

Advice on low-fat diets for obesity (Review)

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ABSTRACT

Background

Overweight and obesity are global health problems contributing to an ever increasing noncommunicable disease burden. Calorie restriction can achieve short-term weight loss but the weight loss has not been shown to be sustainable in the long-term. An alternative approach to calorie restriction is to lower the fat content of the diet. However, the long-term effects of fat-restricted diets on weight loss have not been established.

Objectives

To assess the effects of advice on low-fat diets as a means of achieving sustained weight loss, using all available randomised clinical trials. This review focused primarily on participants who were overweight or clinically obese and were dieting for the purpose of weight reduction. Since we were particularly interested in the ability of participants to sustain weight loss over a longer period of time, we focused on studies of 'free living' men and women who were given dietary advice rather than provision of food or money to purchase food.

Search strategy

We searched the Cochrane Controlled Trials Register (Cochrane Library Issue 2, 2001), MEDLINE (up to February 2002), and EMBASE (up to February 2002). We also searched the Science Citation Index (up to January 2001) and bibliographies of studies identified. Date of latest search: February 2002.

Selection criteria

Trials were included if they fulfilled the following criteria: 1) they were randomised controlled clinical trials of low-fat diets versus other weight-reducing diets, 2) the primary purpose of the study was weight loss, 3) participants were followed for at least six months, 4) the study participants were adults (18 years or older) who were overweight or obese (BMI >25 kg/m²) at baseline. Studies including pregnant women or patients with serious medical conditions were excluded. Two people independently applied the inclusion criteria to the studies identified. Disagreement was resolved by discussion or by intervention of a third party.

Data collection and analysis

Data were extracted by three independent reviewers and meta-analysis performed using a random effects model. Weighted mean differences of weight loss were calculated for treatment and control groups at 6, 12 and 18 months.

Main results

Four studies were included at the six month follow-up, five studies at the 12 month follow-up and three studies at the 18 month follow-up. There was no significant difference in weight loss between the two groups at six months (WMD 1.7 kg, 95% CI -1.4 to 4.8 kg). The weighted sum of weight loss in the low fat group was -5.08 kg (95% CI -5.9 to -4.3 kg) and in the control group was -6.5 kg, (95% CI -7.3 to -5.7 kg). There was no significant difference in weight loss between the two groups at 12 months (WMD 1.1 kg, 95% CI -1.6 to 3.8 kg). The weighted sum of weight loss in the low fat group was -2.3 kg (95% CI -3.2 to -1.4 kg) and in the control group was -3.4 kg (95% CI -4.2 to -2.6 kg). There was no significant difference in weight loss between the two groups at 18 months (WMD 3.7 kg, 95% CI -1.8 to 9.2). The weighted sum of weight loss in the control group was -2.3 kg (95% CI -3.5 to -1.2 kg) and in the low fat group there was a weight gain of 0.1 kg (95% CI -0.8 to 1 kg). There was significant heterogeneity in the results for weight loss at six months and 12 months.

Apart from one study which showed a slight but statistically significant difference in total cholesterol in the low fat group at one year follow-up, there were no significant differences between the dietary groups for other outcome measures such as serum lipids, blood pressure and fasting plasma glucose. Studies measuring other factors such as perceived wellness and quality of life reported conflicting results.

Authors' conclusions

The review suggests that fat-restricted diets are no better than calorie restricted diets in achieving long term weight loss in overweight or obese people. Overall, participants lost slightly more weight on the control diets but this was not significantly different from the weight loss achieved through dietary fat restriction and was so small as to be clinically insignificant.

PLAIN LANGUAGE SUMMARY

LOW FAT DIETS ARE NO BETTER THAN OTHER WEIGHT REDUCING DIETS IN ACHIEVING LONG-TERM WEIGHT LOSS

Overweight and obesity are global health problems that are associated with many chronic diseases. Generally, overweight people have been able to lose weight through energy-restricted dieting but maintaining that weight loss has been less successful. There has been some evidence that low fat diets might help people to sustain the weight loss long-term. This review found that low fat diets were no better than other types of weight reducing diets in achieving and maintaining weight loss over 12 to 18 months.

BACKGROUND

THE PROBLEM OF OBESITY

Overweight and obesity are global health problems affecting both developed and developing countries and contributing to an ever increasing noncommunicable disease burden (WHO 1998). Recent surveys estimate that one in every two adults in the USA is either overweight or obese, an increase of 25% over the last three decades (Flegal 1998). In most countries of Western Europe the prevalence of obesity in adults is 10% to 25% and in some countries in the Americas it is 20% to 25%. For women in Eastern European and Mediterranean countries the prevalence of obesity increases up to 40% (WHO 1998). In the UK, the prevalence of obesity has more than doubled between 1980 and 1993, a trend that is similar for both men and women of all age groups (Carmichael 1999).

COSTS

The health and economic costs of excessive weight are enormous. Overweight and obesity are associated with an increased incidence of a number of diseases and risk factors, including cardiovascular disease, type 2 diabetes, hypertension, stroke, dyslipidemia, osteoarthritis and some cancers (Burton 1985; Must 1999). There is also increasing evidence that overweight and obesity are associated with increased mortality. The Nurses' Health Study demonstrated that 53% of all deaths among women with a BMI > 29 could be attributed directly to obesity (Manson 1995) and several international studies have found that mortality increased two to three fold for obese men and women (Barbagallo 2001; Katzmarzyk 2001). However, the relationship between obesity and mortality is not straightforward, with the relationship being weaker in women

(Bender 1998), in older people (Bender 1999), and in people who are physically fit (Lee 1999). The economic consequences are serious as obesity accounts for 5.5 to 7% of national health expenditures in the USA and 2.0 to 3.5% in other countries for which estimates have been reported (Thompson 2001).

MANAGEMENT OPTIONS

In view of the global epidemic of overweight and obesity and the associated disease burden, identifying the best strategies to achieve weight reduction and weight maintenance is urgently required. However, the 1993 National Institutes of Health Technology Assessment Conference on methods for voluntary weight loss and control painted a gloomy picture (Wadden 1993). Whilst methods of weight reduction such as calorie restriction diets and appetite suppressant drugs have reasonably good short term effects, at one and two year follow-ups most of this weight had been regained. A recent review of long-term outcomes for dietary treatment of obesity found a 15% success rate among 2131 individuals followed for a median of five years after a dietary intervention (Ayyad 2000). Success was defined as maintenance of all weight initially lost (or further weight reduction) or maintenance of at least 9 to 11 kg of initial weight loss. In all studies, the initial diet of the participants was either a very low calorie diet or a low calorie diet.

LOW FAT DIETS

An alternative approach to restricting the total energy content of the diet is to alter the fat content of the diet. By shifting the dietary pyramid from high-fat foods to low-fat, high carbohydrate foods (preferably complex carbohydrates), patients need to increase the amount of food they eat if they are to sustain their weight. Most

people only compensate to a small extent (Lissner 1987), and thus there is a net energy reduction. Some evidence that this method may work has been an accidental (and often ignored) finding of several randomised, controlled trials, mostly in patients with established heart disease. The most dramatic example perhaps is that of Ornish's 'Lifestyle Heart Trial' (Ornish 1990). This trial randomised about 80 patients with established coronary heart disease to either standard dietary advice or to an ultra low-fat diet (<10% of total daily energy intake) and group support. Most patients randomised to the ultra low-fat diet showed a reversal of their coronary artery lesions, but in addition, a surprising side effect of the diet was an average weight loss of 10 kg at the end of the first year of the trial (compared with no weight loss in those patients randomised to the standard dietary advice). A similar incidental effect was seen in a trial by Singh (Singh 1992) who merely suggested to a random half of patients after their first myocardial infarction that they eat more fruits, vegetables, grains, pulses and nuts. This group had lost 4 kg more than the control group after one year. Furthermore, results from a trial by Hjermann (Hjermann 1981), which aimed to lower cardiovascular risk factors, show that the small but clinically important amount of weight loss associated with a low fat diet appears to be maintained over a number of years; a mean weight loss of 3 kg was observed in patients randomised to a low fat diet (27% of total daily energy intake) but not in the control group after four years of follow up.

It is important to note that these trials were conducted in non-obese groups, and that the participants were not trying to lose weight, but were using a low fat diet for other reasons. A more recent meta-analysis by Astrup (Astrup 2000) on the role of dietary fat in body fatness concluded that dietary fat restriction prevented weight gain in participants of normal weight and produced a weight loss in overweight participants. However, of the 16 trials included in this review, none had weight loss as the primary goal. It is possible that people with disease are more motivated to adhere to a diet, and it is therefore not clear how effective low-fat diets are in achieving sustained weight loss when used for the express purpose of weight loss in obese or overweight people.

Thus, the aim of this systematic review was to assess the efficacy of low-fat diets compared with other weight reducing diets in achieving long-term weight loss among overweight and obese people. To stay as near as possible to the 'real life' situation, we focus on advice given to people on low fat diets, rather than including interventions provided under artificial conditions, for example diets provided free of charge or commercially produced diets.

OBJECTIVES

To assess the effects of advice on low-fat diets as a means of achieving sustained weight loss, using all available randomised clinical trials. This primarily focuses on participants who are overweight or clinically obese and are dieting for the purpose of weight re-

duction. Since we were particularly interested in the ability of participants to sustain weight loss over a longer period of time, we focused on studies of 'free living' men and women who were given dietary advice rather than provision of food or money to purchase food.

CRITERIA FOR CONSIDERING STUDIES FOR THIS REVIEW

Types of studies

All randomised controlled clinical trials of advice on low-fat diets versus other weight-reducing diets, provided that (a) the primary purpose of the study was weight loss, and (b) patients were followed for at least six months.

Types of participants

Adults living in the community, 18 years or older, who were overweight or obese (BMI >25 kg/m²) at baseline. Studies including pregnant women or patients with serious medical conditions were excluded.

Types of intervention

The intervention must have included advice about how to achieve a diet with less than or equal to 30% of calories coming from total fat or advice which would lead to an eating pattern that would achieve this. Advice could be provided by dietitians, health professionals, or investigators in verbal or written form. Trials were excluded if either the intervention diet or the comparison diet was (a) provided, either free of charge or for payment, or (b) commercially produced or consisting of whole diet substitutes. The comparison intervention could be any type of weight-reducing diet apart from a low-fat diet.

Types of outcome measures

We considered the following outcome measures to be relevant:

MAIN OUTCOME MEASURE

1. Indicators of body mass (for example, weight, body mass index (BMI))

ADDITIONAL OUTCOME MEASURES

1. Mortality (total and cardiovascular)
2. Cardiovascular events (myocardial infarction, stroke)
3. Serum lipids (total cholesterol, HDH cholesterol, LDL cholesterol, triglycerides)
4. Blood pressure
5. Glycated haemoglobin and fasting plasma glucose
6. Adverse effects of diet
7. Quality of life

TIMING OF OUTCOME MEASUREMENT

We aimed to assess outcome measurements in the short (six months), medium (seven months to one year) and long (more than one year) term.

SEARCH METHODS FOR IDENTIFICATION OF STUDIES

See: Cochrane Metabolic and Endocrine Disorders Group methods used in reviews.

The following sources were included in the literature search process: The Cochrane Controlled Trials Register (Cochrane Library Issue 2, 2001), MEDLINE, EMBASE, Science Citation Index, bibliographies, and handsearching. The original searches of MEDLINE and EMBASE were conducted from the beginning of each database until January 2001. The search was updated in February 2002.

ELECTRONIC SEARCHES

The Cochrane Library includes search results from several electronic databases and handsearch results from multiple journals. It was searched using the following strategy:

NOTES: unless stated otherwise, search terms are free text terms; MeSH: Medical subject heading (Medline medical index term); an asterisk (*) stands for 'any character(s)'

- #1 DIET (MeSH term, all subheadings included)
- #2 DIET (in the text)
- #2 WEIGHT-LOSS (MeSH term, all subheadings included)
- #3 WEIGHT next LOSS (in the text)
- #4 WEIGHT next REDUC* (in the text)
- #5 WEIGHT next INCREAS* (in the text)
- #6 #1 or #2 or #3 or #4 or #5

The MEDLINE database was searched with a combined topic and publication type search (written for Silver Platter).

TOPIC SEARCH

- #1 DIET (MeSH term, all subheadings included)
- #2 DIETARY-FATS (MeSH term, all subheadings included)
- #3 DIETARY-CARBOHYDRATES (MeSH term, all subheadings included)
- #4 DIET-THERAPY (MeSH term, all subheadings included)
- #5 DIET-FAT-RESTRICTED (MeSH term, all subheadings included)
- #6 DIET-REDUCING (MeSH term, all subheadings included)
- #7 #1 or #2 or #3 or #4 or #5 or #6
- #8 ENERG* or CALORI* or CARBOHYDRATE* (in the text)
- #9 FAT or FATS (in the text)
- #11 DECREAS* or LOW* or RESTRICT* or REDUC* (in the text)
- #12 FREE or INCREAS* or HIGH or AD LIB* (in the text)
- #13 #11 or #12

- #14 #10 with #13
- #15 #7 or #14
- #16 WEIGHT and #15 (in the text)
- #17 (TG=ANIMAL) not (TG=HUMAN) and (TG=ANIMAL)

PUBLICATION TYPE - RANDOMISED CONTROLLED TRIALS

- #18 RANDOMIZED-CONTROLLED-TRIAL (in publication type)
- #19 CONTROLLED-CLINICAL-TRIAL in (in publication type)
- #20 RANDOMISED CONTROLLED TRIALS (in the text)
- #21 random-allocation (MeSH term, all subheadings included)
- #22 double-blind-method (MeSH term, all subheadings included)
- #23 single-blind method (MeSH term, all subheadings included)
- #24 #18 or #19 or #20 or #21 or #22 or #23

COMBINED SEARCH

- #25 #16 not #17
- #26 #25 and #24

The references of all relevant studies were searched in the Science Citation Index to identify any additional trials.

HANDSEARCHING

The references of two recent UK (Glenny 1997) and USA (NIH 1998) government-sponsored literature reviews of therapy for obesity were searched to identify relevant RCTs. The UK NHS Centre for Reviews and Dissemination prepared a report on interventions in the treatment and prevention of obesity. The search strategy for this review covered 23 electronic databases including MEDLINE (1966-96), EMBASE (1974-96), PsycLit (1967-96) and Science Citation Index (1974-95). The US National Institutes of Health recently convened a guideline panel on the treatment of obesity. To provide evidence for the panelists, the NIH searched MEDLINE (1984-1996) and references of retrieved articles. The NIH and NHS reviews required minimum study durations of four months and one year, respectively.

The bibliographic references of all retrieved reports of RCTs and relevant reviews were assessed for additional reports of trials according to the criteria described above.

METHODS OF THE REVIEW

TRIALS SELECTION

The titles and abstracts of the records identified through aforementioned search strategies were independently screened by two investigators. Articles were rejected on initial screen if the reviewers determined from the title and abstract that the study (a) was not a report of a randomized controlled trial, (b) did not

address a low fat diet, (c) did not have a follow-up period that was at least six months in duration, or (d) was in children less than 18 years old. When a title/abstract could not be rejected with certainty, the full text of the article was obtained for further evaluation. The full text of all selected articles was examined independently by two investigators to identify all relevant trials. Differences in opinion were resolved by consensus.

QUALITY ASSESSMENT OF TRIALS

The trials were assessed independently by two investigators using specific quality criteria adapted from Chalmers (Chalmers 1990). The quality criteria related to the following aspects of study methodology:

1. Randomisation and concealment of allocation
2. Blinding of caregivers, participants and, in particular, outcome assessors
3. Follow-up and intention-to-treat analysis

Trials were categorised based on the extent to which they met the quality criteria:

A = all criteria met

B = one or more criteria only partially met

C = one or more criteria not met

We had planned to investigate the influence of quality in a sensitivity analysis.

DATA EXTRACTION

Three reviewers independently extracted data from the studies. Differences were resolved by the fourth reviewer. The data extraction form incorporated the following aspects of the trial:

1. General Information - full citation, language;
2. Trial characteristics - study design, study setting, duration, randomisation (and method), allocation concealment (and method), blinding (patients, people administering treatment, outcome assessors), check of blinding;
3. Intervention - characteristics of diets in treatment and comparison groups, description of nutrition advice, inclusion of behavioural or psychological component, advice regarding of physical activity, use of weight-reducing medication, duration of intervention and duration of follow-up, replicability of intervention;
4. Patients - sampling method, inclusion and exclusion criteria, total number and number in comparison groups, sex, age, and other relevant baseline characteristics (weight, BMI, % body fat, serum lipids, blood pressure), similarity of groups at baseline (including any co-morbidity), assessment of compliance, withdrawals/losses to follow-up (reasons/description), subgroups;
5. Outcomes - weight, BMI, % body fat, serum lipids (total cholesterol, LDL cholesterol, HDL cholesterol, VLDL cholesterol, triglycerides), glycemic profile (glycated haemoglobin, fasting plasma glucose), blood pressure, any other outcomes assessed;

6. Results - for outcomes and times of assessment (including a measure of variation), if necessary converted to measures of effect specified below; intention-to-treat analysis.

Authors were not contacted for further information.

DATA ANALYSIS

Data were entered into the Cochrane Review Manager (REVMAN) software and analysed using MetaView, the statistical component of REVMAN. Both random and fixed effects models were used to pool data. Effect sizes are presented as weighted mean differences with 95 percent confidence intervals. We had planned to express results of dichotomous variables as Mantel Haenszel odds ratios (OR) with 95 percent confidence intervals. The chi-square method was used to assess heterogeneity with the significance set at $p < 0.1$.

SUBGROUP ANALYSES

We had planned to perform subgroup analyses in order to explore effect size differences as follows, if there was a significant result for the main outcome measure:

1. Duration of intervention (short, medium, long - based on data)
2. Type of low-fat diet (fixed low-energy or ad-libitum)
3. Type of comparison diet (fixed low-energy, high-monounsaturated fat)
4. Length of follow-up (short term - 6 months, medium term - 12 months, long term - 18 months)

SENSITIVITY ANALYSES

We had planned to perform sensitivity analyses in order to explore the influence of the following factors on effect size:

1. Repeating the analyses excluding any unpublished studies
2. Repeating the analyses taking account of study quality, as specified above
3. Repeating the analyses excluding any very long or large studies to establish how much they dominate the results
4. Repeating the analyses excluding studies using the following filters: diagnostic criteria, language of publication, source of funding (industry versus other), country

We had planned to test the robustness of the results by repeating the analyses using different measures of effects size (risk difference, odds ratio etc.) and different statistical models (fixed and random effects models).

DESCRIPTION OF STUDIES

TRIALS IDENTIFIED

Over 3000 citations with their abstracts were obtained from electronic searches carried out in 2000. Two investigators reviewed the abstracts and found that only eight trials met the inclusion criteria. Three further trials were found through handsearching, giving a total of 11 potentially relevant trials. Two trials were presented

in more than one publication, yielding a total of eight individual trials. The latest search conducted in February 2002 retrieved one additional trial, bringing the total to nine individual trials.

EXCLUDED STUDIES

Following an evaluation of the abstract and methods section of the nine individual studies, three studies were excluded from the review. One study (Pritchard 1996) compared a low fat diet with aerobic exercise but the people in the control group were told not to change their diet (i.e. this was not a comparison of two forms of diet). Another study (Toubro 1997) compared initial weight loss between slow and rapid weight loss methods (not low fat compared with another diet method) followed by a weight maintenance program where a low fat diet was compared with a fixed energy diet. The third study (Westerterp 1996) was excluded for several reasons: a) the participants were not necessarily overweight or obese at baseline (BMI for women was between 21 and 28 kg/m² and for men between 24 and 30 kg/m²), b) the participants in the intervention group were instructed to select low-fat foods whilst participants in the comparison group were instructed to select full-fat foods and to consume a minimum of 37 grams of fat per day, thus there was no weight-reducing comparison diet, and c) participants shopped in the study supermarket where supplies were provided free of charge.

INCLUDED STUDIES

Six trials (nine publications) met the inclusion criteria and were included in the review. The studies are described in the table 'Characteristics of Included Studies'. One study (Baxter 1995) reported the follow-up data in three separate publications (Shah 1994; Jeffery 1995; Shah 1996) with Baxter being the only author to be included on all papers. One trial (Pascale 1995) divided patients into two groups: those with type 2 diabetes and those with a family history of type 2 diabetes. Since the participants with diabetes did not meet the inclusion criteria (7% had a history of myocardial infarction and 11% had a history of angina), only the participants with a family history of diabetes were included in the analysis.

STUDIES

All six of the included studies were parallel design, randomized controlled trials. The median study size was 106 participants with a range of 46 to 135.

The length of the intervention varied from three months (Baron 1986) to four months (Pascale 1995) to six months (Baxter 1995; Lean 1997; Harvey-Berino 1998) to 18 months (McManus 2001). Four studies (Baxter 1995; Lean 1997; Harvey-Berino 1998; McManus 2001) provided outcome data at six months, five studies (Baron 1986; Baxter 1995; Pascale 1995; Harvey-Berino 1998; McManus 2001) provided outcome data at 12 months, and three studies (Baxter 1995; Harvey-Berino 1998; McManus 2001) provided outcome data at 18 months. The three publications of one trial (Baxter 1995) reported follow-up data at six months (first publication), 12 months (second publication) and 18 months (third

publication). The two publications of Harvey-Berino 1998 reported follow-up at six months (first publication) and at 12 and 18 months (second publication). In both cases of multiple publications, the data for six month comparisons were taken from the first publication which reported on the largest number of participants (before drop-outs had occurred), and data for the 12 month follow-up was taken from the second publication.

PARTICIPANTS AND SETTING

There was a total of 594 participants in the six trials. The majority of participants (92%) was female with three trials restricted to women only (Baxter 1995; Pascale 1995; Lean 1997). Participants ranged in age from 18 to 66 years with the mean age between 40 and 50 years. All participants were either overweight or obese (defined as BMI >25 kg/m² or at least 120% of ideal body weight according to the Metropolitan Life Insurance Tables). Participants were free from serious medical conditions.

All trials were conducted in a community setting in cities in the USA (Baxter 1995; Pascale 1995; Harvey-Berino 1998; McManus 2001) or the UK (Baron 1986; Lean 1997). Participants in three of the USA studies (Baxter 1995; Pascale 1995; Harvey-Berino 1998) were recruited from newspaper advertisements whilst participants in the remaining study (McManus 2001) were recruited through letters mailed to primary care physicians at a major hospital and via posted announcements. Participants in one UK study (Baron 1986) were recruited from diet clubs and employee groups in the area. It is unclear where participants were recruited from in the other UK study (Lean 1997) but the setting was a hospital outpatients' clinic.

INTERVENTIONS

Dietary interventions varied from low fat versus low calorie (Harvey-Berino 1998), fixed calorie low fat versus fixed calorie low carbohydrate (Baron 1986; Lean 1997), low fat ad libitum versus low calorie (Baxter 1995), fixed calorie low fat versus fixed calorie moderate fat (McManus 2001) to fixed calorie low fat versus fixed calorie (Pascale 1995). The amount of fat recommended in the low fat diets was expressed as either grams per day (ranging from 20 to 30 g/day) or percentage of total energy intake (20%). Most dietary advice was given to participants by the study investigators or study dietitians together with a variety of different written materials such as diet instruction sheets, sample menus and recipes.

Five studies incorporated group sessions. Four studies held weekly sessions (Baron 1986; Pascale 1995; Harvey-Berino 1998; McManus 2001) and one study held weekly sessions for six weeks and fortnightly sessions for 20 weeks (Baxter 1995). In the remaining study, participants were reviewed individually at six week intervals in the hospital outpatient clinic (Lean 1997).

Pascale 1995, Harvey-Berino 1998, and McManus 2001 incorporated behavioural modification principles, self-management skills and advice regarding physical activity and exercise for both their

treatment and control groups. Baxter 1995 counselled participants on self-monitoring and how to increase physical activity.

None of the studies used weight-reducing medication as part of the intervention.

OUTCOME MEASURES

All studies included the main outcome measure of weight loss and all studies, apart from Baron 1986, reported body mass index (BMI) at six months. Four studies reported percent body fat (Baxter 1995; Harvey-Berino 1998; Lean 1997; McManus 2001) and three studies reported waist-hip ratio (Baxter 1995; Lean 1997; McManus 2001).

Of the six trials included in the review, three reported serum lipids (Baron 1986; Pascale 1995; Lean 1997), one reported blood pressure (Lean 1997), and two reported fasting plasma glucose (Baron 1986; Pascale 1995). No study reported glycated haemoglobin during the follow-up period. Only one study reported adverse effects of the diet (Baron 1986), although two studies measured the palatability/distaste of the diet (Baxter 1995; Harvey-Berino 1998) and Harvey-Berino 1998 also measured additional factors which could influence adherence to the diet including cost, inconvenience and deprivation. Only one study reported quality of life outcomes (Baxter 1995).

None of the trials included the additional outcome measures of mortality (total and cardiovascular) or cardiovascular events (myocardial infarction, stroke).

METHODOLOGICAL QUALITY

All studies were categorised as C indicating that one or more criteria were not met.

RANDOMIZATION

All studies were parallel design randomised controlled trials although the method of randomisation and allocation concealment processes were not described in any of the trials apart from McManus 2001. However, all studies reported 'no significant differences' between treatment groups on any of the baseline characteristics.

BLINDING

Blinding of caregivers and participants was either not done or not clearly specified. In most studies it was unclear whether outcome assessment was conducted blindly and who actually measured the outcome factors.

DROP-OUTS AND WITHDRAWALS

Drop-outs and withdrawals varied from 11% (Baron 1986) to 25% (Lean 1997) to 33% (Pascale 1995) to 40% (Baxter 1995; Harvey-Berino 1998; McManus 2001). Two studies included an

intention-to-treat analysis (Lean 1997; McManus 2001), all other studies were analysed by treatment received.

RESULTS

HETEROGENEITY

The results for the test of heterogeneity for the overall results (low fat diet versus control diet in all participants) were significant for weight loss at each of the time periods and significant for change in BMI at the six and 12 month follow-up. Visual inspection of the analyses suggests that the heterogeneity was due to the trial by Harvey-Berino 1998 and excluding that trial from the analysis did in fact eliminate the heterogeneity. The results of this trial were qualitatively similar to other trials in that there was a greater reduction in weight in the control group (low calorie) as compared to the low fat group. However, unlike many of the other studies, the difference in weight between the two groups was significant at each time point. One way in which this trial differed from the others was that there was probably no difference in absolute fat consumption between the two comparison groups. That is, the low calorie group reduced both their fat and carbohydrate consumption in order to maintain their daily intake within the 1000-1200 cal/day.

Weighted Mean Differences (WMD) have been calculated using the random effects method.

MAIN OUTCOME MEASURE - WEIGHT LOSS

6 MONTH RESULTS

Four studies (Baxter 1995; Lean 1997; Harvey-Berino 1998; McManus 2001) reported weight loss at the six month follow-up (comparison 01.01). There was no significant difference in weight loss between the two groups at six months (WMD 1.7 kg, 95% CI -1.4 to 4.8 kg). The weighted sum of weight loss in the low fat group was -5.08 kg (95% CI -5.9 to -4.3 kg) and in the control group was -6.5 kg, (95% CI -7.3 to -5.7 kg). Two of the four studies (Lean 1997; Harvey-Berino 1998) reported greater weight loss in the control group as compared to the low-fat group at six months, however only Harvey-Berino 1998 had significantly greater weight loss in the control group.

12 MONTH RESULTS

Five studies (Baron 1986; Baxter 1995; Pascale 1995; Harvey-Berino 1998; McManus 2001) reported weight loss at the 12 month follow-up (comparison 01.02). There was no significant difference in weight loss between the two groups at 12 months (WMD 1.1 kg, 95% CI -1.6 to 3.8 kg). The weighted sum of weight loss in the low fat group was -2.3 kg (95% CI -3.2 to -1.4 kg) and in the control group was -3.4 kg (95% CI -4.2 to -2.6 kg). Three of the five studies (Baron 1986; Pascale 1995; Harvey-Berino 1998) reported greater weight loss in the control group as compared to the low-fat group at 12 months, however only

Harvey-Berino 1998 had significantly greater weight loss in the control group.

18 MONTH RESULTS

Three studies (Baxter 1995; Harvey-Berino 1998; McManus 2001) reported weight loss at the 18 month follow-up (comparison 01.03). There was no significant difference in weight loss between the two groups at 18 months (WMD 3.7 kg, 95% CI -1.8 to 9.2). The weighted sum of weight loss in the control group was -2.3 kg (95% CI -3.5 to -1.2 kg) and in the low fat group there was a weight gain of 0.1 kg (95% CI -0.8 to 1 kg). Two of the three trials (Harvey-Berino 1998; McManus 2001) reported significantly greater weight loss in the control group at 18 months.

BODY MASS INDEX

Four studies (Baxter 1995; Lean 1997; Harvey-Berino 1998; McManus 2001) reported change in BMI at the six month follow-up (comparison 01.04). There was no significant difference in the change in BMI between the two groups at six months (WMD 0.7, 95% CI -0.6 to 2.0). Only one trial (Harvey-Berino 1998) reported a significantly reduced BMI in the control group as compared to the low fat group.

Three studies (Pascale 1995; Harvey-Berino 1998; McManus 2001) reported change in BMI at the 12 month follow-up (comparison 01.05). There was no significant difference in the change in BMI between the two groups at 12 months (WMD 1.2, 95% CI -0.7 to 3.0). Only one trial (Harvey-Berino 1998) reported a significantly reduced BMI in the control group as compared to the low fat group.

Only two studies (Harvey-Berino 1998; McManus 2001) reported change in BMI at the 18 month follow-up (comparison 01.06). There was a significant difference in the change in BMI between the two groups at 12 months (WMD 2.4, 95% CI 1.5 to 3.3) with the control group having a greater reduction in BMI as compared to the low fat group. The results of these two studies were homogeneous.

PERCENT BODY FAT

Four studies (Baxter 1995; Lean 1997; Harvey-Berino 1998; McManus 2001) reported change in percent body fat at the six month follow-up. However, the results from Harvey-Berino 1998 were not reported consistently between the two publications and it was decided not to include them in a single overall estimate of effect (comparison 01.07). There was no significant difference in the change in percent body fat between the groups at the six month follow-up (WMD 0.01, 95% CI -0.88 to 0.90). The test for heterogeneity for this outcome measure was not significant.

Only two studies (Harvey-Berino 1998; McManus 2001) reported change in percent body fat at the 12 month follow-up (comparison 01.08). There was a significant reduction in the percent body fat in the control group compared with the treatment group at

12 months (WMD 2.94, 95% CI 0.42 to 5.47). The test for heterogeneity for this outcome measure was not significant.

WAIST-HIP RATIO

Three studies (Baxter 1995; Lean 1997; McManus 2001) reported change in waist-hip ratio at the six month follow-up (comparison 01.09). There was no significant difference in waist-hip ratio between the groups (WMD 0, 95% CI -0.01 to 0.02). The test for heterogeneity for this outcome measure was not significant.

ADDITIONAL OUTCOME MEASURES

SERUM LIPIDS

Three studies reported changes in serum lipids at three different timepoints over the follow-up period (Baron 1986; Pascale 1995; Lean 1997). Baron 1986 found a modest but non-significant fall in total cholesterol and HDL cholesterol at one month, however there were no significant differences between the dietary groups on any lipid parameter at either the one month or three months follow-up. Lean 1997 found a significant reduction in total cholesterol in the low fat group at three months (difference from baseline = -0.33 mmol/L; 95% CI -0.55 to -0.10) and at six months (difference from baseline = -0.34 mmol/L; 95% CI -0.56 to -0.13), however, there were no significant differences between the two dietary groups at either timepoint for any of the lipid parameters. Pascale 1995 found a significant difference in total cholesterol at one year follow-up. Patients in the low-fat group had significantly greater improvements than those on calorie reduction alone (low fat group -0.18 mmol/L; 95% CI -0.46 to 0.10 versus calorie reduction group 0.24 mmol/L; 95% CI -0.32 to 0.80). There were no significant differences between the dietary groups on any other lipid parameter.

BLOOD PRESSURE

Only one study (Lean 1997) measured changes in blood pressure from baseline and found no significant differences between the dietary groups at the 6 month follow-up. In both groups the changes in blood pressure were minimal and non-significant.

GLUCOSE PROFILE

Two studies (Baron 1986; Pascale 1995) reported fasting plasma glucose at different timepoints. Baron 1986 reported fasting plasma glucose at one month and six months follow-up and Pascale 1995 reported it at 12 months follow-up. In both cases there were no significant differences between the dietary groups.

OTHER EFFECTS OF THE DIETS

The only specific adverse effect associated with one of the dietary interventions was reported by Baron 1986. In this study the control group (low carbohydrate diet) complained of experiencing constipation more than the low fat group (23% versus 3%). Two studies (Baxter 1995; Harvey-Berino 1998) measured other factors associated with dietary adherence. At the six month follow-

up, Harvey-Berino 1998 found that participants in the control diet (low energy) had a significantly greater increase in perceived wellness than those in the low fat group. There were no differences between the two diet groups in relation to other factors such as distaste, cost or feelings of deprivation. However, the control group reported an increase in the perceived inconvenience of the diet. Baxter 1995 found that participants in the control diet (low energy) reported a significant deterioration in palatability and quality of life.

DIFFERENCES BETWEEN THE STUDIES

Baxter 1995 was the only study to show a reduction in weight in the low fat compared to the low energy group at each time point, although the difference was not significant. However, comparisons between the two groups indicates that participants in the low fat group consumed significantly less fat, protein and total energy at baseline, prior to any dietary advice.

In most studies the losses to follow-up were relatively evenly distributed between the groups. In McManus 2001, where the intervention continued for 18 months, the low fat group lost proportionately more participants at each time point. At six months there were 62% of participants remaining in the control group and only 45% remaining in the low fat group. By 12 months the difference was 54% in the control group and only 25% in the low fat group. At 18 months participation had fallen to 48% and 20%, respectively. However, at 18 months the investigators were able to contact and weigh 60% of the participants from both groups, even though some were no longer adhering to the diet.

SUBGROUP ANALYSES

No subgroup analyses were conducted due to the small number of studies identified and the differences among the studies.

SENSITIVITY ANALYSES

No sensitivity analyses were conducted due to the small number of studies identified and the generally poor quality of the studies. Apart from McManus 2001, no study clearly described the randomisation procedure and no study provided details on blinding of caregivers, participants or outcome assessors. Two studies (Lean 1997; McManus 2001) included an intention to treat analysis but the information provided in McManus 2001 was scant and did not allow the data to be combined for a single effect measure.

DISCUSSION

SUMMARY OF FINDINGS

The results of this systematic review show that there is no real difference between a low fat diet and other weight-reducing diets in terms of long-term weight loss. In most of the studies, apart from one (Harvey-Berino 1998), there were small, non-significant

differences in weight loss between the low fat diet groups and the comparison groups. Harvey-Berino 1998 reported significantly greater reductions in weight among the control participants at all time points and McManus 2001 reported similar results at the 18 month follow-up. However, both of these studies had losses to follow-up of 40% and should be viewed cautiously. Furthermore, the overall weight loss over the moderate to long term in all studies was so small (2 to 4 kg) as to be clinically insignificant.

The changes in other measures of effect, such as serum lipids and blood pressure, were also unremarkable and clinically insignificant. There were some factors, such as feelings of wellness and quality of life, which may be important considerations as they can affect dietary adherence. However, the results of these were contradictory between the studies in which they were measured and do not allow us to make any firm conclusions about how the different diets might affect the perceived well being of individuals.

LIMITATIONS OF THE REVIEW

The two main problems associated with the assessment of the effectiveness of diet interventions in overweight and obese individuals is the paucity of long-term studies and the relatively large losses to follow-up. The six studies included in this review, while being longer than most diet studies, showed up to 40% losses to follow-up. In one study, (McManus 2001) there was a proportionally larger drop-out rate in the low fat group compared with the control group such that at 18 months only 20% of the low fat group remained in the study compared with almost half of the control group. Thus, it is not possible to make valid conclusions about the relative effectiveness of the different dietary interventions. Furthermore, including an intention to treat analysis using the last value (i.e. weight) carried forward may not be an appropriate solution since most people lose weight initially and then regain it over time. Thus, carrying forward an earlier weight for the final analysis would tend to overestimate the loss of weight long-term.

The results of the studies in terms of the main outcome measure (weight loss) were heterogeneous. As mentioned previously, this was mainly due to the results of one study (Harvey-Berino 1998) and whilst not qualitatively different to most of the other studies (apart from Baxter 1995) it showed a much greater and statistically significant reduction in weight in the control group. The reasons for this difference is not clear. The subjects were of similar age, predominantly female and recruited through advertisements. The dietary interventions were delivered in a similar way to the other studies and it appeared that the same individuals (a therapist and a dietitian) were responsible for leading both groups in their weekly sessions. The only major difference between this study and the others is that there was no absolute difference between the two groups in terms of fat consumption during the follow-up. However, based on self-report, the energy intake in the low fat group was slightly less than the low calorie group at 12 and 18 months and seems to be incongruent with the differences in weight loss.

In the only study (Baxter 1995) to report a greater weight loss in the low fat group compared with the control group at each time point, there were established differences in the patterns of eating at baseline indicating that the low fat group already consumed less fat and had a lower energy intake. The low fat group reduced their fat intake to a greater extent than the low energy group over the course of the intervention.

This review suggests that fat-restricted diets are no better than calorie restricted diets in achieving long term weight loss in overweight or obese people. Overall, participants lost slightly more weight on the control diets but this was not significantly different from the weight loss achieved through dietary fat restriction and was so small as to be clinically insignificant.

AUTHORS' CONCLUSIONS

Implications for practice

While this review did not show any long-term weight loss benefits associated with low fat diets, dietary fat restriction has been shown to reduce the incidence of cardiovascular events, particularly in high risk patients (Hooper 2000). However, overweight and obese individuals have considerable difficulty in maintaining dietary restrictions over a long period of time. Recognition of their dietary preferences may facilitate adherence to one type of diet in the long-term.

Implications for research

Further high quality research is needed to identify which type of weight loss diet is most efficacious in the long-term. Future trials would incorporate appropriate methods of randomisation and blinding of outcome assessors. Whilst drop-outs and withdrawals can not always be controlled, every effort should be made to ascertain the reasons for withdrawals so that factors affecting dietary

adherence can be further elucidated. The influence of different types of counselling and support associated with the dietary intervention could be investigated in a factorial design.

NOTES

The protocol for this review was handled by the Cochrane Hypertension Group. The review has now moved under the auspices of the Cochrane Metabolic and Endocrine Disorders Group which has been involved in the final editing of the review.

POTENTIAL CONFLICT OF INTEREST

None known.

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REFERENCES

References to studies included in this review

Baron 1986 *{published data only}*

Baron JA, Schori A, Crow B, Carter R, Mann J. A randomized controlled trial of low carbohydrate and low fat/high fiber diets for weight loss. *American Journal of Public Health* 1986;**76**:1293–6.

Baxter 1995 *{published data only}*

Jeffery RW, Hellerstedt W, French S, Baxter J. A randomized trial of counseling for fat restriction versus calorie restriction in the treatment of obesity. *International Journal of Obesity* 1995;**19**:132–7.

Shah M, Baxter J, McGovern P, Garg A. Nutrient and food intake in obese women on a low-fat or low-calorie diet. *American Journal of Health Promotion* 1996;**10**:179–82.

Shah M, McGovern P, French S, Baxter J. Comparison of a low-fat, ad libitum complex-carbohydrate diet with a low-energy diet in moderately obese women. *American Journal of Clinical Nutrition* 1994;**59**:980–4.

Harvey-Berino 1998 *{published data only}*

Harvey-Berino J. Calorie restriction is more effective for obesity treatment than dietary fat restriction. *Annals of Behavioral Medicine* 1999;**21**:35–9.

*Harvey-Berino J. The efficacy of dietary fat vs total energy restriction for weight loss. *Obesity Research* 1998;**6**(3):202–7.

Lean 1997 *{published data only}*

Lean MEJ, Han TS, Prvan T, Richmond PR, Avenell A. Weight loss with high and low carbohydrate 1200 kcal diets in free living women. *European Journal of Clinical Nutrition* 1997;**51**:243–8.

McManus 2001 *{published data only}*

McManus K, Antinoro L, Sacks F. A randomized controlled trial of a moderate-fat, low-energy diet compared with a low fat, low-energy diet for weight loss in overweight adults. *International Journal of Obesity and Related Metabolic Disorders* 2001;**25**:1503–11.

Pascale 1995 *{published data only}*

Pascale RW, Wing RR, Butler BA, Mullen M, Bononi P. Effects of a behavioral weight loss program stressing calorie restriction versus calorie plus fat restriction in obese individuals with NIDDM or a family history of diabetes. *Diabetes Care* 1995;**18**:1241–8.

References to studies excluded from this review**Pritchard 1996**

*Pritchard JE, Nowson CA, Wark JD. Bone loss accompanying diet-induced or exercise-induced weight loss: a randomised controlled study. *International Journal of Obesity* 1996;**20**:513–20.

Toubro 1997

Toubro S, Astrup A. Randomised comparison of diets for maintaining obese subjects' weight after major weight loss: ad lib, low fat, high carbohydrate diet v fixed energy diet. *British Medical Journal* 1997;**314**:29–34.

Westerterp 1996

Westerterp KR, Verboeket-van de Venne WP, Westerterp-Plantenga MS, Velthuis-te Wierik EJM, de Graaf C, Weststrate JA. [Dietary fat and body fat: an intervention study]. *International Journal of Obesity* 1996;**20**:1022–6.

Additional references**Astrup 2000**

Astrup A, Ryan L, Grunwald G, Storgaard M, Saris W, Melanson E, Hill JO. The role of dietary fat in body fatness: evidence from a preliminary meta-analysis of ad libitum low-fat dietary intervention studies. *British Journal of Nutrition* 2000;**83 Suppl 1**:S25–32.

Ayyad 2000

Ayyad C, Andersen T. Long-term efficacy of dietary treatment of obesity: a systematic review of studies published between 1931 and 1999. *Obesity Reviews* 2000;**1**:113–9.

Barbagallo 2001

Barbagallo CM, Cavera G, Sapienza M, Noto D, Cefalu AB, Pagano M, et al. Prevalence of overweight and obesity in a rural southern Italy population and relationships with total and cardiovascular mortality: the Ventimiglia di Sicilia project. *International Journal of Obesity and Related Metabolic Disorders* 2001;**25**:185–90.

Bender 1998

Bender R, Trautner C, Spraul M, Berger M. Assessment of excess mortality in obesity. *American Journal of Epidemiology* 1998;**147**:42–8.

Bender 1999

Bender R, Jöckel KH, Trautner C, Spraul M, Berger M. Effect of age on excess mortality in obesity. *Journal of the American Medical Association* 1999;**281**:1498–504.

Burton 1985

Burton BT, Foster WR, Hirsch J, Vanitallie TB. Health implications of obesity: NIH consensus development conference. *International Journal of Obesity and Related Metabolic Disorders* 1985;**9**:155–69.

Carmichael 1999

Carmichael AR. Treatment for morbid obesity. *Postgraduate Medical Journal* 1999;**75**:7–12.

Chalmers 1990

Chalmers I, Adams M, Dickersin K, Hetherington J, Tarnow-Mordi W, Meinert C, et al. A cohort study of summary reports of controlled trials. *Journal of the American Medical Association* 1990;**263**:1401–5.

Douketis 1999

Douketis JD, Feightner JW, Attia J, Feldman WF. Periodic health examination, 1999 update. Detection, prevention and treatment of obesity. Canadian Task Force on Preventive Health Care. *Canadian Medical Association Journal* 1999;**169**:513–25.

Flegal 1998

Flegal MD, Carroll RJ, Kuczmarski RJ, Johnson CL. Overweight and obesity in the United States: prevalence and trends, 1960–1994. *International Journal of Obesity and Related Metabolic Disorders* 1998;**22**:39–47.

Glenny 1997

Glenny A-M, O'Meara S, Melville A, Sheldon T, Wilson C. The treatment and prevention of obesity: a systematic review of the literature. *International Journal of Obesity* 1997;**21**:715–37.

Hardeman 2000

Hardeman W, Griffin S, Johnston M, Kinmonth AL, Wareham NJ. Interventions to prevent weight gain: a systematic review of psychological models and behaviour change models. *International Journal of Obesity* 2000;**24**:131–43.

Hjermann 1981

Hjermann I, Holme I, Velve Byre K. Effect of diet and smoking intervention on the incidence of coronary heart disease. Report from the Oslo Study Group of a randomised trial in healthy men. *Lancet* 1981;**2 (8259)**:1303–10.

Hooper 2000

Hooper L, Summerbell CD, Higgins JPT, Thompson RL, Clements G, Capps N, et al. Reduced or modified dietary fat for prevention of cardiovascular disease (Cochrane Review). *The Cochrane Library* 2000, Issue 2.

Katzmarzyk 2001

Katzmarzyk PT, Craig CL, Bouchard C. Original article underweight, overweight and obesity: relationships with mortality in the 13-year follow-up of the Canada Fitness Survey. *Journal of Clinical Epidemiology* 2001;**54**:916–20.

Lee 1999

Lee CD, Blair SN, Jackson AS. Cardiorespiratory fitness, body composition, and all-cause and cardiovascular disease mortality in men. *American Journal of Clinical Nutrition* 1999;**69**:373–80.

Lissner 1987

Lissner L, Levitsky DA, Strupp BJ, Kalkwarf HJ, Roe DA. Dietary fat and the reduction of energy intake in human subjects. *American Journal of Clinical Nutrition* 1987;**46**:886–92.

Manson 1995

Manson JE, Willett WC, Stampfer MJ, Colditz GA, Hunter DJ, Hankinson SE, et al. Body weight and mortality among women. *New England Journal of Medicine* 1995;**333**:677–85.

Must 1999

Must A, Spadano J, Coakley EH, Field AE, Colditz G, Dietz WH. The disease burden associated with overweight and obesity. *Journal of the American Medical Association* 1999;**282**:1523–9.

NIH 1998

National Heart, Lung, and Blood Institute. Bethesda, Maryland: National Institutes of Health. Clinical guidelines on the identification, evaluation, and treatment of overweight and obesity in adults. http://www.nhlbi.nih.gov/nhlbi/guidelns/ob_home.htm 1998.

Ornish 1990

Ornish D, Brown SE, Scherwitz LW. Can lifestyle changes reverse coronary heart disease?. *Lancet* 1990;**336**:129–33.

Singh 1992

Singh R. Randomised controlled trial of cardioprotective diet in patients with recent acute myocardial infarction: results of one year follow up. *British Medical Journal* 1992, (304):1015–9.

Thompson 2001

Thompson D, Wolf AM. The medical-care cost burden of obesity. *Obesity Reviews* 2001;**2**:189–97.

Wadden 1993

Wadden TA. Treatment of obesity by moderate and severe caloric restriction. *Annals of Internal Medicine* 1993;**119**:688–93.

WHO 1998

World Health Organisation (WHO). Obesity: Preventing and managing the Global Epidemic - Report of a WHO Consultation on Obesity, 3-5 June 1997, Geneva, WHO/NUT/NCD/98.1.

* Indicates the major publication for the study

T A B L E S**Characteristics of included studies**

Study	Baron 1986
Methods	DESIGN: Parallel; Randomisation method not described; BLINDING: patients - no caregivers - no outcome assessors - no DURATION OF INTERVENTION: 3 months DROPOUTS: 11%
Participants	COUNTRY: Britain N = 135 AGE RANGE: 16 - 70 years

Characteristics of included studies (Continued)

	MEAN AGE: 40 MALES: 15% WEIGHT ENTRY CRITERIA: weight > upper limit of acceptable weight for 'medium' framed person (Met Life) EXCLUSION CRITERIA: dieted in last 3 months; within 6 months of childbirth or still breastfeeding
Interventions	INTERVENTION DIET: N=69 1000-1200 kcal/day; low fat//high fibre; fat not > 30g/day CONTROL DIET: N=66 1000- 1200 kcal/day; low carbohydrate/ low fibre; carbohydrate not > 50 g/day BOTH GROUPS: General orientation to dieting and limited discussion of behavioural techniques and value of exercise. Given diet instruction sheets and verbal advice. Weekly meetings with group (at diet club) for 3 months FOLLOW-UP: 12 months
Outcomes	BODY MEASURES: weight LIPID PROFILE: (only at 3 month follow-up) Total, HDL, LDL, and VLDL cholesterol, triglycerides GLUCOSE PROFILE: (only at 3 month follow-up) fasting plasma glucose
Notes	
Allocation concealment	B – Unclear

Study	Baxter 1995
Methods	DESIGN: Parallel; Randomisation method not described; BLINDING: patients - no caregivers - unclear outcome assessors - unclear DURATION OF INTERVENTION: 6 months DROPOUTS: 40% Analysis by treatment received
Participants	COUNTRY: USA N = 122 AGE RANGE: 25 - 45 years MEAN AGE: 36 MALES: 0% WEIGHT ENTRY CRITERIA: 120-140% of ideal body weight (Met Life); EXCLUSION CRITERIA:

Characteristics of included studies (Continued)

	smokers, consumed >20 alcoholic drinks/week, pregnant or lactating, suffered from chronic disease or psychiatric problems
Interventions	INTERVENTION DIET: N=61 low fat, ad libitum complex carbohydrate (down to 20 g fat/day over 8 weeks) CONTROL DIET: N=61 low energy - 4184- 5021 kJ/day); reduce fat to 30% of total energy; BOTH GROUPS: Dietitian gave advice on how to follow diets and specific food recommendations; provided examples of meals; given counselling on self-monitoring and how to increase physical activity; completed exercise and food diary daily; also given written materials. Met for 16 group sessions over 6 months - weekly for 6 weeks then fortnightly for 20 weeks. FOLLOW-UP 12 and 18 months
Outcomes	BODY MEASURES: weight (each time period), BMI, % body fat, waist-hip ratio (only at 6-month follow-up) OTHER: Quality of Life, Palatability, Satiety (only at 6 and 12 month follow-ups)
Notes	
Allocation concealment	B – Unclear

Study **Harvey-Berino 1998**

Methods	DESIGN: Parallel; Randomisation method not described; BLINDING: patients - no caregivers - unclear outcome assessors - unclear DURATION OF INTERVENTION: 6 months DROPOUTS: 40% Analysis by treatment received
Participants	COUNTRY: USA N = 80 AGE RANGE: 25 - 45 years MEAN AGE: 38 MALES: 19% WEIGHT ENTRY CRITERIA: 120%-140% of ideal body weight (Met Life) EXCLUSION CRITERIA: smokers, pregnant or lactating, history of chronic disease or psychosis
Interventions	INTERVENTION DIET: N=? (number allocated not provided) low fat diet- 22-26 g/day; unrestricted carbohydrates CONTROL DIET: N=? (number allocated not provided) low calorie diet - 1000-1200 cal/day BOTH GROUPS: Given advice on how to follow diet; given counselling on behavioural modification strategies and self-management skills and how to increase physical activity; completed exercise and food diary daily;

Characteristics of included studies (Continued)

	Weekly meetings with group for 6 months FOLLOW-UP: 12 and 18 months
Outcomes	BODY MEASURES: weight, BMI, % body fat OTHER: wellness, distaste, cost, inconvenience, deprivation, family issues
Notes	
Allocation concealment	B – Unclear

Study	Lean 1997
Methods	DESIGN: Parallel; Randomisation method not described; BLINDING: patients - unclear caregivers - no outcome assessors - unclear DURATION OF INTERVENTION: 6 months DROPOUTS: 25% Included intention to treat analysis
Participants	COUNTRY: Scotland N = 110 AGE RANGE: 18 - 68 years MEAN AGE: 51 MALES: 0% WEIGHT ENTRY CRITERIA: BMI > or = 25 kg/m ² EXCLUSION CRITERIA: free from active disease
Interventions	INTERVENTION DIET: N=57 1200 kcal high carbohydrate diet - carbohydrate (58%), fat (21%), protein (21%) CONTROL DIET: N=53 1200 kcal low carbohydrate diet - carbohydrate (35%), fat (35%), protein (30%) BOTH GROUPS: Dietitian gave advice on how to follow diets and specific food recommendations; provided with specially written recipes and other written material; Reviewed every 6 weeks for 6 months (in hospital outpatients); telephone contact by dietitian. FOLLOW-UP: 12 months
Outcomes	BODY MEASURES: weight, BMI, % body fat, waist-hip ratio LIPID PROFILE: total, HDL and LDL cholesterol, triglycerides OTHER: blood pressure

Characteristics of included studies (Continued)

Notes

Allocation concealment B – Unclear

Study	McManus 2001
Methods	DESIGN: Parallel; Randomisation method described; BLINDING: patients - unclear caregivers - unclear outcome assessors - unclear DURATION OF INTERVENTION: 18 months DROPOUTS: 40% Included intention to treat analysis
Participants	COUNTRY: USA N = 101 AGE RANGE: 34-54 years MEAN AGE: 44 MALES: 12% WEIGHT ENTRY CRITERIA: BMI between 26.5 to 46 kg/m ² ; EXCLUSION CRITERIA: smokers, suffering from chronic disease , unwilling to attend weekly classes
Interventions	INTERVENTION DIET: N=51 low-fat 1200-1500 kcal - carbohydrate (60-65%), fat (20%), protein (15-20%) CONTROL DIET: N=50 Moderate fat 1200-1500 kcal - carbohydrate (45-50%), fat (35%), protein (15-20%) BOTH GROUPS: Dietitians (one to each group) gave advice on how to follow diets and specific food recommendations; provided with meal plans and sample menus; teaching modules addressed behavioural modification skills and physical activity; completed daily food diary; Weekly meetings with group for 18 months FOLLOW-UP: 12 and 18 months
Outcomes	BODY MEASURES: weight, BMI, % body fat, waist-hip ratio
Notes	
Allocation concealment	B – Unclear

Study	Pascale 1995
Methods	DESIGN: Parallel; Randomisation method not described; BLINDING: patients - unclear caregivers - unclear

outcome assessors - unclear
 DURATION OF INTERVENTION:
 4 months
 DROPOUTS: 33%
 Analysis by treatment received

Participants	COUNTRY: USA N = 46 AGE RANGE: 34 - 51 years MALES: 0% WEIGHT ENTRY CRITERIA: Weight > or = 20% above ideal body weight (Met Life) EXCLUSION CRITERIA: not having a biological parent with type 2 diabetes
Interventions	INTERVENTION DIET: N=23 1000-1500 kcal/ day; low fat (20% total energy) CONTROL DIET: N=23 1000- 1500 kcal/day; BOTH GROUPS: Given advice on how to follow diet; given counselling on behavioural modification strategies and self-management skills and how to increase physical activity; completed exercise and food diary daily; Weekly meetings with group for 4 months FOLLOW-UP: 12 months
Outcomes	BODY MEASURES: weight, BMI LIPID PROFILE: total, HDL and LDL cholesterol, triglycerides GLUCOSE PROFILE: fasting plasma glucose
Notes	
Allocation concealment	B – Unclear

Characteristics of excluded studies

Study	Reason for exclusion
Pritchard 1996	Low fat diet compared with aerobic exercise; control group told not to change diet
Toubro 1997	Initial weight loss compared between slow and rapid weight loss (not low fat compared with another diet method) followed by weight maintenance program
Westerterp 1996	1. Not all participants were obese or overweight 2. Control diet was not weight reducing - participants advised to consume a minimum of 37g of fat/day 3. Participants shopped freely in study supermarket and was diet provided free of charge

ANALYSES

Comparison 01. Low fat diet vs other type of diet

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Mean weight loss at 6 months	4	282	Weighted Mean Difference (Random) 95% CI	1.72 [-1.39, 4.83]
02 Mean weight loss at 12 months	5	312	Weighted Mean Difference (Random) 95% CI	1.06 [-1.62, 3.75]
03 Mean weight loss at 18 months	3	183	Weighted Mean Difference (Random) 95% CI	3.66 [-1.84, 9.15]
04 Mean change in BMI at 6 months	4	282	Weighted Mean Difference (Random) 95% CI	0.69 [-0.58, 1.96]
05 Mean change in BMI at 12 months	3	117	Weighted Mean Difference (Random) 95% CI	1.18 [-0.69, 3.04]
06 Mean change in BMI at 18 months	2	109	Weighted Mean Difference (Random) 95% CI	2.44 [1.54, 3.33]
07 Mean change in percent body fat at 6 months	3	224	Weighted Mean Difference (Random) 95% CI	0.01 [-0.88, 0.90]
08 Mean change in percent body fat at 12 months	2	88	Weighted Mean Difference (Random) 95% CI	2.94 [0.42, 5.47]
09 Mean change in waist-hip ratio at 6 months	3	224	Weighted Mean Difference (Random) 95% CI	0.00 [-0.01, 0.02]

INDEX TERMS

Medical Subject Headings (MeSH)

*Diet, Fat-Restricted; Energy Intake; Obesity [*diet therapy]; Weight Loss

MeSH check words

Female; Humans; Male

COVER SHEET

Title	Advice on low-fat diets for obesity
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Contribution of author(s)	SANDI PIROZZO: searching for trials, initial screening of studies, trial selection, quality assessment of trials, data extraction, data analysis, development of final review CAROLYN SUMMERBELL: protocol development, searching for trials, quality assessment of trials, data extraction CATE CAMERON: searching for trials, initial screening of studies, trial selection, quality assessment of trials, data extraction PAUL GLASZIOU: protocol development, data analysis and interpretation, editing and proofreading of final document
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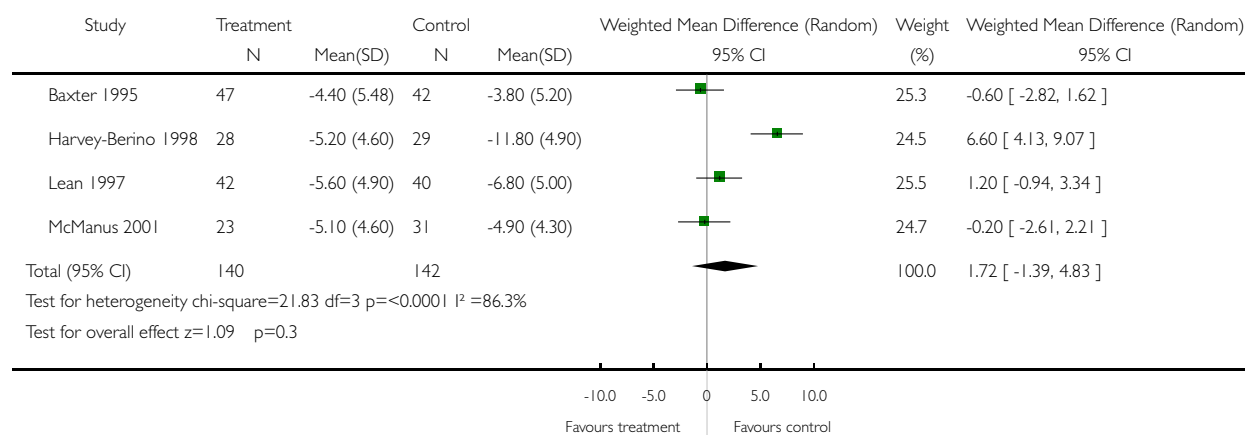
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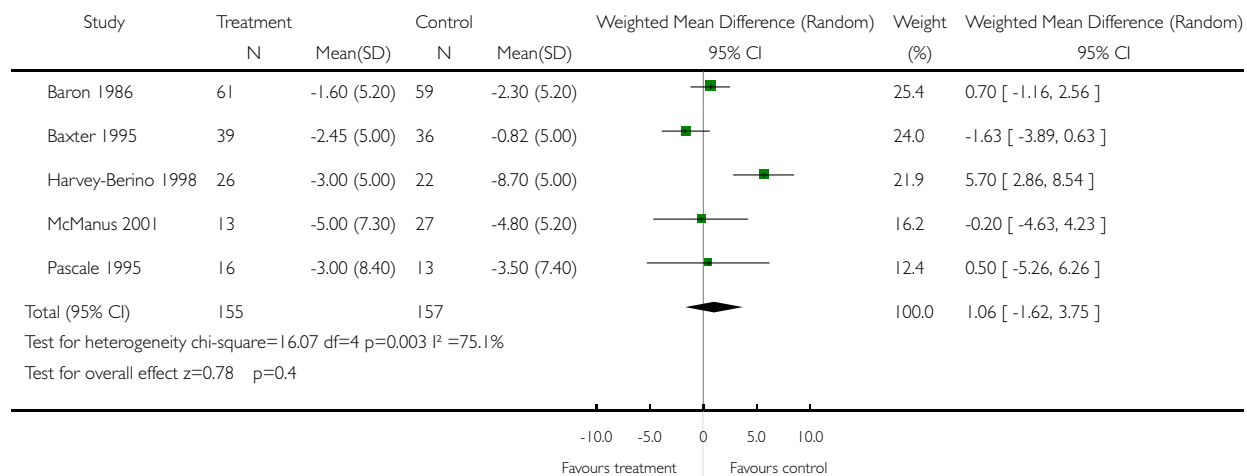


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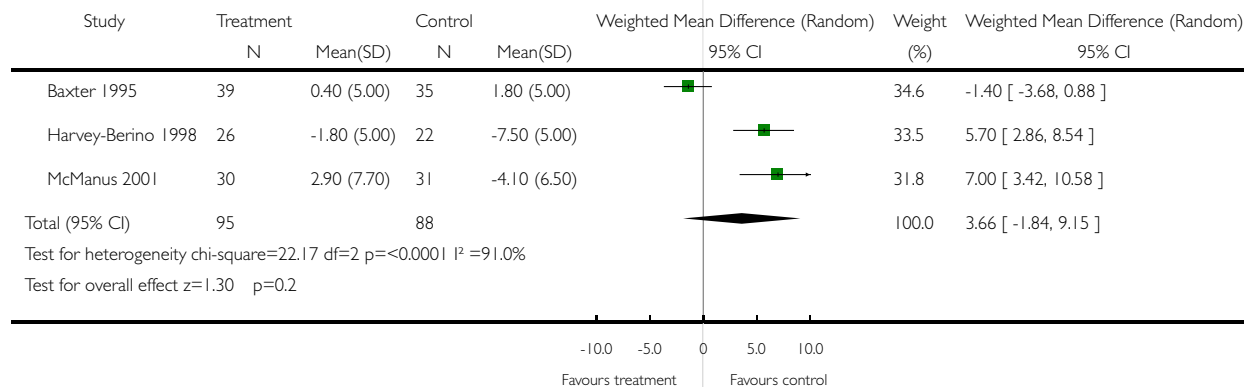


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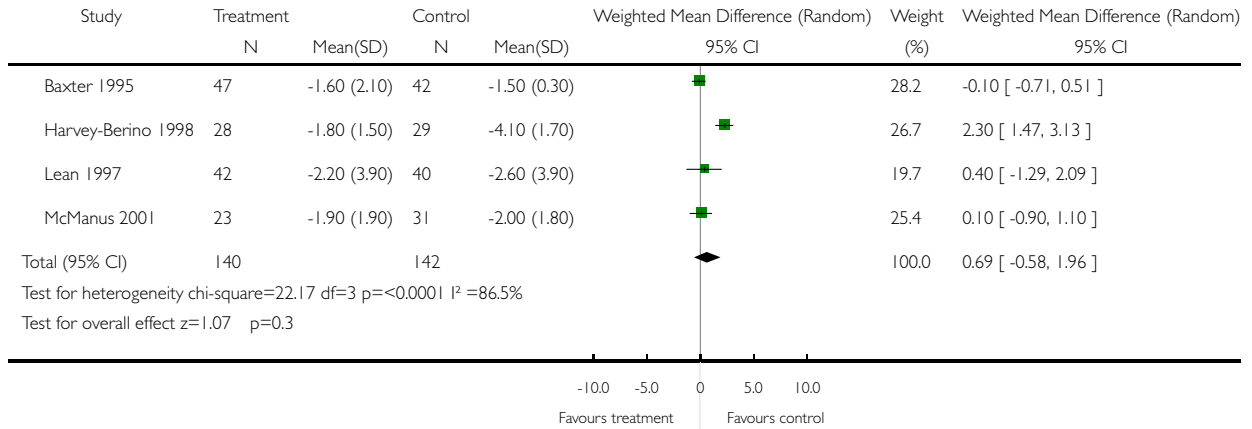


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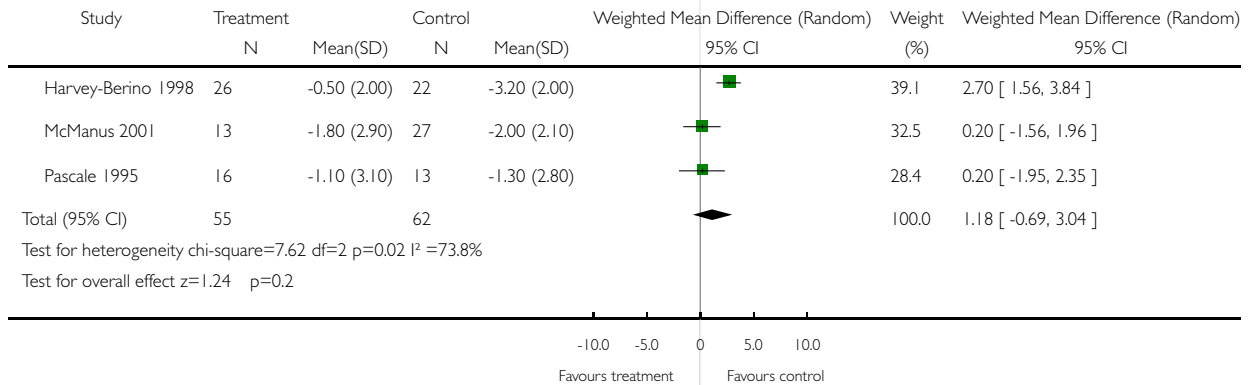


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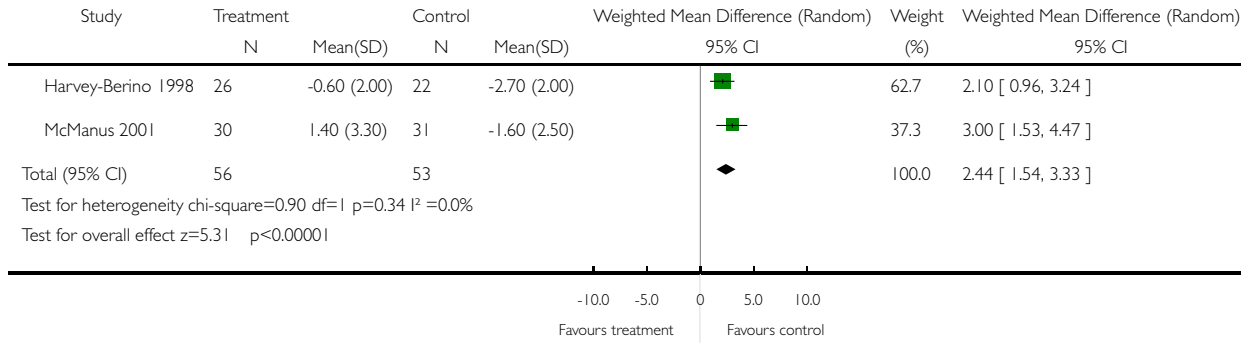


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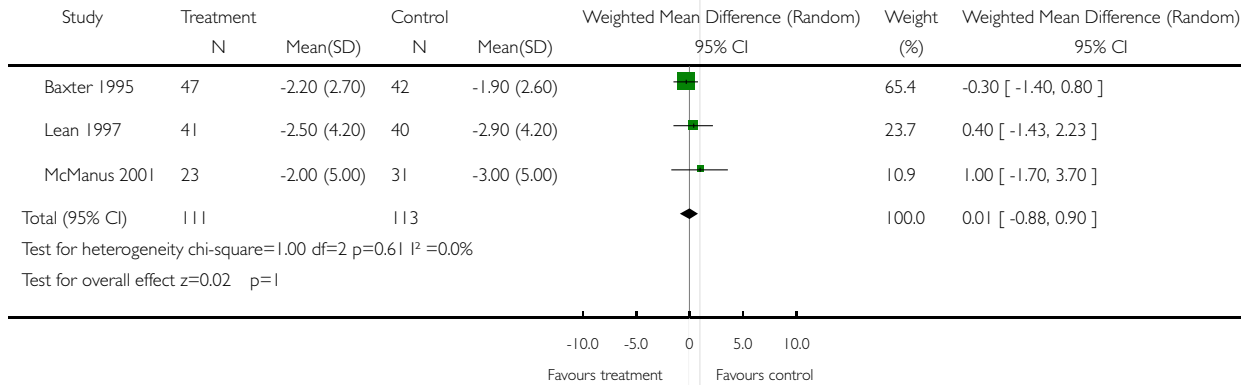


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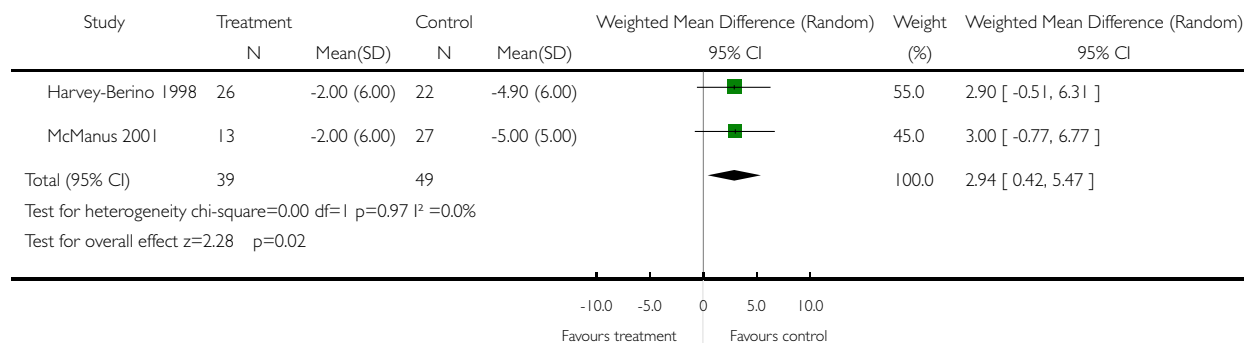


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