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Long-term non-pharmacological weight loss interventions for adults with type 2 diabetes mellitus (Review)

Norris SL, Zhang X, Avenell A, Gregg E, Brown T, Schmid CH, Lau J

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[Intervention Review]

Long-term non-pharmacological weight loss interventions for adults with type 2 diabetes mellitus

Susan L Norris[1], Xuanping Zhang[2], Alison Avenell[3], Edward Gregg[2], Tamara Brown[4], Christopher H Schmid[5], Joseph Lau[6]

[1]Department of Medical Informatics and Clinical Epidemiology, Oregon Health Sciences University, Portland, Oregon, USA. [2]Division of Diabetes Translation, Center for Disease Control and Prevention, Atlanta, Georgia, USA. [3]Health Services Research Unit, University of Aberdeen, Aberdeen, UK. [4]School of Health & Social Care, Centre for Food, Physical Activity and Obesity, University of Teesside, Middlesbrough, UK. [5]Tufts University School of Medicine, Boston, Massachusetts, USA. [6]New England Medical Centre/Tufts Evidence-based Practice Center Institute for Clinical Research and Health Policy Studies, Tufts Medical Centre, Boston, MA, USA

Contact address: Susan L Norris, Department of Medical Informatics and Clinical Epidemiology, Oregon Health Sciences University, 3181 SW Sam Jackson Park Road, Mail Stop B1CC, Portland, Oregon, 97239, USA. norriss@ohsu.edu.

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ABSTRACT

Background

Most persons with type 2 diabetes are overweight and obesity worsens the metabolic and physiologic abnormalities associated with diabetes.

Objectives

The objective of this review is to assess the effectiveness of lifestyle and behavioral weight loss and weight control interventions for adults with type 2 diabetes.

Search methods

Studies were obtained from computerized searches of multiple electronic bibliographic databases, supplemented with hand searches of selected journals and consultation with experts in obesity research.

Selection criteria

Studies were included if they were published or unpublished randomized controlled trials in any language, and examined weight loss or weight control strategies using one or more dietary, physical activity, or behavioral interventions, with a follow-up interval of at least 12 months.

Data collection and analysis

Effects were combined using a random effects model.

Main results

The 22 studies of weight loss interventions identified had a 4,659 participants and follow-up of 1 to 5 years. The pooled weight loss for any intervention in comparison to usual care among 585 subjects was 1.7 kg (95 % confidence interval [CI] 0.3 to 3.2), or 3.1% of baseline body weight among 517 subjects. Other main comparisons demonstrated non significant results: among 126 persons receiving a physical activity and behavioral intervention, those who also received a very low calorie diet lost 3.0 kg (95% CI -0.5 to 6.4), or 1.6% of baseline body weight, more than persons receiving a low-calorie diet. Among 53 persons receiving identical dietary and behavioral interventions,

those receiving more intense physical activity interventions lost 3.9 kg (95% CI -1.9 to 9.7), or 3.6% of baseline body weight, more than those receiving a less intense or no physical activity intervention. Comparison groups often achieved significant weight loss (up to 10.0 kg), minimizing between-group differences. Changes in glycated hemoglobin generally corresponded to changes in weight and were not significant when between-group differences were examined. No data were identified on quality of life and mortality.

Authors' conclusions

Weight loss strategies using dietary, physical activity, or behavioral interventions produced small between-group improvements in weight. These results were minimized by weight loss in the comparison group, however, and examination of individual study arms revealed that multicomponent interventions including very low calorie diets or low calorie diets may hold promise for achieving weight loss in adults with type 2 diabetes.

PLAIN LANGUAGE SUMMARY

Long-term non-pharmacological weight loss interventions for adults with type 2 diabetes mellitus

Most persons with type 2 diabetes are overweight, and the health of these persons can be improved with weight loss. Weight loss is very difficult to achieve in the long-term, however, particularly among persons with diabetes. This systematic review of diet, physical activity, and behavioral interventions for weight loss, revealed a decrease in weight of 1.7 kg at one year or more. These results were minimized by weight loss in the comparison group, however. No data were identified on quality of life or mortality.

BACKGROUND

Description of the condition

Diabetes mellitus is a metabolic disorder resulting from a defect in insulin secretion, insulin action, or both. A consequence of this is chronic hyperglycaemia (i.e. elevated levels of plasma glucose) with disturbances of carbohydrate, fat and protein metabolism. Long-term complications of diabetes mellitus include retinopathy, nephropathy and neuropathy. The risk of cardiovascular disease is increased. For a detailed overview of diabetes mellitus, please see under 'Additional information' in the information on the Metabolic and Endocrine Disorders Group in *The Cochrane Library* (see 'About the Cochrane Collaboration', 'Collaborative Review Groups (CRGs)'). For an explanation of methodological terms, see the main Glossary in *The Cochrane Library*.

The prevalence of obesity and diabetes continues to increase in the developed world, with recent self-reported, survey data indicating that more than 56% of adults are overweight, and about 20% are obese (Mokad 2001). Overweight is defined as a body mass index (BMI) of 25 to 29.9 kg/m^2, and obesity as a BMI of ≥30 kg/m^2 (NHLBI 1998). Of U.S. adults over the age of 20 years, 8.6% have diabetes, of which one third are undiagnosed (CDC 2002). Both obesity and weight gain are major risk factors for diabetes (Maggio 1997; Pi-Sunyer 2000) and every 1-kg increase in average self-reported weight is associated with a 9% relative increase in the prevalence of diabetes (Mokdad 2000). Eighty to ninety percent of persons with type 2 diabetes are obese (Wing 2000) and obesity worsens the metabolic and physiologic abnormalities associated with diabetes, particularly hyperglycemia, hyperlipidemia, and hypertension (Maggio 1997; Wing 2000).

Description of the intervention

One of the cornerstones of diabetes care for overweight persons is weight loss, as insulin sensitivity and glycemic control improve (Pi-Sunyer 2000), and moderate, intentional weight loss is associated with a reduced mortality (Williamson 2000). For persons with diabetes, weight loss improves lipid profiles, decreasing triglycerides and low-density lipoprotein (LDL) cholesterol levels, and improves blood pressure (Maggio 1997), mental health, and quality of life (Wing 1987; Wing 1991). However, these benefits are thought to be clinically meaningful only if weight loss is sustained over time (Wing 1985).

Dietary and behavioral treatment for weight loss can produce an average loss of 8% of initial body weight over 3 to 12 months (NHLBI 1998). However, it is difficult to define effective weight control measures for the long term in the general population (NHLBI 1998; O'Meara 1998). The majority of obese patients regain most of the weight initially lost in successful interventions (Maggio 1997; Wadden 1989; Wing 1985). Skender and colleagues note that most of the weight lost in the early phase (16 to 20 weeks) is regained within 2 to 5 years (Skender 1996). Even when weight loss is effectively achieved using consistent, multi-factorial behavioral therapy for 6 months or more, one-third of weight loss is usually regained over the subsequent year (Perri 1993).

Obese or overweight persons with diabetes may face different and additional issues from non-diabetic persons trying to achieve weight loss. Studies suggest that persons with diabetes lose less weight than nondiabetic persons and they regain their weight more rapidly (Wing 2000), although the mechanisms responsible are unclear and the validity of this observation has not been systematically examined. (Wing 2000). Complex treatment regimens for diabetes, hypertension, and hyperlipidemia complicate behavioral change aimed at weight reduction.

It is thus important to evaluate the scope of our knowledge on the effectiveness of dietary, physical activity, and behavioral interventions for weight loss and weight control in type 2 diabetes. Behavioral strategies are based on behavioral and learning principles and provide tools for overcoming barriers to improving and optimizing diet and physical activity levels. Most importantly, effective long-term interventions must be defined for these populations. In addition, it is important to determine areas of uncertainty where further research is needed.

Why it is important to do this review

We have identified two relevant systematic reviews in the English literature. Brown et al. (Brown 1996) examined the effectiveness of weight loss interventions in obese persons with type 2 diabetes. They searched the published and unpublished English language literature prior to 1995. Outlier studies were removed to achieve homogeneity, interventions were stratified very broadly (all behavioral interventions in one stratum, for example), and pooled effects included all types of study designs (i.e. pre versus post and randomized controlled trials). These researchers found that diet alone had the largest effect on weight loss and metabolic control, while behavioral therapies alone and exercise alone produced the smallest changes in weight. They found few studies with follow-up intervals longer than 6 months.

Ciliska et al. (Ciliska 1995) also reviewed the literature on the results of weight loss in obese persons with non-insulin dependent diabetes. They searched the published, English language literature from 1985 forward and included only studies with a comparison group. They synthesized studies in a narrative fashion, and concluded that weight loss and metabolic control can be achieved, but not maintained.

These two reviews provide useful information but are outdated. Another useful summary is that of Boulé and colleagues (Boule 2001) in a meta-analysis (based on a Cochrane review) of the effects of exercise on glycemic control and BMI in type 2 diabetes. They focused on predetermined programs of physical activity, and did not focus on weight loss as a goal for studies included in their review.

The aims of this review are to provide a comprehensive examination of the effectiveness of long-term weight loss and weight control interventions in adults with type 2 diabetes. This review will be updated at regular intervals to reflect the addition of new research.

OBJECTIVES

The objective of this study is to assess the effectiveness of long-term weight loss and weight control interventions for adults type 2 diabetes.

Primary research questions

- which intervention strategies achieve or maintain weight loss, and what characteristics of those strategies correlate with weight loss or maintenance?
- what characteristics of populations correlate with weight loss?
- how does follow-up interval relate to weight loss?

Secondary research question

- what intervention strategies affect lipids, blood pressure, glycemic control, morbidity and mortality, and quality of life?

METHODS

Criteria for considering studies for this review

Types of studies

We included randomized controlled trials (RCTs) with a follow-up period of 12 months or greater as long-term weight loss is needed to produce effects on health outcomes such as cardiovascular disease events (Wing 1985). We define follow-up period as the time from randomization until the last measurement in the study. The intervention itself may be of any duration. We had initially planned to include all types of study designs, however, since we identified an adequate number of RCTs, we decided to restrict this review to RCTs only.

Types of participants

Participants were persons ≥18 years of age with type 2 diabetes. If the type of diabetes was not specified, studies were included if they involved adults with diabetes, with or without insulin treatment. Studies of mixed type 1 and type 2 populations were included if outcomes were reported separately for persons with type 2 diabetes. Persons labelled with "non-insulin-dependent diabetes" (NIDDM) were assumed to have type 2 diabetes. Studies involving only "insulin-dependent diabetes" (IDDM) participants were excluded unless there was information to indicate that they had type 2 disease (e.g., concurrent use of oral hypoglycemic agents and insulin).

The acceptable diagnostic criteria for diabetes included those described by the National Diabetes Data Group standards (NDDG 1979), the World Health Organization standards (Alberti 1998; WHO 1980; WHO 1985) or the American Diabetes Association standards (ADA 1997). If the diagnostic criteria were not given in the study, the author's statement of the diagnosis of diabetes among study participants was accepted.

Study participants were of any weight or BMI at baseline; they did not have to be overweight or obese. Weight loss or weight maintenance decreases cardiovascular risk in persons with a BMI less than 25.0 kg/m^2 (Eriksson 1991; Kuller 2001; Ornish 1998) (the lower limit for overweight). In addition, when Brown and colleagues reviewed weight loss interventions in diabetes (Brown 1996) they found that many studies did not clearly identify participants as overweight or obese, and when they used overweight/obese as an inclusion criteria they had to eliminate many studies.

Types of interventions

Interventions included in the review had weight loss or weight control as one of the primary stated goals of the intervention. Interventions where weight loss is a secondary or unexpected result were not included. Interventions focused on the patient, rather than the provider or health care system. Interventions which focus on changing provider behavior were excluded, even when outcomes are measured in the patient (e.g., an intervention to educate providers about weight loss counselling, with patient weight the main outcome).

Interventions were classified as dietary, physical activity, or behavioral strategies. Dietary programs involve providing recommendations and/or material support for achieving a specific dietary regime where the goal is weight loss or weight control. All types of dietary programs initiated for the purpose of weight loss or control were examined in this review, including low-calorie diets (800 to 1,500 kcal/day) and very low calorie diets (<800 kcal/day) (NHLBI 1998). Studies were excluded if the sole purpose of the intervention was nutrition education or to teach about diet (e.g., carbohydrate and fat exchanges, food consumption and the relationship to glycemia), but not explicitly to achieve weight loss or weight control.

Physical activity programs were included if one of the primary goals of the program was to achieve weight loss or weight control by increased physical activity. Physical activity interventions included a specific approach to increasing activity levels, including counseling, an exercise prescription, or participation in either a supervised or unsupervised exercise program. When it was simply stated that participants were advised to increase their level of exercise, with no details of the intervention, was not considered a physical activity program.

Behavioral strategies are based on behavioral and learning principles and address barriers to diet or physical activity (NHLBI 1998). These strategies include one or more of the following interventions: education, cognitive-behavioral therapy (e.g., stimulus control, reinforcement, goal setting), social support, or psychotherapy.

Studies were included that examined the combined effect of two or more of the interventions discussed above.

Excluded interventions

We excluded pharmacologic therapy, surgery, acupuncture, and hypnosis for the purpose of weight loss as these interventions have very different mechanisms of action and are best dealt with by a separate review. We also excluded herbal remedies and dietary supplements. Provider-focused interventions will be excluded, as mentioned above.

Types of comparison interventions

We included studies with a range of comparison groups in order to determine which interventions were more effective than others.

The comparison group could receive

- no intervention;
- usual care;
- the same intervention at a different intensity (frequency, duration, time frame for delivery);
- any other weight loss or weight control intervention: behavioral strategy, dietary program, physical activity program, drug therapy, surgery).

Effect modifiers

We planned on examining the following effect modifiers, If there were sufficient data: adherence to treatment, initial weight, comorbidities, change in smoking status, physical activity, baseline glycemic control, change in hypoglycemic medications, and medications for comorbidities such as hypertension and hyperlipidemia.

Types of outcome measures

Primary outcomes

- weight, body mass index (BMI), % weight loss from baseline weight, abdominal fat distribution;
- mortality;
- quality of life.

Secondary outcomes

- morbidity;
- cardiovascular disease events;
- glycated hemoglobin (GHb);
- fasting blood sugar;
- serum lipids;
- blood pressure;
- adverse events;
- cardiovascular fitness;
- incidence of hypertension;
- biliary tract disease.

Timing of outcome assessment

Studies with a follow-up period of 12 months or greater were included in this review. In order for weight loss to produce long-term effects on health outcomes such as cardiovascular disease events, the demonstration of long-term weight loss is needed (Wing 1985). Therefore, we excluded interventions for which follow-up was less than 12 months, and data from all follow-up intervals greater than or equal to 12months were obtained.

Search methods for identification of studies

Electronic searches

Using Medical Subject Headings (MeSH) and text words, we searched the following databases between the date indicated and May 2004: MEDLINE (1966), EMBASE (1980), CINAHL (1982), ERIC (1980), PsychInfo (1967), Web of Science (1981), Biosis (1969), Nutrition Abstracts and Review (1980), *The Cochrane Library* (2004, issue 2), and the Cochrane Central Register of Controlled Trials (2004, issue 2). We manually searched journals expected to have the highest relevance, from 1980: Diabetes Care, International Journal of Obesity and Related Metabolic Disorders, Obesity Research (commenced in 1993), American Journal of Clinical Nutrition, and Journal of the American Dietetic Association. Lists of all included studies and relevant reviews were examined and experts in obesity were consulted for additional citations. The National Heart, Lung, and Blood Institute 1998 review (NHLBI 1998) and the University of York, National Health Centre for Reviews and Dissemination review (UYCRD 1997) were reviewed for relevant citations.

There were no language restrictions on our searches.

Search strategies: MEDLINE search strategy is displayed under Appendix 1. Search strategies for other databases can be obtained from the authors.

Searching other resources

Conference proceedings and abstracts were included in a sensitivity analysis, but not in the primary review, because there was insufficient detail available in these to evaluate the intervention and the quality of the study. Dissertations were excluded, as these are difficult to locate in full text.

Data collection and analysis

Selection of studies

The titles and abstracts were obtained from the searches of the electronic databases noted above and potentially relevant full-text articles were then screened. Two people screened the MEDLINE titles and abstracts.

Data extraction and management

For studies that fulfilled inclusion criteria, two reviewers independently abstracted relevant population and intervention characteristics using a standardized template and consensus was achieved through discussion. Outcomes examined included weight loss, percent weight loss (based on individual data), BMI, fasting blood glucose, glycated hemoglobin, blood pressure, and lipid concentrations. Abstraction of data was not blinded, as there is no evidence that blinding of this process decreases bias in the conduct of systematic reviews and meta-analyses (Berlin 1997; Irwig 1994). We attempted to contact the authors for missing data or when we needed clarification of the data presented.

For continuous outcomes we abstracted for each study group the baseline sample size, pre- and post- intervention mean and measure of dispersion (SD [standard deviation], standard error of the mean (SEM), or 95% confidence interval) for the intervention and comparison groups. When necessary, mean and SD were approximated from figures using an image scanner to optimize resolution. If only range (Rhiel 1986) for interquartile range (Hoaglin 1983) were given as the measure of variation, the standard deviation (SD) was estimated.

Assessment of risk of bias in included studies

We assessed internal validity by examining each study for potential selection, attrition, and detection bias (Clarke 2001) factors thought to have significant effects on measured outcomes in intervention studies (Feinstein 1985). Studies were not excluded on the basis of poor quality; a sensitivity analysis was planned to compare results between studies with potential bias and those without.

Measures of treatment effect

Glycated hemoglobin [either hemoglobin A1 (HbA1) or hemoglobin A1c (HbA1c)] was measured with a variety of techniques. We converted studies reporting HbA1 to HbA1c values using a formula (Little 1991), and conducted a sensitivity analysis using only studies which reported HbA1c in the original data.

Assessment of heterogeneity

Heterogeneity was examined using a standard chi-squared test and a significance level of alpha=0.1, in view of the low power of such

tests. Heterogeneity was also examined with I^2 , where I^2 values of 75% indicate a high level of heterogeneity (Higgins 2003). When heterogeneity was found, we attempted to determine potential reasons for it by examining individual study characteristics and those of subgroups of the main body of evidence.

We analyzed the effects of treatment in individual study arms so as to examine within-group changes for both intervention and comparison groups. These effects were also pooled using the DerSimonian and Laird random-effects model (DerSimonian 1954).

Assessment of reporting biases

Funnel plots were used in exploratory data analysis to assess for the potential existence of small sample bias. There are a number of explanations for the asymmetry of a funnel plot, including true heterogeneity of effect with respect to study size, poor methodological design of small studies (Sterne 2001), and publication bias. Thus this exploratory data tool may be misleading (Tang 2000; Thornton 2000) and we did not place undue emphasis on this tool (Tang 2000).

Data synthesis

When data were available which were sufficiently similar with respect to interventions and outcomes, pooled estimates of effect were obtained using Review Manager software. For continuous variables reported in the same scale, the absolute differences in outcome between each follow-up and the baseline measure was reported for each study group (delta I and delta C). The estimate of variance of (delta I) and (delta C) was calculated from the outcome measures in each study group using the formula Vpre+ Vpost - 2r(SDpre*SDpost), where Vpre is the variance of the mean baseline outcome, Vpost is the variance of the mean follow-up outcome, r is the correlation between the baseline and follow-up values, and SDpre and SDpost are the standard errors of the baseline and follow-up groups, respectively. The variance of (delta) was then calculated as the sum of the variance of (delta I) and the variance of (delta C). Because studies do not report r, and its true value is unknown, a sensitivity analysis was performed using values of 0.25, 0.5, 0.75 and 1.0. Tabular data and the figure are presented using r=0.75, unless otherwise noted.

Data were pooled using the random-effects model, with the DerSimonian and Laird formula for calculating between-study variance (DerSimonian 1954). Each study was weighted by the inverse of the study variance.

Meta-regression was performed to determine whether various study-level characteristics (follow-up interval, duration of the intervention, number of intervention contacts, total attrition, year of publication) affected the between-group change in weight. We examined interaction terms for all models. We used SAS for the meta-regression (version 8.02, SAS Institute Inc., Cary, N.C.).

Subgroup analysis and investigation of heterogeneity

Should the quantity of data permit, we planned to examine subgroups based on intervention components, care delivered to the comparison group, and demographic characteristics.

Sensitivity analysis

We compared the results of fixed- and random-effects models and different values of the correlation coefficient between pre-and post-values. Should the quantity of data permit, we planned to perform a sensitivity analysis based on attrition rates, use of last-outcome-carried-forward, and language of publication.

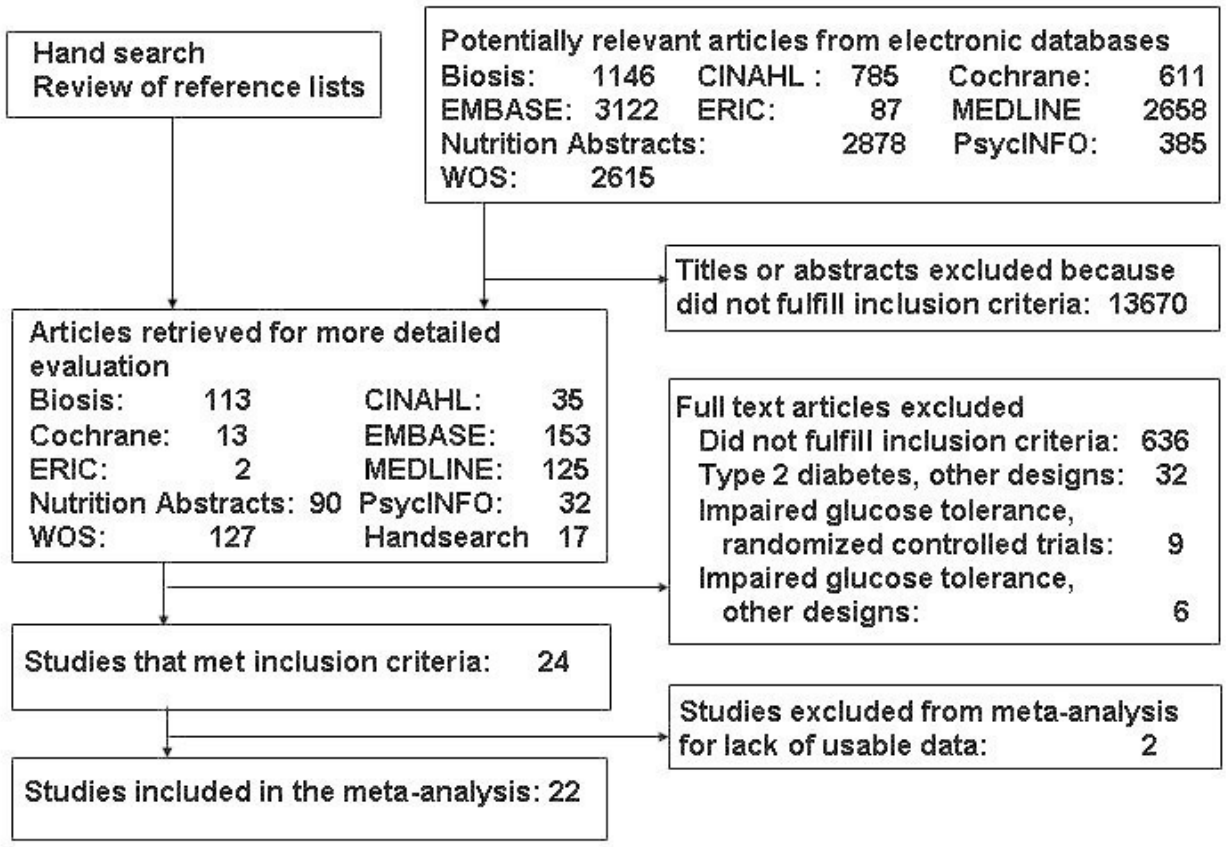
RESULTS

Description of studies

Results of the search

The study flow diagram is presented in Figure 1; no unpublished studies were identified. Two studies were excluded from our meta-analysis: one (Heitzmann 1987) fulfilled our inclusion criteria but did not provide any measure of dispersion for outcomes, and another (Ash 2003) combined intervention and control groups.

Figure 1. Study flow diagram

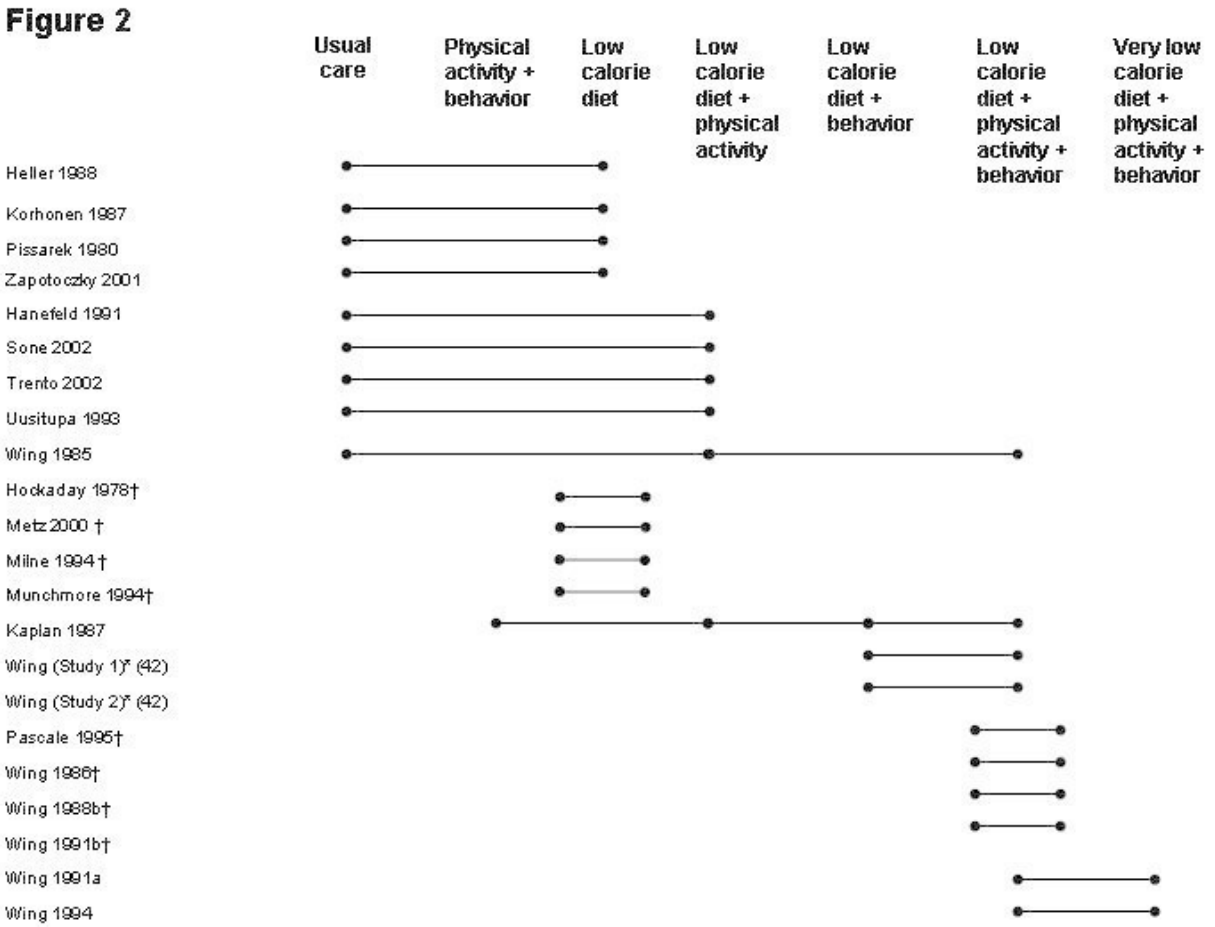


Included studies

Characteristics of the 22 eligible studies (in 21 publications) (Wing 1991a; Wing 1985 (BM); Heller 1988; Korhonen 1987; Pissarek 1980; Zapotoczky 2001; Hanefeld 1991; Sone 2002; Trento 2002; Uusitupa 1993; Hockaday 1978; Metz 2000; Milne 1994; Muchmore 1994; Kaplan 1987 (D+PA); Wing 1988a (Study 1); Wing 1988a (Study 2); Pascale 1995; Wing 1986; Wing 1988b; Wing 1991b; Wing 1994) are shown in the Table of Included Studies. (Wing reported two studies in one publication (Wing 1988a (Study 1)). All studies focused on weight loss interventions, with or without subsequent interventions to maintain weight; no study addressed interventions for weight control in persons with diabetes who were not overweight or obese. The 22 studies had a total of 4,659 participants (range 20 to 2,205). Follow-up intervals ranged between 1 and 5 years, and the interventions lasted 10 weeks to 5 years. Mean age was 55 years and mean duration of diabetes 6.5 years (means not weighted). Mean baseline weight for the comparison groups was 91.8 kg (range, 76.4 to 106.8 kg) and mean body mass index was 33.2 kg/m^2 (range, 23.0 to 38.1 kg/m2). The only study with a BMI ≤25 kg/m^2 involved a weight loss intervention where the goal was a BMI ≤22 kg/m^2 (Sone 2002).

The interventions included in this review are heterogeneous with respect to their components (Figure 2). There were considerable differences in the care provided to the comparison group. In nine studies this group received usual care (Wing 1985 (BM); Heller 1988; Korhonen 1987; Pissarek 1980; Zapotoczky 2001; Hanefeld 1991; Sone 2002; Trento 2002; Uusitupa 1993), but in six studies the comparison group received a dietary, physical activity, and a behavioral intervention, differing from the intervention group only in the number of calories delivered (very low calorie diet versus low calorie diet) (Wing 1991a; Wing 1994), the type of behavioral intervention (specifically self-monitoring blood glucose (Wing 1986; Wing 1988b) or spousal involvement in education (Wing 1991b), or the type of diet (Pascale 1995). Four studies examined different intensities and methods of delivery of a low calorie diet (Hockaday 1978; Metz 2000; Milne 1994; Muchmore 1994).

Figure 2.



Risk of bias in included studies

Most participants were from a clinic population, and participants either self-selected (n=8), were selected by providers (n=2), or the sampling method was unclear (n=6). Three studies obtained participants by probability sampling (Pissarek 1980; Trento 2002; Wing 1991b). In another two studies the entire accessible population was examined (29,33). The randomization procedure was described in only two studies (Trento 2001; Metz 2000) and allocation concealment was adequately reported in only one (Metz 2000). Attrition ranged between 0% and 30%, and five studies had completion rates less than 80%. Blinding of the assessor was reported in only one study (Metz 2000) and blinding of the provider in just one as well (Trento 2001).

Effects of interventions

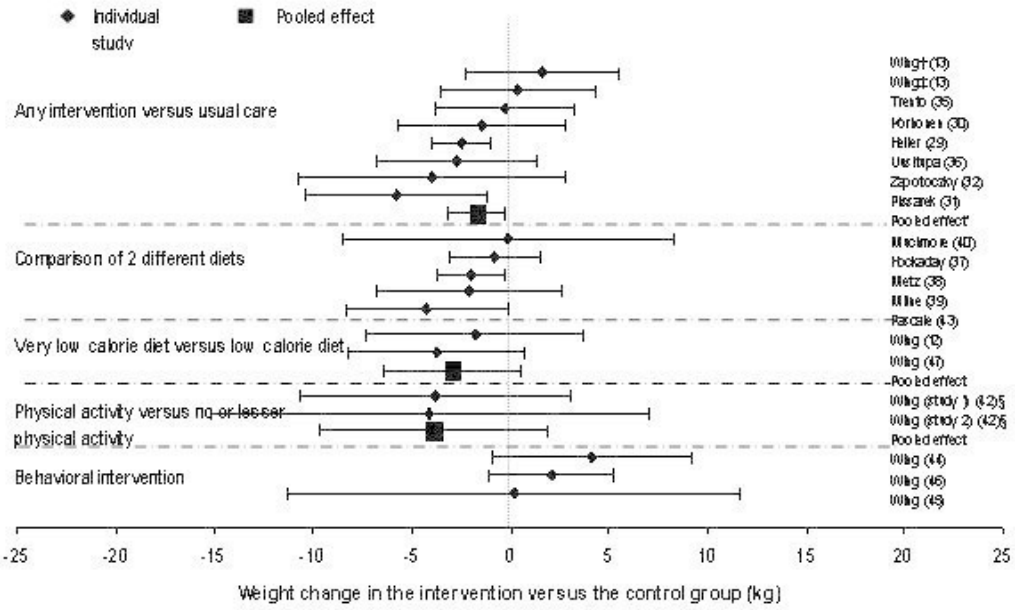
Weight

The effects of interventions on between-group change in weight are shown in Figure 3 and Appendix 2. Due to heterogeneity of interventions and comparisons, we believed it appropriate to obtain pooled estimates for only three groups of studies (Appendix 2; Appendix 3) any intervention versus usual care, very low calorie diet versus low calorie diet, and physical activity versus no or less intensive physical activity. In the first group (seven studies with available data; one study had two intervention groups (Wing 1985 (BM)) the intervention group received a dietary intervention with or without a behavioral or activity intervention (Wing 1985 (BM);Heller 1988; Korhonen 1987; Pissarek 1980; Zapotoczky 2001; Uusitupa 1993; Trento 2001), and the pooled effect for interventions with a follow-up between 1 and 2 years was a reduction in weight of 1.7 kg (95% CI, 0.3 to 3.2) (585 subjects) (3.1% of baseline weight, 517 subjects). In the two studies that compared very low calorie diets with low calorie diets (Wing 1991a; Wing 1994) the pooled effect was a nonsignificant reduction of 3.0 kg (95% CI, -0.5 to 6.4) (1.6% of baseline weight) (126 subjects) at 72 and 104 weeks of follow-up. In the two studies by Wing et al. reported in a single article (Wing 1988a (Study 1); Wing 1988a (Study 2)), in which a combination of dietary, physical activity, and behavioral interventions was compared to identical interventions with either no or less physical activity, the pooled effect among 53 subjects was also not significant: a loss of 3.9 kg (95% CI, -1.9 to 9.7) (3.6%).

Within-group changes in weight for the intervention and comparison groups are presented in Appendix 3. Effects are pooled by intervention type, regardless of randomization (i.e., each study arm is treated as a pre- versus post-design study). Weight change for control groups ranged from a gain of 2.1 kg (a group receiving usual care) (Uusitupa 1993) to a loss of 8.2 kg (a 1000 kcal/day deficit diet with 20 visits over 52 weeks (Wing 1986)). In the intervention groups, weight loss ranged from 0.6 kg (a 5-visit intervention with

group counseling on a high-carbohydrate, low-fat diet (39)) to 8.6 kg (a combined in-patient out-patient 800 kcal/day diet (Pissarek 1980)). More marked weight loss was noted in an intervention group (14.5 kg) as well as in the control group (10.0 kg) at preliminary (1 year) follow-up with a very low calorie diet combined with a physical activity and a behavioral intervention (Wing 1995). The pooled effects for six intervention types, including usual care (Appendix 3), revealed that all produced significant (p<0.05) weight loss, with a very low calorie diet combined with physical activity and behavioral therapy producing the largest effect.

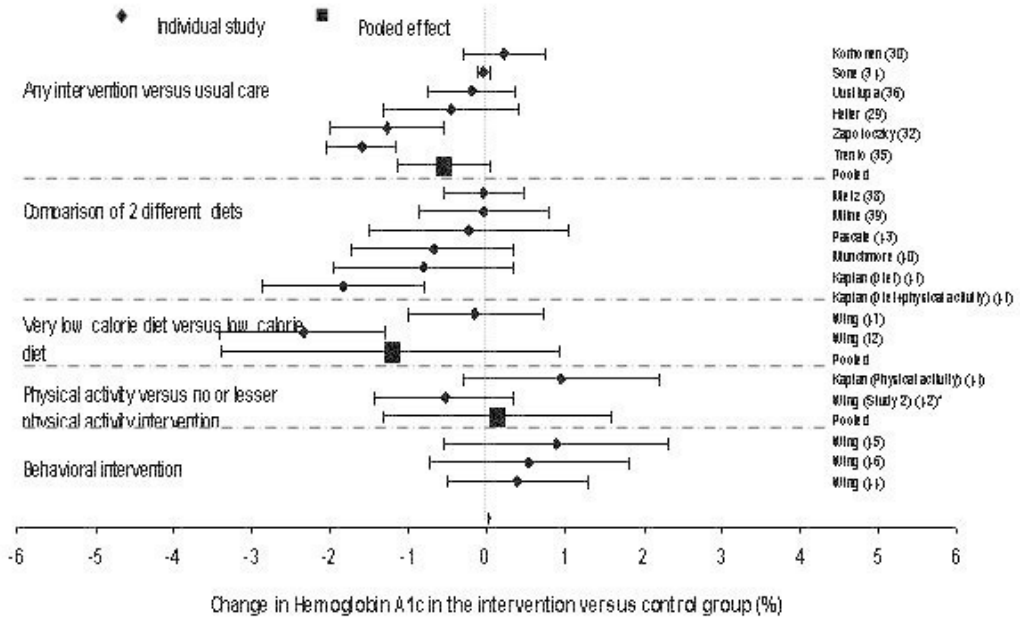
Figure 3. Between-group change in weight (kg) stratified by intervention type.



Other outcomes

Between-group changes in HbA1c (Figure 4; Appendix 2) (range, -2.6% to 1.0%) generally corresponded to changes in weight, and between-group pooled estimates were generally not significant (Appendix 4; Appendix 5), although several included studies did have a significant decrease in HbA1c (Wing 1991a; Wing 1991a; Kaplan 1987 (D+PA) (diet and physical activity (Trento 2001). Between-study heterogeneity was significant (P<0.05) for these small groups of studies.

Figure 4. Between-group change in hemoglobin A1c (%), stratified by intervention type.

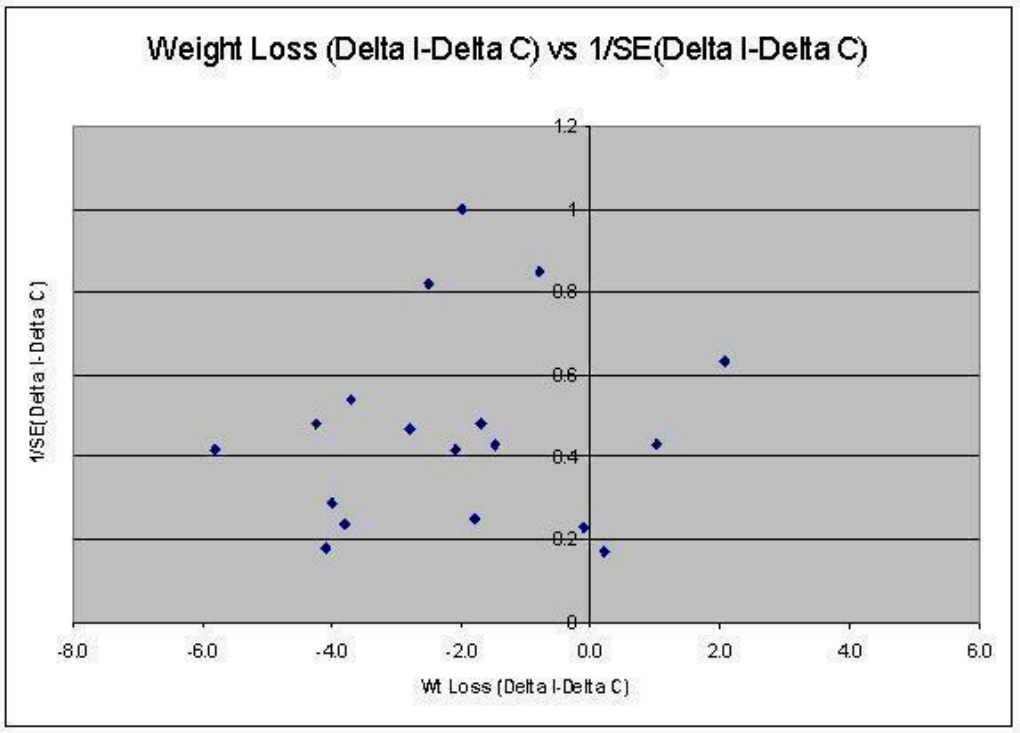


Systolic blood pressure was examined in six studies (Zapotoczky 2001; Sone 2002; Trento 2002; Uusitupa 1993; Metz 2000; Wing 1994), with a between-group change ranging between 1 mm Hg and -4 mm Hg; similar results were noted for diastolic blood pressure. Thirteen studies reported between-group change in total cholesterol (Wing 1991a; Pissarek 1980; Zapotoczky 2001; Hanefeld 1991; Sone 2002; Trento 2002; Uusitupa 1993; Hockaday 1978; Metz 2000; Milne 1994; Wing 1988a (Study 1); Pascale 1995; Wing 1994) (range, -0.4 mmol/l [-7.2 mg/dl] to 0.3 mmol/l [5.9 mg/dl]). No data were identified on mortality, morbidity, adverse events, or quality of life among the studies included in this review.

Regression and sensitivity analyses

The funnel plot was asymmetric, indicating potential small sample bias (Figure 5). For net change in weight, we found no significant interactions with follow-up interval, duration of the intervention, number of intervention contacts, or year of publication and weight. Higher total attrition rates were correlated with increased weight loss (p=0.028).

Figure 5.



Sensitivity analyses showed only minor changes in pooled estimates and 95% CI when the correlation between pre- and post-values was assigned different values. Because most studies did not report components of quality that were assessed (method of randomization, allocation concealment, and blinding of the assessor), we could not examine the effects of these variables on outcomes.

Pooled effects for studies reporting only HbA1c produced no significant differences from the outcomes achieved by converting HbA1 measures to HbA1c. The performance of stratified analyses was limited by sparse data and there were not enough studies to examine whether a physical activity intervention increased the effectiveness of dietary interventions.

DISCUSSION

Summary of main results

Randomized, controlled trials of weight loss interventions using diet with or without physical activity or behavioral interventions report only small additional declines in weight and HbA1c over those achieved by comparison groups. A partial explanation for these small changes is that the comparison group often had moderate weight loss (up to 10.0 kg), minimizing between-group differences. Cointerventions and contamination of the comparison group, as well as the "intervention effect" of study participation likely contributed to weight loss in comparison groups.

Our examination of weight change in individual study arms (intervention and comparison) produced somewhat more promising results. Although not large, the magnitude of weight loss demonstrated from combined dietary, physical activity, and behavioral interventions is associated with improved health outcomes (NHLBI 1998). Sustained, intensive interventions (Pissarek 1980; Zapotoczky 2001) and combined initial (Wing 1991a) or intermittent (Wing 1994) very low calorie diet appear to have the most effect on weight loss, and a low calorie diet combined with physical activity and behavioral interventions was also effective (Wing 1988a (Study 1)). However, these conclusions are based on a small number of studies and it is well established that healthy changes in diet and physical activity are difficult to maintain in the long-term (NHLBI 1998; Glenny 1997).

The results of our analysis of single arms of studies must be interpreted with caution. The observed effects are not confined to the effect of the intervention, as in our analysis of between-group change, where the groups were obtained through randomization. Extraneous factors, both known and unknown, may be responsible for the observed effects.

At a population level, a decrease in weight of 2 to 3 kg and a decrease in HbA1c of 0.3% may well have significant health benefits, whether through small improvements in a large segment of the population, or through larger benefits achieved among the population subset with more substantial weight or HbA1c reductions (Khaw 2001).

Potential biases in the review process

Our review has limitations. First, the studies examined were very heterogeneous with respect to the interventions, limiting quantitative syntheses. Second, we had insufficient power to examine either the effectiveness of specific component interventions, or the relationships between intervention characteristics and outcomes. Third, this review is limited to published studies; although we contacted experts for additional unpublished data, none was obtained. Fourth, attrition is an important issue in weight loss studies because selective loss to follow-up has been demonstrated; higher attrition occurs among those who do not achieve a weight loss goal (Kramer 1989), as demonstrated here with a positive relationship between higher attrition rates and increased weight loss among completers. Participants were most commonly self-selected and thus possibly more motivated to complete the study; applicability to general populations may thus be limited. Fifth, the quality of individual studies in this review varied. Adequate randomization procedures and concealment of allocation were reported in only a few studies and blinding of the assessor was rarely implemented. Sixth, the funnel plot indicated potential small sample bias; in other words, the published studies identified in this review, with relatively small sample sizes, may represent a subset of the total body of literature. The identified studies may represent a select group reporting more weight loss than might be found if the total body of literature was available.

Agreements and disagreements with other studies or reviews

Our findings are consistent with those found in non-diabetic populations, where comprehensive, intensive group dietary and behavioral programs produced similar mean losses in weight: 8 kg to 10 kg at 6 months with a regain of 30% to 35% of weight loss at 1 year (Wadden 2000; Kramer 1989). Our finding that very low calorie diets are not significantly more effective than low calorie diets in a small number of studies is not inconsistent with the conclusions of a prior review that found the two interventions equally effective in general populations at greater than 1 year of follow-up (NHLBI 1998). A comprehensive review of the effectiveness of weight-loss interventions in persons with diabetes (Brown 1996) indicated that dietary interventions alone produced an average weight loss of 9 kg and behavioral programs alone a loss of 3 kg at short-term follow-up; few studies examined outcomes beyond 6 months.

Healthy lifestyle changes with weight loss and a decrease in diabetes incidence have been demonstrated in the long-term among persons with impaired glucose tolerance or impaired fasting glucose, who are at high risk of developing diabetes (DPPRG 2002; Tuomilehto 2001). Whether the lifestyle interventions in these two large trials can be translated to diabetic populations has yet to be determined, although we also found that more intensive and sustained interventions may be more effective.

AUTHORS' CONCLUSIONS

Implications for practice

In conclusion, weight loss and control in the long term appear to be difficult to achieve for adults with type 2 diabetes employing currently used lifestyle and behavioral strategies, although we found a clinically meaningful decrease in weight with some interventions. Perhaps other strategies in conjunction with lifestyle interventions should be considered for weight loss or control. Pharmacotherapy achieves modest, but statistically significant, weight loss over 26 to 52 weeks in general populations (Norris 2004). Surgical interventions can produce substantial weight loss at up to 10 years of follow-up in general populations (Pories 1992; Sjostrom 1999) and among persons with diabetes (Pories 1992; ADA 1997). Much remains to be learned about how to implement dietary, physical activity, and behavioral interventions designed to achieve weight loss and weight control in the long term and whether intensive interventions such as those successfully used in persons with impaired glucose tolerance are effective among diabetic populations.

Implications for research

Future research needs to focus on sustained interventions for weight loss and control and long-term outcomes for health and quality of life. The economic efficiency of effective long-term weight loss interventions needs to be established. Effective interventions for weight control in persons not currently overweight need further attention. Methodologic standards need to be followed with rigorous application of good study design principles: allocation concealment, minimization of attrition, follow-up of dropouts, comparison of dropouts to completers at baseline, and intention-to-treat analyses.

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CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Hanefeld 1984

Methods	Companion to Hanefeld 1991
Participants	
Interventions	
Outcomes	
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Hanefeld 1988

Methods	Companion to Hanefeld 1991
Participants	
Interventions	
Outcomes	
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Hanefeld 1991

Methods	Follow-up: 260w No. study arms: one Setting: Germany, diabetes clinic Number: 1139 Comparison: Usual care
Participants	Age: 47y Sex: 43%F Duration DM: NR Treatment: Diet only BL wt, BMI: NR, 28.9 BL GHb: NR
Interventions	Duration: 260 w Frequency: q3m No. contacts: 20 Group/individual: Group Medium: In-person Facilitator: Unclear Diet: Individualized low calorie diet (3350-6281KJ/d); fat<35% intake; structured inten-

Hanefeld 1991 *(Continued)*

	sive general health education PA: Group exercise sessions and unsupervised program; including aerobic training Behavioral: None reported
Outcomes	Weight: BMI: Y >5% loss (%): FBS: Y GHb: Cholesterol: Y LDL: HDL: TG: Y SBP: Y DBP: Y Other: smoking, change DM medications, PA
Notes	Sampling method: Entire accessible population Jadad Score: 1,0,0,B Randomization procedure: NR Allocation concealment: Unclear Attrition: 12% Blinding pt: NR Blinding assessor: No Blinding provider: No BL comparable: FBS higher in C, but controlled for in analysis

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Hartwell 1986

Methods	Companion to Kaplan 1987
Participants	
Interventions	
Outcomes	
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	High risk	C - Inadequate

Heitzmann 1987

Methods	Follow-up: 78w No. study arms: Three Setting: USA, setting unclear Number: 44 Comparison: Muscle relaxation
Participants	Age: 53y Sex: 52%F Duration DM: NR Treatment: 60% insulin or oral agents BL wt, BMI: 81.7, NR BL GHb: 10.7
Interventions	Duration: Unclear Frequency: 7 weekly meetings, 2 home visits No. contacts: 9 Group/individual: Group Medium: In-person Facilitator: Nutritionist Diet: All 3 intervention groups got dietary advice; details unclear PA: Three intervention groups told to monitor PA; details unclear Behavioral: I1: self-monitoring wt and PA; I2: cognitive modification group: positive self-statements, goal-setting; I3: combined intervention
Outcomes	Weight: Y BMI: >5% loss (%): FBS: GHb: Cholesterol: LDL: HDL: TG: SBP: DBP:
Notes	Sampling method: referred by doc or through public service announcements Jadad Score: 2,0,0,A Randomization procedure: Adequate Allocation concealment: Adequate Attrition: 20% Blinding pt: No Blinding assessor: NR Blinding provider: No BL comparable: Yes

Heitzmann 1987 *(Continued)*

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Low risk	A - Adequate

Heller 1988

Methods	Follow-up: 52w No. study arms: Two Setting: UK, University Hospital Number: 87 Comparison: Usual care
Participants	Age: 56y Sex: 45%F Duration DM: NR Treatment: Diet only BL wt, BMI: 86.1, 32.0 BL GHb: 12.7
Interventions	Duration: 26w Frequency: Weekly x 3; then 3m and 6m No. contacts: 5 visits Group/individual: Group Medium: In-person Facilitator: Nurse and dietician Diet: Exclude sugar, high fiber; other details unclear PA: None Behavioral: Self-monitoring
Outcomes	Weight: Y BMI: >5% loss (%): FBS: GHb: Y Cholesterol: LDL: HDL: TG: SBP: DBP:
Notes	Sampling method: Entire accessible population Jadad Score: 1,0,1,B Randomization procedure: NR Allocation concealment: Unclear Attrition: 14% Blinding pt: No Blinding assessor: NR Blinding provider: No BL comparable: Yes

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Hockaday 1978

Methods	Follow-up: 52w No. study arms: Two Setting: UK, diabetes clinic Number: 93 Comparison: Low CHO, calorie restricted diet
Participants	Age: 52y Sex: 44%F Duration DM: NR Treatment: Diet only BL wt, BMI: 76.4, NR BL GHb: NR
Interventions	Duration: 52w Frequency: One month then q3m No. contacts: 4 visits Group/individual: Individual Medium: In-person Facilitator: Dietician Diet: I: 54% CHO, increased polyunsaturated fatty acids; C: 40% CHO; both got restricted calorie diets PA: None Behavioral: None
Outcomes	Weight: Y BMI: >5% loss (%): FBS: Y GHb: Cholesterol: Y LDL: HDL: TG: SBP: DBP:
Notes	Sampling method: Unclear Jadad Score: 1,0,0,B Randomization procedure: NR Allocation concealment: Unclear Attrition: NR Blinding pt: No Blinding assessor: NR Blinding provider: No BL comparable: No; increased wt in I

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Julius 1993

Methods	Companion to Hanefeld 1991
Participants	
Interventions	
Outcomes	
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Kaplan 1985

Methods	Companion to Kaplan 1987
Participants	
Interventions	
Outcomes	
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	High risk	C - Inadequate

Kaplan 1987 (D+PA)

Methods	Follow-up: 78w No. study arms: Three Setting: intervention groups (diet, PA, diet + PA) USA; setting unclear Number: 76 Study design: Quasi-randomized trial Comparison: Weekly didactic presentations on general diabetes care
Participants	Age: 55y Sex: 58%F Duration DM: NR Treatment: 37% diet only, 25% insulin BL wt, BMI: 92.2, NR BL GHb: 8.2
Interventions	Duration: 10w Frequency: weekly No. contacts: 10 Group/individual: Group Medium: In-person Facilitator: Dietician, psychology graduate student, physical education graduate student Diet: All 4 groups got low calorie diet; diet only group got behavioral modification treatment PA: PA group: 1 supervised, and 2 unsupervised sessions q week Behavioral: All 3 treatment groups: self-monitoring, goal setting, planning, feedback

Kaplan 1987 (D+PA) *(Continued)*

Outcomes	Weight: Y (no data by group) BMI: >5% loss (%): FBS: GHb: Y Cholesterol: LDL: HDL: TG: SBP: DBP: Other: Quality of life, cost effectiveness
Notes	Sampling method: Self (patient) selected Jadad Score: 1,0,1,C Randomization procedure: By group attended Allocation concealment: No Attrition: 3% Blinding pt: No Blinding assessor: NR Blinding provider: No BL comparable: Yes

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	High risk	C - Inadequate

Kaplan 1987 (diet)

Methods	Follow-up: 78w No. study arms: Three Setting: intervention groups (diet, PA, diet + PA) USA; setting unclear Number: 76 Study design: Quasi-randomized trial Comparison: Weekly didactic presentations on general diabetes care
Participants	Age: 55y Sex: 58%F Duration DM: NR Treatment: 37% diet only, 25% insulin BL wt, BMI: 92.2, NR BL GHb: 8.2
Interventions	Duration: 10w Frequency: weekly No. contacts: 10 Group/individual: Group Medium: In-person Facilitator: Dietician, psychology graduate student, physical education graduate student Diet: All 4 groups got low calorie diet; diet only group got behavioral modification treatment PA: PA group: 1 supervised, and 2 unsupervised sessions q week Behavioral: All 3 treatment groups: self-monitoring, goal setting, planning, feedback
Outcomes	Weight: Y (no data by group) BMI: >5% loss (%): FBS: GHb: Y Cholesterol: LDL: HDL: TG: SBP: DBP: Other: Quality of life, cost effectiveness
Notes	Sampling method: Self (patient) selected Jadad Score: 1,0,1,C Randomization procedure: By group attended Allocation concealment: No Attrition: 3% Blinding pt: No Blinding assessor: NR Blinding provider: No BL comparable: Yes

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	High risk	C - Inadequate

Kaplan 1987 (PA)

Methods	Follow-up: 78w No. study arms: Three Setting: intervention groups (diet, PA, diet + PA) USA; setting unclear Number: 76 Study design: Quasi-randomized trial Comparison: Weekly didactic presentations on general diabetes care
Participants	Age: 55y Sex: 58%F Duration DM: NR Treatment: 37% diet only, 25% insulin BL wt, BMI: 92.2, NR BL GHb: 8.2
Interventions	Duration: 10w Frequency: weekly No. contacts: 10 Group/individual: Group Medium: In-person Facilitator: Dietician, psychology graduate student, physical education graduate student Diet: All 4 groups got low calorie diet; diet only group got behavioral modification treatment PA: PA group: 1 supervised, and

Kaplan 1987 (PA) *(Continued)*

	2 unsupervised sessions q week Behavioral: All 3 treatment groups: self-monitoring, goal setting, planning, feedback
Outcomes	Weight: Y (no data by group) BMI: >5% loss (%): FBS: GHb: Y Cholesterol: LDL: HDL: TG: SBP: DBP: Other: Quality of life, cost effectiveness
Notes	Sampling method: Self (patient) selected Jadad Score: 1,0,1,C Randomization procedure: By group attended Allocation concealment: No Attrition: 3% Blinding pt: No Blinding assessor: NR Blinding provider: No BL comparable: Yes

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	High risk	C - Inadequate

Korhonen 1987

Methods	Follow-up: 52w No. study arms: Two Setting: Finland, university clinic Number: 71 Comparison: Written materials from doctor at first visit
Participants	Age: 56y Sex: 48%F Duration DM: NR Treatment: Diet only BL wt, BMI: 89.7, 32.2 BL GHb: 10.9
Interventions	Duration: 52w Frequency: 1,2,3,6,12m No. contacts: 5 visits Group/individual: Individual Medium: In person Facilitator: Nurse Diet: Individualized LCD, low saturated fat, increased complex CHOs and vegetables PA: None Behavioral: None
Outcomes	Weight: Y BMI: >5% loss (%): FBS: Y GHb: Y Cholesterol: Y (narrative only) LDL: HDL: TG: SBP: Y (narrative only) DBP:
Notes	Sampling method: Unclear Jadad Score: 1,0,1,B Randomization procedure: NR Allocation concealment: Unclear Attrition: 11.2% Blinding pt: No Blinding assessor: NR Blinding provider: No BL comparable: NR

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Laitinen 1993

Methods	Compansion to Uusitupa 1993
Participants	
Interventions	
Outcomes	
Notes	

Risk of bias

Laitinen 1993 *(Continued)*

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Laitinen 1994a

Methods	Compansion to Uusitupa 1993
Participants	
Interventions	
Outcomes	
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Laitinen 1994b

Methods	Compansion to Uusitupa 1993
Participants	
Interventions	
Outcomes	
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Lindahl 1999

Methods	Compansion to Uusitupa 1993
Participants	
Interventions	
Outcomes	

Lindahl 1999 *(Continued)*

Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Lindner 1992

Methods	Companion to Hanefeld 1991
Participants	
Interventions	
Outcomes	
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	D - Not used

McCarron 1997

Methods	Compansion to Metz 2000
Participants	
Interventions	
Outcomes	
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	D - Not used

McCarron 2001

Methods	Compansion to Metz 2000
Participants	

McCarron 2001 *(Continued)*

Interventions	
Outcomes	
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Low risk	A - Adequate

Metz 1997

Methods	Companion to Metz 2000
Participants	
Interventions	
Outcomes	
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Low risk	A - Adequate

Metz 2000

Methods	Follow-up: 52w No. study arms: Two Setting: USA, multicenter academic centers Number: 119 Comparison: Same diet, self-selected foods
Participants	Age: 54y Sex: 58%F Duration DM: NR Treatment: No insulin BL wt, BMI: NR, 34.5 BL GHb: 8.8
Interventions	Duration: 52w Frequency: Monthly No. contacts: 12 visits Group/individual: Individual Medium: In-person and telephone Facilitator: Nutritionist Diet: Reduced calories using pre-prepared meals; 22% fat; calories not specified PA: None Behavioral: None
Outcomes	Weight: Y BMI: >5% loss (%): Y FBS: Y GHb: Y Cholesterol: Y LDL: Y HDL: Y TG: Y SBP: Y DBP: Y
Notes	Sampling method: Self (patient) selected Jadad Score: 2,2,1,A Randomization procedure: Adequate Allocation concealment: Adequate Attrition: 23% total Blinding pt: No Blinding assessor: Yes Blinding provider: No BL comparable: Yes

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Low risk	A - Adequate

Milne 1994

Methods	Follow-up: up to 78w, average 52w No. study arms: Two Setting: New Zealand, community hospital Number: 64 Comparison: 500kcal/d deficit diet
Participants	Age: 59y Sex: 55%F Duration DM: 4.8y Treatment: Diet or oral agents BL wt, BMI: 78.3, 29.0 BL GHb: 9.0
Interventions	Duration: 78w Frequency: No. contacts: 5 visits Group/individual: Group Medium: In-person Facilitator: NR Diet: Modified fat; high CHO/fiber PA: None Behavioral: Social support
Outcomes	Diet: Modified fat; high CHO/fiber PA: None Behavioral: Social support
Notes	Weight: Y BMI: >5% loss (%): FBS: GHb: Y Cholesterol: Y LDL: Y HDL: Y TG: Y SBP: DBP:

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Muchmore 1994

Methods	Follow-up: 52w No. study arms: Two Setting: USA, large group practice Number: 23 Comparison: Identical amount of attention; focused on ADA guidelines of general nutrition principles
Participants	Age: 59y Sex: 61%F Duration DM: 5.5y Treatment: 26% diet only; 76 % oral agents BL wt, BMI: 99.1, 33.3 BL GHb: 10.5
Interventions	Duration: 32w Frequency: weekly X 8, then irregular No. contacts: 11 Group/individual: Combined Medium: In-person Facilitator: dietician; nurse educator Diet: Individual dietary counseling: low calorie diet; focus on CHO counting and SMBG PA: None Behavioral: Unclear
Outcomes	Diet: Individual dietary counseling: low calorie diet; focus on CHO counting and SMBG PA: None Behavioral: Unclear
Notes	Weight: Y BMI: >5% loss (%): FBS: GHb: Y Cholesterol: LDL: HDL: TG: SBP: DBP:

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	High risk	C - Inadequate

Pascale 1992

Methods	Companion to Wing 1995
Participants	
Interventions	
Outcomes	

Pascale 1992 *(Continued)*

Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Pascale 1995

Methods	Follow-up: 52w No. study arms: Two Setting: USA, academic center Number: 44 Comparison: 1000-1500kcal/d; same behavioral sessions
Participants	Age: 56y Sex: 100%F Duration DM: NR Treatment: No insulin BL wt, BMI: 93.1, 36.4 BL GHb: 10.9
Interventions	Duration: 40w Frequency: weekly for 16w, then 1,2,4,6m No. contacts: 20 visits Group/individual: Both group and individual Medium: In-person Facilitator: Trained therapist Diet: Low fat (20% total calories) and 1000-1500kcal/d diet PA: Graded goals for programmed activity Behavioral: 16w course: stimulus control, problem solving, social skills training, goal setting
Outcomes	Diet: Low fat (20% total calories) and 1000-1500kcal/d diet PA: Graded goals for programmed activity Behavioral: 16w course: stimulus control, problem solving, social skills training, goal setting
Notes	Weight: Y BMI: Y >5% loss (%): FBS: Y GHb: Y Cholesterol: Y LDL: Y HDL: Y TG: Y SBP: DBP:

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Pissarek 1980

Methods	Follow-up: 108w No. study arms: Two Setting: Germany, academic center Number: 150 Comparison: One session routine dietary advice
Participants	Age: 51y Sex: 60%F Duration DM: NR Treatment: No insulin, 53% diet only BL wt, BMI: 82.8, NR BL GHb: NR
Interventions	Duration: 12w Frequency: 2w in-patient, then weekly No. contacts: 24 visits Group/individual: Individual Medium: In-person Facilitator: physician Diet: 800 kcal/diet for persons >120% IBW PA: None Behavioral: None
Outcomes	Diet: 800 kcal/diet for persons >120% IBW PA: None Behavioral: None
Notes	Weight: Y BMI: >5% loss (%): FBS: GHb: Cholesterol: Y LDL: HDL: TG: Y SBP: DBP:

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Smith 1991

Methods	Companion to wing 1994
Participants	
Interventions	
Outcomes	
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Sone 2002

Methods	Follow-up: 156w No. study arms: Two Setting: Japan, multicenter, diabetes Clinics Number: 2205 Comparison: Usual care
Participants	Age: 59y Sex: 45%F Duration DM: 11.3y Treatment: 21% diet only, 20% insulin BL wt, BMI: NR, 23.0 BL GHb: 7.8
Interventions	Duration: 156w Frequency: clinic visits (uncertain frequency), telephone call q2w No. contacts: 78 visits Group/individual: Individual Medium: In-person, written, telephone Facilitator: nurse, other Diet: Weight loss counseling (details unclear); goal BMI<22 PA: PA counseling, (details unclear), pedometer Behavioral: Self-monitoring, feedback
Outcomes	Diet: Weight loss counseling (details unclear); goal BMI<22 PA: PA counseling, (details unclear), pedometer Behavioral: Self-monitoring, feedback
Notes	Weight: BMI: Y >5% loss (%): FBS: Y GHb: Y Cholesterol: Y LDL: HDL: Y TG: Y SBP: Y DBP: Y

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Trento 2001

Methods	Compansion to Trento 1998
Participants	
Interventions	
Outcomes	

Trento 2001 *(Continued)*

Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Trento 2002

Methods	Compansion to Trento 1998
Participants	
Interventions	
Outcomes	
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Trento 1998

Methods	Follow-up: 52, 108 and 225w No. study arms: Two Setting: Italy, academic center Number: 112 Comparison: Usual one-on-one clinic visits q3m
Participants	Age: 62y Sex: 46%F Duration DM: 9.6y Treatment: 14% diet only, 86% oral agents BL wt, BMI: 77.8, 27.9 BL GHb: 7.4
Interventions	Duration: 52, 108 and 225w Frequency: 11/4.3y No. contacts: 11 visits Group/individual: Group Medium: In-person Facilitator: Physicians Diet: Educational sessions on overweight, meal planning, food choices, BS control, smoking PA: Counseled to increase PA Behavioral: SMBG, SM wt, role playing, problem-solving
Outcomes	Weight: Y BMI: Y

Trento 1998 *(Continued)*

	>5% loss (%): FBS: Y GHb: Y Cholesterol: Y LDL: HDL: Y TG: Y SBP: Y DBP: Y Other: Quality of life, economic outcomes
Notes	Sampling method: Probability sampling accessible population Jadad Score: 2,1,1,B Randomization procedure: Random number table Allocation concealment: Unclear Attrition: 20% at 4y Blinding pt: No Blinding assessor: Unclear Blinding provider: Yes, at regular clinic visits BL comparable: No: control better educated and more DM knowledge

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Uusitupa 1996

Methods	Compansion to Uusitupa 1993
Participants	
Interventions	
Outcomes	
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Uusitupa 1993

Methods	Follow-up: 52 and 104w No. study arms: Two Setting: Finland, academic diabetes center Number: 86 Comparison: Usual care in community clinic q3m
Participants	Age: 53y Sex: 43%F Duration DM: 2y Treatment: Diet only BL wt, BMI: 88.8, 31.6 BL GHb: 7.8
Interventions	Duration: 12w run-in, then 104w Frequency: 11 visits in 2y No. contacts: 11 visits Group/individual: Individual Medium: In-person and written Facilitator: Dietician, physician, nurse Diet: Individualized ener-

Uusitupa 1993 *(Continued)*

	gy restricted, low fat (<30% total energy), increased unrefined CHOs PA: Encouraged to walk, jog, other, 3-4 times a week Behavioral: None
Outcomes	Diet: Individualized energy restricted, low fat (<30% total energy), increased unrefined CHOs PA: Encouraged to walk, jog, other, 3-4 times a week Behavioral: None
Notes	Weight: Y BMI: Y >5% loss (%): FBS: Y GHb: Y Cholesterol: Y LDL: Y HDL: Y TG: Y SBP: Y DBP: Y

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Vanninen 1993

Methods	Compansion to Uusitupa 1993
Participants	
Interventions	
Outcomes	
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Vanninen 1994

Methods	Compansion to Uusitupa 1993
Participants	
Interventions	
Outcomes	
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Vanninen 1992

Methods	Compansion to Uusitupa 1993
Participants	
Interventions	
Outcomes	
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Wing 1987

Methods	Companion to Wing 1985
Participants	
Interventions	
Outcomes	
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Wing 1988b

Methods	Follow-up: 68w No. study arms: Setting: USA, academic center Number: 20 Comparison: Same education; SMBG but no goals or teaching on how to adjust intake and activity
Participants	Age: 53y Sex: 65%F Duration DM: NR Treatment: 20% diet only, 80% oral agents BL wt, BMI: 90.5, NR BL GHb: 10.5
Interventions	Duration: 68w Frequency: 22 meetings No. contacts: 22 Group/individual: Combined Medium: In-person Facilitator: NR Diet: Both groups: Low calorie (1000-1500kcal/w) with increased complex CHO and fiber PA: Both groups: Walking, goal to 10 miles/w Behavioral: Both groups: goal setting, controlling eating cues, planning, self-reinforcement, problem solving. Intervention: SMBG with instruction how to adjust intake and activity in response to BG
Outcomes	Diet: Both groups: Low calorie (1000-1500kcal/w) with increased complex CHO and fiber PA: Both groups: Walking, goal to 10 miles/w Behavioral: Both groups: goal setting, controlling eating cues, planning, self-reinforcement, problem solving. Intervention: SMBG with instruction how to adjust intake and activity in response to BG

Wing 1988b *(Continued)*

Notes	Weight: Y BMI: >5% loss (%): FBS: GHb: Y Cholesterol: LDL: HDL: TG: SBP: DBP:

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Wing 1985 (BM)

Methods	Follow-up: 68w No. study arms: Three Setting: groups: behavioral modification, nutrition education; usual care USA, academic center Number: 53 Comparison: Standard care, monthly meetings
Participants	Age: 55y Sex: 62%F Duration DM: 5.9y Treatment: 25% diet only; 75% oral agents BL wt, BMI: 96.4, 34.8 BL GHb: 9.3
Interventions	Duration: 16w Frequency: weekly No. contacts: Group/individual: Combined Medium: In-person, written materials Facilitator: behavioral psychologist, nutritionist Diet: All groups: (wt x 12)-1000 calories/d; nutrition education: exchange lists plan, basic information PA: Behavioral modification: goal 1000 kcal/w via walking Behavioral: Behavioral modification: stimulus control, goal setting, self-monitoring, change cognitions, financial incentives
Outcomes	Diet: All groups: (wt x 12)-1000 calories/d; nutrition education: exchange lists plan, basic information PA: Behavioral modification: goal 1000 kcal/w via walking Behavioral: Behavioral modification: stimulus control, goal setting, self-monitoring, change cognitions, financial incentives
Notes	Weight: Y BMI: >5% loss (%): FBS: Y, for whole group GHb: Y, for whole group Cholesterol: Y, for whole group LDL: HDL: Y, for whole group TG: Y, for whole group SBP: Y, for whole group DBP: Y, for whole group

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Wing 1985 (NE)

Methods	Follow-up: 68w No. study arms: Three Setting: groups: behavioral modification, nutrition education; usual care USA, academic center Number: 53 Comparison: Standard care, monthly meetings
Participants	Age: 55y Sex: 62%F Duration DM: 5.9y Treatment: 25% diet only; 75% oral agents BL wt, BMI: 96.4, 34.8 BL GHb: 9.3
Interventions	Duration: 16w Frequency: weekly No. contacts: Group/individual: Combined Medium: In-person, written materials Facilitator: behavioral psychologist, nutritionist Diet: All groups: (wt x 12)-1000 calories/d; nutrition education: exchange lists plan, basic information PA: Behavioral modification: goal 1000 kcal/w via walking Behavioral: Behavioral modification: stimulus control, goal setting, self-monitoring, change cognitions, financial incentives
Outcomes	Diet: All groups: (wt x 12)-1000 calories/d; nutrition education: exchange lists plan, basic information PA: Behavioral modification: goal 1000 kcal/w via walking Behavioral: Behavioral modification: stimulus control, goal setting, self-monitoring, change cognitions, financial incentives

Wing 1985 (NE) *(Continued)*

Notes	Weight: Y BMI: >5% loss (%): FBS: Y, for whole group GHb: Y, for whole group Cholesterol: Y, for whole group LDL: HDL: Y, for whole group TG: Y, for whole group SBP: Y, for whole group DBP: Y, for whole group

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Wing 1986

Methods	Follow-up: 62w No. study arms: Two Setting: USA academic center Number: 50 Comparison: 1000kcal/d diet with 20 visits
Participants	Age: 54y Sex: 78%F Duration DM: NR Treatment: 50% oral agents, 50% insulin BL wt, BMI: 96.4, NR BL GHb: 10.9
Interventions	Duration: 52w Frequency: 20 visits/52w No. contacts: 20 visits Group/individual: Combined Medium: In-person Facilitator: NR Diet: Both groups: 1000kcal/d deficit PA: Both groups, walking encouraged Behavioral: Intervention: SMBG with adjusting of intake and activity; both groups: self-monitoring intake, planning, decrease stimuli, social support
Outcomes	Diet: Both groups: 1000kcal/d deficit PA: Both groups, walking encouraged Behavioral: Intervention: SMBG with adjusting of intake and activity; both groups: self-monitoring intake, planning, decrease stimuli, social support
Notes	Weight: Y BMI: >5% loss (%): FBS: Y GHb: bY Cholesterol: for combined group LDL: HDL: TG: SBP: for combined group DBP:

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Wing 1988a (Study 1)

Methods	Follow-up: 62w No. study arms: Two Setting: USA, setting NR Number: 25 Comparison: Same diet and behavioral interventions; light calisthetics and flexibility exercises
Participants	Age: 54y Sex: 84%F Duration DM: 4.6y Treatment: 52% diet, 48% oral agents BL wt, BMI: 98.9, 37.5 BL GHb: 9.6
Interventions	Duration: 62w Frequency: 2 times a week for 10w, then monthly times 6 No. contacts: 26 Group/individual: Group Medium: In-person Facilitator: NR Diet: Caloric deficit for goal 1kg/w loss PA: Supervised walking 2 times a week, 1 time unsupervised Behavioral: Rate of eating, stimulus control, coping with social pressure, pre-planning, relapse prevention; both groups
Outcomes	Diet: Caloric deficit for goal 1kg/w loss PA: Supervised walking 2 times a week, 1 time unsupervised Behavioral: Rate of eating, stimulus control, coping with social pressure, pre-planning, relapse prevention; both groups

Wing 1988a (Study 1) *(Continued)*

Notes	Weight: Y BMI: >5% loss (%): FBS: GHb: Cholesterol: LDL: HDL: TG: SBP: DBP:

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Wing 1988a (Study 2)

Methods	Follow-up: 62w No. study arms: Two Setting: USA, setting NR Number: 30
Participants	Age: 56y Sex: 70%F Duration DM: 7.0y Treatment: 27% insulin, 63% oral agents BL wt, BMI: 102, 37.9 BL GHb: 10.9
Interventions	Duration: 62w Frequency: 3 times a week for 10w, then weekly for 10 weeks, then monthly No. contacts: Group/individual: Group Medium: In-person Facilitator: NR Comparison: Same diet and behavioral interventions; no PA Diet: Caloric deficit for goal 1kg/w loss PA: Supervised walking 3 times a week Behavioral: Rate of eating, stimulus control, coping with social pressure, pre-planning, relapse prevention; both groups
Outcomes	Diet: Caloric deficit for goal 1kg/w loss PA: Supervised walking 3 times a week Behavioral: Rate of eating, stimulus control, coping with social pressure, pre-planning, relapse prevention; both groups
Notes	Weight: Y BMI: Y >5% loss (%): FBS: Y GHb: Y Cholesterol: Y LDL: HDL: Y TG: Y SBP: DBP:

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Wing 1991a

Methods	Follow-up: 72w No. study arms: Two Setting: USA academic center Number: 36 Comparison: LCD 4200-6300J/d
Participants	Age: 51y Sex: 76%F Duration DM: 7.0y Treatment: 18% diet only, 21% using insulin BL wt, BMI: 104.5, 38.1 BL GHb: 10.4
Interventions	Duration: 72w Frequency: No. contacts: 24 visits Group/individual: Group Medium: In-person Facilitator: Team Diet: VLCD for 8 weeks, followed by low calorie diet (4200-6300/d PA: Both groups: walking, advance to 10 miles/w Behavioral: Both groups: self-monitoring BG and intake, relapse prevention, stimulus control, modify cognitions
Outcomes	Diet: VLCD for 8 weeks, followed by low calorie diet (4200-6300/d PA: Both groups: walking, advance to 10 miles/w Behavioral: Both groups: self-monitoring BG and intake, relapse prevention, stimulus control, modify cognitions
Notes	Weight: Y BMI: Y >5% loss (%): FBS: GHb: Y Cholesterol: Y LDL: HDL: Y TG: Y SBP: DBP:

Risk of bias

Wing 1991a *(Continued)*

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Wing 1991b

Methods	Follow-up: 72w No. study arms: Two Setting: USA, setting unclear Number: 49 Comparison: No spouse attending meetings
Participants	Age: 52y Sex: 58%F Duration DM: NR Treatment: 26% diet only, 21% insulin BL wt, BMI: 102.4, 35.7 BL GHb: 10.3
Interventions	Duration: 78w Frequency: 20 meetings total both groups No. contacts: 20 Group/individual: Group Medium: In-person Facilitator: Team Diet: Both groups: 20w behavioral weigh loss program with 1200-1500 kcal/d diet PA: Both groups: walking to 1000 Kcal/w Behavioral: Spouse attended with intervention group; both groups: goal setting, problem solving, stimulus control
Outcomes	Diet: Both groups: 20w behavioral weigh loss program with 1200-1500 kcal/d diet PA: Both groups: walking to 1000 Kcal/w Behavioral: Spouse attended with intervention group; both groups: goal setting, problem solving, stimulus control
Notes	Weight: Y BMI: Y >5% loss (%): FBS: Y GHb: Y Cholesterol: LDL: HDL: TG: SBP: DBP:

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Wing 1994

Methods	Follow-up: 52 and 104w No. study arms: Two Setting: USA, academic medical center Number: 93 Comparison: 1000-1200kcal/d, weekly meetings
Participants	Age: 52y Sex: 65%F Duration DM: 6.8y Treatment: 25% on insulin; stopped at beginning of study BL wt, BMI: 107.7, 38.3 BL GHb: 10.5
Interventions	Duration: 52w Frequency: weekly No. contacts: Group/individual: Group Medium: In-person Facilitator: Team Diet: 400-500kcal/d for weeks 1-12, 24-36, otherwise 1000-1200kcal/d PA: Both groups, walk 10 miles/w Behavioral: Both groups: goal-setting, self-monitoring, SMBG, stimulus control, pre-planning, relapse prevention
Outcomes	Diet: 400-500kcal/d for weeks 1-12, 24-36, otherwise 1000-1200kcal/d PA: Both groups, walk 10 miles/w Behavioral: Both groups: goal-setting, self-monitoring, SMBG, stimulus control, pre-planning, relapse prevention
Notes	Weight: Y BMI: >5% loss (%): FBS: Y GHb: Y Cholesterol: Y LDL: Y HDL: Y TG: Y SBP: Y DBP: Y

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Wing 1995

Methods	Follow-up: 52w No. study arms: Two Setting: USA, community recruitment, setting unclear Number: 93 Comparison: 1000-1200 kcal/d, low fat
Participants	Age: 51.8y Sex: 68%F Duration DM: 6.8y Treatment: 23% insulin, 60% oral agents BL wt, BMI: 106.8, 37.9 BL GHb: NR
Interventions	Duration: 52w Frequency: weekly, 52 visits No. contacts: 52 visits Group/individual: Group Medium: In-person Facilitator: Team of therapists Diet: VLCD weeks 1-12 and 24-36 (approx. 500kcal/d); otherwise 1000-1200 kcal/d, low fat PA: Both groups: encouraged to walk 10 miles/w Behavioral: Both groups: self-monitoring, stimulus control, goal setting
Outcomes	Diet: VLCD weeks 1-12 and 24-36 (approx. 500kcal/d); otherwise 1000-1200 kcal/d, low fat PA: Both groups: encouraged to walk 10 miles/w Behavioral: Both groups: self-monitoring, stimulus control, goal setting
Notes	Weight: Y BMI: >5% loss (%): FBS: GHb: Cholesterol: LDL: HDL: TG: SBP: DBP:

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Wing 1996

Methods	Companion to Wing 1995
Participants	
Interventions	
Outcomes	
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Wing 1997

Methods	Companion to Wing 1994
Participants	
Interventions	
Outcomes	

Wing 1997 *(Continued)*

Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Zapotoczky 2001

Methods	Follow-up: 52w No. study arms: Two Setting: Austria, academic internal medicine clinic Number: 36
Participants	Age: 58y Sex: 68%F Duration DM: NR Treatment: 56% diet only, 44% oral agents BL wt, BMI: 82.3, NR BL GHb: 8.0
Interventions	Duration: 12m Frequency: Monthly No. contacts: 12 visits Group/individual: Group Medium: In-person Facilitator: Dietician Comparison: Usual care Diet: Educational program using ADA nutrition guidelines PA: One group exercise session Behavioral: One "psychoeducation" session
Outcomes	Diet: Educational program using ADA nutrition guidelines PA: One group exercise session Behavioral: One "psychoeducation" session
Notes	Weight: Y BMI: >5% loss (%): FBS: GHb: Y Cholesterol: Y LDL: Y HDL: Y TG: Y SBP: Y DBP: Y

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

BL, baseline
BMI, body mass index mg/m2
CHO, carbohydrate
DBP, diastolic blood pressure
DM diabetes mellitus
F, female
FBS, fasting blood sugar
m, month
NR, not reported
SBP, systolic blood pressure
w, week
y, year
Y, yes

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Agurs-Collins 1997	Follow-up 6 months
Altmann 1987	Study includes persons with diabetes, but no outcomes for this subgroup
Arauz 2001	General diabetes education; follow-up 4 months

Study	Reason for exclusion
Bloomgarden 1987	General diabetes education; weight loss not specific focus
Boehm 1993	General diabetes education; weight loss was the focus for only some participants and no details were given of the dietary intervention
Brown 2002	General diabetes education; no information on caloric restriction or specific diet
Caplan 1995	Weight loss was not goal; no dietary intervention
Currey 1977	Persons with diabetes were included, but no outcomes for this subgroup
Dalmau Llorca 2003	Intervention was not focused on weight loss
De Luis 2001	No weight outcomes
Di Loreto 2003	Not primarily a weight loss intervention; focuses on physical activity
Fernandez Suarez1995	Not a dietary program
Frost 1989	Follow-up 12 weeks
Gaede 2001	General diabetes education; goal was not weight loss
Gallagher 1984	Goal was not weight loss
Gallagher 1987	Goal was not weight loss
Garcia 1996	Goal was not weight loss
Genuth 1979	No weight data at follow-up
Giacco 2000	Not a weight loss intervention
Gilliland 2002	Lifestyle intervention; goal was not weight loss; no explicit calorie restricted diet
Henry 1986	Intervention was for 60 to 365 days and no average given; assume less than 1 year
Hughes 1999	Type 1 and type 2 diabetes combined; no type 2 specific data
Jayasuriya 2000	No weight data at follow-up
Kanders 1989	18 month weight loss intervention with persons wtih a subset; but no weight or other specific outcomes
Karlsson 1998	Reports data from other studies with no original data
Keyserling 2002	Weight loss was not the goal
Kirk 2001	Weight loss was not the goal; main focus was an exercise consultation
Kirkman 1994	General diabetes education; primary goal was improved glycemic control
Luscombe 2002	Follow-up 12 weeks
Mancini 1981	Persons with diabetes were included, but no diabetes-specific outcomes were presented

Study	Reason for exclusion
Manning 1998	Type 1 and type 2 diabetes were combined
Mengham 1999	Type 1 and type 2 diabetes were combined
Murphy 1999	Not a weight loss intervention
Nothwehr 2001	Not a weight loss intervention
Reaven 1985	Follow-up interval unclear, but appears to be less than 1 year
Ridgeway 1999	General diabetes education
Schafer 1987	Type 1 and type 2 diabetes combined
Simmons 1998	Type 1 and type 2 diabetes combined
Simonen 2000	Outcomes for both randomized groups were combined
Solerte 1989	Type 1 and type 2 diabetes combined
Szybinski 1978	Follow-up 24 days
Toobert 2003	Follow-up 6 months
Tudor-Locke 2004	Follow-up 16 weeks; primary goal not weight loss
Turnin 1992	Type 1 and type 2 diabetes combined
Ueda 1999	No weight outcomes
Werdier 1984	Unclear if wt loss is the goal; not weight outcomes at 12 months or more

Characteristics of ongoing studies *[ordered by study ID]*

Look AHEAD 2003

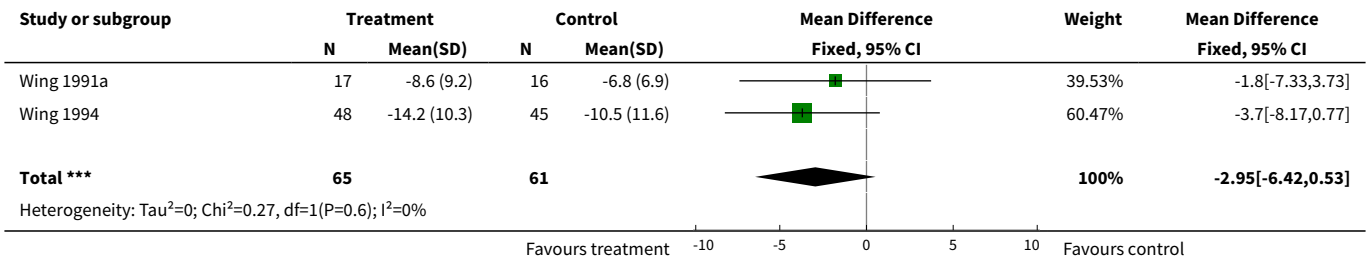
Trial name or title	Look AHEAD (Action for Health in Diabetes)
Methods	
Participants	Overweight and obese persons wtih type 2 diabetes
Interventions	Intensive weight loss program delivered over 4 years
Outcomes	Time to incidence of a major cardiovascular disease event, cost effectiveness, quality of life
Starting date	2001
Contact information	Mark Espeland PhD; mespelan@wfubmc.edu
Notes	

DATA AND ANALYSES

Comparison 1. VLCD vs different intervention (1-10: fixed models. 11-20: random models, rho=0.75)

Outcome or sub-group title	No. of studies	No. of partici-pants	Statistical method	Effect size
1 weight loss (kg)	2	126	Mean Difference (IV, Fixed, 95% CI)	-2.95 [-6.42, 0.53]
2 BMI	2	126	Mean Difference (IV, Fixed, 95% CI)	-1.08 [-2.33, 0.17]
3 FBS	2	126	Mean Difference (IV, Fixed, 95% CI)	-1.42 [-2.30, -0.54]
4 GHb	2	126	Mean Difference (IV, Fixed, 95% CI)	-1.03 [-1.71, -0.36]
5 Total Choles-terol	2	126	Mean Difference (IV, Fixed, 95% CI)	0.26 [0.01, 0.51]
6 HDL	2	126	Mean Difference (IV, Fixed, 95% CI)	0.06 [0.00, 0.11]
7 Triglycerides	2	126	Mean Difference (IV, Fixed, 95% CI)	0.17 [-0.14, 0.48]
8 weight loss (kg)	2	126	Mean Difference (IV, Random, 95% CI)	-2.95 [-6.42, 0.53]
9 BMI	2	126	Mean Difference (IV, Random, 95% CI)	-1.08 [-2.33, 0.17]
10 FBS	2	126	Mean Difference (IV, Random, 95% CI)	-2.51 [-6.42, 1.39]
11 GHb	2	126	Mean Difference (IV, Random, 95% CI)	-1.23 [-3.38, 0.93]
12 Total Choles-terol	2	126	Mean Difference (IV, Random, 95% CI)	0.24 [-0.06, 0.54]
13 HDL	2	126	Mean Difference (IV, Random, 95% CI)	0.06 [0.00, 0.11]
14 Triglycerides	2	126	Mean Difference (IV, Random, 95% CI)	0.17 [-0.14, 0.48]
15 % weight loss	2	126	Mean Difference (IV, Fixed, 95% CI)	-1.61 [-4.25, 1.03]
16 % weight loss (random)	2	126	Mean Difference (IV, Random, 95% CI)	-1.61 [-4.25, 1.03]

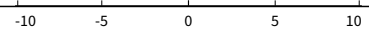
Analysis 1.1. Comparison 1 VLCD vs different intervention (1-10: fixed models. 11-20: random models, rho=0.75), Outcome 1 weight loss (kg).



Study or subgroup	Treatment N	Treatment Mean(SD)	Control N	Control Mean(SD)	Mean Difference Fixed, 95% CI	Weight	Mean Difference Fixed, 95% CI
Test for overall effect: Z=1.66(P=0.1)							

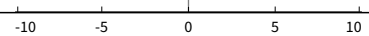
Analysis 1.2. Comparison 1 VLCD vs different intervention (1-10: fixed models. 11-20: random models, rho=0.75), Outcome 2 BMI.

Study or subgroup	Treatment N	Treatment Mean(SD)	Control N	Control Mean(SD)	Mean Difference Fixed, 95% CI	Weight	Mean Difference Fixed, 95% CI
Wing 1991a	17	-3.2 (3.1)	16	-2.7 (3.8)		27.55%	-0.5[-2.88,1.88]
Wing 1994	48	-5 (3.5)	45	-3.7 (3.7)		72.45%	-1.3[-2.77,0.17]
Total ***	**65**		**61**			**100%**	**-1.08[-2.33,0.17]**
Heterogeneity: Tau^2=0; Chi^2=0.32, df=1(P=0.57); I^2=0%							
Test for overall effect: Z=1.7(P=0.09)							



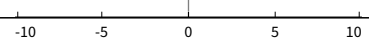
Analysis 1.3. Comparison 1 VLCD vs different intervention (1-10: fixed models. 11-20: random models, rho=0.75), Outcome 3 FBS.

Study or subgroup	Treatment N	Treatment Mean(SD)	Control N	Control Mean(SD)	Mean Difference Fixed, 95% CI	Weight	Mean Difference Fixed, 95% CI
Wing 1991a	17	-3.8 (3.1)	16	0.8 (2.7)		20.29%	-4.6[-6.55,-2.65]
Wing 1994	48	-3 (2.7)	45	-2.4 (2.2)		79.71%	-0.61[-1.59,0.37]
Total ***	**65**		**61**			**100%**	**-1.42[-2.3,-0.54]**
Heterogeneity: Tau^2=0; Chi^2=12.82, df=1(P=0); I^2=92.2%							
Test for overall effect: Z=3.17(P=0)							



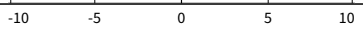
Analysis 1.4. Comparison 1 VLCD vs different intervention (1-10: fixed models. 11-20: random models, rho=0.75), Outcome 4 GHb.

Study or subgroup	Treatment N	Treatment Mean(SD)	Control N	Control Mean(SD)	Mean Difference Fixed, 95% CI	Weight	Mean Difference Fixed, 95% CI
Wing 1991a	17	-1 (1.4)	16	1.3 (1.7)		40.19%	-2.35[-3.41,-1.29]
Wing 1994	48	0.1 (2.1)	45	0.3 (2.2)		59.81%	-0.15[-1.02,0.72]
Total ***	**65**		**61**			**100%**	**-1.03[-1.71,-0.36]**
Heterogeneity: Tau^2=0; Chi^2=9.83, df=1(P=0); I^2=89.82%							
Test for overall effect: Z=3.01(P=0)							



Analysis 1.5. Comparison 1 VLCD vs different intervention (1-10: fixed models. 11-20: random models, rho=0.75), Outcome 5 Total Cholesterol.

Study or subgroup	Treatment N	Treatment Mean(SD)	Control N	Control Mean(SD)	Mean Difference Fixed, 95% CI	Weight	Mean Difference Fixed, 95% CI
Wing 1991a	17	0.3 (0.8)	16	0.3 (0.8)		19.84%	-0.02[-0.57,0.53]
Wing 1994	48	0 (0.8)	45	-0.3 (0.6)		80.16%	0.33[0.05,0.61]
Total ***	**65**		**61**			**100%**	**0.26[0.01,0.51]**
Heterogeneity: Tau^2=0; Chi^2=1.23, df=1(P=0.27); I^2=18.86%							
Test for overall effect: Z=2.07(P=0.04)							



Analysis 1.6. Comparison 1 VLCD vs different intervention (1-10: fixed models. 11-20: random models, rho=0.75), Outcome 6 HDL.

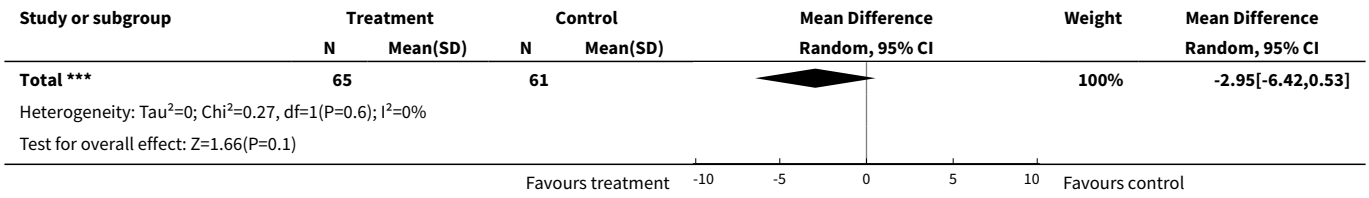
Study or subgroup	Treatment N	Treatment Mean(SD)	Control N	Control Mean(SD)	Mean Difference Fixed, 95% CI	Weight	Mean Difference Fixed, 95% CI
Wing 1991a	17	0.2 (0.2)	16	0.1 (0.2)		17.86%	0.09[-0.04,0.22]
Wing 1994	48	0.1 (0.2)	45	0.1 (0.2)		82.14%	0.05[-0.01,0.11]
Total ***	**65**		**61**			**100%**	**0.06[0,0.11]**
Heterogeneity: Tau^2=0; Chi^2=0.29, df=1(P=0.59); I^2=0%							
Test for overall effect: Z=2.03(P=0.04)							

Analysis 1.7. Comparison 1 VLCD vs different intervention (1-10: fixed models. 11-20: random models, rho=0.75), Outcome 7 Triglycerides.

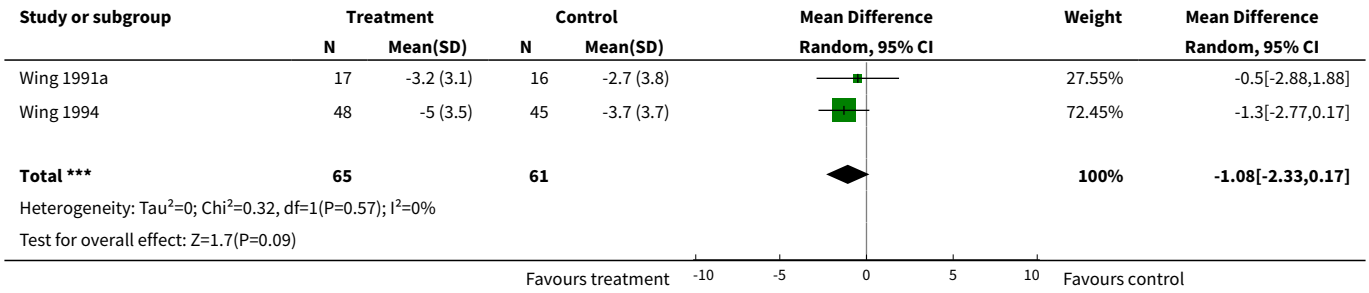
Study or subgroup	Treatment N	Treatment Mean(SD)	Control N	Control Mean(SD)	Mean Difference Fixed, 95% CI	Weight	Mean Difference Fixed, 95% CI
Wing 1991a	17	-0.1 (0.5)	16	-0.3 (0.9)		35.9%	0.16[-0.36,0.68]
Wing 1994	48	-0.7 (0.8)	45	-0.9 (1.1)		64.1%	0.18[-0.21,0.57]
Total ***	**65**		**61**			**100%**	**0.17[-0.14,0.48]**
Heterogeneity: Tau^2=0; Chi^2=0, df=1(P=0.95); I^2=0%							
Test for overall effect: Z=1.09(P=0.28)							

Analysis 1.8. Comparison 1 VLCD vs different intervention (1-10: fixed models. 11-20: random models, rho=0.75), Outcome 8 weight loss (kg).

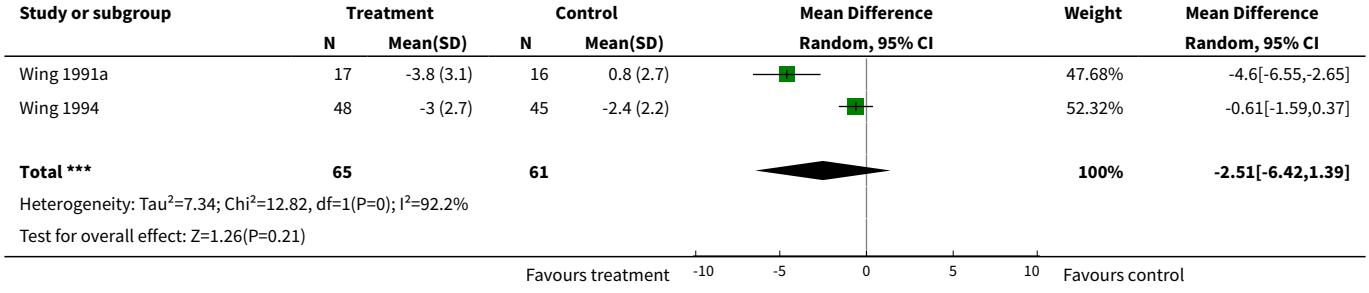
Study or subgroup	Treatment N	Treatment Mean(SD)	Control N	Control Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
Wing 1991a	17	-8.6 (9.2)	16	-6.8 (6.9)		39.53%	-1.8[-7.33,3.73]
Wing 1994	48	-14.2 (10.3)	45	-10.5 (11.6)		60.47%	-3.7[-8.17,0.77]



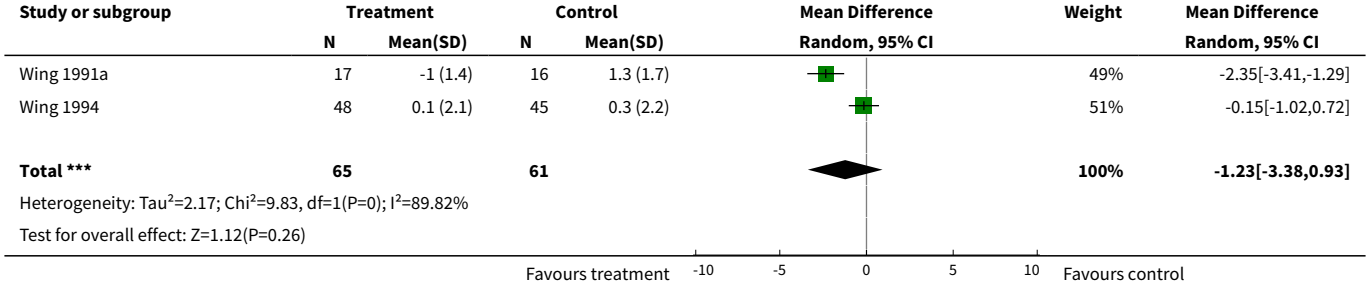
Analysis 1.9. Comparison 1 VLCD vs different intervention (1-10: fixed models. 11-20: random models, rho=0.75), Outcome 9 BMI.



Analysis 1.10. Comparison 1 VLCD vs different intervention (1-10: fixed models. 11-20: random models, rho=0.75), Outcome 10 FBS.

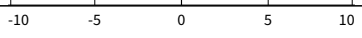


Analysis 1.11. Comparison 1 VLCD vs different intervention (1-10: fixed models. 11-20: random models, rho=0.75), Outcome 11 GHb.



Analysis 1.12. Comparison 1 VLCD vs different intervention (1-10: fixed models. 11-20: random models, rho=0.75), Outcome 12 Total Cholesterol.

Study or subgroup	Treatment N	Treatment Mean(SD)	Control N	Control Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
Wing 1991a	17	0.3 (0.8)	16	0.3 (0.8)		25.53%	-0.02[-0.57,0.53]
Wing 1994	48	0 (0.8)	45	-0.3 (0.6)		74.47%	0.33[0.05,0.61]
Total ***	**65**		**61**			**100%**	**0.24[-0.06,0.54]**
Heterogeneity: Tau^2=0.01; Chi^2=1.23, df=1(P=0.27); I^2=18.86%							
Test for overall effect: Z=1.58(P=0.11)							



Analysis 1.13. Comparison 1 VLCD vs different intervention (1-10: fixed models. 11-20: random models, rho=0.75), Outcome 13 HDL.

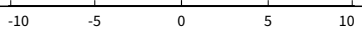
Study or subgroup	Treatment N	Treatment Mean(SD)	Control N	Control Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
Wing 1991a	17	0.2 (0.2)	16	0.1 (0.2)		17.86%	0.09[-0.04,0.22]
Wing 1994	48	0.1 (0.2)	45	0.1 (0.2)		82.14%	0.05[-0.01,0.11]
Total ***	**65**		**61**			**100%**	**0.06[0,0.11]**
Heterogeneity: Tau^2=0; Chi^2=0.29, df=1(P=0.59); I^2=0%							
Test for overall effect: Z=2.03(P=0.04)							

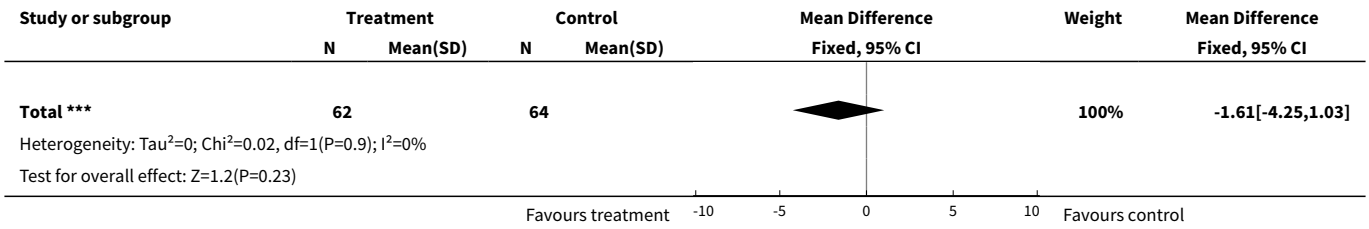
Analysis 1.14. Comparison 1 VLCD vs different intervention (1-10: fixed models. 11-20: random models, rho=0.75), Outcome 14 Triglycerides.

Study or subgroup	Treatment N	Treatment Mean(SD)	Control N	Control Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
Wing 1991a	17	-0.1 (0.5)	16	-0.3 (0.9)		35.9%	0.16[-0.36,0.68]
Wing 1994	48	-0.7 (0.8)	45	-0.9 (1.1)		64.1%	0.18[-0.21,0.57]
Total ***	**65**		**61**			**100%**	**0.17[-0.14,0.48]**
Heterogeneity: Tau^2=0; Chi^2=0, df=1(P=0.95); I^2=0%							
Test for overall effect: Z=1.09(P=0.28)							

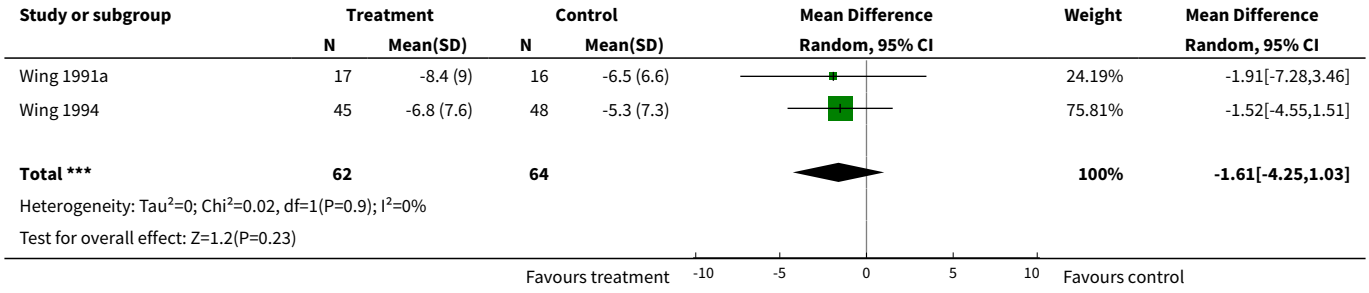
Analysis 1.15. Comparison 1 VLCD vs different intervention (1-10: fixed models. 11-20: random models, rho=0.75), Outcome 15 % weight loss.

Study or subgroup	Treatment N	Treatment Mean(SD)	Control N	Control Mean(SD)	Mean Difference Fixed, 95% CI	Weight	Mean Difference Fixed, 95% CI
Wing 1991a	17	-8.4 (9)	16	-6.5 (6.6)		24.19%	-1.91[-7.28,3.46]
Wing 1994	45	-6.8 (7.6)	48	-5.3 (7.3)		75.81%	-1.52[-4.55,1.51]





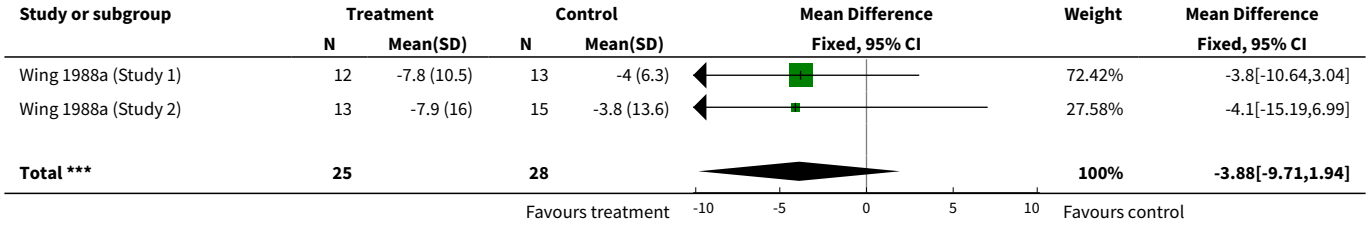
Analysis 1.16. Comparison 1 VLCD vs different intervention (1-10: fixed models. 11-20: random models, rho=0.75), Outcome 16 % weight loss (random).

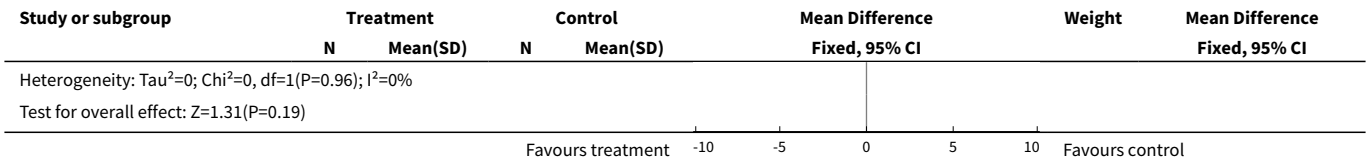


Comparison 2. PA (1-10: fixed models. 11-20: random models, rho=0.75)

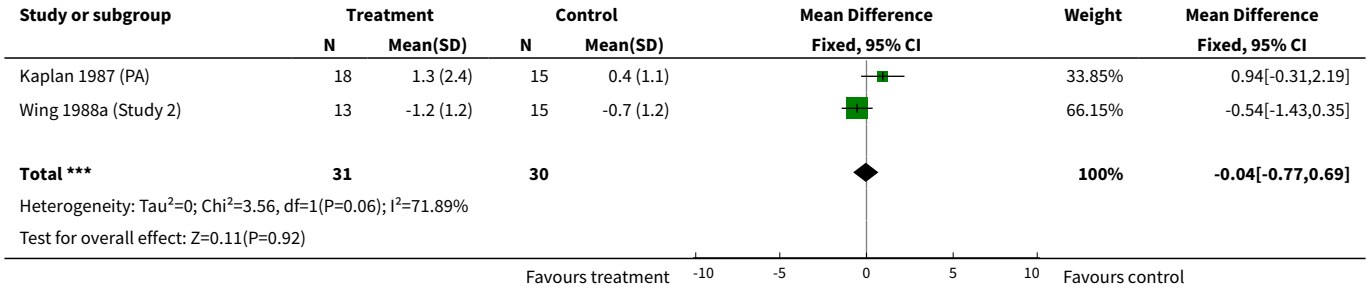
Outcome or sub-group title	No. of studies	No. of partici-pants	Statistical method	Effect size
1 weight loss (kg)	2	53	Mean Difference (IV, Fixed, 95% CI)	-3.88 [-9.71, 1.94]
2 GHb	2	61	Mean Difference (IV, Fixed, 95% CI)	-0.04 [-0.77, 0.69]
3 weight loss (kg)	2	53	Mean Difference (IV, Random, 95% CI)	-3.88 [-9.71, 1.94]
4 GHb	2	61	Mean Difference (IV, Random, 95% CI)	0.13 [-1.31, 1.58]
5 % weight loss	2	53	Mean Difference (IV, Fixed, 95% CI)	-3.58 [-9.89, 2.74]
6 % weight loss (ran-dom)	2	53	Mean Difference (IV, Random, 95% CI)	-3.58 [-9.89, 2.74]

Analysis 2.1. Comparison 2 PA (1-10: fixed models. 11-20: random models, rho=0.75), Outcome 1 weight loss (kg).

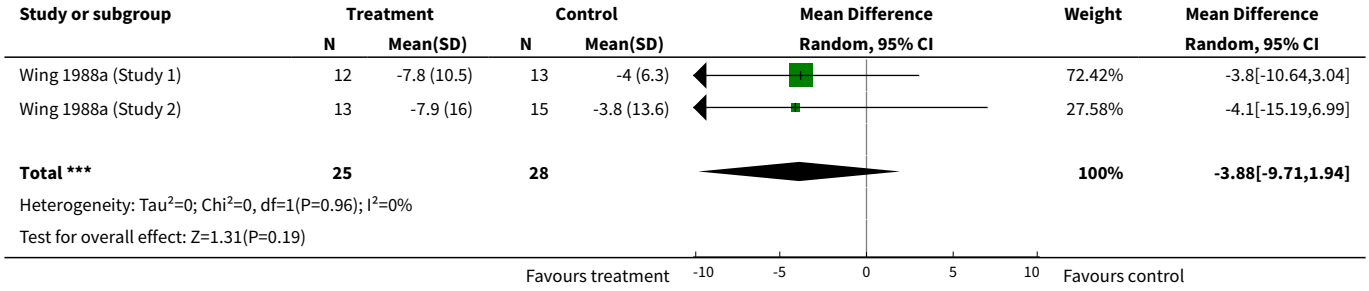




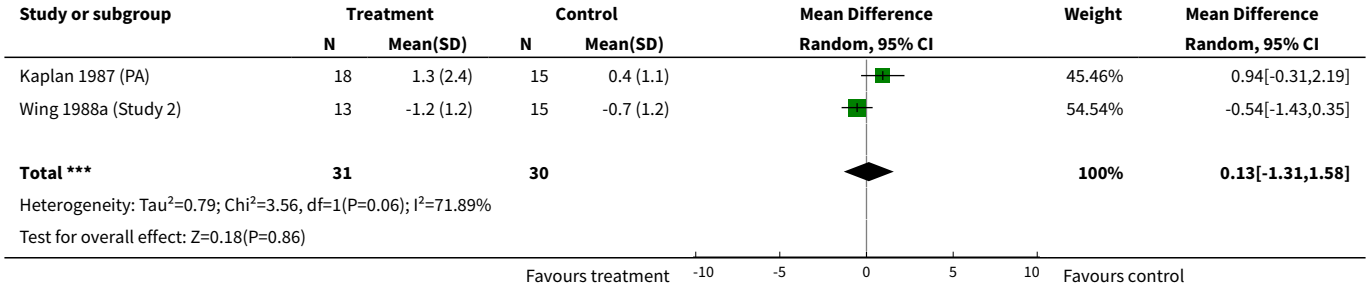
Analysis 2.2. Comparison 2 PA (1-10: fixed models. 11-20: random models, rho=0.75), Outcome 2 GHb.



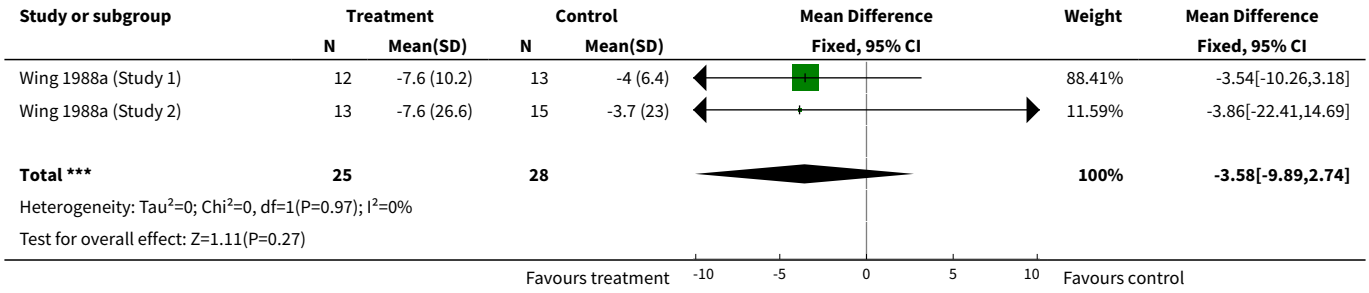
Analysis 2.3. Comparison 2 PA (1-10: fixed models. 11-20: random models, rho=0.75), Outcome 3 weight loss (kg).



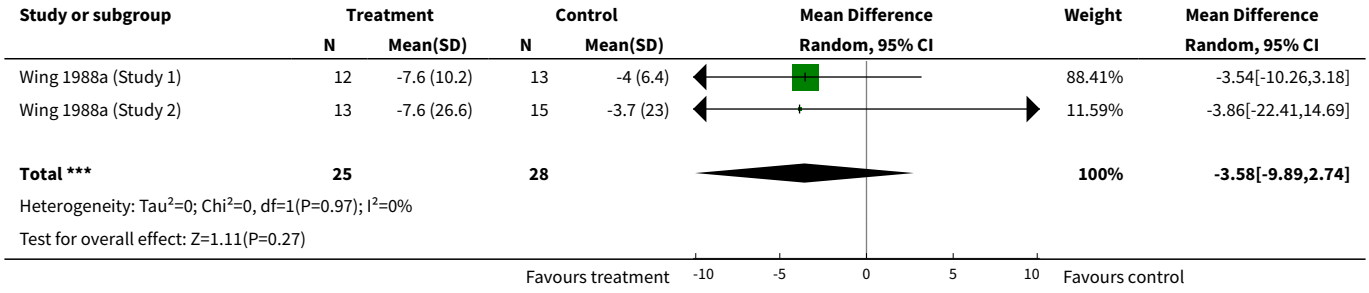
Analysis 2.4. Comparison 2 PA (1-10: fixed models. 11-20: random models, rho=0.75), Outcome 4 GHb.



Analysis 2.5. Comparison 2 PA (1-10: fixed models. 11-20: random models, rho=0.75), Outcome 5 % weight loss.



Analysis 2.6. Comparison 2 PA (1-10: fixed models. 11-20: random models, rho=0.75), Outcome 6 % weight loss (random).



Comparison 3. Any intervention vs usual care (F/U</=2y) (1-11: fixed models. 12-22: random models, rho=0.75)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 weight loss (kg)	8	585	Mean Difference (IV, Fixed, 95% CI)	-1.91 [-3.00, -0.82]
2 BMI	2	192	Mean Difference (IV, Fixed, 95% CI)	-0.57 [-1.44, 0.31]
3 FBS	3	272	Mean Difference (IV, Fixed, 95% CI)	0.34 [-0.11, 0.80]
4 GHb	5	381	Mean Difference (IV, Fixed, 95% CI)	-0.74 [-0.99, -0.48]
5 SBP	2	114	Mean Difference (IV, Fixed, 95% CI)	-1.85 [-6.41, 2.70]
6 DBP	2	114	Mean Difference (IV, Fixed, 95% CI)	0.0 [-2.49, 2.49]
7 Total Cholesterol	4	344	Mean Difference (IV, Fixed, 95% CI)	0.06 [-0.02, 0.14]
8 HDL	3	226	Mean Difference (IV, Fixed, 95% CI)	0.11 [0.06, 0.17]
9 Triglycerides	4	344	Mean Difference (IV, Fixed, 95% CI)	-0.36 [-0.58, -0.14]
10 % weight loss	6	517	Mean Difference (IV, Fixed, 95% CI)	-3.10 [-4.48, -1.72]

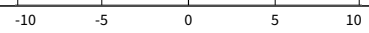
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
11 weight loss (kg)	8	585	Mean Difference (IV, Random, 95% CI)	-1.72 [-3.15, -0.29]
12 BMI	2	192	Mean Difference (IV, Random, 95% CI)	-0.57 [-1.44, 0.31]
13 FBS	3	272	Mean Difference (IV, Random, 95% CI)	0.32 [-0.37, 1.00]
14 GHb	5	381	Mean Difference (IV, Random, 95% CI)	-0.67 [-1.44, 0.10]
15 SBP	2	114	Mean Difference (IV, Random, 95% CI)	-1.85 [-6.41, 2.70]
16 DBP	2	114	Mean Difference (IV, Random, 95% CI)	0.0 [-2.49, 2.49]
17 Total Cholesterol	4	344	Mean Difference (IV, Random, 95% CI)	-0.13 [-0.41, 0.15]
18 HDL	3	226	Mean Difference (IV, Random, 95% CI)	0.09 [-0.05, 0.23]
19 Triglycerides	4	344	Mean Difference (IV, Random, 95% CI)	-0.36 [-0.58, -0.14]
20 % weight loss	6	517	Mean Difference (IV, Random, 95% CI)	-3.10 [-4.48, -1.72]

Analysis 3.1. Comparison 3 Any intervention vs usual care (F/U</=2y) (1-11: fixed models. 12-22: random models, rho=0.75), Outcome 1 weight loss (kg).

Study or subgroup	Treatment N	Treatment Mean(SD)	Control N	Control Mean(SD)	Mean Difference Fixed, 95% CI	Weight	Mean Difference Fixed, 95% CI
Heller 1988	40	-5.5 (3.8)	47	-3 (3.2)		52.81%	-2.5[-4,-1]
Korhonen 1987	40	-4.7 (8.7)	40	-3.2 (10.5)		6.64%	-1.47[-5.7,2.76]
Pissarek 1980	58	-9 (14)	60	-3.2 (11.4)		5.57%	-5.8[-10.42,-1.18]
Trento 2001	56	-1.4 (9)	56	-1.1 (10)		9.58%	-0.3[-3.82,3.22]
Uusitupa 1993	40	-0.6 (9.4)	46	2.1 (9.8)		7.22%	-2.71[-6.76,1.34]
Wing 1985 (BM)	17	-1.8 (4.7)	17	-3.4 (6.7)		7.78%	1.64[-2.27,5.55]
Wing 1985 (NE)	17	-3 (4.7)	17	-3.4 (6.7)		7.78%	0.39[-3.52,4.3]
Zapotoczky 2001	18	-5.9 (11.1)	16	-1.9 (8.9)		2.61%	-3.99[-10.73,2.75]
Total * **	**286**		**299**			**100%**	**-1.91[-3,-0.82]**
Heterogeneity: Tau²=0; Chi²=9.19, df=7(P=0.24); I²=23.82%							
Test for overall effect: Z=3.44(P=0)							

Analysis 3.2. Comparison 3 Any intervention vs usual care (F/U</=2y) (1-11: fixed models. 12-22: random models, rho=0.75), Outcome 2 BMI.

Study or subgroup	Treatment N	Treatment Mean(SD)	Control N	Control Mean(SD)	Mean Difference Fixed, 95% CI	Weight	Mean Difference Fixed, 95% CI
Trento 2001	56	-0.7 (3)	56	-0.2 (2.8)		65.81%	-0.5[-1.58,0.58]



Study or subgroup	Treatment N	Treatment Mean(SD)	Control N	Control Mean(SD)	Mean Difference Fixed, 95% CI	Weight	Mean Difference Fixed, 95% CI
Uusitupa 1993	40	-0.1 (3.6)	40	0.6 (3.3)		34.19%	-0.7[-2.2,0.8]
Total ***	**96**		**96**			**100%**	**-0.57[-1.44,0.31]**
Heterogeneity: Tau^2=0; Chi^2=0.05, df=1(P=0.83); I^2=0%							
Test for overall effect: Z=1.27(P=0.2)							

Favours treatment -10 -5 0 5 10 Favours control

Analysis 3.3. Comparison 3 Any intervention vs usual care (F/U</=2y) (1-11: fixed models. 12-22: random models, rho=0.75), Outcome 3 FBS.

Study or subgroup	Treatment N	Treatment Mean(SD)	Control N	Control Mean(SD)	Mean Difference Fixed, 95% CI	Weight	Mean Difference Fixed, 95% CI
Korhonen 1987	40	-2.7 (2.1)	40	-2.8 (2.3)		23.05%	0.19[-0.76,1.14]
Trento 2001	56	0.1 (1.8)	56	-0.8 (2)		41.21%	0.9[0.19,1.61]
Uusitupa 1993	40	0.5 (1.6)	40	0.7 (1.9)		35.74%	-0.2[-0.96,0.56]
Total ***	**136**		**136**			**100%**	**0.34[-0.11,0.8]**
Heterogeneity: Tau^2=0; Chi^2=4.41, df=2(P=0.11); I^2=54.6%							
Test for overall effect: Z=1.47(P=0.14)							

Favours treatment -10 -5 0 5 10 Favours control

Analysis 3.4. Comparison 3 Any intervention vs usual care (F/U</=2y) (1-11: fixed models. 12-22: random models, rho=0.75), Outcome 4 GHb.

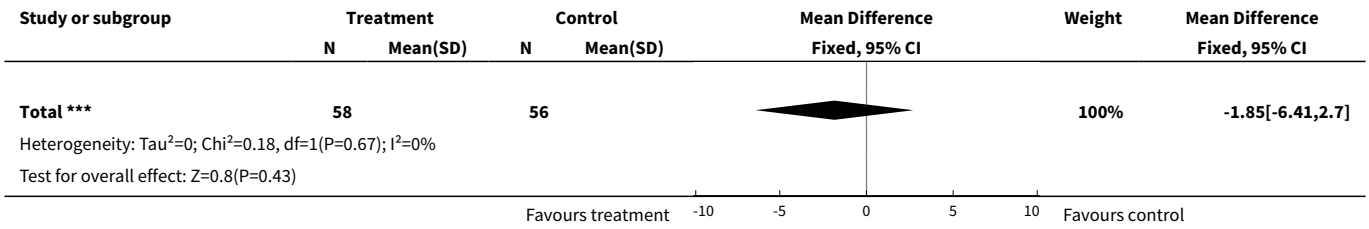
Study or subgroup	Treatment N	Treatment Mean(SD)	Control N	Control Mean(SD)	Mean Difference Fixed, 95% CI	Weight	Mean Difference Fixed, 95% CI
Heller 1988	36	-2.9 (1.8)	39	-2.5 (2)		8.83%	-0.45[-1.31,0.41]
Korhonen 1987	40	-1.5 (1.2)	40	-1.7 (1.2)		24.07%	0.21[-0.31,0.73]
Trento 2001	56	-0.4 (0.9)	56	1.2 (1.4)		34.21%	-1.6[-2.04,-1.16]
Uusitupa 1993	40	-0.5 (1.2)	40	-0.3 (1.3)		20.59%	-0.2[-0.76,0.36]
Zapotoczky 2001	18	-1 (1.1)	16	0.3 (1.1)		12.29%	-1.28[-2.01,-0.55]
Total ***	**190**		**191**			**100%**	**-0.74[-0.99,-0.48]**
Heterogeneity: Tau^2=0; Chi^2=33.92, df=4(P<0.0001); I^2=88.21%							
Test for overall effect: Z=5.65(P<0.0001)							

Favours treatment -10 -5 0 5 10 Favours control

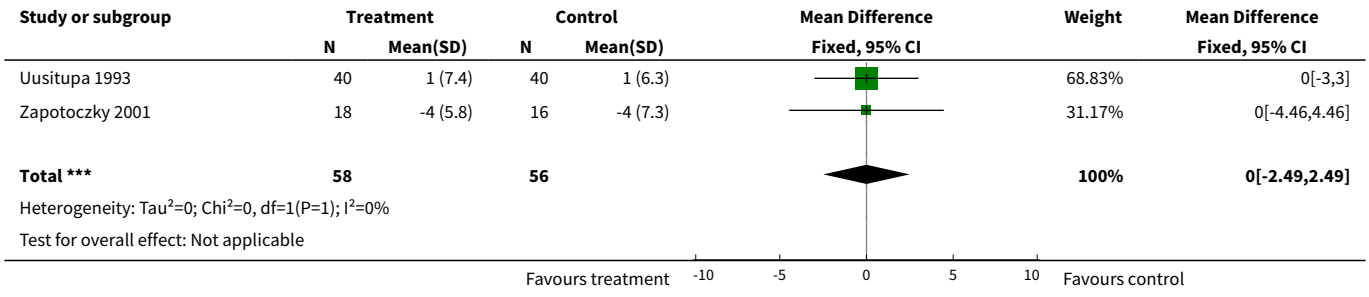
Analysis 3.5. Comparison 3 Any intervention vs usual care (F/U</=2y) (1-11: fixed models. 12-22: random models, rho=0.75), Outcome 5 SBP.

Study or subgroup	Treatment N	Treatment Mean(SD)	Control N	Control Mean(SD)	Mean Difference Fixed, 95% CI	Weight	Mean Difference Fixed, 95% CI
Uusitupa 1993	40	6 (12.6)	40	7 (14.7)		57.47%	-1[-7.01,5.01]
Zapotoczky 2001	18	-1 (9.5)	16	2 (11.1)		42.53%	-3[-9.98,3.98]

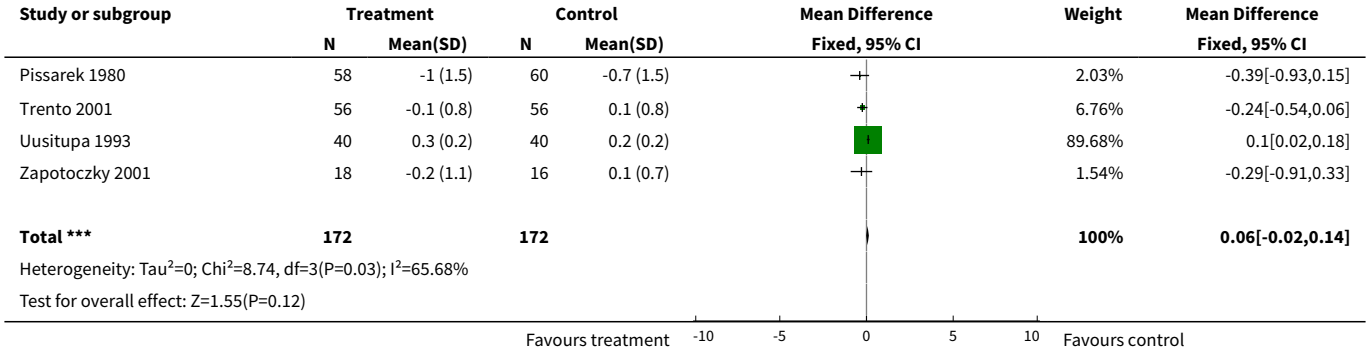
Favours treatment -10 -5 0 5 10 Favours control



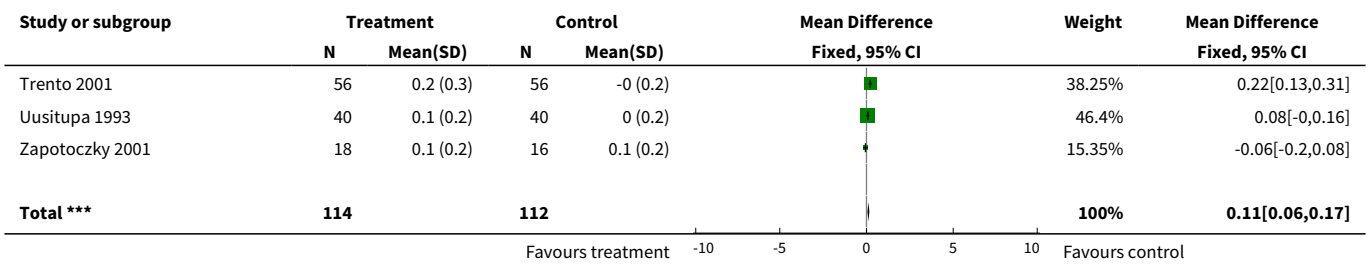
Analysis 3.6. Comparison 3 Any intervention vs usual care (F/U</=2y) (1-11: fixed models. 12-22: random models, rho=0.75), Outcome 6 DBP.



Analysis 3.7. Comparison 3 Any intervention vs usual care (F/U</=2y) (1-11: fixed models. 12-22: random models, rho=0.75), Outcome 7 Total Cholesterol.



Analysis 3.8. Comparison 3 Any intervention vs usual care (F/U</=2y) (1-11: fixed models. 12-22: random models, rho=0.75), Outcome 8 HDL.

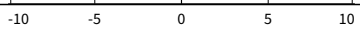


Study or subgroup	Treatment N	Treatment Mean(SD)	Control N	Control Mean(SD)	Mean Difference Fixed, 95% CI	Weight	Mean Difference Fixed, 95% CI
Heterogeneity: Tau²=0; Chi²=11.86, df=2(P=0); I²=83.14%							
Test for overall effect: Z=3.96(P<0.0001)							

Favours treatment Favours control

Analysis 3.9. Comparison 3 Any intervention vs usual care (F/U</=2y) (1-11: fixed models. 12-22: random models, rho=0.75), Outcome 9 Triglycerides.

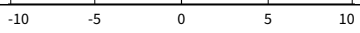
Study or subgroup	Treatment N	Treatment Mean(SD)	Control N	Control Mean(SD)	Mean Difference Fixed, 95% CI	Weight	Mean Difference Fixed, 95% CI
Pissarek 1980	58	-0.9 (2.2)	60	-0.4 (1.3)		11.05%	-0.52[-1.17,0.13]
Trento 2001	56	-0.5 (1.1)	56	0 (0.5)		48.88%	-0.5[-0.81,-0.19]
Uusitupa 1993	40	-0.2 (0.9)	40	-0 (0.9)		28.79%	-0.15[-0.55,0.25]
Zapotoczky 2001	18	-0.4 (1.3)	16	-0.3 (0.5)		11.28%	-0.14[-0.78,0.5]
Total ***	**172**		**172**			**100%**	**-0.36[-0.58,-0.14]**
Heterogeneity: Tau²=0; Chi²=2.51, df=3(P=0.47); I²=0%							
Test for overall effect: Z=3.27(P=0)							



Favours treatment Favours control

Analysis 3.10. Comparison 3 Any intervention vs usual care (F/U</=2y) (1-11: fixed models. 12-22: random models, rho=0.75), Outcome 10 % weight loss.

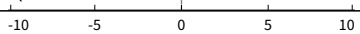
Study or subgroup	Treatment N	Treatment Mean(SD)	Control N	Control Mean(SD)	Mean Difference Fixed, 95% CI	Weight	Mean Difference Fixed, 95% CI
Heller 1988	40	-6.3 (4.4)	47	-3.5 (3.7)		63.93%	-2.8[-4.53,-1.07]
Korhonen 1987	40	-5.4 (10.1)	40	-3.6 (11.7)		8.26%	-1.86[-6.66,2.94]
Pissarek 1980	58	-10.5 (16.3)	60	-3.9 (13.9)		6.36%	-6.69[-12.16,-1.22]
Trento 2001	56	-1.8 (11.8)	56	1.6 (12.9)		9.09%	-3.42[-8,1.16]
Uusitupa 1993	40	-0.7 (10.6)	46	2.4 (10.9)		9.18%	-3.05[-7.61,1.51]
Zapotoczky 2001	18	-6.7 (12.8)	16	-2.1 (10.2)		3.19%	-4.52[-12.25,3.21]
Total ***	**252**		**265**			**100%**	**-3.1[-4.48,-1.72]**
Heterogeneity: Tau²=0; Chi²=2.17, df=5(P=0.82); I²=0%							
Test for overall effect: Z=4.41(P<0.0001)							



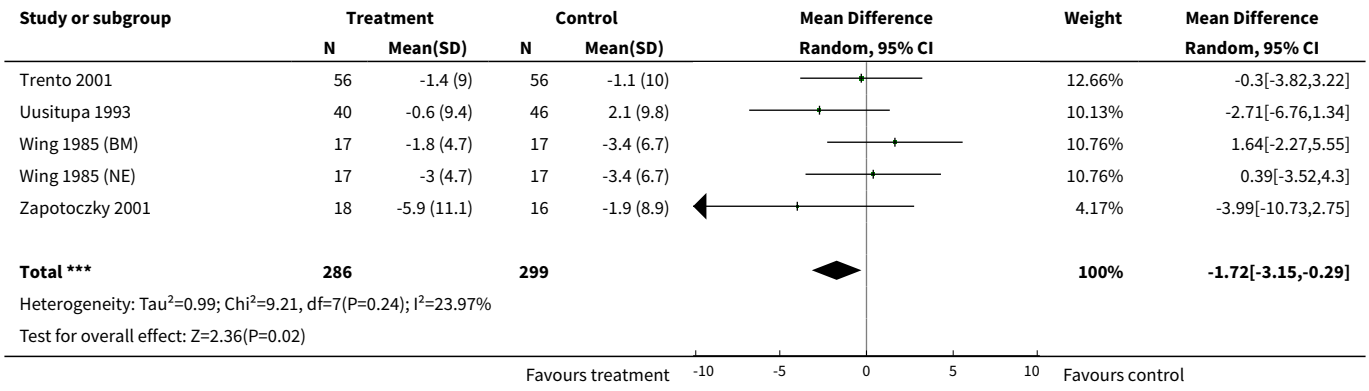
Favours treatment Favours control

Analysis 3.11. Comparison 3 Any intervention vs usual care (F/U</=2y) (1-11: fixed models. 12-22: random models, rho=0.75), Outcome 11 weight loss (kg).

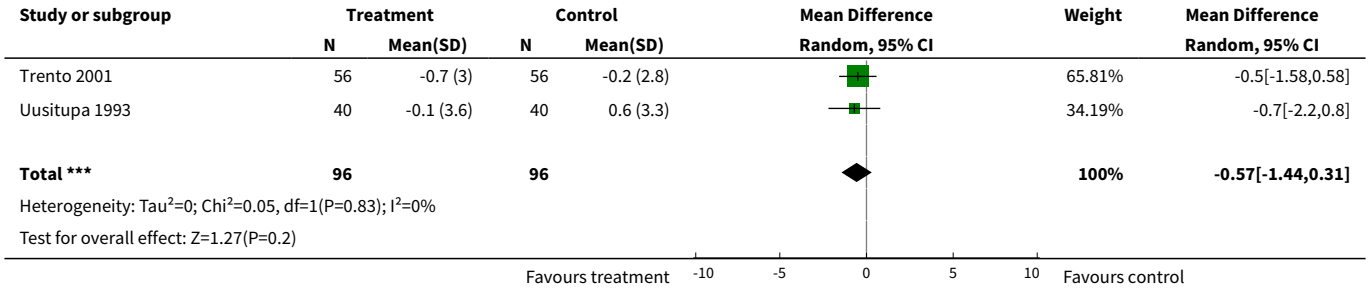
Study or subgroup	Treatment N	Treatment Mean(SD)	Control N	Control Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
Heller 1988	40	-5.5 (3.8)	47	-3 (3.2)		33.85%	-2.5[-4,-1]
Korhonen 1987	40	-4.7 (8.7)	40	-3.2 (10.5)		9.45%	-1.47[-5.7,2.76]
Pissarek 1980	58	-9 (14)	60	-3.2 (11.3)		8.21%	-5.8[-10.4,-1.2]



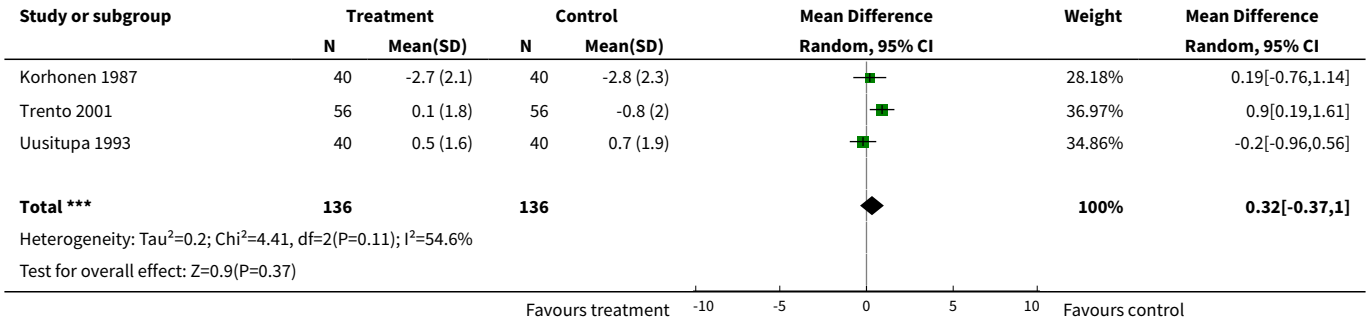
Favours treatment Favours control



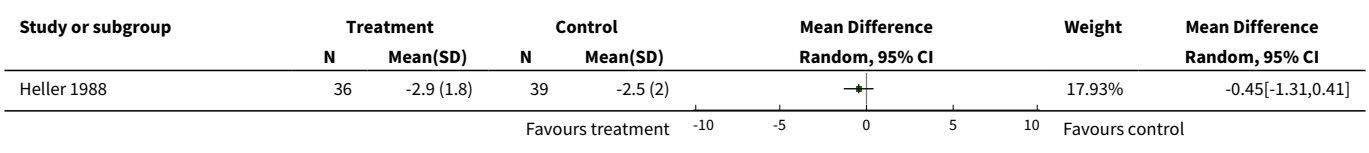
Analysis 3.12. Comparison 3 Any intervention vs usual care (F/U</=2y) (1-11: fixed models. 12-22: random models, rho=0.75), Outcome 12 BMI.



Analysis 3.13. Comparison 3 Any intervention vs usual care (F/U</=2y) (1-11: fixed models. 12-22: random models, rho=0.75), Outcome 13 FBS.



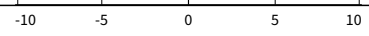
Analysis 3.14. Comparison 3 Any intervention vs usual care (F/U</=2y) (1-11: fixed models. 12-22: random models, rho=0.75), Outcome 14 GHb.



Study or subgroup	Treatment N	Mean(SD)	Control N	Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
Korhonen 1987	40	-1.5 (1.2)	40	-1.7 (1.2)		20.89%	0.21[-0.31,0.73]
Trento 2001	56	-0.4 (0.9)	56	1.2 (1.4)		21.49%	-1.6[-2.04,-1.16]
Uusitupa 1993	40	-0.5 (1.2)	40	-0.3 (1.3)		20.55%	-0.2[-0.76,0.36]
Zapotoczky 2001	18	-1 (1.1)	16	0.3 (1.1)		19.14%	-1.28[-2.01,-0.55]
Total * **	**190**		**191**			**100%**	**-0.67[-1.44,0.1]**

Heterogeneity: Tau^2=0.67; Chi^2=33.92, df=4(P<0.0001); I^2=88.21%

Test for overall effect: Z=1.7(P=0.09)

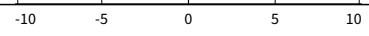


Analysis 3.15. Comparison 3 Any intervention vs usual care (F/U</=2y) (1-11: fixed models. 12-22: random models, rho=0.75), Outcome 15 SBP.

Study or subgroup	Treatment N	Mean(SD)	Control N	Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
Uusitupa 1993	40	6 (12.6)	40	7 (14.7)		57.47%	-1[-7.01,5.01]
Zapotoczky 2001	18	-1 (9.5)	16	2 (11.1)		42.53%	-3[-9.98,3.98]
Total * **	**58**		**56**			**100%**	**-1.85[-6.41,2.7]**

Heterogeneity: Tau^2=0; Chi^2=0.18, df=1(P=0.67); I^2=0%

Test for overall effect: Z=0.8(P=0.43)



Analysis 3.16. Comparison 3 Any intervention vs usual care (F/U</=2y) (1-11: fixed models. 12-22: random models, rho=0.75), Outcome 16 DBP.

Study or subgroup	Treatment N	Mean(SD)	Control N	Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
Uusitupa 1993	40	1 (7.4)	40	1 (6.3)		68.83%	0[-3,3]
Zapotoczky 2001	18	-4 (5.8)	16	-4 (7.3)		31.17%	0[-4.46,4.46]
Total * **	**58**		**56**			**100%**	**0[-2.49,2.49]**

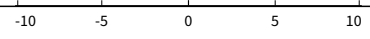
Heterogeneity: Tau^2=0; Chi^2=0, df=1(P=1); I^2=0%

Test for overall effect: Not applicable

Analysis 3.17. Comparison 3 Any intervention vs usual care (F/U</=2y) (1-11: fixed models. 12-22: random models, rho=0.75), Outcome 17 Total Cholesterol.

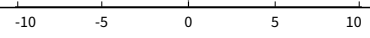
Study or subgroup	Treatment N	Mean(SD)	Control N	Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
Pissarek 1980	58	-1 (1.5)	60	-0.7 (1.5)		16.26%	-0.39[-0.93,0.15]
Trento 2001	56	-0.1 (0.8)	56	0.1 (0.8)		28.77%	-0.24[-0.54,0.06]
Uusitupa 1993	40	0.3 (0.2)	40	0.2 (0.2)		41.37%	0.1[0.02,0.18]

Study or subgroup	Treatment N	Treatment Mean(SD)	Control N	Control Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
Zapotoczky 2001	18	-0.2 (1.1)	16	0.1 (0.7)		13.6%	-0.29[-0.91,0.33]
Total ***	**172**		**172**			**100%**	**-0.13[-0.41,0.15]**
Heterogeneity: Tau^2=0.05; Chi^2=8.74, df=3(P=0.03); I^2=65.68%							
Test for overall effect: Z=0.92(P=0.36)							



Analysis 3.18. Comparison 3 Any intervention vs usual care (F/U</=2y) (1-11: fixed models. 12-22: random models, rho=0.75), Outcome 18 HDL.

Study or subgroup	Treatment N	Treatment Mean(SD)	Control N	Control Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
Trento 2001	56	0.2 (0.3)	56	-0 (0.2)		35.06%	0.22[0.13,0.31]
Uusitupa 1993	40	0.1 (0.2)	40	0 (0.2)		35.94%	0.08[-0,0.16]
Zapotoczky 2001	18	0.1 (0.2)	16	0.1 (0.2)		29%	-0.06[-0.2,0.08]
Total ***	**114**		**112**			**100%**	**0.09[-0.05,0.23]**
Heterogeneity: Tau^2=0.01; Chi^2=11.86, df=2(P=0); I^2=83.14%							
Test for overall effect: Z=1.22(P=0.22)							

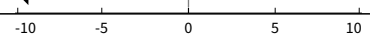


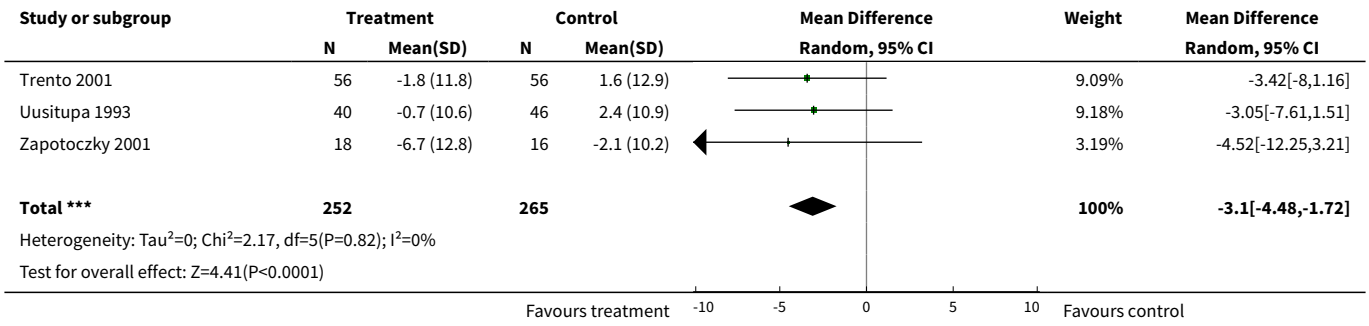
Analysis 3.19. Comparison 3 Any intervention vs usual care (F/U</=2y) (1-11: fixed models. 12-22: random models, rho=0.75), Outcome 19 Triglycerides.

Study or subgroup	Treatment N	Treatment Mean(SD)	Control N	Control Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
Pissarek 1980	58	-0.9 (2.2)	60	-0.4 (1.3)		11.05%	-0.52[-1.17,0.13]
Trento 2001	56	-0.5 (1.1)	56	0 (0.5)		48.88%	-0.5[-0.81,-0.19]
Uusitupa 1993	40	-0.2 (0.9)	40	-0 (0.9)		28.79%	-0.15[-0.55,0.25]
Zapotoczky 2001	18	-0.4 (1.3)	16	-0.3 (0.5)		11.28%	-0.14[-0.78,0.5]
Total ***	**172**		**172**			**100%**	**-0.36[-0.58,-0.14]**
Heterogeneity: Tau^2=0; Chi^2=2.51, df=3(P=0.47); I^2=0%							
Test for overall effect: Z=3.27(P=0)							

Analysis 3.20. Comparison 3 Any intervention vs usual care (F/U</=2y) (1-11: fixed models. 12-22: random models, rho=0.75), Outcome 20 % weight loss.

Study or subgroup	Treatment N	Treatment Mean(SD)	Control N	Control Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
Heller 1988	40	-6.3 (4.4)	47	-3.5 (3.7)		63.93%	-2.8[-4.53,-1.07]
Korhonen 1987	40	-5.4 (10.1)	40	-3.6 (11.7)		8.26%	-1.86[-6.66,2.94]
Pissarek 1980	58	-10.5 (16.3)	60	-3.9 (13.9)		6.36%	-6.69[-12.16,-1.22]

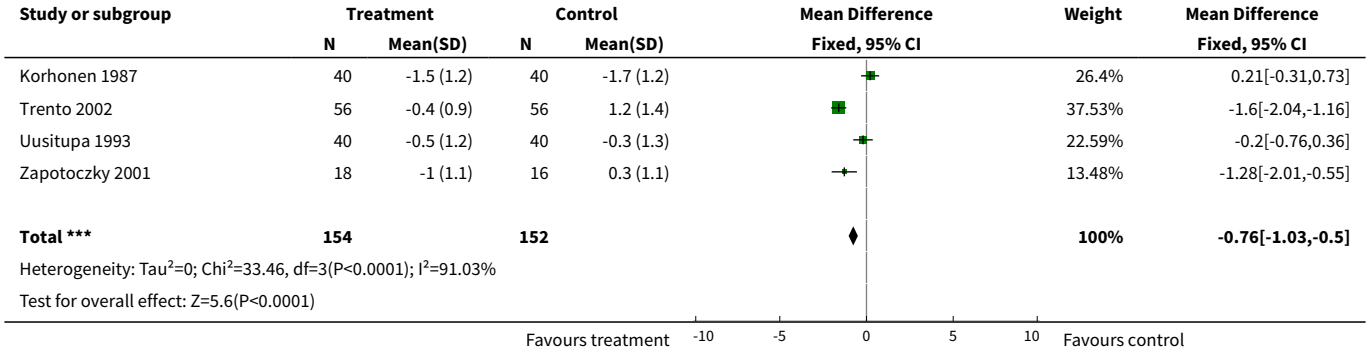




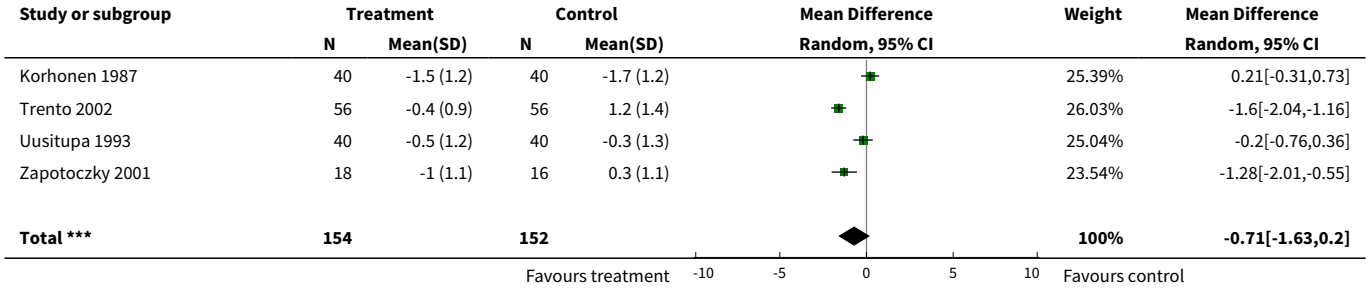
Comparison 4. Any intervention vs usual care (1-2y follow-up) (HbA1c in original paper)

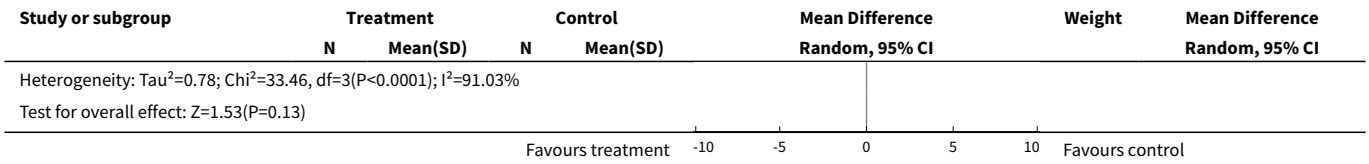
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 GHb (fixed model)	4	306	Mean Difference (IV, Fixed, 95% CI)	-0.76 [-1.03, -0.50]
2 GHb (random model)	4	306	Mean Difference (IV, Random, 95% CI)	-0.71 [-1.63, 0.20]

Analysis 4.1. Comparison 4 Any intervention vs usual care (1-2y follow-up) (HbA1c in original paper), Outcome 1 GHb (fixed model).



Analysis 4.2. Comparison 4 Any intervention vs usual care (1-2y follow-up) (HbA1c in original paper), Outcome 2 GHb (random model).





APPENDICES

Appendix 1. Search strategy

ELECTRONIC SEARCHES:

Unless otherwise stated, search terms were free text terms; exp = exploded MeSH: Medical subject heading (Medline medical index term); the dollar sign ($) stands for any character(s); the question mark (?) = to substitute for one or no characters; tw = text word; pt = publication type; sh = MeSH: Medical subject heading (Medline medical index term); adj = adjacency.

1. diabetes mellitus, non insulin dependent[MeSH Terms]
2. insulin resistance[MeSH Terms]
3. obesity in diabetes[MeSH Terms]
4. impaired glucose toleranc*[Title/Abstract]
5. impaired fasting glucose
6. glucose intoleranc*[Title/Abstract]
7. insulin resist*[Title/Abstract]
8. MODY[Title/Abstract]
9. dm2[Title/Abstract]
10. niddm[Title/Abstract]
11. iidm[Title/Abstract]
12. non insulin depend*[Title/Abstract]
13. noninsulin depend*[Title/Abstract]
14. noninsulindepend*[Title/Abstract]
15. non insulin?depend*[Title/Abstract]
16. type 2 diab*[Title/Abstract]
17. type II diab*[Title/Abstract]
18. keto* resist* diabet*[Title/Abstract]
19. non keto* diabet*[Title/Abstract]
20. nonketo* diabet*[Title/Abstract]
21. adult onset diabet*[Title/Abstract]
22. late onset diabet*[Title/Abstract]
23. matur* onset diabet*[Title/Abstract]
24. slow onset diabet*[Title/Abstract]
25. stabl* onset diabet*[Title/Abstract
26. metabolic* syndrom*[Title/Abstract]
27. plurimetabolic* syndrom*[Title/Abstract]
28. pluri metabolic* syndrom*[Title/Abstract]
29. or/1-28
30. dermatomyositis[MeSH Terms]
31. Myotonic dystrophy[MeSH Terms]
32. Diabetes insipidus[MeSH Terms]
33. dermatomyositis[Title/Abstract]
34. myotonic dystroph*[Title/Abstract]
35. diabet* insipidus[Title/Abstract]
36. or/30-35
37. 29 not 36
38. obesity[MeSH Terms]
39. obes*[Title/Abstract]

(Continued)

40. weight gain*[Title/Abstract]
41. weight gain[MeSH Terms]
42. weight loss[Title/Abstract]
43. weight loss[MeSH Terms]
44. body mass index [Title/Abstract]
45. body mass index[MeSH Terms]
46. adipos* [Title/Abstract]
47. overweight[Title/Abstract]
48. over weight [Title/Abstract]
49. overload syndrom*[Title/Abstract]
50. overeat*[Title/Abstract]
51. over eat*[Title/Abstract]
52. overfeed*[Title/Abstract]
53. over feed*[Title/Abstract]
54. weight cycling[Title/Abstract]
55. weight reduc*[Title/Abstract]
56. weight losing[Title/Abstract]
57. weight maint*[Title/Abstract]
58. weight decreas*[Title/Abstract]
59. weight watch*[Title/Abstract]
60. weight control*[Title/Abstract]
61. or/38-60
62. exercise[MeSH Terms]
63. "physical education and training"[MeSH Terms]
64. "physical fitness"[MeSH Terms]
65. exercis*[Title/Abstract]
66. exertion*[Title/Abstract]
67. sport*[Title/Abstract]
68. walking[Title/Abstract]
69. jogging[Title/Abstract]
70. swimming[Title/Abstract]
71. strength train*[Title/Abstract]
72. resistance train*[Title/Abstract]
73. aerobic train*[Title/Abstract]
74. physical education*[Title/Abstract]
75. physical fitness[Title/Abstract]
76. training[Title/Abstract]
77. Life style[MeSH Terms]
78. Health education[MeSH Terms]
79. health behavior[MeSH Terms]
80. health promotion[MeSH Terms]
81. sports[MeSH Terms]
82. exertion[MeSH Terms]
83. exercise-therapy[MeSH Terms]
84. nutrition[MeSH Terms]
85. nutrition*[Title/Abstract]
86. diet therapy[MeSH Terms]
87. feeding-behavior[MeSH Terms]
88. life style[Title/Abstract]
89. lifestyle[Title/Abstract]
90. health* behav*[Title/Abstract]
91. health* educ*[Title/Abstract]
92. health* promot*[Title/Abstract]
93. physic* activ*[Title/Abstract]
94. bicyc*[Title/Abstract]
95. cycling[Title/Abstract]
96. weight lift*[Title/Abstract]
97. gymnastic*[Title/Abstract]
98. danc*[Title/Abstract]
99. diabetic diet[MeSH Terms]
100. diet*[Title/Abstract]

(Continued)

101. diet therapy[MeSH Terms]
102. or/62-101
103. 37 and 61 and 102

Appendix 2. Outcomes summary

Study	Follow-up	Intervention	Weight Di-Dc (95%CI)	GHb Di-Dc (95%CI)
Hanefeld 1991	260	LCD + PA	NR	NR
Heller 1988	52	LCD	-2.5 (-4.0, -1.0)	-0.5 (-1.3, 0.4)
Hockaday 1978	52	LCD	-0.8 (-3.1, 1.5)	NR
Kaplan 1987 (D)	78	LCD	NR	-0.8 (-2.0, 0.3)
Kaplan 1987 (D + PA)	78	LCD + PA	NR	-1.8 (-2.9, -0.8)
Kaplan 1987 (PA)	78	PA	NR	0.9 (-0.3, 2.2)
Korhonen 1987	52	LCD	-1.5 (-5.7, 2.8)	0.2 (-0.3, 0.7)
Metz 2000	52	LCD	-2.0 (-3.7, -0.3)	-0.04 (-0.6, 0.5)
Milne 1994	78	LCD	-2.1 (6.8, 2.6)	-0.04 (-0.9, 0.8)
Muchmore 1994	52	LCD	-0.1 (-8.5, 8.3)	-0.7 (-1.7, 0.3)
Pascale 1995	52	LCD + PA + B	-4.2 (-8.6, -0.1)	-0.2 (-1.5, 1.0)
Pissarek 1980	108	LCD	-5.8 (-10.4, -1.2)	NR
Sone 2002	156	LCD + PA	NR	-0.1 (-0.1, 0.0)
Trento 2002	52/104/225	LCD + PA	-0.6 (-3.6, 2.4) -0.3 (-4.2, 3.6) -0.3 (-3.8, 3.2)	-0.2 (-0.6, 0.2) -0.8 (-1.2, -0.4) -1.6 (-2.0, -1.2)
Uusitupa 1993	52/104	LCD + PA	-2.8 (-4.5, -1.1) -2.7 (-6.8, 1.3)	-0.2 (-0.7, 0.3) -0.2 (-0.8, 0.4)
Wing 1986	62	LCD + PA + B	4.1 (-0.9, 9.2)	0.4 (-0.5, 1.3)
Wing 1988a (Study 1)	62	LCD + PA + B	-3.8 (-10.6, 3.0)	NR
Wing 1988a (Study 2)	62	LCD + PA + B	-4.1 (-15.2, 7.0)	-0.5 (-1.4, 0.4)
Wing 1985 (NE)	68	LCD + PA	0.4 (-3.5, 4.3)	NR
Wing 1985 (BM)	68	LCD + PA + B	1.6 (-2.3, 5.6)	NR
Wing 1988b	68	LCD + PA + B	0.2 (-11.2, 11.6)	0.9 (-0.6, 2.3)
Wing 1991b	72	LCD + PA + B	2.1 (-1.1, 5.2)	0.5 (-0.7, 1.8)

(Continued)

Wing 1991a	72	VLCD + PA + B	-1.8 (-7.3, 3.7)	-2.4 (-3.4, -1.3)
Wing 1994	52/104	VLCD + PA + B	-3.7 (-8.2, 0.8) -1.5 (-5.1, 2.1)	-0.2 (-1.0, 0.7) -0.2 (-1.2, 0.9)
Zapotoczky 2001	52	LCD	-4.0 (-10.7, 2.8)	-1.3 (-2.0, -0.6)

B, behavioral intervention
C, control group
CI, confidence interval
D, diet
I, intervention group
LCD, low calorie diet
NR, not reported
PA, physical activity
VLCD, very low calorie diet

Di-Dc is the between-group difference

Appendix 3. Meta-analysis results for weight change for single study arms

Intervention	Number studies	N	Estimate effect	Heterogeneity (p)
Usual care	7	564	-2.0 (-3.5 to -0.6)	0.05
Low calorie diet	12	917	-3.7 (-5.1 to -2.3)	<0.0001
Low calorie diet, physical activity	3	232	-1.8 (-3.2 to -0.3)	0.61
Low calorei diet, behavioral intervention intervention	2	53	-4.0 (-7.2 to -0.7)	1.00
Low calorie diet, activity, behavioral intervention	13	485	-4.1 (-5.4 to -2.9)	0.10
Very low calorie diet, activity, behavioral intervention	2	126	-7.7 (-9.8 to -5.5)	0.55

Appendix 4. Summary of pooled estimates, fixed-effects model: Intervention versus usual care

Outcome	Number studies	N	rho = 0.25	rho = 0.50	rho = 0.75	rho = 1.00
Weight (kg)	7	585	-2.4 (95%CI -3.2 to -0.3)	-2.2 (95%CI -3.5 to -1.0)	-1.9 (95%CI -3.0 to -0.8)	-1.5 (95%CI -1.5 to -1.5)

(Continued)

% wt loss (%)	6	517	-2.9 (95%CI -4.5 to -1.4)	-3.0 (95%CI -4.5 to -1.5)	-3.1 (95%CI -4.5 to -1.7)	-1.9 (95%CI -1.9 to -1.9)
Body mass index (mg/m2)	2	192	-0.6 (95%CI -2.1 to 0.9)	-0.6 (95%CI -1.8 to 0.7)	-0.6 (95%CI -1.4 to 0.3)	-0.7 (95%CI -0.7 to -0.6)
Fasting glucose (mmol/l)	3	272	0.3 (95%CI -0.5 to 1.1)	0.3 (95%CI -0.3 to 1.0)	0.3 (95%CI -0.1 to 0.8)	0.2 (95%CI 0.2 to 0.2)
Glycated hemoglobin (%)	5	381	-0.4 (95%CI -0.8 to 0.1)	-0.4 (95%CI -0.7 to 0)	-0.4 (95%CI -0.6 to -0.1)	0.2 (95%CI 0.2 to 0.2)
Systolic blood pressure (mmHg)	2	114	-1.9 (95%CI -9.5 to 5.7)	-1.9 (95%CI -8.2 to 4.4)	-1.9 (95%CI -6.4 to 2.7)	-1.5 (95%CI -2.8 to -0.2)
Diastolic blood pressure(mmHg)	2	114	0 (95%CI -4.2 to 4.2)	0 (95%CI -3.5 to 3.5)	0 (95%CI -2.5 to 2.5)	0 (95%CI -0.2 to 0.2)
Total cholesterol (mmol/l)	4	344	-0.2 (95%CI -0.5 to 0.2)	-0.2 (95%CI -0.4 to 0.1)	0.1 (95%CI 0 to 0.1)	-0.1 (95%CI -0.1 to -0.1)
LDL cholesterol (mmol/l)	1	34	-0.1 (95%CI -0.9 to 0.7)	-0.1 (95%CI -0.8 to 0.5)	-0.1 (95%CI -0.6 to 0.4)	-0.1 (95%CI -0.3 to 0.0)
HDL cholesterol (mmol/l)	3	226	0.1 (95%CI 0.0 to 0.2)	0.1 (95%CI 0.0 to 0.2)	0.1 (95%CI 0.1 to 0.2)	0.0 (95%CI 0.0 to 0.0)
Triglycerides (mmol/l)	3	226	-0.4 (95%CI -0.7 to 0)	-0.4 (95%CI -0.7 to -0.1)	-0.4 (95%CI -0.6 to -0.1)	-0.2 (95%CI -0.2 to -0.1)

Appendix 5. Summary of pooled estimates, random-effect model: Intervention versus usual care

Outcome	Number studies	N	rho = 0.25	rho = 0.50	rho = 0.75	rho = 1.00
Weight (kg)	7	585	- 2.4 (95% CI -3.7 to -1.1) Q = 4.7 p = 0.7 I squared = 0%	- 2.2 (95% CI -3.5 to -1.0) Q = 6.0 p = 0.5 I squared = 0%	- 1.7 (95% CI -3.2 to -0.3) Q = 9.2 p = 0.2 I squared = 24.0%	- 2.1 (95% CI -3.0 to -1.3) Q = 66.2 p < 0.00001 I squared = 92.3%
% wt loss (%)	6	517	- 2.9 (95% CI -4.5 to -1.4) Q = 0.8 p = 1.0 I squared = 0%	- 3.0 (95% CI -4.5 to -1.5) Q = 1.2 p = 1.0 I squared = 0%	- 3.1 (95% CI -4.5 to -1.7) Q = 2.2 p = 0.8 I squared = 0%	- 3.5 (95% CI -4.6 to -2.5) Q = 90.5 p < 0.00001 I squared = 94.5%
Body mass index (mg/m2)	2	192	- 0.6 (95% CI -2.1 to 0.9) Q = 0.0 p = 0.9 I squared = 0%	- 0.6 (95% CI -1.8 to 0.7) Q = 0.0 p = 0.9 I squared = 0%	- 0.6 (95% CI -1.4 to 0.3) Q = 0.1 p = 0.8 I squared = 0%	- 0.6 (95% CI -0.8 to -0.4) Q = 4.8 p = 0.03 I squared = 79.3%
Fasting glycose (mmol/l)	3	272	0.3 (95% CI -0.5 to 1.1) Q = 1.5	0.3 (95% CI -0.4 to 1.0) Q = 2.3	0.3 (95% CI -0.4 to 1.0) Q = 4.4	0.3 (95% CI -0.2 to 0.8) Q = 166.1

(Continued)

			p = 0.5 I squared = 0%	p = 0.3 I squared = 11.5% - 0.6 (95% CI -2.1 to 0.9) Q = 0.0 p = 0.9 I squared = 0%	p = 0.1 I squared = 54.6%	p < 0.00001 I squared = 98.8%
Glycated hemoglobin (%)	5	381	-0.4 (95% CI -0.9 to 0.2) Q = 3.6 p = 0.3 I squared = 15.5%	-0.3 (95% CI -0.8 to 0.2) Q = 5.3 p = 0.2 I squared = 43.0%	-0.3 (95% CI -0.8 to 0.2) Q = 10.2 p = 0.02 I squared = 70.7%	-0.3 (95% CI -0.8 to 0.2) Q = 266.7 p < 0.00001 I squared = 98.9%
Systolic blood pressure (mmHg)	2	114	-1.9 (95% CI -9.5 to 5.7) Q = 0.1 p = 0.8 I squared = 0%	-1.9 (95% CI -8.2 to 4.4) Q = 0.1 p = 0.8 I squared = 0%	-1.9 (95% CI -6.4 to 2.7) Q = 0.2 p = 0.7 I squared = 0%	-1.7 (95% CI -3.5 to 0.2) Q = 1.6 p = 0.2 I squared = 37.0%
Diastolic blood pressure (mmHg)	2	114	0 (95% CI -4.2 to 4.2) Q = 0 p = 1.0 I squared = 0%	0 (95% CI -3.5 to 3.5) Q = 0 p = 1.0 I squared = 0%	0 (95% CI -2.5 to 2.5) Q = 0 p = 1.0 I squared = 0%	0 (95% CI -0.2 to 0.2) Q = NA p = NA I squared = NA
Total cholesterol (mmol/l)	4	344	-0.2 (95% CI -0.5 to 0.2) Q = 1.1 p = 0.8 I squared = 0%	-0.2 (95% CI -0.4 to 0.1) Q = 1.6 p = 0.7 I squared = 0%	-0.1 (95% CI -0.4 to 0.2) Q = 8.7 p = 0.03 I squared = 65.7%	-0.2 (95% CI -0.5 to 0.1) Q = 99.5 p < 0.00001 I squared = 97.0%
LDL cholesteorl (mmol/l)	1	34	-0.1 (95% CI -0.9 to 0.7) Q = NA p = NA I squared = NA	-0.1 (95% CI -0.8 to 0.5) Q = NA p = NA I squared = NA	-0.1 (95% CI -0.6 to 0.4) Q = NA p = NA I squared = NA	-0.1 (95% CI -0.3 to 0.0) Q = NA p = NA I squared = NA
HDL cholesterol (mmol/l)	3	226	0.1 (95% CI 0.0 to 0.3) Q = 4.3 p = 0.1 I squared = 52.9%	0.1 (95% CI -0.1 to 0.2) Q = 6.3 p = 0.04 I squared = 68.3%	0.1 (95% CI -0.1 to 0.2) Q = 11.9 p = 0.003 I squared = 83.1%	0.1 (95% CI -0.2 to 0.4) Q = 154.6 p < 0.00001 I squared = 99.4%
Triglycerides (mmol/l)	3	226	-0.4 (95% CI -0.7 to 0) Q = 1.0 p = 0.8 I squared = 0%	-0.4 (95% CI -0.7 to -0.1) Q = 1.4 p = 0.7 I squared = 0%	-0.4 (95% CI -0.6 to -0.1) Q = 2.5 p = 0.5 I squared = 0%	-0.2 (95% CI -0.4 to -0.1) Q = 7.3 p = 0.06 I squared = 58.6%

WHAT'S NEW

Date	Event	Description
28 October 2008	Amended	Converted to new review format.

CONTRIBUTIONS OF AUTHORS

SUSAN L. NORRIS: Study supervision, study concept and design, acquisition of data, analysis and interpretation of the data, drafting and critical revision of the manuscript

XUANPING ZHANG: Study concept and design, acquisition of data, analysis and interpretation of the data, critical revision of the manuscript, technical support

ALISON AVENELL: Study concept and design, analysis and interpretation of the data, critical revision of the manuscript

EDWARD GREGG: Study concept and design, analysis and interpretation of the data, critical revision of the manuscript

TAMARA J BROWN: Acquisition of data, analysis and interpretation of the data

CHRISTOPHER SCHMID: Analysis and interpretation of the data, critical revision of the manuscript

JOSEPH LAU: Study concept and design, analysis and interpretation of the data, critical revision of the manuscript

DECLARATIONS OF INTEREST

None identified

With regard to the contribution of S. Norris, the views expressed in this review are those of the author, and no official endorsement by the Agency for Healthcare Research and Quality or the U.S. Department of Health and Human Services is intended or should be inferred.

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