Supplementary Table 1a – Electronic search strategies adopted to search for RCTs comparing reduced with usual fat intake (1)

This was the Ovid MEDLINE search strategy, which was modified for use in the other databases .

1 randomized controlled trial.pt.
2 controlled clinical trial.pt.
3 Randomized Controlled Trials/
4 Random Allocation/
5 Double-Blind Method/
6 Single-Blind Method/
7 or/1-6
8 Animal/ not Human/
9 7 not 8 (419534)
10 (lipid$ adj5 (low$ or reduc$ or modifi$)).mp.
11 (cholesterol$ adj5 (low$ or modific$ or reduc$)).mp.
12 11 or 10
13 exp Nutrition Therapy/
14 (diet$ or food$ or nutrition$).mp.
15 14 or 13
16 12 and 15
17 (fat adj5 (low$ or reduc$ or modifi$ or animal$ or saturat$ or unsatur$)).mp.
18 exp Diet, Atherogenic/
19 exp Diet Therapy/
20 17 or 18 or 19 or 16
21 cardiovascular diseases/ or exp heart diseases/ or exp vascular diseases/
22 cerebrovascular disorders/ or exp brain ischemia/ or exp carotid artery diseases/ or exp dementia, vascular/ or exp intracranial arterial diseases/ or exp "intracranial embolism and thrombosis"/ or exp intracranial hemorrhages/ or exp stroke/
23 (coronar$ adj5 (bypas$ or graft$ or disease$ or event$)).mp.
24 (cerebrovasc$ or cardiovasc$ or mortal$ or angina$ or stroke or strokes).mp.
25 (myocardi$ adj5 (infarct$ or revascular$ or ischaemi$ or ischemi$)).mp. (190649)
26 (morbid$ adj5 (heart$ or coronar$ or ischaem$ or ischem$ or myocard$)).mp.
27 (vascular$ adj5 (peripheral$ or disease$ or complication$)).mp.
28 (heart$ adj5 (disease$ or attack$ or bypass$)).mp.
29 27 or 26 or 21 or 25 or 28 or 24 or 22 or 23
30 9 and 29 and 20

Supplementary Table 1b – Electronic search strategies adopted to search for RCTs and cohort studies in children and adults for this review and another on effects of Sugar (2).

Medline search

1. exp Weight Gain/
2. exp Weight Loss/
3. obesity.ab,ti.
4. obese.ab,ti.
5. adipos$.ab,ti.
6. weight gain.ab,ti.
7. weight loss.ab,ti.
8. overweight.ab,ti.
9. over weight.ab,ti.
10. overeat$.ab,ti.
11. over eat$.ab,ti.
12. weight change$.ab,ti.
13. ((bmi or body mass index) adj2 (gain or loss or change)).ab,ti.
14. body fat$.ab,ti.
15. body composition.ab,ti.
16. body constitution.ab,ti.

17. fat.ab,ti.
18. fats.ab,ti.
19. fatty.ab,ti.
20. oils.ab,ti.
21. (sugar and (diet$ or food$ or consumption)).ab,ti.
22. syrup.ab,ti.
23. exp Dietary Carbohydrates/
24. exp Sweetening Agents/

25. fiber.ab,ti.
26. fibre.ab,ti.
27. polysaccharide$.ab,ti.
28. starch.ab,ti.
29. starchy.ab,ti.
30. carbohydrate$.ab,ti.
31. lipid$.ab,ti.
32. linoleic acid$.ab,ti.
33. sterols.ab,ti.
34. stanols.ab,ti.
35. (sugar$ and (diet$ or food$ or consumption)).ab,ti.
36. hydrogenated dietary oils.ab,ti.
37. hydrogenated lard.ab,ti.
38. hydrogenated oils.ab,ti.
39. (supplements and (diet$ or food$)).ab,ti.
40. (supplement and (diet$ or food$)).ti.

41. Animals/

42. randomized controlled trial.pt.
43. controlled clinical trial.pt.
44. exp Randomized Controlled Trials/
45. exp Random Allocation/
46. exp Double-Blind Method/
47. exp Single-Blind Method/
48. clinical trial.pt.
49. exp Clinical Trials/
50. clinical trial.tw.
51. ((singl$ or doubl$ or treble$ or tripl$) and (mask$ or blind$)).tw.
52. latin square.tw.
53. exp PLACEBOS/
54. placebo.tw.
55. random.tw.
56. *Research Design/
57. Comparative Study/
58. exp Evaluation Studies/
59. exp Follow-Up Studies/
60. exp Prospective Studies/
61. exp Cross-Over Studies/
62. control.tw.
63. prospectiv$.tw.
64. volunteer$.tw.

65. exp INCIDENCE/
66. incidence.tw.
67. exp PREVALENCE/
68. prevalence.tw.
69. exp Risk Factors/
70. risk.tw.
71. exp Time Factors/
72. exp Epidemiologic Studies/
73. exp Population Surveillance/
74. exp etiology/
75. cohort$.tw.
76. (cross adj1 section$ adj5 (stud$ or trial$ or design$)).tw.
77. (prospectiv$ adj5 (stud$ or trial$ or design$)).tw.
78. (longitudinal adj5 (stud$ or trial$ or design$)).tw.
79. (follow up adj5 (stud$ or trial$ or design$)).tw.
80. (experimental$ adj5 (stud$ or trial$ or design$)).tw.
81. (quasiexperimental$ adj5 (stud$ or trial$ or design$)).tw.
82. (comparative adj5 (stud$ or trial$ or design$)).tw.
83. (correlation adj5 (stud$ or trial$ or design$)).tw.
84. (evaluat$ adj5 (stud$ or trial$ or design$)).tw.
85. (observation$ adj5 (stud$ or trial$ or design$)).tw.
86. (volunteer$ adj5 (stud$ or trial$ or design$)).tw.
87. (retrospectiv$ adj5 (stud$ or trial$ or design$)).tw.
88. evaluation studies.tw.
89. ecologic$.tw.
90. (time adj3 series).tw.

91. exp Case-Control Studies/

92. (case adj3 control$).tw.
93. (case adj3 series).tw.
94. case study/
95. letter.pt.
96. exp Drug Therapy/
97. exp Surgery/
98. exp Biochemical Phenomena/
99. exp OBESITY/dt, ec, ra, ri, rt, su, ve [Drug Therapy, Economics, Radiography, Radionuclide Imaging, Radiotherapy, Surgery, Veterinary]
100. exp HIV/
101. exp HIV infections/
102. cancer.ti.
103. (tumour or tumor).ti.
104. lung.ti.
105. asthma.ti.

106. or/1-16
107. or/17-24
108. or/25-40
109. 107 or 108
110. 106 and 109
111. 110 not 41
112. or/42-64
113. or/65-90
114. 112 or 113
115. 111 and 114
116. or/91-105
117. 115 not 116
118. limit 117 to (english language and humans and yr="2006-2010")

Supplementary Table 2 – Detailed characteristics of included adult RCTs

Aukland reduced fat 1999 (3)

Participants	People with impaired glucose intolerance or high normal blood glucose (New Zealand) CVD risk: moderate Control: unclear how many randomised (176 between both groups), unclear how many analysed (112 between both groups at 5 years) Intervention: as above Mean years in trial: 4.1 over whole trial % male: control 80%, intervention 68% Age: mean control 52.0 (SE 0.8), intervention 52.5 (SE 0.8) BMI, kg/m^2: control 29.1 (sd 0.6), intervention 29.3 (sd 0.6)
Interventions	Reduced fat vs usual diet Control aims: usual diet Intervention aims: reduced fat diet (no specific goal stated) Control methods: usual intake Intervention methods: monthly meetings to follow a 1 year structured programme aimed at reducing fat in the diet, includes education, personal goal setting, self-monitoring Weight goals: Weight and calories not mentioned, diet was "aimed solely at reducing the total amount of fat in their diet" Total fat intake (at 1 year): low fat 26.1 (SD 7.7), cont 33.6 (SD 7.8)%E Saturated fat intake (at 1 year): low fat 10.0 (SD 4.2), cont 13.4 (SD 4.7)%E Style: diet advice Setting: community
Outcomes	Stated trial outcomes: lipids, glucose, blood pressure Available outcomes: weight, total, LDL and HDL cholesterol, TGs, BP
Notes	ITT analysis: No, 51/88? int, 52/88? cont Available data on dietary intake: reported at 6mo, 1, 2, 3 and 5 yrs. 5 year data used in main analysis.

BDIT Pilot Studies 1996 (4)

Participants	Women with mammographic dysplasia (Canada) CVD risk: low Control: 147 randomised, 110 at over 8 years Intervention: 148 randomised, 104 at over 8 years Mean years in trial: control 7.5, intervention 6.8 % male: 0 Age: mean control 45, intervention 44 (all >30) BMI, kg/m^2: control 24.3 (3.6), intervention 24.3 (3.8)
Interventions	Reduced fat intake vs usual diet Control aims: healthy diet advice, no alteration in dietary fat advised, aim to maintain weight Intervention aims: total fat 15%E, replace fat by complex CHO, aim to maintain weight Control methods: seen for advice once every 4 months for 12 months Intervention methods: seen for advice once a month for 12 months Weight goal: Low fat group - "isocaloric exchange of complex carbohydrate for fat. We tried to maintain an isocaloric diet to avoid weight loss..". Not discussed for control group. Total fat intake (at 9.2 years): low fat 31.7 (SD 7.3)%E, cont 35.3 (SD 5.6)%E Saturated fat intake (at 9.2 years): low fat 10.6 (SD 4.6), cont 12.3 (SD 4.6)%E Style: diet advice Setting: community
Outcomes	Stated trial outcomes: dietary fat, serum cholesterol Available outcomes: weight, BMI, total and HDL cholesterol
Notes	Weight data available for 1 year, 2 years and 9 years. Unclear whether participants were still in the trial by 9 years (these seem to be short term pilot studies), so 2 year data used in main analysis. ITT analysis: No, 76/148 int, 78/147 cont

beFIT 1997 (5-7)

Participants	Women and men with mild hypercholesterolaemia (USA) CVD risk: moderate Control: unclear how many randomised, 192 analysed Intervention: unclear how many randomised, 217 analysed Mean years in trial: unclear (max duration 0.5 years) % male: 52 (not divided by intervention group) Age: mean 43.2 (not divided by intervention group) (all >30) BMI, kg/m^2: control unclear, intervention unclear (women 27.7 (sd 5.8), men 27.0 (sd 3.3))
Interventions	Reduced and modified fat vs usual diet Control aims:asked to delay dietary changes (provided intervention after the randomised trial) Intervention aims: total fat <30%E, SFA <7%E, dietary chol<200mg/d Control methods: usual intake Intervention methods: 8 weekly classes with nutrition info and behaviour modification with spouses, plus individual appointments at 3 and 6 months Weight goals: intervention group "assigned food group pattern for their calorie needs", no information for control group. Total fat intake (at 6 months): int 25.2 (SD unclear)%E, cont unclear - no significant difference from baseline 34 (SD unclear)%E Saturated fat intake (at 6 months): int 7.6% (SD unclear)%E, cont unclear - no significant difference from baseline 12 (SD unclear)%E Style: diet advice Setting: community
Outcomes	Stated trial outcomes: lipids Available outcomes: weight, total, LDL and HDL cholesterol, TGs (but variance data only provided for the randomised comparison for LDL cholesterol)
Notes	Weight: control 'no change', intervention -2.7kg at 6 months ITT analysis: No, 426/692 overall Weight data: reported at 6 months only

Bloemberg 1991 (8)

Participants	Men with untreated raised total cholesterol (the Netherlands) CVD risk: moderate Control: randomised 41, analysed 40 Intervention: randomised 39, analysed 39 Mean years in trial: control 0.5, randomised 0.5 % male: 100% Age: mean control 47.5 (SD 8.0), intervention 47.2 (SD 8.3) BMI, kg/m^2: control 26.3 (sd 2.3), intervention 26.0 (2.6)
Interventions	Reduced and modified fat vs usual diet Control aims: usual diet Intervention aims: 30%E from fat, PUFA/SFA 1.0, dietary cholesterol 20mg.MJ. Control methods: no advice provided Intervention methods: individual advice provided face to face, followed by 2 phone calls and 5 mailings of information on healthy foods Weight goals: weight and calories not mentioned Total fat intake (change to 6 months): int -5.0 (SD 6.5) (33.5 overall), cont -1.5 (SD 5.9) (36.8 overall) %E Saturated fat intake (change to 6 months): int -4.3 (SD 3.9), cont -0.7 (SD 2.9)%E Style: diet advice Setting: community
Outcomes	Stated trial outcomes: lipids Available outcomes: weight, total and HDL cholesterol
Notes	ITT analysis: No, 39/39 int, 40/41 cont Weight data: reported as change at 5 and 26 weeks only

BRIDGES 2001 (9)

Participants	Women diagnosed with stage I or II breast cancer over the past 2 years (USA) CVD risk: low Control: randomised unclear (at least 56), analysed 56 Intervention: randomised unclear (at least 50), analysed 50 Mean years in trial: unclear (1 year max follow up) % male: 0 Age: mean control unclear (71% postmenopausal), intervention unclear (56% postmenopausal) (all 20-65) BMI, kg/m^2: control unclear, intervention unclear (cont mean weight 74.3kg, est BMI 29.8, int mean weight 70.6kg, est BMI 28.3)
Interventions	Reduced fat vs usual diet Control aims: no formal intervention Intervention diet aims: total fat 20%E, high fibre, plant based micronutrients Intervention stress: separate parallel arm, stress reduction programme (data not used here) Control methods: no formal intervention Intervention methods: nutrition intervention programme, 15 sessions (42 hours) over 15 weeks, group-based, dietitian led, 2 individual sessions using social cognitive theory and patient centred counselling to increase self efficacy and confidence Weight goals: "reduction in body mass was not a primary goal of NEP. (NEP was neither designed nor presented to participants as a weight loss or weight control program)." The control group was presented as "individual choice". Total fat intake (at 12 months): low fat 29.9 (SD unclear), cont 33.6 (SD unclear)%E Saturated fat intake: unclear Style: diet advice Setting: community
Outcomes	Stated trial outcomes: diet and BMI Available outcomes: weight
Notes	ITT analysis: No, 48/49 int, 46/55 cont Weight data: reported at 12 months only

Canadian DBCP 1997 (10)

Participants	Women with mammographic densities >50% breast area (Canada) CVD risk: low Control: randomised 448+, analysed 401 Intervention: randomised 448+, analysed 388 Mean years in trial: control 2.0, randomised 2.0 (note, papers suggest a 10 year follow up overall) % male: 0% Age: mean control 45.9 (SD unclear), intervention 46.5 (SD unclear) BMI, kg/m^2: control unclear (mean weight 61.1kg, ht 1.63, BMI 23.0), intervention unclear (mean weight 61.0kg, ht 1.63, BMI 23.0)
Interventions	Reduced fat vs usual diet Control aims: usual diet Intervention aims: total fat 15%E, protein 20%E, CHO 65%E, isocaloric diet Control methods: encouraged to continue usual diet, interviewed by dietitian every 4 months during first year, then every 3 months in the second year Intervention methods: dietary prescription using food exchange (fat calories replaced by CHO), met with dietitian monthly during first year, then every 3 months. Scales, recipes, shopping guide provided. Weight goals: "calories derived from fat were replaced by isocaloric exchange with carbohydrate". Total fat intake (at 2 years): int 21.3 (SD 6.2), cont 31.8 (SD 6.7)%E Saturated fat intake (at 2 years): int 7.1 (SD 2.5), cont 11.5 (SD 3.3)%E Style: diet advice Setting: community
Outcomes	Stated trial outcomes: incidence of breast cancer Available outcomes: weight
Notes	Weight data available for 1 and 2 years, 2 year data used in main analysis ITT analysis: no, 388/403+ int, 401/414+ cont

CARMEN 2000 (11;12)

Participants	Healthy overweight people, BMI 26-34 (Europe, 5 centres) CVD risk: low Control: unclear how many randomised, 77 analysed (290 randomised over all 3 arms) Intervention with simple CHO: unclear how many randomised, 76 analysed Intervention with complex CHO: unclear how many randomised, 83 analysed Mean years in trial: unclear (max duration 0.5 years) % male: control 48%, simple CHO intervention 47%, complex CHO intervention 52% Age: mean control 38 (SD 9), simple CHO intervention 41 (SD 9), complex CHO intervention 38 (SD 9) BMI, kg/m^2: control 30.4 (2.6), intervention simple CHO 30.9 (2.8), complex CHO 30.2 (2.8)
Interventions	Reduced fat vs usual diet Control aims: to attain national "normal" intake Intervention aims: total fat reduced by 10%E with increases in simple or complex CHO Control methods: trial shop provided local selection of a specific set of national "normal" intake foods Intervention methods: trial shop provided local selection of a specific set of low fat and high simple or complex CHO foods Weight goals: food provided ad libitum to all groups Total fat intake (at 6 months): low fat complex CHO 27.8 (SD unclear)%E, low fat simple CHO 25.5 (SD unclear)%E, cont 36.5 (SD unclear)%E Saturated fat intake (at 6 months): low fat complex CHO 9.9 (SD unclear)%E, low fat simple CHO 8.6 (SD unclear)%E, cont 12.7 (SD unclear)%E Style: food provided Setting: community
Outcomes	Stated trial outcomes: weight, body composition, lipids Available outcomes: weight, total, LDL and HDL cholesterol, TGs
Notes	ITT analysis: No, overall 236/290 (no. randomised not reported by group) Weight data: reported at 6 months only

CARMEN MS sub-study 2002 (11)

Methods	RCT (data for this study excludes the 13 participants that were included in the main CARMEN data set)
Participants	People with at least 3 risk factors for metabolic syndrome (Europe, 5 centres) CVD risk: moderate Control: 12 randomised, 8 analysed Intervention with simple CHO: 10 randomised, 9 analysed Intervention with complex CHO: 11 randomised, 9 analysed Mean years in trial: control 0.4, simple CHO 0.5, complex CHO 0.5 % male: control 0%, simple CHO 33%, complex CHO 22% Age: mean control 47.5 (SD 3.9), simple CHO intervention 44.7 (SD 4.7), complex CHO intervention 43.4 (SD 4.5) BMI, kg/m^2: control unclear, intervention unclear
Interventions	Reduced fat vs usual diet Control aims: to attain national "normal" intake Intervention aims: total fat reduced by 10%E with increases in simple or complex CHO Control methods: trial shop provided local selection of a specific set of national "normal" intake foods Intervention methods: trial shop provided local selection of a specific set of low fat and high simple or complex CHO foods Weight goals: food provided ad libitum to all groups Total fat intake (at 6 months): low fat complex CHO 27.1 (SD 4.8), low fat simple CHO 20.6 (SD 6.6), cont 30.4 (SD 2.3)%E Saturated fat intake: unclear Style: food provided Setting: community
Outcomes	Stated trial outcomes: weight, body composition, lipids Available outcomes: BMI, total, LDL and HDL cholesterol, TGs, diastolic BP
Notes	ITT analysis: No, 9/11 complex CHO, 9/10 simple CHO, 8/12 cont Weight data: reported at 6mo only

de Bont 1981 non-obese (13)

Participants	Women with type 2 diabetes (UK) CVD risk: moderate Control: randomised unclear (total in control and intervention 148), analysed 65 (for obese and non-obese) Intervention: randomised unclear, analysed 71 (for obese and non-obese) Mean years in trial: control 0.5, randomised 0.5 % male: 0% Age: mean control 54 (SD 8), intervention 56 (SD 7), (all 35-64) (for obese and non-obese) BMI, kg/m^2: control unclear, intervention unclear (this subgroup were chosen as BMI <28, weight cont 59.0kg, est BMI 23.6, int 60.1kg, est BMI 24.1)
Interventions	Reduced and modified fat vs usual diet Control aims: usual diet but with CHO ≤ 40%E Intervention aims: 30%E from fat, focus on reducing meat fat, dairy foods, and substituting margarines to improve the SFA/PUFA ratio, CHO increased to maintain energy intake. Control methods: 3 home visits from a nutritionist over the 6 months of the trial Intervention methods: 3 home visits from a nutritionist over the 6 months of the trial Weight goals: to maintain the required total energy intake the proportion of carbohydrates in these diets was increased. Total fat intake (change to 6 months): int -10.1 (SD 10.8) (overall 31.1), cont -1.0 (SD 10.5) (overall 41.8) %E (for obese and non-obese) Saturated fat intake (change to 6 months): int -8.1 (SD 5.8), cont -1.1 (SD 5.7)%E (for obese and non-obese) Style: diet advice Setting: community
Outcomes	Stated trial outcomes: diet, weight, lipids Available outcomes: weight, total and HDL cholesterol, triglycerides
Notes	Outcome data separated by those obese (BMI ≥28) or not obese at baseline ITT analysis: No, 136/148 participants overall (obese and non-obese) Weight data: reported at 6mo only

de Bont 1981 obese (13)

Participants	Women with type 2 diabetes (UK) CVD risk: moderate Control: randomised unclear (total in control and intervention 148), analysed 71 (for obese and non-obese) Intervention: randomised unclear, analysed 65 (for obese and non-obese) Mean years in trial: control 0.5, randomised 0.5 % male: 0% Age: mean control 54 (SD 8), intervention 56 (SD 7), (all 35-64) (for obese and non-obese) BMI, kg/m^2: control unclear, intervention unclear (this subgroup were chosen as BMI ≥28, weight cont 84.8kg, est BMI 34.0, int 84.2kg, est BMI 33.7)
Interventions	Reduced and modified fat vs usual diet Control aims: usual diet but with CHO ≤ 40%E Intervention aims: 30%E from fat, focus on reducing meat fat, dairy foods, and substituting margarines to improve the SFA/PUFA ratio, CHO increased to maintain energy intake. Control methods: 3 home visits from a nutritionist over the 6 months of the trial Intervention methods: 3 home visits from a nutritionist over the 6 months of the trial Weight goals: to maintain the required total energy intake the proportion of carbohydrates in these diets was increased. Total fat intake (change to 6 months): int -10.1 (SD 10.8) (overall 31.1), cont -1.0 (SD 10.5) (overall 41.8) %E (for obese and non-obese) Saturated fat intake (change to 6 months): int -8.1 (SD 5.8), cont -1.1 (SD 5.7)%E (for obese and non-obese) Style: diet advice Setting: community
Outcomes	Stated trial outcomes: diet, weight, lipids Available outcomes: weight, total and HDL cholesterol, triglycerides
Notes	Outcome data separated by those obese (BMI ≥28) or not obese at baseline ITT analysis: No, 136/148 participants overall (obese and non-obese) Weight data: reported at 6mo only

DEER 1998 exercise men (14)

Participants	Men with raised LDL and low HDL cholesterol (USA) CVD risk: moderate Control: randomised 50, analysed 47 Intervention: randomised 51, analysed 48 Mean years in trial: control 1.0, intervention 1.0 % male: 100% Age: mean 47.8 (SD 8.9) for all men (including the non-exercise part of this trial) BMI, kg/m^2: control unclear, intervention unclear (baseline weight, but not BMI, provided but not by group, weight mean 69.6kg, sd 10.5, est BMI 26.0)
Interventions	Reduced fat vs usual diet Control aims: usual diet (and exercise intervention) Intervention aims: NCEP step 2 diet: <30%E from fat, <7%E from SFA, <200mg/d cholesterol (and exercise intervention) Control methods: no advice provided Intervention methods: individual advice provided face to face, followed by 8 1-hour group sessions during first 12 weeks, then monthly contact with dietitians by mail, phone, individual or group appointment Weight goals: "weight loss was not emphasised". Total fat intake (change to 12 months): int -8.2 (SD 5.9) (22.2 overall), cont -0.5 (SD 5.7) (29.9 overall) %E Saturated fat intake (change to 12 months): int -3.9 (SD 2.6), cont -0.1 (SD 2.6)%E Style: diet advice Setting: community
Outcomes	Stated trial outcomes: dietary intake and lipids Available outcomes: weight, total, LDL and HDL cholesterol, triglycerides, systolic and diastolic BP
Notes	Factorial trial re exercise, and reported by gender ITT analysis: No, 48/51 int, 47/50 cont Weight data: reported as change to 1 year only

DEER 1998 exercise women (14)

Participants	Postmenopausal women with raised LDL and low HDL cholesterol (USA) CVD risk: moderate Control: randomised 44, analysed 43 Intervention: randomised 43, analysed 43 Mean years in trial: control 1.0, intervention 1.0 % male: 0% Age: mean 56.9 (SD 5.1) for all women (including the non-exercise part of this trial) BMI, kg/m^2: control unclear, intervention unclear (baseline weight, but not BMI, provided but not by group, weight mean 69.6kg, sd 10.5, est BMI 26.0)
Interventions	Reduced fat vs usual diet Control aims: usual diet (and exercise intervention) Intervention aims: NCEP step 2 diet: <30%E from fat, <7%E from SFA, <200mg/d cholesterol (and exercise intervention) Control methods: no advice provided Intervention methods: individual advice provided face to face, followed by 8 1-hour group sessions during first 12 weeks, then monthly contact with dietitians by mail, phone, individual or group appointment Weight goals: "weight loss was not emphasised". Total fat intake (change to 12 months): int -8.0 (SD 5.8) (28.7 overall), cont 0.3 (SD 6.9) (20.4 overall) %E Saturated fat intake (change to 12 months): int -3.0 (SD 2.3), cont 0.2 (SD 3.1)%E Style: diet advice Setting: community
Outcomes	Stated trial outcomes: dietary intake and lipids Available outcomes: weight, total, LDL and HDL cholesterol, triglycerides, systolic and diastolic BP
Notes	Factorial trial re exercise, and reported by gender. ITT analysis: No, 43/43 int, 43/44 cont Weight data: reported as change to 1 year only

DEER 1998 no exercise men (14)

Participants	Men with raised LDL and low HDL cholesterol (USA) CVD risk: moderate Control: randomised 47, analysed 46 Intervention: randomised 49, analysed 49 Mean years in trial: control 1.0, intervention 1.0 % male: 100% Age: mean 47.8 (SD 8.9) for all men (including the exercise part of this trial) BMI, kg/m^2: control unclear, intervention unclear (baseline weight, but not BMI, provided but not by group, weight mean 69.6kg, sd 10.5, est BMI 26.0)
Interventions	Reduced fat vs usual diet Control aims: usual diet (and usual exercise) Intervention aims: NCEP step 2 diet: <30%E from fat, <7%E from SFA, <200mg/d cholesterol (and usual exercise) Control methods: no advice provided Intervention methods: individual advice provided face to face, followed by 8 1-hour group sessions during first 12 weeks, then monthly contact with dietitians by mail, phone, individual or group appointment Weight goals: "weight loss was not emphasised". Total fat intake (change to 12 months): int -8.0 (SD 8.1) (22.4 overall), cont -0.7 (SD 5.9) (29.7 overall) %E Saturated fat intake (change to 12 months): int -3.4 (SD 3.2), cont 0.0 (SD 2.4)%E Style: diet advice Setting: community
Outcomes	Stated trial outcomes: dietary intake and lipids Available outcomes: weight, total, LDL and HDL cholesterol, triglycerides, systolic and diastolic BP
Notes	Factorial trial re exercise, and reported by gender ITT analysis: No, 49/49 int, 46/47 cont Weight data: reported as change to 1 year only

DEER 1998 no exercise women (14)

Participants	Postmenopausal women with raised LDL and low HDL cholesterol (USA) CVD risk: moderate Control: randomised 47, analysed 46 Intervention: randomised 46, analysed 45 Mean years in trial: control 1.0, intervention 1.0 % male: 0% Age: mean 56.9 (SD 5.1) for all women (including the exercise part of this trial) BMI, kg/m^2: control unclear, intervention unclear (baseline weight, but not BMI, provided but not by group, weight mean 69.6kg, sd 10.5, est BMI 26.0)
Interventions	Reduced fat vs usual diet Control aims: usual diet (and usual exercise) Intervention aims: NCEP step 2 diet: <30%E from fat, <7%E from SFA, <200mg/d cholesterol (and usual exercise) Control methods: no advice provided Intervention methods: individual advice provided face to face, followed by 8 1-hour group sessions during first 12 weeks, then monthly contact with dietitians by mail, phone, individual or group appointment Weight goals: "weight loss was not emphasised". Total fat intake (change to 12 months): int -5.7 (SD 7.4) (overall 22.7), cont -0.2 (SD 6.7) (overall 28.2) %E Saturated fat intake (change to 12 months): int -2.4 (SD 2.8), cont 0.2 (SD 2.8)%E Style: diet advice Setting: community
Outcomes	Stated trial outcomes: dietary intake and lipids Available outcomes: weight, total, LDL and HDL cholesterol, triglycerides, systolic and diastolic BP
Notes	Factorial trial re exercise, and reported by gender ITT analysis: No, 46/47 int, 45/46 cont Weight data: reported as change to 1 year only

German Fat Reduced 1996 (15)

Participants	Women with BMI 24-29 (Germany) CVD risk: low Control: randomised 35, analysed 32 Intervention: randomised 35, analysed 35 Mean years in trial: control 0.7, intervention 0.8 % male: 0 Age: mean control 46, intervention 48 (all 40-60) BMI, kg/m^2: control 28 (sd 3), intervention 27 (3)
Interventions	Reduced fat vs usual diet Control aims: advice to buy foods from trial shop, usual fat foods supplied Intervention aims: advice to buy foods from trial shop, low fat foods supplied Control methods: trial shop provided ad libitum usual fat foods Intervention methods: trial shop provided ad libitum low fat foods Weight goals: Foods supplied ad libitum and free of charge Total fat intake (at 9 months): low fat 35.1 (SD unclear), cont 35.5 (SD unclear)%E Saturated fat intake: unclear Style: food provided Setting: community
Outcomes	Stated trial outcomes: weight Available outcomes: weight, total, LDL and HDL cholesterol, TG
Notes	ITT analysis: No, 35/35 int, 32/35 cont Weight data: only reported at 9 months

Kentucky Low Fat 1990 (16;17)

Participants	Moderately hypercholesterolaemic, non-obese Caucasian men and women aged 30-50 (USA) CVD risk: moderate Control: randomised 62, analysed 51 Intervention: randomised 56, analysed 47 Mean years in trial: control 0.91, intervention 0.92 % male: control 61, intervention 66 Age: mean control 40.3 (SD 5.4), intervention 40.7 (SD 5.2) (all 30-50) BMI, kg/m^2: control unclear, intervention unclear (control mean weight 71.4kg, ht 1.70m, BMI 24.7, int weight 72.0kg, ht 1.74m, BMI 23.8)
Interventions	Reduced fat diet vs usual diet Control aims: no diet intervention Intervention aims: 25%E from fats, 20%E from protein, 55%E from CHO, <200mg chol /day (Also an intervention arm with similar aims plus increased fibre intake) Control methods: no intervention Intervention methods: seminars and individual eating patterns taught, 10 weeks teaching and 40 weeks maintenance Weight goals: Participants were directed to maintain initial body weight throughout the study Total fat intake (at 1 year): low fat 30 (SD 7.5), cont 31 (SD 5.7)%E Saturated fat intake (at 1 year): low fat 9 (SD 2.7), cont 10 (SD 2.9)%E Style: diet advice Setting: community
Outcomes	Stated trial outcomes: diet composition, lipids Available outcomes: weight, total, LDL and HDL cholesterol
Notes	ITT analysis: No, 47/56 int, 51/62 cont Weight data: only reported at 1 year

Kuopio Reduced & Mod 1993 (18)

Participants	Free-living people aged 30-60 with serum total cholesterol levels 6.5-8.0mmol/L (Finland) CVD risk: moderate Control (monoene enriched): randomised 41, analysed 41 Intervention AHA: randomised 41, analysed 41 Mean years in trial: for all 4 groups 0.5 % male: control 46, AHA 46 Age: mean control 46.4, AHA 47.3 (all 30-60) BMI, kg/m^2: control 25.6 (sd 4.2), intervention AHA 26.2 (sd 4.0)
Interventions	Reduced and modified fat vs modified fat diet Control aims Mono: total fat 38%E, SFA <14%E, MUFA 18%E, PUFA <6%E, rapeseed oil, rapeseed spread and skimmed milk provided Intervention aims AHA: total fat 30%E, SFA <10%E, MUFA 10%E, PUFA 10%E, sunflower oil, sunflower spread and skimmed milk provided Control and intervention methods: given written dietary instructions and a diet plan with checking and reinforcement for 3 visits, then at 2, 6, 12, 18 and 26 weeks Weight goals: Dietary written instructions were designed for 5 energy levels (1800, 2000, 2400, 2800 and 3200) based on individual diet and activity assessment Total fat intake (weeks 14-28): low & mod fat 34 (SD 4), cont 35 (SD 5)%E Saturated fat intake (weeks 14-28): low & mod fat 11 (SD 2), cont 11 (SD 2)%E Style: dietary advice & supplement (food) Setting: community
Outcomes	Stated trial outcomes: lipids and blood pressure Available outcomes: BMI, total, LDL and HDL cholesterol, TG, BP
Notes	(the Kuopio trials share a common control group) ITT analysis: Yes, no drop outs Weight data: no weight data, BMI reported at 6 months only

Kuopio Reduced Fat 1993 (18)

Participants	Free-living people aged 30-60 with serum total cholesterol levels 6.5-8.0mmol/L (Finland) CVD risk: moderate Control: randomised 37, analysed 37 Intervention low fat: randomised 40, analysed 40 Mean years in trial: for both groups 0.5 % male: control 46, low fat 48 Age: mean control 43.2, low fat 45.8 (all 30-60) BMI, kg/m^2: control 25.6 (sd 4.2), intervention low fat 26.5 (3.4)
Interventions	Reduced fat vs usual diet (low fat vs control) Control aims: advised total fat 38%E, SFA <18%E, MUFA 15%E, PUFA <5%E, rapeseed oil, butter and semi-skimmed milk provided Intervention aims low fat: total fat 28-30%E, SFA <14%E, MUFA 10%E, PUFA 4%E, butter and rapeseed spread and skimmed milk provided Control and intervention methods: given written dietary instructions and a diet plan with checking and reinforcement for 3 visits, then at 2, 6, 12, 18 and 26 weeks Weight goals: Dietary written instructions were designed for 5 energy levels (1800, 2000, 2400, 2800 and 3200) based on individual diet and activity assessment Total fat intake (weeks 14-28): low fat 31 (SD 5), cont 36 (SD 5)%E Saturated fat intake (weeks 14-28): low fat 12 (SD 2), cont 15 (SD 2)%E Style: dietary advice & supplement (food) Setting: community
Outcomes	Stated trial outcomes: lipids and blood pressure Available outcomes: BMI, total, LDL and HDL cholesterol, TG, BP
Notes	(the Kuopio trials share a control group) ITT analysis: Yes, no drop outs Weight data: no weight data, BMI reported at 6 months only

Mastopathy Diet 1988 (19)

Participants	Women with severe cyclical mastopathy for at least 5 years (Canada) CVD risk: low Control: randomised 10, analysed 9 Intervention: randomised 11, analysed 10 Mean years in trial: control 0.45, intervention 0.45 % male: 0% Age: mean control 36, intervention 38 (variances unclear) BMI, kg/m^2: control unclear, intervention unclear (cont mean weight 61.7kg, ht 1.65m, BMI 22.7, int mean weight 58.1kg, ht 1.63m, BMI 21.9)
Interventions	Reduced fat vs usual diet Control aims: given principles of healthy diet, not counselled to alter fat content Intervention aims: total fat 15%E, CHO 65%E Control methods: seen every 2 months to monitor symptoms, nutrition and biochemistry Intervention methods: seen monthly to monitor symptoms, nutrition and biochemistry, teaching materials included food guide, recipes, product information and advice on eating out Weight goals: the intervention goals included the isocaloric replacement of complex carbohydrate for fat (no mention for control group) Total fat intake (at 6 months): low fat 22.8 (SD unclear), cont 33.4 (SD unclear)%E Saturated fat intake (at 6 months): low fat 8.8 (SD unclear), cont 12.3 (SD unclear)%E Style: diet advice Setting: community
Outcomes	Stated trial outcomes: mastopathy symptoms, plasma hormone and lipids Available outcomes: weight, total cholesterol (but variance data not provided)
Notes	Total cholesterol rose by 0.09mmol/L in control group (from 4.5 to 4.59) and fell by 0.15mmol/L in intervention group (4.84 to 4.69). Weight changed in the intervention group (mean fall of 2.1kg over 6 months, no variance provided), but change, or otherwise, in control group not mentioned. ITT analysis: No, 10/11 int, 9/10 cont Weight data: reported at 6 months only – stated no significant difference between int and cont at 6 months, fall in weight of 2.1 kg in int (no variance reported), no change reported for cont.

MeDiet 2006 (20)

Participants	Healthy postmenopausal women with above median serum testosterone (Italy) CVD risk: low Control: randomised 57, analysed at 6 months 55 Intervention: randomised 58, analysed at 6 months 51 Mean years in trial: control 4.38, intervention 4.28 % male: 0 Age: mean unclear (age range 48-69) BMI, kg/m^2: control unclear, intervention unclear (no baseline weight or BMI provided)
Interventions	Reduced and modified fat vs usual diet Control aims: advised to increase fruit and vegetable intake Intervention aims: taught Sicilian diet including reduced total, saturated and omega-6 fats, increased blue fish (high in omega 3), increased whole cereals, legumes, seeds, fruit and vegetables Control methods: advice Intervention methods: taught Sicilian diet and cooking by professional chefs, with a weekly cooking course including social dinners Weight goals: Not mentioned Total fat intake (at 6 months): low & mod fat 30.9 (SD 11.4), cont 34.0 (SD 11.8)%E Saturated fat intake (at 6 months): low & mod fat 8.4 (SD 3.0), cont 11.2 (SD 5.0)%E Style: diet advice Setting: community
Outcomes	Stated trial outcomes: breast cancer, weight, lipids, wellbeing Available outcomes: weight
Notes	Weight data provided at 6 months (fall of 0.6kg in control group, fall of 1.3kg in intervention group), but without variance information. ITT analysis: No, 51/58 int, 55/57 cont Weight data: reported at 6 months only

Moy 2001 (21)

Participants	Middle-aged siblings of people with early CHD, with at least one CVD risk factor (USA) CVD risk: moderate Control: randomised 132, analysed 118 Intervention: randomised 135, analysed 117 Mean years in trial: 1.9 % male: control 49%, intervention 55% Age: control mean 45.7 (SD 7), intervention 46.2 (SD 7) BMI, kg/m^2: control 29.5 (7), intervention 28.5 (5)
Interventions	Reduced fat intake vs. usual diet Control: physician management (physicians informed on risk factor management). Intervention: nurse management, aim total fat 40g/d or less Control methods: physician management with risk factor management at 0, 1 and 2 years Intervention methods: nurse management, appointments 6-8 weekly for 2 years Weight goals: not mentioned Total fat intake (at 2 years): low fat 34.1 (SD unclear), cont 38.0 (SD unclear)%E Saturated fat intake (at 2 years): low fat 11.5 (SD unclear), cont 14.4 (SD unclear)%E Style: diet advice Setting: community
Outcomes	Stated trial outcomes: dietary intake Available outcomes: BMI, HDL and LDL cholesterol, TG
Notes	ITT analysis: No, 117/135 int, 118/132 cont Weight data: not reported, BMI reported at 2 years only

MSFAT 1995 (22)

Participants	Healthy people aged 20-55 (Netherlands) CVD risk: low Control: randomised unclear (120?), analysed 103 Intervention: randomised unclear (120?), analysed 117 Mean years in trial: control 0.46, intervention 0.49 % male: control 50%, intervention 50% Age: mean control men 35.6 (SD 10), control women 36.0 (SD 11), intervention men 35.5 (SD 11), intervention women 36.0 (sd 12) (all 19-55) BMI, kg/m^2: control women 25.0 (sd 2.0), control men 24.9 (sd 2.2), intervention women 24.7 (sd 2.0), intervention men 24.9 (sd 2.3)
Interventions	Reduced fat vs usual diet Control aims: advised to use products from trial shop ad lib. (usual fat products provided) Intervention aims: advised to use products from trial shop ad lib. (low fat products provided) Control methods: participants obtained foods in a study shop at least once a week Intervention methods: participants obtained foods in a study shop at least once a week Weight goals: ad libitum diet Total fat intake (at 6 months): low fat 34.7 (SD unclear), cont 42.7 (SD unclear)%E Saturated fat intake (at 6 months): low fat 14.2 (SD unclear), cont 18.2 (SD unclear)%E Style: food provided Setting: community
Outcomes	Stated trial outcomes: weight, vitamin and fatty acid intake, anti-oxidative capacity Available outcomes: weight (for subgroup), weight and lipids provided for larger group, but without variance data
Notes	ITT analysis: No, 117/120 int, 103/120 cont Weight data: reported at 6 months only

NDHS Open 1st L&M 1968 (23)

Participants	Free living men (USA) CVD risk: low Control: randomised 382, analysed 341 Intervention B: randomised 385, analysed 332 Intervention X: randomised 54, analysed 46 Mean years in trial: control 1.0, B 0.9, C 0.9, X 0.9 % male: 100 Age: unclear (all 45-54) BMI, kg/m^2: control unclear, intervention unclear (all participants mean weight 81.0, ht 1.78, BMI 25.6)
Interventions	Reduced and modified fat diet vs. usual diet Control aims: total fat 40%E, SFA 16-18%E, dietary chol 650-750mg/d, P/S 0.4 Intervention B: total fat 30%E, SFA <9%E, dietary chol 350-450mg/d, PUFA 15%E, P/S 1.5 Intervention X: total fat 30%E, SFA <9%E, dietary chol 350-450mg/d, PUFA 15%E, P/S 1.5 Control methods: dietary advice to reduce saturated fat and cholesterol (plus 10 follow up visits with nutritionist), purchase of 'usual fat' items from a trial shop Intervention B methods: dietary advice to reduce saturated fat and cholesterol (plus 10 follow up visits with nutritionist), plus purchase of appropriately reduced and modified fat items from a trial shop Intervention X methods: dietary advice but no trial shop Weight goals: Weight and calories not mentioned Total fat intake (through study): B 29.7 (SD unclear)%E, X 31.7 (SD unclear), cont 34.9 (SD unclear)%E Saturated fat intake (through study): B 7.1 (SD unclear)%E, X 8.9 (SD unclear), cont 11.6 (SD unclear)%E Style: B diet provided, X - diet advice Setting: community
Outcomes	Stated trial outcomes: lipid levels and dietary assessment Available outcomes: total cholesterol (some weight and BP data presented but no variance info)
Notes	At 52 weeks weight change in the control was not presented, weight change in B was -2.4kg. Average weight change over the first year (mean of weights at weeks 6, 12, 20, 28, 36 and 44 weeks) was -2.45kg (-5.4lb) for the low fat group (B) and -1.91kg (-4.2lb) for the modified fat group (C) and -1.95kg (-4.3lb) for the control group (D). At 52 weeks diastolic BP change from baseline was -2.2 kg in control, -1.9 in B and -5.8 in X.

	ITT analysis: No, 332/385 int B, 348/390 int C, 341/382 cont D Weight data: reported as composite of 6 weights taken over 1 year

NDHS Open 2nd L&M 1968 (23)

Participants	Free living men who had participated in NDHS 1st studies (USA) CVD risk: low Control: randomised 304, analysed 280 Intervention BC: randomised 194, analysed 179 Mean years in trial: control 0.6, intervention BC 0.6 % male: 100 Age: unclear (all 45-54) BMI, kg/m^2: control unclear, intervention unclear (no baseline weight or BMI provided)
Interventions	Reduced and modified fat vs usual diet Control aims: total fat 40%E, SFA 16-18%E, dietary chol 650-750mg/d, P/S 0.4, X - advice to continue usual diet Intervention aims: BC total fat 30-40%E, SFA reduced, dietary chol 350-450mg/d, increased PUFA, P/S 1.5-2.0 Control methods: dietary advice to reduce saturated fat and cholesterol (plus 10 follow up visits with nutritionist), purchase of 'usual fat' items from a trial shop Intervention BC methods: dietary advice to reduce saturated fat and cholesterol (plus 10 follow up visits with nutritionist), plus purchase of appropriately reduced and modified fat items from a trial shop Weight goals: Weight and calories not mentioned Total fat intake (through study): BC 32.5 (SD unclear)%E, cont 35.5 (SD unclear)%E Saturated fat intake (through study): BC 7.4 (SD unclear)%E, cont 12.0 (SD unclear)%E Style: food provided Setting: community
Outcomes	Stated trial outcomes: lipid levels and dietary assessment Available outcomes: weight
Notes	Weight data provided for the BC intervention group -1.8kg (-4lb over 6 months), and -0.9kg (-2lb) for modified fat diet G, -1.4kg (-3lb) for modified fat diet F. No info provided for the control group (D). ITT analysis: No, 179/194 BC, 112/127 F, 103/120 G Weight data: reported at 1 year only

Nutrition & Breast Health (24)

Participants	Pre-menopausal women at increased risk of breast cancer (USA) CVD risk: low Control: randomised 53, analysed 50 Intervention: randomised 69, analysed 47 Mean years in trial: control 1.0, intervention 0.8 % male: control 0%, intervention 0% Age: mean 38 (SD 7) - not provided by study arm (all 21-50) BMI, kg/m^2: control unclear, intervention unclear (cont mean weight 66.4kg, est BMI 26.6, int mean weight 67.3kg, est BMI 27.0)
Interventions	Reduced fat vs usual diet Control aims: followed usual diet, given daily food guide pyramid (half of this group randomised to 9 portions/d of fruit and vegetables advice) Intervention aims: total fat 15%E (half of this group randomised to 9 portions/d of fruit and vegetables advice) Control methods: no dietary counselling (offered this at the end of study), but those given fruit and veg advice had support as below Intervention methods: met dietitian every 2 weeks until compliant, monthly group meetings, counselling on home diets, restaurants, parties, social support, eating at work, exchange booklets, cookbook Weight goals: "goals were derived such that baseline energy intake would be maintained while meeting study goals". Total fat intake (at 12 months): low fat 15.7 (SD 5.1)%E, cont 32.7 (SD 6.1)%E Saturated fat intake (at 12 months): low fat 7.2 (SD unclear)%E, cont 11.6 (SD unclear)%E Style: diet advice Setting: community
Outcomes	Stated trial outcomes: body weight, dietary compliance Available outcomes: weight, total, LDL and HDL cholesterol, TG, BMI (but variance data not provided for any but weight)
Notes	Change from baseline to 12 months for the control (n=23), control plus fruit & veg (n=25), low fat (n=24), low fat plus fruit & veg (n=23): Total cholesterol mg/dl: 9, 2, -8, 0 TGs mg/dl: -7, 1, 5, 8 HDL chol mg/dl: 0, 0, -4, 0 LDL chol mg/dl: 11, 2, -6, -2 BMI kg/m2: 0, 4, -13, 0 For weight end data only are provided (no change data) although the intervention group were considerably heavier at baseline (149 and 154lb) than control groups (both 143 lb).

	ITT analysis: No, 25/26, 25/27, 24/40, 23/29 (order as above) Weight data: reported at 1 year only

Pilkington 1960 (25)

Participants	Men with angina or who have had an MI (UK) CVD risk: high Reduced fat: randomised unclear, analysed 12 Modified fat: randomised unclear, analysed 23 Mean years in trial:reduced fat 1.1, modified fat 1.1 % male: reduced fat 100%, modified fat 100% Age: not stated BMI, kg/m^2: control unclear (weight 72.6kg, sd 4.3, est BMI 24.8), intervention unclear (weight 72.1kg, sd6.9, est BMI 24.7)
Interventions	Reduced fat vs Modified fat diet Reduced fat aims: total fat 20g/d, advice to avoid dairy fats except skimmed milk plus 1 egg or 21g cheese/d. Lean meat and fish each allowed once/d, other non-fatty foods allowed in unlimited quantities. Modified fat aims: fat aims not stated, dairy produce avoided except skimmed milk, 90ml/d soya oil provided, lean meat originally prohibited but allowed after 6 months along with 113g/wk of 'relatively unsaturated margarine'. Fish and vegetables allowed freely. Reduced fat methods: unclear, 'dietary histories taken before and during treatment' Modified fat methods: unclear, 'dietary histories taken before and during treatment' Weight goals: Non-fatty foods not restricted, no weight goals mentioned Total fat intake (during treatment): low fat 15.8 (SD unclear)%E, mod fat 36 (SD unclear)%E Saturated fat intake: unclear Style: diet advice Setting: community
Outcomes	Stated trial outcomes: lipids Available outcomes: weight, total and LDL cholesterol
Notes	ITT analysis: unclear, 12 int, 23 cont assessed, but unclear how many randomised Weight data: reported once “during treatment” (mean 13.6mo follow up)

Polyp Prevention 1996 (26;27)

Participants	People with at least one adenomatous polyp of the large bowel removed (USA) CVD risk: low Control: 1042 randomised, 947 analysed Intervention: 1037 randomised, 958 analysed Mean years in trial: control 3.05, intervention 3.05 % male: control 64%, intervention 66% Age: mean control 61.5, intervention 61.4 (all at least 35) BMI, kg/m^2: control 27.5 (sd 3.1), intervention 27.6 (3.1)
Interventions	Low fat vs usual diet Control: general dietary guidelines Intervention: total fat 20%E, 18g fibre/1000kcal, 5-8 servings fruit and veg daily Control methods: leaflet, no additional information or behaviour modification Intervention methods: >50 hours of counselling over 4 years, included skill building, behaviour modification, self monitoring and nutritional materials Weight goals: "weight loss is permitted but not encouraged....counselled to replace fat intake with increased intake of fruit, vegetable and grain products rather than reduce total calorie intake." Total fat intake (at 4 years): low fat 23.8 (SD 6.0), cont 33.9 (SD 5.9)%E Saturated fat intake: unclear Style: diet advice Setting: community
Outcomes	Stated trial outcomes: recurrence of polyps, prostate cancer Available outcomes: weight, total cholesterol
Notes	ITT analysis: No, 919/958 int, 907/947 cont Weight data: reported at 1, 2, 3 and 4 years. 4 year data used in main analysis

Rivellese 1994 (28)

Participants	Adults with primary hyperlipoproteinaemia (Italy) CVD risk: moderate Intervention reduced fat: 33 randomised, 27 analysed Intervention modified fat: 30 randomised, 17 analysed Mean years in trial: reduced fat 0.4, modified fat 0.4 % male: reduced fat 82%, modified fat 63% Age, years: reduced fat 47.4 mean (SD 10.3), modified fat 48.6 (SD 8.1) BMI, kg/m^2: control 24.4 (sd 2.9), intervention 25.2 (sd 2.7)
Interventions	Reduced fat vs Modified fat diet Reduced fat aims: total fat 25%E, SFA 8%E, MUFA 15%, PUFA 2%, dietary chol <300mg/d, CHO 58%, protein 17%E, soluble fibre 41g/d Modified fat aims: total fat 38%E, SFA <10%E, MUFA 20%E, PUFA 10%E, dietary chol<300mg/d, CHO 47%E, protein 15%E, soluble fibre 19g/d Reduced fat methods:seen monthly by dietitian and doctor, feedback based on 7 day food diary each time Modified fat methods: seen monthly by dietitian and doctor, feedback based on 7 day food diary each time Weight goals: Neither weight or energy intake goals mentioned for either group Total fat intake (at 5-6 months): low fat 27 (SD unclear)%E, mod fat 36 (SD unclear)%E Saturated fat intake (at 5-6 months): low fat 6 (SD unclear)%E, mod fat 7 (SD unclear)%E Style: diet advice Setting: community
Outcomes	Stated trial outcomes: metabolic effects Available outcomes: weight, total, LDL and HDL cholesterol, TGs
Notes	Weight data were presented without variance info. Participants in the low fat arm lost 1.8kg over the 6 months, the modified fat diet arm lost 1.6kg. ITT analysis: No, 27/33 reduced fat, 17/30 modified fat Weight data: reported at 6 months only

***Simon Low Fat Breast CA** (29)*

Participants	Women with a high risk of breast cancer (USA) CVD risk: low Control: randomised 96, analysed 75 Intervention: randomised 98, analysed 72 Mean years in trial: control 1.8, intervention 1.7 % male: 0 Age: mean control 46, intervention 46 BMI, kg/m^2: control 28.1 (4.9), intervention 25.2 (4.7)
Interventions	Reduced fat vs usual diet Control aims: usual diet Intervention aims: total fat 15%E Control methods: continued usual diet Intervention methods: Biweekly individual dietetic appointments over 3 months followed by monthly individual or group appointments, including education, goal setting, evaluation, feedback and self-monitoring Weight goals: weight and calorie goals not discussed Total fat intake (at 12 months): low fat 18.0 (SD 5.6), cont 33.8 (SD 7.4)%E Saturated fat intake (at 12 months): low fat 6.0 (SD unclear), cont 11.3 (SD unclear)%E Style: diet advice Setting: community
Outcomes	Stated trial outcomes: intervention feasibility Available outcomes: weight, total, LDL and HDL cholesterol, TGs
Notes	ITT analysis: No, 67/98 int, 76/96 cont Weight data: reported at 3, 6, 9 and 12 months, 12 mo data used in main analysis.

Sondergaard 2003 (30)

Participants	People with IHD plus total cholesterol at least 5mmol/L (Denmark) CVD risk: high Control: 63 randomised, 52 analysed Intervention: 68 randomised, 63 analysed Mean years in trial: 1.0 % male: control 79%, intervention 62% age: control mean 62.8 (SD 10.5), intervention mean 62.1 (SD 9.3) BMI, kg/m^2: control 26.7 (sd 4.2), intervention 26.6 (3.9)
Interventions	Reduced and modified fat intake vs. usual diet Control: aims unclear Intervention: aims reductions in total and saturated fat, replace fats with oils, 600g fruit and vegetables/d, fatty fish at least once a week, eat plenty of bread and cereals Control methods: booklets plus one dietetic interview, and 3 monthly clinical review Intervention methods: 1 hour nutrition interview every 3 months, plus 3 monthly clinical review Weight goals: Total fat intake (at 12 months): low & mod fat 26.2 (SD 5.1), cont 28.9 (SD 7.9)%E Saturated fat intake (at 12 months): unclear Style: diet advice Setting: community
Outcomes	Stated trial outcomes: endothelial function Available outcomes: weight, total, LDL and HDL cholesterol, TG
Notes	No outcome data provided on weight, except the statement "in both groups, body weight remained unchanged after 12 months". ITT analysis: Not relevant Weight data: (not) reported at 1 yr only

Strychar 2009 (31)

Participants	People with well controlled type I diabetes mellitus (Canada) CVD risk: moderate Intervention reduced fat: 18 randomised, 15 analysed Intervention modified fat: 17 randomised, 15 analysed Mean years in trial: reduced fat 0.46, modified fat 0.47 % male: reduced fat unclear, modified fat unclear Age, years: 37.9 (8.1 SD) (not specified by study arm) BMI, kg/m^2: control 24.3 (2.6), intervention 24.3 (2.7)
Interventions	Reduced fat vs Modified fat diet Reduced fat aims: total fat 27-30%E, SFA ≤10%E, MUFA 10%, CHO 54-57% Modified fat aims: total fat 37-40%E, SFA ≤10%E, MUFA 20%E, CHO 43-46%E Reduced fat methods: after initial dietary advice monitored weekly by phone by a dietitian (24 hour food recall). Glycaemia, insulin doses, CHO at meals, hypoglycaemic attacks all self-monitored daily and reported weekly. Modified fat methods: after initial dietary advice monitored weekly by phone by a dietitian (24 hour food recall). Glycaemia, insulin doses, CHO at meals, hypoglycaemic attacks all self-monitored daily and reported weekly. Total fat intake (at 6 months): not stated Saturated fat intake (at 6 months): not stated Style: diet advice Setting: community
Outcomes	Stated trial outcomes: Triglycerides and other CVD risk factors Available outcomes: weight; BMI; total, LDL and HDL cholesterol; TGs; systolic and diastolic blood pressure *ITT analysis:* No, 15/18 int, 15/17 cont *Weight data:* reported at 6 months only

***Swedish Breast CA 1990** (32-34)*

Participants	Women who had had surgery for breast cancer (Sweden) CVD risk: low Control: randomised 121, analysed 63 Intervention: randomised 119, analysed 106 Mean years in trial: control 1.9, randomised 1.5 % male: 0% Age: mean 58 (not described by randomisation group) BMI, kg/m^2: control unclear (5%<20, 67% 20-24.9, 28% ≥25), intervention unclear (8% <20, 62% 20-24.9, 30% ≥25)
Interventions	Reduced fat vs usual diet Control aims: usual diet Intervention aims: 20-25%E from fat, increase energy from CHO to replace lost energy Control methods: no advice provided, only seen at baseline and 2 years Intervention methods: 4-6 sessions during the first 2 months, group meetings every 6-8 weeks, evening classes in low fat cooking, 3 monthly counselling during the first year, then at 18 months Weight goals: "The total energy and/or protein intake was to be held constant". Total fat intake (at 2 years): int -12.9 (SD unclear) (24 overall), cont -3.1 (SD unclear) (34.1 overall) %E Saturated fat intake (change to 2 years): int -6.8 (SD unclear), cont -1.9 (SD unclear)%E Style: diet advice Setting: community
Outcomes	Stated trial outcomes: dietary intake Available outcomes: weight, BMI
Notes	No exact variance or p-values reported for weight and BMI outcomes, so have estimated variance from p<0.05 for the difference between the 2 arms for weight. As p>0.05 for BMI no variance could be estimated. ITT analysis: unclear, as no. of participants not reported for weight (probably 63/121 int, 106/119 cont) Weight data: only reported at 2 years

Veterans Dermatology 1994 ***(35)***

Participants	People with non-melanoma skin cancer (USA) CVD risk: low Control: randomised 67, analysed 58 Intervention: randomised 66, analysed 57 Mean years in trial: 1.9 % male: control 67%, intervention 54% Age: mean control 52.3 (SD 13.2), intervention 50.6 (SD 9.7) BMI, kg/m^2: control unclear, intervention unclear (cont mean weight 80kg, est BMI 29.7, int mean weight 81kg, est BMI 30.1)
Interventions	Reduced fat vs. usual diet Control aims: no dietary advice Intervention aims: total fat 20%E, protein 15%E, CHO 65%E Control methods: no dietary change, 4 monthly clinic visits Intervention methods: 8 weekly classes, with behavioural techniques, plus 4 monthly clinic visits Weight goals: "to maintain body weight .... patients were instructed to increase their intake of carbohydrate, particularly complex carbohydrate" Total fat intake ("during study" months 4-24): low fat 20.7 (SD 5.5), cont 37.8 (SD 4.1)%E Saturated fat intake ("during study, months 4-24): low fat 6.6 (SD 1.8), cont 12.8 (SD 2.0)%E Style: diet advice Setting: community
Outcomes	Stated trial outcomes: incidence of actinic keratosis and non-melanoma skin cancer Available outcomes: none (weight data provided, but no variance info)
Notes	At 2 years control -1.5kg n=50?, intervention -1kg n=51? ITT analysis: unclear, as no. of participants not reported for weight Weight data: reported every 4 months for 2 years on graph, without any variance data

***WHEL 2007** (36)*

Participants	Women with previously treated early breast cancer (USA) CVD risk: low Control: randomised 1561, analysed 1551 Intervention: randomised 1546, analysed 1537 Mean years in trial: unclear, 11 years max, around 11 years mean? % male: 0 Age: control mean 53.0 (SD 9.0), intervention mean 53.3 (SD 8.9) BMI, kg/m^2: control 27.1 (sd 6.0), intervention 27.7 (6.6)
Interventions	Reduced fat intake vs usual diet Control: aim 30%E from fat Intervention: aim 15-20%E from fat, 5veg/d, 3 fruit/d, 16oz veg juice and 30g/d fibre Control methods: given print materials only Intervention methods: telephone counselling programme (31 calls by study end), cooking classes (12 offered in first year, 4 attended on average) and monthly newsletters (48 by study end), all focused on self-efficacy, self-monitoring and barriers, retaining motivation Weight goal: Intervention goal was to achieve the change in dietary pattern without weight reduction, weight and calories not mentioned in the control group. Total fat intake (at 72 months): low fat 28.9 (SD 9.0), cont 32.4 (SD 8.0)%E Saturated fat intake (at 72 months): low fat 7.2 (SD unclear), cont 8.9 (SD unclear)%E Style: diet advice Setting: community
Outcomes	Stated trial outcomes: mortality, invasive breast cancer Available outcomes: weight, total, LDL and HDL cholesterol, TG
Notes	Weight reported at 1, 2, 3, 4 and 6 years, and 6 year data used in main analysis. ITT analysis: No, 1308/1537 low fat, 1313/1551 cont

***WHI 2006** (37)*

Participants	Post-menopausal women aged 50-79 (USA) CVD risk: mixed, mostly low but some participants had CVD at baseline Control: randomised 29294, analysed 29294 Intervention: randomised 19541, analysed 19541 Mean years in trial: control 8.1, intervention 8.1 % male: 0 Age: mean int 62.3 (SD 6.9), control 62.3 (SD 6.9) BMI, kg/m^2: control 29.1 (sd 5.9), intervention 29.1 (sd 5.9)
Interventions	Reduced fat vs. usual diet Control: diet-related education materials Intervention: low fat diet (20% E from fat) with increased fruit and vegetables Control methods: given copy of 'Dietary Guidelines for Americans' Intervention methods: 18 group sessions with trained and certified nutritionists in the first year, quarterly maintenance sessions thereafter, focusing on diet and behaviour modification Weight goals: "the intervention did not include total energy reduction or weight-loss goals". Total fat intake (at 5&7 years): int 29.8 (SD 8.3)%E, cont 38.1 (SD 7.2)%E Saturated fat intake (at 5&7 years): int 10.1 (SD 3.3)%E, cont 13.2 (SD 3.2)%E Style: dietary advice Setting: community
Outcomes	Stated trial outcomes: breast cancer, mortality, other cancers, cardiovascular events, diabetes Available outcomes: weight, BMI, waist circumference, total, LDL and HDL cholesterol, TGs, systolic and diastolic BP
Notes	Weight data available at 1, 3 and 5&7 years, plus last available assessment (mean 7.5 years follow up). 5&7 year data used for main analysis ITT analysis: no, 16297/19524 int, 25056/29272 cont

WHT Feasibility 1990 (38)

Participants	Women at increased risk of breast cancer (USA) CVD risk: low Control: randomised 184, analysed 159 Intervention: randomised 119, analysed 102 Mean years in trial: control 1.9, randomised 1.9 % male: 0% Age: mean control 55.6 (SD 6.3), intervention 55.6 (SD 6.2) BMI, kg/m^2: control 25 (sd 4), intervention 26 (sd 4)
Interventions	Reduced fat vs usual diet Control aims: maintain usual diet Intervention aims: 20%E from fat Control methods: no advice provided, only seen at baseline, then 6, 12 and 24 months for assessment Intervention methods: women were given flexible diet plans and responsible for their own monitoring, they had individual appointments with a nutritionist at 2 and 12 weeks, plus small group meetings (weekly for 8 weeks, then biweekly for 8 weeks, then monthly to 2 years) Weight goals: weight and calories not mentioned Total fat intake (at 2 years): int 22.6 (SD 7.1), cont 36.8 (SD 8.0)%E Saturated fat intake (at 2 years): int 7.2 (SD 2.7), cont 12.3 (SD 3.6)%E Style: diet advice Setting: community
Outcomes	Stated trial outcomes: dietary intake/feasibility Available outcomes: weight, total cholesterol
Notes	Weight data provided at 6, 12 and 24 months. 2 year data used in main analysis ITT analysis: No, 159/184 int, 102/119 cont

***WHT:FSMP 2003** (38)*

Participants	Post-menopausal women from diverse ethnic and socioeconomic backgrounds (USA) CVD risk: low Control: randomised 883, analysed 649 at 6mo, 443 at 12mo, 194 at 18mo. Intervention: randomised 1325, analysed 1071 at 6mo, 698 at 12mo, 285 at 18mo Mean years in trial: unclear, follow up from 6 to 18 months % male: 0% Age: mean control 59.8 (SD 6.6), intervention 60.1 (SD 6.6) BMI, kg/m^2: control 29.1 (sd 4.8), intervention 28.7 (sd 4.6)
Interventions	Reduced fat vs usual diet Control aims: maintain usual diet Intervention aims: up to 20%E from fat, reduced saturated fat and dietary cholesterol, increased fruit, vegetables and wholegrains Control methods: pamphlet on general dietary guidelines provided, no other follow up, seen at baseline, then 6, 12 and 18 months for assessment Intervention methods: women allocated to groups of 8-15 women with a nutritionist leader, meeting weekly for 6 weeks, bi-weekly for 9 months then quarterly. Women provided with personal fat gram goals. Weight goals: weight and calories not mentioned Total fat intake (at 1 year): int 25.4 (SD unclear), cont 36.0 (SD unclear)%E Saturated fat intake (at 1 year): int 8.7 (SD unclear), cont 12.1 (SD unclear)%E Style: diet advice Setting: community
Outcomes	Stated trial outcomes: dietary intake/feasibility Available outcomes: weight, BMI, blood pressure
Notes	Weight and BMI data only found for 6 months of intervention ITT analysis: No, 1071/1325 int, 649/883 cont

WINS 1993 (39)

Participants	Women with localised re-sected breast cancer (USA) CVD risk: low Control: 1462 randomised, 1462 analysed Intervention: 975 randomised, 975 analysed Mean years in trial: overall 5.0 % men: 0 Age: control mean 58.5 (95% CI 43.6 to 73.4), intervention mean 58.6 (95% CI 44.4 to 72.8) (all post-menopausal) BMI, kg/m^2: control 27.5 (sd 5.8), intervention 27.6 (sd 6.3)
Interventions	Reduced fat intake vs. usual diet Control aims: minimal nutritional counselling focused on nutritional adequacy Intervention aims: total fat 15-20%E Control methods: 1 baseline dietetic session plus 3-monthly sessions Intervention methods: 8 bi-weekly individual dietetic sessions, then optional monthly group sessions, incorporating individual fat gram goals, social cognitive theory, self-monitoring, goal setting, modelling, social support and relapse prevention and management Weight goals: "fat gram goals were based on energy needed to maintain weight, and no counselling on weight reduction was provided", not mentioned for control. Total fat intake (at 1 year): low fat 20.3 (SD 8.1), cont 29.2 (SD 7.4)%E Saturated fat intake (at 1 year): low fat 10.4 (SD 6.7), cont 16.6 (SD 9.3)%E Style: dietary advice Setting: community
Outcomes	Stated trial outcomes: dietary fat intake, total cholesterol, weight and waist Available outcomes: weight, BMI
Notes	Weight data reported at 1, 3 and 5. 5 year data used in main analysis ITT analysis: No, 386/975 low fat, 998/1462 cont

Footnotes

CHO = carbohydrates,
chol = cholesterol,
CVD = cardiovascular disease,
ITT: intention to treat
MI = myocardial infarction
P/S = polyunsaturated / saturated fat ratio,
%E = percent of total energy intake,

Supplementary Table 3. Effects within included adult RCTs of lower vs. usual fat intake on serum lipids and blood pressure.

CVD risk factor	Effect size (95% CI)	No. of comparisons, I^2
LDL cholesterol, mmol/L	-0.12 (-0.21 to -0.04)	21, 60%
HDL cholesterol, mmol/L	-0.01 (-0.03 to -0.00)	22, 0%
Total cholesterol, mmol/L	-0.19 (-0.26 to -0.11)	23, 47%
Triglycerides, mmol/L	-0.01 (-0.09 to 0.07)	20, 51%
Total/HDL cholesterol	-0.10 (-0.16 to -0.04)	7, 0%
Systolic blood pressure, mmHg	-1.16 (-1.95 to -0.37)	9, 0%
Diastolic blood pressure, mmHg	-0.83 (-1.52 to -0.13)	10, 26%

Supplementary Table 4. Data on dietary intake of energy, sugars, carbohydrate, protein and alcohol during the diet period of RCTs comparing low fat with usual fat intake.

Trial	Energy intake (SD), kcal		Sugars intake, %E		CHO intake, %E		Protein intake, %E		Alcohol intake, %E		No. of participts	
	Int.	Cont	Int.	Cont	Int.	Cont	Int.	Cont	Int.	Cont	Int.	Cont
Aukland reduced fat, 1yr	1887 (672)	2269 (750)			54.2 (10.5)	45.8 (10.9)	18.4 (3.5)	16.6 (3.9)	3.6 (7.0)	5.7 (7.0)	49	61
BDIT Pilot Studies, 9yr	1460 (376)	1578 (365)			49.6 (7.5)	46.9 (6.2)	15.5 (2.4)	15.3 (2.6)	2.3 (3.3)	1.7 (2.4)	76	81
BeFIT	(data not reported in control groups)											
Bloemberg, Δ to 6mo					4.4 (6.5)	1.2 (6.1)	0.33 (2.9)	0.57 (1.7)			39	41
BRIDGES, 6mo	-34 (79)	+ 22 (79)									48	46
Canadian DBCP, 2yrs	1540 (317)	1759 (437)			60.3 (8.3)	48.8 (8.1)	18.0 (3.2)	16.9 (2.8)			104	100
CARMEN, Δ to 6mo CC=high complex CHO, SC=high simple CHO	CC: -430 (573), SC: -167 (502)	-191 (573)	CC: -3.5 (5.4), SC: +7.2 (5.7)	-0.9 (4.5)	CC: +4.7 (4.8), SC: +8.4 (5.5)	-1.6 (4.8)	CC: +3.6 (2.5), SC: +1.5 (2.0)	+0.9 (2.4)	CC: -0.5 (2.4), SC: +0.3 (2.6)	0.0 (2.5)	CC 83, SC 76	77
CARMEN MS sub-study, 6mo	CC: 1495 (537) SC: 2451 (747)	1958 (467)									CC: 9, SC: 9	8
De Bont, Δ to 6mo	-98 (369)	-120 (485)			7.9 (9.5)	-0.1 (10.9)	2.4 (7.0)	1.7 (5.9)	-0.2 (1.6)	-0.4 (2.6)	71	65
DEER (diet alone), Δ to 1 yr	Women: -220 (356) Men: -285 (541)	Women: -19 (367), Men: -25 (482)			Women: +5.5 (8.0) Men: +8.0 (9.3)	Women: -0.2 (7.3) Men: +1.1 (6.6)					46, 49	45, 46
DEER (diet & ex), Δ to	Women: -191	Women: -54			Women: +7.8	Women: -0.3					43, 48	43, 47

Trial	Energy intake (SD), kcal		Sugars intake, %E		CHO intake, %E		Protein intake, %E		Alcohol intake, %E		No. of participts	
	Int.	Cont	Int.	Cont	Int.	Cont	Int.	Cont	Int.	Cont	Int.	Cont
1 yr	(343), Men: -167 (516)	(410), Men: +141 (437)			(6.2), Men: +9.3 (8.3)	(7.9), Men: +1.4 (6.3)						
German Fat Reduced, wk10	1867 (529)	2112 (634)			42.0 (11.8)	40.2 (10.0)	15.6 (3.6)	13.6 (3.6)			35	32
Kentucky Low Fat, 1yr	1882 (521)	2010 (528)			53 (8.9)	50 (7.9)	17 (3.4)	18 (4.3)			47	51
Kuopio, wks 14-28	AHA 1791 (382), Mono 1887 (478) Low fat 1648 (430)	1982 (406)			AHA 48 (5) Mono 47 (6) Low fat 51 (5)	46 (6)	AHA 17 (2) Mono 17 (20) Low fat 19 (3)	16 (2)			AHA 41 Mono 41 Low fat 40	37
Mast-opathy Diet, 6mo	1491 (NR)	1676 (NR)			56.3 (NR)	48.1 (NR)	17.9 (NR)	15.8 (NR)	4.8 (NR)	4.2 (NR)	10	9
MeDiet, 6mo	1676 (639)	1654 (498)	18.7 (6.9)	21.9 (9.2)	27.2 (17.0)	25.8 (11.0)	14.9 (4.7)	16.2 (5.1)	5.6 (11.1)	1.6 (2.2)	51?	55?
Moy, 2 yr	1825 (NR)	2092 (NR)									117	118
MSFAT, 6mo	2460 (NR)	2699 (NR)			47 (NR)	41 (NR)	16 (NR)	14 (NR)	3 (NR)	3 (NR)	117	103
NDHS Open 1st 6mo	B: 2154 (432)	C: 2262 (435) D: 2228 (456)			B: 48.7 (12.3)	C: 45.3 (12.1) D: 44.7 (11.7)	B: 18.6 (3.4)	C: 17.6 (3.1) D: 17.4 (3.1)	B: 3.7 (3.7)	C: 3.6 (4.0) D: 3.8 (4.0)	B: 339	C: 355 D: 346
NDHS Open 2nd 6mo	BC: 2249 (492)	F: 2196 (427) G: 2169 (420)			BC: 45.7 (12.7)	F: 44.1 (11.1) G: 43.3 (11.4)	BC: 17.3 (3.5)	F: 7.3 (3.0) G: 17.7 (2.9)	BC: 3.5 (4.2)	F: 4.2 (4.0) G: 4.0 (4.5)	BC: 491	F: 214 G: 194
Nutrition & Breast Health,	1780 & 1960	1571 & 1687									23 & 25	24 & 23

Trial	Energy intake (SD), kcal		Sugars intake, %E		CHO intake, %E		Protein intake, %E		Alcohol intake, %E		No. of participts	
	Int.	Cont	Int.	Cont	Int.	Cont	Int.	Cont	Int.	Cont	Int.	Cont
1yr												
Pilkington, 1yr	NR	NR									12	23
Polyp Prevention Trial, yr 4	1978 (471)	2030 (518)			58.3 (7.4)	47.1 (7.2)	17.3 (2.5)	16.5 (2.4)			605	581
Rivellese, 6mo	NR	NR	14	10	55	48	18	16			27	17
Simon Low Fat, 1yr	1570 (NR)	1594 (NR)									65	68
Sondergaard, 12mo					52.3 (6.4)	48.5 (8.7)	17.0 (2.9)	16.6 (3.1)	4.5 (5.3)	6.4 (7.4)	62	51
Strychar, 6mo	NR	NR									15	15
Swedish Breast CA, Δ to 2 yrs	-215 (p<0.01)	-143 (p<0.01)	+4.8 (p<0.01)	+1.4 (p<0.01)	+11.0 (p<0.01)	+2.7 (p<0.01)	+1.7 (p<0.01)	+0.3 (p>0.05)	+0.2 (p>0.05)	+0.4 (p>0.05)	63	106
Veteran's Dermatol., during trial	1995 (564)	2196 (615)			60.3 (6.3)	44.6 (6.9)	17.7 (2.2)	15.7 (2.4)	3.2 (3.4)	3.2 (3.9)	57?	58?
WHEL, 1yr	1664 (345)	1635 (384)			65.3 (8.5)	57.1 (9.3)					197	196
WHI, 7.5yrs	1446 (510)	1564 (595)			52.7 (9.8)	44.7 (8.5)					14246	22083
WHT: feasibility, 2yrs	1356 (358)	1617 (391)			59.0 (8.8)	46.9 (8.9)	19.2 (3.9)	16.8 (3.8)			163	101
WHT: FSMP, Δ to 18mo	-488 (NR)	-255 (NR)									285	194
WINS, 5yr	-167 (p <0.0001 vs. cont)	0									380	648

Supplementary Table 5. Characteristics and results of included cohort studies in adults

Study	Participants at baseline	+ / 0 / -	Results and/or estimate of effect?
CARDIA Ludwig 1999 (40) **USA**	2909 healthy black and white young adults **Baseline Age:18-30** yrs **Follow-up:** 10 yrs **%E from fat:** unclear (lower quintile <30, upper >41.7) **BMI:** unclear	**+** (weight) in black men and women **0** (weight) in white men and women	**Multiple dietary assessments – but appear to be using baseline data in analysis** Adjusted means of 10 year body weight according to quintiles of total fat as a percentage of total energy. P for trend 0.32 in white men and women (quintile 1 weight 168.6lb, quintile 5 weight 169.4lb), 0.03 for black men and women (quintile 1 weight 182.1lb, quintile 5 weight 185.7lb).
Danish Diet Cancer & Health Study Halkjaer 2009 (41;42) **Denmark**	22570 women & 20126 men **Baseline Age:50-64** yrs **Follow-up:** 5 yrs **%E from fat:** unclear (approx 32% in women, 33% in men) **BMI:** median 24.7 women, 26.1 men	**0** (Δwaist) women **0** (Δwaist) men	**Single dietary assessment used.** Association between total fat intake at baseline and change in waist circumference over 5 years suggested no statistically significant effects in women (mean change in waist circumference -0.03 cm/MJ/d total fat, 95% CI -0.20 to 0.14) or men (mean change in waist circumference 0.06 cm/MJ/d total fat, 95% CI -0.05 to 0.17).
Danish MONICA Iqbal 2006 (43) **Denmark**	900 women & 862 men **Baseline Age:30-60** yrs **Follow-up:** 5 yrs **%E from fat:** 43.8% (SD 6.5 women, 42.7 (SD 6.3) men **BMI:** 23.4 (SD 3.7 women, 25.1 (SD 3.3) men	**0** (Δweight) women **0** (Δweight) men	**Single dietary assessment used.** Regression assessment of total fat as %E and other dietary factors as a function of change in body weight suggested no significant effects of %E from fat on 5 year change in body weight in women (unadjusted beta 0.47, SE 0.89, p0.60, adjusted beta 0.86, SE 0.92, p0.35) or men (unadjusted beta -0.14, SE 0.69, p0.84, adjusted beta 0.11, SE 0.69, p0.87)
Health Professionals Follow-Up Study (HPFUS) Coakley 1998 (44) **USA**	19478 male health professionals **Baseline Age:45-75** yrs **Follow-up:** 4 yrs **%E from fat:** unclear, energy adjusted fat intake mean 69.6g/d (SD 13.8) **BMI:** unclear	**+** (Δweight) 45-54yrs men **+** (Δweight) 55-64yrs men **0** (Δweight) 65+ yrs men	**Single dietary assessment used.** Multivariate regression analyses determined whether total fat intake and other habits were predictive of 4-year weight change, and found that a change of adjusted fat intake of 10g/d predicted 0.10kg of weight change over 4 years (p<0.001 for ages 45-54 and 55-64 years, p>0.05 for age 65+).
Memphis Klesges 1992 (45-47) **USA**	152 women and 142 men (Caucasian health professionals) **Baseline Age: 24-52** yrs **Follow-up:** 2 yrs **%E from fat:** mean 36.8 (SD 6.1) women, 36.0 (SD 5.4) men **BMI:** mean 24.8 (SD 5.0) women, 27.8 (SD 4.3) men	**+** (Δweight) women **0** (Δweight) men **0** (Δwaist) women **-** (Δwaist) men	**Multiple dietary assessments – but appear to be using baseline data in analysis** Stepwise multivariate regression analyses assessed whether various lifestyle factors were predictive of weight change over 2 years. Percentage of energy as fat was predictive of weight change in women (coefficient 0.53, SE 0.16, p 0.0010) but not in men (exact data not provided). Hierarchical linear regression assessed effects of lifestyle factors on change in waist circumference over 2 years, and found no significant effect in women (coefficient -0.04, p 0.50) but a statistically significant negative relationship in men (coefficient -0.05, p 0.04)
NHANES Follow-up Kant 1995 (48)	4567 women & 2580 men **Baseline Age: 25-74** yrs **Follow-up:** mean 10.6 (SD 5) yrs	**+** (Δweight) <50 yrs women **0** (Δweight) 50+ yrs women	**Single dietary assessment used.** Univariate regression analyses assessed whether fat as %E is predictive of 10 year weight change and found no significant effects

Study	Participants at baseline	+ / 0 / -	Results and/or estimate of effect?
USA	**%E from fat:** mean 36.4 (SD 5.0) women, 37.0 (SD 10.1) men **BMI:** mean 25.2 (SD 5.0) women, 25.9 (SD 5.0) men	**0** (Δweight) <50 yrs men **0** (Δweight) 50+ yrs men	in women (Beta -0.011, SE 0.017, p 0.51) or men (Beta 0.043, SE 0.022, p 0.06). Effects were similar in multivariate regression in women (Beta -0.033, SE 0.019, p 0.08 for women overall, Beta -0.053, SE 0.025, p 0.04 for women aged <50yrs, Beta -0.019, SE 0.030, p 0.55 for women aged 50+) or men (Beta 0.021, SE 0.022, p 0.33 for men overall, Beta -0.004, SE 0.028, p 0.88 for men aged <50yrs, Beta -0.058, SE 0.035, p 0.10 for men aged 50+).
Nurses Health Study Colditz 1990 (49) **USA**	31940 women (nurses) **Baseline Age:** 30-55+ **Follow-up:** 8 yrs **%E from fat:** unclear **BMI:** unclear	**0** (Δweight) women	**Single dietary assessment used.** Correlation between total fat (g/d) and weight gain over subsequent 4 years (beta -0.0007, t -0.4), not statistically significant.
Pawtucket HHP Parker 1997 (50) **USA**	289 women and 176 men **Baseline Age:** 18-64 yrs **Follow-up:** 4 yrs **%E from fat:** unclear **BMI:** mean 26.5 (SD 5.0)	**0** (Δweight) women & men	**Single dietary assessment used.** Multiple regression assessed association of weight change with different nutrients at baseline. Found no effect of total fat in grams on weight change over 4 years (coefficient 2.30, p 0.71)
SEASONS Ma 2005 (51) **USA**	275 healthy women & 297 healthy men **Baseline Age:** 20-70 yrs **Follow-up:** 1 yr **%E from fat:** mean 36.7 (SD 9.0) **BMI:** mean 27.4 (SD 5.5)	**0** (BMI) women & men – with no energy adjustment	**Multiple dietary assessments – but appear to be using baseline data in analysis** Regression analyses to assess effects of total fat %E on BMI. Longitudinal effect was not statistically significant (coefficient 0.005, p 0.07)
Women's Gothenburg Lissner 1997 (52) **Sweden**	361 women **Baseline Age: 38-60** yrs **Follow-up:** 6 yrs **%E from fat:** mean 34.1 (SD 4.0) lower fat group, 42.3 (SD 3.0) higher fat group **BMI:** mean 24.6 (SD 4.1) lower fat group, 24.1 (SD 4.1) higher fat group	**+** (Δweight) sedentary **0** (Δweight) mederate **0** (Δweight) active	**Single dietary assessment used.** Multivariate regression used to test for interactive effects of dietary fat intake on weight change over 6 years. A significant effect of high vs low %E from fat was found in sedentary women (high fat women gained 2.64kg while low fat women lost 0.64kg over 6 years, p 0.03) but this was lost with further energy adjustment. No effects were seen in more active women (2 categories) where those with low and high fat intakes all gained 1-2kg on average.

Key: + = positive relationship found between fat intake and weight outcome;
0 = no relationship found between fat intake and weight outcome;
- = negative (inverse) relationship found between fat intake and weight outcome.

Supplementary Table 6. Risk of bias of included cohort studies.

Study	Number lost to follow-up	Baseline similarity by total fat intake, funding, control groups	Adjustments (where stratified not counted as not being adjusted)*	Method of assess-ment	Risk of Bias **
CARDIA Ludwig 1999 (40) **USA**	5111 attended original screening, 3609 attended at years 1, 7 and 10, 2909 included in analysis **43% lost** **Reasons:** exclusion of those who were pregnant or lactating, with diabetes, on lipid or BP medication or with extreme dietary factors.	**Different**. Those with lower total fat intake were more likely to be women, non-smokers, more physically active, with higher alcohol and vitamin supplement intake. **Funded by**: USNHLB, USNIDDKD **Control Group:** Internal	Weight was adjusted for baseline weight. Analysis adjusted for energy, sex, age, field centre, education, energy intake, physical activity, cigarette smoking, alcohol intake, vitamin supplement use. **All adjusted for.**	**Interviewer-administered FFQ (700 foods)**	**High**
Danish Diet Cancer & Health Study Halkjaer 2009 (41;42) **Denmark**	57043 at at baseline, 44897 re-assessed 5 years later. **21% lost** **Reasons:** 1781 had died, 435 emigrated, remainder did not want to participate or did not reply.	Data not reported. **Unclear** **Funded by:** National Danish Research Foundation, DiOGenes (EU funding) **Control Group:** Internal	BMI, energy, age, smoking, alcohol, wine, beer, spirits, sporting activity **Not adjusted for ethnicity, or socioeconomic status**	**192-item semi-quantitative FFQ checked by dietitian**	**High**
Danish MONICA Iqbal 2006 (43) **Denmark**	2025 at at baseline, 1762 re-assessed 5 years later. **13% lost** **Reasons:** missing or very high energy or unknown history of family obesity	Data not reported. **Unclear** **Funded by:** Apotekerfonden & Danish Ministry for Health **Control Group:** Internal	Baseline BMI, age, physical activity, smoking, education level, cohort, volume, energy intake. **Not adjusted for ethnicity**	**Weighed 7-day food record**	**Mod-erate**
Health Professionals Follow-Up Study (HPFUS) Coakley 1998 (44) **USA**	36353 returned 1992 questionnaire, of whom 19478 were included in this analysis. **46% lost** **Reasons:** 9345 had cancer, heart disease, diabetes or stroke, 7530 were missing key information	Data not reported. **Unclear** **Funded by:** NIH and Centres for Disease Control **Control Group:** Internal	Baseline weight, energy, height, activity, TV viewing, high BP, high cholesterol **Not adjusted for ethnicity, socioeconomic status**	**FFQ**	**High**
Memphis Klesges 1992 (45-47) **USA**	417 were enrolled, 294 were included in weight change analysis, and 230 in the waist circumference change analysis. **29% lost (weight), 45% lost (waist)** **Reasons:** "attrition" for weight change, no explanation of further losses for waist circumference data.	Data not reported. **Unclear** **Funded by:** NHLBI and Tennessee Centres of Excellence **Control Group:** Internal	Gender, age, pregnancy status, smoking, alcohol, family risk of obesity, energy intake, sports activity, work activity, leisure activity, change from baseline of energy, fat intake, activity, cigarettes. **Not adjusted for socioeconomic status**	**Willett's FFQ**	**High**
NHANES Follow-up Kant 1995 (48)	14407 were enrolled and eligible, 7147 were included in analysis. **50% lost**	Higher fat as %E associated with younger age, more smoking, higher levels of	Baseline age, race, education, BMI, energy intake, smoking, physical	**Single 24-hour dietary recall**	**High**

Study	Number lost to follow-up	Baseline similarity by total fat intake, funding, control groups	Adjustments (where stratified not counted as not being adjusted)*	Method of assess-ment	Risk of Bias **
USA	**Reasons:** no dietary info, unsatisfactory 24 hour recalls, atypical intake, proxies, mistakes, pregnant or lactating participants, lack of weight data, death.	morbitidy **Funded by:** unclear **Control Group:** Internal	activity, duration of follow up, alcohol, morbidity, special diet, parity. **All adjusted for**		
Nurses Health Study Colditz 1990 (49) **USA**	Of 121700 women enrolled, 38724 were eligible for this study, 31940 women included in analyses **17% lost** **Reasons:** non-respondent or invalid FFQ	Data not reported. **Unclear** **Funded by:** NIH **Control Group:** Internal	Age, BMI, energy intake **Not adjusted for ethnicity, physical activity, socioeconomic status**	**61-item FFQ**	**High**
Pawtucket HHP Parker 1997 (50) **USA**	Of 1081 enrolled, FFQ administered to random sub-sample of 556, 465 included in analysis **16% lost** **Reasons:** those excluded were those who did not attend both relevant appointments, and were more male, less educated, less active, greater BMI	Data not reported. **Unclear** **Funded by:** NHLBI **Control Group:** Internal	Age, BMI, energy, smoking, activity **Not adjusted for sex, ethnicity, or socioeconomic status**	**Willett's FFQ with categories added for fats, oils, sweets, snacks and dairy products**	**High**
SEASONS Ma 2005 (51) **USA**	Of 1257 in original cohort, 641 completed baseline questionnaire & one blood draw, 572 included in analyses **11% lost** **Reasons:** unclear, did not attend further appointments	Data not reported. **Unclear** **Funded by:** NHLBI **Control Group:** Internal	None **Not adjusted for age, sex, energy, ethnicity, physical activity or socioeconomic status**	**7 day dietary recall**	**High**
Women's Gothenburg Lissner 1997 (52) **Sweden**	Of 1462 in main cohort, 437 randomly selected and asked for dietary information, 361 included in analysis. **17% lost** **Reasons:** 64 did not return for weight assessment, 12 had chronic illness so excluded.	Higher fat as %E associated with younger age, higher energy intake, more walking and lifting at work, greater likelihood of being a smoker **Funded by:** Swedish Medical Research Council **Control Group:** Internal	Baseline body weight, activity, smoking, age, energy **Not adjusted for ethnicity, or socioeconomic status**	**Dietary interview including frequency of 69 food items**	**High**

* Of age, sex, energy intake, ethnicity, physical activity (and/or TV watching) and socioeconomic (which includes educational status)

** Moderate risk of bias was suggested where <20% were lost to follow up, up to 2 factors were unadjusted for in the design or analysis, and diet was assessed using a 24-hour recall or diet diary. All other studies were at high risk of bias.

Supplementary Table 7. Risk of bias of included child cohort studies.

Study	Number lost to follow-up	Baseline similarity, funding, control group	Adjustments* (other than energy intake reported elsewhere)	Method of assess-ment	Risk of bias**
Butte 2007 (53) USA Viva la Familia Study	1030 at baseline, with 879 returning after one year. 15% lost Lost characteristics: none stated	Data not reported. Unclear **Funded by:** NIH, USDA/ARS Control group: internal	Adjusted for sex, age, age squared, and Tanner stage and BMI status in GEE. Not parental BMI, physical activity and SES (3)	**24-hour recall**, measured by a registered dietitian	High
Davison 2001 (54) USA	197 participants at study entry, 192 re-assessed two years later 3% lost Lost characteristics: none stated	Data not reported. Unclear Funded by: NIH Control group: internal	BMI, levels of activity, familial risk of overweight, change in BMI (mother), enjoyment of activity (father), total energy intake (father), and girls' percentage fat intake (girls). Not SES (1)	24-hour dietary recall	Moder-ate
Klesges 1995 (55) USA	203 children at baseline, 146 at follow-up 28% lost **Lost characteristics: "**no significant differences" (p>0.15) in BMI, energy intake, fat as %E, physical activity, sex or familial obesity risk between those attending at 2 years and those not attending	Data not reported. Unclear **Funded by:** National Heart Lung and Blood Institute Control group: internal	Age, sex, BMI, physical activity Not ethnicity, SES (2)	Dietary FFQ	High

* Of age, sex, energy intake, ethnicity, parental BMI, physical activity (and/or TV watching) and socioeconomic (which includes educational status)

** Moderate risk of bias was suggested where <20% were lost to follow up, up to 3 factors were unadjusted for in the design or analysis, and diet was assessed using a 24-hour recall or diet diary. All other studies were at high risk of bias.

Supplementary Table 8. Characteristics and results of included child cohort studies.

Study	Participants at baseline	+ / 0 / -	Results and/or estimate of effect
Butte 2007 USA Viva la Familia Study	1030 boys & girls (unclear how many of each, Hispanic) **Age:** unclear, 4-19yr? **Follow-up**: 1 yr **%E from fat**: 34.0 (6.0) **BMI:** not stated	+ (Δ weight)	Single dietary assessment **Analysis:** %E from fat was positively correlated with 1 yr weight gain (kg/y). For 798 participants generalised estimating equations (GEE) suggested β –coefficient 0.044, sd 0.018, p=0.014.
Davison 2001 USA	197 non-Hispanic white girls **Age:** 5.4 (0.4) yrs **Follow-up:** 2 yrs (age 7.3 ±0.3) **%E from fat:** 31 (sd unclear) **BMI:** 15.8 (1.4)	+ (Δ BMI)	Single dietary assessment **Analysis:** In hierarchical regression models, girls fat intake (as %E) at 5 yrs had a significant relationship with change in BMI from 5 to 7 years, p=0.02.
Klesges 1995 USA	110 boys and 93 girls **Age:** 3-5yrs (boys 4.4 (0.5), girls 4.3 (0.5) **Follow-up**: 2 yr **%E from fat:** boys and girls 33.0 (5.0) **BMI:** boys 16.1 (1.4), girls 16.1 (1.2)	0 /+ /0/0 (Δ BMI)	Multiple dietary assessments **Analysis:** assessed whether baseline %E from fat, change from baseline to 1 year, 1 yr to 2 yrs, or baseline to 2 yrs (along with other variables) predicted change in BMI over 2 yrs Multiple regression analysis suggested lower baseline %E from fat correlated to lower BMI change (regression coefficient = 0.034, p=0.05 – marginal signficance) at 2yrs, 0.17k/m^2per 5% more E from fat. Change in %E from fat over the last year was correlated with BMI change (regression *numbers not legible, probably p=0.01*), 0.20kg/m^2 per 5%E from fat change. Change in %E from fat from baseline to 1 yr, and baseline to 2 yrs did not predict change in BMI.

Key: + = positive ss relationship found between fat intake and weight outcome;
0 = no ss relationship found between fat intake and weight outcome;
- = negative (inverse) ss relationship found between fat intake and weight outcome.

ss: statistically significant

Supplementary Table 9. GRADE assessment of effect of total fat reduction on body weight in adults

Relationship between total fat intake and body weight in adults

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Lower dietary total fat intake	Control	Relative (95% CI)	Absolute		
Weight (kg) (follow-up 6 to 96 months; measured with: kg; Better indicated by lower values)												
27	randomised trials	No serious risk of bias[1]	No serious inconsistency[2]	No serious indirectness[3]	no serious imprecision[4]	Publication bias not detected, dose response gradient[5,6]	22447	31352	-	MD 1.57 lower (1.97 to 1.16 lower)[7]	⊕⊕⊕⊕ HIGH	CRITICAL

[1] While most studies were un-blinded and randomisation was rarely well enough described to assess allocation concealment, the results from these studies were remarkably consistent in their direction. Sensitivity analyses removing studies without clear allocation concealment did not lose the statistically significant weight loss in the low fat arm, and neither did running fixed (rather than random) effects meta-analysis or removing studies with attention bias favouring those in the low fat arm, or those with other interventions alongside the fat reduction. The consistent weight loss was despite the fact that none of the studies included intended to alter weight in either arm, so that publication bias on this outcome is unlikely. Together this suggests that risk of bias was low.

[2] The direction of effects in these RCTs were remarkably consistent - in almost every study participants eating lower total fat intakes were lower in weight (on average) at the study end than participants eating a higher percentage of total fat. The only inconsistency (where heterogeneity arose) was in the size of this effect. The heterogeneity was partly explained by the degree of reduction of fat intake, and by the level of control group fat intake, together explaining 58% of between-study variance. The reduction in weight in those taking on lower fat diets was seen in very different populations and from 6 months to several years. It was also consistent when studies that gave additional support, time or encouragement to the low fat arms were excluded, and where studies that delivered additional dietary interventions (on top of the change in dietary fats) were included. The results were consistent in direction, and much of the heterogeneity in the size of the effect was explained by the selected factors.

[3] All RCTs included directly compared (and randomised participants to) lower vs. higher fat intake; therefore there was no indirectness in intervention. All studies were conducted in industrialised countries so potential to generalize to other cultural contexts is limited. Nonetheless there is no reason to believe that the effect would be different in different populations. There are changes in diets in many countries around the world which are resulting in greater similarity in diets in developed and developing countries. Additionally the industrialised countries represented included a wide variety of baseline (or control group) fat intakes, and the effect appeared similar at all of these levels. The studies all addressed weight directly, and did not use proxy measures.

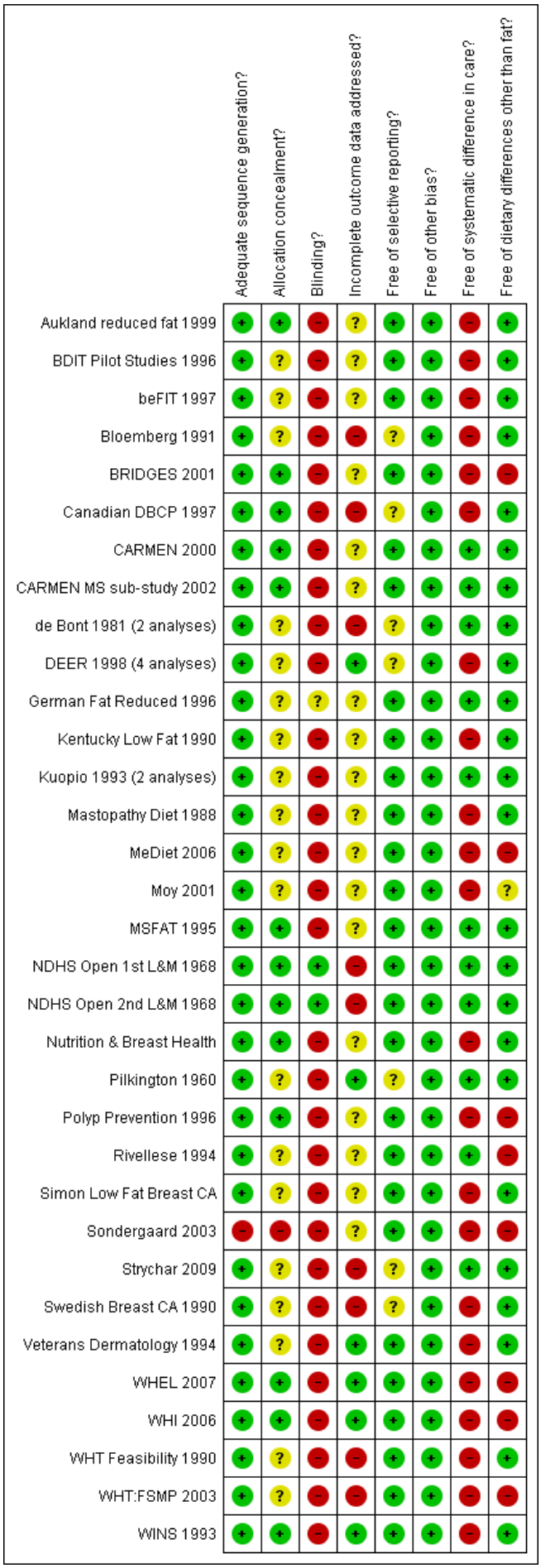
[4] Imprecision was unlikely, as over 14000 participants were included in RCTs of at least 6 months duration, and effect sizes were highly statistically significant. There was no imprecision.

[5] Subgrouping supported the presence of a dose response gradient in that studies that altered the total fat intake between intervention and control by less than 5% of energy had negligible effect on weight, while greater differences in total fat intake were associated with statistically significant differences in weight. This was supported by the meta-regression, which suggested statistically significant relationship between the degree of fat reduction and of weight loss.

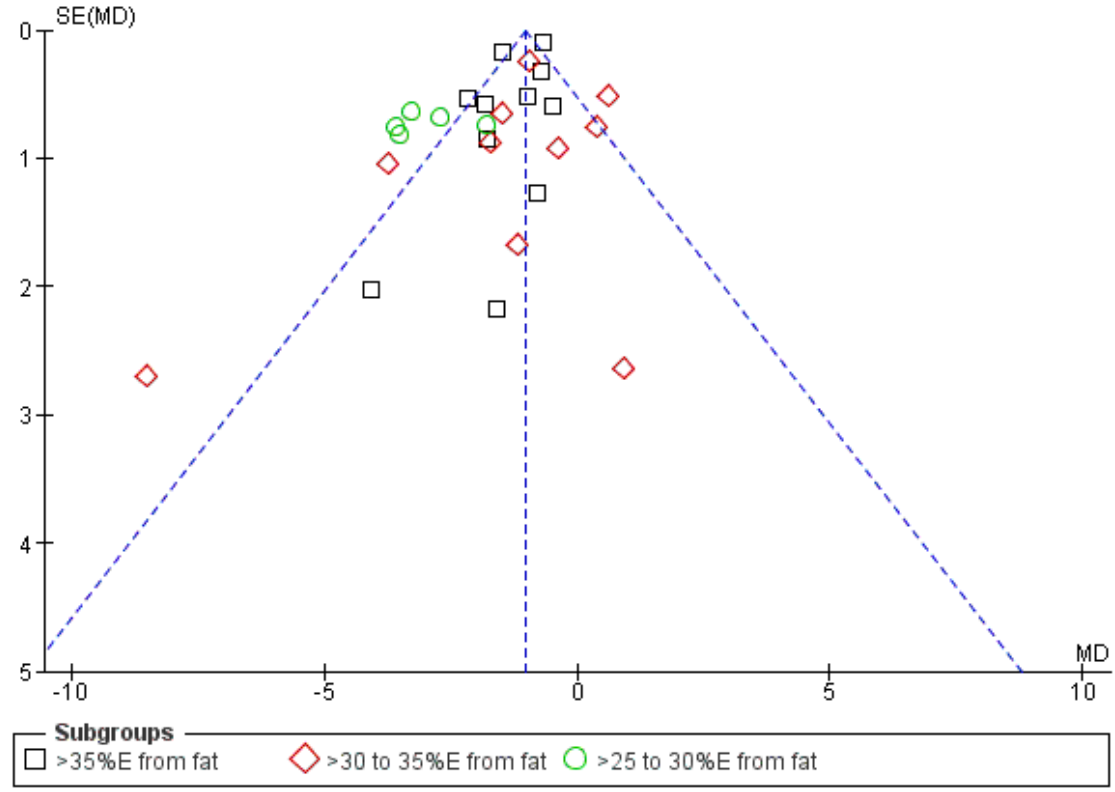
[6] The funnel plot did not suggest publication bias.

[7] The data presented are those for weight (in kg), but the meta-analyses on body mass index (BMI) and waist circumference both also showed small and statistically significant effects such that a lower fat intake related to lower BMI (MD -0.56kg/m^2, 95% CI -0.75 to -0.38, 9 trials, I2 36%) and lower waist circumference (MD -0.5cm, 95% CI -0.98 to -0.02, 1 trial).

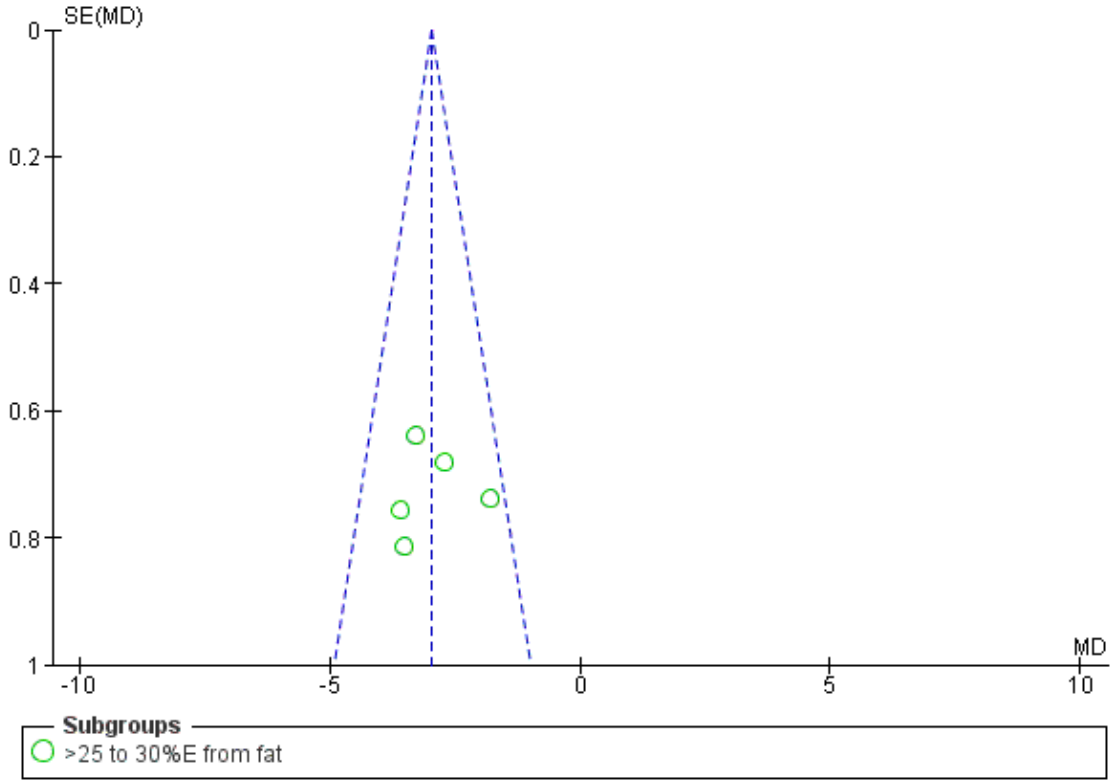
Supplementary Figure 1: Quality assessment of RCTs included in the review



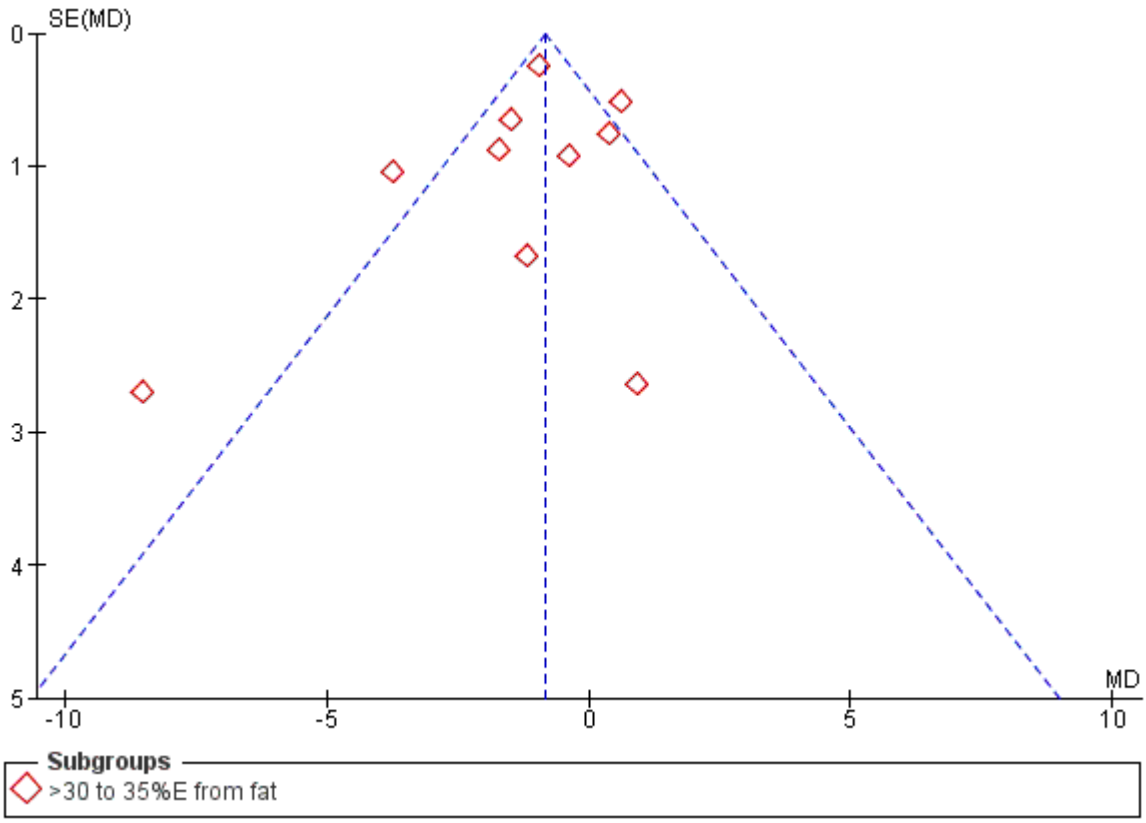
Supplementary Figure 2. Funnel plot of RCTs of lower vs. usual fat intake on body weight.



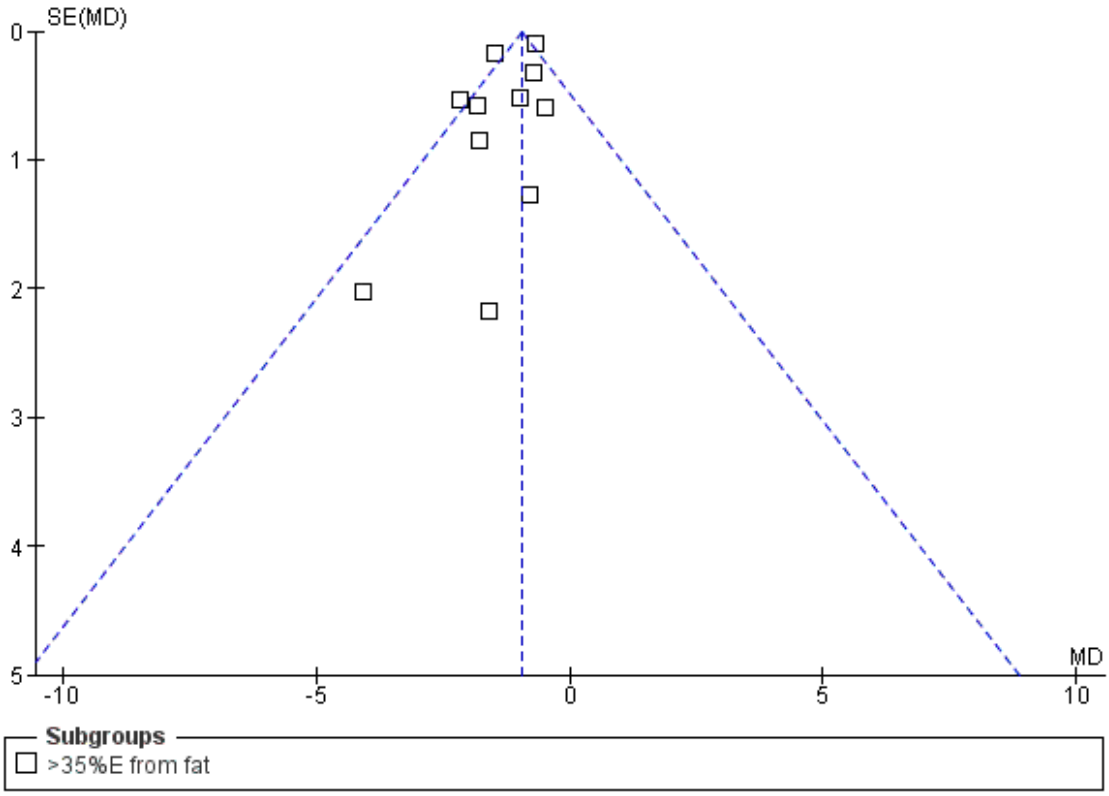
2a. Full set of studies



2b. Subgroup of studies including >25 to 30% of energy from fat in the control group

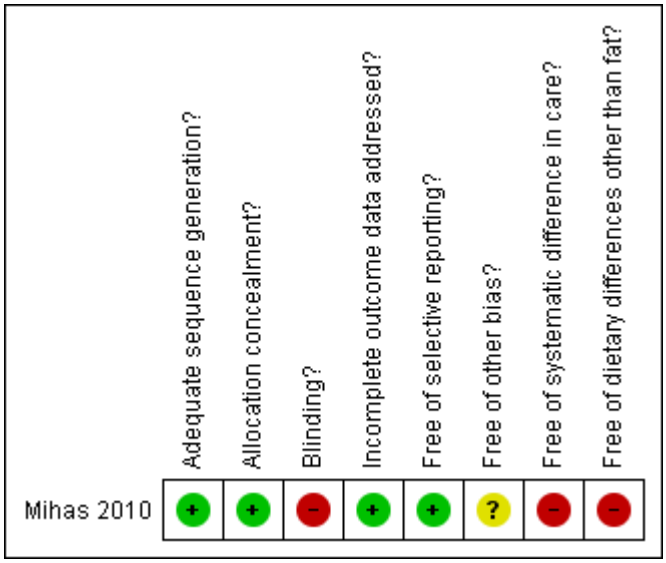


2c. Subgroup of studies including >30 to 35% of energy from fat in the control group

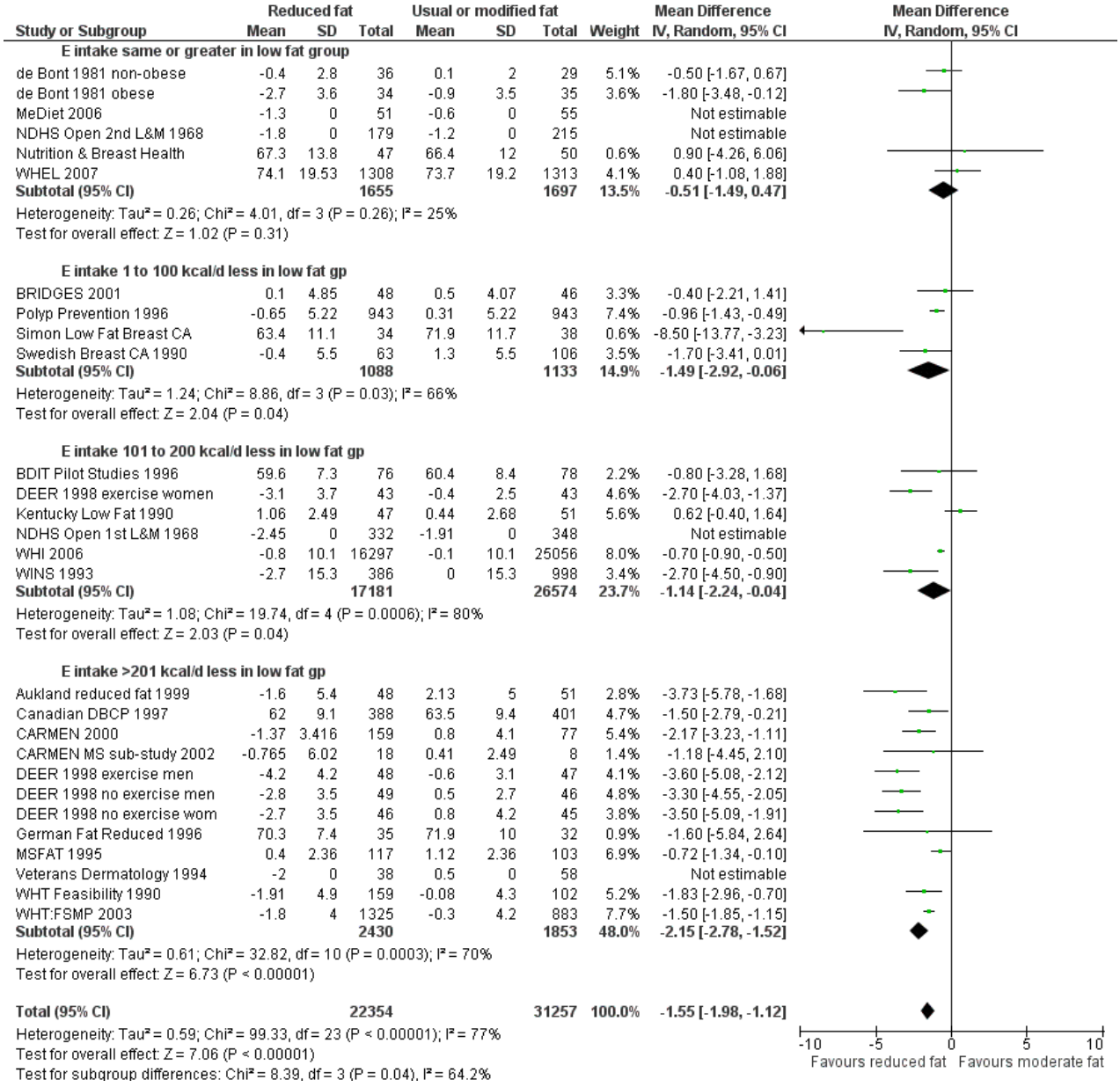


2d. Subgroup of studies including >35% of energy from fat in the control group

Supplementary Figure 3. Quality assessment of child RCTs included in the review



Supplementary Figure 4. Subgrouping by degree of energy reduction in the reduced fat group compared to the control group.



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Ref Type: Generic

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