoradiation with curative intent.
Interventions	Nutrition counselling following the American Dietetic Association Medical Nutrition Therapy protocol for radiation oncology versus a talk on general nutrition and a booklet.
Outcomes	Dietary intake, treatment interruption and health-related QoL.
Notes	Currently reported as an abstract only, needs further assessment once the full-text paper is available to determine the appropriate comparison group.

Shatenstein 2017

Methods	Quasi-experimental (3 clinics intervention, the remainder control).
Participants	67 elderly people (aged ≥ 70 years) with early stage dementia recruited with their carers.
Interventions	Tailored nutritional intervention versus usual care.
Outcomes	Nutrient intake.
Notes	2008 paper reported the following outcomes would be measured: questionnaire (socio-demographic, general health information, medication use, health perception and physical activity), VAS for hunger and appetite, functional status (ADL and IADL), weight, height, grip strength, nutrient intake. Need to contact the authors to determine if group allocation was randomised.

Smith 2020

Methods	RCT.
Participants	308 free-living older people (over 50 years) attending GP services and at risk of malnutrition (MUST).
Interventions	Dietary advice plus low volume ONS (Fortisip Compact) versus dietary advice alone.
Outcomes	Energy and protein intake.
Notes	This study seems to meet the inclusion criteria for comparison 3 of the review.

Soderstrom 2020

Methods	Multicentre RCT.
Participants	671 older participants (> 65 years) malnourished on hospital admission.
Interventions	Individualised dietary advice versus ONS versus individualised dietary advice + ONS versus no intervention.
Outcomes	Survival.
Notes	This trial has four arms and could be included in comparison 1 (dietary advice versus no advice), comparison 2 (dietary advice versus ONS), comparison 3 (dietary advice +ONS versus dietary advice) and comparison 5 (dietary advice+ONS versus no intervention).

Stratton 2007

Methods	RCT. Duration to be confirmed.
Participants	50 adults (42 females, 8 males) with hip fractures. Mean age 82 years (range 46 - 97 years). All participants at risk of malnutrition assessed by MUST.
Interventions	Intervention (n = 26): oral nutritional ONS (300 kcal/carton). Control (n = 24): readily available snacks (300 kcal/portion).
Outcomes	Mortality, number of participants with complications, energy, protein and micronutrient intake.
Notes	Full paper not published. Available as an abstract only. This seems to meet the inclusion criteria for comparison 2 of the review but needs full assessment once the final paper is available.

Sudarsanam 2011

Methods	Pilot RCT.
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Sudarsanam 2011 *(Continued)*

Participants	103 participants with tuberculosis alone or tuberculosis-HIV coinfectionx receiving anti-tuberculous therapy.
Interventions	Dietary advice from a dietitian plus a locally made macronutrient supplement versus dietary advice alone.
Outcomes	Primary outcome: treatment outcome (cure, completion or failure, interruption) . Secondary outcomes: body composition, compliance and treatment outcome at 1 year.
Notes	This study looks eligible for inclusion in comparison 3 (dietary advice plus ONS versus dietary advice alone).

Sui 2020

Methods	RCT.
Participants	60 older people with squamous cell carcinoma of the oesophagus.
Interventions	"multidisciplinary team nutrition intervention" versus routine nutritional intervention.
Outcomes	BMI, nutritional status, adverse events, treatment time.
Notes	Article in Chinese and needs translation before it can be fully evaluated.

Tharun 2020

Methods	RCT.
Participants	109 participants with cirrhosis of the liver.
Interventions	Dietary counselling to reinforce nutritional goals supported by telephone calls every 2 weeks versus standard care.
Outcomes	Mortality, complications, anthropometry.
Notes	Published as an abstract only. The details of the dietary counselling needs to be assessed against the inclusion criteria once a full-text publication is available.

Torbergson 2019

Methods	RCT.
Participants	113 participants admitted to hospital with hip fracture.
Interventions	An individualised plan made by a clinical nutritionist on improving food intake plus 2 protein-enriched nutrition drinks daily plus a multivitamin supplement versus routine care.
Outcomes	Micronutrient status, bone turnover markers, body weight.

Torbergesen 2019 *(Continued)*

Notes	Seems to be eligible for inclusion in comparison 5 (dietary advice +ONS versus routine care).
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Touger Decker 1997

Methods	Randomised trial
Participants	48 people who were edentate, with limited natural dentition or old dentures planned for denture insertion.
Interventions	Individualized dietary counselling versus no counselling
Outcomes	Nutrition risk status, dietary intake, perceived biting and chewing problems
Notes	This study is currently identified as an abstract only. A full publication needs to be identified to enable assessment against the inclusion criteria for the review.

UMIN000032234

Methods	Not described.
Participants	People on dialysis, over 65 years of age.
Interventions	Nutritional guidance aimed at adequate intake of energy and protein using nutrient supplement versus conventional treatment.
Outcomes	Primary outcomes: dietary intake, survival. Secondary outcomes: biochemical status, body composition, bone density, complications, hospital admissions.
Notes	It has not been possible to see the trial record and so not possible to evaluate against the inclusion criteria. Once a full-text publication is available assessment against the inclusion criteria needed.

van der Werf 2020

Methods	RCT.
Participants	107 participants with metastatic colorectal cancer receiving first-line chemotherapy.
Interventions	Individualised nutritional counselling by a dietitian to include ONS and EN as needed versus usual care.
Outcomes	Primary outcome: proportion of participants with a clinically relevant decrease in skeletal muscle area. Secondary outcomes: body weight, QoL, treatment toxicity, progression free and overall survival.
Notes	Only 8% of participants received EN and so relevant for inclusion in comparison 4 (dietary advice plus ONS if required versus routine care).

Vazquez-Sanchez 2019

Methods	RCT.
Participants	106 hospitalised participants with malnutrition.
Interventions	Nutritional counselling by case manager nurses versus standard healthcare.
Outcomes	Nursing Outcomes Classification criteria - compliance behaviour, knowledge, nutritional status and nutritional risk (M UST), degree of dependence (Barthel's Functional Independence).
Notes	This study meets the inclusion criteria. The details of the nutritional counselling need to be clarified in order to determine the comparison group.

Verho 2017

Methods	RCT.
Participants	Independently living older adults after discharge from hospital.
Interventions	Personalised nutrition care plan with ONS when required versus usual care.
Outcomes	Nutritional intake.
Notes	Currently available as an abstract only. When a full-text publication is available this needs assessment against the inclusion criteria.

Wills 2019

Methods	RCT.
Participants	78 participants with amyotrophic lateral sclerosis
Interventions	Nutritional counseling in person from a registered dietitian versus nutritional counseling supported by an mHealth application versus standard care (general counseling on balanced nutrition from a doctor or nurse).
Outcomes	<p>Primary outcomes: weight change, safety and tolerability, compliance with the dietary intervention.</p> <p>Secondary outcomes: dietary intake</p> <p>Tertiary outcomes: patient-reported outcomes measurement information system short form (PROMIS SF), QoL.</p>
Notes	This meets the criteria for inclusion in comparison 1 (dietary advice versus no dietary advice).

Wu 2018

Methods	5-group RCT.
Participants	40 frail or pre-frail participants attending the Miaoli General Hospital, Taiwan.

Wu 2018 (Continued)

Interventions	(1) control group (leaflet 'The Daily Food Guide') versus (2) Multinutrient group + leaflet 'The Daily Food Guide' versus (3) multinutrient, soy protein and multivitamin group + leaflet 'The Daily Food Guide' versus (4) individualised nutrition education from a dietitian to consume a nutritious diet plus 10 g/d mixed nuts and 25 g/d milk powder.
Outcomes	Nutritional status, dietary intake, anthropometry, frailty, depression, urinary nitrogen and creatinine.
Notes	Group 4 versus group 1 could be considered for inclusion in comparison 1 (dietary advice versus no advice). More details needed on what the multinutrient intervention consists of to fully evaluate.

Yang 2019

Methods	RCT.
Participants	82 older participants (> 65 years) with pneumonia and malnutrition.
Interventions	Individualised dietary advice versus standard nutritional supplements with no dietary advice.
Outcomes	Primary outcome: malnutrition risk score (MNA-SF). Secondary outcomes: anthropometry, biochemical status, nutritional requirements, nutritional intake, adherence to dietary prescription, length of stay and hospital admissions.
Notes	This study seems to be eligible for comparison 2 (dietary advice versus and oral nutritional supplement). Check the details of the "standard nutritional supplements".

Yang 2020

Methods	RCT.
Participants	120 participants with oesophageal cancer undergoing radiotherapy.
Interventions	Individualised nutritional counselling plus ONS versus individualised nutritional counselling.
Outcomes	BMI, patient-generated SGA, serum albumin, haemoglobin, white blood cell count, prealbumin, platelets, adverse events.
Notes	This study looks eligible for inclusion in comparison 3 (dietary advice plus ONS versus dietary advice alone).

Zhang 2018b

Methods	RCT.
Participants	64 participants with GI malignancy admitted to hospital.
Interventions	States "added with nutritional support".
Outcomes	Short-term efficacy, adverse events, change in nutritional status.

Zhang 2018b (Continued)

Notes	This study is published in Chinese and needs translation to allow evaluation of what "nutritional support" entails.
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Zhou 2011

Methods	RCT.
Participants	104 adults with end-stage renal disease receiving peritoneal dialysis.
Interventions	Nutritional intervention and individualized nursing versus self-diet and routine nursing for 6 months.
Outcomes	Nutritional risk, handgrip strength, anthropometry (TSF, MAC, MAMC), QoL, status of renal disease and general clinical condition.
Notes	Paper published in Chinese and need translation to determine whether it meets the inclusion criteria for any of the comparison groups.

Zhu 2019

Methods	RCT.
Participants	114 participants with gastrointestinal cancer and at nutritional risk treated with surgery .
Interventions	Dietary guidance from a physician plus ONS versus dietary guidance from a physician alone.
Outcomes	Anthropometry, biochemical status, infections, complications, GI functional status, QoL.
Notes	This study meets the inclusion criteria for comparison 3 (dietary advice plus ONS versus dietary advice alone).

ADL: activities of daily living
 APACHE: Acute Physiology and Chronic Health Evaluation
 BMI: body mass index
 COPD: chronic obstructive pulmonary disease
 EN: enteral nutrition
 FEV1: forced expiratory volume in one second
 FFMI: fat-free mass index
 GI: gastrointestinal
 GP: general practitioner
 IADL: instrumental activities of daily living
 HE: hepatic encephalopathy
 LASA: longitudinal Amsterdam aging study questionnaire
 MAC: mid-arm circumference
 MAMC: mid-arm muscle circumference
 MNA: mini nutritional assessment
 MUST: malnutrition universal screening tool
 NUTRIC: nutrition risk in critically ill
 ONS: oral nutritional supplement
 PG-SGA: patient-generated subjective global assessment
 PN: parenteral nutrition
 QoL: quality of life
 RCT: randomised controlled trial

SGA: subjective global assessment
 SOFA: sequential organ failure assessment
 TSF: triceps skinfold thickness
 TUG: timed up and go
 VAS: visual analogue scale

Characteristics of ongoing studies [ordered by study ID]

ACTRN12612001253897

Study name	Porvoo Sarcopenia & Nutrition Trial.
Methods	RCT.
Participants	Community-dwelling older adults in Finland (target recruitment 250 participants).
Interventions	Written information on dietary protein and nutrition in old age + instruction on simple exercises + encouragement to use vitamin D supplementation for all participants. Randomisation to no supplementation, protein supplementation, placebo supplement.
Outcomes	Physical performance (physical performance battery), handgrip strength, gait speed, balance, chair stand test, 2-minute step test, compliance to interventions, patient-reported benefits and adverse events, MNA, diet quality questionnaire, dietary intake, body composition (BMI, BIA), cognition, QoL, use of health and social care services, number of falls, mortality, biochemical status.
Starting date	April 2012.
Contact information	Mikko Bjorkman (mikko.bjorkman@helsinki.fi).
Notes	Seems to meet the inclusion criteria for comparison 3 but needs full assessment following publication.

ChiCTR2000028963

Study name	
Methods	RCT.
Participants	Patients with head and neck cancer planned to undergo radiotherapy.
Interventions	Individualized and professional nutritional dietary counseling, as well as oral nutritional supplements (ONS) with an intervention duration of 12 weeks. The ONS was a 500 ml total nutrition formula (containing 500 kcal energy, 21 g protein, and corresponding amounts of other nutrients) given daily versus routine nutrition education by a clinician.
Outcomes	Primary outcome: body weight. Secondary outcomes: BMI, anthropometry, handgrip strength, calf circumference, PG-SGA, QoL, depression, biochemical status, performance status, body composition, stand-walk test.
Starting date	
Contact information	
Notes	Not possible to access the full trial report but this looks like it is eligible for inclusion in comparison 5 (dietary advice + ONS versus routine care).

CTRI/2019/05/019387

Study name	CTRI/2019/05/019387
Methods	2-group trial (no details of whether randomised).
Participants	Individuals with cirrhosis and frailty and sarcopenia.
Interventions	Stated as "home-based intensive nutrition therapy" versus standard medical management.
Outcomes	Primary outcomes: frailty score, physical performance, prognostic score. Secondary outcomes: unplanned hospitalisation, death, need for liver transplantation, anthropometry.
Starting date	
Contact information	
Notes	Not possible to access the trial registry report and so full details no available. The intervention needs to be evaluated against the inclusion criteria once a full-text publication is available.

Munk 2020

Study name	
Methods	RCT
Participants	200 oncology, gastrointestinal and medical patients from Herlev Gentofte Hospital, Denmark
Interventions	Individualised dietary counseling and provision of a package at hospital discharge containing energy and protein-rich meals and snacks plus protein-rich ONS and recommendation to take a daily multivitamin tablet
Outcomes	Primary outcomes: hospital admissions & LoS Secondary outcomes: 30-day readmissions & LoS, QoL, Appetite, physical performance status, dietary intake, energy & protein requirements, nutritional status, mortality and evaluation of the intervention.
Starting date	
Contact information	
Notes	Once the full trial is published assess for inclusion in comparison 4 or comparison 5.

NCT02440165

Study name	Basic Care Revisited: Early nutrition intervention for outpatients (BCR_N_).
Methods	Multi-centre cluster-RCT.
Participants	150 participants attending surgical outpatient clinics.

NCT02440165 (Continued)

Interventions	Early nursing intervention (malnutrition screening + standardised nutrition care plan (individualised advice+energy and protein rich meals and ONS) versus usual care for 6 months.
Outcomes	BMI, nutritional intake, length of stay, QoL, patient satisfaction, costs, process evaluation.
Starting date	January 2015.
Contact information	Getty Huisman - de Waal (getty.huisman-deaal@radboudumc.nl); Maud Heinen (maud.heinen@radboudumc.nl).
Notes	Seems to meet the inclusion criteria for comparison 4 but needs full assessment following publication.

NCT02763904

Study name	Systematic oral nutritional support in hospitalized, moderately hypophagic patients at nutritional risk.
Methods	RCT.
Participants	286 hospitalised individuals at nutritional risk.
Interventions	Intensive nutritional counselling + ONS versus intensive nutritional counselling.
Outcomes	Body composition (phase angle BIA), function (handgrip strength), nutritional intake, infections, adverse events (GI intolerance).
Starting date	July 2016.
Contact information	Emanuelle Cereda (elcereda@smatteo.pv.it).
Notes	Seems to meet the inclusion criteria for comparison 3 but needs full assessment following publication.

NCT02892747

Study name	Dietetics education focused on malnutrition prevention (NUTRICOEUR).
Methods	RCT.
Participants	295 adults with chronic heart failure, BMI \geq 18.5.
Interventions	Personalised education program for the prevention of malnutrition versus usual follow-up by cardiologist and nutritionist.
Outcomes	Number of hospitalisations, length of hospital stay, reason for hospitalisation, nutritional intake (sodium, energy, protein), QoL, Minnesota Living With Heart Failure Questionnaire, burden of diet questionnaire, compliance, unplanned hospitalisation for cardiac complications, mortality.
Starting date	September 2016.
Contact information	Veronique Benedyga (veronique.benedyga@aphp.fr).

NCT02892747 (Continued)

Notes	Seems to meet the inclusion criteria for comparison 1 but needs full assessment following publication.
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NCT03075189

Study name	
Methods	RCT.
Participants	38 individuals recruited from a geriatric ward in a Danish hospital.
Interventions	Protein-enriched snacks/dishes in the morning and late evening, before bedtime and on discharge individualised dietary counseling focusing on choosing protein-rich foods and on protein rich meals versus normal hospital food without enrichment and no dietary counseling at discharge.
Outcomes	<p>Primary outcome: recorded protein intake</p> <p>Secondary outcomes: anthropometric measurements (weight, height, body composition estimated with bioimpedance), functional ability (De Morton Mobility Index) and Barthels ADL-index), hand grip strength, sarcopenic status (SARC-F), quality of life (EQ-5D-3L), length of stay and 30-day readmissions after discharge.</p>
Starting date	March 2017
Contact information	Lars Holm, Associate professor, University of Copenhagen
Notes	The trial is listed as completed in 2017 but no results available. This looks to be eligible for comparison 1 (dietary advice versus no dietary advice). Evaluate once more detail and results available

NCT03114202

Study name	NCT03114202
Methods	RCT.
Participants	90 participants with head and neck cancers undergoing radiotherapy.
Interventions	Individualised nutrition counselling from a dietitian versus .
Outcomes	Nutrition counselling by hospital nurses.
Starting date	April 2017.
Contact information	Jose Eluf Neto+55(11)3061-8278 jose.eluf@hc.fm.usp.br Sheilla Faria+55(35)3701-9745 shefaria@hotmail.com
Notes	This looks like it should be included in comparison 1 (dietary advice versus no advice). Assess once a full publication is available. Note in 2020 this group published a retrospective study on this population Faria et al Cancer Treatment & Research Communications. Need to check whether this is the same study?

NCT03191253

Study name	Changing Health Through Food Support (CHEFS) program.
Methods	RCT.
Participants	200 HIV positive adults living on a low income.
Interventions	Individualised nutritional counselling, provision of medically-appropriate food support and group-based nutrition education versus routine care from Project Open Hand.
Outcomes	Viral load, QoL, severity of depression (Patient Health Questionnaire PHQ-9), adherence to anti-retroviral therapy, diet quality, food security (HFSS).
Starting date	July 2016.
Contact information	None provided.
Notes	Seems to meet the inclusion criteria for comparison 4 but needs full assessment following publication.

NCT03315195

Study name	Preoperative oral nutritional supplement vs conventional dietary advice in major gastrointestinal surgery.
Methods	RCT.
Participants	268 adults undergoing major gastrointestinal surgery.
Interventions	Dietary advice versus oral nutritional supplement and dietary advice.
Outcomes	Postoperative complications.
Starting date	November 2017.
Contact information	Nattapanee Sukphol (nattapanee_benz@hotmail.com); Narongsak Rungsakulkji (narongsak.run@mahidol.ac.th).
Notes	Seems to meet the inclusion criteria for comparison 3 but needs full assessment following publication.

NCT03352388

Study name	Effects of dairy and berry-based snacks on nutritional and functional status and quality of life in older people (MAVIRE1).
Methods	RCT.
Participants	85 older people (over 70 years) receiving home-care services.
Interventions	High-protein dairy-based products and energy-enriched berry products versus no additional snacks for 3 months.

NCT03352388 (Continued)

Outcomes	Nutritional status (MNA), serum albumin, serum prealbumin, handgrip strength, BMI, MAMC, haemoglobin, C-reactive protein, activity and sleep (ActiGraph monitoring), QoL.
Starting date	September 2015.
Contact information	Senior researchers, Riitta Torronen and Irma Nykanen.
Notes	Seems to meet the inclusion criteria for comparison 1 but needs full assessment following publication.

NCT03519139

Study name	
Methods	RCT.
Participants	40 older medical inpatients (> 65 years) with at least two comorbidities.
Interventions	Individualised dietary counselling versus routine care.
Outcomes	Primary outcome: 30 day hospital readmission. Secondary outcomes: hospital readmission up to 60 days, time between admissions, nutritional status, functional status, muscle strength, QoL, mortality, adverse events.
Starting date	February 2018.
Contact information	Jens Rikardt Andersen, Associate Professor, University of Copenhagen
Notes	This meets the inclusion criteria for comparison 1 (dietary advice versus routine care). Assess once a full publication is available.

NCT03540784

Study name	Effects of WB-EMS and High Protein Diet in IBD Patients.
Methods	RCT.
Participants	Outpatients with inflammatory bowel disease.
Interventions	High protein nutritional intervention (dietary counselling from a dietitian) versus WB-EMS supervised exercise training and high protein nutritional intervention versus routine care.
Outcomes	Primary outcome: skeletal muscle mass. Secondary outcomes: body composition, physical function, QoL, physical activity, disease activity, inflammation status.
Starting date	01 October 2013.
Contact information	University of Erlangen-Nürnberg Medical School.
Notes	Comparison group to be determined once the full trial report is available.

NCT03995303

Study name	HOMEFOOD Study.
Methods	RCT.
Participants	200 older adults at nutritional risk who have been discharged from hospital.
Interventions	An individualised nutrition care plan based on estimated requirements and nutritional goals plus ONS if required and home delivered meals versus routine care at hospital discharge.
Outcomes	Body weight, body composition, nutritional status, function (sit to stand, balance test), nutritional intake, handgrip strength, cognitive function, QoL.
Starting date	June 2018.
Contact information	Professor Alfons Ramel.
Notes	This seems to meet the inclusion criteria for comparison 4 (dietary advice plus ONS if required). Evaluate fully when a full-text publication is available.

NCT04628117

Study name	Effect of Oral Nutritional Supplementation on Oxidative Stress in Protein-energy Wasting Patients With Peritoneal Dialysis
Methods	RCT.
Participants	22 participants with end-stage kidney disease receiving continuous peritoneal dialysis.
Interventions	Nutritional counselling plus 237 ml/day of ONS for kidney disease versus nutritional counselling alone.
Outcomes	Change in oxidative stress levels, change in protein-energy wasting, change in dietary intake.
Starting date	October 2021.
Contact information	Francisco Gerardo Yanowsky Escatell, Principal Investigator, Hospital Civil Juan I. Menchaca, Mexico.
Notes	The intervention looks to be eligible for inclusion in comparison 3 (dietary advice plus ONS versus dietary advice alone). Assess against the inclusion criteria once a full-text report is available.

PACTR201108000303396

Study name	Assessing the impact of a food supplement on the nutritional status and body composition of HIV-infected Zambian women on ARVs.
Methods	Random assignment to intervention or control group by the sister in charge at the clinic - implies quasi-randomised.

PACTR201108000303396 (Continued)

Participants	200 HIV infected females commencing antiretroviral therapy at 1 of 2 urban clinics in Lusaka, Zambia.
Interventions	Advice on good nutrition + a food supplement versus advice on good nutrition.
Outcomes	Nutritional status (weight, height, 4-site skinfold measurements, body composition (BIA), total body water, HIV-related clinical outcomes (viral load, CD4 count), dietary intake.
Starting date	Not available.
Contact information	Author for correspondence on published protocol Andrew Hills (ahills@mmri.mater.org.au).
Notes	Might meet the inclusion criteria for comparison three of the review but needs full assessment following publication.

BIA: bioelectrical impedance analysis

BMI: body mass index

GI: gastro-intestinal

HFSS: US Household Food Security Survey

MAMC: mid-arm muscle circumference

ONS: oral nutritional supplement

PG-SGA: patient-generated Subjective Global Assessment

QoL: quality of life

RCT: randomised controlled trial

DATA AND ANALYSES

Comparison 1. Dietary advice compared with no advice

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1.1 Mortality	16		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
1.1.1 Up to 3 months	7	574	Risk Ratio (M-H, Random, 95% CI)	0.87 [0.26, 2.96]
1.1.2 4 to 6 months	10	1028	Risk Ratio (M-H, Random, 95% CI)	0.88 [0.61, 1.27]
1.1.3 12 months and over	5	1445	Risk Ratio (M-H, Random, 95% CI)	1.07 [0.59, 1.91]
1.2 Number of people admitted or readmitted to hospital	4		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
1.2.1 4 to 6 months	3	259	Risk Ratio (M-H, Random, 95% CI)	1.33 [0.55, 3.18]
1.2.2 12 months and over	2	230	Risk Ratio (M-H, Random, 95% CI)	0.64 [0.36, 1.13]
1.3 Length of hospital stay (days)	4		Mean Difference (IV, Random, 95% CI)	Subtotals only
1.3.1 Up to 3 months	1	148	Mean Difference (IV, Random, 95% CI)	-1.10 [-1.35, -0.85]
1.3.2 4 to 6 months	3	212	Mean Difference (IV, Random, 95% CI)	1.93 [-3.42, 7.28]

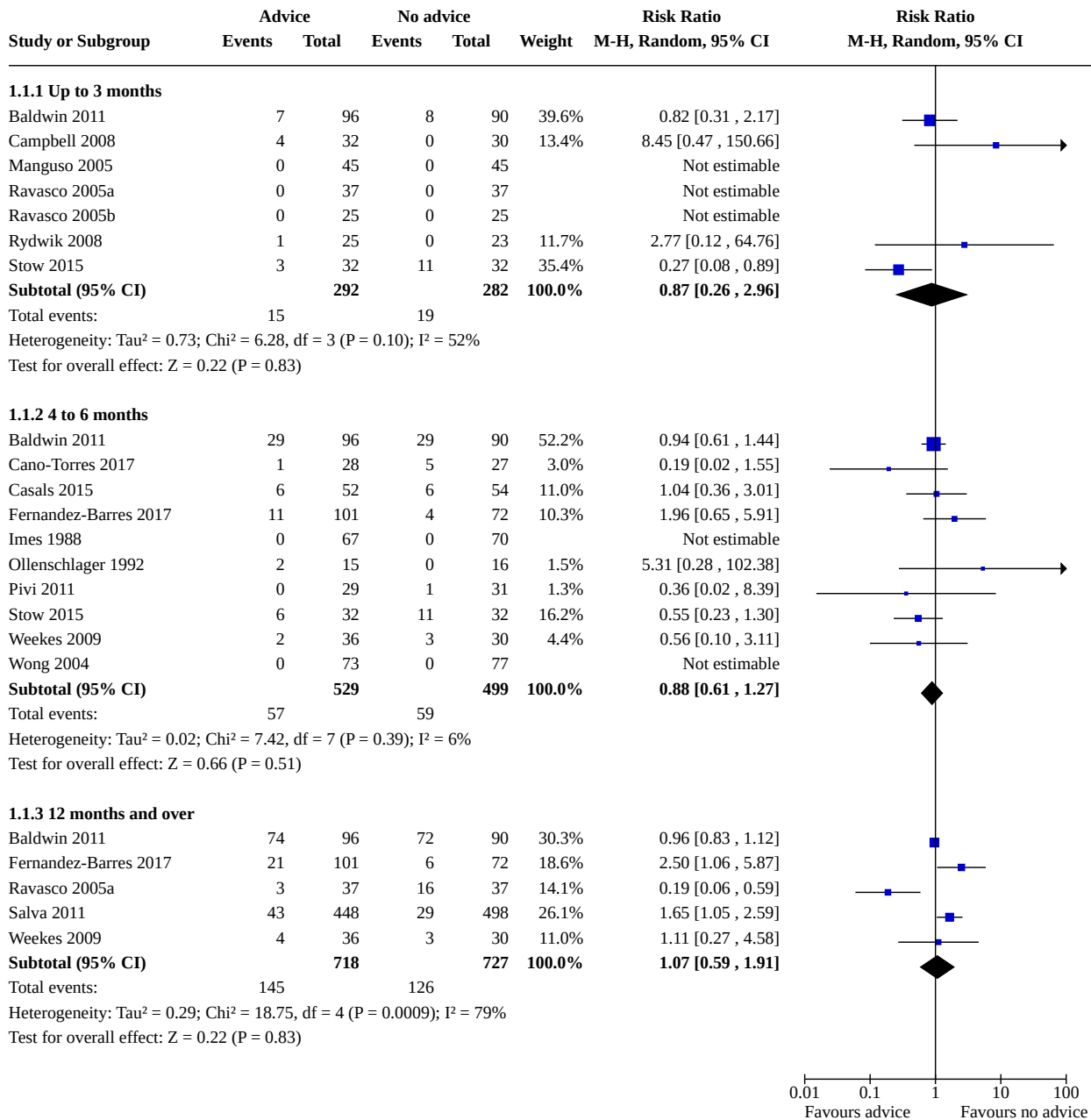
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1.3.3 12 months and over	1	57	Mean Difference (IV, Random, 95% CI)	-3.00 [-11.58, 5.58]
1.4 Complications	2	288	Std. Mean Difference (IV, Random, 95% CI)	-0.10 [-0.34, 0.13]
1.4.1 Up to 3 months	1	148	Std. Mean Difference (IV, Random, 95% CI)	0.00 [-0.32, 0.32]
1.4.2 4 to 6 months	1	140	Std. Mean Difference (IV, Random, 95% CI)	-0.21 [-0.55, 0.12]
1.5 Change in weight (kg)	18		Mean Difference (IV, Random, 95% CI)	Subtotals only
1.5.1 Up to 3 months	10	802	Mean Difference (IV, Random, 95% CI)	0.97 [0.06, 1.87]
1.5.2 4 to 6 months	6	573	Mean Difference (IV, Random, 95% CI)	1.61 [0.09, 3.13]
1.5.3 12 months and over	7	1216	Mean Difference (IV, Random, 95% CI)	2.95 [0.75, 5.16]
1.6 Change in BMI (kg/m²)	12		Mean Difference (IV, Random, 95% CI)	Subtotals only
1.6.1 Up to 3 months	2	181	Mean Difference (IV, Random, 95% CI)	0.34 [-0.24, 0.92]
1.6.2 4 to 6 months	7	596	Mean Difference (IV, Random, 95% CI)	0.26 [-0.08, 0.60]
1.6.3 12 months and over	5	1148	Mean Difference (IV, Random, 95% CI)	2.17 [0.25, 4.09]
1.7 Change in fat-free mass (kg)	3		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
1.7.1 Up to 3 months	2	98	Std. Mean Difference (IV, Random, 95% CI)	0.29 [-0.11, 0.69]
1.7.2 4 to 6 months	1	40	Std. Mean Difference (IV, Random, 95% CI)	0.62 [-0.02, 1.26]
1.7.3 12 months and over	1	35	Std. Mean Difference (IV, Random, 95% CI)	0.83 [0.14, 1.53]
1.8 Change in mid-arm circumference (cm)	7		Mean Difference (IV, Random, 95% CI)	Subtotals only
1.8.1 Up to 3 months	2	176	Mean Difference (IV, Random, 95% CI)	0.23 [-0.61, 1.07]
1.8.2 4 to 6 months	3	120	Mean Difference (IV, Random, 95% CI)	0.14 [-0.37, 0.65]
1.8.3 12 months and over	4	126	Mean Difference (IV, Random, 95% CI)	0.65 [-0.20, 1.50]
1.9 Change in mid-arm muscle circumference (cm)	6		Mean Difference (IV, Random, 95% CI)	Subtotals only
1.9.1 Up to 3 months	2	119	Mean Difference (IV, Random, 95% CI)	1.05 [0.71, 1.39]
1.9.2 4 to 6 months	2	66	Mean Difference (IV, Random, 95% CI)	0.56 [0.07, 1.04]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1.9.3 12 months and over	4	128	Mean Difference (IV, Random, 95% CI)	2.04 [-0.07, 4.15]
1.10 Change in triceps skinfold thickness (mm)	7		Mean Difference (IV, Random, 95% CI)	Subtotals only
1.10.1 Up to 3 months	3	254	Mean Difference (IV, Random, 95% CI)	-0.95 [-1.83, -0.08]
1.10.2 4 to 6 months	2	67	Mean Difference (IV, Random, 95% CI)	0.89 [-0.25, 2.04]
1.10.3 12 months and over	4	128	Mean Difference (IV, Random, 95% CI)	1.24 [-0.84, 3.31]
1.11 Change in energy intake (kcal)	12		Mean Difference (IV, Random, 95% CI)	Subtotals only
1.11.1 Up to 3 months	9	536	Mean Difference (IV, Random, 95% CI)	242.63 [-40.31, 525.56]
1.11.2 4 to 6 months	4	356	Mean Difference (IV, Random, 95% CI)	97.17 [20.22, 174.12]
1.11.3 12 months and over	1	111	Mean Difference (IV, Random, 95% CI)	52.00 [-64.88, 168.88]
1.12 Final energy intake (kcal)	3		Mean Difference (IV, Random, 95% CI)	Subtotals only
1.12.1 Up to 3 months	2	276	Mean Difference (IV, Random, 95% CI)	-45.91 [-390.74, 298.92]
1.12.2 4 to 6 months	1	124	Mean Difference (IV, Random, 95% CI)	-20.00 [-320.10, 280.10]
1.12.3 12 months and over	1	50	Mean Difference (IV, Random, 95% CI)	194.00 [34.33, 353.67]
1.13 Change in protein intake (g)	8		Mean Difference (IV, Random, 95% CI)	Subtotals only
1.13.1 Up to 3 months	5	354	Mean Difference (IV, Random, 95% CI)	12.50 [2.80, 22.19]
1.13.2 4 to 6 months	4	356	Mean Difference (IV, Random, 95% CI)	3.02 [2.60, 3.43]
1.13.3 12 months and over	1	111	Mean Difference (IV, Random, 95% CI)	4.00 [-0.51, 8.51]
1.14 Final protein intake (g)	5		Mean Difference (IV, Random, 95% CI)	Subtotals only
1.14.1 Up to 3 months	4	416	Mean Difference (IV, Random, 95% CI)	8.29 [1.24, 15.34]
1.14.2 4 to 6 months	1	124	Mean Difference (IV, Random, 95% CI)	5.00 [-7.32, 17.32]
1.14.3 6 to 12 months	1	50	Mean Difference (IV, Random, 95% CI)	11.80 [10.73, 12.87]
1.15 Change in grip strength (kg force)	2		Mean Difference (IV, Random, 95% CI)	Subtotals only

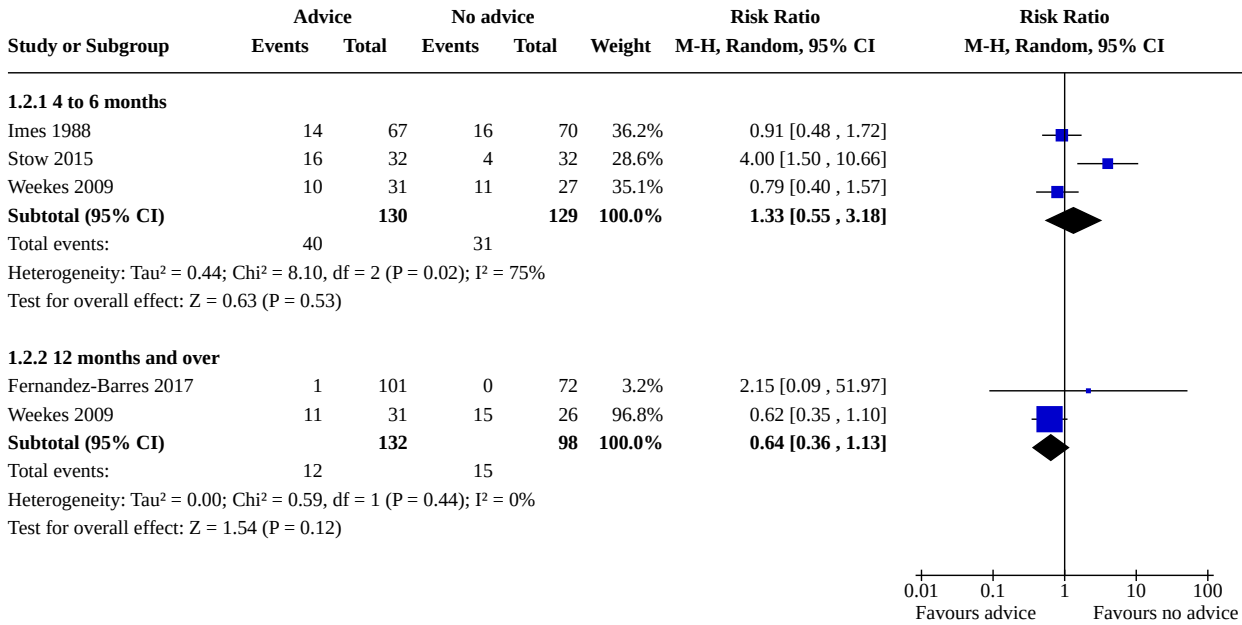
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1.15.1 Up to 3 months	1	24	Mean Difference (IV, Random, 95% CI)	-0.98 [-3.38, 1.42]
1.15.2 4 to 6 months	2	57	Mean Difference (IV, Random, 95% CI)	-0.86 [-3.32, 1.59]
1.15.3 12 months and over	1	37	Mean Difference (IV, Random, 95% CI)	0.30 [-1.32, 1.92]
1.16 Change in global QoL	7		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
1.16.1 Up to 3 months	5	421	Std. Mean Difference (IV, Random, 95% CI)	3.30 [1.47, 5.13]
1.16.2 Up to 3 months (FAACT)	1	124	Std. Mean Difference (IV, Random, 95% CI)	0.03 [-0.32, 0.38]
1.16.3 4 to 6 months	3	208	Std. Mean Difference (IV, Random, 95% CI)	0.52 [-0.00, 1.04]
1.16.4 4 to 6 months (FAACT)	1	70	Std. Mean Difference (IV, Random, 95% CI)	-0.05 [-0.52, 0.42]
1.16.5 12 months and over	2	97	Std. Mean Difference (IV, Random, 95% CI)	5.71 [-3.70, 15.12]
1.17 QoL - change in physical function	7		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
1.17.1 Up to 3 months	5	429	Std. Mean Difference (IV, Random, 95% CI)	3.38 [1.54, 5.23]
1.17.2 4 to 6 months	2	146	Std. Mean Difference (IV, Random, 95% CI)	0.44 [-0.47, 1.35]
1.17.3 4 to 6 months (SGRQ)	1	41	Std. Mean Difference (IV, Random, 95% CI)	0.38 [-0.24, 1.01]
1.17.4 12 months and over (SF-36)	1	35	Std. Mean Difference (IV, Random, 95% CI)	0.65 [-0.03, 1.33]
1.17.5 12 months and over (SGRQ)	1	34	Std. Mean Difference (IV, Random, 95% CI)	0.04 [-0.64, 0.71]
1.18 QoL - change in mental function	7		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
1.18.1 Up to 3 months	5	421	Std. Mean Difference (IV, Random, 95% CI)	2.99 [1.30, 4.67]
1.18.2 4 to 6 months	2	146	Std. Mean Difference (IV, Random, 95% CI)	0.49 [-0.61, 1.59]
1.18.3 12 months and over	1	34	Std. Mean Difference (IV, Random, 95% CI)	0.64 [-0.05, 1.34]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1.19 QoL - change in social function	6		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
1.19.1 Up to 3 months	5	419	Std. Mean Difference (IV, Random, 95% CI)	3.52 [-1.71, 5.32]
1.19.2 4 to 6 months (SF-36)	1	40	Std. Mean Difference (IV, Random, 95% CI)	0.10 [-0.52, 0.72]
1.19.3 4 to 6 months (SGRQ)	1	41	Std. Mean Difference (IV, Random, 95% CI)	0.11 [-0.50, 0.73]
1.19.4 12 months and over (SF-36)	1	34	Std. Mean Difference (IV, Random, 95% CI)	0.36 [-0.32, 1.04]
1.19.5 12 months and over (SGRQ)	1	34	Std. Mean Difference (IV, Random, 95% CI)	1.17 [0.44, 1.91]
1.20 QoL - change in cognitive function	4		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
1.20.1 Up to 3 months	4	284	Std. Mean Difference (IV, Random, 95% CI)	3.43 [0.79, 6.07]
1.21 QoL - change in pain	5		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
1.21.1 Up to 3 months	4	376	Std. Mean Difference (IV, Random, 95% CI)	-5.48 [-8.13, -2.84]
1.21.2 4 to 6 months	1	40	Std. Mean Difference (IV, Random, 95% CI)	0.30 [-0.32, 0.93]
1.21.3 12 months and over	1	34	Std. Mean Difference (IV, Random, 95% CI)	0.22 [-0.46, 0.90]
1.22 QoL - change in energy/fatigue	5		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
1.22.1 Up to 3 months	4	375	Std. Mean Difference (IV, Random, 95% CI)	-5.95 [-8.65, -3.25]
1.22.2 4 to 6 months	1	40	Std. Mean Difference (IV, Random, 95% CI)	0.06 [-0.56, 0.69]
1.22.3 12 months and over	1	35	Std. Mean Difference (IV, Random, 95% CI)	0.34 [-0.33, 1.01]

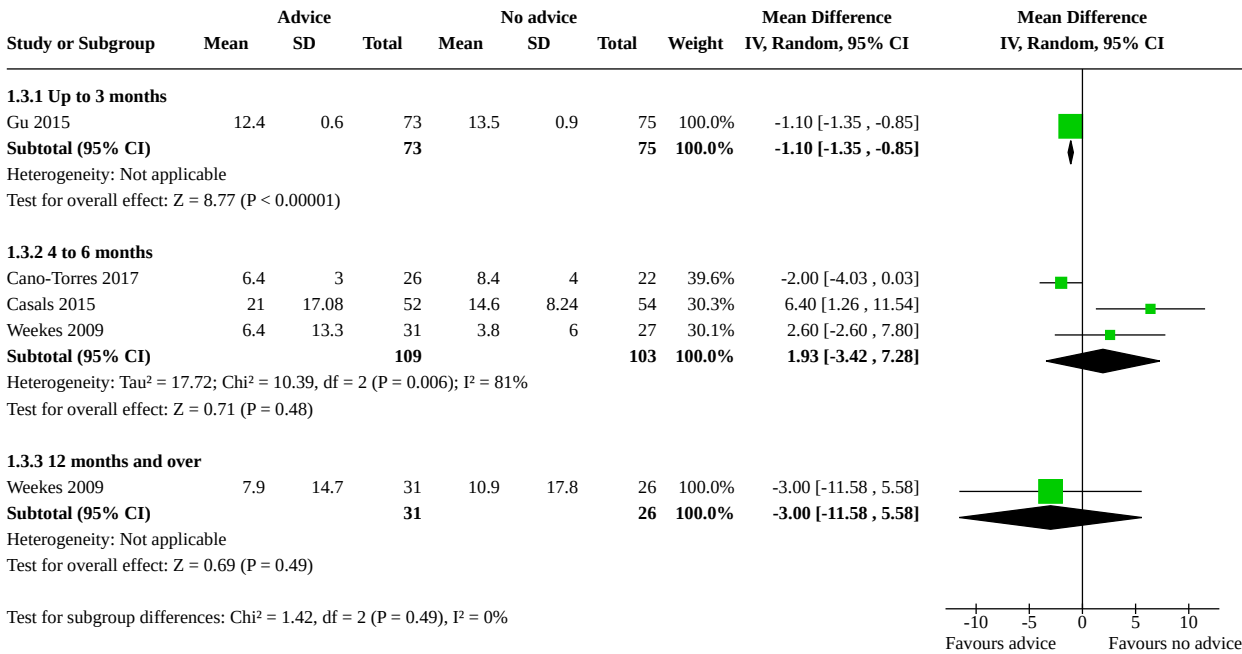
Analysis 1.1. Comparison 1: Dietary advice compared with no advice, Outcome 1: Mortality



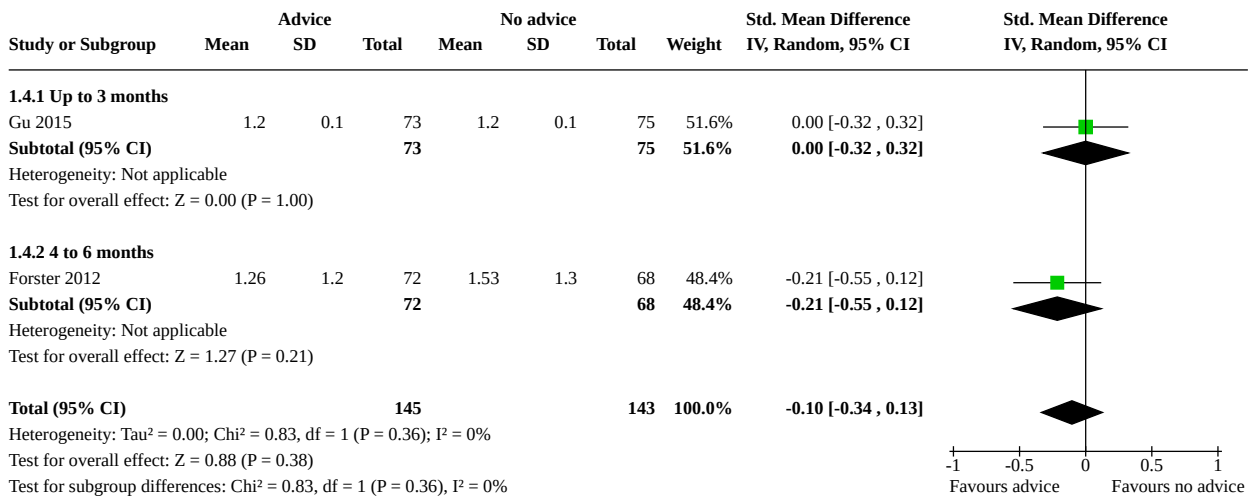
Analysis 1.2. Comparison 1: Dietary advice compared with no advice, Outcome 2: Number of people admitted or readmitted to hospital



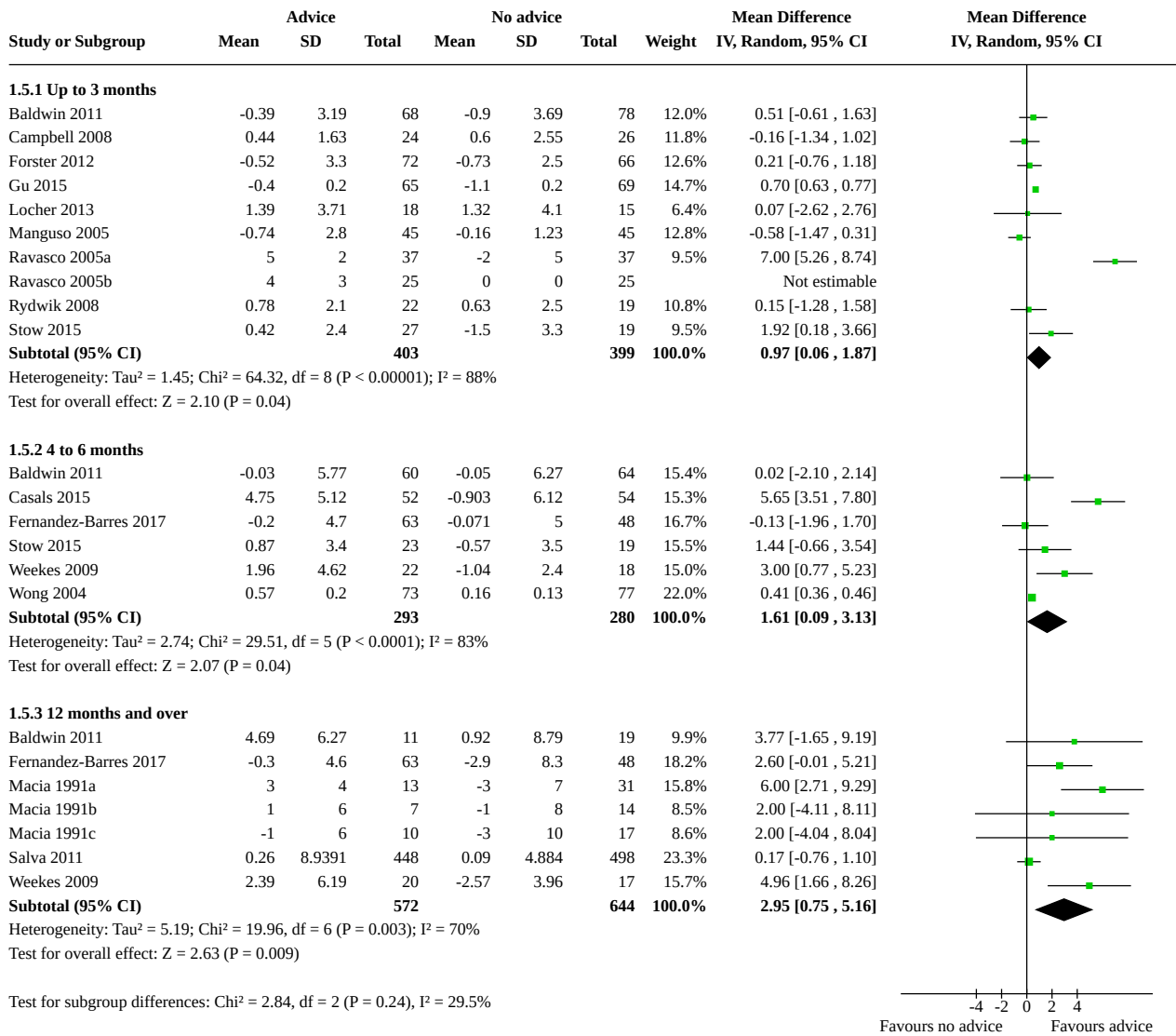
Analysis 1.3. Comparison 1: Dietary advice compared with no advice, Outcome 3: Length of hospital stay (days)



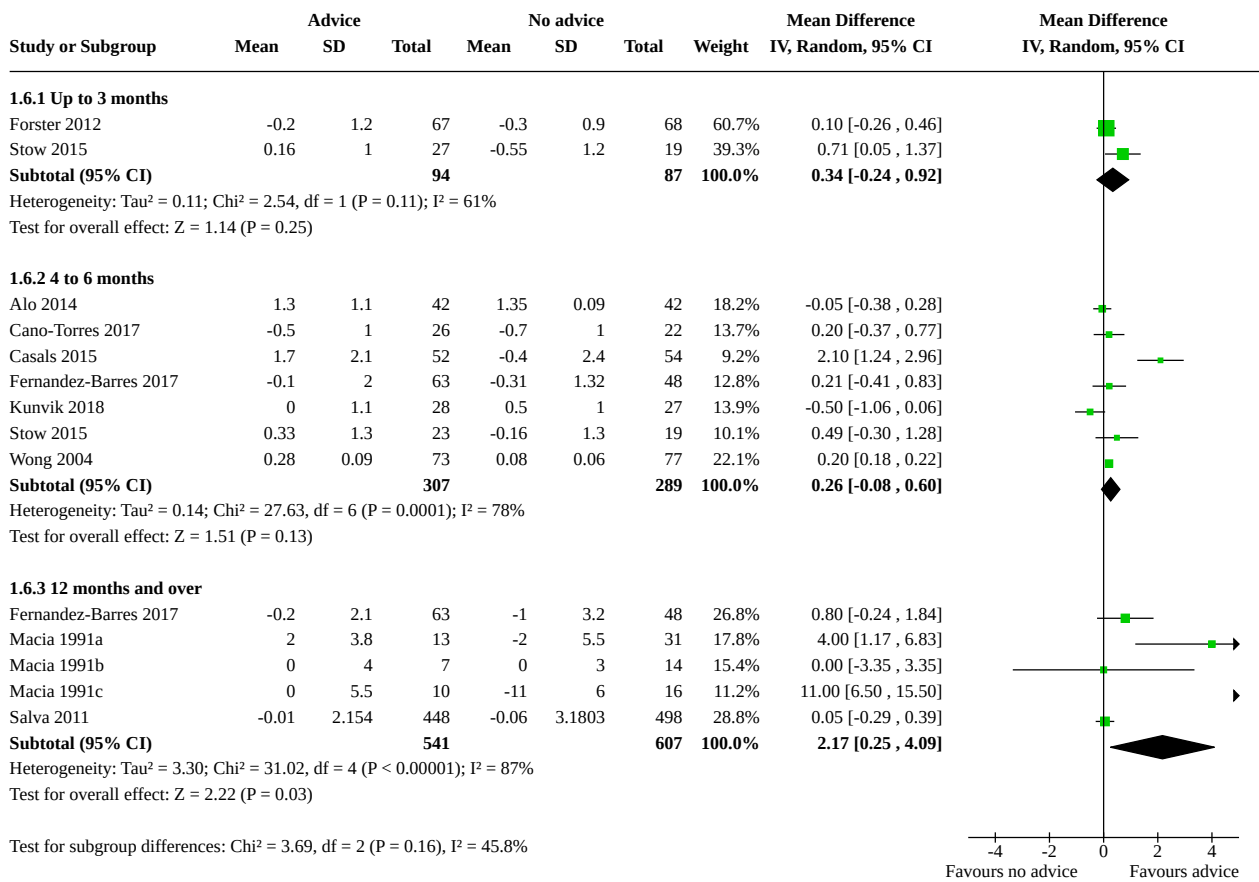
Analysis 1.4. Comparison 1: Dietary advice compared with no advice, Outcome 4: Complications



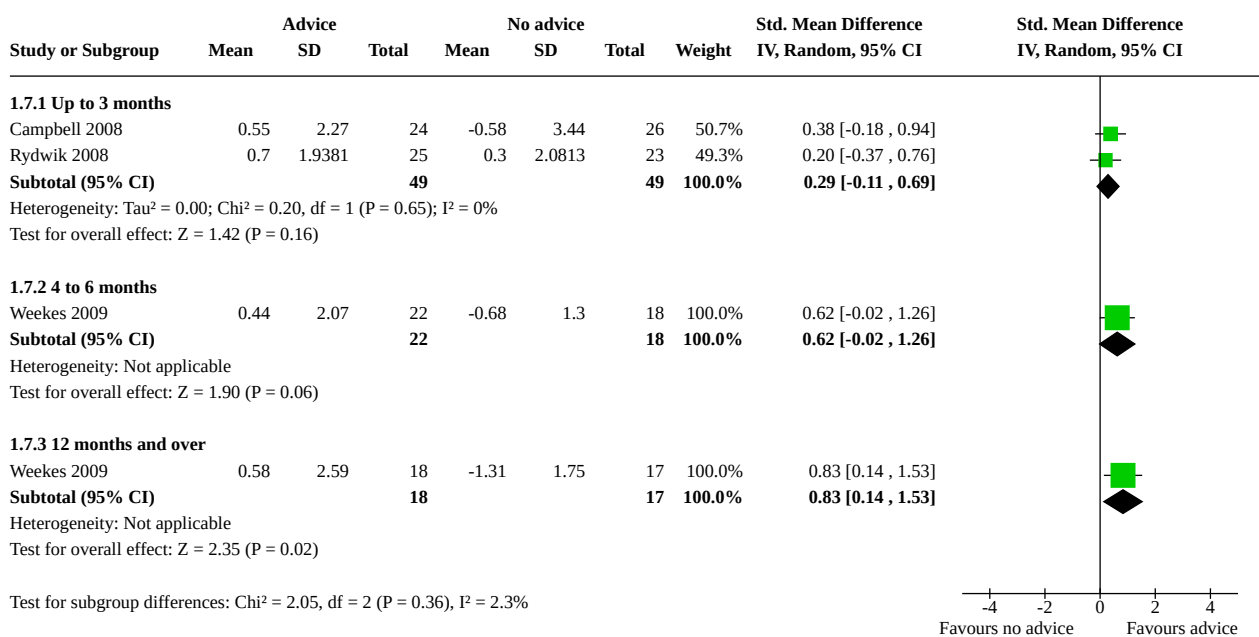
Analysis 1.5. Comparison 1: Dietary advice compared with no advice, Outcome 5: Change in weight (kg)



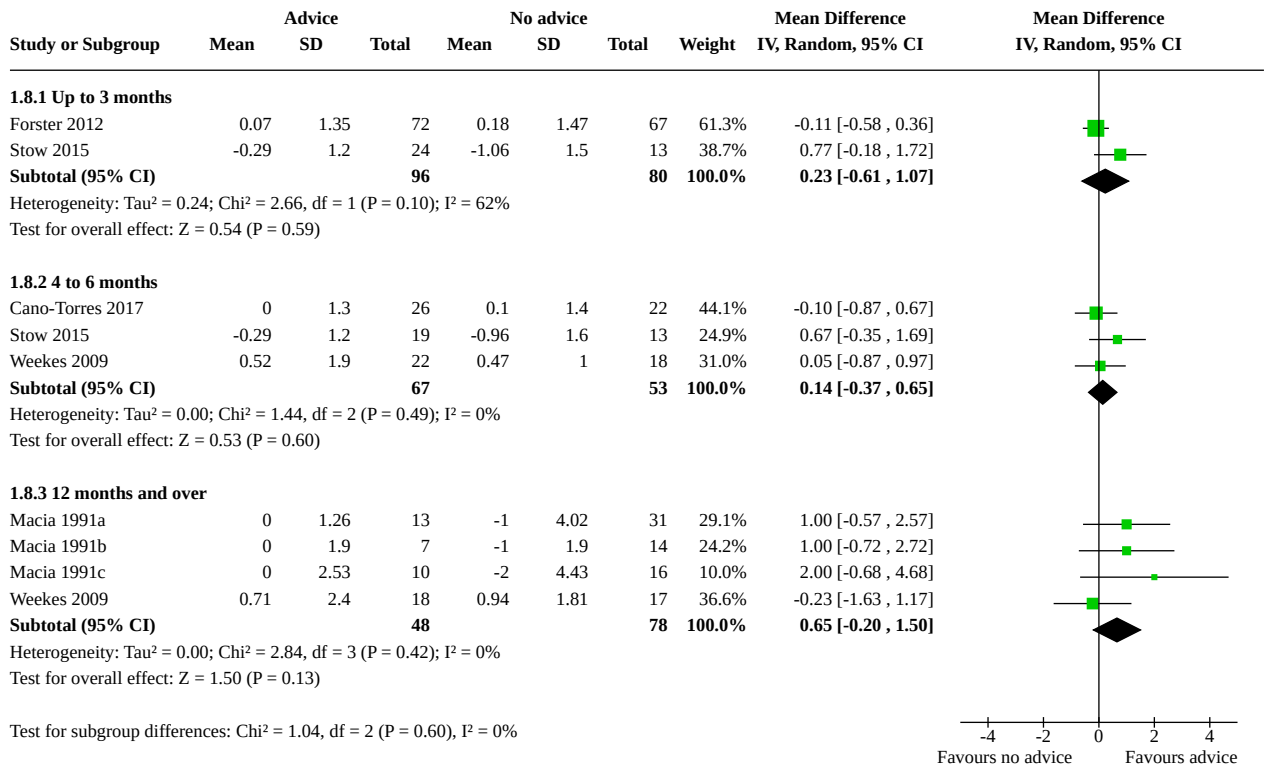
Analysis 1.6. Comparison 1: Dietary advice compared with no advice, Outcome 6: Change in BMI (kg/m²)



Analysis 1.7. Comparison 1: Dietary advice compared with no advice, Outcome 7: Change in fat-free mass (kg)

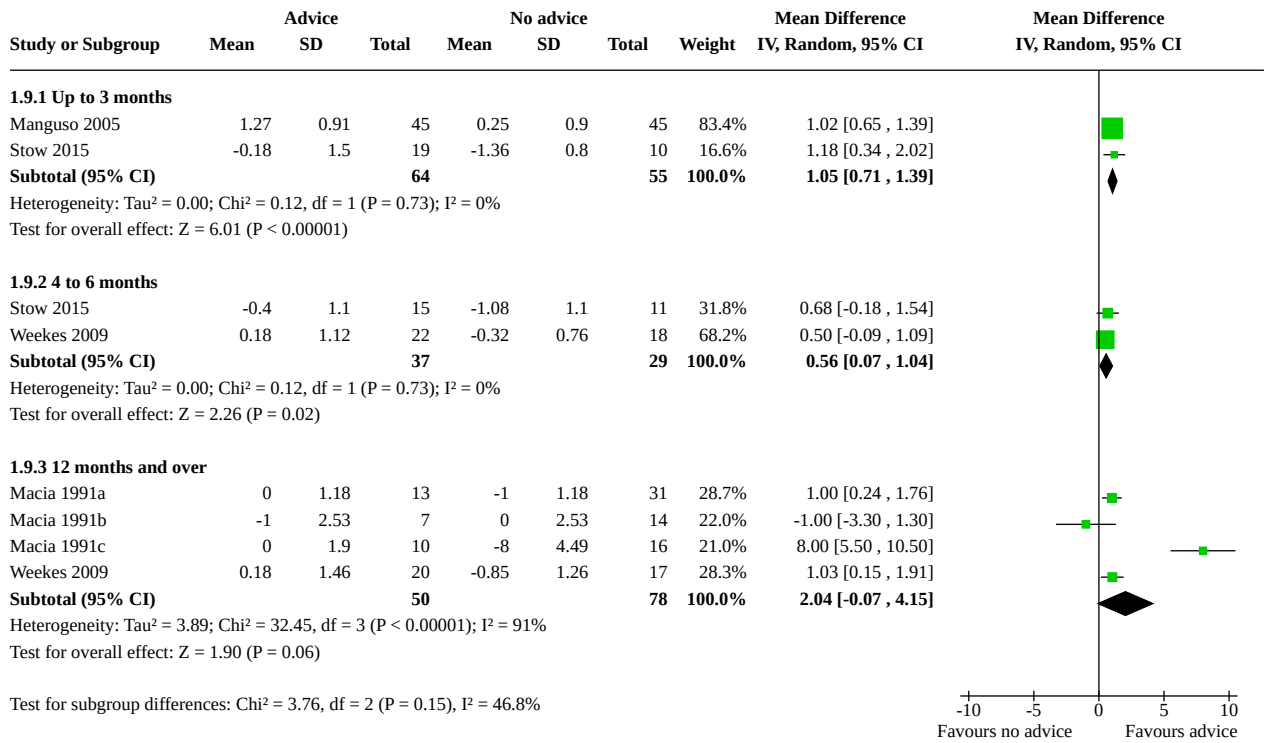


Analysis 1.8. Comparison 1: Dietary advice compared with no advice, Outcome 8: Change in mid-arm circumference (cm)

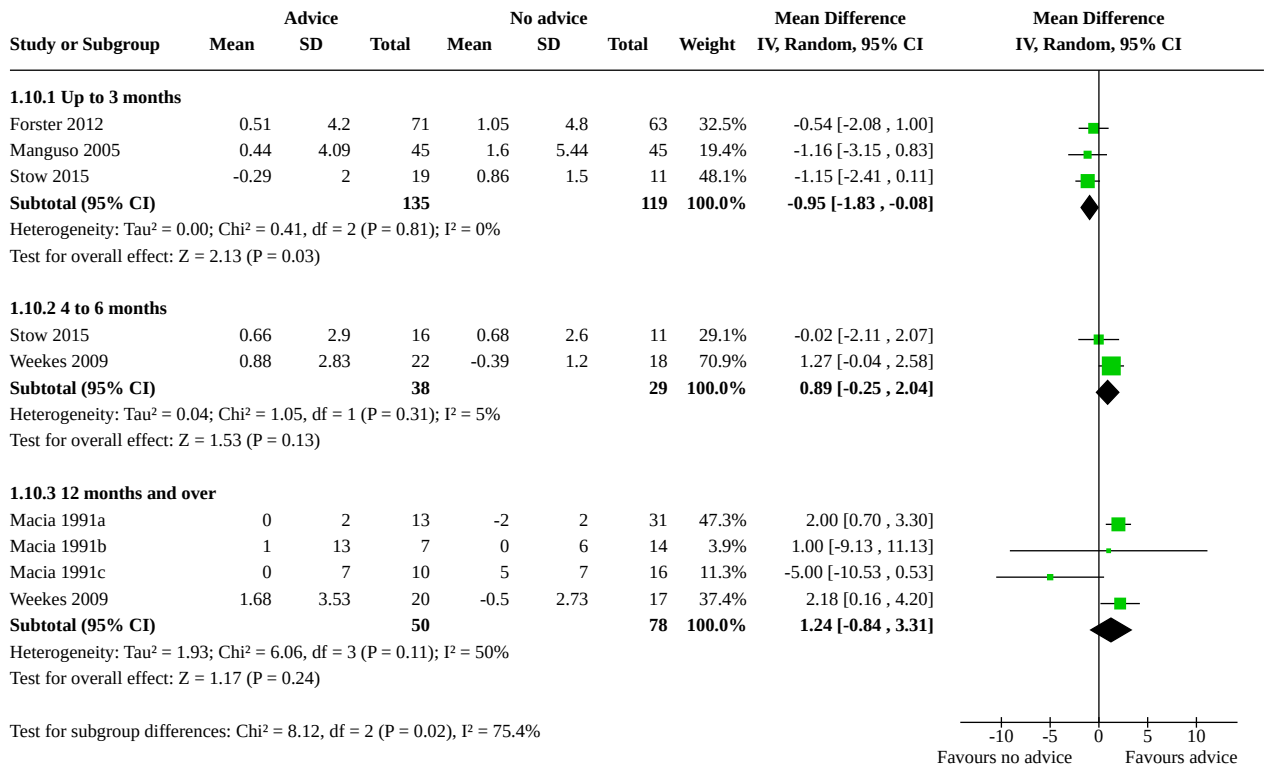


Favours no advice Favours advice

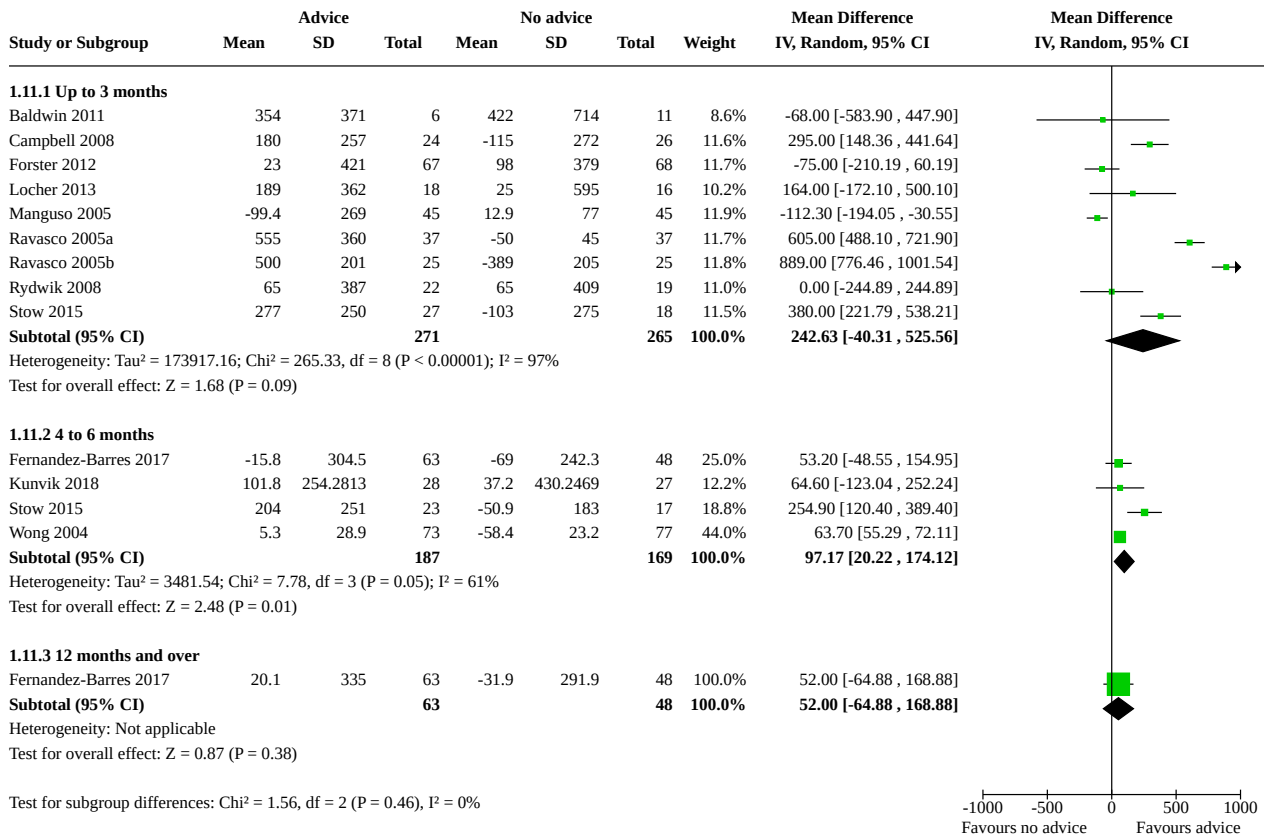
Analysis 1.9. Comparison 1: Dietary advice compared with no advice, Outcome 9: Change in mid-arm muscle circumference (cm)



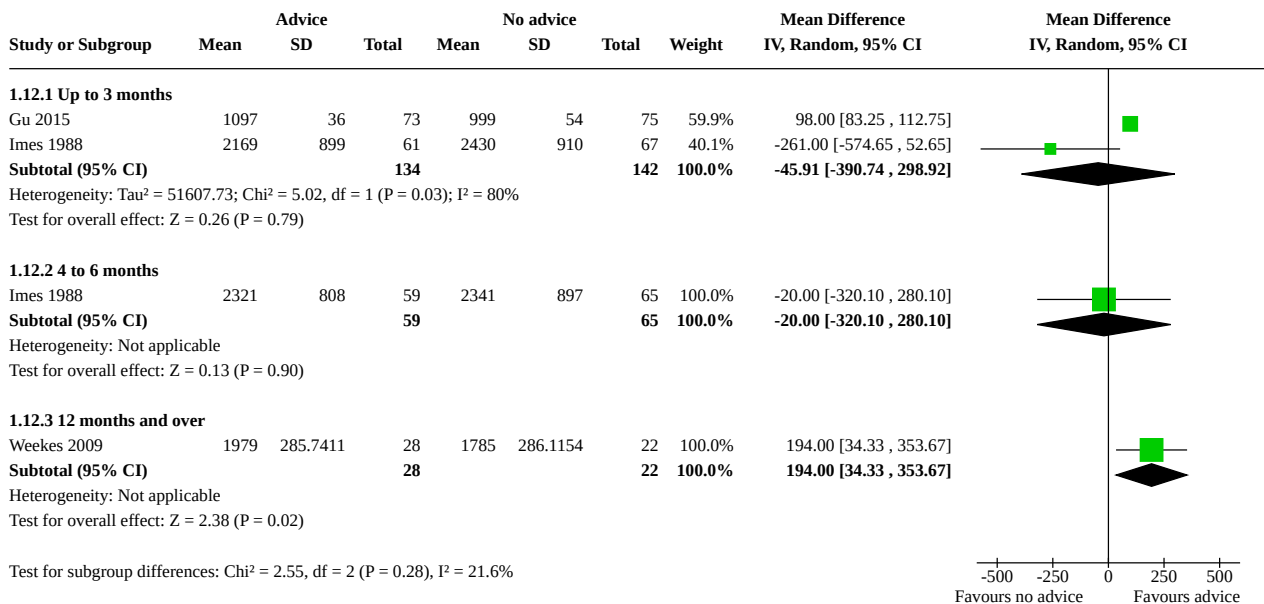
Analysis 1.10. Comparison 1: Dietary advice compared with no advice, Outcome 10: Change in triceps skinfold thickness (mm)



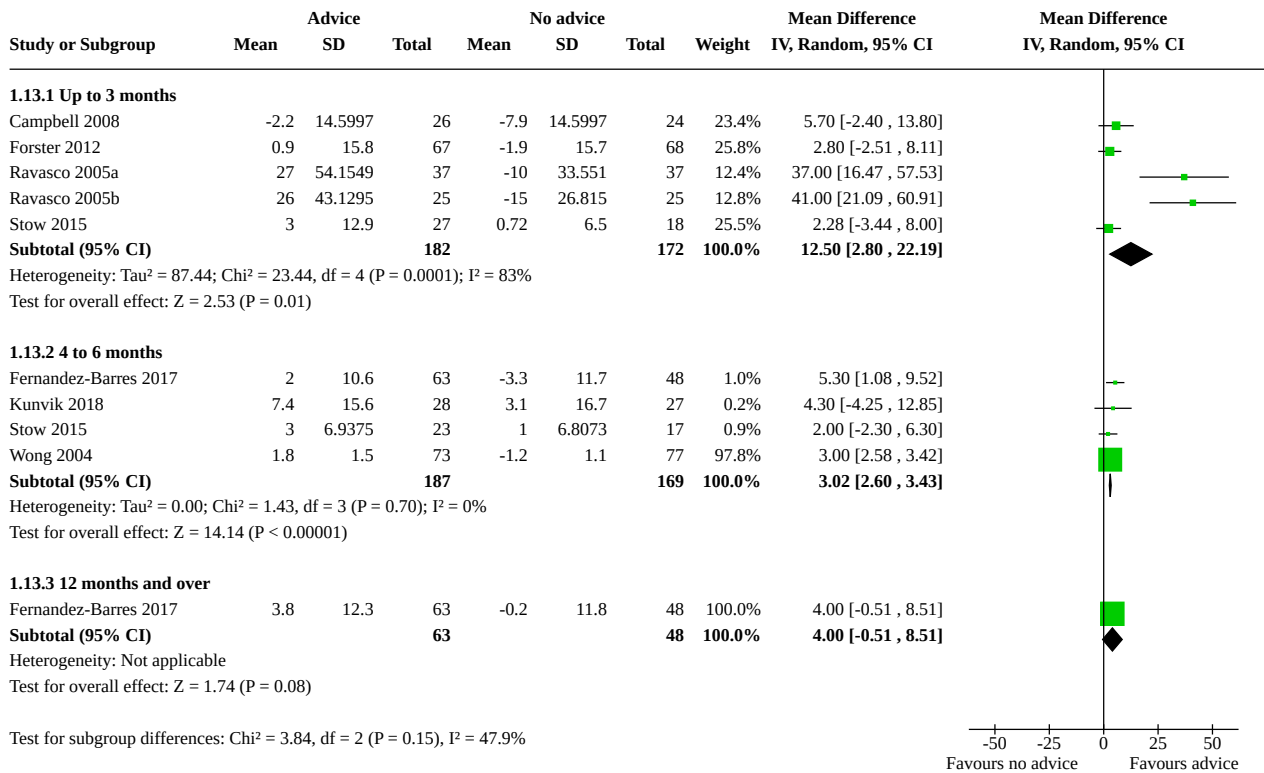
Analysis 1.11. Comparison 1: Dietary advice compared with no advice, Outcome 11: Change in energy intake (kcal)



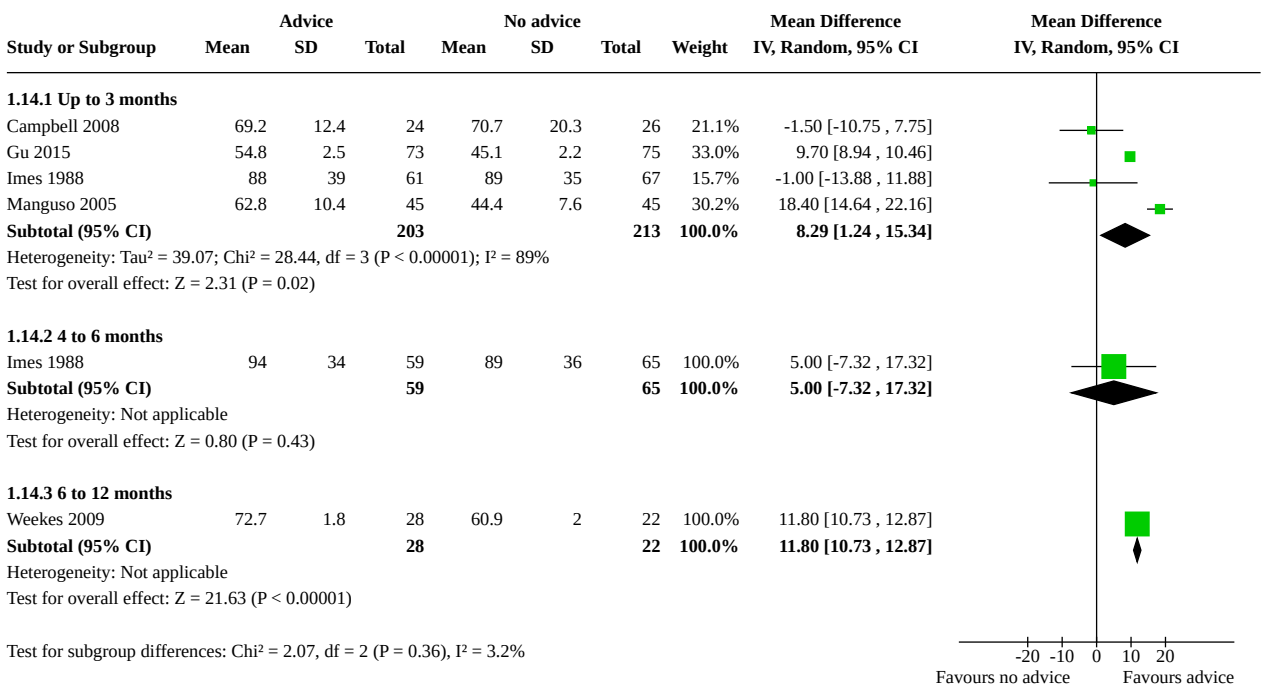
Analysis 1.12. Comparison 1: Dietary advice compared with no advice, Outcome 12: Final energy intake (kcal)



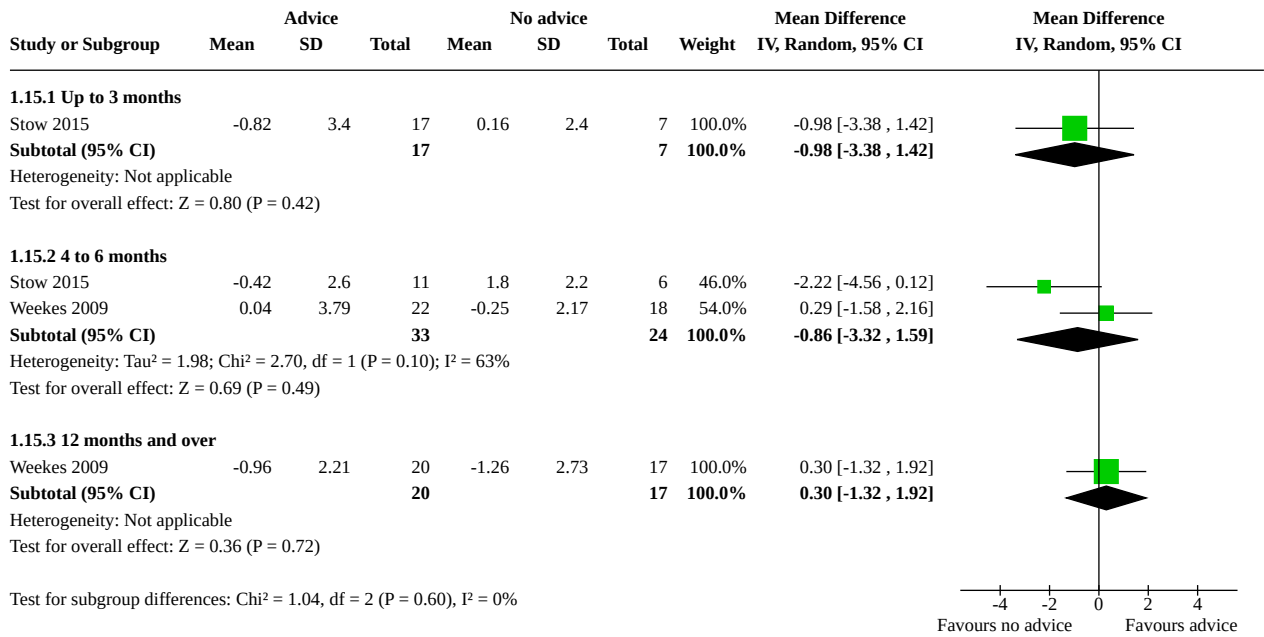
Analysis 1.13. Comparison 1: Dietary advice compared with no advice, Outcome 13: Change in protein intake (g)



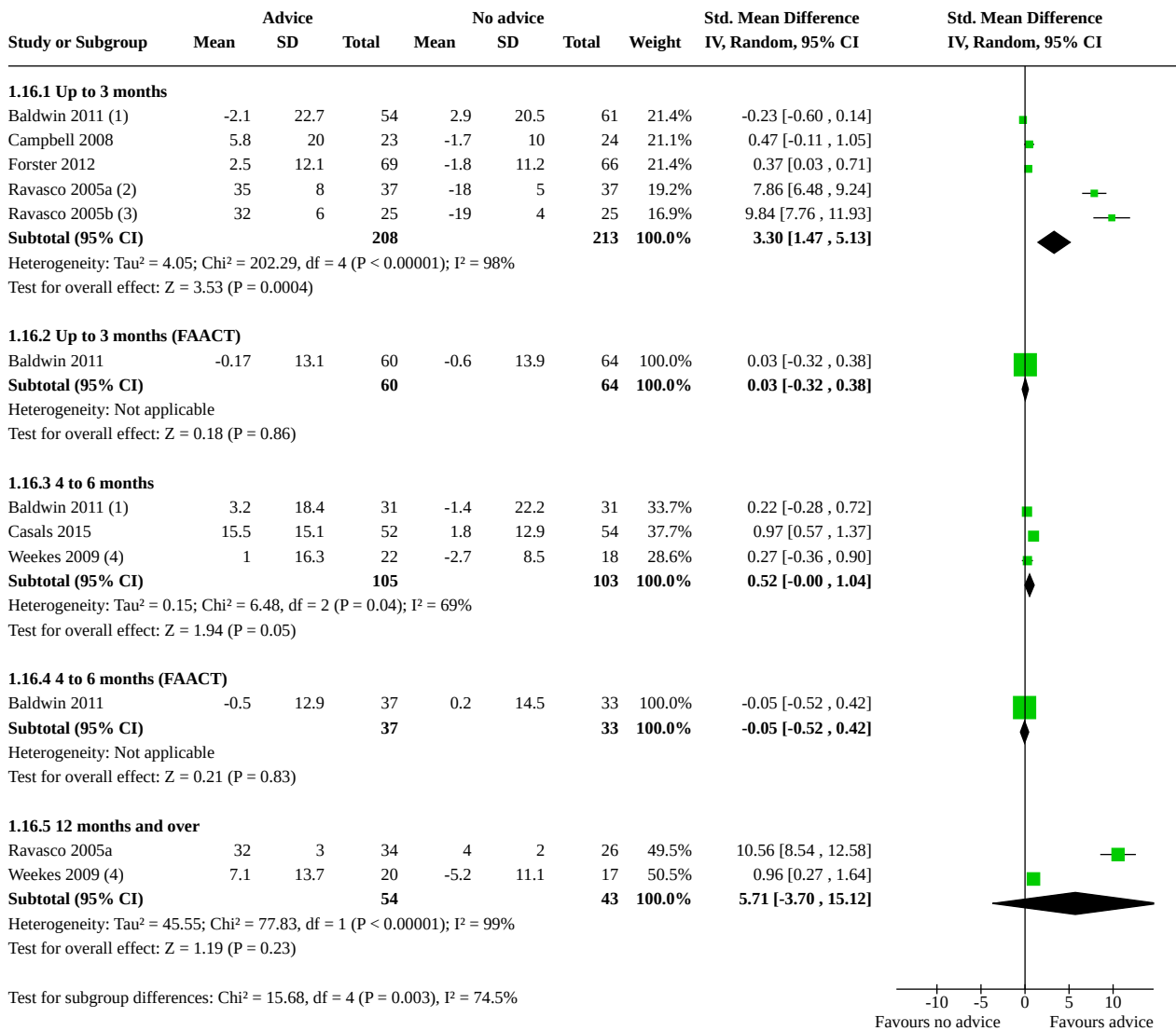
Analysis 1.14. Comparison 1: Dietary advice compared with no advice, Outcome 14: Final protein intake (g)



Analysis 1.15. Comparison 1: Dietary advice compared with no advice, Outcome 15: Change in grip strength (kg force)

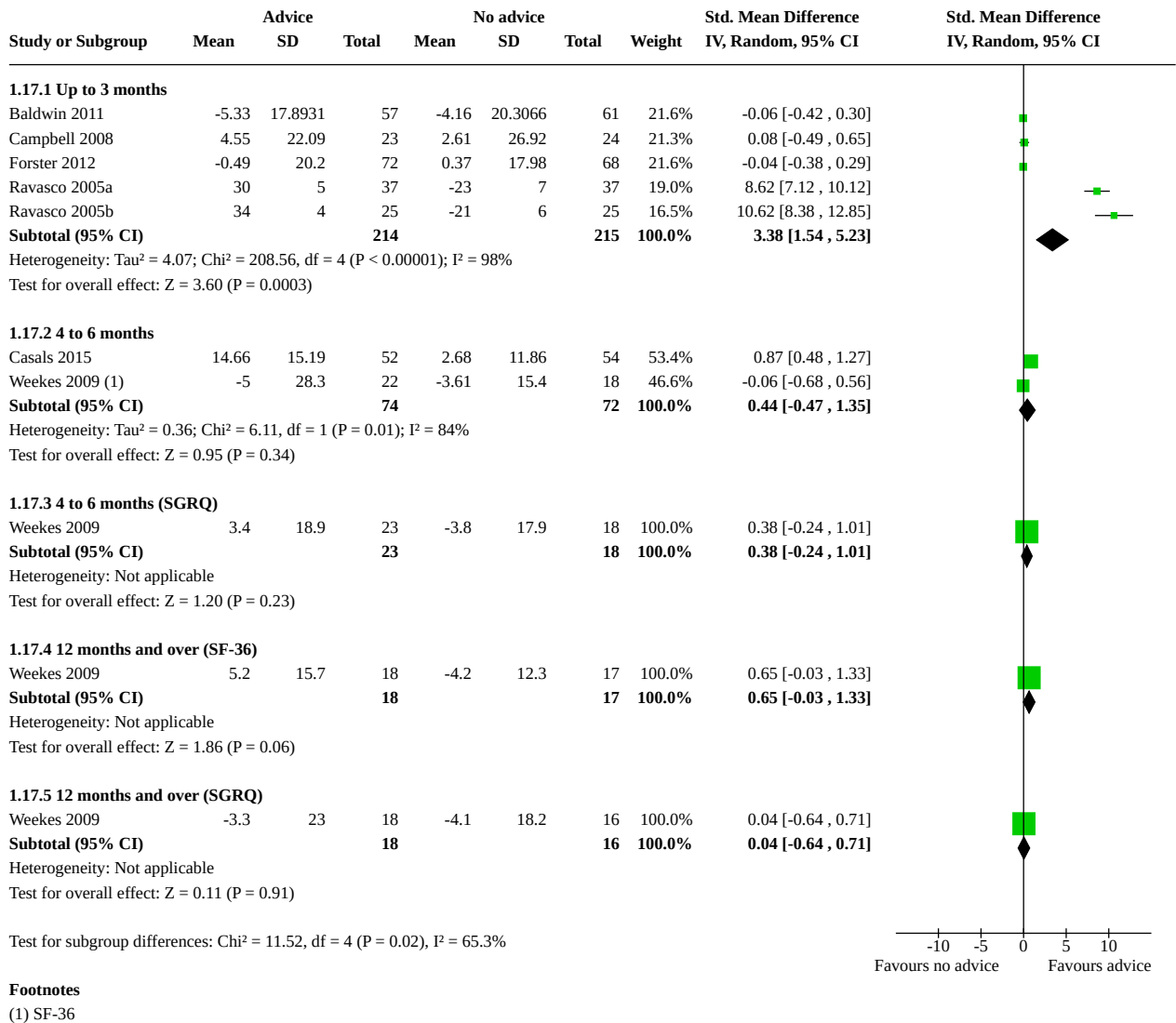


Analysis 1.16. Comparison 1: Dietary advice compared with no advice, Outcome 16: Change in global QoL



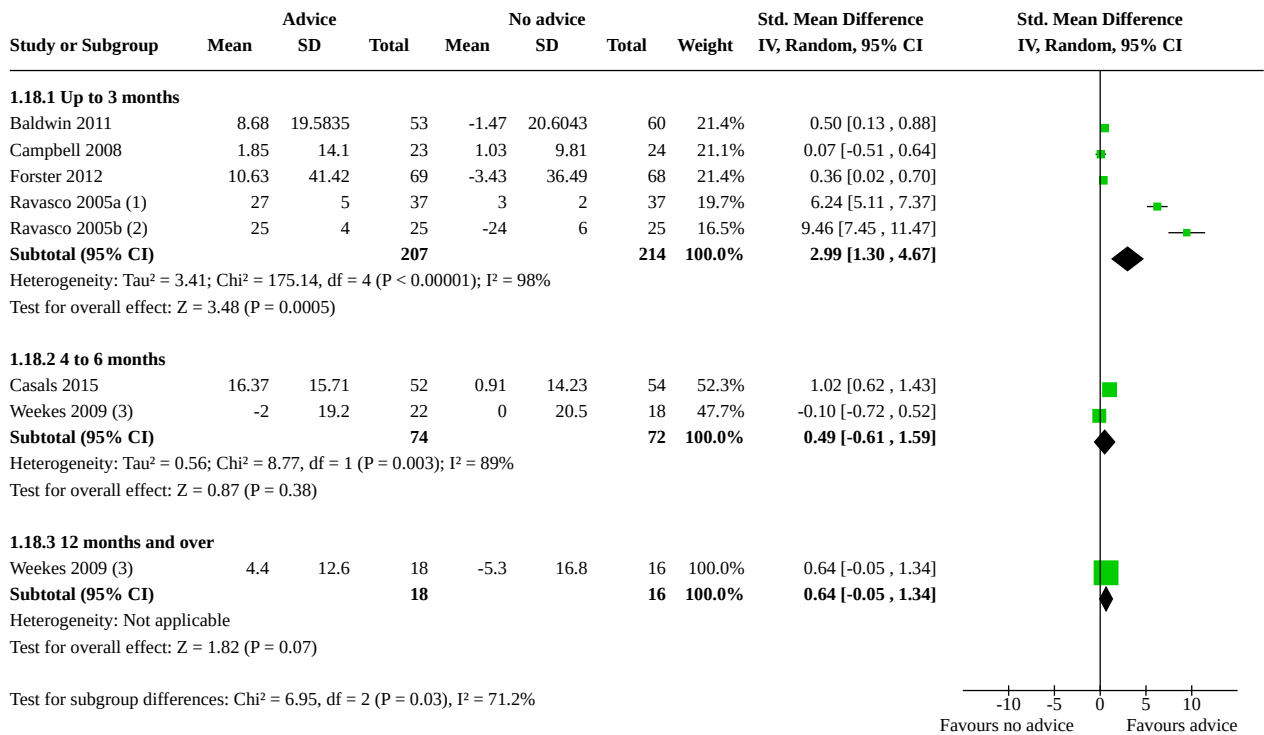
Footnotes
 (1) EORTC
 (2) Colo-rectal participants
 (3) Head and neck participants
 (4) SGRQ

Analysis 1.17. Comparison 1: Dietary advice compared with no advice, Outcome 17: QoL - change in physical function



Footnotes
(1) SF-36

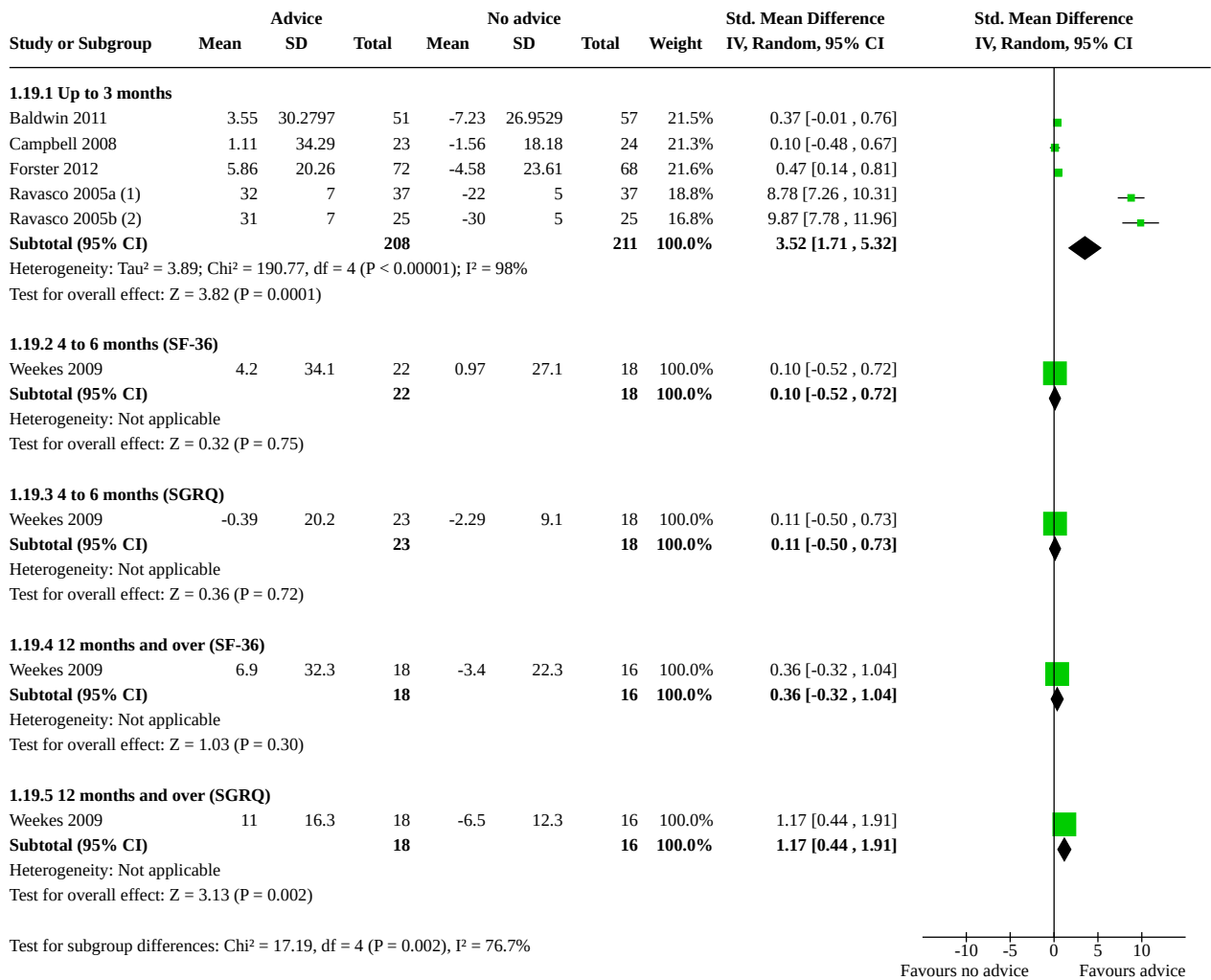
Analysis 1.18. Comparison 1: Dietary advice compared with no advice, Outcome 18: QoL - change in mental function



Footnotes

- (1) Colo-rectal participants
- (2) Head and neck participants
- (3) SF-36

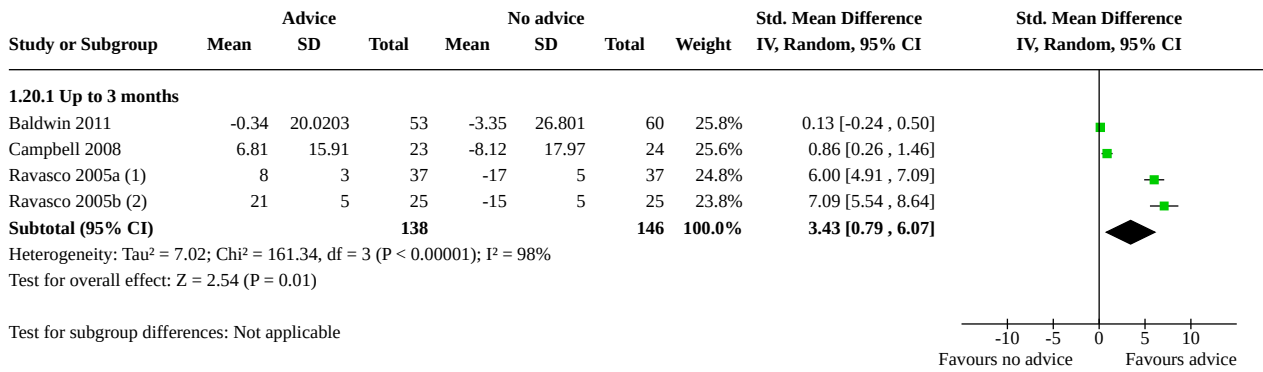
Analysis 1.19. Comparison 1: Dietary advice compared with no advice, Outcome 19: QoL - change in social function



Footnotes

- (1) Colo-rectal participants
- (2) Head and neck participants

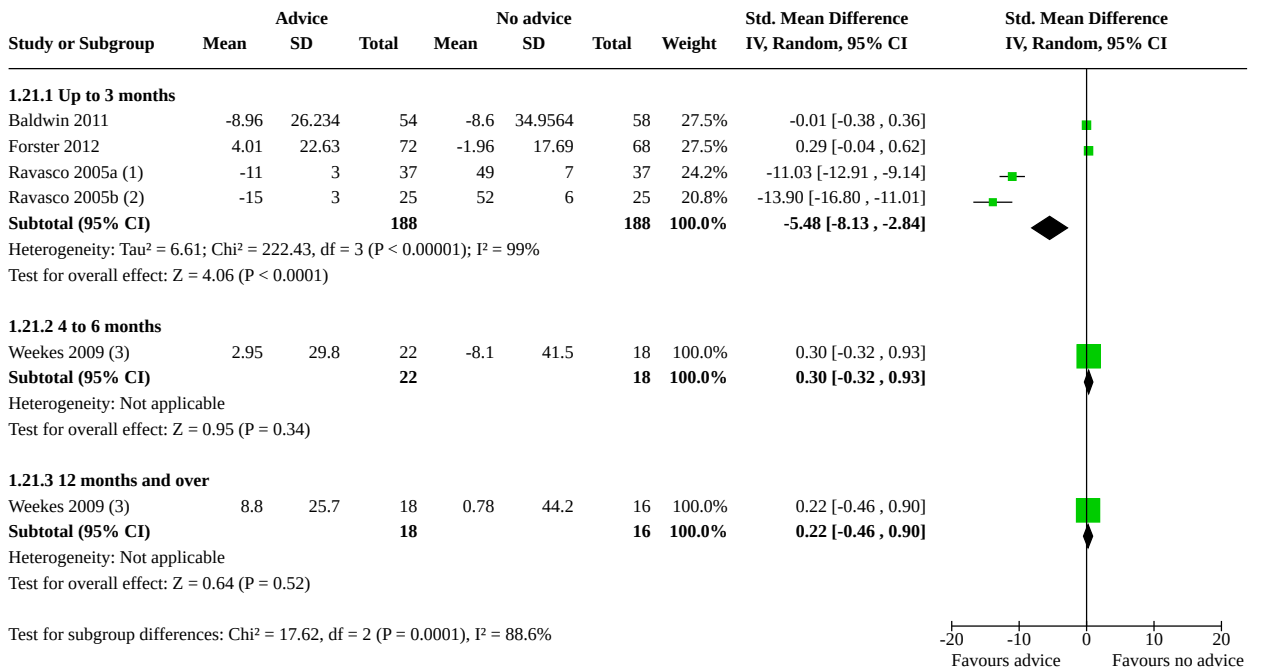
Analysis 1.20. Comparison 1: Dietary advice compared with no advice, Outcome 20: QoL - change in cognitive function



Footnotes

- (1) Colo-rectal participants
- (2) Head and neck participants

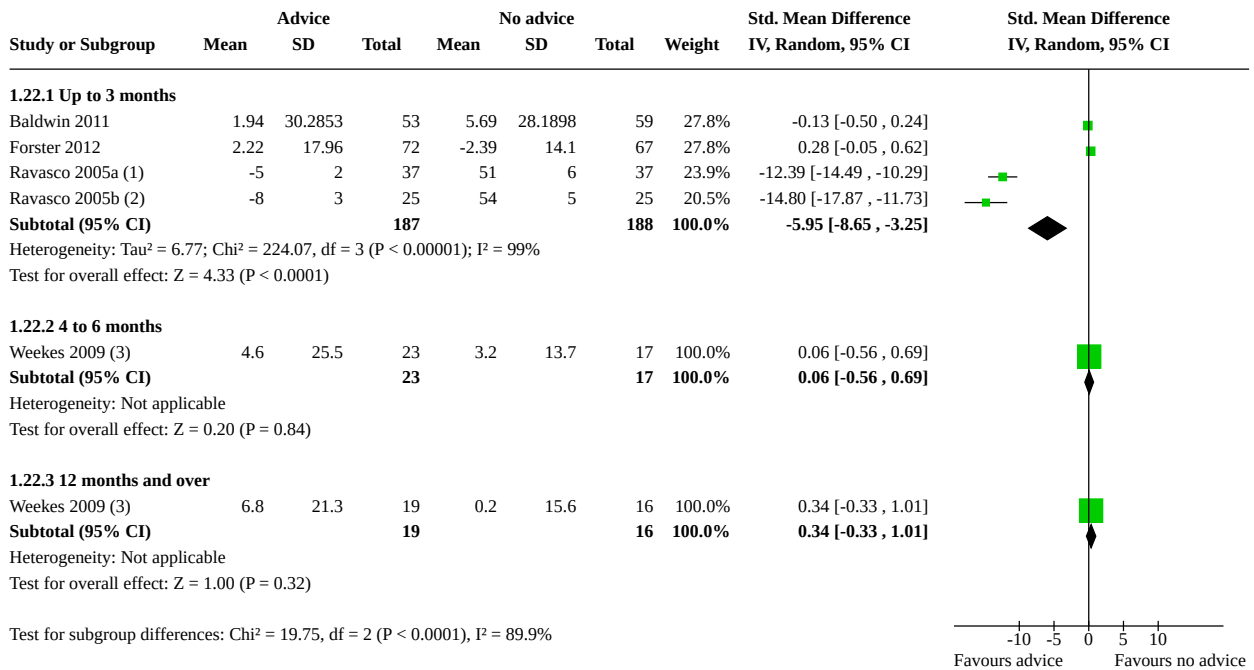
Analysis 1.21. Comparison 1: Dietary advice compared with no advice, Outcome 21: QoL - change in pain



Footnotes

- (1) Colo-rectal participants
- (2) Head and neck participants
- (3) SF-36

Analysis 1.22. Comparison 1: Dietary advice compared with no advice, Outcome 22: QoL - change in energy/fatigue



Footnotes

- (1) Colo-rectal participants
- (2) Head and neck participants
- (3) SF-36

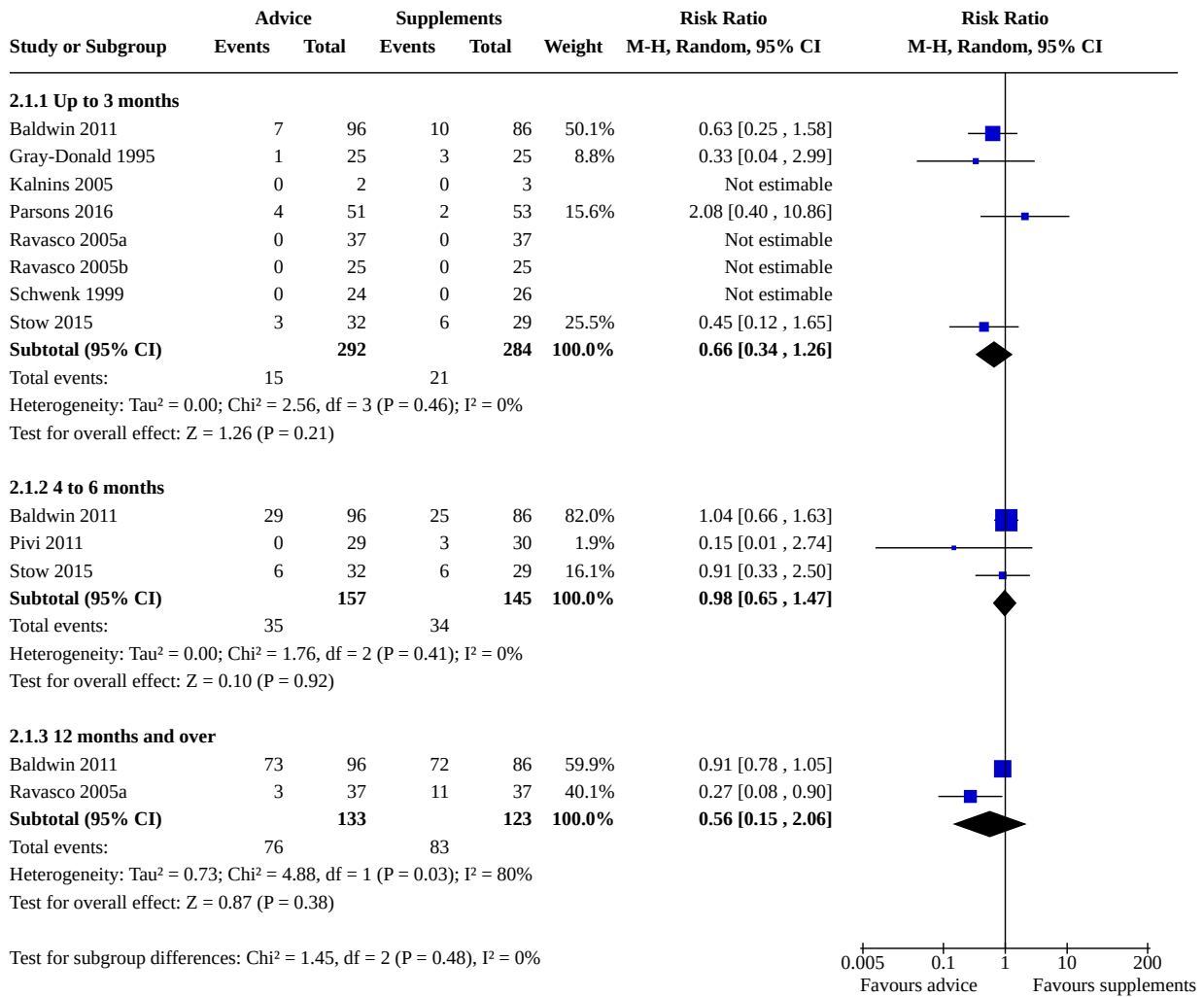
Comparison 2. Dietary advice compared with nutritional supplements

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
2.1 Mortality	9		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
2.1.1 Up to 3 months	8	576	Risk Ratio (M-H, Random, 95% CI)	0.66 [0.34, 1.26]
2.1.2 4 to 6 months	3	302	Risk Ratio (M-H, Random, 95% CI)	0.98 [0.65, 1.47]
2.1.3 12 months and over	2	256	Risk Ratio (M-H, Random, 95% CI)	0.56 [0.15, 2.06]
2.2 Number of people admitted or readmitted to hospital	2	111	Risk Ratio (M-H, Fixed, 95% CI)	2.30 [1.02, 5.15]
2.2.1 Up to 3 months	1	50	Risk Ratio (M-H, Fixed, 95% CI)	0.36 [0.04, 3.24]
2.2.2 4 to 6 months	1	61	Risk Ratio (M-H, Fixed, 95% CI)	3.62 [1.37, 9.60]
2.3 Change in weight (kg)	9		Mean Difference (IV, Random, 95% CI)	Subtotals only
2.3.1 Up to 3 months	9	517	Mean Difference (IV, Random, 95% CI)	-0.14 [-2.01, 1.74]
2.3.2 4 to 6 months	1	44	Mean Difference (IV, Random, 95% CI)	0.03 [-1.72, 1.78]
2.4 Change in BMI (kg/m²)	2		Mean Difference (IV, Random, 95% CI)	Subtotals only

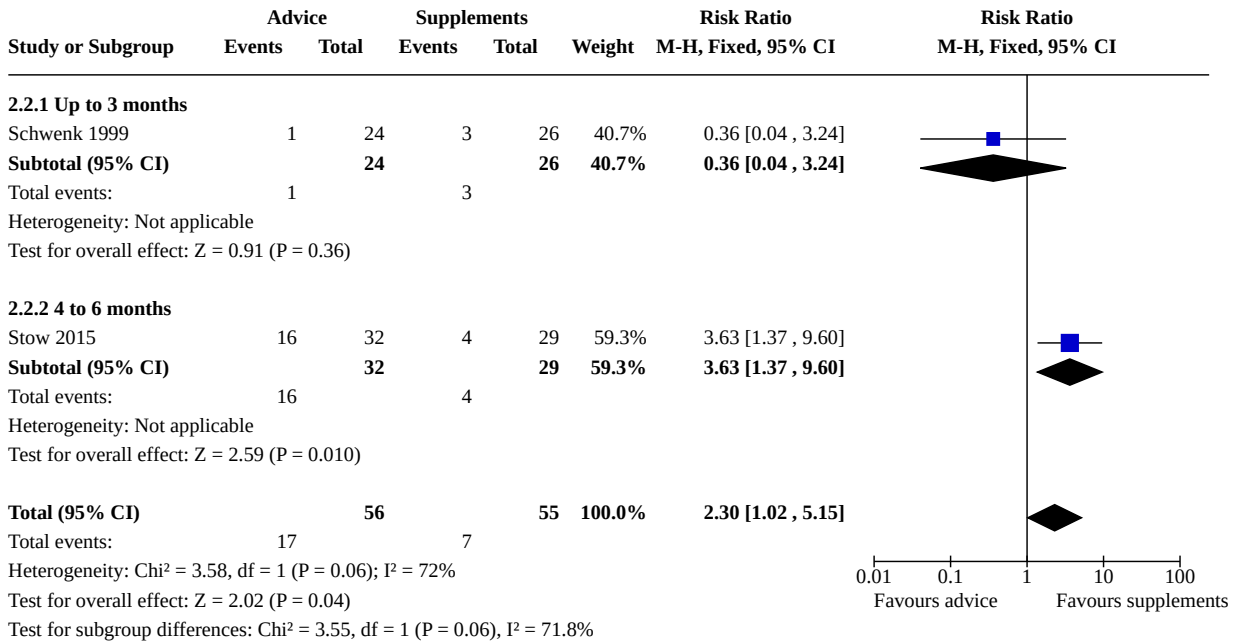
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
2.4.1 Up to 3 months	2	97	Mean Difference (IV, Random, 95% CI)	-0.21 [-0.64, 0.23]
2.4.2 4 to 6 months	1	44	Mean Difference (IV, Random, 95% CI)	-0.01 [-0.72, 0.70]
2.5 Change in mid-arm muscle circumference (cm)	3		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
2.5.1 Up to 3 months	2	81	Mean Difference (IV, Fixed, 95% CI)	0.43 [-0.36, 1.22]
2.5.2 4 to 6 months	2	80	Mean Difference (IV, Fixed, 95% CI)	-0.11 [-1.07, 0.85]
2.6 Change in mid-arm circumference (cm)	2		Mean Difference (IV, Random, 95% CI)	Subtotals only
2.6.1 Up to 3 months	2	91	Mean Difference (IV, Random, 95% CI)	-0.17 [-0.72, 0.38]
2.6.2 4 to 6 months	1	20	Mean Difference (IV, Random, 95% CI)	-0.15 [-4.30, 4.00]
2.7 Change in triceps skin-fold thickness (mm)	4		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
2.7.1 Up to 3 months	3	129	Mean Difference (IV, Fixed, 95% CI)	-0.75 [-1.55, 0.05]
2.7.2 4 to 6 months	2	68	Mean Difference (IV, Fixed, 95% CI)	-0.99 [-8.96, 6.98]
2.8 Change in energy intake (kcal)	8		Mean Difference (IV, Random, 95% CI)	Subtotals only
2.8.1 Up to 3 months	8	327	Mean Difference (IV, Random, 95% CI)	-1.52 [-206.23, 203.20]
2.8.2 4 to 6 months	1	25	Mean Difference (IV, Random, 95% CI)	-145.00 [-598.85, 308.85]
2.9 Change in protein intake (g)	4		Mean Difference (IV, Random, 95% CI)	Subtotals only
2.9.1 Up to 3 months	4	221	Mean Difference (IV, Random, 95% CI)	-13.09 [-19.23, -6.96]
2.9.2 4 to 6 months	1	25	Mean Difference (IV, Random, 95% CI)	-6.00 [-9.91, -2.09]
2.10 Change in grip strength (kg force)	2		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
2.10.1 Up to 3 months	2	69	Mean Difference (IV, Fixed, 95% CI)	0.32 [-1.10, 1.74]
2.10.2 4 to 6 months	1	17	Mean Difference (IV, Fixed, 95% CI)	-0.07 [-2.35, 2.21]
2.11 Change in global QoL	4		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
2.11.1 Up to 3 months	4	283	Std. Mean Difference (IV, Random, 95% CI)	1.26 [-0.32, 2.85]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
2.11.2 Up to 3 months (FAACT)	1	120	Std. Mean Difference (IV, Random, 95% CI)	-0.04 [-0.40, 0.31]
2.11.3 4 to 6 months	1	62	Std. Mean Difference (IV, Random, 95% CI)	0.07 [-0.43, 0.57]
2.11.4 4 to 6 months (FAACT)	1	68	Std. Mean Difference (IV, Random, 95% CI)	-0.15 [-0.63, 0.33]
2.11.5 12 months and over	1	63	Std. Mean Difference (IV, Random, 95% CI)	10.68 [8.69, 12.67]
2.12 QoL - change in physical function	3		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
2.12.1 Up to 3 months	3	236	Std. Mean Difference (IV, Random, 95% CI)	2.41 [-0.79, 5.61]
2.13 QoL - change in mental function	3		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
2.13.1 Up to 3 months	3	232	Std. Mean Difference (IV, Random, 95% CI)	3.45 [-0.24, 7.15]
2.14 QoL - change in social function	3		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
2.14.1 Up to 3 months	3	232	Std. Mean Difference (IV, Random, 95% CI)	3.13 [-0.21, 6.48]
2.15 QoL - change in cognitive function	3		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
2.15.1 Up to 3 months	3	234	Std. Mean Difference (IV, Random, 95% CI)	4.23 [0.05, 8.42]
2.16 QoL - change in pain	3		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
2.16.1 Up to 3 months	3	236	Std. Mean Difference (IV, Random, 95% CI)	-5.42 [-11.40, 0.56]
2.17 QoL - change in energy/fatigue	3		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
2.17.1 Up to 3 months	3	232	Std. Mean Difference (IV, Random, 95% CI)	-8.41 [-18.21, 1.39]

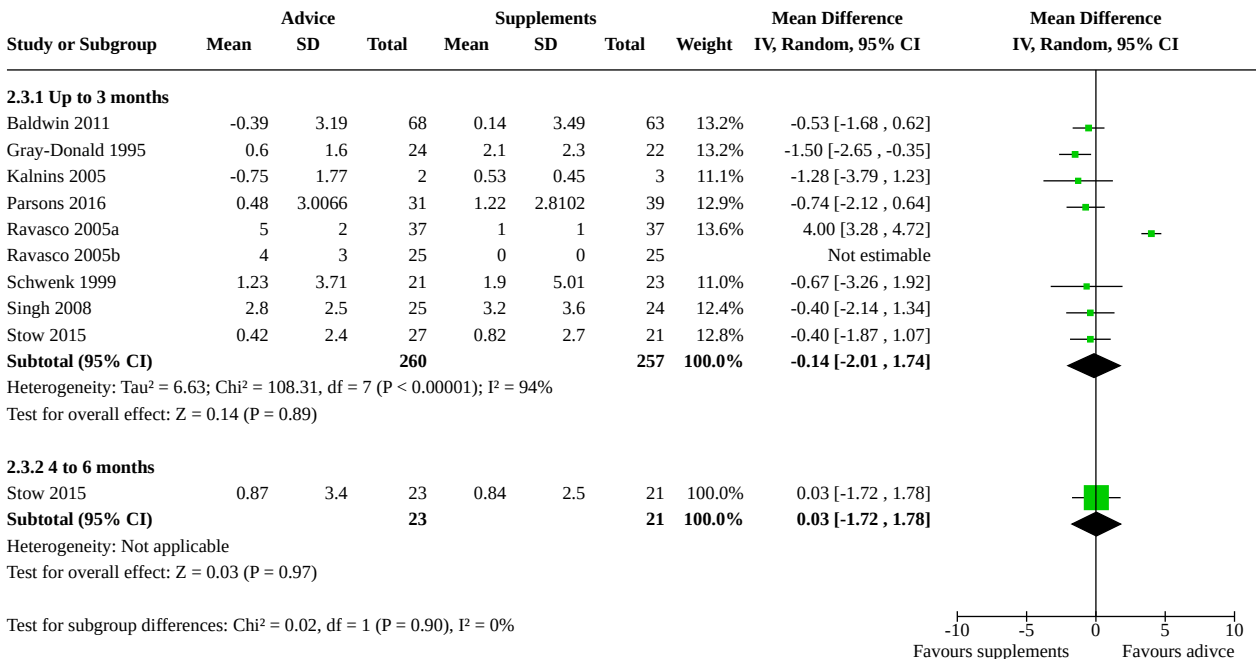
Analysis 2.1. Comparison 2: Dietary advice compared with nutritional supplements, Outcome 1: Mortality



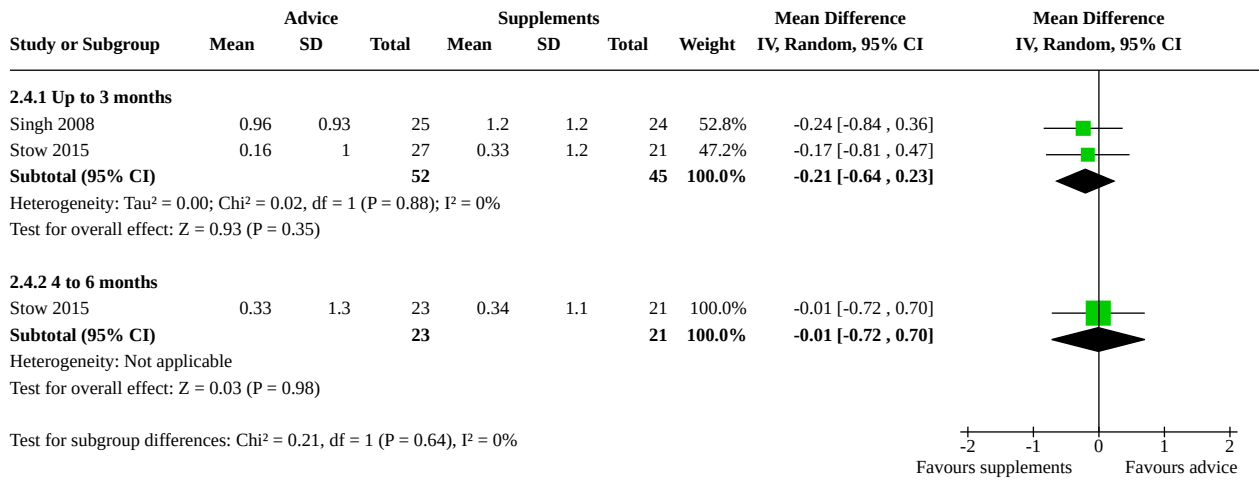
Analysis 2.2. Comparison 2: Dietary advice compared with nutritional supplements, Outcome 2: Number of people admitted or readmitted to hospital



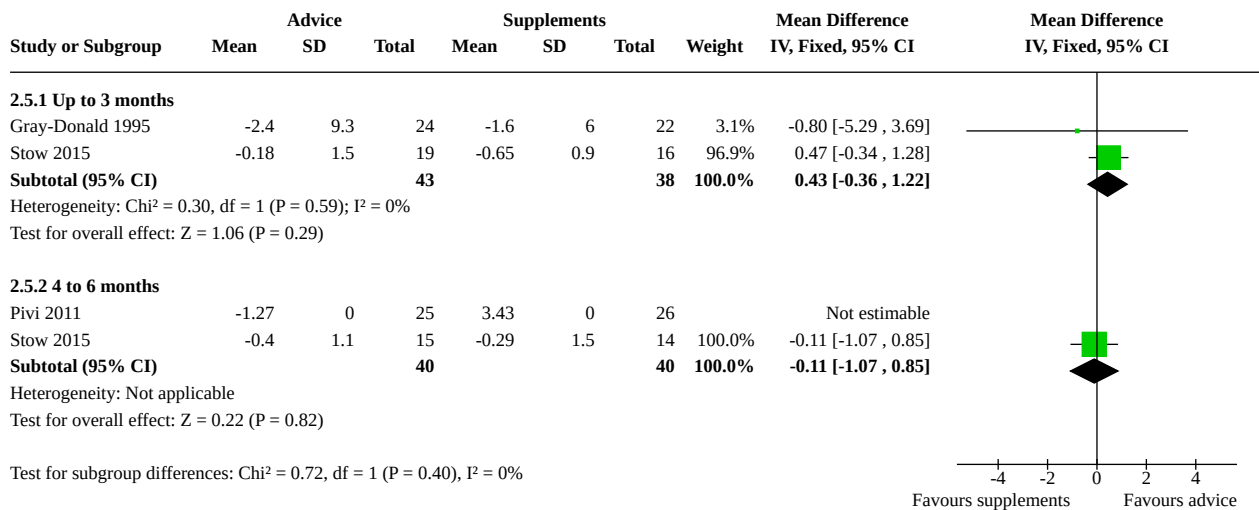
Analysis 2.3. Comparison 2: Dietary advice compared with nutritional supplements, Outcome 3: Change in weight (kg)



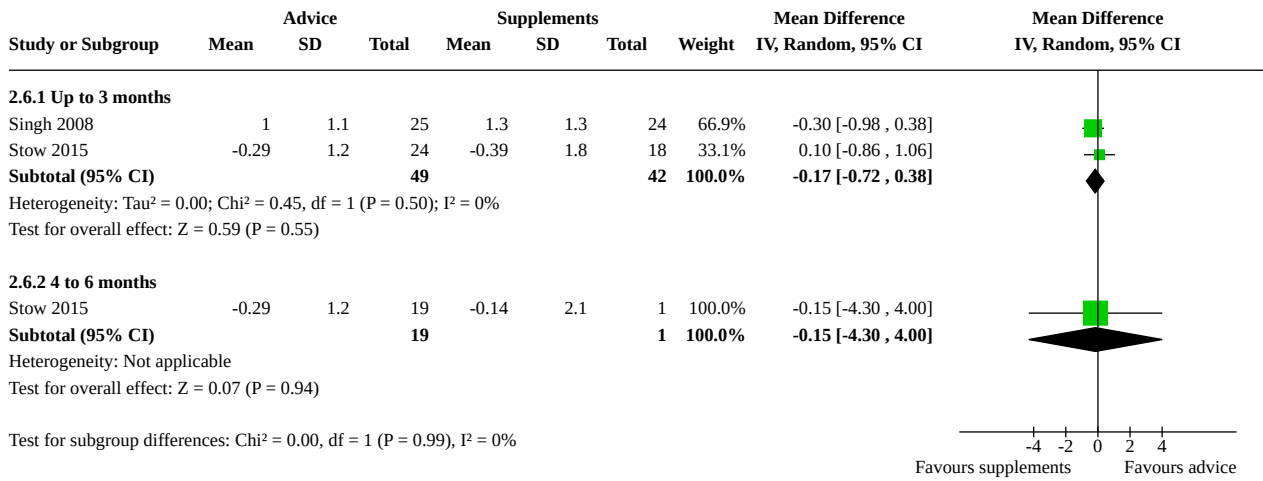
Analysis 2.4. Comparison 2: Dietary advice compared with nutritional supplements, Outcome 4: Change in BMI (kg/m²)



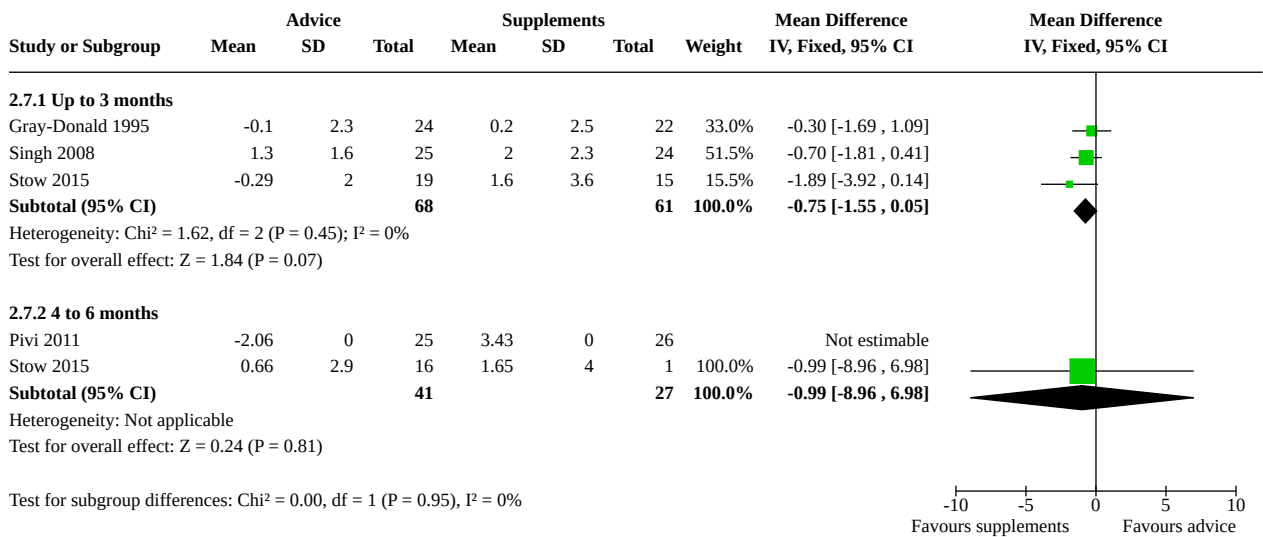
Analysis 2.5. Comparison 2: Dietary advice compared with nutritional supplements, Outcome 5: Change in mid-arm muscle circumference (cm)



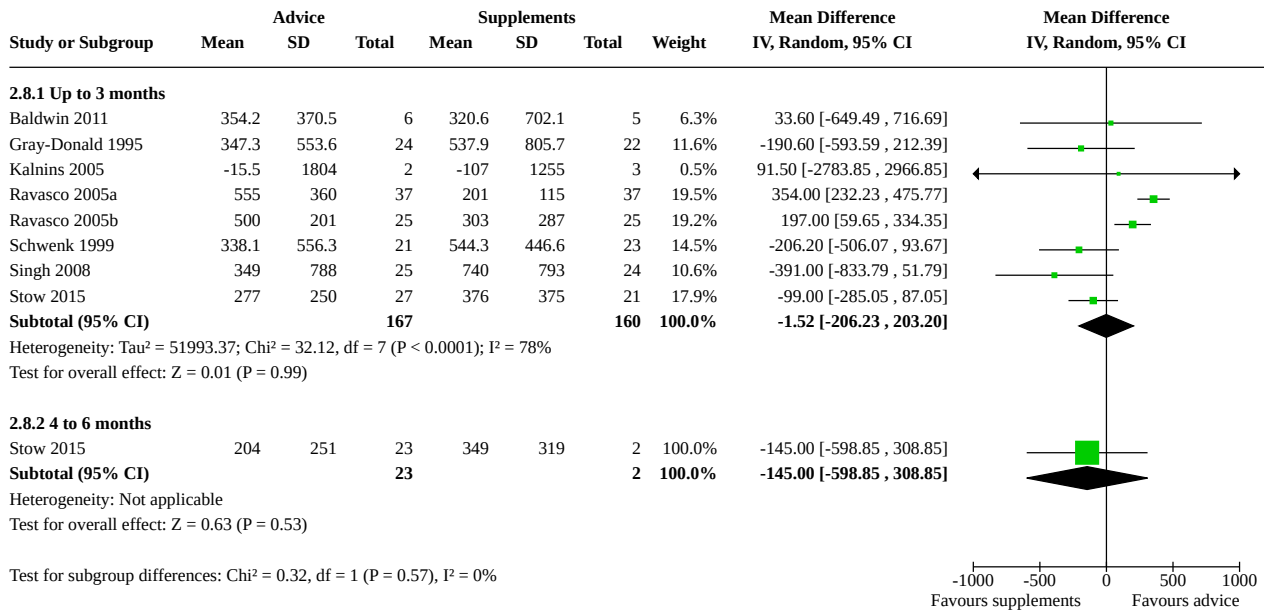
Analysis 2.6. Comparison 2: Dietary advice compared with nutritional supplements, Outcome 6: Change in mid-arm circumference (cm)



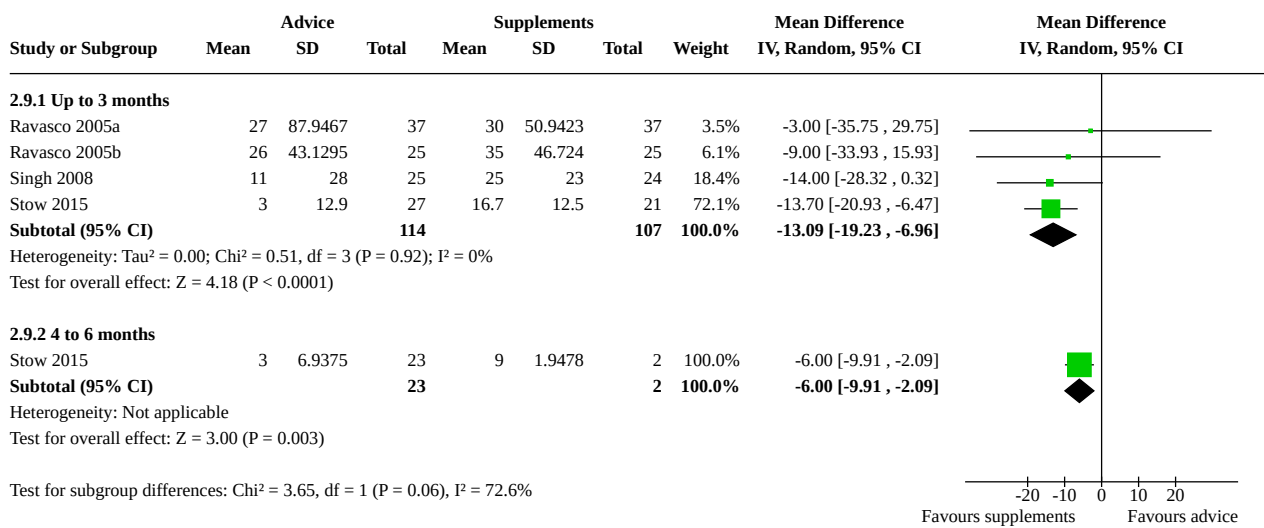
Analysis 2.7. Comparison 2: Dietary advice compared with nutritional supplements, Outcome 7: Change in triceps skinfold thickness (mm)



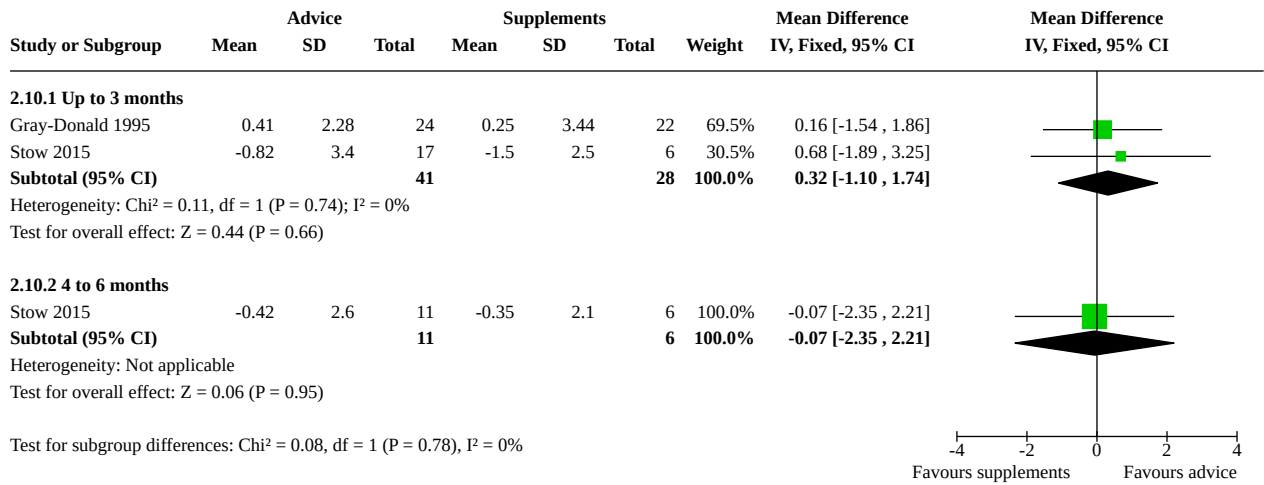
Analysis 2.8. Comparison 2: Dietary advice compared with nutritional supplements, Outcome 8: Change in energy intake (kcal)



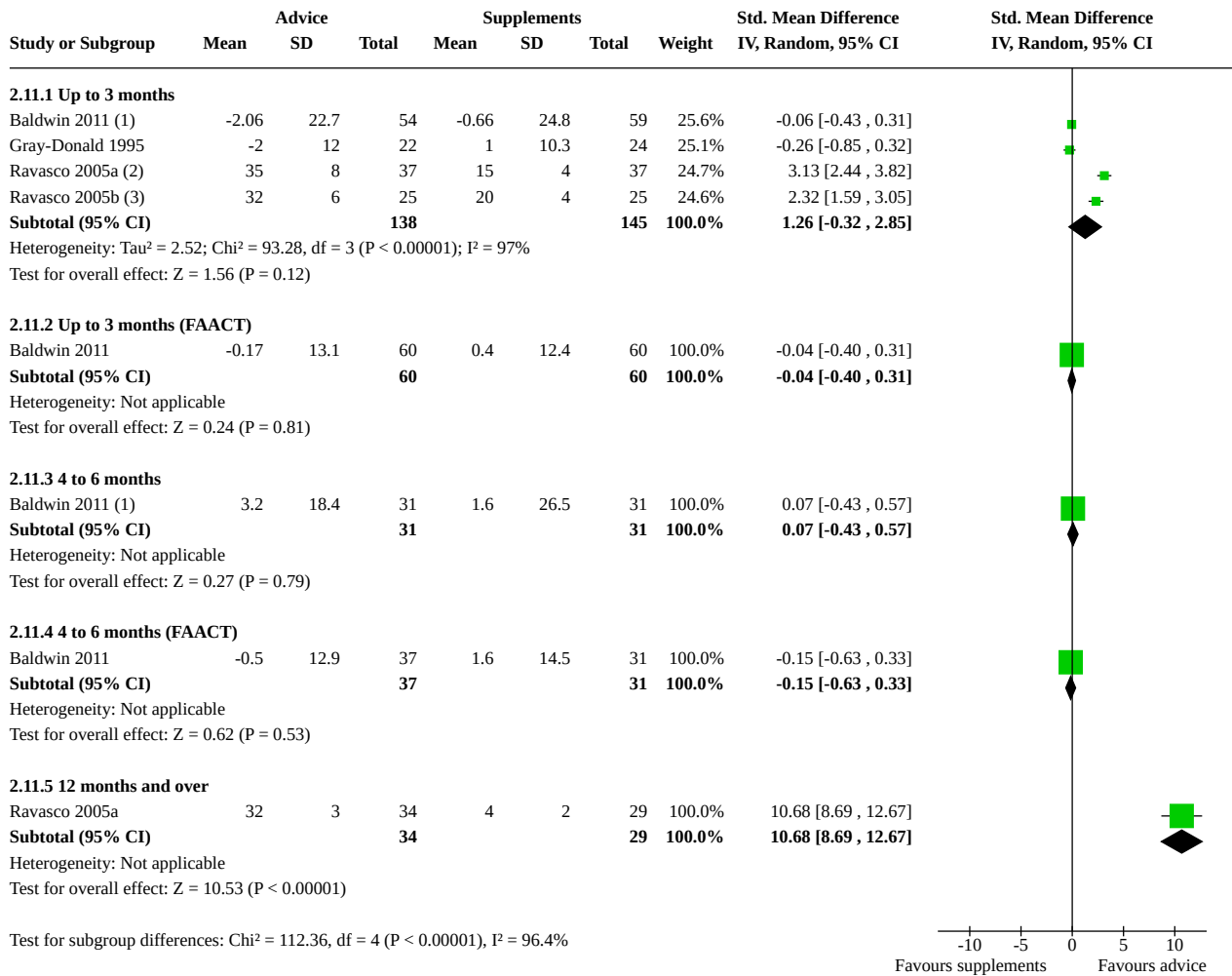
Analysis 2.9. Comparison 2: Dietary advice compared with nutritional supplements, Outcome 9: Change in protein intake (g)



Analysis 2.10. Comparison 2: Dietary advice compared with nutritional supplements, Outcome 10: Change in grip strength (kg force)



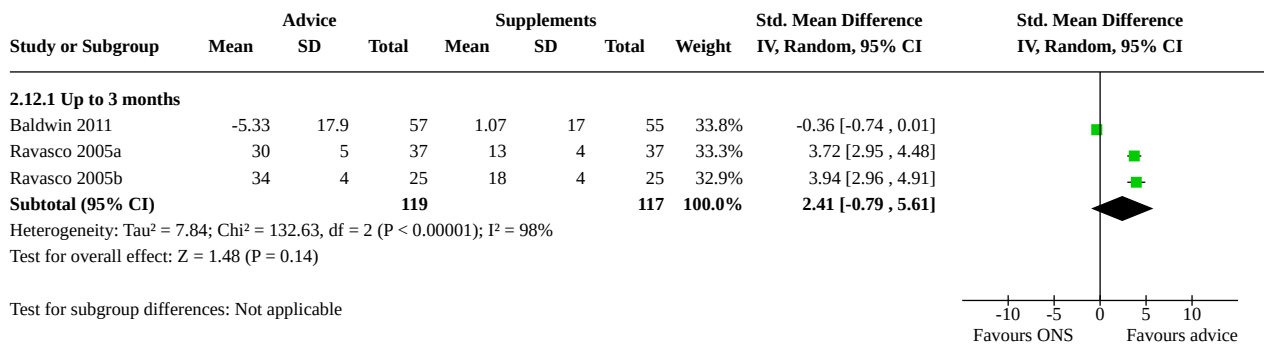
Analysis 2.11. Comparison 2: Dietary advice compared with nutritional supplements, Outcome 11: Change in global QoL



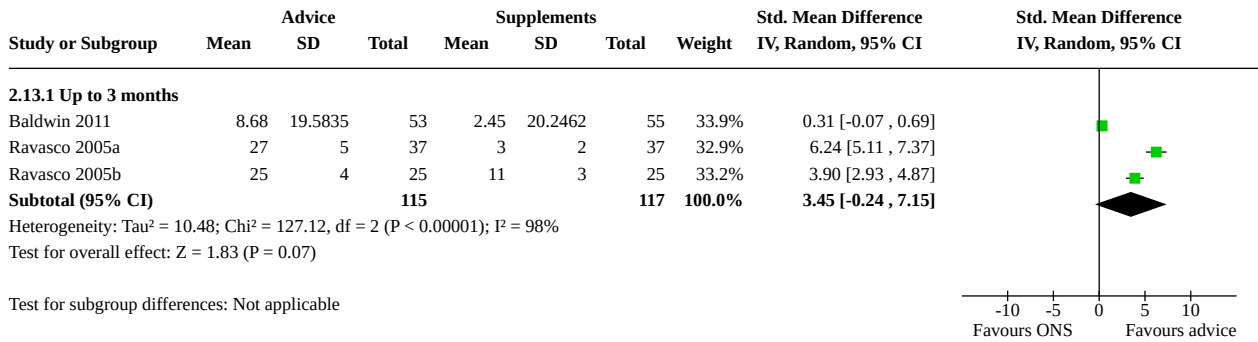
Footnotes

- (1) EORTC
- (2) Colo-rectal participants
- (3) Head and neck participants

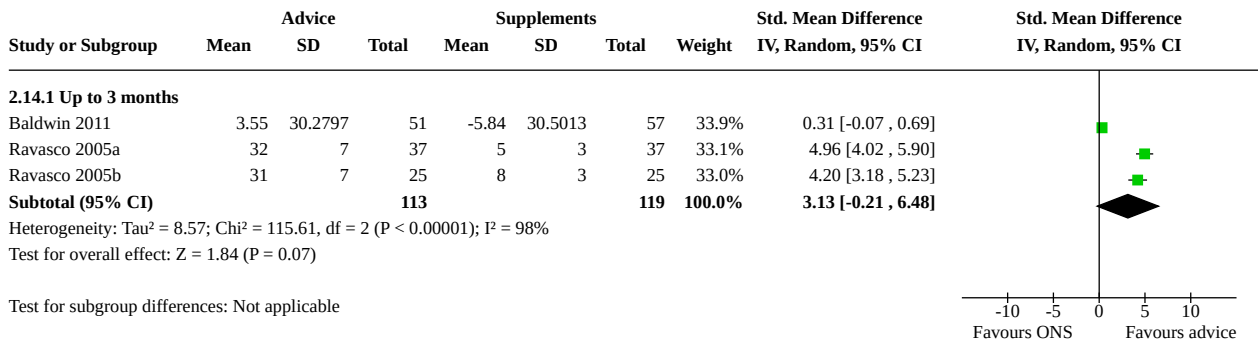
Analysis 2.12. Comparison 2: Dietary advice compared with nutritional supplements, Outcome 12: QoL - change in physical function



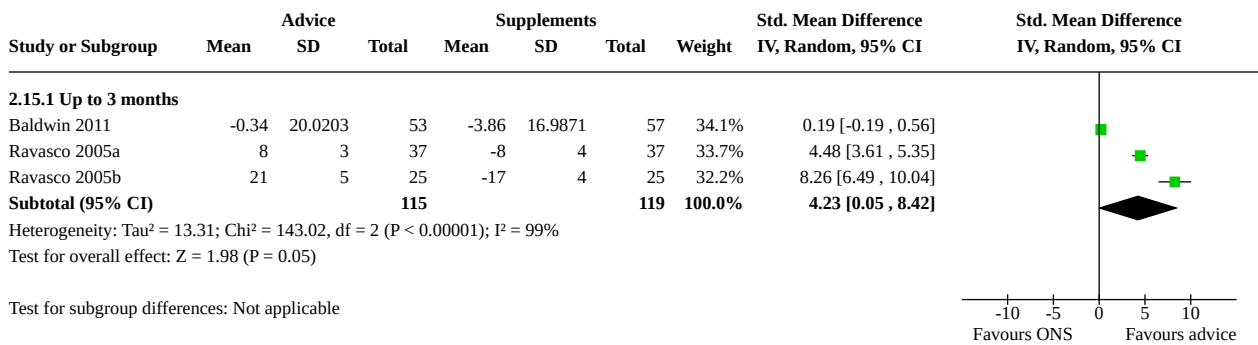
Analysis 2.13. Comparison 2: Dietary advice compared with nutritional supplements, Outcome 13: QoL - change in mental function



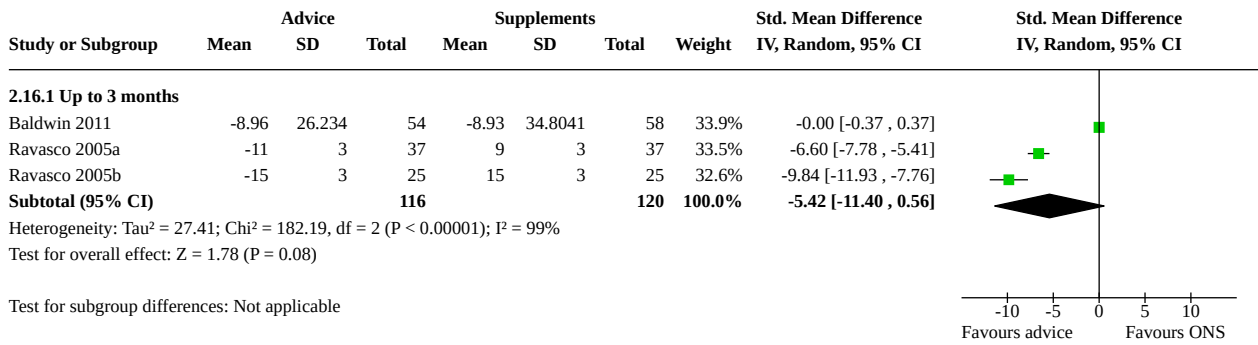
Analysis 2.14. Comparison 2: Dietary advice compared with nutritional supplements, Outcome 14: QoL - change in social function



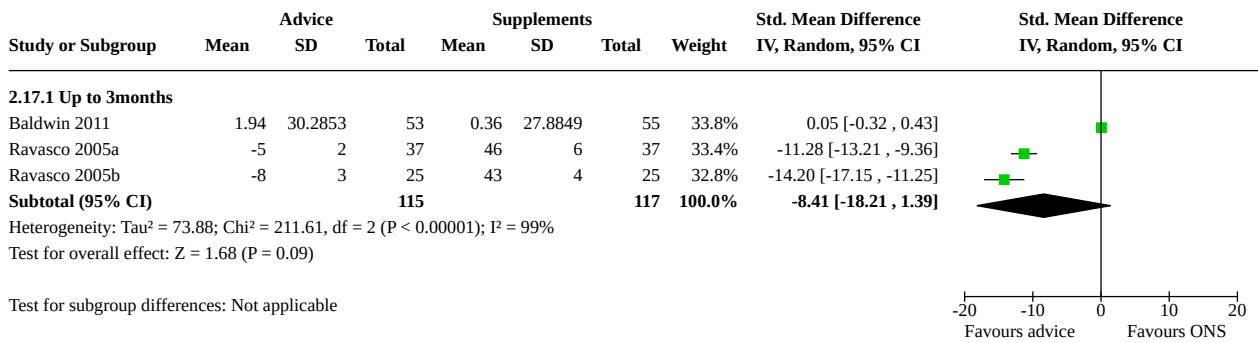
Analysis 2.15. Comparison 2: Dietary advice compared with nutritional supplements, Outcome 15: QoL - change in cognitive function



Analysis 2.16. Comparison 2: Dietary advice compared with nutritional supplements, Outcome 16: QoL - change in pain



Analysis 2.17. Comparison 2: Dietary advice compared with nutritional supplements, Outcome 17: QoL - change in energy/fatigue



Comparison 3. Dietary advice compared with dietary advice plus nutritional supplements

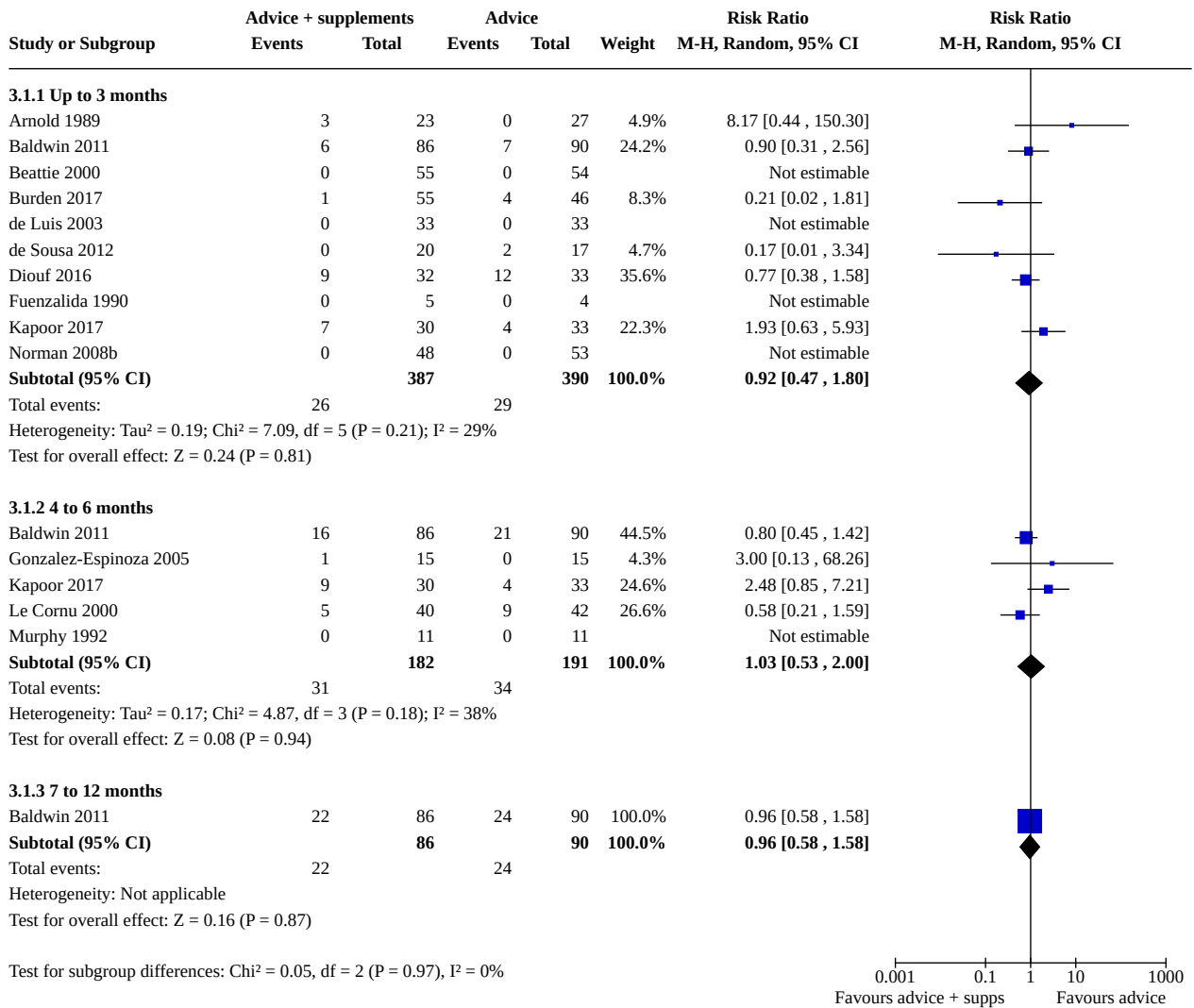
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
3.1 Mortality	13		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
3.1.1 Up to 3 months	10	777	Risk Ratio (M-H, Random, 95% CI)	0.92 [0.47, 1.80]
3.1.2 4 to 6 months	5	373	Risk Ratio (M-H, Random, 95% CI)	1.03 [0.53, 2.00]
3.1.3 7 to 12 months	1	176	Risk Ratio (M-H, Random, 95% CI)	0.96 [0.58, 1.58]
3.2 Number of people admitted or readmitted to hospital	2	142	Risk Ratio (M-H, Random, 95% CI)	1.20 [0.58, 2.48]
3.2.1 Up to 3 months	1	114	Risk Ratio (M-H, Random, 95% CI)	1.70 [1.04, 2.77]
3.2.2 4 to 6 months	1	28	Risk Ratio (M-H, Random, 95% CI)	0.84 [0.50, 1.42]
3.3 Length of hospital stay (days)	2	202	Mean Difference (IV, Random, 95% CI)	-1.07 [-4.10, 1.97]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
3.3.1 Up to 3 months	2	202	Mean Difference (IV, Random, 95% CI)	-1.07 [-4.10, 1.97]
3.4 Complications	4	345	Risk Ratio (M-H, Fixed, 95% CI)	0.79 [0.60, 1.05]
3.4.1 Up to 3 months	3	317	Risk Ratio (M-H, Fixed, 95% CI)	0.75 [0.56, 0.99]
3.4.2 4 to 6 months	1	28	Risk Ratio (M-H, Fixed, 95% CI)	1.92 [0.57, 6.54]
3.5 Change in weight (kg)	16		Mean Difference (IV, Random, 95% CI)	Subtotals only
3.5.1 Up to 3 months	14	931	Mean Difference (IV, Random, 95% CI)	1.15 [0.42, 1.87]
3.5.2 4 to 6 months	4	209	Mean Difference (IV, Random, 95% CI)	2.27 [-0.44, 4.98]
3.5.3 7 to 12 months	1	31	Mean Difference (IV, Random, 95% CI)	0.14 [-4.24, 4.52]
3.6 Change in BMI (kg/m²)	7	378	Mean Difference (IV, Random, 95% CI)	0.42 [-0.31, 1.16]
3.6.1 Up to 3 months	6	350	Mean Difference (IV, Random, 95% CI)	0.51 [-0.30, 1.33]
3.6.2 Four to six months	1	28	Mean Difference (IV, Random, 95% CI)	-0.10 [-0.47, 0.27]
3.7 Change in fat free mass (kg)	3		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
3.7.1 Up to 3 months	3	187	Std. Mean Difference (IV, Random, 95% CI)	0.10 [-0.18, 0.39]
3.8 Change in mid-arm muscle circumference (cm)	5		Mean Difference (IV, Random, 95% CI)	Subtotals only
3.8.1 Up to 3 months	4	241	Mean Difference (IV, Random, 95% CI)	0.78 [0.37, 1.18]
3.8.2 4 to 6 months	2	60	Mean Difference (IV, Random, 95% CI)	1.20 [-0.63, 3.03]
3.9 Change in triceps skin-fold thickness (mm)	6	393	Mean Difference (IV, Random, 95% CI)	1.06 [0.14, 1.97]
3.9.1 Up to 3 months	6	393	Mean Difference (IV, Random, 95% CI)	1.06 [0.14, 1.97]
3.10 Change in energy intake (kcal)	9		Mean Difference (IV, Random, 95% CI)	Subtotals only
3.10.1 Up to 3 months	7	464	Mean Difference (IV, Random, 95% CI)	344.46 [164.21, 524.71]
3.10.2 4 to 6 months	3	75	Mean Difference (IV, Random, 95% CI)	362.75 [128.53, 596.97]
3.11 Final energy intake (kcal/day)	4	140	Mean Difference (IV, Fixed, 95% CI)	303.81 [110.58, 497.03]
3.11.1 Up to 3 months	4	140	Mean Difference (IV, Fixed, 95% CI)	303.81 [110.58, 497.03]

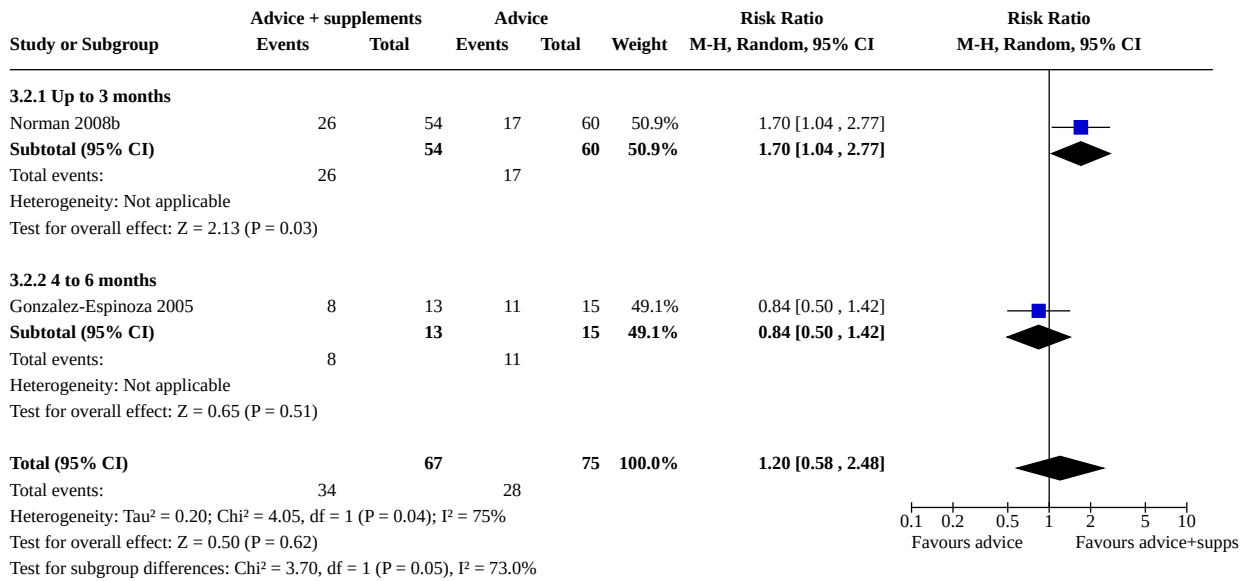
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
3.12 Change in protein intake (g)	3		Mean Difference (IV, Random, 95% CI)	Subtotals only
3.12.1 Up to 3 months	3	230	Mean Difference (IV, Random, 95% CI)	12.21 [6.39, 18.03]
3.12.2 4 to 6 months	1	32	Mean Difference (IV, Random, 95% CI)	16.20 [4.83, 27.57]
3.13 Final protein intake (g/day)	6	239	Mean Difference (IV, Fixed, 95% CI)	11.76 [5.59, 17.93]
3.13.1 Up to 3 months	6	239	Mean Difference (IV, Fixed, 95% CI)	11.76 [5.59, 17.93]
3.14 Change in grip strength (kg force)	6		Mean Difference (IV, Random, 95% CI)	Subtotals only
3.14.1 Up to 3 months	6	537	Mean Difference (IV, Random, 95% CI)	1.07 [-0.22, 2.37]
3.15 Change in global QoL	4		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
3.15.1 Up to 3 months	4	321	Std. Mean Difference (IV, Random, 95% CI)	0.33 [0.09, 0.57]
3.15.2 Up to 3 months (FAACT)	1	113	Std. Mean Difference (IV, Random, 95% CI)	-0.02 [-0.39, 0.35]
3.15.3 4 to 6 months	2	90	Std. Mean Difference (IV, Random, 95% CI)	0.35 [-0.55, 1.24]
3.15.4 4 to 6 months (FAACT)	1	62	Std. Mean Difference (IV, Random, 95% CI)	-0.40 [-0.90, 0.10]
3.16 QoL - change in physical function	4		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
3.16.1 Up to 3 months	4	324	Std. Mean Difference (IV, Random, 95% CI)	0.51 [0.08, 0.95]
3.16.2 4 to 6 months	1	32	Std. Mean Difference (IV, Random, 95% CI)	0.08 [-0.62, 0.77]
3.17 QoL - change in mental function	4		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
3.17.1 Up to 3 months	4	316	Std. Mean Difference (IV, Random, 95% CI)	0.29 [-0.25, 0.83]
3.17.2 4 to 6 months	1	32	Std. Mean Difference (IV, Random, 95% CI)	0.27 [-0.42, 0.97]
3.18 QoL - change in social function	3		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
3.18.1 up to 3 months	3	214	Std. Mean Difference (IV, Random, 95% CI)	0.06 [-0.33, 0.45]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
3.18.2 4 to 6 months	1	32	Std. Mean Difference (IV, Random, 95% CI)	0.87 [0.14, 1.60]
3.19 QoL - change in cognitive function	2		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
3.19.1 Up to 3 months	2	137	Std. Mean Difference (IV, Random, 95% CI)	0.11 [-0.23, 0.45]
3.19.2 4 to 6 months	1	32	Std. Mean Difference (IV, Random, 95% CI)	0.40 [-0.30, 1.10]
3.20 QoL - change in pain	3		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
3.20.1 Up to 3 months	3	219	Std. Mean Difference (IV, Random, 95% CI)	-0.06 [-0.36, 0.23]
3.20.2 4 to 6 months	1	32	Std. Mean Difference (IV, Random, 95% CI)	0.12 [-0.57, 0.82]
3.21 QoL - change in energy/fatigue	3		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
3.21.1 Up to 3 months	3	218	Std. Mean Difference (IV, Random, 95% CI)	-0.16 [-0.84, 0.51]
3.21.2 4 to 6 months	1	32	Std. Mean Difference (IV, Random, 95% CI)	-0.31 [-1.01, 0.38]

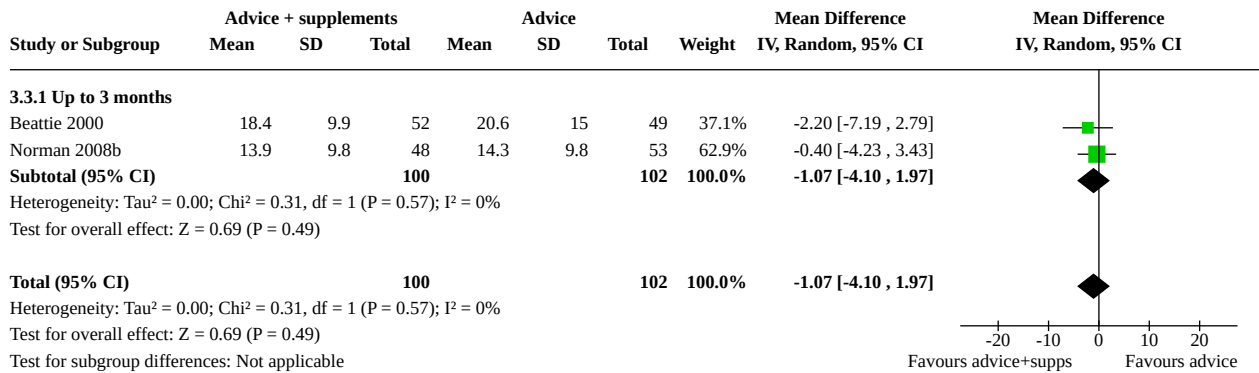
Analysis 3.1. Comparison 3: Dietary advice compared with dietary advice plus nutritional supplements, Outcome 1: Mortality



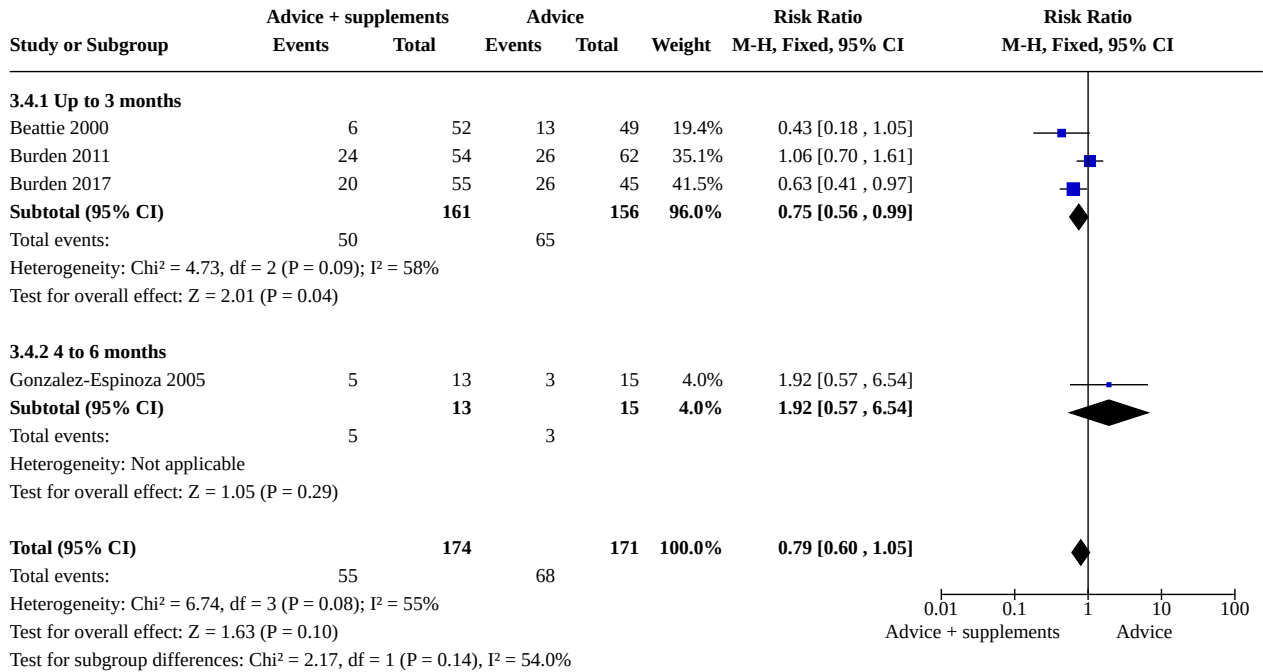
Analysis 3.2. Comparison 3: Dietary advice compared with dietary advice plus nutritional supplements, Outcome 2: Number of people admitted or readmitted to hospital



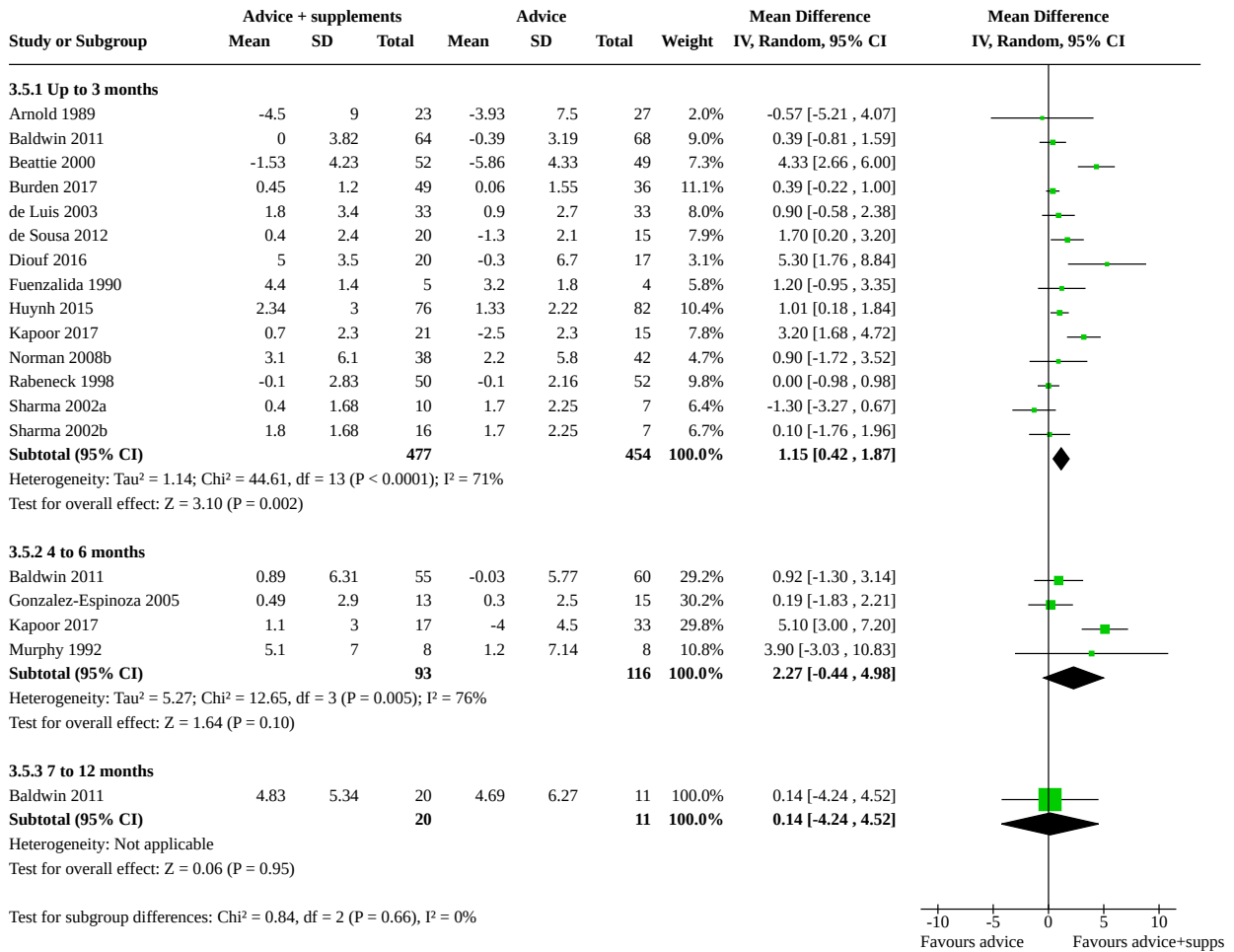
Analysis 3.3. Comparison 3: Dietary advice compared with dietary advice plus nutritional supplements, Outcome 3: Length of hospital stay (days)



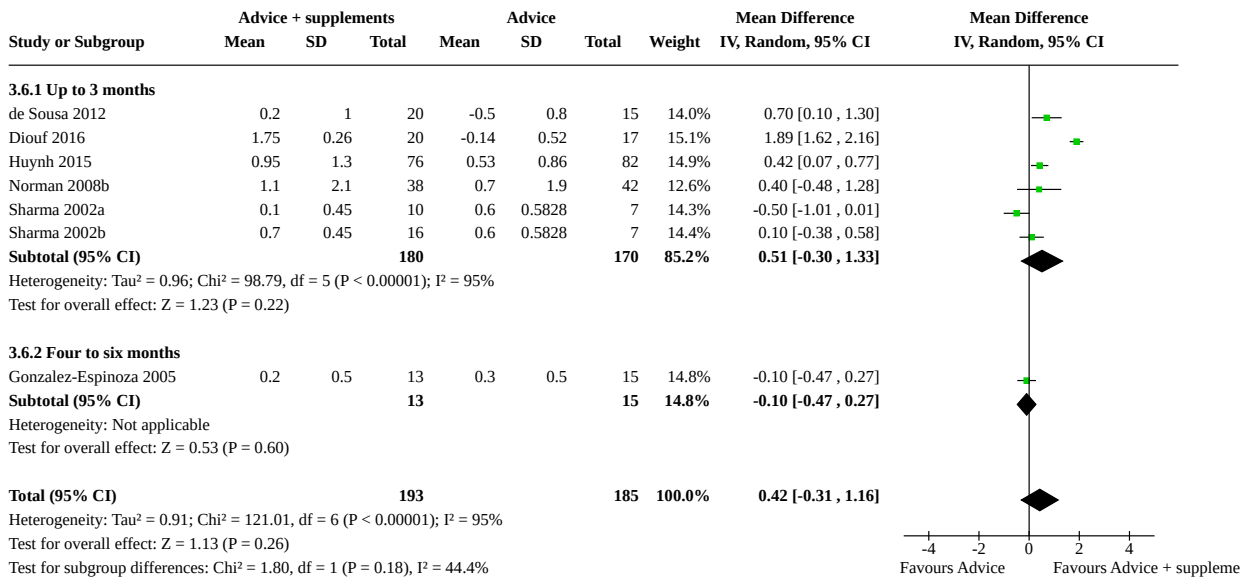
Analysis 3.4. Comparison 3: Dietary advice compared with dietary advice plus nutritional supplements, Outcome 4: Complications



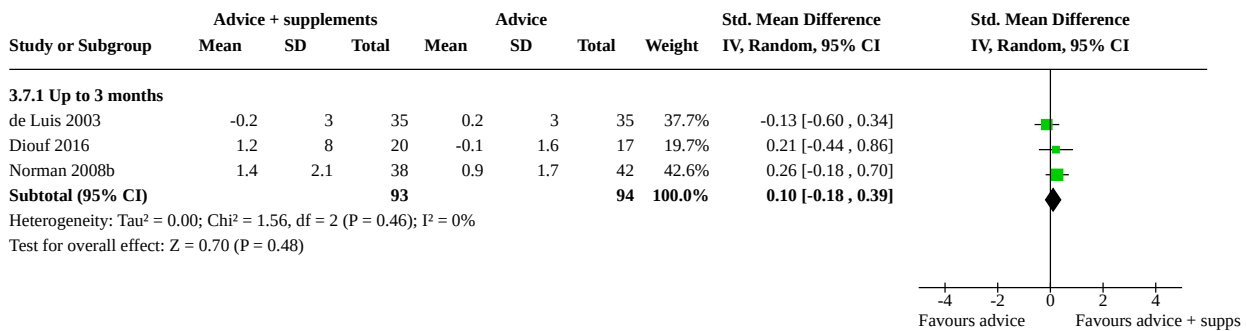
Analysis 3.5. Comparison 3: Dietary advice compared with dietary advice plus nutritional supplements, Outcome 5: Change in weight (kg)



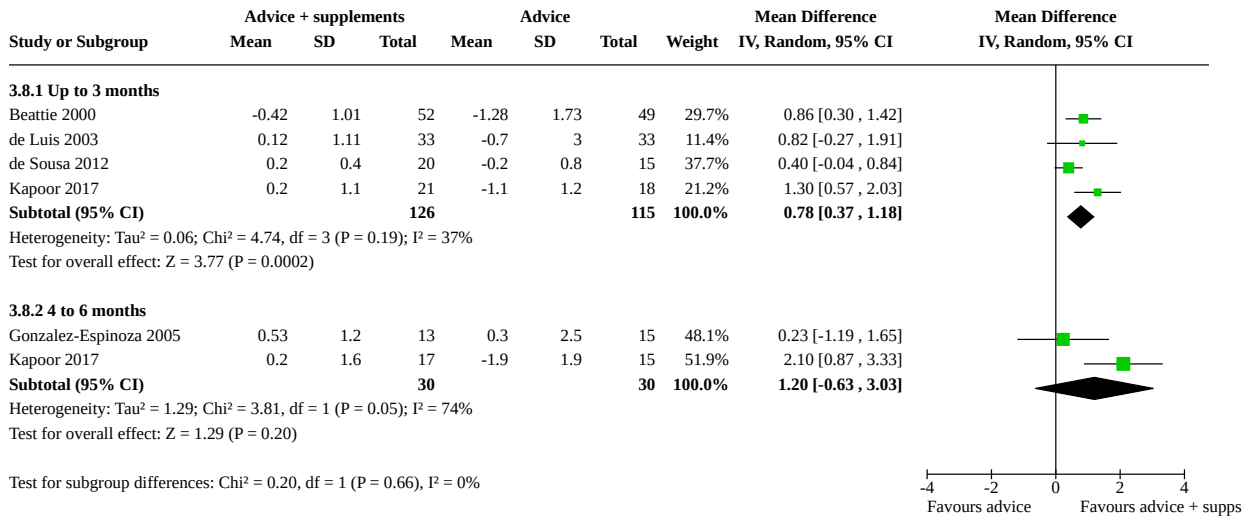
Analysis 3.6. Comparison 3: Dietary advice compared with dietary advice plus nutritional supplements, Outcome 6: Change in BMI (kg/m²)



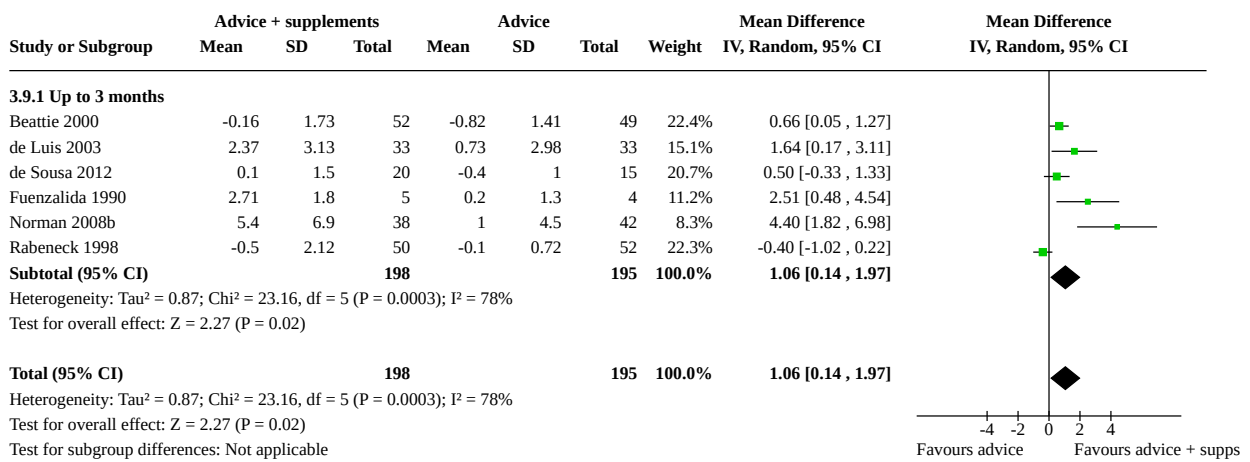
Analysis 3.7. Comparison 3: Dietary advice compared with dietary advice plus nutritional supplements, Outcome 7: Change in fat free mass (kg)



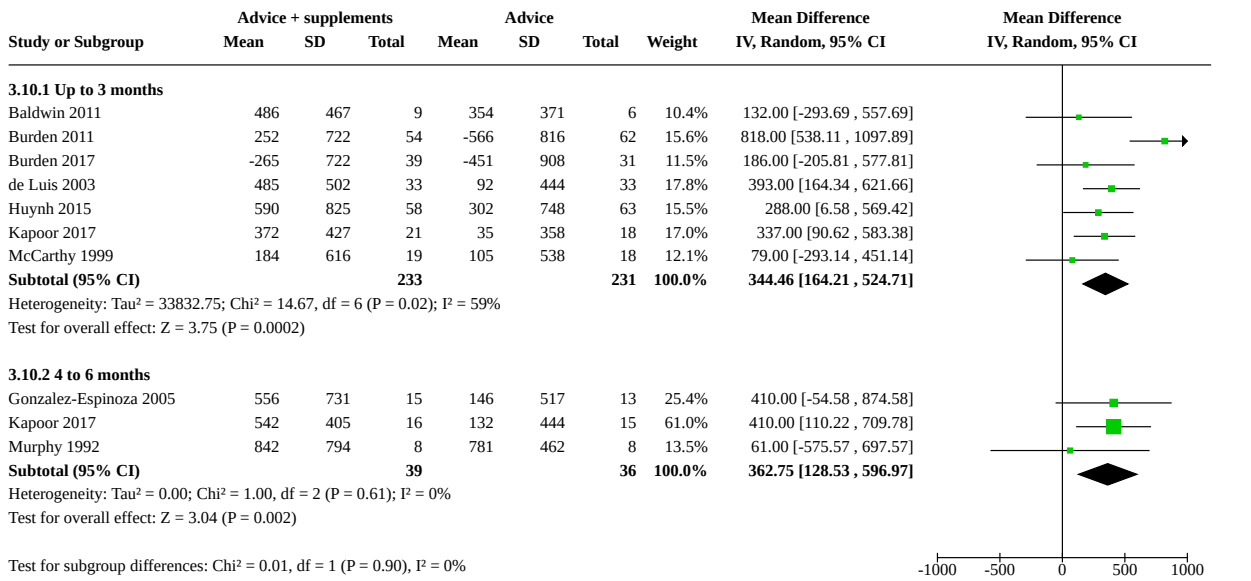
Analysis 3.8. Comparison 3: Dietary advice compared with dietary advice plus nutritional supplements, Outcome 8: Change in mid-arm muscle circumference (cm)



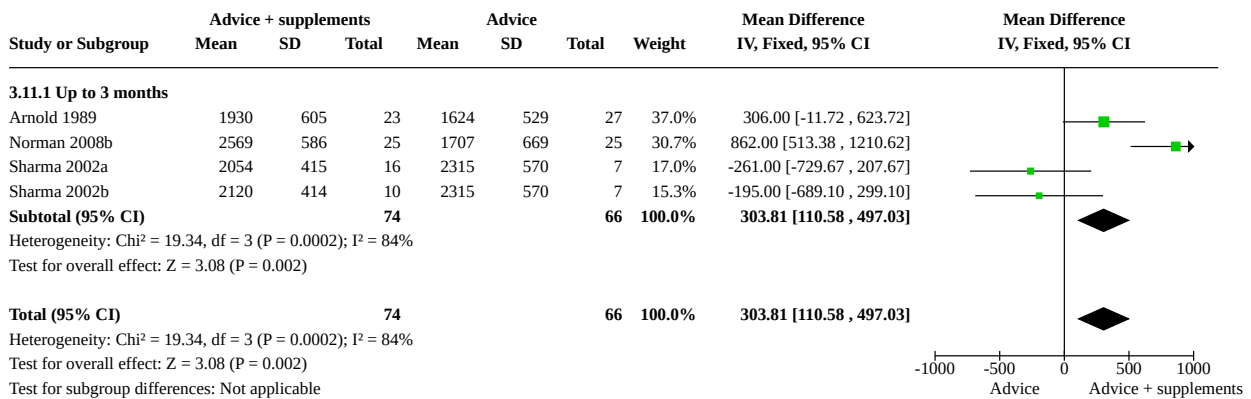
Analysis 3.9. Comparison 3: Dietary advice compared with dietary advice plus nutritional supplements, Outcome 9: Change in triceps skinfold thickness (mm)



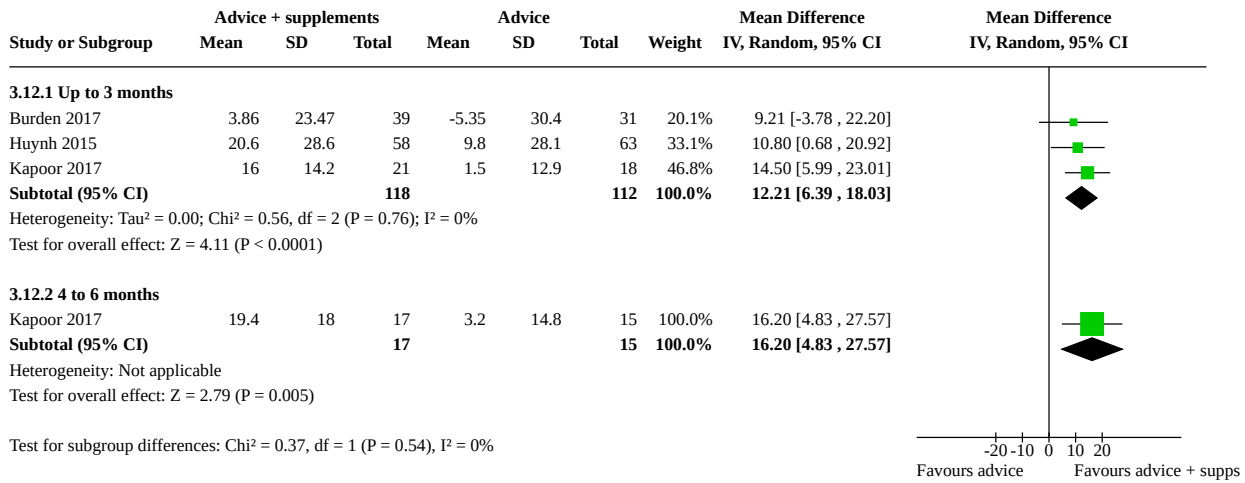
Analysis 3.10. Comparison 3: Dietary advice compared with dietary advice plus nutritional supplements, Outcome 10: Change in energy intake (kcal)



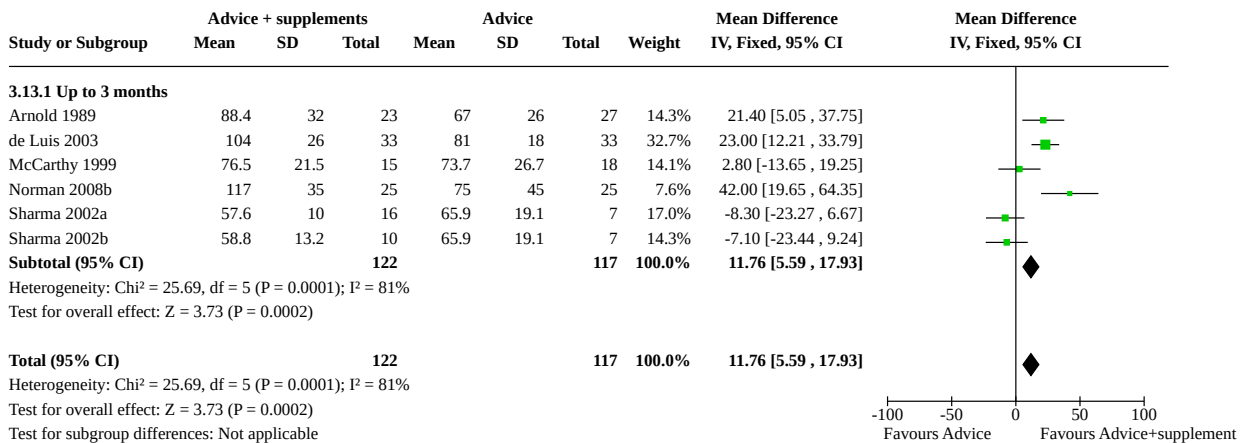
Analysis 3.11. Comparison 3: Dietary advice compared with dietary advice plus nutritional supplements, Outcome 11: Final energy intake (kcal/day)



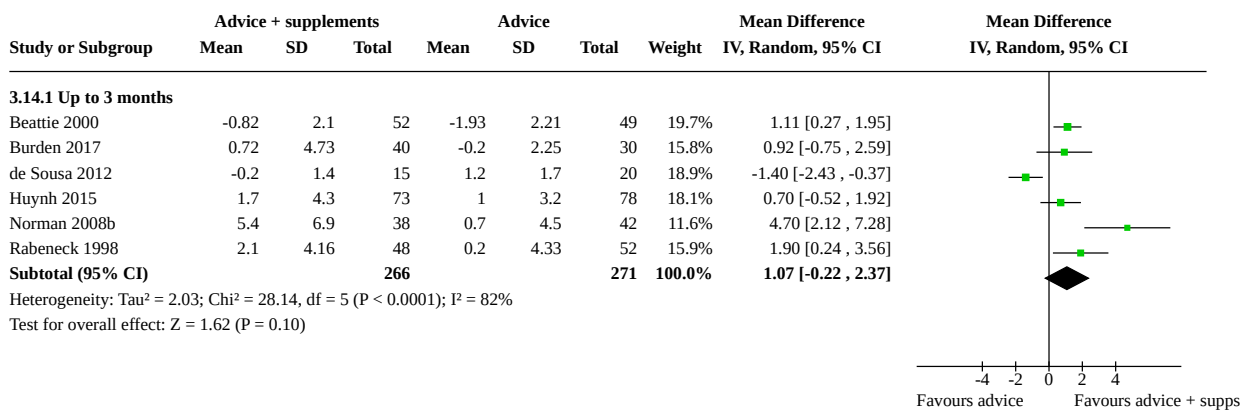
Analysis 3.12. Comparison 3: Dietary advice compared with dietary advice plus nutritional supplements, Outcome 12: Change in protein intake (g)



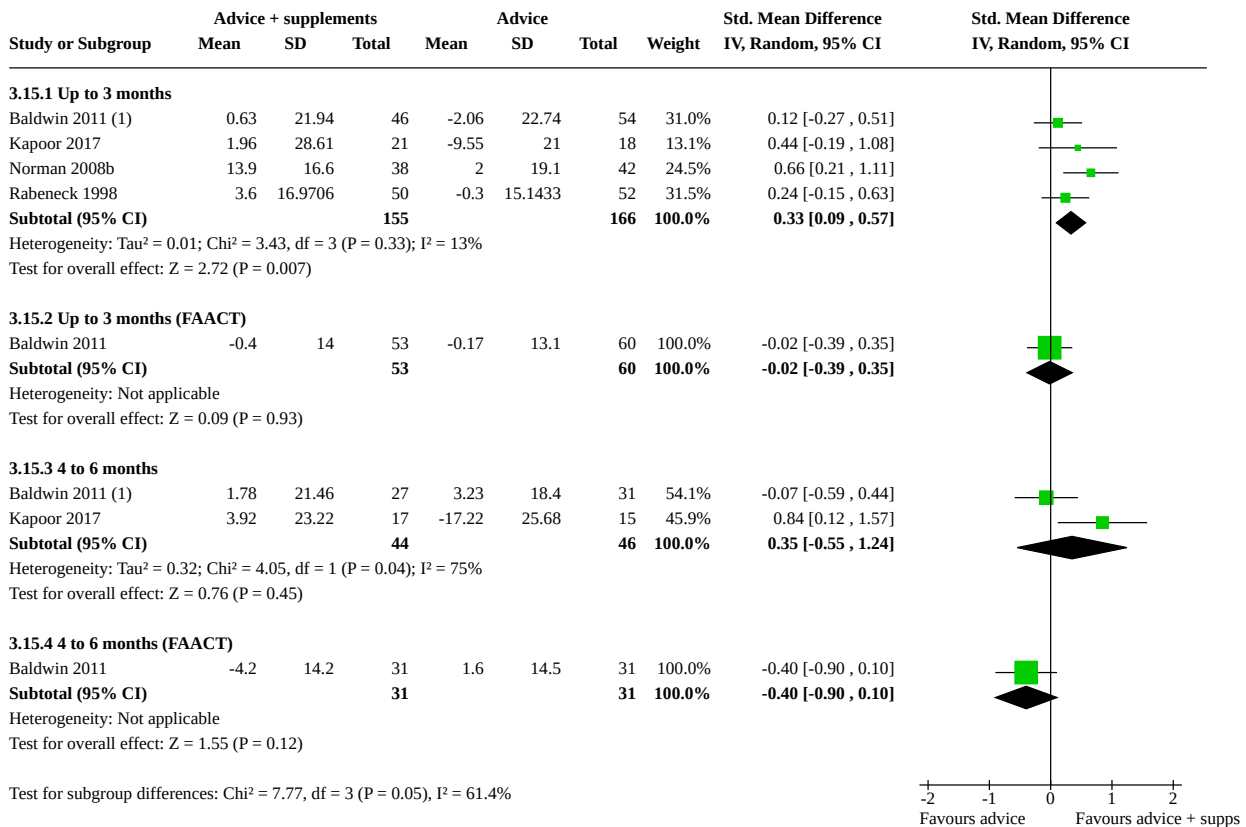
Analysis 3.13. Comparison 3: Dietary advice compared with dietary advice plus nutritional supplements, Outcome 13: Final protein intake (g/day)



Analysis 3.14. Comparison 3: Dietary advice compared with dietary advice plus nutritional supplements, Outcome 14: Change in grip strength (kg force)



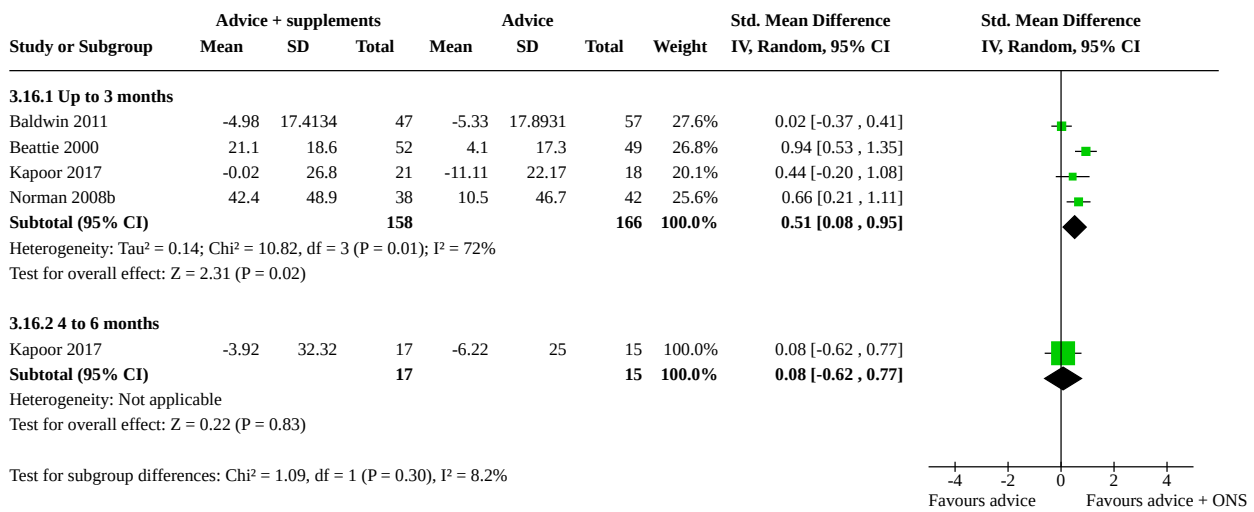
Analysis 3.15. Comparison 3: Dietary advice compared with dietary advice plus nutritional supplements, Outcome 15: Change in global QoL



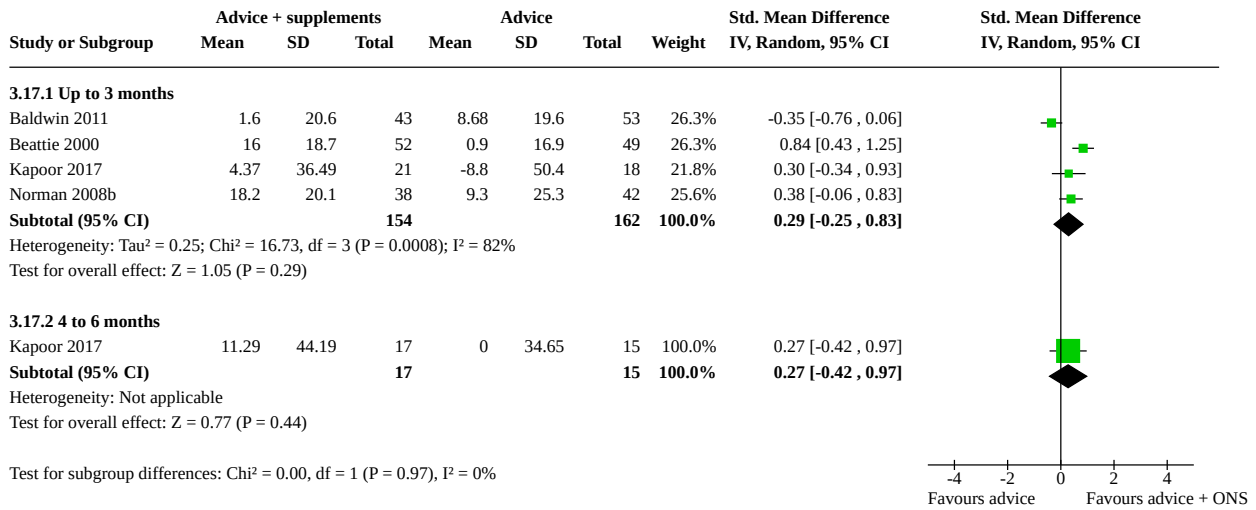
Footnotes

(1) EORTC

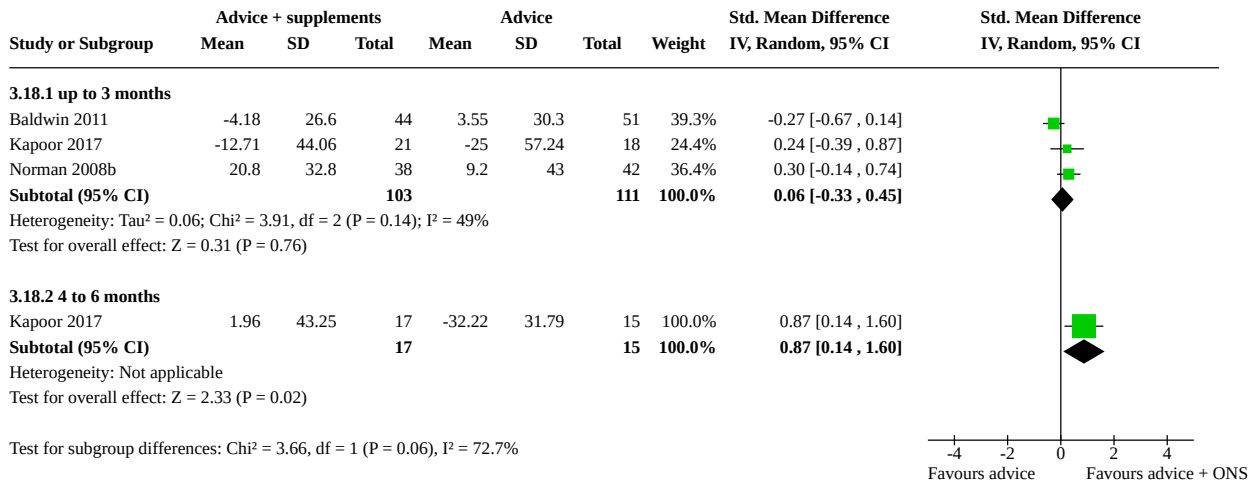
Analysis 3.16. Comparison 3: Dietary advice compared with dietary advice plus nutritional supplements, Outcome 16: QoL - change in physical function



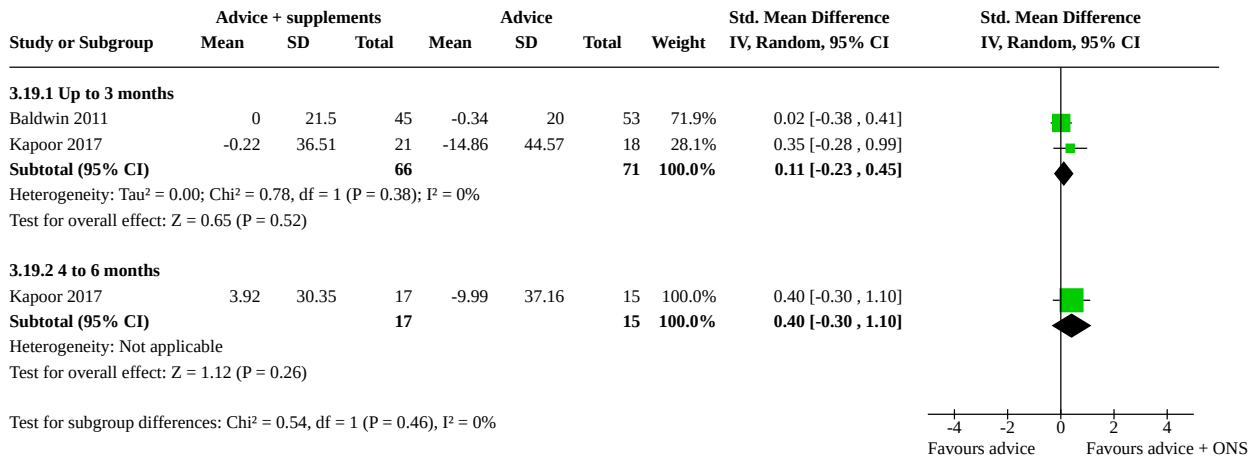
Analysis 3.17. Comparison 3: Dietary advice compared with dietary advice plus nutritional supplements, Outcome 17: QoL - change in mental function



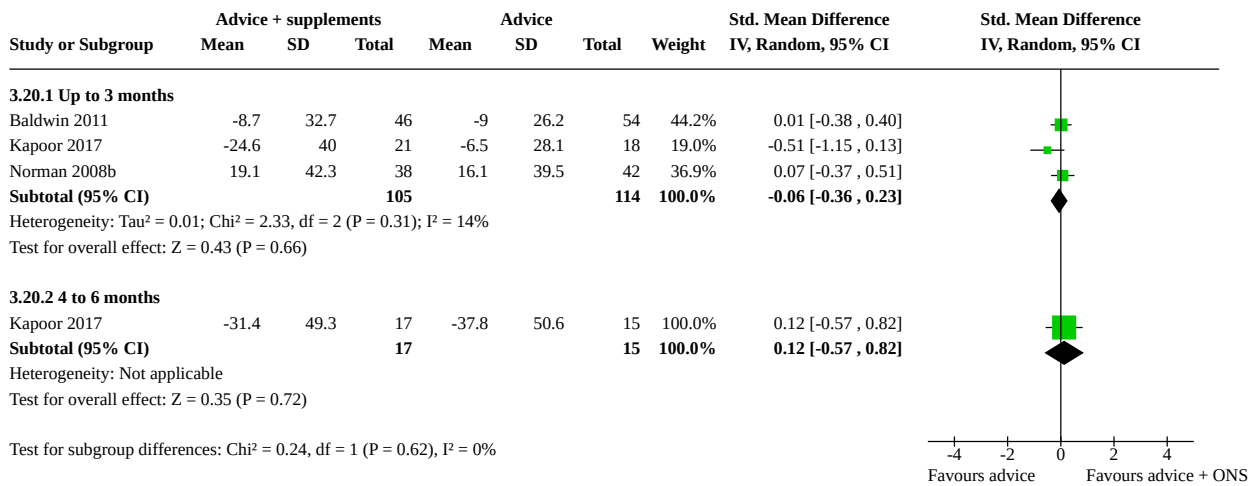
Analysis 3.18. Comparison 3: Dietary advice compared with dietary advice plus nutritional supplements, Outcome 18: QoL - change in social function



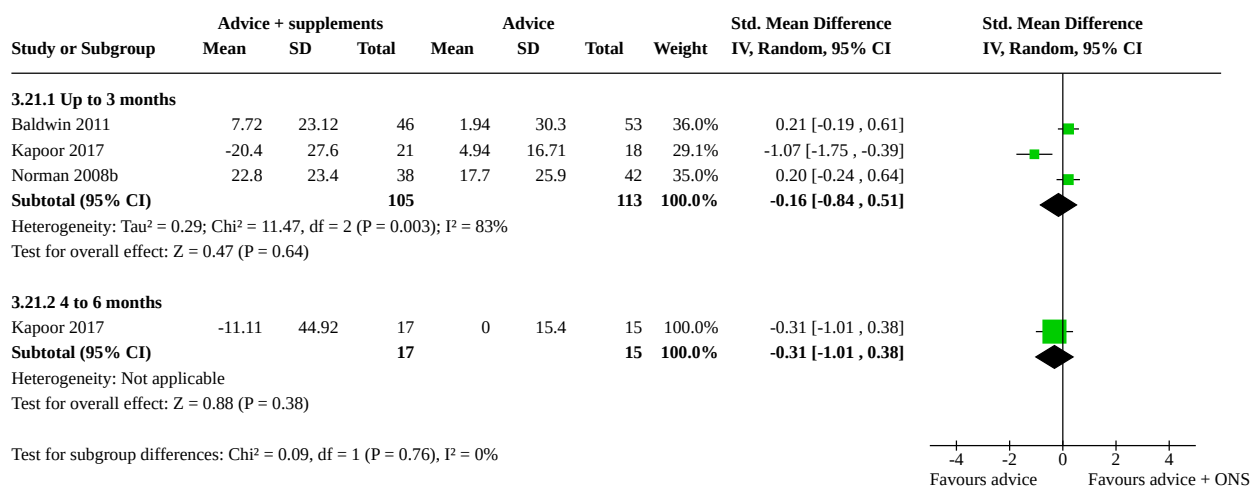
Analysis 3.19. Comparison 3: Dietary advice compared with dietary advice plus nutritional supplements, Outcome 19: QoL - change in cognitive function



Analysis 3.20. Comparison 3: Dietary advice compared with dietary advice plus nutritional supplements, Outcome 20: QoL - change in pain



Analysis 3.21. Comparison 3: Dietary advice compared with dietary advice plus nutritional supplements, Outcome 21: QoL - change in energy/fatigue



Comparison 4. Dietary advice plus supplements if required compared with no advice

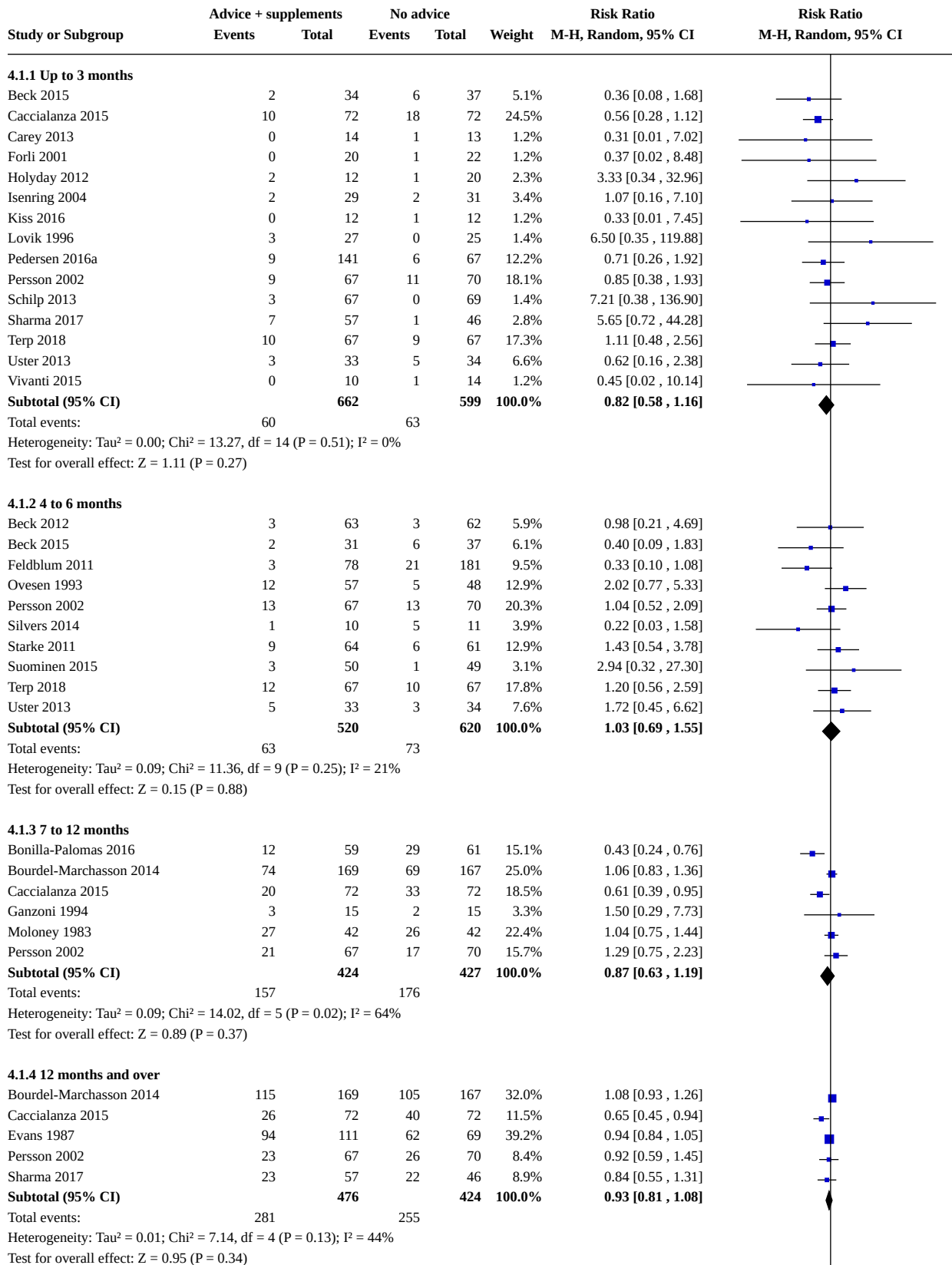
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
4.1 Mortality	26		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
4.1.1 Up to 3 months	15	1261	Risk Ratio (M-H, Random, 95% CI)	0.82 [0.58, 1.16]
4.1.2 4 to 6 months	10	1140	Risk Ratio (M-H, Random, 95% CI)	1.03 [0.69, 1.55]
4.1.3 7 to 12 months	6	851	Risk Ratio (M-H, Random, 95% CI)	0.87 [0.63, 1.19]
4.1.4 12 months and over	5	900	Risk Ratio (M-H, Random, 95% CI)	0.93 [0.81, 1.08]
4.2 Number of people admitted or readmitted to hospital	10		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
4.2.1 Up to 3 months	7	673	Risk Ratio (M-H, Random, 95% CI)	0.83 [0.59, 1.15]
4.2.2 4 to 6 months	5	456	Risk Ratio (M-H, Random, 95% CI)	0.79 [0.58, 1.09]
4.2.3 7 to 12 months	2	456	Risk Ratio (M-H, Random, 95% CI)	0.52 [0.18, 1.55]
4.3 Length of hospital stay (days)	3		Mean Difference (IV, Random, 95% CI)	Subtotals only
4.3.1 Up to 3 months	3	400	Mean Difference (IV, Random, 95% CI)	-0.12 [-2.48, 2.25]
4.4 Complications	3	616	Risk Ratio (M-H, Random, 95% CI)	0.68 [0.40, 1.18]
4.4.1 Up to 3 months	2	280	Risk Ratio (M-H, Random, 95% CI)	0.56 [0.22, 1.46]
4.4.2 7 to 12 months	1	336	Risk Ratio (M-H, Random, 95% CI)	0.88 [0.35, 2.22]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
4.5 Change in weight (kg)	24		Mean Difference (IV, Random, 95% CI)	Subtotals only
4.5.1 Up to 3 months	17	1192	Mean Difference (IV, Random, 95% CI)	1.25 [0.73, 1.76]
4.5.2 4 to 6 months	10	976	Mean Difference (IV, Random, 95% CI)	0.58 [-0.30, 1.45]
4.5.3 7 to 12 months	2	107	Mean Difference (IV, Random, 95% CI)	0.94 [-0.35, 2.23]
4.5.4 12 months and over	2	77	Mean Difference (IV, Random, 95% CI)	2.17 [-1.20, 5.54]
4.6 Change in BMI (kg/m²)	3		Mean Difference (IV, Random, 95% CI)	Subtotals only
4.6.1 Up to 3 months	2	130	Mean Difference (IV, Random, 95% CI)	0.72 [0.06, 1.37]
4.6.2 4 to 6 months	1	27	Mean Difference (IV, Random, 95% CI)	0.80 [-1.12, 2.72]
4.6.3 7 to 12 months	1	78	Mean Difference (IV, Random, 95% CI)	-0.10 [-0.61, 0.41]
4.7 Final BMI (kg/m²)	2		Mean Difference (IV, Random, 95% CI)	Subtotals only
4.7.1 Up to 3 months	2	169	Mean Difference (IV, Random, 95% CI)	1.19 [0.18, 2.20]
4.8 Change in fat free mass (kg)	4		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
4.8.1 Up to 3 months	4	262	Mean Difference (IV, Fixed, 95% CI)	0.82 [0.35, 1.29]
4.8.2 4 to 6 months	2	184	Mean Difference (IV, Fixed, 95% CI)	0.15 [-0.52, 0.82]
4.9 Change in mid-arm circumference (cm)	2	130	Mean Difference (IV, Random, 95% CI)	0.19 [-0.47, 0.85]
4.9.1 Up to 3 months	1	103	Mean Difference (IV, Random, 95% CI)	0.13 [-0.68, 0.94]
4.9.2 4 to 6 months	1	27	Mean Difference (IV, Random, 95% CI)	0.30 [-0.84, 1.44]
4.10 Change in mid-arm muscle circumference (cm)	2	247	Mean Difference (IV, Random, 95% CI)	0.18 [-0.54, 0.90]
4.10.1 Up to 3 months	1	103	Mean Difference (IV, Random, 95% CI)	-0.14 [-0.71, 0.43]
4.10.2 7 to 12 months	1	144	Mean Difference (IV, Random, 95% CI)	0.60 [-0.17, 1.37]
4.11 Change in triceps skinfold thickness (mm)	3	235	Mean Difference (IV, Random, 95% CI)	0.67 [-0.34, 1.69]
4.11.1 Up to 3 months	1	103	Mean Difference (IV, Random, 95% CI)	0.89 [-1.15, 2.93]
4.11.2 4 to 6 months	2	132	Mean Difference (IV, Random, 95% CI)	0.60 [-0.57, 1.77]
4.12 Change in energy intake (kcal)	8		Mean Difference (IV, Random, 95% CI)	Subtotals only

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
4.12.1 Up to 3 months	8	645	Mean Difference (IV, Random, 95% CI)	147.01 [21.55, 272.47]
4.12.2 4 to 6 months	3	290	Mean Difference (IV, Random, 95% CI)	50.31 [-154.15, 254.76]
4.13 Final energy intake (kcal)	3		Mean Difference (IV, Random, 95% CI)	Subtotals only
4.13.1 Up to 3 months	3	327	Mean Difference (IV, Random, 95% CI)	215.17 [-55.09, 485.43]
4.13.2 4 to 6 months	2	195	Mean Difference (IV, Random, 95% CI)	-8.62 [-154.63, 137.39]
4.14 Change in protein intake (g)	8		Mean Difference (IV, Random, 95% CI)	Subtotals only
4.14.1 Up to 3 months	7	610	Mean Difference (IV, Random, 95% CI)	7.76 [0.47, 15.05]
4.14.2 4 to 6 months	3	290	Mean Difference (IV, Random, 95% CI)	3.10 [-7.41, 13.61]
4.14.3 7 to 12 months	1	78	Mean Difference (IV, Random, 95% CI)	5.60 [-3.00, 14.20]
4.15 Change in grip strength (kg force)	9		Mean Difference (IV, Random, 95% CI)	Subtotals only
4.15.1 Up to 3 months	9	801	Mean Difference (IV, Random, 95% CI)	0.18 [-0.36, 0.72]
4.15.2 4 to 6 months	3	214	Mean Difference (IV, Random, 95% CI)	0.28 [-1.02, 1.59]
4.16 Change in global QoL	9		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
4.16.1 Up to 3 months	7	389	Std. Mean Difference (IV, Random, 95% CI)	0.15 [-0.18, 0.48]
4.16.2 4 to 6 months	2	153	Std. Mean Difference (IV, Random, 95% CI)	0.04 [-0.28, 0.36]
4.16.3 7 to 12 months	1	78	Std. Mean Difference (IV, Random, 95% CI)	0.60 [0.14, 1.05]
4.17 Final global QoL	9	797	Std. Mean Difference (IV, Random, 95% CI)	0.36 [-0.06, 0.77]
4.17.1 Up to 3 months	8	526	Std. Mean Difference (IV, Random, 95% CI)	0.25 [-0.36, 0.86]
4.17.2 4 to 6 months	4	271	Std. Mean Difference (IV, Random, 95% CI)	0.43 [0.04, 0.81]
4.18 QoL - change in physical function	7		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
4.18.1 Up to 3 months	6	458	Std. Mean Difference (IV, Random, 95% CI)	0.02 [-0.22, 0.25]
4.18.2 4 to 6 months	2	147	Std. Mean Difference (IV, Random, 95% CI)	-0.08 [-0.40, 0.25]
4.18.3 7 to 12 months	1	144	Std. Mean Difference (IV, Random, 95% CI)	0.02 [-0.31, 0.35]
4.19 QoL - change in mental function	6		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
4.19.1 Up to 3 months	5	435	Std. Mean Difference (IV, Random, 95% CI)	0.29 [0.10, 0.48]
4.19.2 4 to 6 months	1	123	Std. Mean Difference (IV, Random, 95% CI)	0.42 [0.07, 0.78]
4.19.3 7 to 12 months	1	144	Std. Mean Difference (IV, Random, 95% CI)	0.46 [0.13, 0.79]
4.20 QoL - change in social function	2		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
4.20.1 Up to 3 months	2	156	Std. Mean Difference (IV, Random, 95% CI)	0.02 [-0.35, 0.40]
4.21 QoL - change in cognitive function	2		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
4.21.1 Up to 3 months	2	156	Std. Mean Difference (IV, Random, 95% CI)	0.35 [-0.23, 0.92]
4.22 QoL - change in pain	2		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
4.22.1 Up to 3 months	2	156	Std. Mean Difference (IV, Random, 95% CI)	-0.48 [-1.03, 0.07]
4.23 QoL - change in energy/fatigue	2		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
4.23.1 Up to 3 months	2	155	Std. Mean Difference (IV, Random, 95% CI)	-0.58 [-1.61, 0.46]

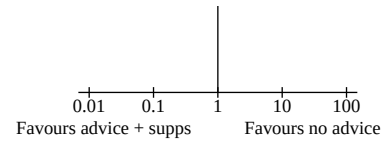
Analysis 4.1. Comparison 4: Dietary advice plus supplements if required compared with no advice, Outcome 1: Mortality



Analysis 4.1. (Continued)

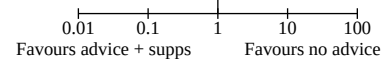
Heterogeneity: $Tau^2 = 0.01$; $Chi^2 = 7.14$, $df = 4$ ($P = 0.13$); $I^2 = 44\%$
Test for overall effect: $Z = 0.95$ ($P = 0.34$)

Test for subgroup differences: $Chi^2 = 0.90$, $df = 3$ ($P = 0.83$), $I^2 = 0\%$

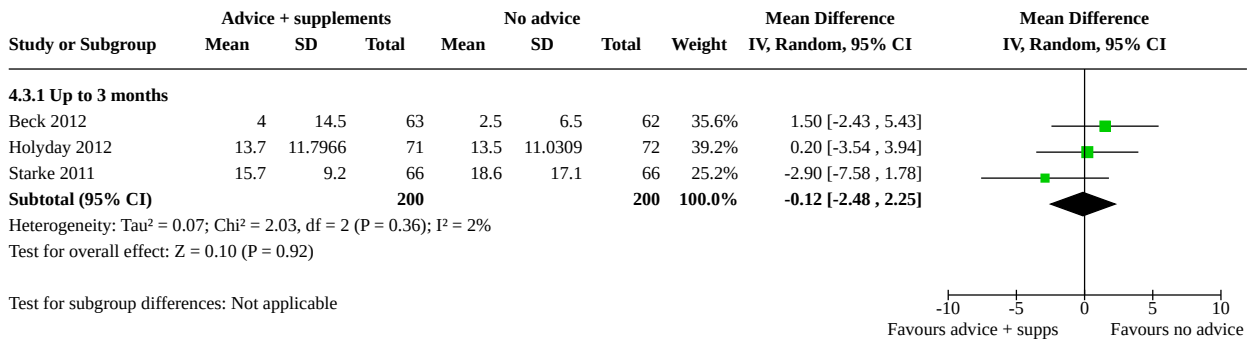


Analysis 4.2. Comparison 4: Dietary advice plus supplements if required compared with no advice, Outcome 2: Number of people admitted or readmitted to hospital

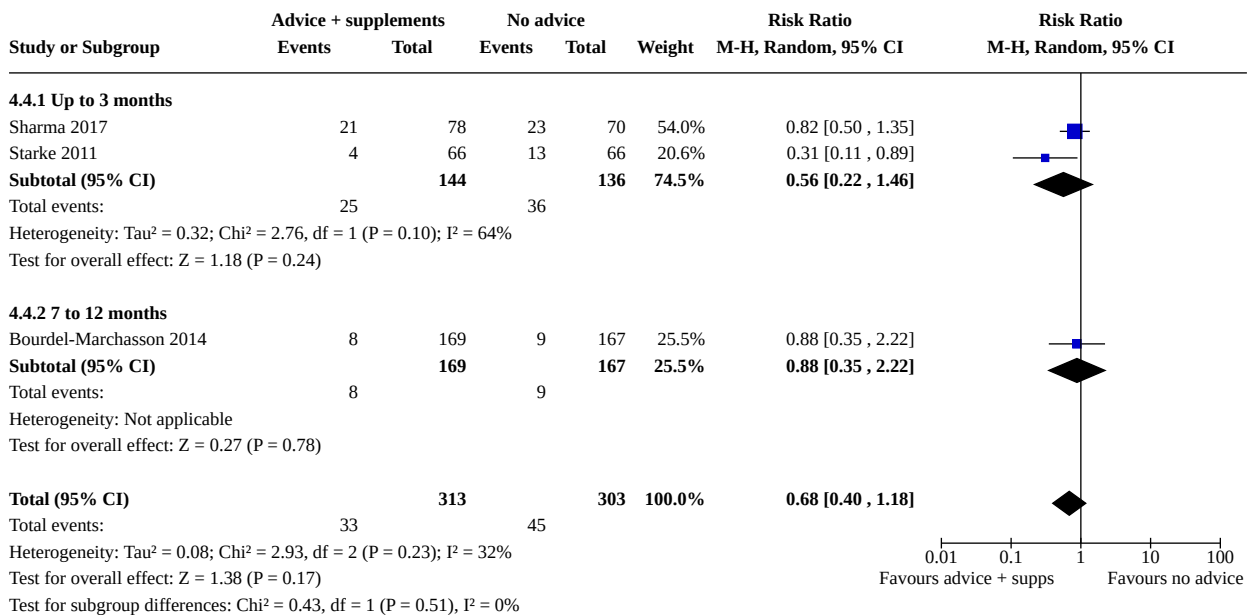
Study or Subgroup	Advice + supplements		No advice		Weight	Risk Ratio M-H, Random, 95% CI	Risk Ratio M-H, Random, 95% CI
	Events	Total	Events	Total			
4.2.1 Up to 3 months							
Holyday 2012	2	12	9	20	5.0%	0.37 [0.10, 1.44]	
Beck 2015	8	34	12	37	11.2%	0.73 [0.34, 1.56]	
Pedersen 2016a	13	73	13	33	13.4%	0.45 [0.24, 0.87]	
Pedersen 2016b	20	68	13	33	15.3%	0.75 [0.43, 1.31]	
Beck 2012	27	63	16	62	16.6%	1.66 [1.00, 2.76]	
Terp 2018	26	67	23	67	18.1%	1.13 [0.72, 1.77]	
Sharma 2017	26	57	29	47	20.4%	0.74 [0.51, 1.06]	
Subtotal (95% CI)		374		299	100.0%	0.83 [0.59, 1.15]	
Total events:	122		115				
Heterogeneity: $Tau^2 = 0.11$; $Chi^2 = 14.21$, $df = 6$ ($P = 0.03$); $I^2 = 58\%$ Test for overall effect: $Z = 1.12$ ($P = 0.26$)							
4.2.2 4 to 6 months							
Holyday 2012	3	12	11	20	7.3%	0.45 [0.16, 1.31]	
Beck 2015	9	34	16	37	14.3%	0.61 [0.31, 1.20]	
Starke 2011	17	64	28	61	20.5%	0.58 [0.35, 0.94]	
Beck 2012	33	63	26	62	25.7%	1.25 [0.86, 1.82]	
Sharma 2017	37	57	35	46	32.2%	0.85 [0.66, 1.10]	
Subtotal (95% CI)		230		226	100.0%	0.79 [0.58, 1.09]	
Total events:	99		116				
Heterogeneity: $Tau^2 = 0.06$; $Chi^2 = 8.83$, $df = 4$ ($P = 0.07$); $I^2 = 55\%$ Test for overall effect: $Z = 1.45$ ($P = 0.15$)							
4.2.3 7 to 12 months							
Bonilla-Palomas 2016	6	59	22	61	43.9%	0.28 [0.12, 0.65]	
Bourdel-Marchasson 2014	48	169	56	167	56.1%	0.85 [0.61, 1.17]	
Subtotal (95% CI)		228		228	100.0%	0.52 [0.18, 1.55]	
Total events:	54		78				
Heterogeneity: $Tau^2 = 0.52$; $Chi^2 = 6.05$, $df = 1$ ($P = 0.01$); $I^2 = 83\%$ Test for overall effect: $Z = 1.17$ ($P = 0.24$)							
Test for subgroup differences: $Chi^2 = 0.62$, $df = 2$ ($P = 0.73$), $I^2 = 0\%$							



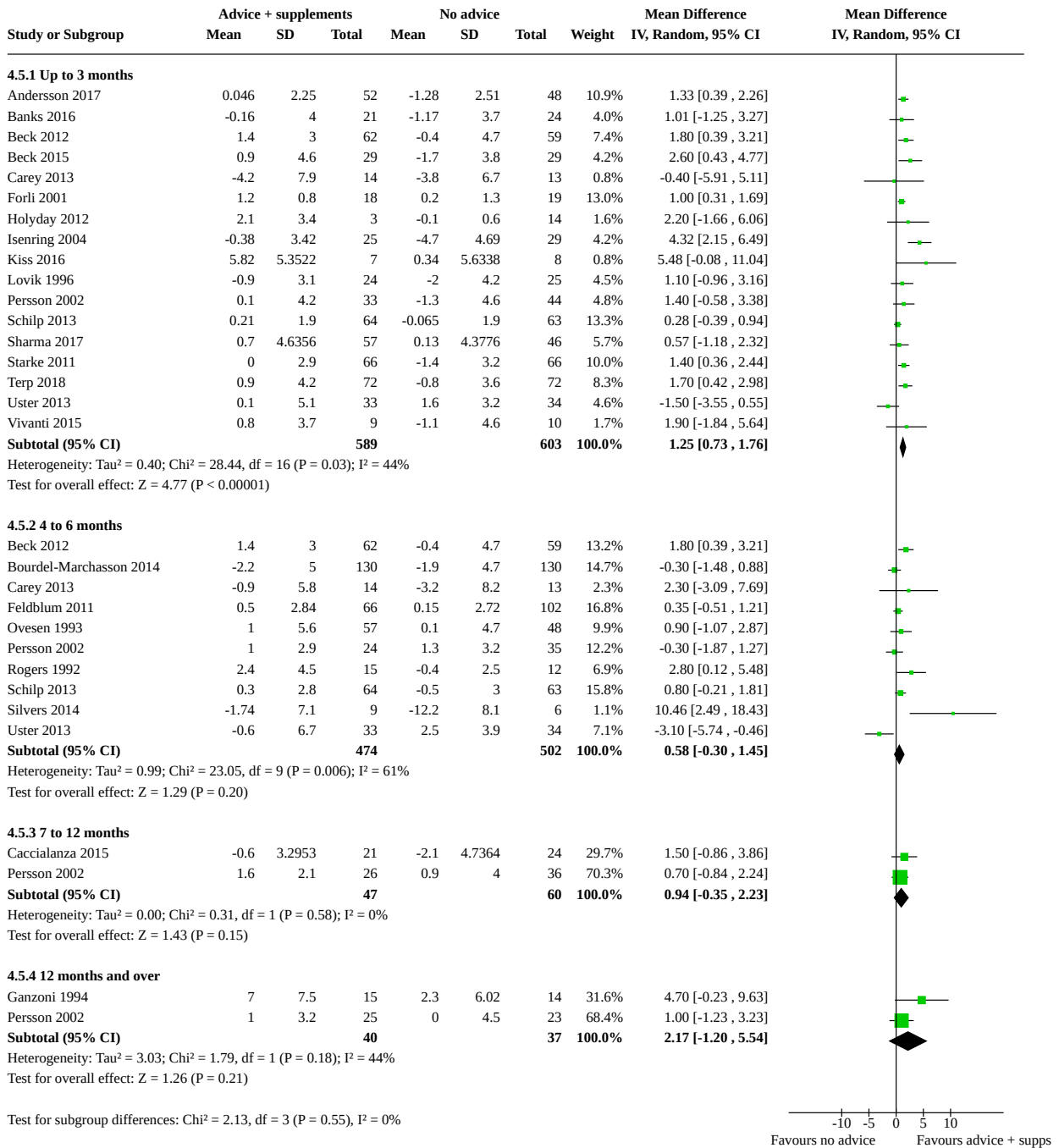
Analysis 4.3. Comparison 4: Dietary advice plus supplements if required compared with no advice, Outcome 3: Length of hospital stay (days)



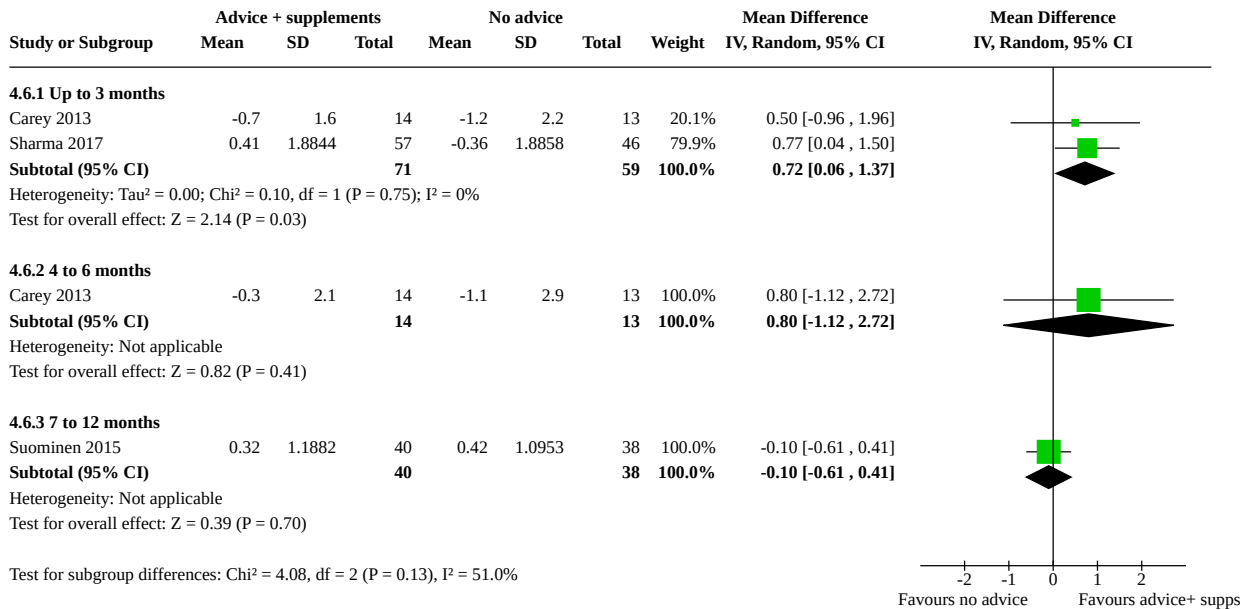
Analysis 4.4. Comparison 4: Dietary advice plus supplements if required compared with no advice, Outcome 4: Complications



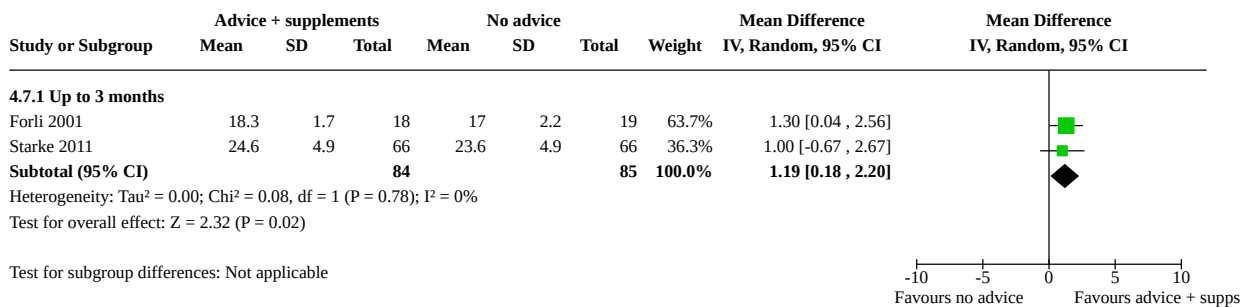
Analysis 4.5. Comparison 4: Dietary advice plus supplements if required compared with no advice, Outcome 5: Change in weight (kg)



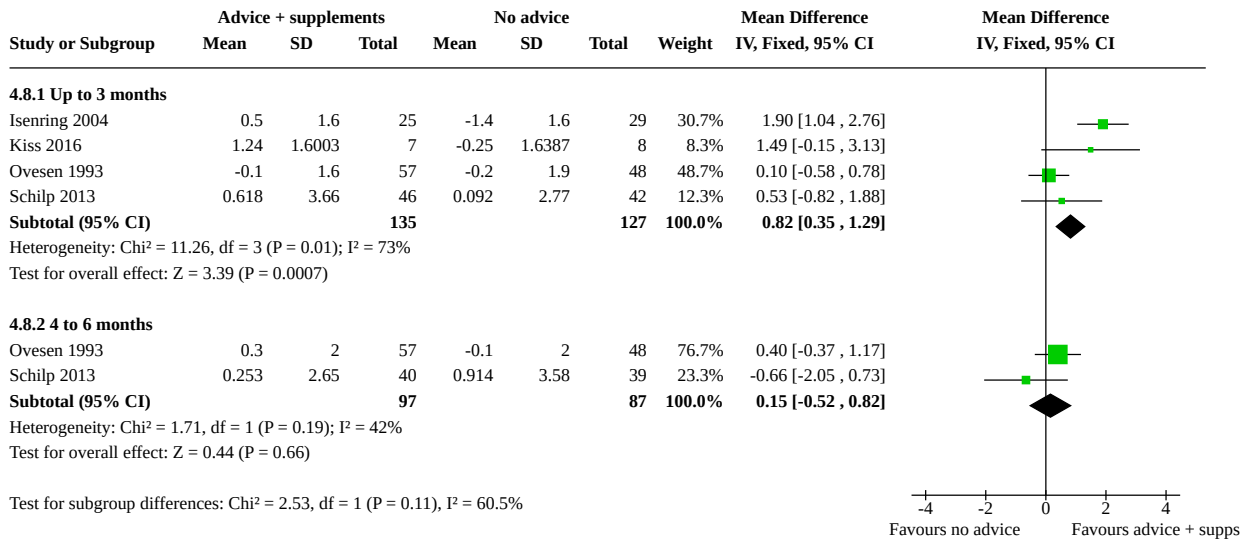
Analysis 4.6. Comparison 4: Dietary advice plus supplements if required compared with no advice, Outcome 6: Change in BMI (kg/m²)



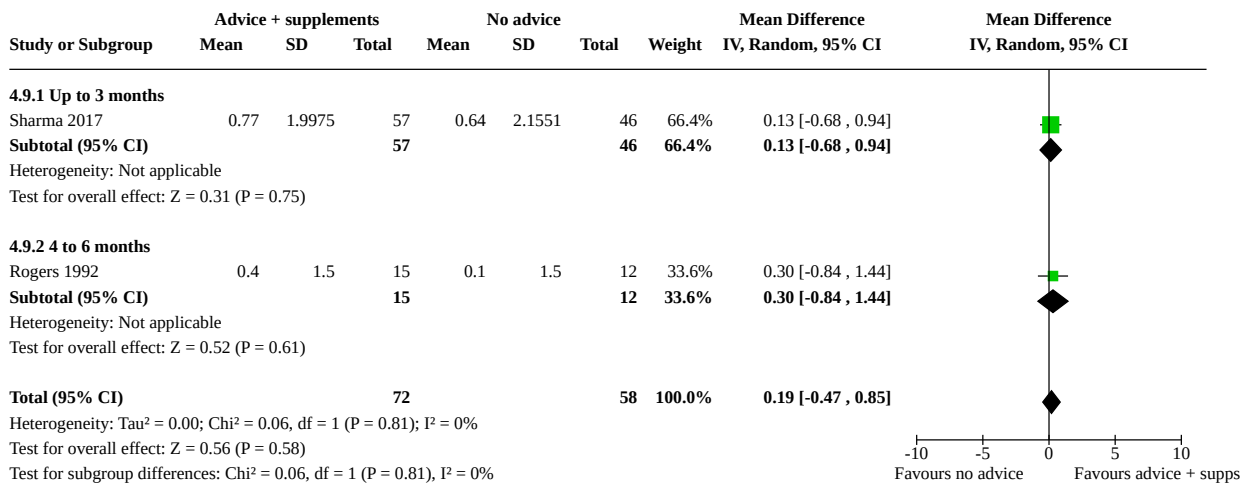
Analysis 4.7. Comparison 4: Dietary advice plus supplements if required compared with no advice, Outcome 7: Final BMI (kg/m²)



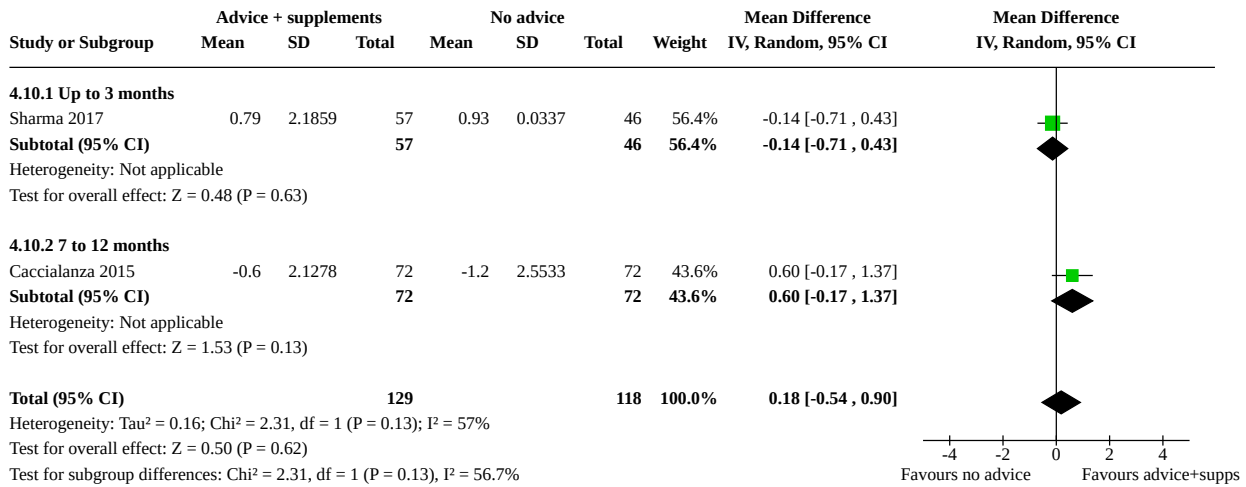
Analysis 4.8. Comparison 4: Dietary advice plus supplements if required compared with no advice, Outcome 8: Change in fat free mass (kg)



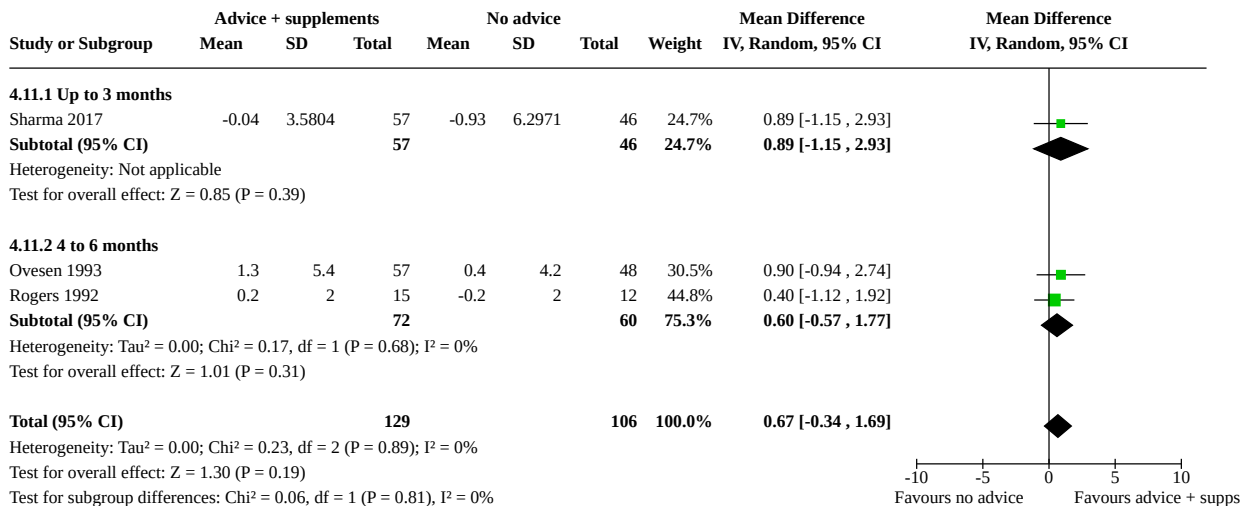
Analysis 4.9. Comparison 4: Dietary advice plus supplements if required compared with no advice, Outcome 9: Change in mid-arm circumference (cm)



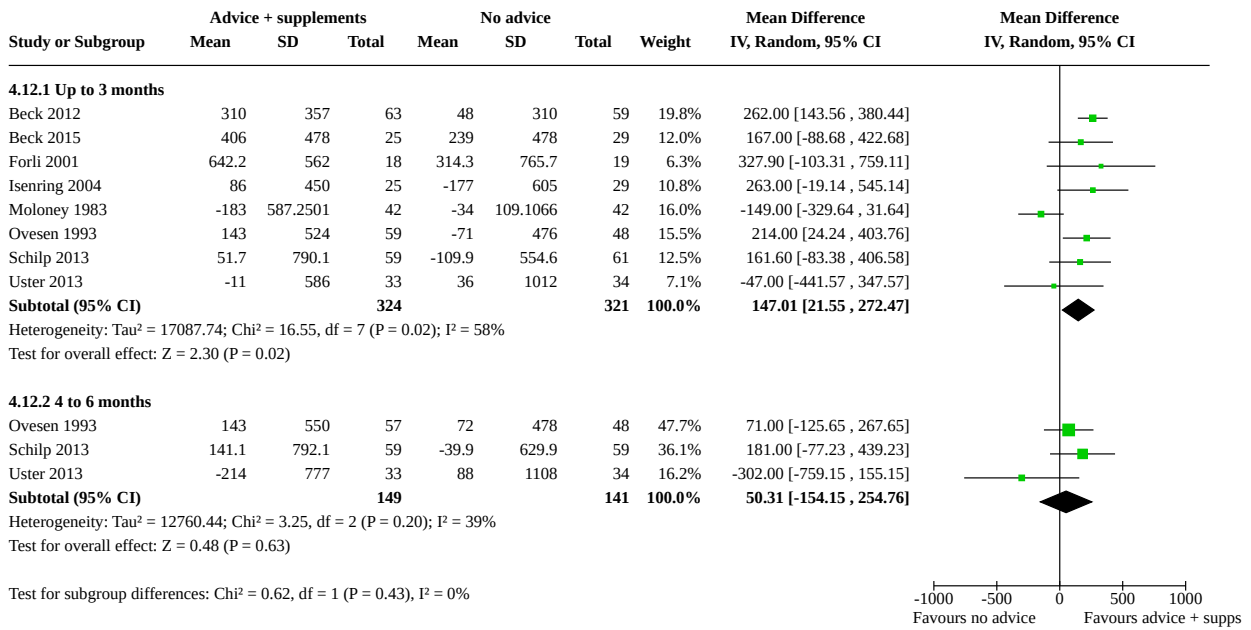
Analysis 4.10. Comparison 4: Dietary advice plus supplements if required compared with no advice, Outcome 10: Change in mid-arm muscle circumference (cm)



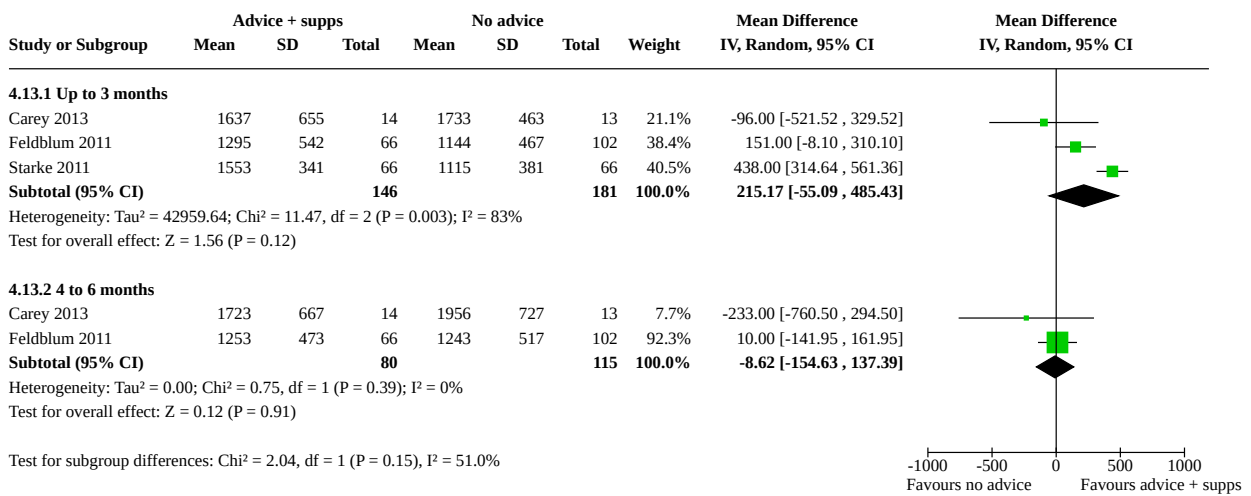
Analysis 4.11. Comparison 4: Dietary advice plus supplements if required compared with no advice, Outcome 11: Change in triceps skinfold thickness (mm)



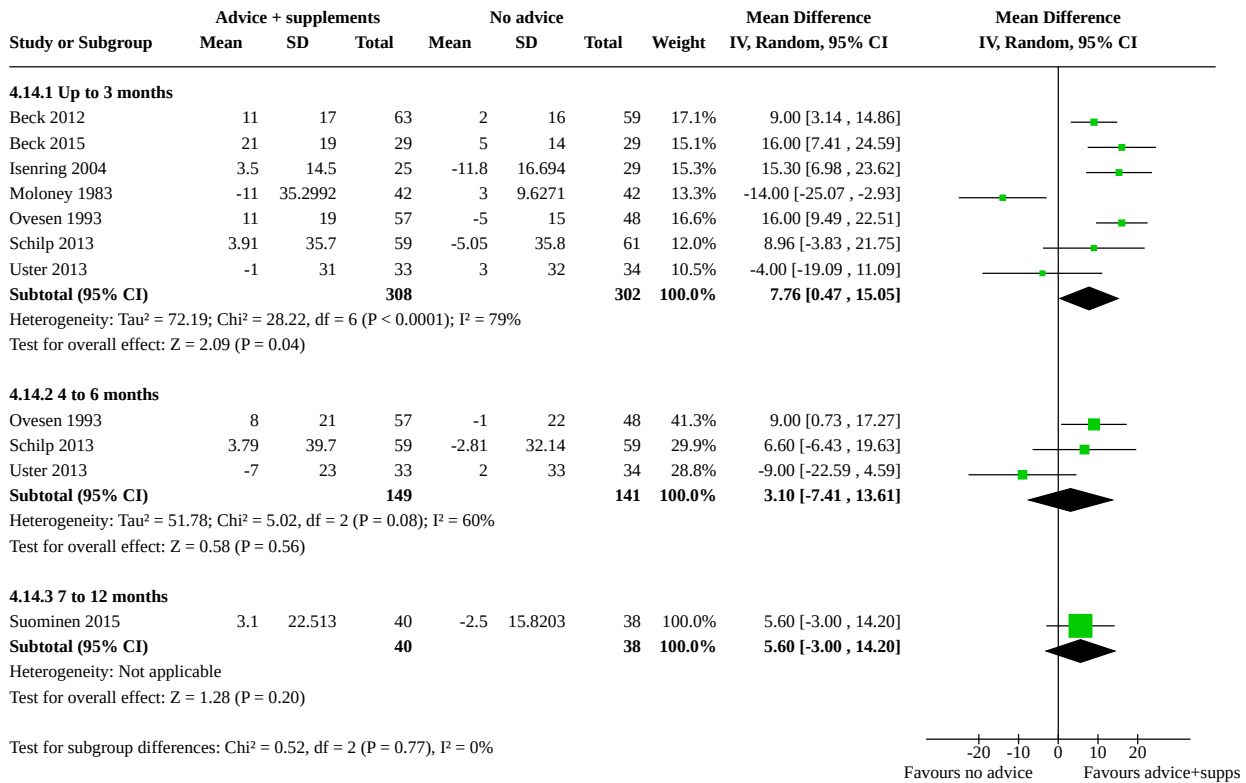
Analysis 4.12. Comparison 4: Dietary advice plus supplements if required compared with no advice, Outcome 12: Change in energy intake (kcal)



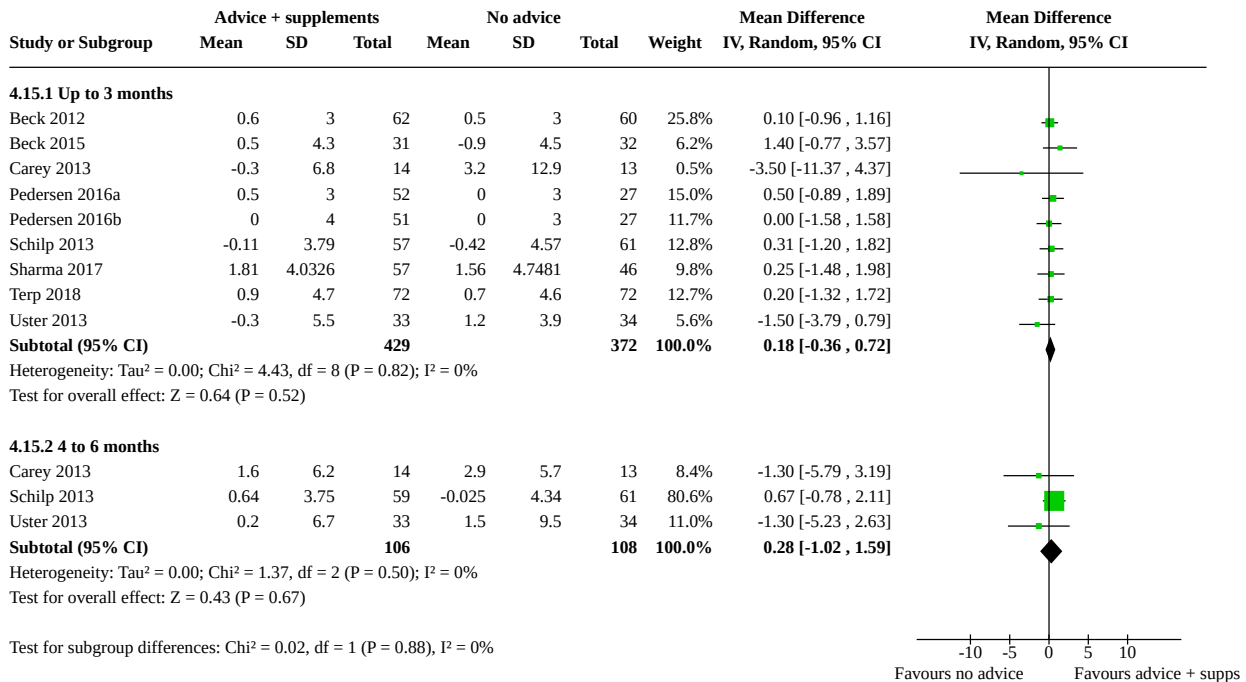
Analysis 4.13. Comparison 4: Dietary advice plus supplements if required compared with no advice, Outcome 13: Final energy intake (kcal)



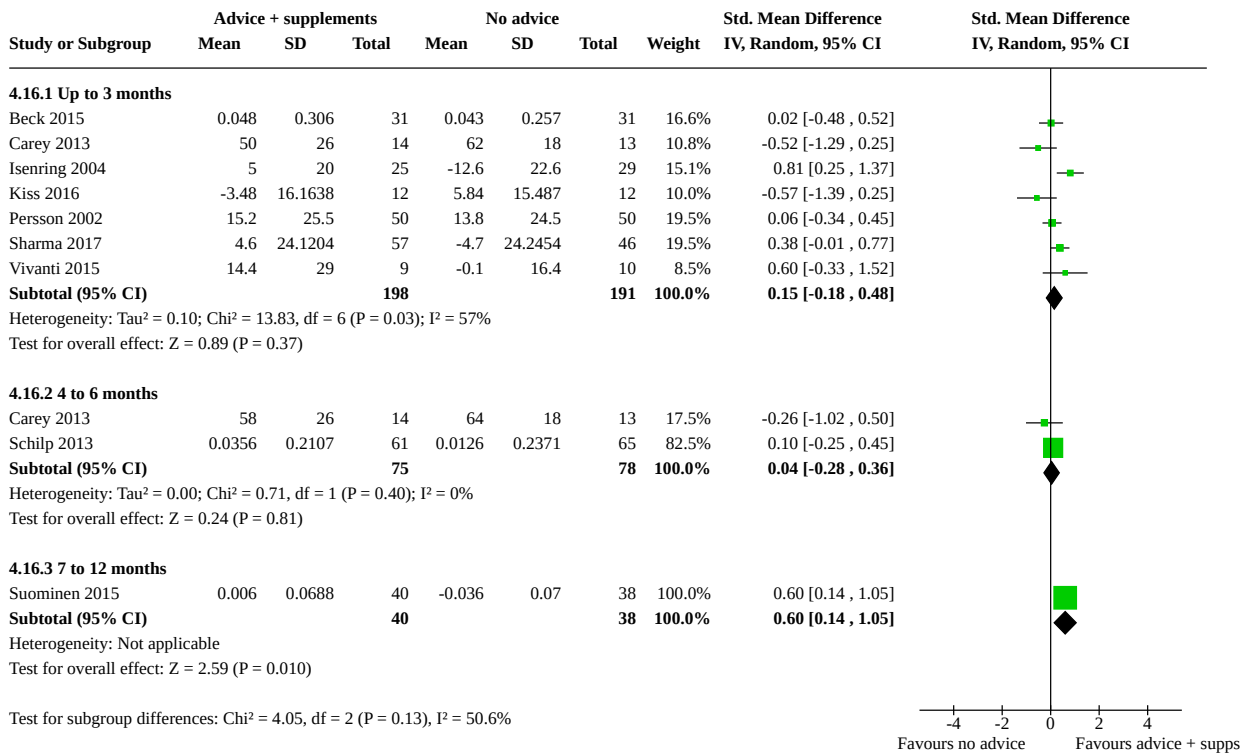
Analysis 4.14. Comparison 4: Dietary advice plus supplements if required compared with no advice, Outcome 14: Change in protein intake (g)



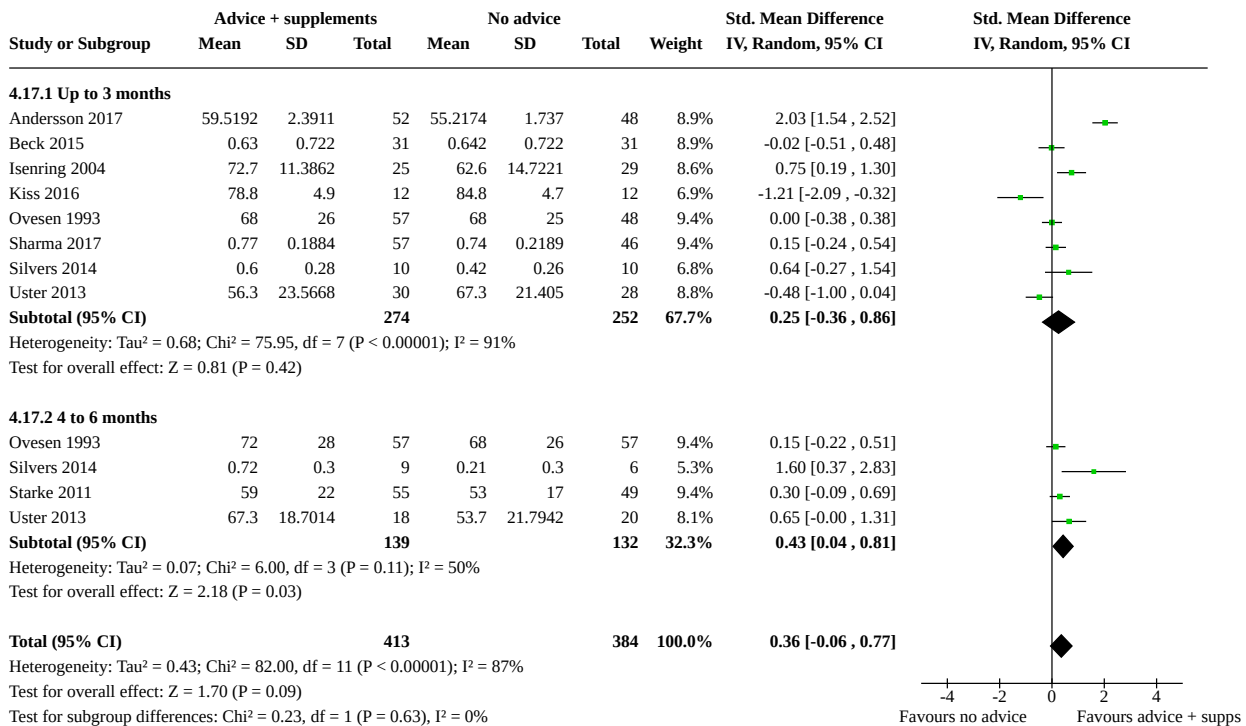
Analysis 4.15. Comparison 4: Dietary advice plus supplements if required compared with no advice, Outcome 15: Change in grip strength (kg force)



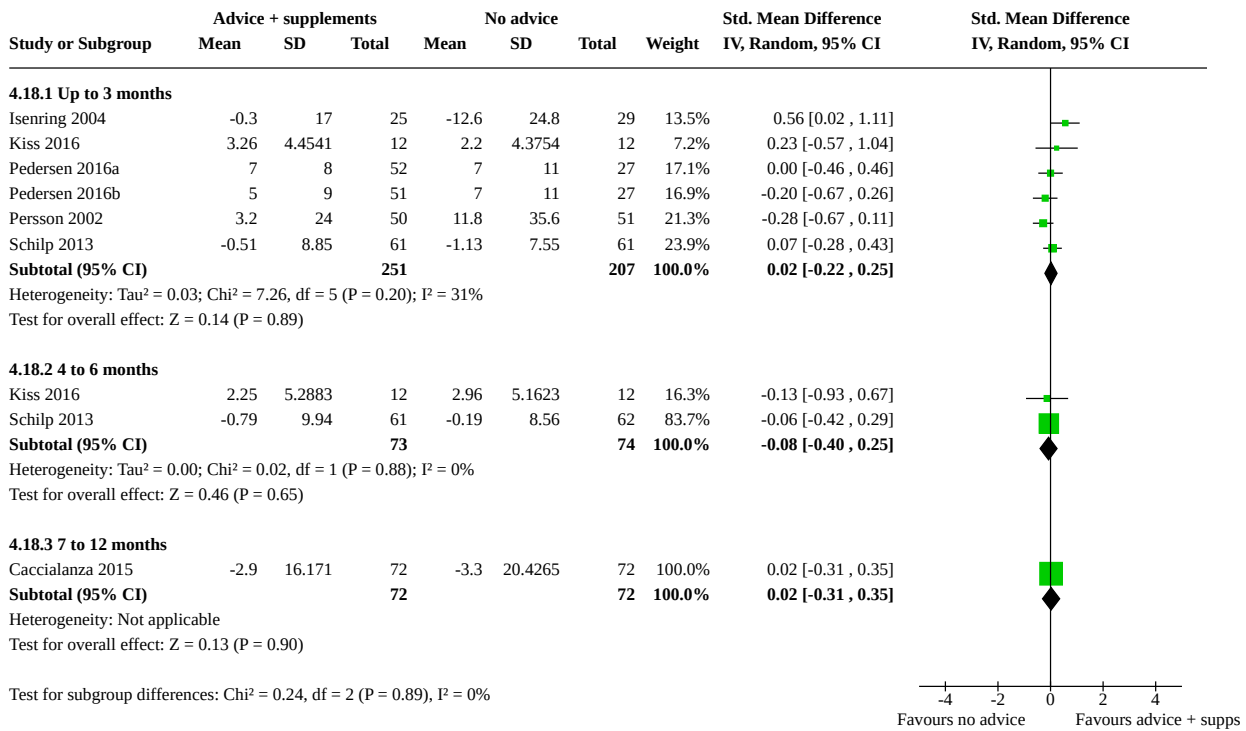
Analysis 4.16. Comparison 4: Dietary advice plus supplements if required compared with no advice, Outcome 16: Change in global QoL



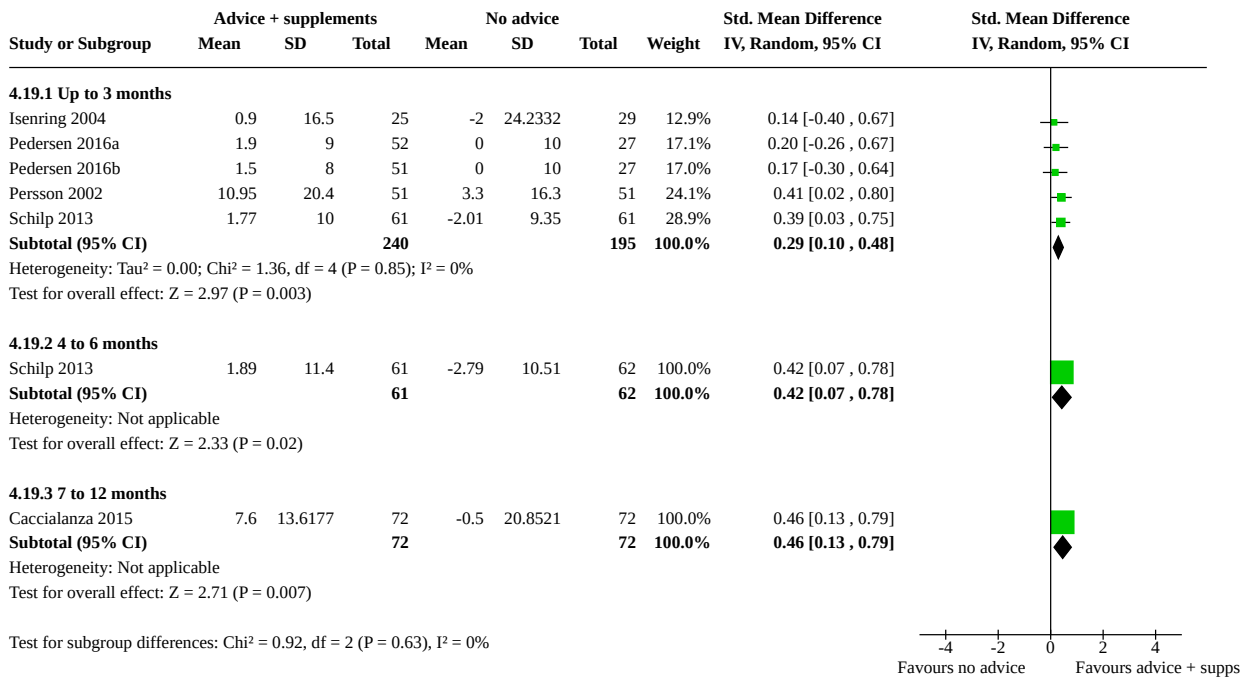
Analysis 4.17. Comparison 4: Dietary advice plus supplements if required compared with no advice, Outcome 17: Final global QoL



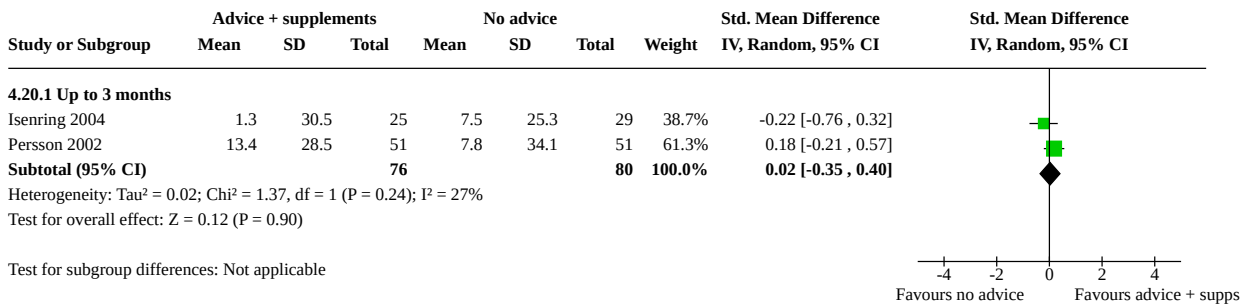
Analysis 4.18. Comparison 4: Dietary advice plus supplements if required compared with no advice, Outcome 18: QoL - change in physical function



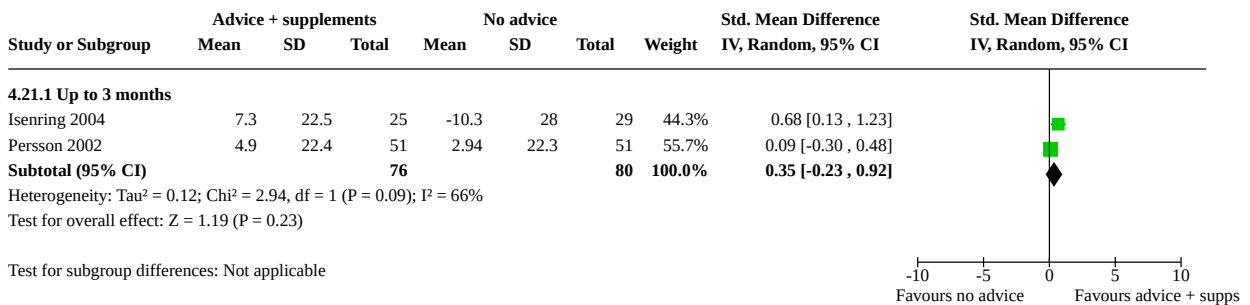
Analysis 4.19. Comparison 4: Dietary advice plus supplements if required compared with no advice, Outcome 19: QoL - change in mental function



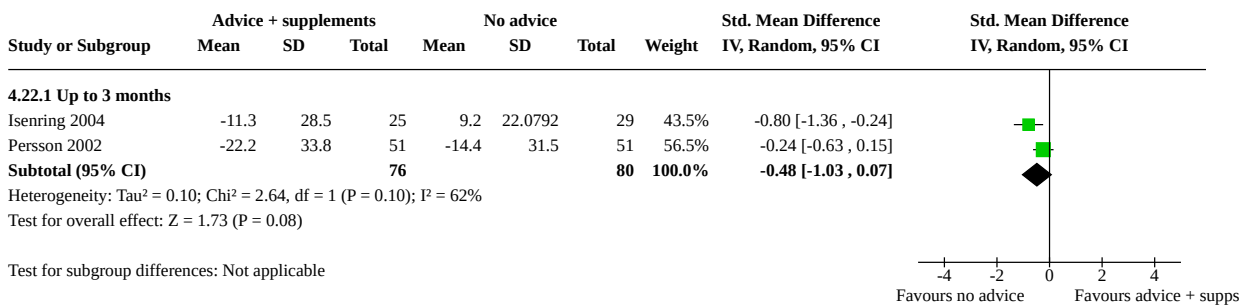
Analysis 4.20. Comparison 4: Dietary advice plus supplements if required compared with no advice, Outcome 20: QoL - change in social function



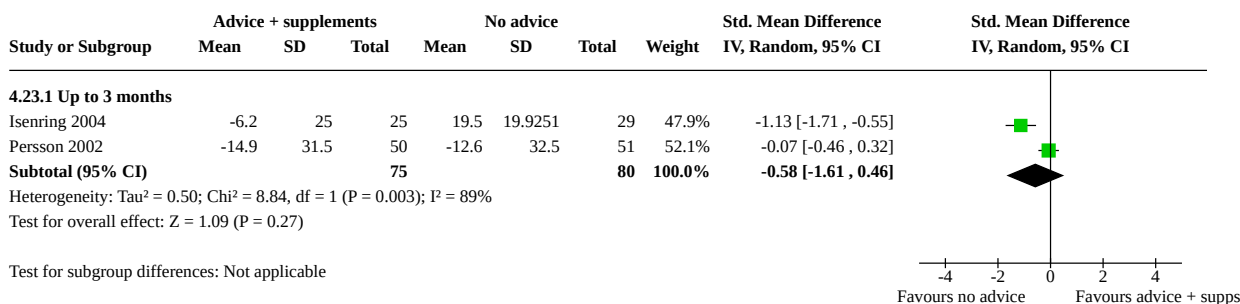
Analysis 4.21. Comparison 4: Dietary advice plus supplements if required compared with no advice, Outcome 21: QoL - change in cognitive function



Analysis 4.22. Comparison 4: Dietary advice plus supplements if required compared with no advice, Outcome 22: QoL - change in pain



Analysis 4.23. Comparison 4: Dietary advice plus supplements if required compared with no advice, Outcome 23: QoL - change in energy/fatigue



Comparison 5. Dietary advice plus supplements compared with no advice and no supplements

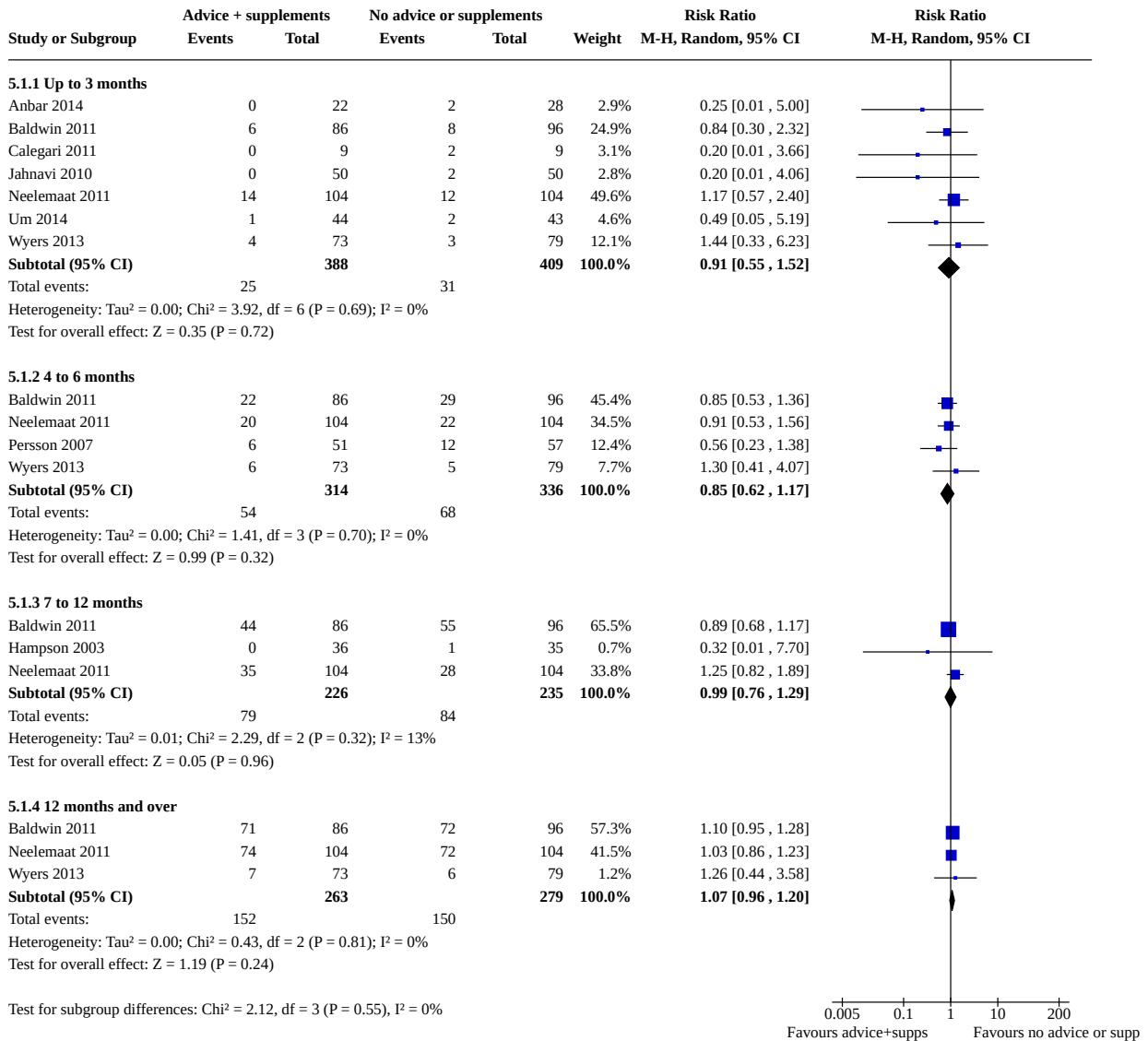
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
5.1 Mortality	9		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
5.1.1 Up to 3 months	7	797	Risk Ratio (M-H, Random, 95% CI)	0.91 [0.55, 1.52]
5.1.2 4 to 6 months	4	650	Risk Ratio (M-H, Random, 95% CI)	0.85 [0.62, 1.17]
5.1.3 7 to 12 months	3	461	Risk Ratio (M-H, Random, 95% CI)	0.99 [0.76, 1.29]
5.1.4 12 months and over	3	542	Risk Ratio (M-H, Random, 95% CI)	1.07 [0.96, 1.20]
5.2 Length of hospital stay (days)	3	405	Mean Difference (IV, Random, 95% CI)	-1.75 [-3.58, 0.08]
5.2.1 Up to 3 months	2	258	Mean Difference (IV, Random, 95% CI)	-1.81 [-3.65, 0.04]
5.2.2 4 to 6 months	1	147	Mean Difference (IV, Random, 95% CI)	1.10 [-12.46, 14.66]
5.3 Complications	1		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
5.3.1 Up to 3 months	1	50	Risk Ratio (M-H, Random, 95% CI)	0.42 [0.20, 0.89]
5.4 Change in weight (kg)	11		Mean Difference (IV, Random, 95% CI)	Subtotals only
5.4.1 Up to 3 months	8	620	Mean Difference (IV, Random, 95% CI)	1.08 [-0.17, 2.33]
5.4.2 4 to 6 months	5	450	Mean Difference (IV, Random, 95% CI)	1.88 [0.90, 2.87]
5.4.3 7 to 12 months	2	110	Mean Difference (IV, Random, 95% CI)	2.60 [1.42, 3.78]
5.5 Change in fat free mass	4		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
5.5.1 Up to 3 months	3	130	Std. Mean Difference (IV, Random, 95% CI)	0.26 [-0.09, 0.62]
5.5.2 4 to 6 months	1	26	Std. Mean Difference (IV, Random, 95% CI)	0.21 [-0.57, 0.99]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
5.5.3 7 to 12 months	1	71	Std. Mean Difference (IV, Random, 95% CI)	0.29 [-0.18, 0.75]
5.6 Change in BMI (kg/m²)	1		Mean Difference (IV, Random, 95% CI)	Subtotals only
5.6.1 Up to 3 months	1	137	Mean Difference (IV, Random, 95% CI)	0.66 [0.19, 1.13]
5.6.2 4 to 6 months	1	131	Mean Difference (IV, Random, 95% CI)	0.44 [-0.09, 0.98]
5.7 Final BMI (kg/m²)	4		Mean Difference (IV, Random, 95% CI)	Subtotals only
5.7.1 Up to 3 months	3	254	Mean Difference (IV, Random, 95% CI)	0.64 [-0.76, 2.04]
5.7.2 4 to 6 months	2	242	Mean Difference (IV, Random, 95% CI)	0.71 [-0.45, 1.87]
5.8 Change in energy intake (kcal)	7		Mean Difference (IV, Random, 95% CI)	Subtotals only
5.8.1 Up to 3 months	5	347	Mean Difference (IV, Random, 95% CI)	319.78 [152.83, 486.73]
5.8.2 4 to 6 months	3	244	Mean Difference (IV, Random, 95% CI)	239.83 [38.74, 440.92]
5.8.3 7 to 12 months	1	63	Mean Difference (IV, Random, 95% CI)	464.00 [270.07, 657.93]
5.9 Final energy intake (kcal)	3		Mean Difference (IV, Random, 95% CI)	Subtotals only
5.9.1 Up to 3 months	3	152	Mean Difference (IV, Random, 95% CI)	399.11 [123.00, 675.22]
5.10 Change in protein intake	2		Mean Difference (IV, Random, 95% CI)	Subtotals only
5.10.1 Up to 3 months	2	285	Mean Difference (IV, Random, 95% CI)	7.14 [-0.46, 14.74]
5.10.2 4 to 6 months	1	135	Mean Difference (IV, Random, 95% CI)	0.92 [-8.93, 10.76]
5.11 Final protein intake (g/day)	4	223	Mean Difference (IV, Random, 95% CI)	17.67 [11.80, 23.55]
5.11.1 Up to 3 months	3	152	Mean Difference (IV, Random, 95% CI)	18.15 [9.37, 26.93]
5.11.2 Up to 12 months	1	71	Mean Difference (IV, Random, 95% CI)	17.00 [7.18, 26.82]
5.12 Change in handgrip strength (kg)	5		Mean Difference (IV, Random, 95% CI)	Subtotals only
5.12.1 Up to 3 months	3	244	Mean Difference (IV, Random, 95% CI)	0.99 [-0.42, 2.40]
5.12.2 4 to 6 months	3	200	Mean Difference (IV, Random, 95% CI)	0.72 [-0.88, 2.31]

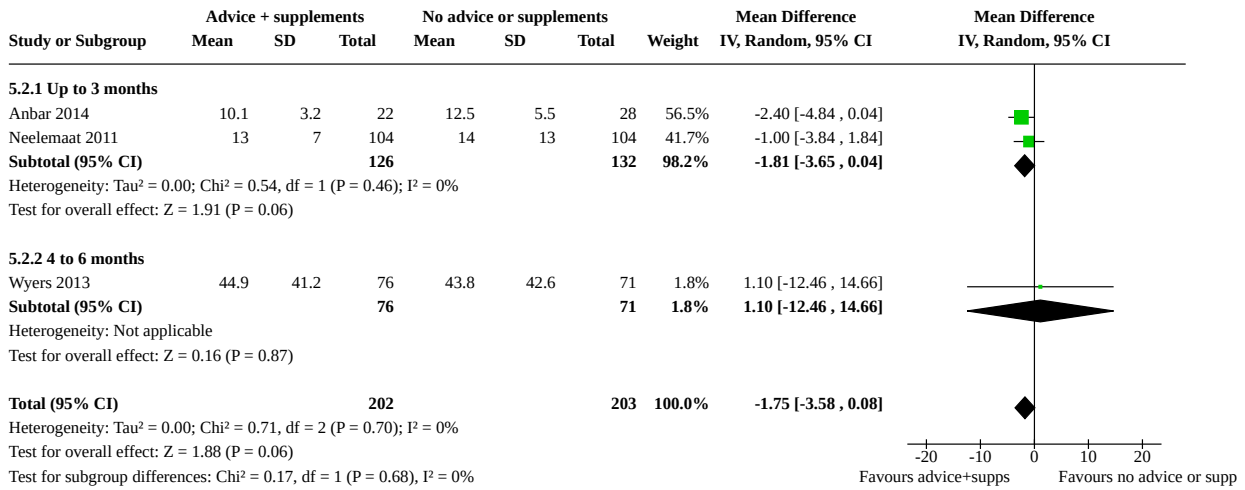
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
5.13 Change in global QoL	4		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
5.13.1 Up to 3 months	4	357	Std. Mean Difference (IV, Random, 95% CI)	0.32 [-0.33, 0.96]
5.13.2 Up to 3 months (FAACT)	1	117	Std. Mean Difference (IV, Random, 95% CI)	0.01 [-0.35, 0.38]
5.13.3 4 to 6 months	3	208	Std. Mean Difference (IV, Random, 95% CI)	0.04 [-0.24, 0.31]
5.13.4 4 to 6 months (FAACT)	1	64	Std. Mean Difference (IV, Random, 95% CI)	-0.30 [-0.80, 0.19]
5.14 QoL - change in physical function	4		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
5.14.1 Up to 3 months	3	242	Std. Mean Difference (IV, Random, 95% CI)	0.37 [-0.11, 0.84]
5.14.2 4 to 6 months	2	90	Std. Mean Difference (IV, Random, 95% CI)	0.63 [0.18, 1.09]
5.15 QoL - change in mental function	4		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
5.15.1 Up to 3 months	3	239	Std. Mean Difference (IV, Random, 95% CI)	0.39 [-0.16, 0.93]
5.15.2 4 to 6 months	2	90	Std. Mean Difference (IV, Random, 95% CI)	0.04 [-0.38, 0.45]
5.16 QoL - change in social function	3		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
5.16.1 Up to 3 months	3	235	Std. Mean Difference (IV, Random, 95% CI)	0.47 [0.02, 0.91]
5.16.2 4 to 6 months	1	36	Std. Mean Difference (IV, Random, 95% CI)	0.40 [-0.26, 1.06]
5.17 QoL - change in cognitive function	2		Std. Mean Difference (IV, Fixed, 95% CI)	Subtotals only
5.17.1 Up to 3 months	2	141	Std. Mean Difference (IV, Fixed, 95% CI)	0.21 [-0.13, 0.54]
5.17.2 4 to 6 months	1	36	Std. Mean Difference (IV, Fixed, 95% CI)	0.29 [-0.37, 0.95]
5.18 QoL - change in pain	3		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
5.18.1 Up to 3 months	3	238	Std. Mean Difference (IV, Random, 95% CI)	0.46 [-0.24, 1.16]
5.18.2 4 to 6 months	1	36	Std. Mean Difference (IV, Random, 95% CI)	0.28 [-0.37, 0.94]
5.19 QoL - change in energy/fatigue	3		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
5.19.1 Up to 3 months	3	239	Std. Mean Difference (IV, Random, 95% CI)	0.14 [-0.16, 0.43]
5.19.2 4 to 6 months	1	36	Std. Mean Difference (IV, Random, 95% CI)	-0.01 [-0.66, 0.64]

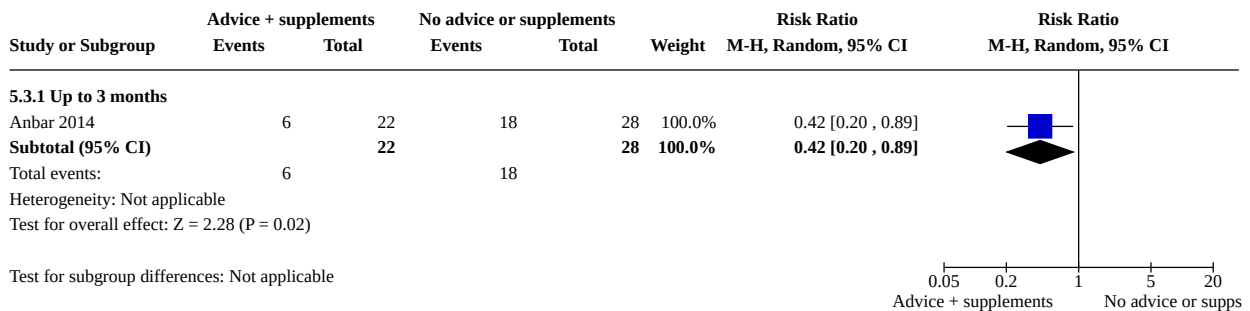
Analysis 5.1. Comparison 5: Dietary advice plus supplements compared with no advice and no supplements, Outcome 1: Mortality



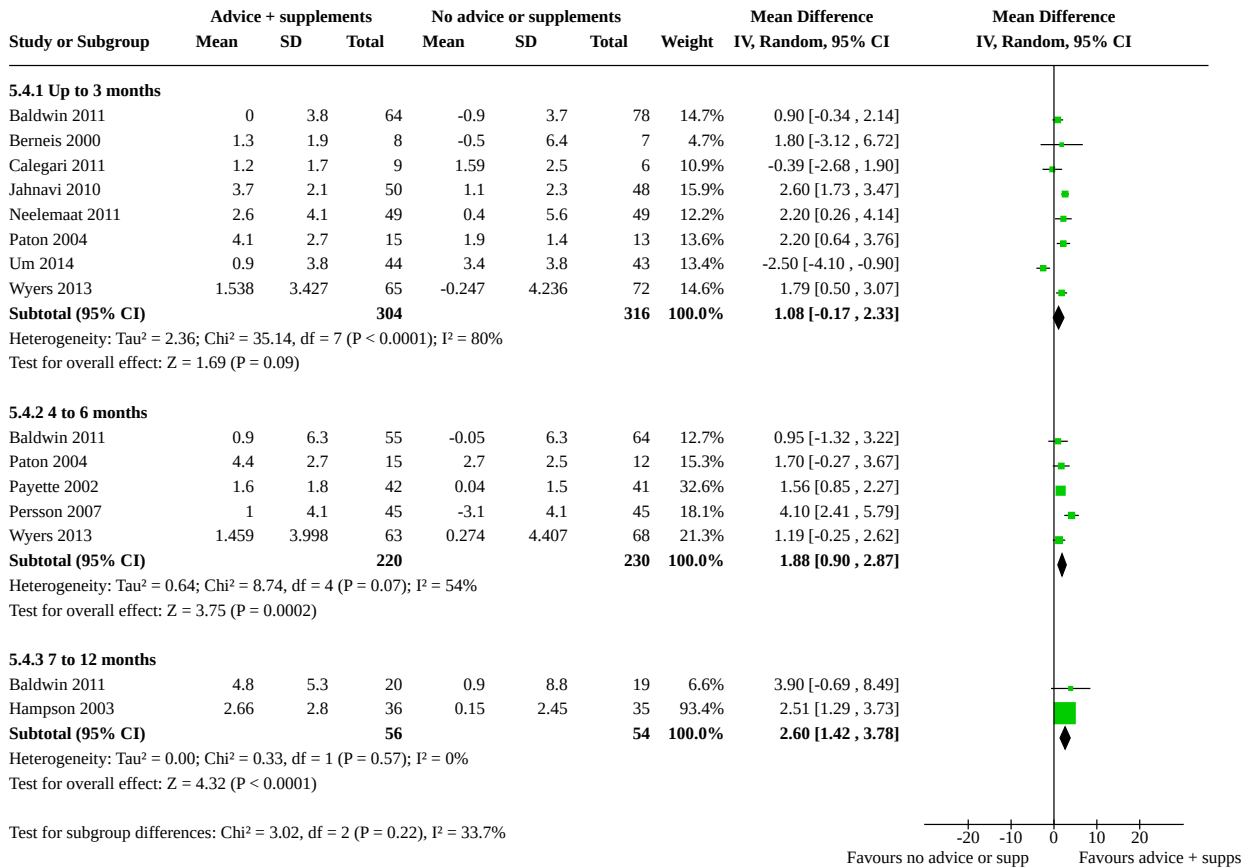
Analysis 5.2. Comparison 5: Dietary advice plus supplements compared with no advice and no supplements, Outcome 2: Length of hospital stay (days)



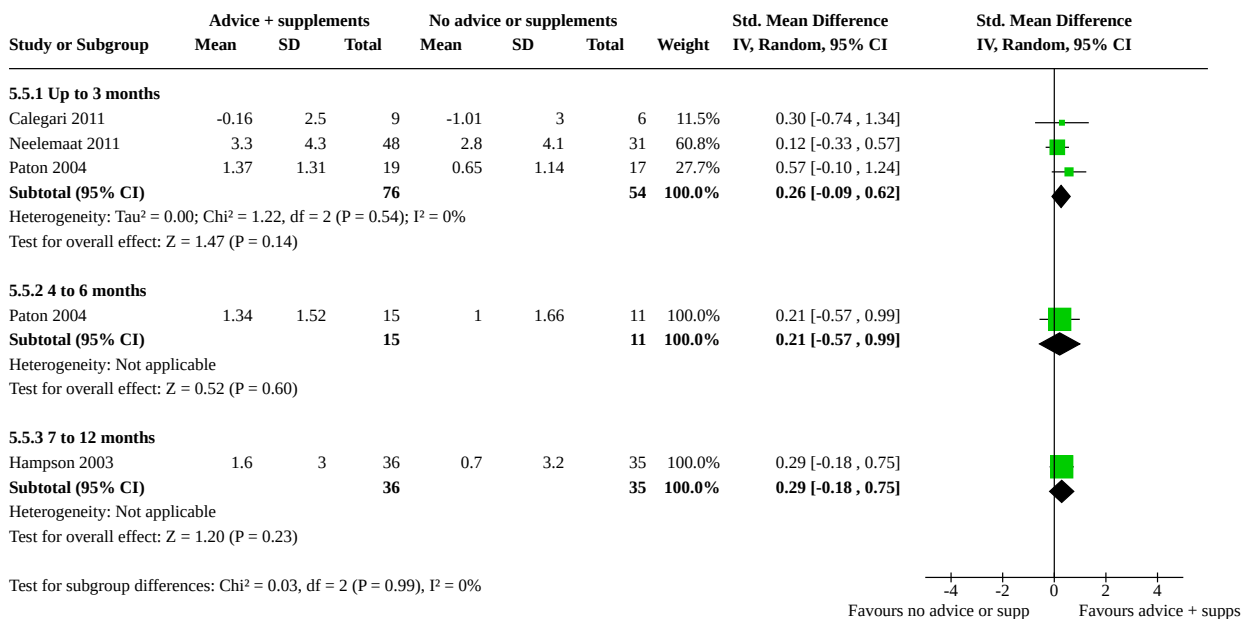
Analysis 5.3. Comparison 5: Dietary advice plus supplements compared with no advice and no supplements, Outcome 3: Complications



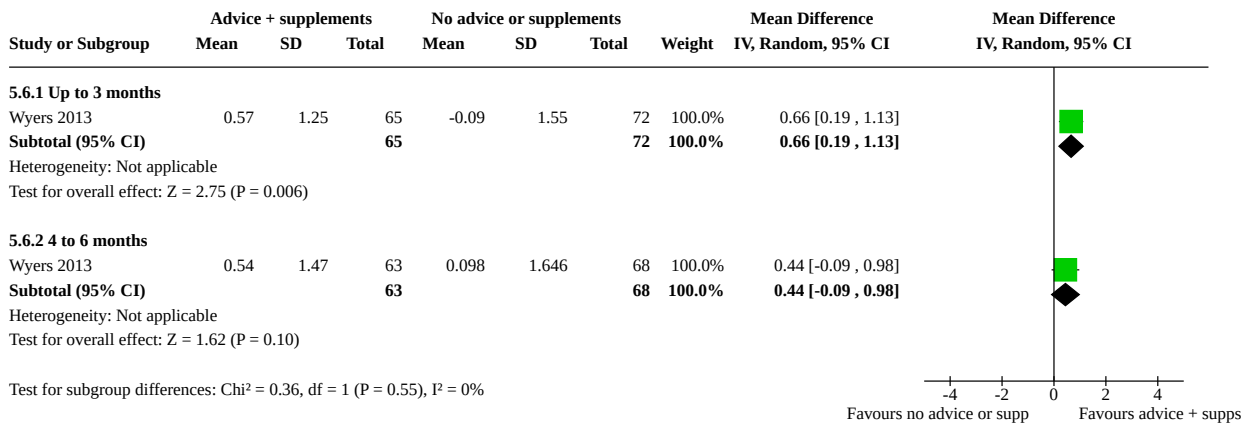
Analysis 5.4. Comparison 5: Dietary advice plus supplements compared with no advice and no supplements, Outcome 4: Change in weight (kg)



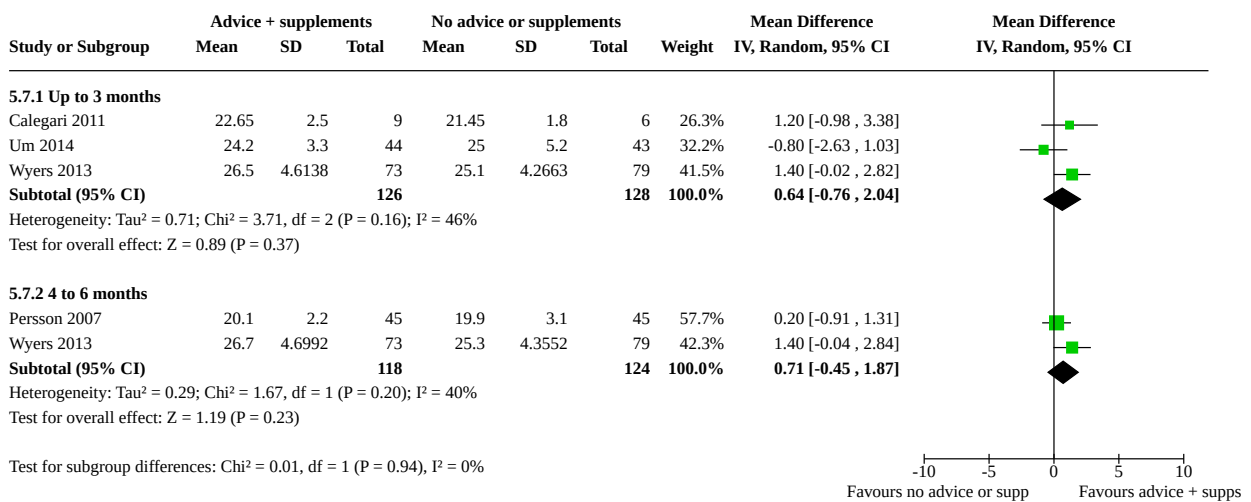
Analysis 5.5. Comparison 5: Dietary advice plus supplements compared with no advice and no supplements, Outcome 5: Change in fat free mass



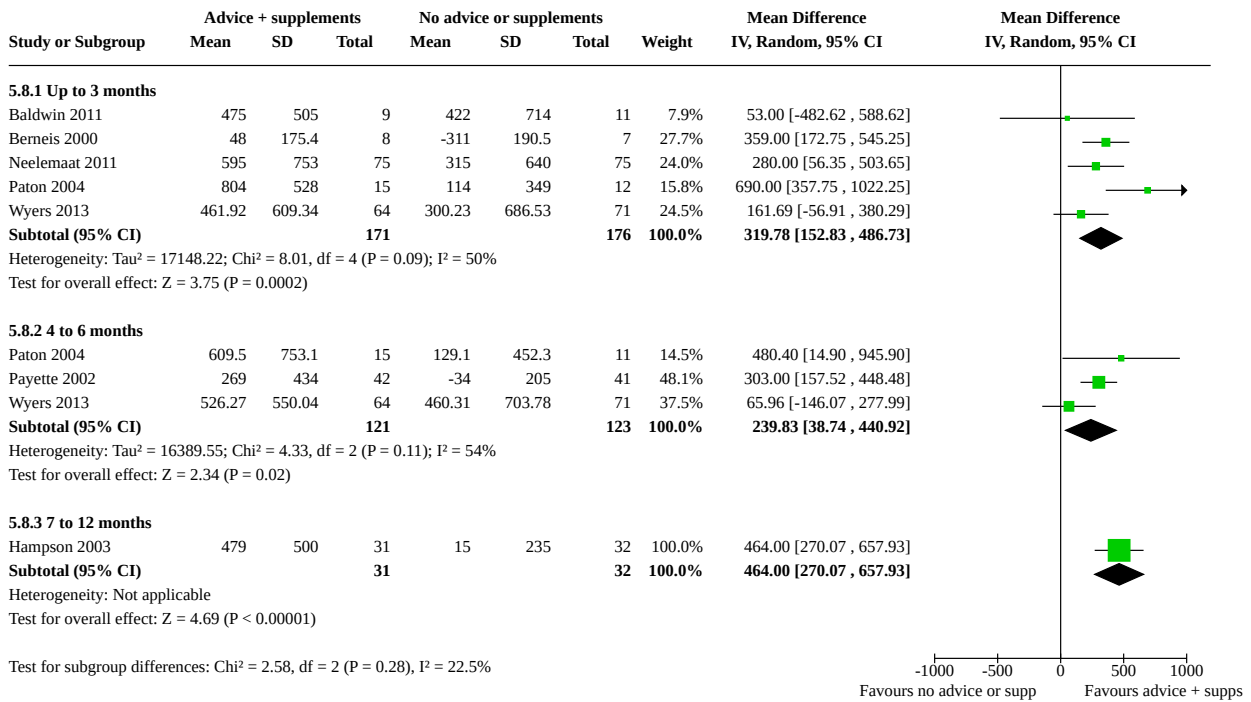
Analysis 5.6. Comparison 5: Dietary advice plus supplements compared with no advice and no supplements, Outcome 6: Change in BMI (kg/m²)



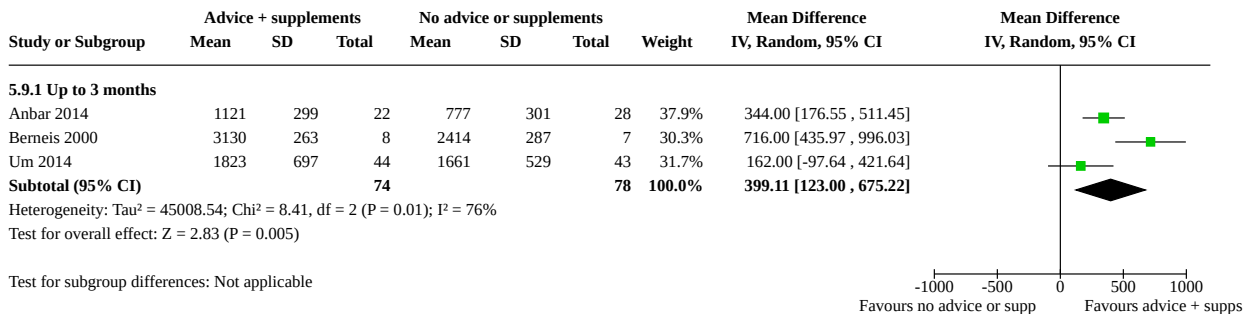
Analysis 5.7. Comparison 5: Dietary advice plus supplements compared with no advice and no supplements, Outcome 7: Final BMI (kg/m²)



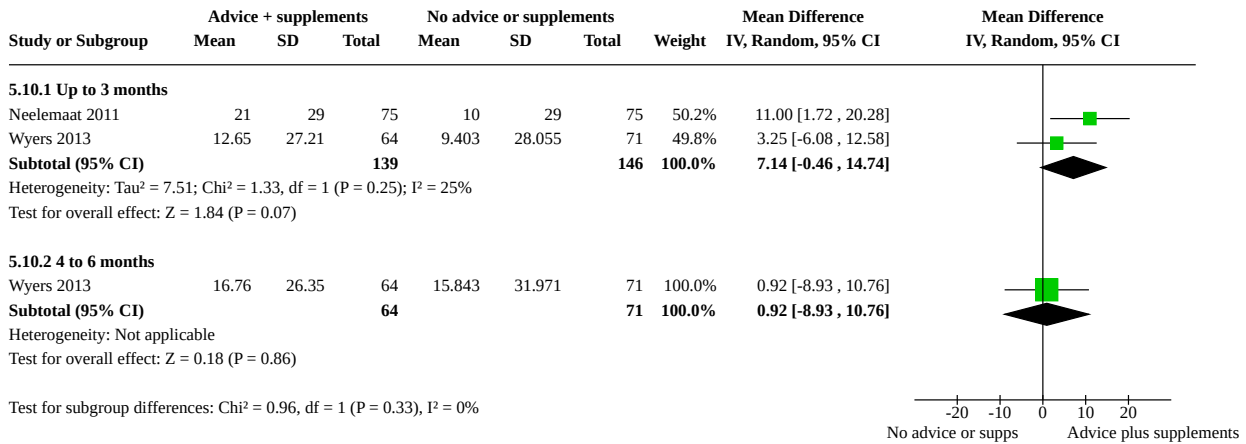
Analysis 5.8. Comparison 5: Dietary advice plus supplements compared with no advice and no supplements, Outcome 8: Change in energy intake (kcal)



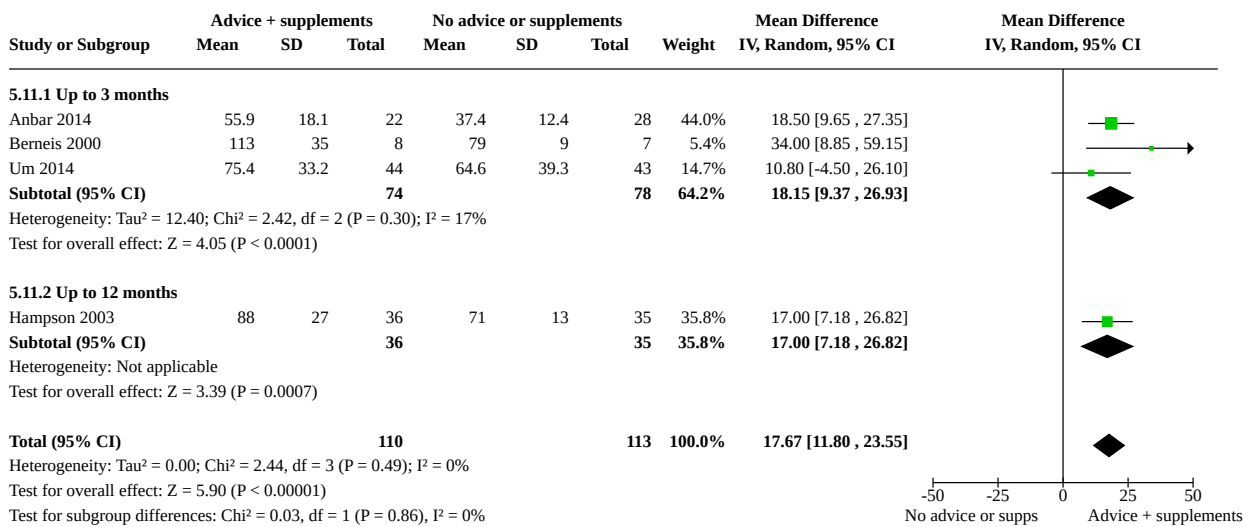
Analysis 5.9. Comparison 5: Dietary advice plus supplements compared with no advice and no supplements, Outcome 9: Final energy intake (kcal)



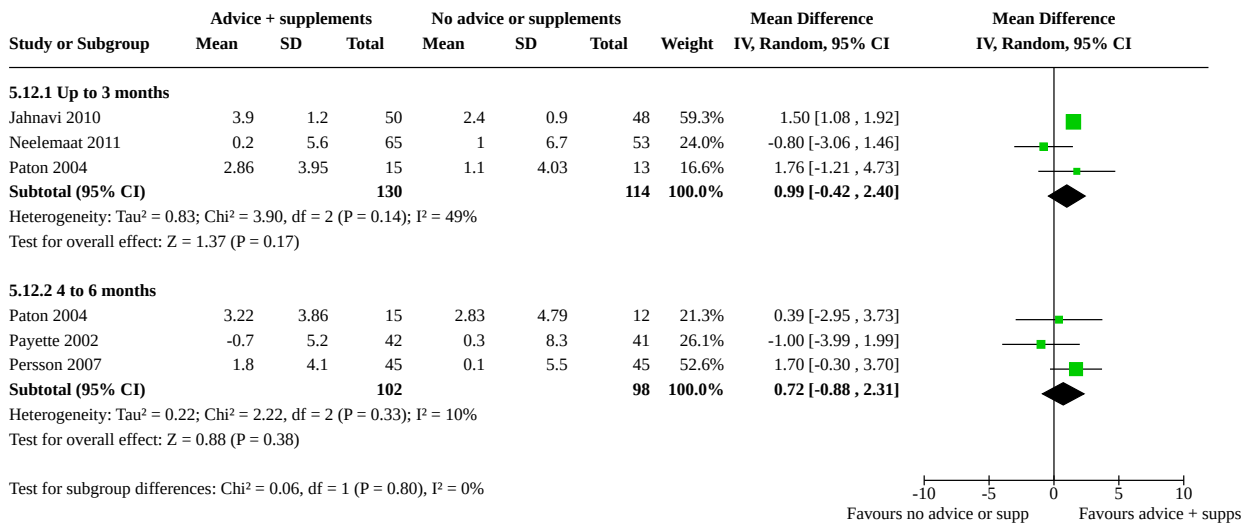
Analysis 5.10. Comparison 5: Dietary advice plus supplements compared with no advice and no supplements, Outcome 10: Change in protein intake



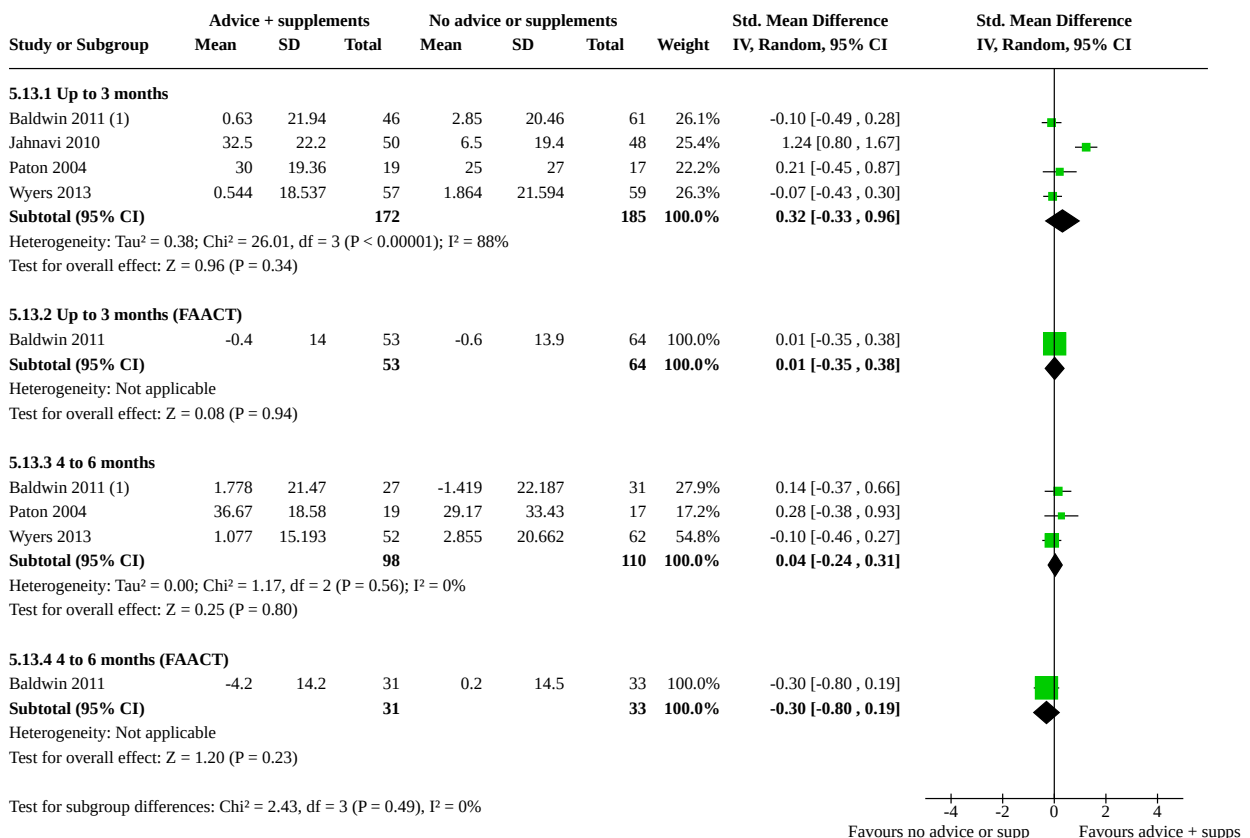
Analysis 5.11. Comparison 5: Dietary advice plus supplements compared with no advice and no supplements, Outcome 11: Final protein intake (g/day)



Analysis 5.12. Comparison 5: Dietary advice plus supplements compared with no advice and no supplements, Outcome 12: Change in handgrip strength (kg)



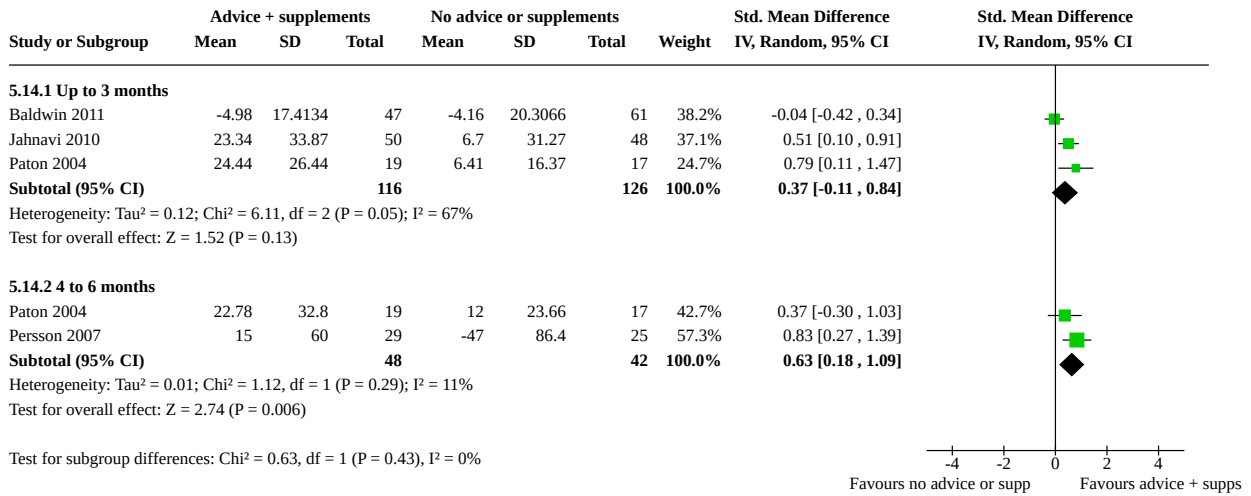
Analysis 5.13. Comparison 5: Dietary advice plus supplements compared with no advice and no supplements, Outcome 13: Change in global QoL



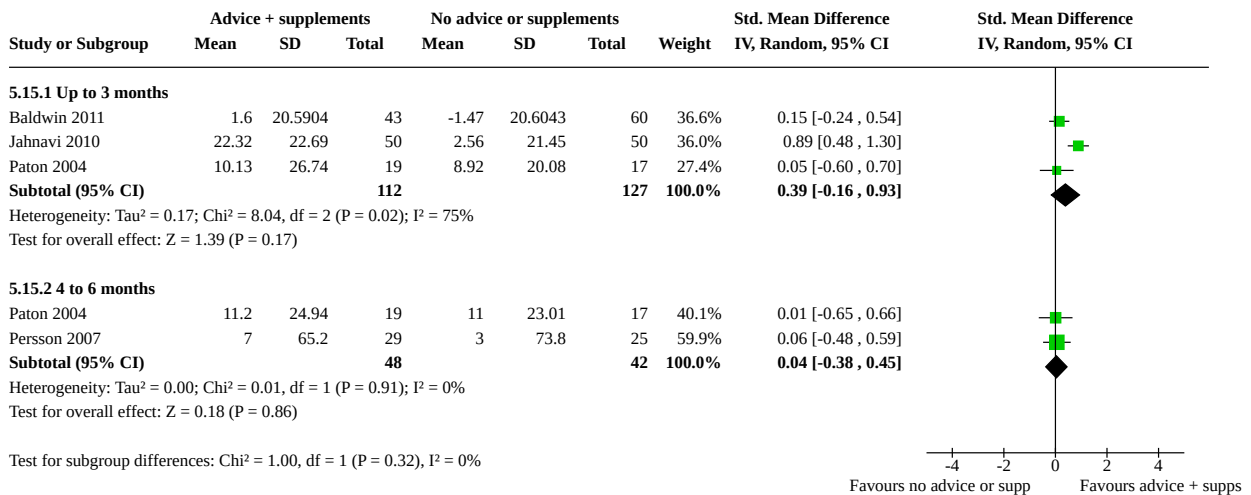
Footnotes

(1) EORTC

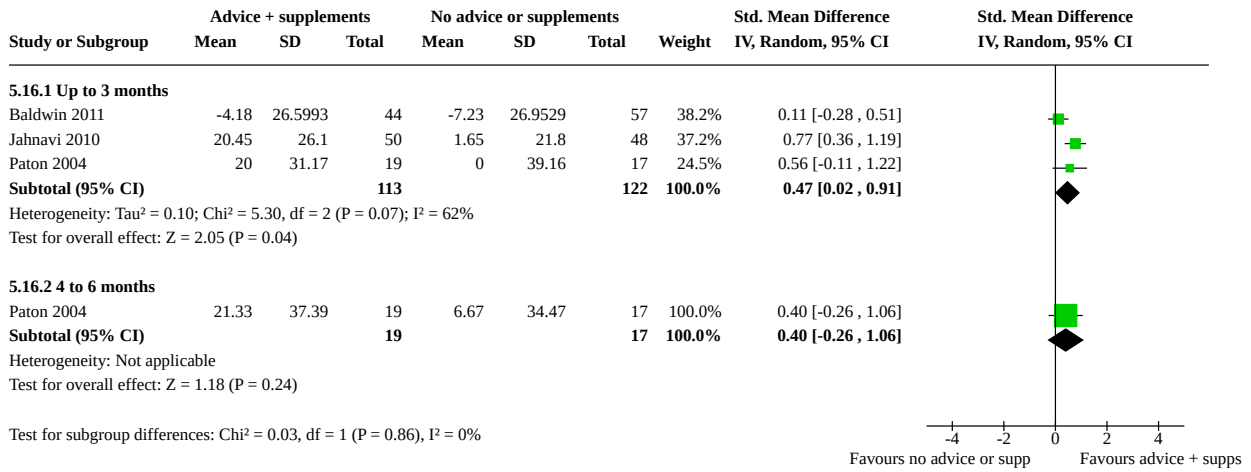
Analysis 5.14. Comparison 5: Dietary advice plus supplements compared with no advice and no supplements, Outcome 14: QoL - change in physical function



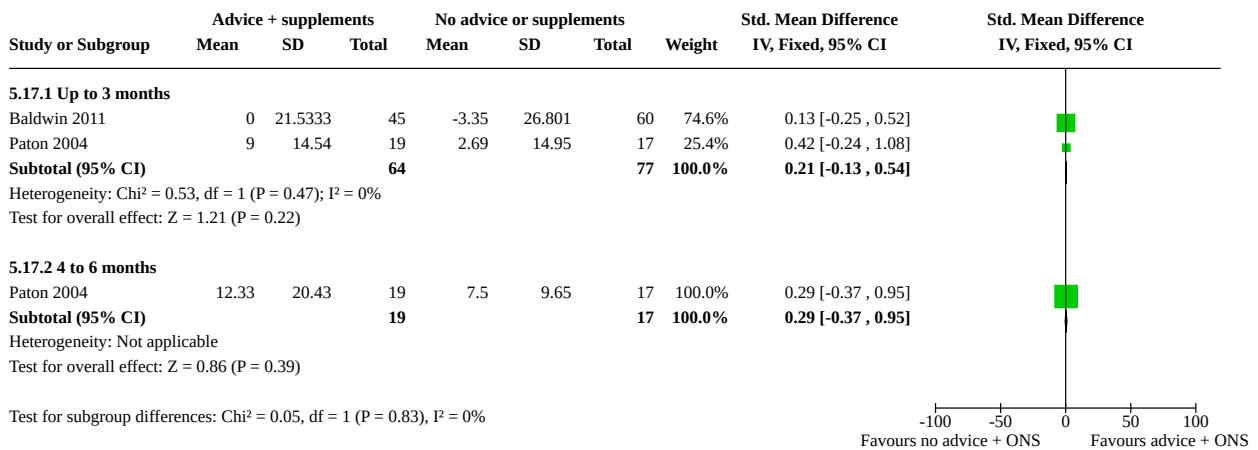
Analysis 5.15. Comparison 5: Dietary advice plus supplements compared with no advice and no supplements, Outcome 15: QoL - change in mental function



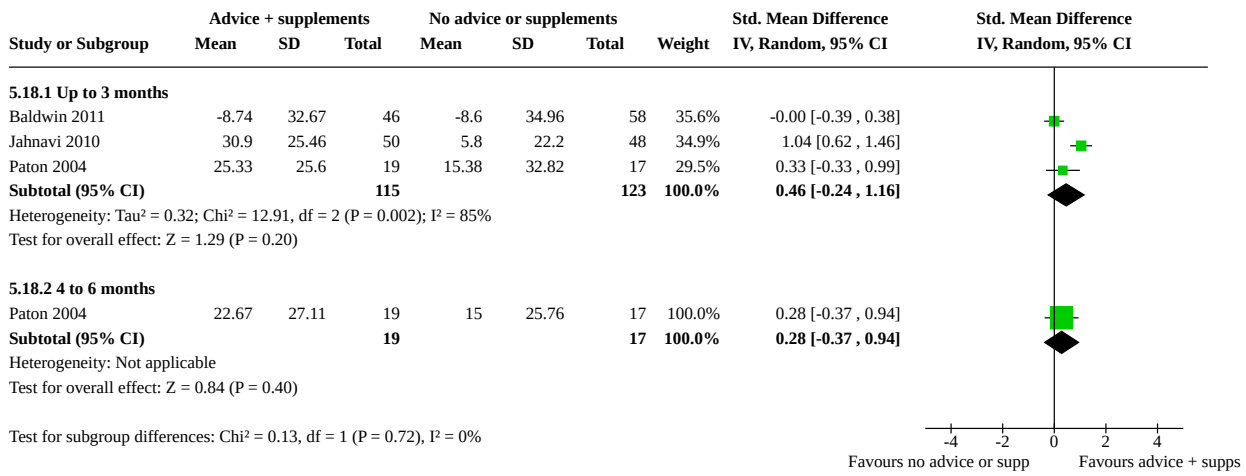
Analysis 5.16. Comparison 5: Dietary advice plus supplements compared with no advice and no supplements, Outcome 16: QoL - change in social function



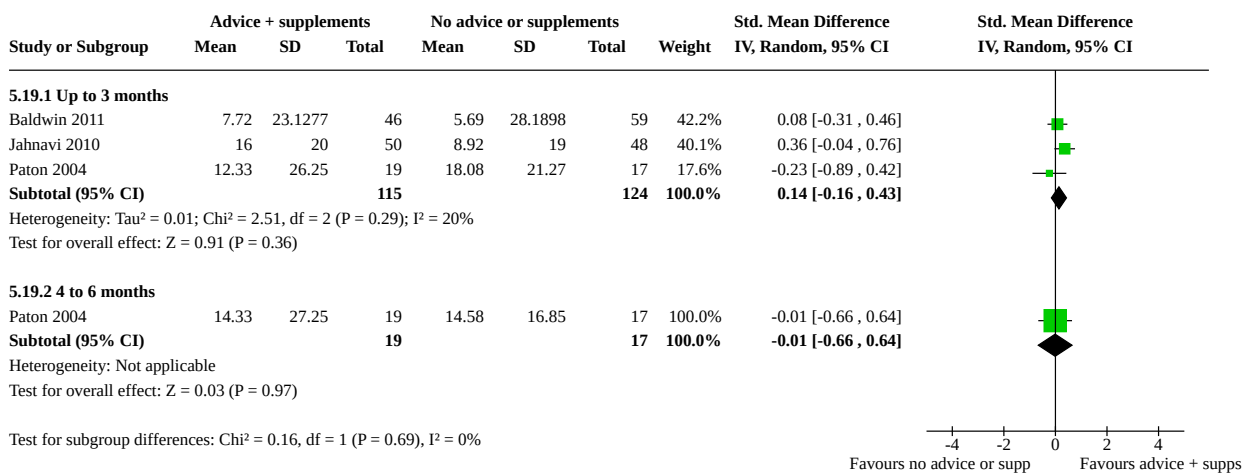
Analysis 5.17. Comparison 5: Dietary advice plus supplements compared with no advice and no supplements, Outcome 17: QoL - change in cognitive function



Analysis 5.18. Comparison 5: Dietary advice plus supplements compared with no advice and no supplements, Outcome 18: QoL - change in pain



Analysis 5.19. Comparison 5: Dietary advice plus supplements compared with no advice and no supplements, Outcome 19: QoL - change in energy/fatigue



ADDITIONAL TABLES

Table 1. Summary of additional clinical outcomes reported in included studies

Study	Clinical measures (generic)	Clinical measures (disease specific)
<i>Dietary advice versus no advice - group 1</i>		
Alo 2014	Haemoglobin concentration	
Baldwin 2011		
Campbell 2008		Estimated glomerular filtration rate, albumin, C-reactive protein
Cano-Torres 2017	Serum biochemistry (U&Es, FBC, glucose, creatinine, lipids)	

Table 1. Summary of additional clinical outcomes reported in included studies (Continued)

Casals 2015	Serum biochemistry (protein, albumin, cholesterol, lymphocytes)	
Dixon 1984		
Fernandez-Barres 2017	Nutritional biochemistry (albumin, haemoglobin, haematocrit, cholesterol)	
Forster 2012	Symptoms & illness (diary), infections, GP visits, hospital visits, prescribed medication, temperature, nutritional biochemistry	
Gu 2015	Complications score	
Imes 1988		Crohn's Disease Activity Index Need for medication Need for surgery Number of work days lost due to Crohn's
Kunvik 2018		
Locher 2013		
Macia 1991		Clinical observation of symptoms Days of suspended treatment
Manguso 2005		Disease severity (Childs Score)
Ollenschlager 1992	No. days with temperature > 38.5 C	Number of complete remissions Clinical symptoms LAS
Pivi 2011	Biochemical status (total protein, albumin, total lymphocyte count)	
Ravasco 2005a (C/R)		Symptom-induced morbidity
Ravasco 2005b (H&N)		Symptom-induced morbidity
Rydwik 2008		
Salva 2011	Caregiver burden (Zarit), Use of healthcare and social resources (Resource Utilisation in Dementia (RUD) scale)	Clinical Dementia Rating scale Neuropsychiatric Inventory scale
Stow 2015	Adverse events, healthcare resource usage	
Tu 2013		
Weekes 2009		Need for medication
Wong 2004		

Table 1. Summary of additional clinical outcomes reported in included studies (Continued)

Dietary advice versus supplements - group 2

Akpele 2004		rate of change of serum albumin
Baldwin 2011		
Gray-Donald 1995		Number of falls
Hernandez 2014	biochemical status % of patients malnourished (defined as serum albumin < 3.5 g/dL)	
Kalnins 2005		Faecal balance studies
Parsons 2016		
Pivi 2011	Biochemical status (total protein, albumin, total lymphocyte count)	
Ravasco 2005a (C/R)		Symptom-induced morbidity
Ravasco 2005b (H&N)		Symptom-induced morbidity
Schwenk 1999		
Singh 2008	Creatinine/height index, nitrogen balance	Abdominal pain score (not validated) Faecal fat Endocrine and exocrine function
Stow 2015	Adverse events, healthcare resource usage	

Dietary advice versus dietary advice and supplements - group 3

Arnold 1989	Serum albumin, serum transferrin	Tumour response Treatment interruptions Radiation side effects
Baldwin 2011		
Beattie 2000		Need for medication Number of wound and chest infections
Burden 2011		Number of participants with infections, need for antibiotics, self-reported adverse events, compliance
Burden 2017		Number of participants with surgical infections, total complications
de Luis 2003	Serum albumin, prealbumin and transferrin	Viral load, CD4

Table 1. Summary of additional clinical outcomes reported in included studies (Continued)

de Sousa 2012	Albumin, total protein, total cholesterol, vit B12, folic acid	MMSE, clock drawing test
Diouf 2016	Haemoglobin, zinc, % anaemic	
Dixon 1984		
Fuenzalida 1990	Biochemical status (full range of tests), Creatinine Height Index, urinary creatinine and urea nitrogen.	Skin antigen testing Lymphocyte count
Gonzalez-Espinoza 2005	Biochemical status (full range of tests)	Number of episodes of peritonitis
Huynh 2015	SGA, prealbumin, albumin, hemoglobin, total protein, CRP	
Kapoor 2017	Sum of skinfolds, PG-SGA, food frequency questionnaire, adherence to dietary supplements	
Kendell 1982	Biochemical status (full range of tests), albumin, transferrin, total lymphocyte count, urinary nitrogen, Creatinine Height Index	
Le Cornu 2000		LOS in ICU, hours on ventilatory support, septic complications, major non-infectious complications, rejections, changes in immunosuppression
McCarthy 1999		
Murphy 1992		
Norman 2008b	Comorbidity count, number of drugs at discharge, albumin, CRP, haemoglobin, white blood cell count, platelets, costs	
Olejko 1984	Comorbidity count	
Rabeneck 1998		
Sharma 2002a	Renal-related outcomes (protein catabolic rate, protein nitrogen appearance, albumin, potassium, phosphate)	Karnofsky Index, Self-reported adverse effects
Swaminathan 2010	Haemoglobin, albumin, total cholesterol, triglycerides,	CD 4 cell count
Wilson 2001	Albumin number of days spent in hospital	Time to nutritional repletion
<i>Dietary advice plus supplements if required versus no advice - group 4</i>		
Andersson 2017	Appetite (DRAQ), self perceived state of health	
Banks 2016	Serum albumin, protein, C-reactive protein, urea, glucose, HbA1C, TIBC, serum iron, serum transferrin, haemoglobin,	PU change, from baseline, in score (PUSH) and area (VISITRAC), length

Table 1. Summary of additional clinical outcomes reported in included studies *(Continued)*

	neutrophil count, lymphocyte count, zinc, magnesium, ascorbate, creatinine	of stay to heal or discharge, early discharge, PU healed, PU worsened, discharged not healed
Beck 2012	Risk of re-admissions, need of social services (home care, home nursing, meals-on-wheels).	
Beck 2015	The economic analysis of time spent by the dietitian, use of oral nutritional supplements (ONS) and number of hospitalisation days	
Bonilla-Palomas 2016		A composite of all-cause death or readmission for worsening of HF.
Bourdel-Marchasson 2014	Hospitalisation for reasons other than chemotherapy, MMS, depression (GDS)	Chemotherapy toxicity
Caccialanza 2015	MAMC	
Carey 2013	SGA	GI symptoms
Endevelt 2011	Biochemical measurements, health care costs	cognition (MMSE), depression (GDS-sf)
Evans 1987		Tumour response to chemotherapy
Feldblum 2011	Albumin, total lymphocyte count, haemoglobin, transferrin, total cholesterol, mortality	Depression (GDS), cognition (MMSE)
Forli 2001		Respiratory function
Ganzoni 1994		Respiratory function
Hampson 2003		Bone mineral density
Holyday 2012	1 month and 6 months emergency frequency	
Isenring 2004	Change in PG-SGA score	
Jensen 1997	Appetite, fatigue, work capacity	
Kiss 2016	Fatigue, PG-SGA score	
Lovik 1996	Serum chemistry (albumin, transferrin)	
Moloney 1983	Micronutrient intake	
Ovesen 1993		Tumour response to chemotherapy
Pedersen 2016a and-Pedersen 2016b		
Persson 2002		
Rogers 1992	Sickness impact profile	
Schilp 2013	Healthcare costs	

Table 1. Summary of additional clinical outcomes reported in included studies (Continued)

Sharma 2017	PG-SGA	complications
Silvers 2014	PG-SGA	
Starke 2011	Number of antibiotic therapies, vit D, vit C, glutathione, compliance to ONS	complications
Suominen 2015		
Terp 2018	Self rated health	
Uster 2013	Appetite (DRAQ), self-perceived state of health (VAS; scores 0-100).	
Vivanti 2015	LOS, number of falls	depression
<i>Dietary advice plus supplements versus no advice and no supplements - group 5</i>		
Anbar 2014	Cumulative energy balance	New pressure sores; complications
Baldwin 2011		
Berneis 2000	Lean body mass, fat mass	CD4 and CD8 counts, biochemical measurements and inflammatory markers (TNF R55, TNF R75, ILR2),
Calegari 2011	Lean body mass and fat mass, biochemical measurements. Tolerance of ONS	
Chandra 1985		Serum prealbumin levels and number achieving seroconversion
Jahnvi 2010		Sputum conversion and treatment completion rates
Neelemaat 2011	Adherence; fat free mass	
Paton 2004	Lean body mass and fat mass	
Payette 2002		
Persson 2007		Peak expiratory flow
Um 2014	Nutritional status (PG-SGA)	
Wyers 2013	Post-operative complications	

CD4: (cluster differentiation 4) cells of T-mediated immune system

C/R: colorectal

FBC:

GDS:

H&N: head and neck

HbA1C:

ILR2: interleukin R2
 LAS: lymphadenopathy syndrome
 LOS:
 MMS:
 MMSE:
 ONS:
 PG-SGA:
 PU:
 SGA:
 TIBC:
 TNF R55: Tumour necrosis factor R55
 TNF R75: Tumour necrosis factor R75
 U&Es:

Table 2. Summary of additional functional outcomes reported in included studies

Study	Functional measures (physical)	Functional measures (status)	notes
<i>Dietary advice versus no advice - group 1</i>			
Alo 2014			
Baldwin 2011			
Campbell 2008			
Cano-Torres 2017			
Casals 2015		Barthel index	mean change scores for intervention and control
Dixon 1984		Karnofsky scale	Pre- and post-intervention (0 and 4 months)
Fernandez-Barres 2017		Degree of dependency (Barthel) Cognitive function (Pfeiffer's) Mood (Yesavage Depression Scale)	mean(SD) baseline and end of intervention (6 months)
Forster 2012		Geriatric Depression Score	Data reported as not different between groups
Gu 2015			
Imes 1988			
Kunvik 2018			
Locher 2013			
Macia 1991			

Table 2. Summary of additional functional outcomes reported in included studies (Continued)

Manguso 2005			
Ollenschlager 1992			
Pivi 2011			
Ravasco 2005a (C/R)			
Ravasco 2005b (H&N)			
Rydwik 2008	Timed up and go Number of step-ups in 30 seconds Walking speed over 10 m Modified figure of 8 test	Functional independence measure Instrumental activities measure	Between and within group differences in domain scores
Salva 2011		ADL & iADL MMSE	
Stow 2015			
Tu 2013			
Weekes 2009	Respiratory muscle function (Pimax, Pe max) Respiratory function (FEV ₁ & FVC)	ADL score Dyspnoea score	
Wong 2004			
Dietary advice versus supplements - group 2			
Akpele 2004			
Baldwin 2011			
Gray-Donald 1995			
Hernandez 2014			
Kalnins 2005	Respiratory function (FEV ₁)		
Parsons 2016			
Pivi 2011			
Ravasco 2005a (C/R)			
Ravasco 2005b (H&N)			

Table 2. Summary of additional functional outcomes reported in included studies (Continued)

Schwenk 1999			
Singh 2008			
Stow 2015			
<i>Dietary advice versus dietary advice and supplements - group 3</i>			
Arnold 1989			
Baldwin 2011			
Beattie 2000			
Burden 2011			
Burden 2017			
de Luis 2003			
de Sousa 2012		Barthel index	
Diouf 2016			
Dixon 1984		Karnofsky scale	Pre- and post-intervention (0 and 4 months)
Fuenzalida 1990	Respiratory function (FEV ₁ & FVC)	Self-assessment of lung function	
Gonzalez-Espinoza 2005			
Huynh 2015			
Kapoor 2017	Physical activity questionnaire, MET		
Kendell 1982			
Le Cornu 2000			
McCarthy 1999			
Murphy 1992			
Norman 2008b	Respiratory function (PEF)		
Olejko 1984			
Rabeneck 1998	Cognitive function (Buschke selective reminding test)		
Sharma 2002a			

Table 2. Summary of additional functional outcomes reported in included studies (Continued)

Swaminathan 2010			
Wilson 2001			
<i>Dietary advice plus supplements if required versus no advice - group 4</i>			
Andersson 2017			
Banks 2016			
Beck 2012	Chair stand	Mobility (DEMMI), rehabilitation capacity, Functional Recovery Score	from baseline to 3 months
Beck 2015	Chair stand	Mobility and ADL	from baseline to 3 months
Bonilla-Palomas 2016			
Bourdel-Marchasson 2014			
Caccialanza 2015		Performance status (ECOG)	from baseline to 12 months
Carey 2013			
Endevelt 2011		ADL (Barthel)	from baseline 6 months
Evans 1987			
Feldblum 2011		ADL (Barthel)	from baseline 6 months
Forli 2001			
Ganzoni 1994	6 minute walking distance		
Hampson 2003			
Holyday 2012			
Isenring 2004			
Jensen 1997	Respiratory function (FEV ₁ & FVC)	Ordinal fatigue scale Lambert disability screening questionnaire	Mean scores at baseline and 4 months
Kiss 2016	Functional status		
Lovik 1996			
Moloney 1983			

Table 2. Summary of additional functional outcomes reported in included studies (Continued)

Ovesen 1993			
Persson 2002			
		ADL, cognitive function, peak expiratory flow	
Pedersen 2016a and Pedersen 2016b	Chair stand test	Geriatric Depression Score, ADL, Avlund mobili- ty tiredness score	
Rogers 1992			
	Respiratory muscle function (Pimax, Pe max)	Perceived dyspnoea (Borg)	
	12 minute walking distance		
Schilp 2013			
	Short		from baseline to 3 and 6 months
	Physical Performance Bat- tery		
Sharma 2017			
Silvers 2014			
Starke 2011			
Suominen 2015			
	Rate of falls		
Terp 2018			
		Barthel index	
Uster 2013			
		Performance status	
Vivanti 2015			
		Performance status (ECOG)	From baseline to 3 and 6 months
		Global Depression Score	
<i>Dietary advice plus supplements versus no advice and no supplements - group 5</i>			
Anbar 2014			
Baldwin 2011			
Berneis 2000			
Calegari 2011			
	6-minute walk test		
Chandra 1985			
Jahnvi 2010			
	Sit-to-stand test		
Neelemaat 2011			
	LASA Functional Limitations Questionnaire and LASA Physical Activity Question- naire; Short Physical Perfor- mance Battery		

Table 2. Summary of additional functional outcomes reported in included studies (Continued)

Paton 2004	Sit-to-stand test
Payette 2002	Sit-to-stand test; knee and elbow extensor tests
Persson 2007	ADL (Katz) Cognitive function (MMSE)
Um 2014	
Wyers 2013	

ADL: activities of daily living
 FEV₁: forced expiratory volume at one second
 FVC: forced expiratory capacity
 MMSE: Mini mental state examination
 Pe max: maximal expiratory mouth pressure
 PEF: peak expiratory flow
 Pimax: maximal inspiratory mouth pressure

Table 3. Summary of quality of life assessments made in included studies

Study	QOL instrument	notes
<i>Dietary advice versus no advice - group 1</i>		
Alo 2014		
Baldwin 2011	EORTC FAACT	Mean change from baseline to 6 and 26 weeks
Campbell 2008	KDQOL-SF	Data provided by author on mean (SD) at baseline and 12 weeks for each component
Cano-Torres 2017		
Casals 2015	SF-12	Mean change from baseline to 6 months
Dixon 1984		
Fernandez-Barres 2017		
Forster 2012	SF-36	Mean change from baseline to 3 months obtained from author
Gu 2015		
Imes 1988		
Kunvik 2018		
Locher 2013		
Macia 1991		

Table 3. Summary of quality of life assessments made in included studies (Continued)

Manguso 2005

Ollenschlager 1992	Subjective well-being using Linear Analogue Self Assessment questionnaire (LASA)	assessed in intervention group only
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Pivi 2011

Ravasco 2005a	EORTC	Mean change from baseline to 12 weeks plus additional data for longer term follow-up provided in 2012 publication
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Ravasco 2005b	EORTC	Mean change from baseline to 12 weeks plus additional data for longer term follow-up provided in 2012 publication
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Rydwick 2008

Salva 2011

Stow 2015	EQ5D-5: Dartmouth COOP Quality of life chart	not reported because of completion by too few residents
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Tu 2013

Weekes 2009	SF-36 SGRQ	Mean change from baseline to 6 and 12 months
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Wong 2004

Dietary advice versus supplements - group 2

Akpele 2004

Baldwin 2011	EORTC FAACT	Mean change from baseline to 6 and 26 weeks
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Gray-Donald 1995	General self-perceived health question General well-being schedule	Mean scores for both groups at baseline and 12 weeks
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Hernandez 2014

Kalnins 2005

Parsons 2016	EuroQol/EQ-5d	scores reported as baseline scores for both intervention groups combined and mean (SE)
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Table 3. Summary of quality of life assessments made in included studies *(Continued)*
 after 6 weeks and 12 weeks by intervention group.

Pivi 2011		
Ravasco 2005a (C/R)	EORTC	Mean change from baseline to 12 weeks plus additional data for longer term follow-up provided in 2012 publication
Ravasco 2005b (H/N)	EORTC	Mean change from baseline to 12 weeks plus additional data for longer term follow-up provided in 2012 publication
Schwenk 1999		
Singh 2008		
Stow 2015	EQ5D-5: Dartmouth COOP Quality of life chart	not reported because of completion by too few residents
<i>Dietary advice versus dietary advice and supplements - group 3</i>		
Arnold 1989		
Baldwin 2011	EORTC FAACT	Mean change from baseline to 6 and 26 weeks
Beattie 2000	SF-36	Summary and mean change scores for physical and mental health at baseline and final assessment
Burden 2011		
Burden 2017		
de Luis 2003		
de Sousa 2012		
Diouf 2016		
Dixon 1984		
Fuenzalida 1990		
Gonzalez-Espinoza 2005		
Huynh 2015		
Kapoor 2017	EORTC-C30	mean change from baseline to 3 months and 6 months
Kendell 1982		
Le Cornu 2000		

Table 3. Summary of quality of life assessments made in included studies (Continued)

McCarthy 1999		
Murphy 1992		
Norman 2008b	SF-36	Mean scores for QALYs for all domains at baseline and 3 months
Olejko 1984		
Rabeneck 1998	30-item QOL instrument (not validated)	
Sharma 2002a		
Swaminathan 2010		
Wilson 2001		
<i>Dietary advice plus supplements if required versus no advice - group 4</i>		
Andersson 2017	EQ-5D	Mean change from baseline to 3 months in all 5 domains
Banks 2016		
Beck 2012		
Beck 2015	EQ-5D	Mean change from baseline to 3 months
Bonilla-Palomas 2016		
Bourdel-Marchasson 2014		
Caccialanza 2015	SF-36	Mean change from baseline to 12 months for PCS and MCS
Carey 2013	EORTC-QLQ-C30	Mean change from baseline to 3 months and 6 months
Endevelt 2011		
Evans 1987		
Feldblum 2011		
Forli 2001		
Ganzoni 1994;		
Hampson 2003		
Holyday 2012		
Isenring 2004	EORTC QLQ-C30	Mean change from baseline to 12 weeks
Jensen 1997	QOL index	Means values at baseline and 4 months
Kiss 2016	FACT-L	From baseline to 3 months following completion of radiation therapy

Table 3. Summary of quality of life assessments made in included studies (Continued)

Lovik 1996		
Moloney 1983		
Ovesen 1993	QOL index (modified)	Mean scores at baseline and 3 and 5 months
Pedersen 2016a; Peder- sen 2016b	SF-36	Mean change of subscores from baseline to eight weeks
Persson 2002	EORTC	Mean scores at baseline and 24 months
Rogers 1992	Sickness Impact Profile	Change after 4 months
Schilp 2013	EQ-5D	Results reported as QALY
Sharma 2002a	EQ-5D	Mean change from baseline to 3 months
Silvers 2014	EORTC-QLQ-C30 and EQ-5D	Mean change from baseline to 6 months
Starke 2011		
Suominen 2015	HRQoL	Mean change from baseline to 12 months
Terp 2018		
Uster 2013	EORTC-C30	Mean change from baseline to 3 and 6 months
Vivanti 2015	EQ-5D	Mean change from baseline to 12 weeks
<i>Dietary advice plus supplements versus no advice and no supplements - group 5</i>		
Anbar 2014	Not reported	
Baldwin 2011	EORTC FAACT	Mean change from baseline to 6 and 26 weeks
Berneis 2000	Medical Outcomes Study Instrument (adapted for use in pa- tients with HIV infec- tion)	Summary scores (physical function, social role, mental health and pain) at baseline and 12 weeks. Scores range from 1 to 6 with 6 being the optimal score.
Calegari 2011	SF-36	Baseline and end of Phase 1 (3 months) scores for all eight domains (physical role functioning, bodily pain, physical functioning, general health, vitality, social functioning, role emotional and mental health).
Chandra 1985	Not reported	
Hampson 2003	Not reported	
Jahnvi 2010	36-item Medical Out- comes Study Short form (adapted for use in pa-	Baseline scores and mean changes at 3 months for all eight domains (physical role functioning, bodily pain, physical functioning, general health, vitality, social functioning, role emotional and mental health)

Table 3. Summary of quality of life assessments made in included studies (Continued)

	tients with HIV infection) i.e. SF-36 (modified)	
Neelemaat 2011	SF-12 and 3-level Euro-Qol-5D (EQ-5D)	EQ-5D was used in the cost effectiveness analysis; QALYs at baseline and difference between groups at 3 months
Paton 2004	30-item Medical Outcomes Study Short form (adapted for use in patients with HIV infection) i.e. SF-36 (modified)	Baseline scores and mean changes at 6, 12 and 24 weeks for all domains
Payette 2002	36-item SF-36	Scores at baseline and 16 weeks for three domains (physical role functioning, emotional role functioning and vitality)
Persson 2007	SF-36	Summary scores at baseline and 4 months for physical and mental domains. Graphical presentation of changes in all domain scores over time.
Um 2014	30-item EORTC	Scores at baseline, end of radiotherapy and 1 month follow-up for function and symptom scales plus global health status
Wyers 2013	3-level EQ-5D	Used in the cost effectiveness analysis; intervention effect for change in QALYs

EORTC: European organisation for research and treatment of cancer

FAACT: functional assessment anorexia-cancer therapy

KDQOL-SF: Kidney Disease Quality of Life Short Form

QOL: quality of life

SF-36: 36-item Short Form Medical Outcomes Study Instrument

SGRQ: St George respiratory questionnaire

Table 4. Dietary advice compared with no advice: outcomes with additional data provided or imputed

Study ID	Outcomes where the author provided data	Outcomes where data were imputed
Alo 2014	BMI	
Baldwin 2011	Mortality, weight, energy intake, handgrip strength, QoL scores	
Campbell 2008	Weight, BCM, protein intake, QoL scores	SD of change for global QoL and protein intake.
Cano-Torres 2017	BMI, MAC	
Fernandez-Barres 2017	mean change (SD) weight, BMI, energy and protein intake	
Forster 2012	Mean change (SD) weight, MAC, TSF, QoL and infections	
Kunvik 2018	BMI, protein intake	
Locher 2013		mean change (SD) calculated from individual patient data reported in the paper.

Table 4. Dietary advice compared with no advice: outcomes with additional data provided or imputed (Continued)

Macia 1991		weight, BMI, MAC, MAMC, TSF; SD of change imputed using a correlation co-efficient of 0.8.
Manguso 2005	Weight, MAMC, TSF, energy intake	
Pivi 2011		
Ravasco 2005a	Mortality, weight, QoL scores	
Ravasco 2005b	Mortality, weight, QoL scores	
Rydwik 2008	Weight, energy intake	
Stow 2015	Mortality, hospital admissions	
Weekes 2009	Weight, MAC, MAMC, FFM, TSF, handgrip strength, SGRQ, SF-36	
Wong 2004	Mortality	

BCM: body cell mass
 BMI: body mass index
 FFM: fat-free mass
 MAC: mid-arm circumference
 MAMC: mid-arm muscle circumference
 QoL: quality of life
 SD: standard deviation
 SF-36: Short-Form 36
 SGRQ: St George's Respiratory Questionnaire
 TSF: triceps skinfold thickness

Table 5. Dietary advice compared with oral nutritional supplements: outcomes with additional data provided or imputed

Study ID	Outcomes where the author provided data	Outcomes where data were imputed
Baldwin 2011	Mortality, weight, energy intake, handgrip strength, QoL scores	
Gray-Donald 1995	Energy intake, handgrip strength	
Kalnins 2005	Weight, energy intake	
Ravasco 2005a	Mortality, weight, QoL scores	
Ravasco 2005b	Mortality, weight, QoL scores	
Schwenk 1999	Energy intake	
Singh 2008	Weight, BMI, MAC, TSF, protein intake	
Stow 2015	Mortality, hospital admissions	

BMI: body mass index; MAC: mid-arm circumference; MAMC: mid-arm muscle circumference; QoL: quality of life; SD: standard deviation; TSF: triceps skinfold thickness.

Table 6. Dietary advice versus dietary advice plus oral nutritional supplements: outcomes with additional data provided or imputed

Study ID	Outcomes where the author provided data	Outcomes where data were imputed
Arnold 1989		Weight read from a graph and SD of change derived by imputation
Baldwin 2011	Mortality, weight, grip strength, QoL scores	
Burden 2011	Energy intake, protein intake	
Burden 2017	Energy intake, protein intake, weight, grip strength	
de Luis 2003	Energy intake, weight, MUAC, TSF	SD of change in FFM imputed from the study by Campbell 2008
Diouf 2016	Weight, FFM, body fat, BMI	
Fuenzalida 1990		SD of change in weight, TSF, MAC derived by calculation from reported P values
Gonzalez-Espinoza 2005	Energy intake, weight, MAC, MAMC	SD of change in BMI derived by imputation from Sharma 2002a . SD for TSF imputed using a correlation coefficient of 0.8
Huynh 2015	Weight, BMI, grip strength, energy intake, protein intake	
Kapoor 2017	Weight, QoL scores, energy intake, protein intake, MUAC	
McCarthy 1999	Energy & protein intake	
Murphy 1992		SD of change in weight & energy intake calculated from reported P values
Norman 2008b	Weight, MAMC, TSF	Data on body cell mass were used in the analysis of FFM and combined using the SMD
Sharma 2002a		SD of change in weight and BMI calculated from reported P values for one intervention group and then used to impute the SD of change for the second intervention group. Duplicate IDs have been used to include the two groups in the analysis.

SD: standard deviation; BMI: body mass index; FFM: fat-free mass; MAMC: mid-arm muscle circumference; MAC: mid-arm circumference; MUAC: mid-upper arm circumferences; QoL: quality of life; TSF: triceps skinfold thickness. format?

Table 7. Dietary advice plus supplements, if required, compared with no advice and no supplements: outcomes with additional data provided or imputed

Study ID	Outcomes where the author provided data	Outcomes where data were imputed
Andersson 2017	Weight	

Table 7. Dietary advice plus supplements, if required, compared with no advice and no supplements: outcomes with additional data provided or imputed (Continued)

Banks 2016	Weight	
Beck 2015	Weight, grip strength, energy and protein intake	
Bourdel-Marchasson 2014	Weight	
Forli 2001	weight, energy intake	
Ganzoni 1994	Weight	
Holyday 2012	Re-admission	
Isenring 2004	Weight, energy & protein intake	SD of change in FFM from 2 studies (Kiss 2016; Ovesen 1993)
Kiss 2016	FFM, weight	
Persson 2002	Weight, energy, QoL	
Rogers 1992		SD of change in weight, TSF, MAMC, handgrip strength from 1 study (Weekes 2009).
Schilp 2013	FFM, weight, grip strength, protein intake, energy intake	
Uster 2013	Mortality, grip strength, protein intake, energy intake	
Vivanti 2015	Information on methodology	

FFM: fat-free mass; SD: standard deviation; QoL: quality of life. format?

Table 8. Dietary advice plus supplements compared with no advice and no supplements: outcomes with additional data provided or imputed

Study ID	Outcomes for which data received from author	Outcomes for which data derived by imputation
Baldwin 2011	Mortality, weight, grip strength, QoL scores	
Berneis 2000		Weight change and SD
Calegari 2011		SD of change in weight imputed from 2 studies (Campbell 2008; Sharma 2002a), SD of change in FFM imputed from 1 study (Campbell 2008).
Paton 2004	Energy intake, n for weight, FFM and handgrip strength	
Payette 2002	Handgrip strength (nb. data on global QoL and MAMC not available)	
Persson 2007	Weight, handgrip	

Table 8. Dietary advice plus supplements compared with no advice and no supplements: outcomes with additional data provided or imputed *(Continued)*

Um 2014

 SD of change in weight imputed from 1 study
 (Baldwin 2011).

Wyers 2013 Weight, QoL, energy- and protein intake

FFM: fat-free mass; MAMC: mid-arm muscle circumference; QoL: quality of life; SD: standard deviation. format?

Table 9. Dietary advice versus no advice: differences at baseline characteristics

Study	Differences at baseline	Risk of bias judgement
Campbell 2008	The numbers of participants malnourished at baseline differed between groups.	Unclear risk
Cano-Torres 2017	Difference in haemoglobin levels between groups, but unlikely to affect outcomes	Low risk
Forster 2012	Intervention group 1 (food group) had significantly higher alcohol intake than micronutrient or control groups.	Unclear risk
Gu 2015	Gender imbalance (more males than females), but unlikely to affect outcomes	Low risk
Imes 1988	Participants in the no advice group were younger and in better clinical condition than those in the group receiving dietary advice.	Unclear risk
Salva 2011	Intervention group were frailer and more of these participants were malnourished or at risk of malnourishment. This trial also has potential sources of bias related to being cluster-randomised	High risk
Stow 2015	Control group (food-based) were heavier, had higher energy, protein and fluid intake as well as higher VAS score. This trial also has potential sources of bias related to being cluster-randomised.	High risk

Table 10. Dietary advice compared with oral nutritional supplements: differences in baseline characteristics

Study	Differences at baseline	Risk of bias judgement
Gray-Donald 1995	Appetite was better in the advice group than in the supplements group.	Unclear risk
Hernandez 2014	Significantly higher total serum protein and creatinine in control group.	Unclear risk
Parsons 2016	Visual analogue score in EQ5D higher in supplement group.	Unclear risk
Stow 2015	Control group (food-based) were heavier, had higher energy, protein and fluid intake as well as higher VAS score. This study also has potential sources of bias related to being cluster randomised.	High risk

Table 11. Dietary advice versus dietary advice plus oral nutritional supplements: differences in baseline characteristics

Study	Differences at baseline	Risk of bias judgement
Beattie 2000	Participants in the advice plus supplements group were significantly younger than those in the advice only group.	Unclear risk
Diouf 2016	Some non-significant minor differences in variables at baseline.	Low risk
Huynh 2015	Baseline characteristics comparable except weight (control group heavier).	Unclear risk
Kapoor 2017	Several differences in baseline characteristics, but baseline parameters adjusted to observe the overall difference between groups using a generalised estimating equation	Low risk
McCarthy 1999	The group receiving nutritional supplements were lighter and received a smaller amount of radiation.	Unclear
Murphy 1992	The group receiving dietary advice plus nutritional supplements were 5 kg heavier at the start of the study than the group receiving dietary advice alone.	Unclear risk
Sharma 2002a	Baseline characteristics only compared for the participants who completed the study and five participants crossed over from the control group to the intervention group.	High risk
Wilson 2001	The dietary counselling and supplement group were significantly older than the dietary group.	Unclear risk

Table 12. Dietary advice plus supplements, if required, compared with no advice and no supplements: differences in baseline characteristics

Study	Differences at baseline	Risk of bias judgement
Carey 2013	Participants in intervention groups weighed less and had lower BMI and MAMC and pre-op weight loss was higher.	Unclear risk
Forli 2001	Some of the assessments of lung function differed significantly between groups.	Unclear risk
Jensen 1997	The participants in the no advice group were significantly older and heavier than those in the advice group.	Unclear risk
Moloney 1983	The treatment group were older than the no treatment group.	Unclear risk
Silvers 2014	Intervention group older and with a higher BMI.	Unclear risk
Uster 2013	Performance status lower in intervention group, comparison of tumour types between groups indicated that patients with head and neck tumours were all randomised to the intervention group, with none in the control group.	Unclear risk

BMI: body mass index

Table 13. Dietary advice plus supplements compared with no advice and no supplements: differences in baseline characteristics

Study	Differences at baseline	Risk of bias judgement
Hampson 2003	Treatment group were significantly lighter and had a lower fat mass than the control group.	Unclear risk of bias
Payette 2002	Baseline characteristics similar apart from age (the control group was significantly younger than the intervention group), but this was judged to be unlikely to affect the outcomes as the mean difference was only 3 years.	Low risk of bias

APPENDICES

Appendix 1. Search strategies used up to 2005

Database	Search terms	Date of latest search
CENTRAL	1. NUTRITION*:ME	Dates between 2002 and 2005
The Cochrane Library	2. NUTR*	
	3. DIET*:ME	
	4. DIET*	
	5. FOOD*:ME	
	6. FOOD	
	7. EATING*:ME	
	8. EAT*	
	9. ENERGY-INTAKE*:ME	
	10. (ENERGY and (NEAR5 and INTAKE))	
	11. (ENERGY and INTAKE)DIET-THERAPY*:ME	
	12. DIETARY-SERVICES*:ME	
	13. DIETETICS*:ME	
	14. FOOD-HABITS*:ME	
	15. FEEDING-BEHAVIOR*:ME	
	16. (#1 or #2) or #3) or #4) or #5) or #6) or #7) or #8) or #9) or #10) or #11) or #12) or #13) or #14) or #15) or #16) or #17)	
	17. DIETARY-SUPPLEMENTS*:ME	
	18. FOOD-FORMULATED*:ME	
	19. SUPPLEM*	
	20. (NUTR* and SUPPLEM*)	
	21. DIET* and SUPPLEM*)	

(Continued)

22. (FOOD* and SUPPLEM*)
23. (#19 or #20) or #21) or #22) or #23) or #24)
24. WEIGHT-GAIN*:ME
25. (WEIGHT and GAIN)
26. (WEIGHT and INCREASE)
27. (WEIGHT and CHANGE)
28. (WEIGHT and FLUCTUATION)
29. NUTRITIONAL-STATUS*:ME
30. (NUTR* and STATUS)
31. ANTHROPOMETRY*:ME
32. ANTHROPOMET*
33. #26 or #27) or #28) or #29) or #30) or #31) or #32) or #33) or #34)
34. ((#18 and #25) and #35)
35. (#18 and #25)

MEDLINE Silver Platter	<ol style="list-style-type: none"> 1. explode "Nutrition"/ all subheadings 2. nutr* 3. explode "Diet"/ all subheadings 4. diet* 5. explode "Food"/ all subheadings 6. food* 7. "Eating"/ all subheadings 8. eat* 9. "Energy-Intake"/ all subheadings 10. energy 11. intake 12. energy intake 13. explode "Diet-Therapy"/ all subheadings 14. explode "Dietary-Services"/ all subheadings 15. "Dietetics"/ all subheadings 16. "Food-Habits"/ all subheadings 17. explode "Feeding-Behavior"/ all subheadings 18. #1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #12 or #13 or #14 or #15 or #16 or #17 19. energy 	Dates between 2002 and 2005
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(Continued)

20. intake
21. energy near5 intake
22. diet*
23. advice
24. diet* near5 advice
25. diet*
26. therapy
27. diet* near5 therapy
28. diet*
29. service*
30. #28 near5 service*
31. counsel*
32. #28 near5 counsel*
33. educat*
34. #2 near5 educat*
35. habit*
36. #6 near5 habit*
37. feed*
38. behav*
39. feed* near5 behav*
40. #21 or #24 or #30 or #33 or #35 or #37 or #39 or #41 or #44 or #1 or #3 or #5 or #7 or #9 or #13 or #14 or #15 or #16 or #17
41. TG=ANIAL
42. TG=HUMAN
43. TG=ANIMAL
44. (TG=ANIMAL)not ((TG=HUMAN)and (TG=ANIMAL))
45. RANDOMIZED-CONTROLLED-TRIAL in PT
46. CONTROLLED-CLINICAL-TRIAL in PT
47. RANDOMIZED-CONTROLLED-TRIALS
48. RANDOM-ALLOCATION
49. DOUBLE-BLIND-METHOD
50. SINGLE-BLIND-METHOD
51. "DIETARY-SUPPLEMENTS"/ all subheadings
52. "FOOD,-FORMULATED"/ all subheadings
53. SUPPLEM*

(Continued)

54. #4 near5 #53
55. #2 near5 #53
56. #6 near5 #53
57. #51 or #52 or #53 or #54 or #55 or #56
58. "Weight-Gain"/ all subheadings
59. weight
60. gain
61. weight near5 gain
62. increas*
63. #59 near5 increas*
64. "Nutritional-Status"/ all subheadings
65. status
66. #2 near5 status
67. improv*
68. intake*
69. (improv* near5 #2) near intake*
70. #58 or #61 or #63 or #64 or #66 or #69
71. explode "Child"/ all subheadings
72. explode "Adult"/ all subheadings
73. #71 not (#71 and (#72))
74. #45 or #46 or #47 or #48 or #49 or #50
75. #18 not #44
76. #18 not #73
77. #75 and #76 and #74
78. #40 not #44
79. #40 not #73
80. #78 and #74
81. #79 and #74
82. #77 and #70
83. #80 and #70
84. #81 and #70
85. #82 and #57
86. #83 and #57
87. #84 and #57

(Continued)

Embase Silver Platter	<ol style="list-style-type: none"> 1. explode "nutrition"/ all subheadings 2. nutr* 3. explode "diet"/ all subheadings 4. diet* 5. explode "food"/ all subheadings 6. food* 7. "eating"/ all subheadings 8. eat* 9. caloric intake 10. "caloric-intake"/ all subheadings 11. energy intake 12. explode "diet-therapy"/ all subheadings 13. explode "health-service"/ all subheadings 14. "dietetics"/ all subheadings 15. explode "feeding-behavior"/ all subheadings 16. feed* near5 behav* 17. #1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16 18. "weight-gain"/ all subheadings 19. weight near5 gain 20. weight near5 increas* 21. #18 or #19 or #20 22. explode "nutritional-status"/ all subheadings 23. nutr* near5 status 24. (improv* near5 nutr*) near intake* 25. #22 or #23 or #24 26. #18 or #19 or #20 or #22 or #23 or #24 27. #17 and #26 	Dates between 2002 and 2005
AMED Ovid	<p>A. nutrition\$ or nutritive or diet or diet therapy or (energy and intake) or dietary service\$ or dietary or eating or</p> <p>food or feeding or feeding behaviour or feeding behavior or food habit\$ or diet advice or dietary advice or</p> <p>dietetics or dietician\$ or caloric intake or calorie intake or (dietary and supplement\$) or (formula\$ and food) or</p> <p>food supplements or elemental).af or dh.fs</p>	Dates between 2002 and 2005

(Continued)

B. weight gain or (weight adj5 gain) or nutrition\$ status or (nutrition\$ adj5 status) or ((improv\$ or gain\$ or

increase\$) adj5 (weight or intake)).af

C. (random\$ or rct\$ or double blind or single blind or treble blind or triple blind or (control\$ and trual\$) or

(clinical adj5 trial\$) or trial or trials or systematic\$ review\$ or metaanal\$ or meta-analys\$).af

((A.ti and B) or (A and B.ti)) and C

CINAHL	1. nutr*	Dates between 2002 and 2005
Silver Platter	2. "Nutrition-Management-(Iowa-NIC)"/ all topical subheadings / in-adulthood , in-old-age, in-middle-age	
	3. explode "Nutrition"/ all topical subheadings / in-adulthood , in-old-age, in-middle-age	
	4. explode "Nutrition-Care-(Saba-HHCC)"/ all topical subheadings / in-adulthood , in-old-age, in-middle-age	
	5. explode "Diet"/ all topical subheadings / in-adulthood , in-old-age, in-middle-age	
	6. diet*	
	7. explode "Food"/ all topical subheadings / in-adulthood , in-old-age, in-middle-age	
	8. food*	
	9. "Eating"/ all topical subheadings / in-adulthood , in-old-age, in-middle-age	
	10. eat*	
	11. "Caloric-Intake"/ all topical subheadings / in-adulthood , in-old-age, in-middle-age	
	12. caloric	
	13. intake	
	14. caloric intake	
	15. explode "Diet-Therapy"/ all topical subheadings / in-adulthood , in-old-age, in-middle-age	
	16. "Nutrition-Therapy-(Iowa-NIC)"/ all topical subheadings / in-adulthood , in-old-age, in-middle-age	
	17. explode "Nutrition-Services"/ all topical subheadings / in-adulthood , in-old-age, in-middle-age	
	18. "Dietetics"/ all topical subheadings / in-adulthood , in-old-age, in-middle-age	
	19. "Research,-Dietetics"/ all topical subheadings / in-adulthood , in-old-age, in-middle-age	
	20. "Education,-Dietetics"/ all topical subheadings / in-adulthood , in-old-age, in-middle-age	

(Continued)

21. explode "Eating-Behavior"/ all topical subheadings / in-adulthood , in-old-age, in-middle-age
22. feed*
23. behav*
24. feed* near5 behav*
25. #1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11 or #14 or #15 or #16 or #17 or #18 or #21 or #24
26. explode "Weight-Gain"/ all topical subheadings / in-adulthood , in-old-age, in-middle-age
27. weight
28. gain
29. weight near5 gain
30. weight
31. increas*
32. weight near5 increas*
33. "Nutritional-Status"/ all topical subheadings / in-adulthood , in-old-age, in-middle-age
34. nutr*
35. status
36. nutr* near5 status
37. improv*
38. nutr*
39. intake
40. improv* near5 nutr* intake
41. "Nutritional-Assessment"/ all topical subheadings / in-adulthood , in-old-age, in-middle-age
42. #26 or #29 or #32 or #33 or #36 or #40 or #41
43. #25 and #42

National Cancer Institute CancerLit

A. nutrition\$ or nutritive or diet or diet therapy or (energy and intake) or dietary service\$ or dietary or eating or
 food or feeding or feeding behaviour or feeding behavior or food habit\$ or diet advice or dietary advice or
 dietetics or dietician\$ or caloric intake or calorie intake or (dietary and supplement\$) or (formula\$ and food) or
 food supplements or elemental).af or dh.fs
 B. weight gain or (weight adj5 gain) or nutrition\$ status or (nutrition\$ adj5 status) or ((improv\$ or gain\$ or
 increase\$) adj5 (weight or intake)).af

Dates between 2002 and 2005

(Continued)

C. (random\$ or rct\$ or double blind or single blind or treble blind or triple blind or (control\$ and trual\$) or (clinical adj5 trial\$) or trial or trials or systematic\$ review\$ or metaanal\$ or meta-analys\$).af
 ((A.ti and B) or (A and B.ti)) and C

ERIC SilverPlatter

1. explode "NUTRITION"
2. nutr*
3. diet*
4. explode "FOOD"
5. food*
6. eat*
7. energy
8. intake
9. energy intake
10. "EATING-HABITS" in DE
11. feed*
12. behav*
13. feed* near5 behav*
14. "FOODS-INSTRUCTION" in DE
15. "OCCUPATIONAL-HOME-ECONOMICS" in DE
16. "NUTRITION-INSTRUCTION" in DE
17. #1 or #2 or #3 or #4 or #5 or #6 or #7 or #9 or #10 or #13 or #14 or #15 or #16
18. explode "BODY-WEIGHT"
19. weight
20. gain
21. weight near5 gain
22. weight
23. increas*
24. weight near5 increas*
25. improv*
26. nutr*
27. intake
28. (improv* near5 nutr*) near intake
29. nutr*
30. status

Dates between 2002
and 2005

(Continued)

31. nutr* near5 status
32. #18 or #21 or #24 or #31
33. #17 and #32

Dissertation Abstracts Silver Platter	<ol style="list-style-type: none"> 1. diet* 2. food* 3. eat* 4. energy 5. intake 6. energy near5 intake 7. caloric 8. intake 9. caloric near5 intake 10. feed* 11. behav* 12. feed* near5 behav* 13. #1 or #2 or #3 or #4 or #5 or #8 or #11 or #14 14. weight 15. gain 16. weight near5 gain 17. weight 18. increas* 19. weight near5 increas* 20. nutr* 21. status 22. nutr* near5 status 23. improv* 24. status 25. intake* 26. (improv* near5 status) near intake* 27. #18 or #21 or #24 or #28 28. #15 and #29 	July 2000
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Appendix 2. Search strategies 2005 to 2010

Database	Search terms	Latest date searched
CENTRAL	<i>not available</i>	
MEDLINE Ovid	1 nutrit*.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (197693) 2 exp *Enteral Nutrition/ or exp *Nutrition Assessment/ or exp *Nutrition Therapy/ or exp *Nutrition Disorders/ (167285) 3 diet*.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (374221) 4 Diet/ or exp *Diet Therapy/ (96580) 5 eat*.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (70476) 6 exp *Food Services/ or exp *Feeding Behavior/ or exp *Food Habits/(35764) 7 food.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (269212) 8 exp *Food, Fortified/ or Food/ or exp *Food, Formulated/ or exp *Food Habits/ or exp *Food Services/ (37268) 9 feed*.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (231101) 10 exp *Eating/ (17444) 11 kalori*.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (47662) 12 exp *Energy Intake/ (7820) 13 exp *Protein-Energy Malnutrition/ or exp *Energy Intake/ (13550) 14 energy.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (250080) 15 oral nutritional supplement.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (25) 16 exp *Dietary Supplements/ (10700) 17 exp *Nutritional Support/ (21933) 18 sip feed.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (17) 19 suppl*.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (287335) 20 exp *Adult/ or exp *Dietary Supplements/ (35396) 21 11 or 7 or 17 or 2 or 1 or 18 or 16 or 13 or 6 or 3 or 9 or 12 or 20 or 14 or 15 or 8 or 4 or 19 or 10 or 5 (1362303) 22 weight.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (626210) 23 weight.mp. (626210) 24 weight gain.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (34990) 25 exp *Weight Gain/ (4196) 26 nutrit* status.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (24171) 27 exp *Nutritional Status/ (6871) 28 27 or 25 or 22 or 24 or 26 or 23 (642887) 29 28 and 21 (180107) 30 limit 29 to yr="2005 - 2008" (34527) 31 limit 30 to humans (22734) 32 limit 31 to controlled clinical trial (200) 33 from 32 keep 1-200 (200) 34 from 33 keep 1-200 (200) 35 from 33 keep 1-200 (200)	February 2010
Embase Ovid	1 nutrit*.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (197693) 2 exp *Enteral Nutrition/ or exp *Nutrition Assessment/ or exp *Nutrition Therapy/ or exp *Nutrition Disorders/ (167285)	February 2010

(Continued)

- 3 diet*.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (374221)
 4 Diet/ or exp *Diet Therapy/ (96580)
 5 eat*.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (70476)
 6 exp *Food Services/ or exp *Feeding Behavior/ or exp *Food Habits/(35764)
 7 food.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (269212)
 8 exp *Food, Fortified/ or Food/ or exp *Food, Formulated/ or exp *Food Habits/ or exp *Food Services/ (37268)
 9 feed*.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (231101)
 10 exp *Eating/ (17444)
 11 kalori*.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (47662)
 12 exp *Energy Intake/ (7820)
 13 exp *Protein-Energy Malnutrition/ or exp *Energy Intake/ (13550)
 14 energy.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (250080)
 15 oral nutritional supplement.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (25)
 16 exp *Dietary Supplements/ (10700)
 17 exp *Nutritional Support/ (21933)
 18 sip feed.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (17)
 19 suppl*.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (287335)
 20 exp *Adult/ or exp *Dietary Supplements/ (35396)
 21 11 or 7 or 17 or 2 or 1 or 18 or 16 or 13 or 6 or 3 or 9 or 12 or 20 or 14 or 15 or 8 or 4 or 19 or 10 or 5 (1362303)
 22 weight.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (626210)
 23 weight.mp. (626210)
 24 weight gain.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (34990)
 25 exp *Weight Gain/ (4196)
 26 nutrit* status.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (24171)
 27 exp *Nutritional Status/ (6871)
 28 27 or 25 or 22 or 24 or 26 or 23 (642887)
 29 28 and 21 (180107)
 30 limit 29 to yr="2005 - 2008" (34527)
 31 limit 30 to humans (22734)
 32 limit 31 to controlled clinical trial (200)
 33 from 32 keep 1-200 (200)
 34 from 33 keep 1-200 (200)
 35 from 33 keep 1-200 (200)

Cinahl EBSCO

(TX+(weight)+OR+(TX+(nutrit*)))

February 2010

+AND+

(TX+(nutrit*))

+OR+(TX+(diet*))

+OR+(TX+(eat))

+OR+(TX+(food))

+OR+(TX+(feed*))

(Continued)

+OR+(TX+(calori*))
+OR+(TX+(energy))
+OR+(TX+(oral+nutritional+supplement))
+OR+(TX+(sip+feed))
+OR+(TX+(suppl*))
+OR+(TX+(educat*))
+OR+(TX+(behav*))
+OR+(TX+(snack))

NOTE: TX denotes a word in the full text

ISI Web of Science (Searched on dates between 2005-2010)	(nutrit* OR diet* OR eat* OR food OR feed* OR calori* OR energy* OR sip OR suppl* OR snack OR educat* OR behav*) AND (nutrit* OR weight gain) AND (random* OR RCT OR control* OR clinical) NOT (child* OR infant OR paediatric) NOT (animal OR rat OR mouse OR guinea pig OR primate OR monkey OR cat OR dog)	February 2010
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Scopus (Searched on dates between 2005-2010)	TITLE-ABSKEY (nutrit* OR diet* OR eat* OR food OR feed* OR calori* OR energy* OR sip OR suppl* OR snack OR educat* KEY (nutrit* OR weight gain)) AND (TITLE-ABS-KEY (random* OR rct OR control* OR clinical)) AND (TITLE-NOT (ABS (child*)) AND NOT (ABS (pregnan*))) AND NOT (ABS (animal* OR rat OR mouse OR guinea pig OR primate OR monkey OR cat OR dog)) AND NOT (ABS NOT (ABS (adolescent*))) AND NOT (ABS (starv*)) AND NOT (ABS (infan*)) AND NOT (ABS (matern*))) AND NOT NOT (ABS (baby)) AND NOT (ABS (babies*)) AND NOT (ABS (neonat*))) AND (LIMIT-TO (PUBYEAR , 2016) OR 2017) OR LIMIT-TO (PUBYEAR , 2018))
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Appendix 3. Search strategies 2013 to 2016

Database	Search strategy	Date searched
CENTRAL	#1 nutrit* #2 MeSH descriptor: [Enteral Nutrition] explode all trees #3 MeSH descriptor: [Nutrition Assessment] explode all trees	25 September 2016

(Continued)

- #4 MeSH descriptor: [Nutrition Therapy] explode all trees
- #5 MeSH descriptor: [Nutrition Disorders] explode all trees
- #6 diet*
- #7 MeSH descriptor: [Diet] this term only
- #8 MeSH descriptor: [Diet Therapy] explode all trees
- #9 eat*
- #10 MeSH descriptor: [Food Services] explode all trees
- #11 MeSH descriptor: [Feeding Behavior] explode all trees
- #12 MeSH descriptor: [Food Habits] explode all trees
- #13 food
- #14 MeSH descriptor: [Food] explode all trees
- #15 MeSH descriptor: [Food, Fortified] explode all trees
- #16 MeSH descriptor: [Food, Formulated] explode all trees
- #17 MeSH descriptor: [Food Habits] explode all trees
- #18 MeSH descriptor: [Food Services] explode all trees
- #19 feed*
- #20 MeSH descriptor: [Eating] explode all trees
- #21 kalori*
- #22 MeSH descriptor: [Energy Intake] explode all trees
- #23 MeSH descriptor: [Protein-Energy Malnutrition] explode all trees
- #24 MeSH descriptor: [Energy Intake] explode all trees
- #25 energy
- #26 oral nutritional supplement
- #27 MeSH descriptor: [Dietary Supplements] explode all trees
- #28 MeSH descriptor: [Nutritional Support] explode all trees
- #29 sip feed
- #30 suppl*
- #31 MeSH descriptor: [Adult] explode all trees
- #32 (#1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17 or #18 or #19 or #20 or #21 or #22 or #23 or #24 or #25 or #26 or #27 or #28 or #29 or #30 or #31)
- #33 weight
- #34 weight gain
- #35 MeSH descriptor: [Weight Gain] explode all trees
- #36 nutrit* status
- #37 MeSH descriptor: [Nutritional Status] explode all trees
- #38 (#33 or #34 or #35 or #36 or #37)
- #39 (#32 and #38)
- #40 (child* or pregnan* or starv* or baby* or babies or pediatric or paediatric or adolescen* or infant or mother* or matern* or obes* or overweight)
- #41 (#39 not #40) Publication Year from 2010 to 2016, in Trials

Search Notes:

Ran search strategy on Cochrane Library 25/9/16

Limits:

1. Publication Year 2010-2016
2. Trials

MEDLINE Ovid

1 nutrit*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
 2 exp *Enteral Nutrition/ or exp *Nutrition Assessment/ or exp *Nutrition Therapy/ or exp *Nutrition Disorders/
 3 diet*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
 4 Diet/ or exp *Diet Therapy/
 5 eat*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
 6 exp *Food Services/ or exp *Feeding Behavior/ or exp *Food Habits/

25 September 2016

(Continued)

7 food.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
 8 exp *Food, Fortified/ or Food/ or exp *Food, Formulated/ or exp *Food Habits/ or exp *Food Services/
 9 feed*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
 10 exp *Eating/
 11 kalori*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
 12 exp *Energy Intake/
 13 exp *Protein-Energy Malnutrition/ or exp *Energy Intake/
 14 energy.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
 15 oral nutritional supplement.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
 16 exp *Dietary Supplements/
 17 exp *Nutritional Support/
 18 sip feed.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
 19 suppl*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
 20 exp *Adult/ or exp *Dietary Supplements/
 21 11 or 7 or 17 or 2 or 1 or 18 or 16 or 13 or 6 or 3 or 9 or 12 or 20 or 14 or 15 or 8 or 4 or 19 or 10 or 5
 22 weight.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
 23 weight.mp.
 24 weight gain.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
 25 exp *Weight Gain/
 26 nutrit* status.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
 27 exp *Nutritional Status/
 28 27 or 25 or 22 or 24 or 26 or 23
 29 28 and 21
 30 limit 29 to yr="2010 - 2016"
 31 limit 30 to humans
 32 limit 31 to (controlled clinical trial or randomized controlled trial)
 33 limit 32 to "all adult (19 plus years)"
 34 (obes* or overweight).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
 35 33 not 34

Search Notes:

Ran search strategy on OVID platform. Includes all of Medline: ePub ahead of print, in-process & other non-indexed citations, OVID medline (R) daily and OVID medline (R) 1946-present) 25/09/16

(Continued)

Limits:

1. 2010-2016
2. Humans
3. Randomised controlled trials & controlled clinical trials
4. Adult aged 19+ years

Embase Ovid	<p>1 nutrit*.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading]</p> <p>2 exp *Enteral Nutrition/ or exp *Nutrition Assessment/ or exp *Nutrition Therapy/ or exp *Nutrition Disorders/</p> <p>3 diet*.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading]</p> <p>4 Diet/ or exp *Diet Therapy/</p> <p>5 eat*.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading]</p> <p>6 exp *Food Services/ or exp *Feeding Behavior/ or exp *Food Habits/</p> <p>7 food.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading]</p> <p>8 exp *Food, Fortified/ or Food/ or exp *Food, Formulated/ or exp *Food Habits/ or exp *Food Services/</p> <p>9 feed*.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading]</p> <p>10 exp *Eating/</p> <p>11 calor*.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading]</p> <p>12 exp *Energy Intake/</p> <p>13 exp *Protein-Energy Malnutrition/ or exp *Energy Intake/</p> <p>14 energy.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading]</p> <p>15 oral nutritional supplement.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading]</p> <p>16 exp *Dietary Supplements/</p> <p>17 exp *Nutritional Support/</p> <p>18 sip feed.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading]</p> <p>19 suppl*.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading]</p> <p>20 exp *Adult/ or exp *Dietary Supplements/</p> <p>21 11 or 7 or 17 or 2 or 1 or 18 or 16 or 13 or 6 or 3 or 9 or 12 or 20 or 14 or 15 or 8 or 4 or 19 or 10 or 5</p> <p>22 weight.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading]</p> <p>23 weight.mp.</p> <p>24 weight gain.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading]</p> <p>25 exp *Weight Gain/</p>	25 September 2016
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(Continued)

26 nutrit* status.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading]
 27 exp *Nutritional Status/
 28 27 or 25 or 22 or 24 or 26 or 23
 29 28 and 21
 30 limit 29 to yr="2010 - 2016"
 31 limit 30 to human
 32 limit 31 to (exclude medline journals and (randomized controlled trial or controlled clinical trial) and (adult <18 to 64 years> or aged <65+ years>))
 33 (obes* or overweight).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading]
 34 32 not 33

Search Notes:

Ran search strategy on OVID platform. Embase 1974 – 2016 September 23

Limits:

1. 2010-2016
2. Human
3. Exclude MEDLINE journals
4. Randomised controlled trials & controlled clinical trials
5. Adult aged 18-64 & 65+ years

<p>CINAHL EBSCO</p>	<p>S1 TX nutrit* OR diet* OR eat OR food OR feed* OR calori* OR energy OR (oral nutritional supplement) OR (sip feed) OR suppl* OR educat* OR behav* OR snack* S2 TX weight OR nutrit* S3 S1 AND S2 S4 (SU Pregnancy) OR (TI pregnan*) S5 (SU child*) OR (TI child*) S6 (SU Infant*) OR (TI infant*) S7 (SU Paediatric*) OR (TI Paediatric*) S8 (SU matern*) OR (TI matern*) S9 (SU mother*) OR (TI mother*) S10 (SU adolescen*) OR (TI adolescen*) S11 S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10 S12 S3 NOT S11 S13 (SU obes*) OR (SU overweight) S14 S12 NOT S13</p> <p>Search Notes:</p> <p>Ran search strategy on EBSCO host platform.</p> <p>Limits:</p> <ol style="list-style-type: none"> 1. Published date 01/02/2010 – 30/09/2016 2. Exclude MEDLINE records 3. All adult 4. Human 	<p>25 September 2016</p>
<p>ISI Web of Science</p>	<p>#1 TS=(nutrit* OR diet* OR eat* OR food OR feed* OR calori* OR energy* OR sip OR suppl* OR snack OR educat* OR behav*) <i>Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=2010-2016</i> #2 TS=(nutrit* OR weight gain)</p>	<p>25 September 2016</p>

(Continued)

Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=2010-2016

#3 TS=(random* OR rct OR control* OR clinical)

Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=2010-2016

#4 TS=(adult*)

Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=2010-2016

#5 #1 AND #2 AND #3 AND #4

Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=2010-2016

#6 ((TS=(child*)) OR (TS=(pregnan*)) OR (TS=(animal* OR rat OR mouse OR guinea pig OR primate OR monkey OR cat OR dog)) OR (TS=(paediatric)) OR (TS=(adolescent*)) OR (TS=(starv*)) OR (TS=(infan*)) OR (TS=(matern*)) OR (TS=(mother*)) OR (TS=(baby)) OR (TS=(babies*)) OR (TS=(neonat*)))

Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=2010-2016

#7 #5 NOT #6

Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=2010-2016

#8 TS=(obes* OR overweight)

Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=2010-2016

#9 #7 NOT #8

Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=2010-2016

Search Notes:

Ran search strategy on Web of Science (Core collection).

Limits:

1. 2010 – 2016 timespan

Scopus	<p>TITLE-ABS-KEY (nutrit* OR diet* OR eat* OR food OR feed* OR calorit* OR energy* OR sip OR suppl* OR snack OR educat* OR behav*)</p> <p>AND</p> <p>(TITLE-ABS-KEY (nutrit* OR weight gain))</p> <p>AND</p> <p>(TITLE-ABS-KEY (random* OR rct OR control* OR clinical))</p> <p>AND</p> <p>(TITLE-ABS (adult*))</p> <p>AND NOT</p> <p>(ABS (child*))</p> <p>AND NOT</p> <p>(ABS (pregnan*))</p> <p>AND NOT</p> <p>(ABS (animal* OR rat OR mouse OR guinea pig OR primate OR monkey OR cat OR dog))</p> <p>AND NOT</p> <p>(ABS (paediatric))</p>	25 September 2016
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(Continued)

AND NOT
(ABS (adolescent*))
AND NOT
(ABS (starv*))
AND NOT
(ABS (infan*))
AND NOT
(ABS (matern*))
AND NOT
(ABS (mother*))
AND NOT
(ABS (baby))
AND NOT
(ABS (babies*))
AND NOT
(ABS (neonat*))
AND NOT
(ABS (obes*))
AND NOT
(ABS (overweight))
AND ORIG-LOAD-DATE AFT 20160925
AND (LIMIT-TO (PUBYEAR , 2010)
OR EXCLUDE (PUBYEAR , 2016 OR limit-to PUBYEAR)
OR EXCLUDE (PUBYEAR , 2014 OR limit-to PUBYEAR)
OR EXCLUDE (PUBYEAR , 2012 OR limit-to PUBYEAR))
Search Notes:
Ran search strategy on Scopus.
Limits:
1. Publication year 2010 – 2016

Appendix 4. Search strategies 2016 to 2018

Database	Search terms	Date searched
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(Continued)

CENTRAL

10 January 2018

#1 nutrit*
 #2 MeSH descriptor: [Enteral Nutrition] explode all trees
 #3 MeSH descriptor: [Nutrition Assessment] explode all trees
 #4 MeSH descriptor: [Nutrition Therapy] explode all trees
 #5 MeSH descriptor: [Nutrition Disorders] explode all trees
 #6 diet*
 #7 MeSH descriptor: [Diet] this term only
 #8 MeSH descriptor: [Diet Therapy] explode all trees
 #9 eat*
 #10 MeSH descriptor: [Food Services] explode all trees
 #11 MeSH descriptor: [Feeding Behavior] explode all trees
 #12 MeSH descriptor: [Food Habits] explode all trees
 #13 food
 #14 MeSH descriptor: [Food] explode all trees
 #15 MeSH descriptor: [Food, Fortified] explode all trees
 #16 MeSH descriptor: [Food, Formulated] explode all trees
 #17 MeSH descriptor: [Food Habits] explode all trees
 #18 MeSH descriptor: [Food Services] explode all trees
 #19 feed*
 #20 MeSH descriptor: [Eating] explode all trees
 #21 calori*
 #22 MeSH descriptor: [Energy Intake] explode all trees
 #23 MeSH descriptor: [Protein-Energy Malnutrition] explode all trees
 #24 MeSH descriptor: [Energy Intake] explode all trees
 #25 energy
 #26 oral nutritional supplement
 #27 MeSH descriptor: [Dietary Supplements] explode all trees
 #28 MeSH descriptor: [Nutritional Support] explode all trees
 #29 sip feed
 #30 suppl*
 #31 MeSH descriptor: [Adult] explode all trees
 #32 (#1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17 or #18 or #19 or #20 or #21 or #22 or #23 or #24 or #25 or #26 or #27 or #28 or #29 or #30 or #31)
 #33 weight
 #34 weight gain
 #35 MeSH descriptor: [Weight Gain] explode all trees
 #36 nutrit* status
 #37 MeSH descriptor: [Nutritional Status] explode all trees
 #38 (#33 or #34 or #35 or #36 or #37)
 #39 (#32 and #38)
 #40 (child* or pregnan* or starv* or baby* or babies or pediatric or paediatric or adolescen* or infant or mother* or matern* or obes* or overweight)
 #41 (#39 not #40) Publication Year from 2016 to 2018

Search Notes:

Ran search strategy on Cochrane Library.

Limits:

1. Publication Year 2016-2018
2. Trials

MEDLINE Ovid

1 nutrit*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

10 January 2018

2 exp *Enteral Nutrition/ or exp *Nutrition Assessment/ or exp *Nutrition Therapy/ or exp *Nutrition Disorders/

(Continued)

3 diet*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

4 Diet/ or exp *Diet Therapy/

5 eat*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

6 exp *Food Services/ or exp *Feeding Behavior/ or exp *Food Habits/

7 food.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

8 exp *Food, Fortified/ or Food/ or exp *Food, Formulated/ or exp *Food Habits/ or exp *Food Services/

9 feed*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

10 exp *Eating/

11 calori*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

12 exp *Energy Intake/

13 exp *Protein-Energy Malnutrition/ or exp *Energy Intake/

14 energy.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

15 oral nutritional supplement.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

16 exp *Dietary Supplements/

17 exp *Nutritional Support/

18 sip feed.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

19 suppl*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

20 exp *Adult/ or exp *Dietary Supplements/

21 11 or 7 or 17 or 2 or 1 or 18 or 16 or 13 or 6 or 3 or 9 or 12 or 20 or 14 or 15 or 8 or 4 or 19 or 10 or 5

22 weight.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept

(Continued)

word, rare disease supplementary concept word, unique identifier, synonyms]

23 weight.mp.

24 weight gain.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

25 exp *Weight Gain/

26 nutrit* status.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

27 exp *Nutritional Status/

28 27 or 25 or 22 or 24 or 26 or 23 29 28 and 21

30 limit 29 to yr="2016 - 2018"

31 limit 30 to humans

32 limit 31 to (controlled clinical trial or randomized controlled trial)

33 limit 32 to "all adult (19 plus years)"

34 (obes* or overweight).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

35 33 not 34

Search notes:

Ran search strategy on OVID platform. Includes all of Medline: ePub ahead of print, in-process & other non-indexed citations, OVID medline (R) daily and OVID medline (R) 1946-present)

Limits:

1. 2016-2018
2. Humans
3. Randomised controlled trials & controlled clinical trials
4. Adult aged 19+ years

Embase Ovid

1 nutrit*.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading]
 2 exp *Enteral Nutrition/ or exp *Nutrition Assessment/ or exp *Nutrition Therapy/ or exp *Nutrition Disorders/
 3 diet*.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading]
 4 Diet/ or exp *Diet Therapy/
 5 eat*.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading]
 6 exp *Food Services/ or exp *Feeding Behavior/ or exp *Food Habits/

10 January 2018

(Continued)

7 food.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading]
 8 exp *Food, Fortified/ or Food/ or exp *Food, Formulated/ or exp *Food Habits/ or exp *Food Services/
 9 feed*.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading]
 10 exp *Eating/
 11 kalori*.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading]
 12 exp *Energy Intake/
 13 exp *Protein-Energy Malnutrition/ or exp *Energy Intake/
 14 energy.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading]
 15 oral nutritional supplement.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading]
 16 exp *Dietary Supplements/
 17 exp *Nutritional Support/
 18 sip feed.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading]
 19 suppl*.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading]
 20 exp *Adult/ or exp *Dietary Supplements/
 21 11 or 7 or 17 or 2 or 1 or 18 or 16 or 13 or 6 or 3 or 9 or 12 or 20 or 14 or 15 or 8 or 4 or 19 or 10 or 5
 22 weight.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading]
 23 weight.mp.
 24 weight gain.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading]
 25 exp *Weight Gain/
 26 nutrit* status.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading]
 27 exp *Nutritional Status/
 28 27 or 25 or 22 or 24 or 26 or 23
 29 28 and 21
 30 limit 29 to yr="2013 - 2016"
 31 limit 30 to human
 32 limit 31 to (exclude medline journals and (randomized controlled trial or controlled clinical trial) and (adult <18 to 64 years> or aged <65+ years>))
 33 (obes* or overweight).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading]
 34 32 not 33

Search notes:

Ran search strategy on OVID platform. Embase 1974 – 2018 Week 2

Limits:

1. 2016-2018

(Continued)

2. Human
3. Exclude MEDLINE journals
4. Randomised controlled trials & controlled clinical trials
5. Adult aged 18-64 & 65+ years

CINAHL EBSCO	S1 TX nutrit* OR diet* OR eat OR food OR feed* OR calori* OR energy OR (oral nutritional supplement) OR (sip feed) OR suppl* OR educat* OR behav* OR snack*	10 January 2018
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S2 TX weight OR nutrit*

S3 S1 AND S2

S4 (SU Pregnancy) OR (TI pregnan*)

S5 (SU child*) OR (TI child*)

S6 (SU Infant*) OR (TI infant*)

S7 (SU Paediatric*) OR (TI Paediatric*)

S8 (SU matern*) OR (TI matern*)

S9 (SU matern*) OR (TI matern*)

S10 (SU adolescen*) OR (TI adolescen*)

S11 S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10

S12 S3 NOT S11

S13 (SU obes*) OR (SU overweight)

S14 S12 NOT S13

Search notes:

Ran search strategy on EBSCO host platform.

10/1/18 @ 3:30pm

Limits:

1. Published date Oct 2016 – Jan 2018
2. Exclude MEDLINE records
3. All adult
4. Human

ISI Web of Science	#1	10 January 2018
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TS=(nutrit* OR diet* OR eat* OR food OR feed* OR calori* OR energy* OR sip OR suppl* OR snack OR educat* OR behav*)

Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=2016-2018

#2 TS=(nutrit* OR weight gain)

Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=2016-2018

#3 TS=(random* OR rct OR control* OR clinical)

(Continued)

Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=2016-2018

#4 TS=(adult*)

Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=2016-2018

#5 #1 AND #2 AND #3 AND #4

Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=2016-2018

#6 ((TS=(child*)) OR (TS=(pregnan*)) OR (TS=(animal* OR rat OR mouse OR guinea pig OR primate OR monkey OR cat OR dog)) OR (TS=(paediatric)) OR (TS=(adolescent*)) OR (TS=(starv*)) OR (TS=(infan*)) OR (TS=(matern*)) OR (TS=(mother*)) OR (TS=(baby)) OR (TS=(babies*)) OR (TS=(neonat*)))

Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=2016-2018

#7 #5 NOT #6

Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=2016-2018

Search notes:

Ran search strategy on Web of Science (Core collection).

Limits:

1. 2016 – 2018 timespan

Scopus	TITLE-ABS-KEY (nutrit* OR diet* OR eat* OR food OR feed* OR calori* OR energy* OR sip OR suppl* OR snack OR educat* OR behav*) AND (TITLE-ABS-KEY (nutrit* OR weight gain)) AND (TITLE-ABS-KEY (random* OR rct OR control* OR clinical)) AND (TITLE-ABS (adult*)) AND NOT (ABS (child*)) AND NOT (ABS (pregnan*)) AND NOT (ABS (animal* OR rat OR mouse OR guinea pig OR primate OR monkey OR cat OR dog)) AND NOT (ABS (paediatric)) AND NOT (ABS (adolescent*)) AND NOT (ABS (starv*)) AND NOT (ABS (infan*)) AND NOT (ABS (matern*)) AND NOT (ABS (mother*)) AND NOT (ABS (baby)) AND NOT (ABS (babies*)) AND NOT (ABS (neonat*)) AND (LIMIT-TO (PUBYEAR , 2016) OR LIMIT-TO (PUBYEAR , 2017) OR LIMIT-TO (PUBYEAR , 2018))	10 January 2018
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Search notes:

Ran search strategy on Scopus.

Limits:

1. Publication year 2016 – 2018

ClinicalTrials.gov	nutrit* OR diet* OR eat OR food OR feed* OR calori* OR energy OR (oral nutritional supplement) OR (sip feed) OR suppl* OR educat* OR behav* OR snack* Interventional Studies (dietary advice) OR (oral nutritional supplement*) OR (dietary counselling) OR (nutrition* counselling) OR (nutrition* supplement*) OR (oral nutrition supplement*) OR dietitian OR dietician OR (sip feed) OR (food fortification) OR (increase* intake) Adult, Senior First posted from 11/10/2016 to 01/10/2018	10 January 2018
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Search notes:

(Continued)

Ran search strategy on Clinical Trials.gov.

Limits:

1. Studies first posted from 11/10/2016 to 10/1/2018
2. Adult & Senior

Appendix 5. Search strategies current version (2021)

Database	Search terms	Date searched
CENTRAL	#1 Malnutrition:ti,ab,kw 4782 #2 Nutrition*:ti,ab,kw 42988 #3 Food*:ti,ab,kw 48413 #4 Diet*:ti,ab,kw 92912 #5 Snack*:ti,ab,kw 2563 #6 Fortifi*:ti,ab,kw 3255 #7 Supplement*:ti,ab,kw 71499 #8 MeSH descriptor: [Diet] explode all trees 18618 #9 MeSH descriptor: [Dietetics] explode all trees 96 #10 MeSH descriptor: [Diet Therapy] explode all trees 5953 #11 MeSH descriptor: [Dietary Supplements] explode all trees 12689 #12 MeSH descriptor: [Nutrition Therapy] explode all trees 9471 #13 MeSH descriptor: [Nutritional Status] explode all trees 2506 #14 MeSH descriptor: [Nutritional Support] explode all trees 3401 #15 MeSH descriptor: [Nutritional Requirements] explode all trees 682 #16 MeSH descriptor: [Nutrition Disorders] explode all trees 19150 #17 MeSH descriptor: [Malnutrition] explode all trees 4294 #18 MeSH descriptor: [Eating] explode all trees 3593 #19 MeSH descriptor: [Food] explode all trees 34794 #20 MeSH descriptor: [Enteral Nutrition] explode all trees 1857 #21 MeSH descriptor: [] explode all trees and with qualifier(s): [diet therapy - DH] 8040 #22 #1 or #2 or #3 #4 or #5 #6 #7 #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17 or #18 or #19 or #20 or #21 96488 #23 (Appointment* or Meet* or Session* or Seminar* or Discuss* or Advise* or Advice or Liais* or Verbal* or Class or Counsel* or Visit*):ti,ab,kw 311638 #24 ("Face to face" or face-to-face or Leaflet* or Booklet* or written or Phone* or Telephone* or Guide* or Guidance or Inform* or Document* or Program or programme):ti,ab,kw 353041 #25 (Recommend* or Monitor* or Manage* or Support* or Educat* or Instruct* or Teach* or Taught):ti,ab,kw 434232 #26 (Personal* or Individual* or Devise* or Prescription* or Prescribe* or Tailor*):ti,ab,kw 192492 #27 ((Prepared NEAR/2 food*) or (Prepared NEAR/2 diet*)):ti,ab,kw 247 #28 MeSH descriptor: [Dietary Services] explode all trees 95 #29 MeSH descriptor: [Feeding Behavior] explode all trees 8947 #30 MeSH descriptor: [Nutrition Assessment] explode all trees 688 #31 MeSH descriptor: [Counseling] explode all trees 5526 #32 #23 or #24 or #25 or #26 or #27 #28 or #29 or #30 or #31 811785 #33 #22 and #32 57014 #34 (breastfed* or breastfeed* or pregnant or baby or babies or caesarean or cesarean or C-section or matern* or mother* or overweight or bariatric or obese or obesity or starv*):ti,ab,kw 105862 #35 #33 not #34 36843 #36 (#33 not #34) not ((children or paediatric* or pediatric*):ti not ((children or paediatric* or pediatric*) and adult*):ti) 33944	01 March 2021

(Continued)

- eSH descriptor: [Nutrition Assessment] explode all trees 680
- #4 MeSH descriptor: [Nutrition Therapy] explode all trees 8971
- #5 MeSH descriptor: [Nutrition Disorders] explode all trees 17148
- #6 diet* 87645
- #7 MeSH descriptor: [Diet] this term only 6603
- #8 MeSH descriptor: [Diet Therapy] explode all trees 5621
- #9 eat* 17506
- #10 MeSH descriptor: [Food Services] explode all trees 357
- #11 MeSH descriptor: [Feeding Behavior] explode all trees 8519
- #12 MeSH descriptor: [Feeding Behavior] explode all trees 8519
- #13 food 45141
- #14 MeSH descriptor: [Food] explode all trees 32218
- #15 MeSH descriptor: [Food, Fortified] explode all trees 1373
- #16 MeSH descriptor: [Food, Formulated] explode all trees 1336
- #17 MeSH descriptor: [Feeding Behavior] explode all trees 8519
- #18 MeSH descriptor: [Food Services] explode all trees 357
- #19 feed* 40437
- #20 MeSH descriptor: [Eating] explode all trees 3448
- #21 calori* 13812
- #22 MeSH descriptor: [Energy Intake] explode all trees 5177
- #23 MeSH descriptor: [Protein-Energy Malnutrition] explode all trees 243
- #24 MeSH descriptor: [Energy Intake] explode all trees 5177
- #25 energy 33189
- #26 oral nutritional supplement 914
- #27 MeSH descriptor: [Dietary Supplements] explode all trees 11667
- #28 MeSH descriptor: [Nutritional Support] explode all trees 3264
- #29 sip feed 51
- #30 suppl* 187237
- #31 MeSH descriptor: [Adult] explode all trees 3442
- #32 (#1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17 or #18 or #19 or #20 or #21 or #22 or #23 or #24 or #25 or #26 or #27 or #28 or #29 or #30 or #31) 334844
- #33 weight 106965
- #34 weight gain 13574
- #35 MeSH descriptor: [Weight Gain] explode all trees 2399

(Continued)

- #36 nutri* status 15152
- #37 MeSH descriptor: [Nutritional Status] explode all trees 2361
- #38 (#33 or #34 or #35 or #36 or #37) 116911
- #39 (#32 and #38) 62672
- #40 (child* or pregnan* or starv* or baby* or babies or pediatric or paediatric or adolescen* or infant or mother* or matern* or obes* or overweight) 352233
- #41 (#39 not #40) with Publication Year from 2018 to 2020, in Trials 4000

Search Notes:

Ran search strategy on Cochrane library.

10/1/20 @ 5:00pm

Limits:

1. Publication Year 2018-2020
2. Trials

Results: 4000 (imported into Endnote 9)

<p>MEDLINE Ovid</p>	<p>#1 nutrit*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]</p> <p>#2 exp *Enteral Nutrition/ or exp *Nutrition Assessment/ or exp *Nutrition Therapy/ or exp *Nutrition Disorders/</p> <p>#3 diet*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]</p> <p>#4 Diet/ or exp *Diet Therapy/</p> <p>#5 eat*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]</p> <p>#6 exp *Food Services/ or exp *Feeding Behavior/ or exp *Food Habits/</p> <p>#7 food.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]</p> <p>#8 exp *Food, Fortified/ or Food/ or exp *Food, Formulated/ or exp *Food Habits/ or exp *Food Services/</p> <p>#9 feed*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]</p> <p>#10 exp *Eating/</p>	<p>10 January 2020</p>
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(Continued)

#11 *calori*.mp.* [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

#12 *exp *Energy Intake/*

#13 *exp *Protein-Energy Malnutrition/ or exp *Energy Intake/*

#14 *energy.mp.* [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

#15 *oral nutritional supplement.mp.* [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

#16 *exp *Dietary Supplements/*

#17 *exp *Nutritional Support/*

#18 *sip feed.mp.* [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

#19 *suppl*.mp.* [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

#20 *exp *Adult/ or exp *Dietary Supplements/*

#21 *11 or 7 or 17 or 2 or 1 or 18 or 16 or 13 or 6 or 3 or 9 or 12 or 20 or 14 or 15 or 8 or 4 or 19 or 10 or 5*

#22 *weight.mp.* [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

#23 *weight.mp.*

#24 *weight gain.mp.* [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

#25 *exp *Weight Gain/*

#26 *nutrit* status.mp.* [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

#27 *exp *Nutritional Status/*

#28 *27 or 25 or 22 or 24 or 26 or 23*

#29 *28 and 21*

(Continued)

#30 (obes* or overweight).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

#31 29 not 30

#32 limit 31 to (humans and yr="2018 - 2020" and "adult (19 to 44 years)" and (controlled clinical trial or randomized controlled trial))

Ran search strategy on OVID platform. Includes all of Medline: ePub ahead of print, in-process & other non-indexed citations, OVID medline (R) daily and OVID medline (R) 1946-present)

10.1.2020 @ 2:00pm

Limits:

1. 2018-2020
2. Humans
3. Randomised controlled trials & controlled clinical trials
4. Adult aged 19+ years

Embase Ovid	<p>1 nutrit*.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word]</p> <p>2 exp *Enteral Nutrition/ or exp *Nutrition Assessment/ or exp *Nutrition Therapy/ or exp *Nutrition Disorders/</p> <p>3 diet*.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word]</p> <p>4 Diet/ or exp *Diet Therapy/</p> <p>5 eat*.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word]</p> <p>6 exp *Food Services/ or exp *Feeding Behavior/ or exp *Food Habits/</p> <p>7 food.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word]</p> <p>8 exp *Food, Fortified/ or Food/ or exp *Food, Formulated/ or exp *Food Habits/ or exp *Food Services/</p> <p>9 feed*.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word]</p> <p>10 exp *Eating/</p> <p>11 calori*.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word]</p> <p>12 exp *Energy Intake/</p> <p>13 exp *Protein-Energy Malnutrition/ or exp *Energy Intake/</p> <p>14 energy.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word]</p>	10 January 2020
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(Continued)

15 oral nutritional supplement.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word]
 16 exp *Dietary Supplements/
 17 exp *Nutritional Support/
 18 sip feed.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word]
 19 suppl*.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word]
 20 exp *Adult/ or exp *Dietary Supplements/
 21 11 or 7 or 17 or 2 or 1 or 18 or 16 or 13 or 6 or 3 or 9 or 12 or 20 or 14 or 15 or 8 or 4 or 19 or 10 or 5
 22 weight.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word]
 23 weight.mp.
 24 weight gain.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word]
 25 exp *Weight Gain/
 26 nutrit* status.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word]
 27 exp *Nutritional Status/
 28 27 or 25 or 22 or 24 or 26 or 23
 29 28 and 21
 30 (obes* or overweight).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word]
 31 limit 29 to (human and exclude medline journals and (randomized controlled trial or controlled clinical trial) and yr="2018 - 2020" and (adult <18 to 64 years> or aged <65+ years>))
 32 31 not 30

Ran search strategy on OVID platform. Embase 1974 – 2018 Week 1
Limits:

1. 2018-2020
2. Human
3. Exclude MEDLINE journals
4. Randomised controlled trials & controlled clinical trials
5. Adult aged 18-64 & 65+ years

CINAHL	S1 TX nutrit* OR diet* OR eat OR food OR feed* OR calori* OR energy OR (oral nutritional supplement) OR (sip feed) OR suppl* OR educat* OR behav* OR snack*	10 January 2020
EBSCO	S2 TX weight OR nutrit*	
	S3 S1 AND S2	
	S4 (SU Pregnancy) OR (TI pregnan*)	
	S5 (SU child*) OR (TI child*)	
	S6 (SU Infant*) OR (TI infant*)	
	S7 (SU Paediatric*) OR (TI Paediatric*)	

(Continued)

S8 (SU matern*) OR (TI matern*)
 S9 (SU mother*) OR (TI mother*)
 S10 (SU adolescen*) OR (TI adolescen*)
 S11 S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10
 S12 S3 NOT S11
 S13 (SU obes*) OR (SU overweight)
 S14 S12 NOT S13

Limiters - Published Date: 20180101-20200131; Exclude MEDLINE records; Human; Publication Type: Randomized Controlled Trial; Age Groups: All Adult

ISI Web of Science #1 TS=(nutrit* OR diet* OR eat* OR food OR feed* OR calori* OR energy* OR sip OR suppl* OR snack OR educat* OR behav*) 10 January 2020

Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=2018-2020

#2 TS=(nutrit* OR weight gain)

Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=2018-2020

#3 TS=(random* OR rct OR control* OR clinical)

Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=2018-2020

#4 TS=(adult*)

Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=2018-2020

#5 1 AND #2 AND #3 AND #4

Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=2018-2020

#6 ((TS=(child*)) OR (TS=(pregnan*)) OR (TS=(obes*)) OR (TS=(animal* OR rat OR mouse OR guinea pig OR primate OR monkey OR cat OR dog)) OR (TS=(paediatric)) OR (TS=(adolescent*)) OR (TS=(starv*)) OR (TS=(infan*)) OR (TS=(matern*)) OR (TS=(mother*)) OR (TS=(baby)) OR (TS=(babies*)) OR (TS=(neonat*)))

Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=2018-2020

#7 #5 NOT #6

Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=2018-2020

Ran search strategy on Web of Science (Core collection).

10.1.2020 @ 4:30pm

Limits:

(Continued)

1. 2018 – 2020 timespan

Results: [2156](#) (imported into Endnote 9)

Scopus	<p>TITLE-ABS-KEY (nutrit* OR diet* OR eat* OR food OR feed* OR calori* OR ener- gy* OR sip OR suppl* OR snack OR educat* OR behav*)</p> <p>AND</p> <p>(TITLE-ABS-KEY (nutrit* OR weight gain))</p> <p>AND</p> <p>(TITLE-ABS-KEY (random* OR rct OR control* OR clinical))</p> <p>AND (TITLE-ABS (adult*))</p> <p>AND NOT</p> <p>(ABS (child*))</p> <p>AND NOT</p> <p>(ABS (pregnan*))</p> <p>AND NOT</p> <p>(ABS (animal* OR rat OR mouse OR guinea pig OR primate OR monkey OR cat OR dog))</p> <p>AND NOT</p> <p>(ABS (paediatric))</p> <p>AND NOT</p> <p>(ABS (adolescent*))</p> <p>AND NOT</p> <p>(ABS (starv*))</p> <p>AND NOT</p> <p>(ABS (infan*))</p> <p>AND NOT</p> <p>(ABS (matern*))</p> <p>AND NOT</p> <p>(ABS (mother*))</p> <p>AND NOT</p> <p>(ABS (baby))</p> <p>AND NOT</p> <p>(ABS (babies*))</p> <p>AND NOT</p> <p>(ABS (neonat*))</p> <p>AND</p>	10 January 2020
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(Continued)

(LIMIT-TO (PUBYEAR , 2018) OR LIMIT-TO (PUBYEAR , 2019) OR LIMIT-TO (PUBYEAR , 2020))

Search Notes:

Ran search strategy on Scopus.

10/1/2020 @ 4:00 pm

Limits:

1. Publication year 2018 – 2020

Results: 534 (imported into Endnote 9)

ClinicalTrials.gov	[Advanced Search Form]	03
	Condition or disease: NOT (obesity OR pregnancy)	March 2021
	Study type: Interventional Studies (Clinical Trials)	
	Age Group: Adult (18-64)	
	Older Adult (65+)	
	Intervention/ treatment: (nutrition OR nutritional OR malnutrition OR dietary OR diet OR food OR eating OR snack) AND (advice OR counseling OR counselling OR education OR educate OR guidance OR guide OR personalised OR personalized OR program OR programme OR support OR information)	
	(4082 results found)	
WHO ICTRP	Database not available in 2020 - 21 due to pandemic.	

WHAT'S NEW

Date	Event	Description
21 December 2021	Amended	In the 'Dates and Events' section, the spelling of the name of one of the new co-authors (Marian de van der Schueren) has been corrected.

HISTORY

Protocol first published: Issue 2, 2000

Review first published: Issue 2, 2001

Date	Event	Description
21 December 2021	New citation required and conclusions have changed	Two new review authors have joined the team (Marian de van der Schueren and Hinke Kruijenga).

Date	Event	Description
		<p>A new comparison of 'dietary advice and prescription of an oral nutritional supplement compared with no advice and no oral nutritional supplement' has been added to the review allowing conclusions to be drawn about this comparison.</p> <p>The authors have added 'complications' as a measure of morbidity and report on this outcome.</p>
21 December 2021	New search has been performed	<p>Following updated searches we added 49 new studies (7098 participants) to the review at this update. A new comparison of 'dietary advice and prescription of an oral nutritional supplement compared with no advice and no oral nutritional supplement' has been added to the review.</p> <p>We have added a summary of findings tables to the review (one for each comparison presented).</p>
22 May 2012	Amended	Contact details updated.
19 July 2011	New citation required but conclusions have not changed	<p>The title of the review has been changed from 'Dietary advice for illness-related malnutrition in adults' to 'Dietary advice with or without oral nutritional supplements for disease-related malnutrition in adults' following advice from the peer reviewers and the editor.</p>
8 June 2011	New search has been performed	<p>In total 12 new studies have been included in the review (Baldwin 2011; Campbell 2008; Chandra 1985; Gonzalez-Espinoza 2005; Manguso 2005; Norman 2008b; Persson 2007; Ravasco 2005b; Rydwik 2008; Sharma 2002a; Singh 2008; Stratton 2007a).</p> <p>Whilst updating this review, a separate group of studies of supportive interventions to enhance nutritional intake have been identified. These studies will be included in a new review. Two studies originally included in this review meet the inclusion criteria of the new review and therefore have been removed from this review at this update and will be included in the new review (Hickson 2004; Turic 1998).</p> <p>After consideration by both authors, 30 new studies have been excluded from the review (Arutiunov 2009; Beck 2008; Botella-Carretero 2008; Carlsson 2005; Duncan 2006; Forli 2006; Idilman 2009; Jie 2009; Krasnoff 2006; Kruizenga 2005; Lejeune 2005; Manders 2009; Nijs 2006; Olofsson 2007; Parrott 2006; Pedersen 2005; Planas 2005; Plank 2008; Rabinovitch 2006; Rasmussen 2006; Rüfenacht 2010; Salas-Salvado 2005; Simmons 2008; Smoliner 2008; Solerte 2008; Swanenburg 2007; Tatsumi 2009; Taylor 2006; Watson 2008; Wouters-Wessling 2005).</p> <p>There are three studies 'Awaiting classification' (Margare 2002a; Penalva 2009a; Shatenstein 2008).</p>
12 November 2008	Amended	Converted to new review format.
14 November 2007	New citation required and conclusions have changed	<p>Substantive amendment.</p> <p>Tessa Parsons and Stuart Logan have stepped down as authors on this review. A new co-author, Elizabeth Weekes, has been recruited.</p>

Date	Event	Description
14 November 2007	New search has been performed	<p>The latest search did not identify any studies eligible for inclusion in the review.</p> <p>Two papers previously listed as 'Awaiting Assessment' have now been moved to 'Included studies' (Kalnins 2005; Weekes 2006). The Kalnins 2005 paper is the primary paper for the previously included study (abstracts) - Kalnins 1996.</p> <p>In the previous version of the review it was unclear how the different studies measured grip strength and so we removed the graphs showing these data and presented the reported means and standard deviations in an additional table. We have now been able to clarify this issue and the data for this outcome is again presented in the analysis.</p> <p>The plain language summary has been updated in light of the current guidance from The Cochrane Collaboration.</p>
15 November 2006	New search has been performed	<p>Eleven studies have been added to the 'Included studies' section and there are now two studies listed as 'Awaiting Assessment'.</p> <p>It is unclear how the different studies have measured grip strength. Until this has been clarified, we have removed the graphs showing these data and presented the reported means and standard deviations in an additional table.</p> <p>The previous version of this review suggested that nutritional supplements were associated with significantly greater short-term weight gains. The addition of data at this update has challenged this finding, although it has not been possible to combine the new data in a meta-analysis. Additionally, this review demonstrates significant improvements in weight in people receiving dietary advice with nutritional supplements rather than dietary advice alone or no intervention. This review has still failed to find any evidence for clinical benefits, such as improved survival, rate of complications and reductions in numbers of hospital admissions and length of stay, of dietary advice.</p>
19 February 2004	New search has been performed	<p>Two studies (McCarthy 1999; Persson 2002) have been added to the 'Included studies' section. Data are not currently available from these studies, but are being sought from the authors. The reviewers aim to incorporate these data into the next update of the review.</p> <p>Data from a study previously included in 'Studies awaiting assessment' has been obtained from the author and this study is now incorporated into the review (Hickson 2002).</p>
27 February 2002	New search has been performed	<p>This includes the addition of one study into the "Studies Awaiting Assessment" section of the review. The Hickson 2002 study has not been published in full, but has been submitted for publication and will be incorporated into a future update of this review.</p>

CONTRIBUTIONS OF AUTHORS

Until January 2007, the original review and all updates were prepared by Christine Baldwin and Tessa Parsons with Stuart Logan acting in a senior author capacity. Christine Baldwin, Tessa Parsons and Stuart Logan contributed to the development of the protocol and preparation of the review. Christine Baldwin and Tessa Parsons conducted the searches, selected studies for inclusion, entered data and prepared the

analyses. Any questions or disagreements were resolved in discussion with Stuart Logan. After this date, both Tessa Parsons and Stuart Logan stepped down as authors on this review.

In 2007 a new co-author, Elizabeth Weekes was recruited and has continued to contribute to all versions up to the current the update.

For the 2021 update two new co-authors joined the team, Marian de van der Scheuren and Hinke Kruizenga. All four authors have contributed equally to the process of selection of studies for inclusion, data entry, preparation of the analyses and interpretation of findings.

Christine Baldwin acts as guarantor of the review.

DECLARATIONS OF INTEREST

The first year of work on the protocol for this review was funded by the British Dietetic Association.

The authors of this review are all authors of studies included in the review, but have not extracted data or assessed risk of bias for any studies they have authored.

MdvdS declares her institution received honoraria for independent lectures which she gave at educational and scientific events organized by Fresenius Kabi, Nutricia; she has also received a grant (paid to her institution) from the Dutch cancer society to perform a nutritional intervention trial.

LW declares receipt of funds from Abbott Nutrition for an educational webinar on the estimation of nutritional requirements and from Nutricia UK for serving on the expert panel of the recently published COPD Malnutrition Pathway; neither of these had any direct bearing on the preparation and completion of this Cochrane Review.

CB and HMK declare no potential conflicts of interest.

SOURCES OF SUPPORT

Internal sources

- Systematic Reviews Training Unit (funded by the London Regional Health Authority), UK

The Systematic Reviews Training Unit at University College London provided a fully funded place on a one year scheme (1998 to 1999) which provided training and support in undertaking a Cochrane systematic review.

External sources

- British Dietetic Association, UK

Through a grant from the General and Education Trust, the British Dietetic Association funded some of the work in the first two years of undertaking this review.

- National Institute for Health Research, UK

This systematic review was supported by the National Institute for Health Research, via Cochrane Infrastructure funding to the Cochrane Cystic Fibrosis and Genetic Disorders Group.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

The authors added the intervention 'dietary advice plus ONS if required compared with no advice and no ONS' post hoc as a result of an additional group of studies they identified during searching and study identification. They considered these studies relevant to this review as they examine dietary advice compared with no advice, but the dietary advice includes information on using ONS if considered 'necessary'.

2021 update

The review authors added the comparison 'dietary advice and prescription of an ONS compared with no advice and no ONS' as a result of closer scrutiny of the studies of dietary advice plus ONS if required. It became clear that studies for this comparison were falling into two distinct groups, those where ONS were sometimes used in addition to dietary advice in only some participants, with the phrase "if judged appropriate" often being used. The review authors recognised a second group of studies, where dietary advice and ONS were given to all participants from the start and so they added this fifth comparison to the review.

The authors have added 'complications' as a measure of morbidity (Primary outcome 2).

The authors have used the Egger Test to look for publication bias and described this in the methods. They have also been able to examine the overall quality of evidence using the GRADE process and complete summary of findings tables.

INDEX TERMS

Medical Subject Headings (MeSH)

Counseling; *Malnutrition [etiology]; *Nutrition Therapy; Quality of Life; Weight Gain

MeSH check words

Adult; Aged; Humans