THE UNIVERSITY of York

NHS CENTRE FOR REVIEWS & DISSEMINATION

Systematic Review of Interventions in the Treatment of Prevention of Obesity

CRD REPORT 10

Systematic Review of Interventions in the Treatment and Prevention of Obesity

NHS Centre for Reviews and Dissemination
University of York

Anne-Marie Glenny
Susan O'Meara

August 1997

ISBN 1 900640 09 0

This report can be ordered from: Publications Office, NHS Centre for Reviews and Dissemination, University of York, York YO1 5DD. Telephone 01904 433648; Facsimile: 01904 433661: email: revdis@york.ac.uk

Price £12.50

The NHS Centre for Reviews and Dissemination is funded by the NHS Executive and the Health Departments of Scotland, Wales and Northern Ireland; a contribution to the Centre is also made by the University of York. The views expressed in this publication are those of the authors and not necessarily those of the NHS Executive or the Health Departments of Scotland, Wales or Northern Ireland.

Printed by York Publishing Services Ltd.

NHS CENTRE FOR REVIEWS AND DISSEMINATION

The NHS Centre for Reviews and Dissemination (CRD) is a facility commissioned by the NHS Research and Development Division. Its aim is to identify and review the results of good quality health research and to disseminate actively the findings to key decision makers in the NHS and to consumers of health care services. In this way health care professionals and managers can ensure their practice reflects the best available research evidence. The reviews will cover: the effectiveness of care for particular conditions; the effectiveness of health technologies; and evidence on efficient methods of organising and delivering particular types of health care.

Further Information

General Enquiries:	01904 433634
Information Service	01904 433707
Publications:	01904 433648
Fax:	01904 433661
Email:	revdis@york.ac.uk

Publications

CRD Reports

1.	Which Way Forward for the Care of Critically Ill Children? (1995)	£7.50
2.	Relationship Between Volume and Quality of Health Care: A Review of the Literature (1995)	£5.00
3.	Review of the Research on the Effectiveness of Health Service Interventions to Reduce Variations in Health (1995)	£12.50
4.	Undertaking Systematic Reviews of Research on Effectiveness. CRD Guidelines for those Carrying Out or Commissioning Reviews (1996)	£7.50
5.	Ethnicity and Health: Reviews of Literature and Guidance for Purchasers in the Areas of Cardiovascular Disease, Mental Health and Haemoglobinopathies (1996)	£12.50
6.	Making Cost-Effectiveness Information Accessible: The NHS Economic Evaluation Database Project. CRD Guidance for Reporting Critical Summaries of Economic Evaluations (1996)	£7.50
7.	A Pilot Study of 'Informed Choice' Leaflets on Positions in Labour and Routine Ultrasound (1996)	£7.50
8.	Concentration and Choice in the Provision of Hospital Services (1997)	
	Summary Report	£6.00
	Part I - Hospital Volume and Quality of Health Outcomes	£12.50
	Part II - Volume and the scope of activity and hospital costs	£9.50
	Part III - Concentration, patient accessibility and utilisation of services	£7.50
	Complete set of reports	£30.00
9.	Preschool Vision Screening: Results of a Systematic Review (1997)	£9.50

Effectiveness Matters

Vol.1 (1995)	(1)	Aspirin and Myocardial Infarction (1995)
	(2)	Helicobacter Pylori and Peptic Ulcer (1995)
Vol.2 (1996)	(1)	Influenza Vaccination and Older People (1996)
	(2)	Screening for Prostate Cancer (1997)

ACKNOWLEDGEMENTS

The NHS Centre for Reviews and Dissemination would like to acknowledge the helpful assistance of the members of the expert panel;

David Booth, University of Birmingham

Michael Brand, San Antonio Cochrane Center

Gill Cowburn, Health Education Authority

Emma Harvey, University of York

Joyces Hughes, Nutrition Unit, Department of Health

Susan Jebb, Dunn Nutrition Centre

Alan Johnson, University of Sheffield

David Johnston, University of Leeds

Peter Kopelman, Royal Hospitals NHS Trust

Michael Lean, University of Glasgow

Alan Maryon-Davis, Lambeth, Southwark and Lewisham HA

Carolyn Summerbell, University of London

and other referees from the Department of Health.

This review was commissioned by the Research and Development Division of the Department of Health to inform the work of the Nutrition Unit by identifying the current state of knowledge of obesity, and to highlight future research needs. The views expressed in this publication may not necessarily be those of the commissioning body.

RESEARCH TEAM:

Julie Glanville

Anne-Marie Glenny

Arabella Melville

Susan O'Meara

Frances Sharp

Trevor Sheldon

Colin Wilson

CONTENTS

EXECUTIVE SUMMARY

Objective

To assess the effectiveness of interventions used in the prevention and treatment of obesity and the maintenance of weight loss.

Background

The prevalence of obesity in developed societies is increasing. In England in 1994 it was estimated that that 13% of men and 16% of women aged 16 to 64 years were obese, double the figures given for 1980. At the current rate of increase, the Health of the Nation target for England (prevalence of obesity 6% for men and 8% for women by the year 2005) is unlikely to be met. Existing evidence shows that avoiding overweight and obesity, and achieving even modest weight loss in obese or overweight persons, is beneficial to health. Health professionals often have negative attitudes towards obese patients, and may lack the resources required for effective management of the condition.

Methods

A qualitative systematic review of the research literature.

Search strategy

In order to identify relevant articles, electronic databases (including MEDLINE, EMBASE and PsychLIT) were searched (1966-January 1997), bibliographies of existing reviews were examined, and experts in the field were consulted.

Inclusion criteria

Randomised controlled trials (RCTs) examining the effectiveness of interventions aimed at preventing or treating obesity, or maintaining weight loss in which participants were observed for a minimum of one year. In areas where no RCTs were available, the inclusion criteria were relaxed to include non-randomised studies with a concurrent control group. Studies had to report baseline and post-intervention measurements of either weight change, fat distribution or fat loss.

Participants

Overweight and obese adults and children, or those considered to be at risk of developing the condition were included. Those suffering from eating disorders were excluded.

Interventions

Behavioural, dietary, exercise, pharmacological, surgical and alternative therapies were considered for inclusion.

Results

Ninety-nine studies (from 97 papers) were included in the review. Most of the research was carried out in North America. The methodological quality of many studies was poor.

Small samples sizes, high drop-out rates and a lack of intention-to-treat analysis posed problems with interpretation of results.

Family therapy programmes were effective in preventing the progression of obesity in already obese children. Programmes aimed at reducing sedentary behaviour are promising for the treatment of obese children.

The prevention of obesity in adults was successfully achieved by a community-based education programme linked with financial incentives. Behavioural, diet and exercise programmes have all been shown to be effective, to some extent, in the treatment of adult obesity, particularly when two or more approaches are used in combination.

Pharmacological interventions, such as centrally acting appetite suppressants (fenfluramine and dexfenfluramine) and selective serotonin reuptake inhibitors (fluoxetine), appear to produce weight loss for up to 9 months, after which time a proportion of participants regain weight. Since this review was completed, the centrally acting appetite suppressants dexfenfluramine and fenfluramine have been withdrawn due to recent case reports of valvular heart disease.

Surgery is normally considered only for morbidly obese patients. This works by reducing gastric capacity and some techniques also alter gut absorption processes. In general the weight loss associated with surgical interventions is greater and more sustained than that achieved by non-surgical methods. However, surgery is associated with complications that may affect the patient's quality of life.

In most cases, weight loss is followed by weight regain a few months after treatment. Maintenance strategies, such as continued contact (either with therapists or self-help peer groups) have been shown to be effective at reducing the amount of regain.

Conclusions

This review has identified some potentially effective interventions for the management of obesity. However, due to problems with methodological quality, it is recommended that research findings indicative of promising interventions are replicated. In addition, the optimum role for the primary health care team needs to be defined and supported by the appropriate resources. The increasing prevalence of overweight and obesity in many western countries represents an important public health problem. Therefore this area deserves greater investment, both in terms of good quality research and service provision.

1. BACKGROUND

This document aims to summarise the evidence from randomised controlled trials about the effectiveness of interventions in preventing and treating obesity, and the maintenance of weight loss. It focuses on behavioural, dietary, exercise, surgical, pharmacological and complementary interventions.

The data in this section have been drawn from previously published reports and literature reviews on obesity and are intended to provide a background context. This information has not been derived as part of the systematic review process.

1.1 The prevalence of obesity

Epidemiological surveys of England indicate that the prevalence of obesity, defined as a body mass index (BMI) of greater than 30kg/m^2,[1] is increasing. In 1994 it was estimated that 13% of men and 16% of women aged 16 to 64 years were obese.[2] In 1980 the respective figures were 6% and 8%.[3] It is estimated that, at this rate of increase, the figures will reach 18% for men and 24% for women by the year 2005.[1]

In addition, the prevalence of overweight, defined as a BMI of over 25 to 30kg/m^2 is increasing. Between 1991 and 1994, the rates for men rose from 39% to 43% and for women from 26% to 29%, for the age range 16-64. At the current rate of increase, the Health of the Nation target for England (prevalence of obesity 6% for men and 8% for women by the year 2005) is unlikely to be met. Various explanations for these increases have been put forward, such as sedentary lifestyles and higher levels of fat intake.[4]

1.2 Who is at risk of becoming obese?

Certain groups of people are at more risk of developing obesity than others. In families where one or both parents are overweight or obese, the children are at greater risk of developing the condition themselves.[5,6] Risk of obesity is also associated with social class.[7] The age standardised prevalence of obesity in women is 22% and 21% in social classes IV and V respectively, compared to 12% and 14% in classes I and II. A similar trend exists for men, but within a narrower range (10% in social class I to 14% and 13% in social classes IV and V respectively).[2] Trends in obesity can also be recognised with respect to educational achievement. Women with no qualifications show a mean BMI of 26.7kg/m^2 as opposed to a figure of 24.6kg/m^2 in those educated to A level or above. Again, this trend is repeated for men.[2] Smoking cessation is also an important risk factor for weight gain, for either sex.

The risk of obesity may vary between different ethnic groups. It has been suggested that Asian people are at greater risk of developing obesity when compared to Afro-Caribbean and Caucasian people.[8] Asians are particularly at risk of developing abdominal obesity, and there is also an increased prevalence of insulin resistance in this group.

Peoples' risk of obesity varies over the life cycle. The risk of obesity for men increases during the late 30s. However, women may face an increased risk at several stages in their lives, for example when entering marriage, during pregnancy, during the menopause, and at retirement.[1] Smoking cessation is also an important risk factor for weight gain for either sex.[9,10] The benefits of targeting specific groups individually as opposed to the population as a whole have yet to be determined.

1.3 Health risks of obesity

Existing evidence shows that avoiding overweight and obesity, and achieving weight loss in obese or overweight persons, is beneficial to health. The Health of the Nation White paper highlights the link between obesity and ill-health, the obese having an increased disposition to a number of conditions. These include coronary heart disease, hypercholesterolaemia, hypertension, diabetes, cholelithiasis, degenerative joint disease, and social and psychological problems.[11] More specifically, it has been demonstrated that there is a link between android or abdominal obesity and coronary heart disease, hypercholesterolaemia, hypertension, and diabetes. Moreover, obstructive sleep apnoea is a health risk of obesity.[12-15] Finally, concern has been expressed over the so called "weight-cycling" or "yo-yo dieting" whereby some individuals alternate between periods of weight loss and weight regain. The results of several studies indicate that weight cycling is associated with an increased risk of mortality, especially cardiovascular mortality.[16-19] However, a recent review of the literature in this area highlighted methodological problems of these studies, and suggested that their results should be treated with caution.[20]

Due to the increasing number of people with obesity, health care professionals and purchasers are under pressure to intervene to reduce the prevalence of the condition.

1.4 Measurements of obesity

The BMI is frequently used as a measure of overweight and obesity. However, health professionals need to be aware that BMI does not take into account such factors as size of body frame, proportion of lean mass, gender and age. A better predictor of cardiovascular risk is the girth (waist) to height ratio because it is a good measure of central (abdominal) fat distribution. Other measurements of obesity include body weight, percentage over ideal body weight, skinfold thickness and body composition.

2. AIMS AND METHOD OF THE REVIEW

The aim of this review was to systematically assess the effectiveness of interventions designed to prevent and treat obesity/overweight, and maintain weight loss.

2.1 Inclusion and exclusion criteria

To be included, studies had to satisfy criteria of relevance, outcome and design.

2.1.1 Relevance

Studies were deemed to be relevant if they reported evaluations of the effectiveness of interventions in any of the following categories:

(a) Prevention of overweight/obesity
(b) Weight reduction in obese/overweight persons
(c) Maintenance of weight loss

Papers that primarily dealt with the treatment of eating disorders such as anorexia nervosa and bulimia nervosa, were excluded.

2.1.2 Outcome

To be included, studies had to report one or more of the following outcomes, presenting a baseline and a post-intervention measurement:

(a) Measures of weight change, for example, absolute weight loss, percentage of weight loss relative to baseline values.
(b) Measures of fat content, for example, body mass index, ponderal index, skin fold thickness, fat free mass, fat loss.
(c) Measures of fat distribution, for example, waist-hip ratio, girth-height ratio, waist size.

2.1.3 Design

As randomised controlled trials (RCTs) provide the most reliable evidence for the effectiveness of interventions, it was decided to include only studies of this design. However, for studies addressing the prevention of obesity, no RCTs were available. Therefore, for this category, non-randomised studies with a concurrent control group were accepted. The latter criteria were also applied to studies of complementary therapies since these interventions are rarely evaluated using randomised controlled trials.

A second principle was that all studies had to observe participants for a minimum of one year. The rationale for introducing this criterion arose from a belief that many interventions appear to be effective in the short term, for example 3 to 6 months. However, it seemed to be more important to evaluate the longer term effects of treatments, as this would provide a more valuable indication of

effectiveness, given the chronic nature of obesity. An initial perusal of the literature revealed that studies differed in duration of treatment schedules and follow-up periods. It was therefore decided to include only those studies that incorporated a minimum of a one year observation period, and this could refer to the intervention itself or to a combination of the intervention with a follow-up phase. The start of the one year period relates to the start of the intervention.

2.2 Search strategy

A preliminary search of MEDLINE for review articles on obesity revealed approximately 50 which helped to formulate the research questions for the review.

Using these review articles plus discussions with identified experts in the field, the list of relevant search terms (appendix 1) was drawn up. The search strategy was devised in conjunction with information scientists in the NHS Centre for Reviews and Dissemination and was adapted to suit particular database indexing systems, for example, MeSH on MEDLINE (see sample strategy in appendix 2). Each database was searched from its starting date to the end of January 1997. A list of the databases searched can be found in appendix 3. Relevant reviews were searched for references that might have been missed in the main searching process.

For papers concerned with alternative therapies the database Allied and Alternative Medicine (AMED) was searched together with that of the Research Council for Complementary Medicine (RCCM) (refer to appendix 4 for search details).

2.3 Inclusions and data extraction

Titles and abstracts of studies identified from the database searches were assessed for relevance. A sample of these assessments was checked by a second reviewer. Full papers were obtained if they appeared to meet our criteria or there was doubt as to whether they should be included. Papers obtained were assessed according to the inclusion criteria. Data were extracted from included papers and entered onto a database generated from the Idealist software. The field definitions are presented in appendix 5. Data extraction was checked by a second reviewer.

3. RESULTS

3.1 Literature search results

The searches of the databases listed in appendix 3 generated more than 10,000 references. After the titles (and where available, abstracts) had been assessed, hard copies of 268 papers which were thought to be relevant, were ordered. On further assessment of obtained papers, 97 articles (96 full articles and 1 abstract) met the inclusion criteria.[21-117] The 97 papers report 99 studies.

It is clear from the results of the electronic searches that there is an abundance of literature on the subject of obesity. In order to make the review manageable, it was limited toRCTs as, in general, they give more reliable estimates of effect. However, the quality of the RCTs identified was not always of a high standard. Although 89 of the studies included in the review stated that participant allocation had been random, only eleven papers explained the method of randomisation. Eight of these papers were concerned with surgical interventions,[82,84,85,88,90,94-96] one with pharmacological interventions,[79] one with behavioural interventions,[48] and one with a comprehensive intervention.[117] In all other cases, the method of randomisation is not stated.

With the exception of the community based interventions, the sample sizes for the studies included were small. Sixty-two of the papers reviewed had less than 30 participants in each group. Some of the smallest sample sizes were seen in the studies on children/adolescents where the size of the intervention groups was as low as ten.[29,30] small sample sizes can reduce statistical power and pose problems with the generalisability of study findings.

Drop-out rate was reported in 97% of the included studies. In the majority of cases drop-outs were excluded from the final data analysis, and only six papers stated that analysis was carried out on an intention to treat basis.[21,32,74,77,112,113] Given that drop-out rates can be high in interventions for weight loss, intention to treat analysis is of importance in order to avoid bias due to non random withdrawal of individuals from the trial.

Over 60% of the RCTs identified were conducted in the USA. Only six studies were performed in the UK, and the remaining papers were mainly from other European countries. This is a reflection of the low level of investment in obesity related research in the UK, and the low priority that this topic area is afforded.

For the purpose of summarising the results of this research, prevention and treatment were considered separately for children and adults, and for type of intervention.

Where possible, graphs have been included at the end of each section to illustrate the mean (or median) changes in parameters measured from baseline to final analysis for each intervention. These are displayed with 95% confidence intervals (95%CI) when data has allowed for their calculation. The graphs do not represent pooled data, but serve as a summary of the information from individual trials.

3.2 Studies focusing on children/adolescents (see table 1)

3.2.1 Prevention of obesity in children

There was only one study concerned with the prevention of obesity in children.[21] This addressed the prevention of the progression of severe obesity in already obese school children, aged 10-11 years, with a BMI greater than 23 kg/m^2. Family therapy was compared to conventional treatment and a no treatment group. For this study conventional therapy refers to dietary counselling by a dietician and regular visits to a paediatrician. The family therapy group received the same counselling and check-ups as the conventional therapy group, but they were additionally offered six family therapy sessions spread over 12 months. An important feature of family therapy was the involvement of the whole family, or as many members as possible, in the intervention. During sessions, therapists attempted to reinforce the resources of the family, for example, the family's own belief systems, in order to encourage an optimal environment for helping the obese child. Significant differences were found at the end of treatment (14-18 months) between the family therapy group and the conventional treatment group with respect to percentage increase in BMI (0.66% versus 2.31% respectively, p=0.042), but this difference was not maintained at one year follow-up. No significant differences were found between the conventional therapy group and the no treatment control group. However, at 1 year follow up, it was demonstrated that the percentage of children with severe obesity (defined as a BMI greater than 30kg/m^2) was significantly less in the family therapy group (5%) than in the control group (29%).

3.2.2 Treating both children and parents together

Three studies were concerned with the treatment of obese children and their parents together.[22-24] In one paper,[22] four RCTs were reported. Only two of the RCTs (Study 1 and Study 4) are relevant to this section. Study 1 examined the effect of targeting the parent for weight loss at the same time as the child, compared to targeting the child alone. A third group, where there was a non-specific target, was also examined. The intervention included behaviour modification and the Traffic Light Diet. The aim of the Traffic Light Diet is to decrease saturated fat and sugar intake by separating foods into three categories according to the traffic light colours of red, yellow, and green. Foods in the "green" category may be eaten freely (for example, raw salads and vegetables), those in the "yellow" group should be approached with caution (for example, eggs and dairy products), and items in the "red" group should be avoided (this includes sweet biscuits, confectionery, and fried foods). Analysis at five years follow-up demonstrated that parents and children who were targeted jointly for weight loss had achieved a decrease in their percentage overweight of 15.3%, whereas children in the other groups showed an increase in percentage overweight.

Study 4 examined different types of exercise (aerobic, lifestyle and callisthenics). Lifestyle exercise refers to a programme that can easily be incorporated into a daily routine, and may include activities such as walking or cycling. All three groups received the Traffic Light Diet, as for Study 1. Parents and children had reciprocal reinforcement contingencies, in which they were encouraged to support the behaviour change of each other. At the 10 year follow-up the children undergoing lifestyle or aerobic exercise had achieved a statistically significant greater change in the percentage overweight

when compared to the callisthenics control group (-19.7%, -10.9% and +12.2% respectively). It should be noted that the sample sizes for these individual studies are not reported within the paper.

Two further studies targeting parents and children together, examine the effects of diet and exercise on weight loss in obese children. Epstein et al[23] compared the effect of adding mastery criteria (strategies for taking control of one's own behaviour) and contingent reinforcement to a Traffic Light Diet and an exercise programme. Families in the experimental group received training in reinforcement strategies for weight loss. Additionally, the adults involved were instructed in parenting skills. Both parents and children had to master the behavioural skills at each of five levels before advancement to the next level. The control group were also taught behaviour change strategies, however, they were not required to demonstrate mastery of these changes. The rate of advancement of the control group through the five levels was yoked to the rate of advancement of the mastery criteria group. The main dependent measure for this study was percent over BMI, calculated using the 50th BMI percentile, based on population standards, as the reference. The changes in percent-over-BMI from baseline to 6 months were -30.1 for the experimental group and -20.0 for the control group. At 6 months post-intervention follow-up the changes from baseline were -26.5 and -16.7, and by 18 months follow-up -15.4 and -10.6 for the experimental and control groups respectively. The differences between the groups with regard to percent-over-BMI were statistically significant post-intervention and 6 months follow-up, but not at 18 months follow-up. A similar pattern of results was seen for both children and adults.

In an earlier study by Epstein et al[24] the effect of adding a lifestyle change exercise programme to the traffic light diet was compared with the diet alone and a no treatment control group. The lifestyle change exercise programme involved increasing voluntary caloric expenditure above normal through a series of gradual steps. A statistically significant difference was demonstrated for the children at 6 months, with the two treatment groups being lighter than the control group, who had gained weight. Data were unavailable at 12 months for the control group, however, both treatment groups remained lighter than at baseline, although there was no differential effect of the treatment. The results for the adults were similar at 6 months; by 12 months, however, there was a statistically significant difference between the diet-plus-exercise group and the diet alone group. The weight of the diet-plus-exercise group remained relatively stable between 6-12 months, the diet alone group regained weight.

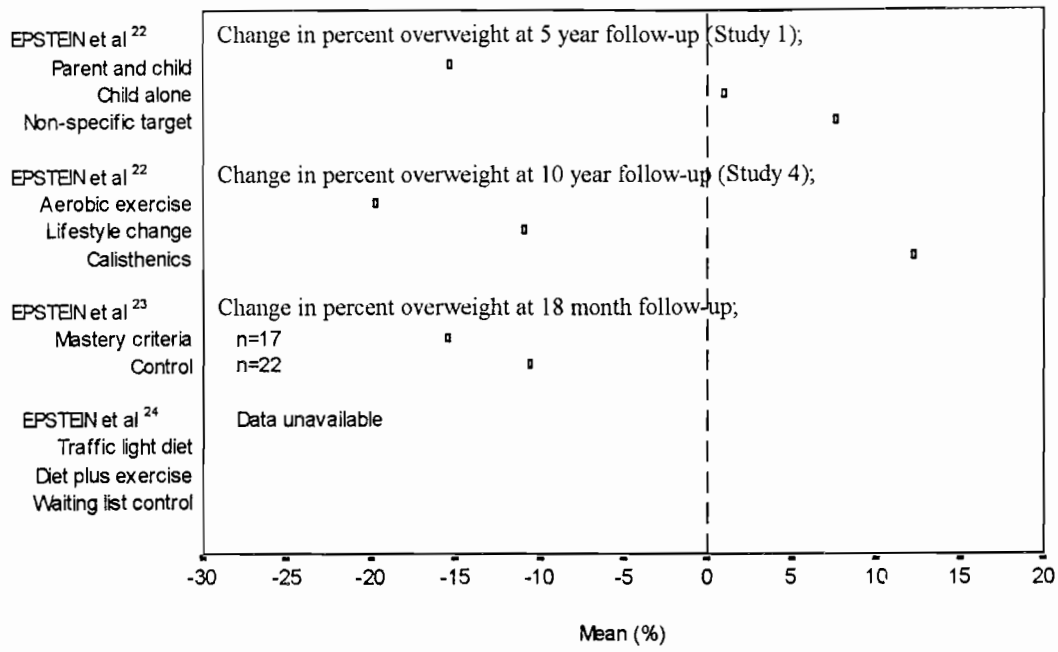

Figure 1: ***Studies examining the treatment of both obese children and parents together***

3.2.3 Parental involvement in the treatment of childhood obesity

Three studies included parental involvement as part of the therapy without targeting the parents for weight loss. Brownell et al[25] suggest that behavioural treatment of adolescent obesity seems to be most effective when the child and parent attend support sessions separately. They examined three levels of parental involvement; mother and child attending concurrent group sessions separately, mother and child attending the same group sessions, and mothers not taking part in the formal treatment programme. The sessions were weekly, lasting for 45-60 minutes, for 16 weeks. The children had to deposit $8 at the start of each month during treatment, with $2 returned each week the child lost 1lb (0.45kg) or more. All subjects received the same programme of behaviour modification, nutrition education, exercise instruction and social support. At 1 year follow-up the mother-child separately group maintained a loss of 7.7±4.1kg (mean±SEM), in contrast to the other two groups which had both gained weight from baseline measurements. Only 12 participants were available in each arm at final analysis.

Epstein et al[26] evaluated the effectiveness of a family-based intervention for childhood obesity in five to eight year olds. Twenty-four girls were recruited and were randomised into two groups, a behavioural management group and a control group receiving a non-behavioural, educational programme. Both groups received the same information on exercise and diet, with families in the experimental group receiving instruction on behavioural management techniques to promote habit change in the children. In this group, the children took some responsibility for self-monitoring, self-reinforcement and goal setting. The control group did not receive any advice on behavioural management techniques. The groups were comparable at baseline for percent overweight, 41.9% and 39.2% for the treatment and control groups respectively. However, by 12 months there was a

statistically significant difference between the two groups with the mean percent overweight being 15.6% for the treatment group and 28.0% for the control group. The sample size of this trial was small, with only 19 children being included in the final analysis.

A twenty-six week behavioural programme focusing on cue control, physical activity, food intake and rewards was used to examine the children's management of their own weight loss.[27] Parental responsibility for the completion of homework assignments and motivation of their children was compared to enhanced child involvement, where the children were trained in self-management techniques. Both groups lost weight during the intervention period, however, there was a trend for weight regain during the follow-up. No statistically significant treatment effects were demonstrated, although this may have been due to lack of power.

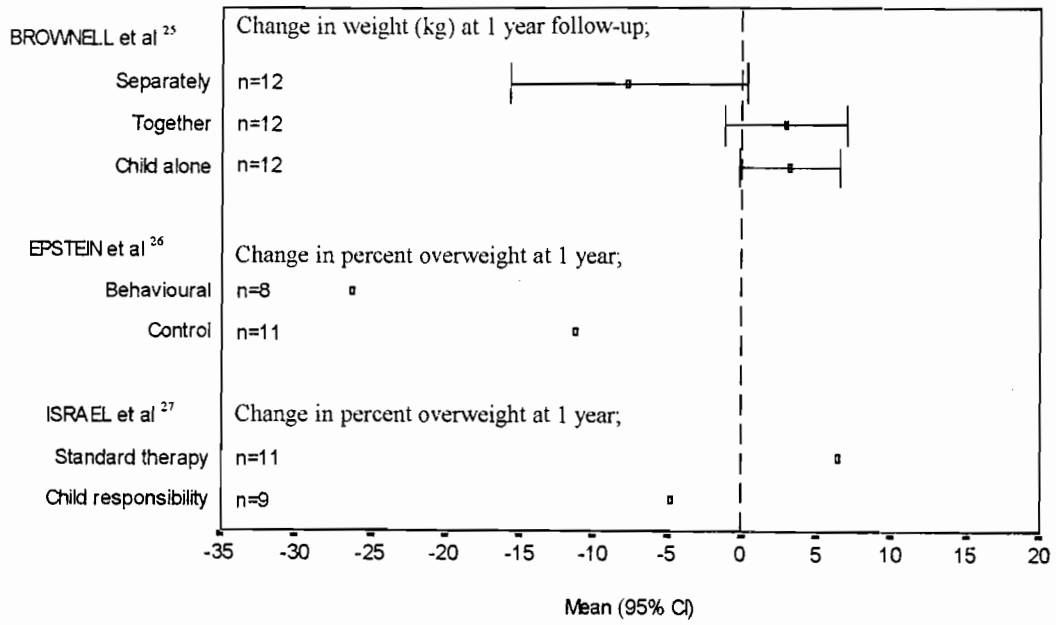

Figure 2: ***Studies assessing the involvement of parents in the treatment of obese children.***

3.2.4 The addition of controlled exercise to diet

Epstein et al[28] examined the effect of adding controlled exercise (supervised aerobic sessions, three times weekly for 6 weeks) to diet for weight loss in obese girls. All families were given identical information on diet, nutrition and behaviour management techniques. They underwent an intensive 8-week treatment programme, followed by 10 monthly maintenance sessions. Parents and children met separately for treatment sessions. In addition to this, children in Group 1 underwent supervised exercise three times a week for the first 6 weeks of treatment, either walking or running 3 miles. The addition of controlled exercise produced statistically significant decreases in body weight (mean weight loss 6.82kg) at six months when compared to diet alone (mean weight loss 3.81kg). This effect was not sustained at twelve months.

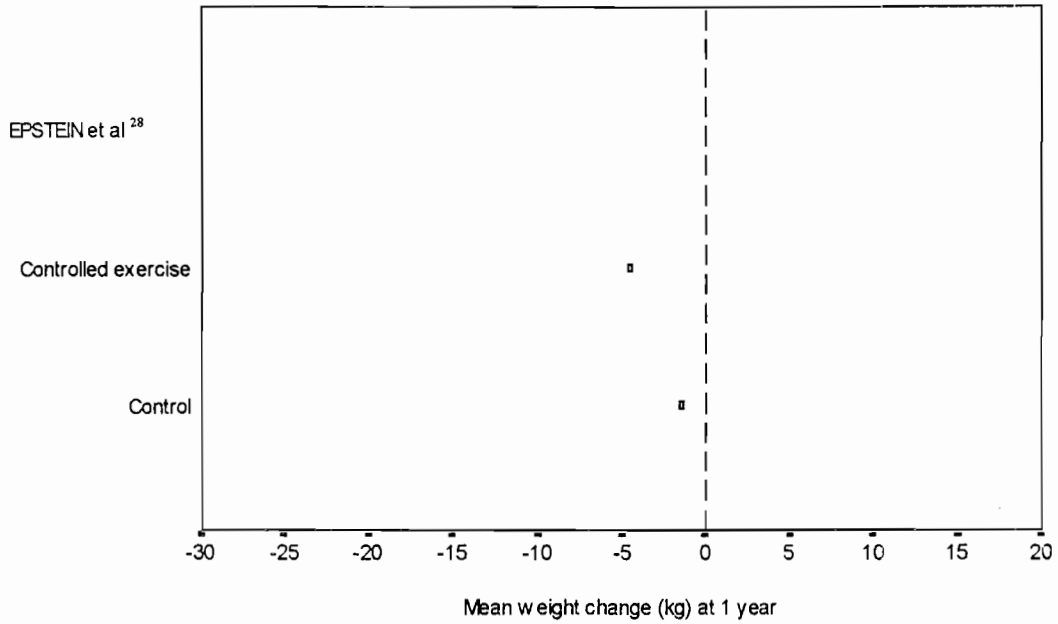

Figure 3: ***Study assessing the addition of controlled exercise to diet.***

3.2.5 Reinforcement of behavioural, diet and exercise strategies

A study conducted by DeWolfe et al[29] examined the reinforcement of behavioural, diet and exercise strategies. All subjects (teenage females, recruited from a student population, aged 14-20 years) underwent an eight week weight reduction programme, comprising of two sessions per week, one session covering the theory and practice of physical education, the second session examining the behavioural control of eating and diet therapy. Each subject was also given advice on the energy intake level required to achieve a weight loss of 0.5kg per week. After the initial eight weeks, students were randomised into three groups, each with a different follow-up strategy. Group 1 received monthly follow-up sessions in which the behavioural, diet and exercise components of the weight control programme were reinforced, and physical measurements were taken. Group 2 also received monthly follow-up sessions, physical measurements were taken but no reinforcement techniques were used. Group 3 had their physical measurements taken at the end of the 12-month follow-up period only. No tests of significance are reported, however, mean weight loss for the group receiving monthly reinforcement was 3.65kg during the one year follow-up compared to a mean loss of 1.9kg for the group undergoing monthly physical measurements alone. Participants with no monthly contact had a mean weight gain of 3.44kg at the one year follow-up. It should be noted that the number of subjects included in the final analysis was extremely small and there is no evidence that the groups were comparable at baseline, therefore, the benefit of regular follow-up sessions after a successful weight loss programme cannot be established from this paper.

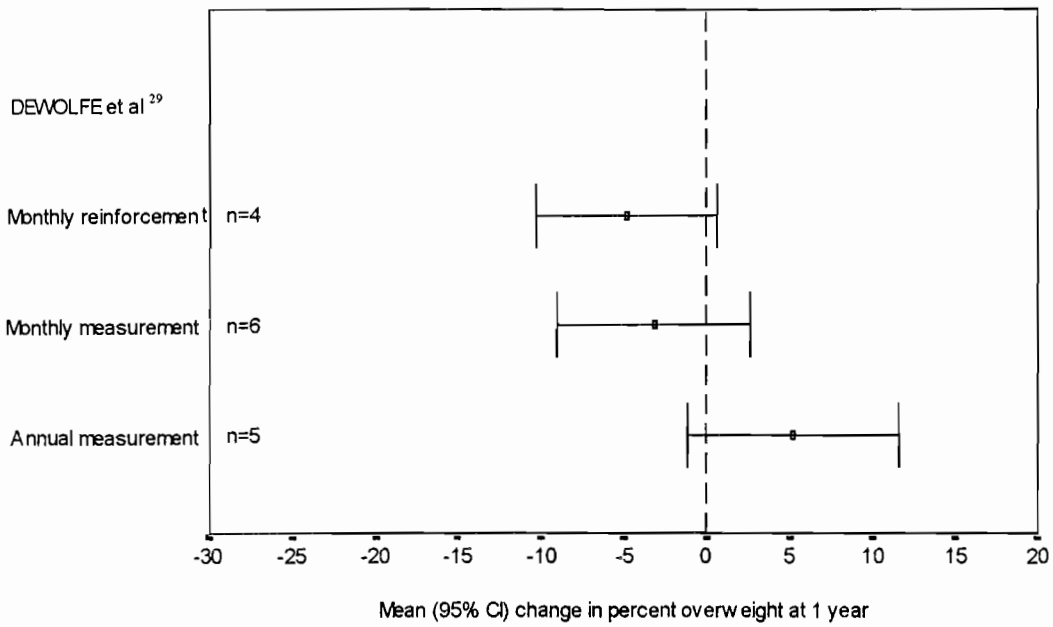

Figure 4: ***Study assessing the effectiveness of reinforcement of behavioural, diet, and exercise weight loss strategies.***

3.2.6 Protein sparing modified fast versus hypocaloric balanced diet

One study evaluated the effects of two different diets, the protein sparing modified fast (PSMF) and the hypocaloric balanced diet (HBD).[30] The PSMF diet consisted of 1.5-2g of high quality protein (lean beef, chicken, turkey, fish or seafood) per kilogram of the ideal body weight per day up to 100g and provided approximately 600-800 kcal/day. The HBD was composed of 800-1000 kcal per day and was derived from the American Diabetes Association exchange lists for meal planning. The mean age of children in the study was 11 years (range 7-17 years). Both groups were placed on their respective diets for the first 10 weeks, and then placed on a 1000 kcal balanced diet. Three months later the calorie intake was increased to 1200 kcal per day. A statistically significant difference was demonstrated for mean weight loss (±sd) at ten weeks, the PSMF diet showing a loss of 11.2±4.4kg compared to a loss of 5.1±4.1kg for HBD. This difference was sustained at six months, although it was no longer statistically significant. At the one year follow-up the mean weight in both groups had returned to baseline levels. However, small sample sizes prevent us from drawing conclusions from these results.

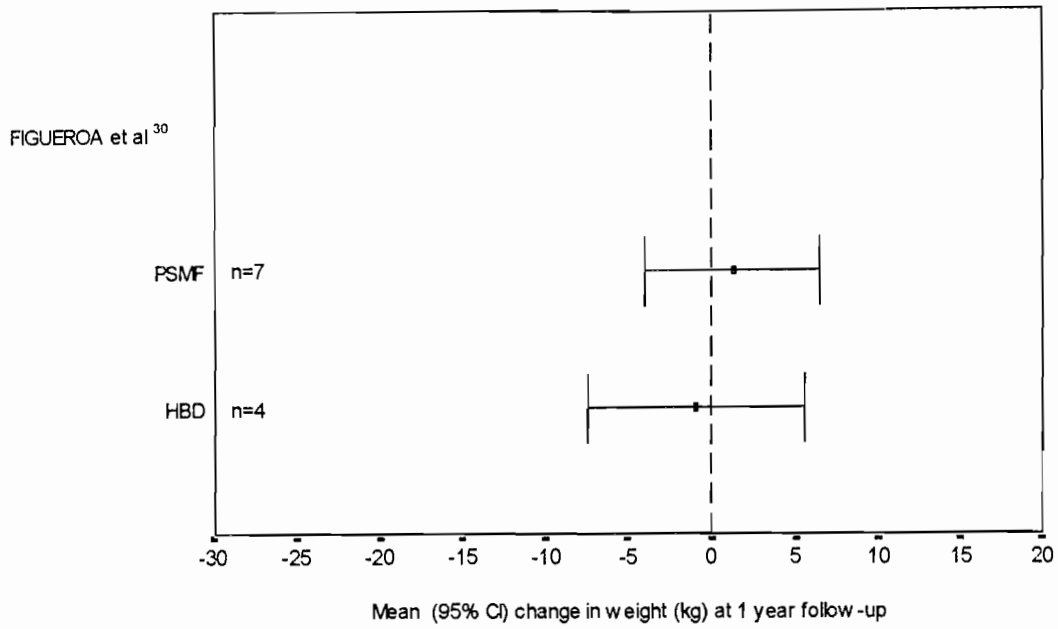

Figure 5*: Study evaluating the effectiveness of a protein sparing modified fast (PSMF) in comparison to a hypocaloric balanced diet (HBD)*

3.2.7 Lifestyle changes

The role of lifestyle changes in weight loss of obese children has been examined in two studies.[31,32] Epstein et al[31] looked at reinforcing different levels of physical activity. The subjects were randomised into three groups: reinforcing decreased sedentary activity; reinforcing increased physical activity; reinforcing both decreased sedentary and increased physical activity. All groups received the traffic light diet and similar information through written material on the positive effects of increased physical activity and the negative effects of sedentary behaviour. There were statistically significant differences in the percentage overweight for children in the decreasing sedentary behaviour group versus children in the exercise group after 4 months of treatment, and the exercise and combined groups after 1 year. The decreased sedentary behaviour group showed a decrease in percent overweight of approximately 19%, the exercise and combined groups showing decreases of 9% and 11% respectively, at 1 year (estimated figures from graph). The results support the hypothesis that reducing access to sedentary activities may be more important in treating childhood obesity than exercise programmes.

Mellin et al[32] compared the 14 week "Shapedown" programme, provided to 37 children, to a no treatment control group, consisting of 29 children. The "Shapedown" programme is based on a number of cognitive, behavioural, affective and interactional techniques, encouraging the adolescents to make "successive, sustainable, small modifications in diet, exercise, relationships, lifestyle, communications, and attitudes". Very low calorie or restrictive diets were avoided. Data were analysed on an intention to treat basis. Weight lost relative to the baseline value decreased significantly during the initial 3 months for the treatment group (-5.9%) but not for the no treatment controls (-0.3%). At 12 months post intervention, the relative weight loss (±sd) compared to baseline was 9.9±14.98% versus 0.1±13.2% for the treatment and control groups respectively.

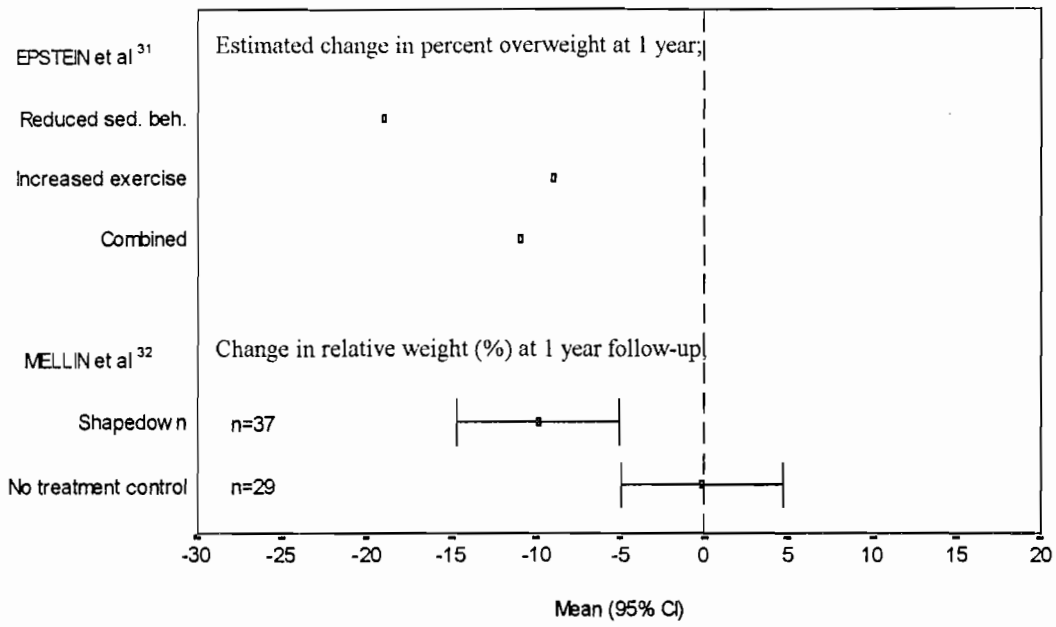

Figure 6: ***Studies evaluating the effectiveness of lifestyle changes, reducing sedentary behaviour. (Reduced sed beh - reduced sedentary behaviour).***

3.2.8 Summary

There is some evidence to support the use of family therapy in the prevention of the progression of obesity to severe obesity, although this needs reinforcing. There is conflicting evidence over the effectiveness of treating obese parents and children together, but this may be due to the variation in interventions studied. Likewise, there is conflicting evidence concerning the involvement of parents in childrens' treatment programmes. It is possible that the value of parental involvement may vary according to the ages of the children concerned, and may be of greater value for younger children (5-8 years of age). It should be noted that sample sizes were small for these studies. No long term benefit for weight loss was demonstrated by the addition of controlled exercise to diet, although a statistically significant decrease in body weight was observed at 6 months. There is no reliable evidence promoting the reinforcement of behavioural, diet and exercise strategies, or the beneficial effects of a protein sparing modified fast versus a hypocaloric diet. The results for studies examining lifestyle changes are the most encouraging, suggesting that decreases in sedentary behaviour and programmes such as "Shapedown" are the most effective way of treating childhood obesity.

3.3 Prevention of obesity in adults (see table 2)

Three studies looking at the prevention of obesity in the community met our inclusion criteria.[33-35] One of these studies may have included some adolescents.[33] This study was part of the Stanford Five-City Project, which was designed to assess the value of community-wide health education on risk factors for cardiovascular disease. It compared six years of an extensive multi-media education programme, targeting all residents between the ages 12-74 years in two cities, with no intervention in two reference cities. All components of the education programme were based on theories of learning and community

change. Only a few initiatives were aimed directly at the obese population. The study was quasi-experimental in design. At six years both groups had gained weight. The results of an independent survey indicate that the mean±se BMI in both groups had increased, and this increase was significantly greater in the control group (1.25±23 compared to 0.57±0.22 for the intervention group).

Forster et al[34] randomised 219 participants to either a weight gain prevention programme or a no treatment control group for a period of 12 months. The prevention programme consisted of monthly newsletters providing information on "diet, exercise, psychological aspects of weight management, the relationship between weight and health, and overweight as a public health problem". Each month participants were required to record their own weight on a postage paid postcard. A financial incentive was also offered to those in the prevention group, with each person authorising the study to withdraw $10 per month from his/her bank account. The money was returned with interest either at the end of the study, or at any other point during the trial. The participants were entitled to the reimbursement, and could chose the timing of this, providing they did not weigh more than they had at baseline. An optional component of the prevention programme was an educational course of four sessions offered midway through the year. During the 12 month intervention the mean weight change, adjusted for height, differed significantly between the two groups. Those undergoing the prevention programme demonstrated a mean (±SE) change in weight of -0.95±0.27kg compared to -0.14±0.27kg for the no treatment control group. The drop-out rate was low, with a total of 210 participants being available for assessment at the end of the 12 months.

The third study in this section reports the evaluation of weight reduction in the Minnesota Heart Health Programme.[35] The study included three pairs of communities matched in size and in type. Both cross-sectional and cohort surveys were included in the trial design. Three communities received a social and behavioural management programme, aimed at alerting the participants about the potential for primary prevention, and providing programmes for changing and maintaining change in these behaviours. The choice of components was based on "multiple theoretical orientations including social learning theory, communications theory, community organisational theory, and a diffusion of innovations".[35] The remaining three communities received no treatment. Results from both the cross-sectional and cohort surveys show BMI rising by approximately 1 BMI unit on average over the 10 year period. This result applies to both the intervention and the control communities. Adjusting for height and other confounding factors, this represents an average increase in weight of approximately 1.8-2.7kg per person.

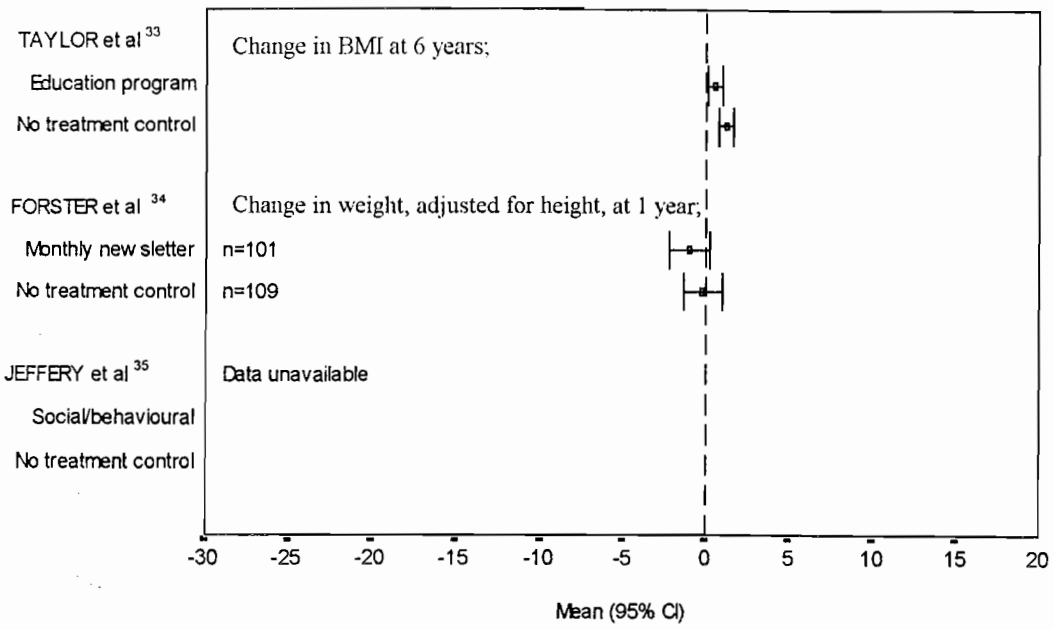

Figure 7: ***Studies examining the prevention of adult-onset obesity.***

3.4 Treatment of obesity by behavioural interventions (see table 3)

3.4.1 Spouse involvement

Four papers evaluated the role of spouse involvement in behavioural treatment programmes for obesity.

Black and Lantz[36] studied married women aged between 23 and 53 years who were at least 10% overweight, but otherwise healthy. All the women attended 10 weekly behavioural treatment sessions where they received instruction on nutrition and behavioural strategies for the modification of eating habits. Subjects were assigned to three groups which involved husbands to differing degrees during the behavioural weight loss programme. The "husband contracting" condition required the husbands to attend the treatment sessions with their wives and provide active encouragement during the weight loss process. The "husband not contracting" condition involved the husband attending the treatment sessions, but not providing active encouragement to his wife's weight loss efforts. Thirdly, the "husband absent" condition meant that the wives attended treatment sessions alone, and that husbands had no role at all in the weight loss programme.

At the end of the 10 week intervention, the weight losses (mean ± sd) from pre-treatment for each group were as follows: husband contracting 4.6±1.8kg, husband not contracting 3.1±1.9kg, and husband absent 3.7±2.8kg. There were no statistically significant between group differences and the results of tests of statistical significance over time are not reported.

From post-treatment to one year follow-up, the women who had attended treatment sessions alone lost significantly more weight than women in the "husband not contracting" group ($p<0.05$). Women in the

"husband contracting" group were not significantly different from the women in the other two conditions. Moreover, there was a statistically significant difference in the effect of the three treatment conditions from baseline to one year follow-up ($p<0.02$). Mean cumulative weight losses at one year follow-up were as follows: "husband contracting" group 7.0kg, "husband not contracting" group 4.2kg, "husband absent" 7.4kg. The generalisability of the results of this study is difficult to establish since data were analysed on very small samples of approximately 11 individuals in each treatment condition.

Dubbert and Wilson[37] recruited married subjects who were at least 7kg overweight, but not more than 100% overweight, and otherwise healthy. These patients were assigned to four treatment conditions. The "couples treatment with proximal goals" condition entailed full involvement of the spouse in all aspects of the treatment programme in conjunction with a prescription of daily goals for calorie intake and expenditure for the obese participant. Secondly, the "couples treatment with distal goals" group was as above except that the calorie related goals were set for a one week time period. The third condition was "individual treatment with proximal goals". This was similar to the first condition except that spouses were not actively involved in the treatment process. The final treatment group was "individual treatment with distal goals", with definitions as described above. All subjects attended treatment sessions where they received instruction on dietary guidelines, exercise recommendations, and behavioural strategies. In the couples treatment conditions, the spouses were required to attend at least half of these sessions, whereas for the individual treatment groups, they were not required to be present at any session. All subjects and all spouses were asked to attend assessment sessions (to monitor body weight) pre-treatment, post-treatment, and at 3 and 6 month follow-up.

By the end of the 19 week weight loss intervention, the overall mean weight loss compared to baseline was statistically significant ($p<0.0001$) at 7.7kg. However, there were no statistically significant between group differences. Overall mean weight losses of 6.8kg were maintained at the 6 month follow-up ($p<0.01$, comparison with baseline level), but there were still no statistically significant differences between any of the four treatment conditions.

At the 12 month post-treatment follow-up (data obtained by telephone or postal questionnaire), the overall mean weight regain was 1.2kg. However, changes in weight were variable with 38.2% of respondents reporting additional weight loss, 49.1% regaining part of their previous losses, and 12.7% weighing more than their pre-treatment weight. At the 30 month post-treatment follow-up (data obtained as for 12 month follow-up), the overall mean weight regain of those who responded was 2kg. At this stage, subjects in the couples treatment groups demonstrated superior maintenance of weight loss compared to the other groups, although the differences were not statistically significant.

Rosenthal et al[38] compared weight loss in three study groups which included either full husband involvement, partial husband involvement, or no husband involvement in the weight loss programme. In the full husband involvement condition, husbands attended all treatment sessions with their wives and actively participated in encouraging and reinforcing successful weight loss activities. In the partial

husband involvement group, husbands attended only some of the treatment sessions and therefore applied those techniques and strategies relevant to the sessions experienced. In the no husband involvement group, the wives attended the behavioural treatment sessions alone.

At the end of the 16 week behavioural intervention, mean weight losses were as follows: full husband involvement group 4.7kg, partial husband involvement 4.9kg, and no husband involvement 3.2kg. There was a statistically significant weight loss across the three treatment groups when values were compared to baseline ($p<0.001$). A greater mean weight loss was achieved by the women in both groups involving the husband in the weight loss programme compared to those where the husband was excluded ($p<0.001$), but no statistically significant differences were demonstrated between the two levels of husband involvement.

At the 3 year follow-up, data from the two husband involvement groups were combined and compared to results derived from subjects who participated alone. At this time, no statistically significant differences were observed between husband involvement and no husband involvement conditions. The mean weight loss for the former was 4.4kg when measurements were compared to baseline, and 3.6kg for the latter.

The role of spouse involvement in the treatment of obesity using behavioural therapy in conjunction with a reduced calorie intake was examined by Pearce et al.[39] Altogether there were five treatment conditions. In the first, the co-operative spouse group, spouses were asked to attend treatment sessions and to participate fully to help their partners to lose weight. Treatment strategies included mutual monitoring of eating behaviour, by subjects and spouses. Women in the second group attended treatment sessions alone and did not receive any support from their spouses. In addition, the women unobtrusively monitored the behaviour of their spouses, but the activity was not mutual. Thirdly, the wives alone condition entailed subjects attending behavioural treatment sessions alone with no participation from spouses, and no monitoring activities. Fourthly, the alternative treatment group received instruction on the hypothetical and underlying causes of overeating, self-understanding, and insight into eating behaviours. Finally, there was a waiting list control group who were offered treatment at the end of the 10 week treatment programme.

At the end of the intervention, all groups, with the exception of the delayed treatment control group, had lost statistically significant amounts of weight compared to baseline values ($p<0.001$) but there were no statistically significant differences between these treatment conditions. Mean weight losses in the four active treatment groups ranged from 1.6kg to 6.5kg. The delayed treatment control group gained 0.2kg during this time. Sample sizes were small, 12 in each of the active treatment groups and 14 in the control group.

At the 12 month follow-up, the co-operative spouse group had statistically significant superior mean weight losses to both the alternative treatment group and the wives alone group (8.3kg, 0.3kg (gain), and 2.2kg respectively). The non-participating spouse group also had significantly higher mean weight

losses compared to the alternative treatment group (mean loss of 5.6kg versus mean gain of 0.3kg). There were no statistically significant differences for any of the other group comparisons.

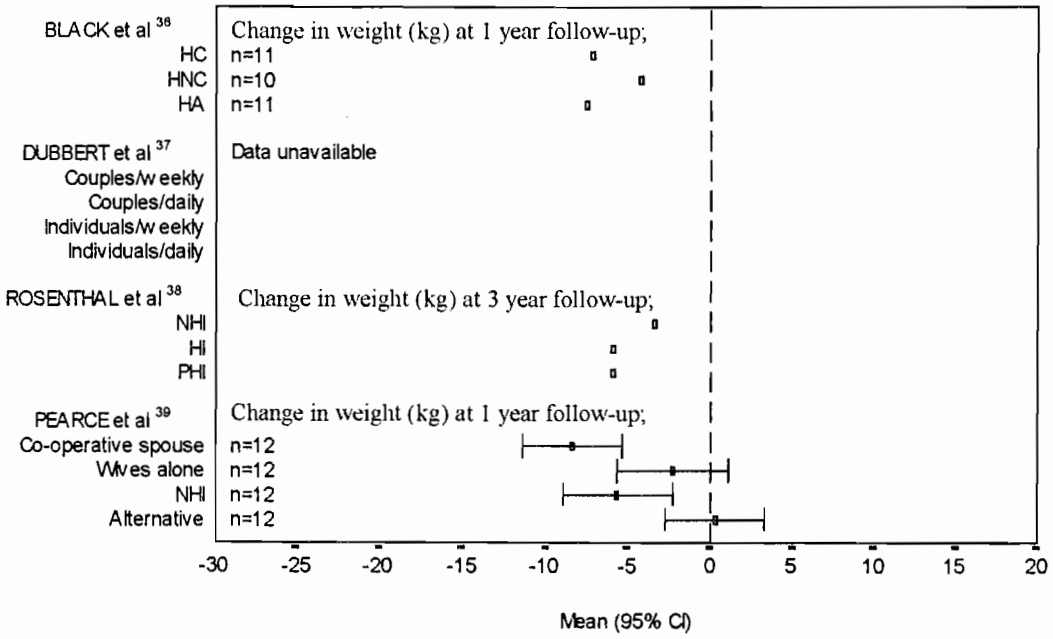

Figure 8: ***Studies evaluating the effectiveness of spouse involvement in behavioural strategies for weight loss. (HC - husband contracting; HNC - husband not contracting; HA - husband absent; NHI - no husband involvement; HI - full husband involvement; PHI - partial husband involvement).***

3.4.2 Interventions based on cognitive therapy

Cognitive therapy is concerned with the modification of behaviour through the influence of thought processes.[118] The main principles of this treatment approach include the modification of current behaviour patterns, new adaptive learning, problem solving, and a collaborative relationship between client and therapist.[119] There were six studies in the current review which came into this category.

The effectiveness of the inclusion of "Value Self Confrontation" (VSC) techniques in a behavioural therapy package was compared to a group discussion condition and a no treatment control group.[40] The authors describe VSC as a method which brings about a change in behaviour through a re-ranking of personal values. In the study, it was attempted to encourage changes in eating behaviour by asking subjects to compare their own values with those of successful and unsuccessful weight losers, and thereby modify their own hierarchy of values. These issues were discussed and reinforced during behavioural treatment sessions. The VSC group had lost significantly more weight than the other two groups combined at the end of the 2 month intervention (2.03kg versus 0.28kg), however at the one year follow-up there were no significant inter group differences.

Bennett classified overweight female subjects into low loser or high loser groups according to their weight loss during a preliminary diet period.[41] The sample was stratified according to this distinction and subjects were randomly assigned to receive one of three behavioural treatments. The first was

instruction in cue avoidance (avoiding the situations that provide the temptation to overeat), the second was cognitive rehearsal (rehearsing behaviour in anticipation of situations where temptation is present), and the third was social pressure (modifying behaviour through social support and group interaction). At the end of the 16 week treatment, all groups demonstrated statistically significant mean weight losses. Subjects in the cue avoidance group lost significantly more weight than those in the social pressure group, and high losers lost significantly more than low losers. The only statistically significant result at the one year follow-up was for the overall mean weight loss over time.

In a second study, conducted by Bennett,[42] overweight women were assigned to four treatment conditions. The first group received behavioural instruction sessions relating to cognitive rehearsal, as explained previously. Those in the second condition were trained in the use of insight control, defined as the development of an awareness of thinking patterns in problem situations and gaining a greater degree of self-control with respect to overeating. The third group received an individual contact condition whereby subjects were encouraged to exercise their own self-control abilities, without recourse to specific behavioural strategies. Finally, those assigned to group contact received the core programme only, as provided to all the study participants. This consisted of individualised nutritional advice and social support, with progressively faded therapist contact.

There were no statistically significant between group differences at any point during the study or follow-up. There was a statistically significant effect for weight loss across all groups over time at 16 weeks and at one year follow-up, when values were compared to baseline measurement ($p<0.001$ at both time points). The mean weight loss across all participants at the end of the 16 week intervention was 4.9kg, and at one year follow-up 2.4kg.

Jones et al[43] conducted a study of overweight, but otherwise healthy women, who had been referred to a District Dietetic Service from medical practitioners. The purpose of the study was to evaluate the effects of including behavioural therapy in a conventional NHS dietetic weight reducing clinic, without the presence of a clinical psychologist. A 2x2x2 factorial design incorporated the following conditions: leaflet (describing and recommending cue avoidance) versus no leaflet, diary (self-monitoring of dietary activities) versus no diary, and group treatment with a dietician versus individual treatment.

Following the 20 week intervention, post-treatment values were compared to baseline, and the mean ($\pm$sd) overall weight loss was 5.3$\pm$3.6kg. The group treatment mode produced statistically significant greater weight losses compared to those receiving individual treatment ($p<0.05$). There was also a statistically significant effect for the interaction between group treatment and leaflets ($p<0.05$). At the one year follow-up, the mean overall weight loss was 4.0$\pm$5.4kg. No statistically significant effects were demonstrated at this point.

Cognitive therapy may be performed as part of a treatment package sometimes referred to as standard behavioural therapy (SBT). The elements of a SBT programme for the treatment of obesity may vary

according to the methods employed by individual psychologists. However, there are some components that are likely to be common to most programmes.

Firstly, SBT does not normally involve efforts to establish the underlying causes of current eating behaviours, as is the case for psychoanalytical approaches. Furthermore, instruction and training in the application of behavioural strategies is provided so that current eating habits may be modified, and become compatible with good health. Any techniques that are presented may be demonstrated and rehearsed through role play. It is usual that the client and therapist will set goals collaboratively, for example, for calorie intake, or amount of body weight to be lost during a given time.[120] Verbal and written material may also be presented on such topics as nutritional guidelines, food shopping and exercise. Information regarding these issues, as well as the behavioural techniques, may be reinforced several times during the treatment programme, or during follow-up or maintenance phases.

Participants are required to attend behavioural treatment sessions, normally with a clinical psychologist present. During these sessions, the emphasis is on modifying current undesirable eating behaviours through the application of behavioural strategies. These strategies may include self-monitoring, stimulus control, reinforcement, and problem solving. Self-monitoring involves the observation and recording of certain behaviours by the subject. Records may be made using diaries, inventories or questionnaires. Stimulus control is a similar concept to cue avoidance, and is concerned with avoiding the temptation to overeat. Specific advice may include removing undesirable food from the house, modification of food storage so that it is not immediately visible, reducing the rate of eating, and always eating in the same place so as to reduce the number of stimuli associated with overeating. Reinforcement strategies are concerned with supporting favourable eating behaviour through the use of rewards. This may be done by the participant, as in the case of self-reinforcement, or by other parties, such as family members or therapists. Problem solving approaches entail the identification of difficulties in connection with weight loss and patients are then encouraged to solve these in a systematic way, using their own resources. This process is usually facilitated through collaboration with a therapist, and sometimes also through group support.

Perri et al[44] employed a SBT approach to evaluate the effect of lengthening the duration of behavioural treatment for obesity. Adult volunteers who were 25-100% overweight, but otherwise healthy, were assigned to one of two treatment conditions. A group who received 20 weekly standard behavioural therapy sessions were compared to a second group who received the same intervention during 40 weekly sessions.

The extended therapy group achieved a statistically significant greater mean(±sd) weight loss at 40 weeks, 13.64±9.00kg versus 6.41±5.99kg ($p<0.05$). A similar difference was maintained at 72 weeks, 9.85±8.21kg versus 4.61±5.16kg ($p<0.05$). However, it should be noted that the post-treatment follow-up for the extended treatment group is twenty weeks shorter than that of the other group. Data analysis also demonstrates a statistically significant overall difference at both 40 weeks and 72 weeks, when measurements are compared to baseline values.

Meyers et al[45] compared three different methods of providing an 8 week cognitive behavioural treatment programme for weight loss. One group received the programme by attending meetings, led by a therapist. A second group were treated as the first, except that their treatment sessions were videotaped. The third group did not have live contact with a therapist, but viewed the videotaped meetings from their homes, on a scheduled television broadcast. These three treatment groups were compared to a waiting list control group, who were offered the treatment regime offered to the first group, at the end of the 8 week intervention period.

At the end of the 8 week intervention, the first three groups had an overall statistically significant weight loss compared to the control group.(approximately 4.3 kg versus 0.9 kg), but there were no statistically significant differences between the three active treatment groups. At 15 month follow-up, the three groups had regained lost weight, significantly so in the case of the second (videotaped) group. This study provided some information about cost-effectiveness and concluded that the televised programme was significantly more cost effective than either of the live contact groups.

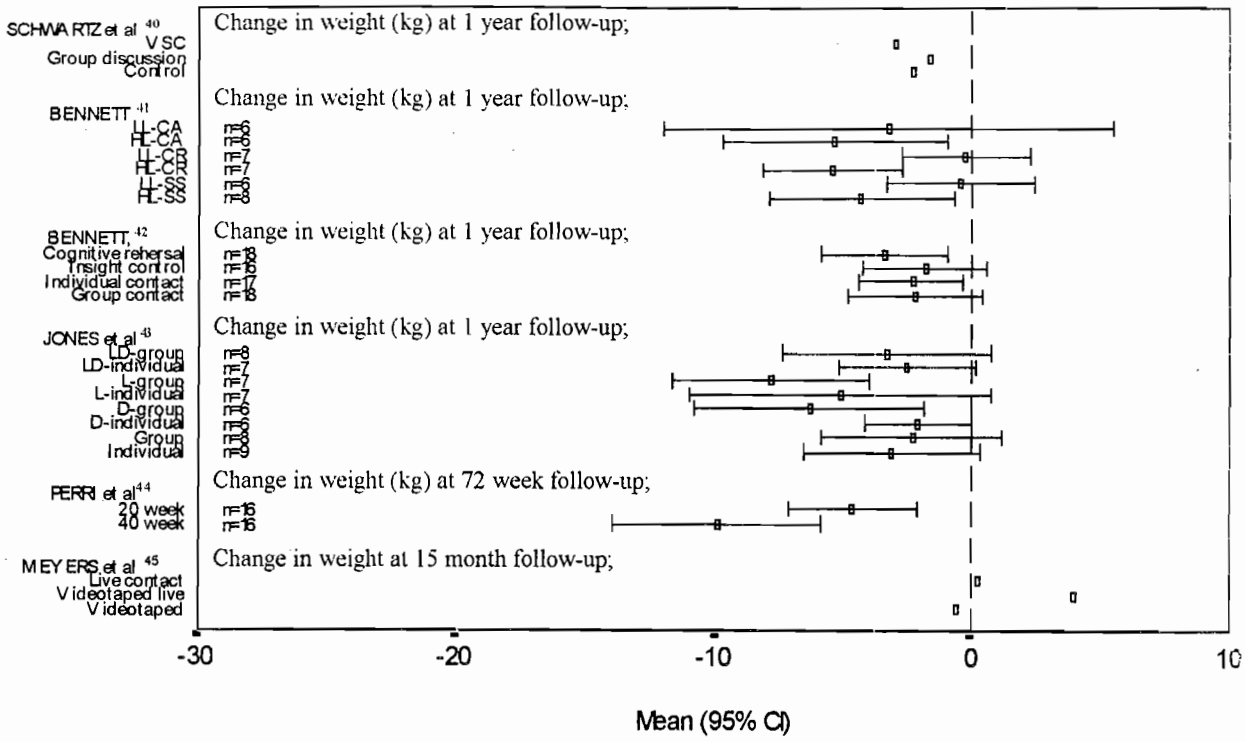

Figure 9: ***Studies examining interventions based on cognitive therapy. (VSC - value self confrontation; LL - low loser; HL - high loser; CA - cue avoidance; CR - cognitive rehearsal; SS - social support; L - leaflet; D - diary).***

3.4.3 Individual versus group therapy

Jeffery et al[46] studied monetary contracting as a behavioural strategy for obesity, whereby a monetary deposit made by each participant at the first treatment meeting would be refunded in stages, according

to weight loss. Participants were allocated to six different groups varying by type of contract, that is, group or individual, and by how much money was paid as a deposit by participants (US$30, $150 or $300). For those in the individual contract groups, cash was refunded according to that individual's weight loss since the previous meeting. Refunds for those in the group contract conditions were dependent upon the average weight loss of that group.

At the end of the 15 week intervention, there was a statistically significant treatment effect for all the groups when values were compared to baseline. Moreover, subjects in the group contract conditions lost a statistically significant greater amount of weight compared to those in the individual contract groups. However, at twelve month follow-up, these differences were not maintained, and all groups had regained significant amounts of weight. The size of the monetary contract was not found to be a statistically significant factor in determining weight loss at any stage of the study.

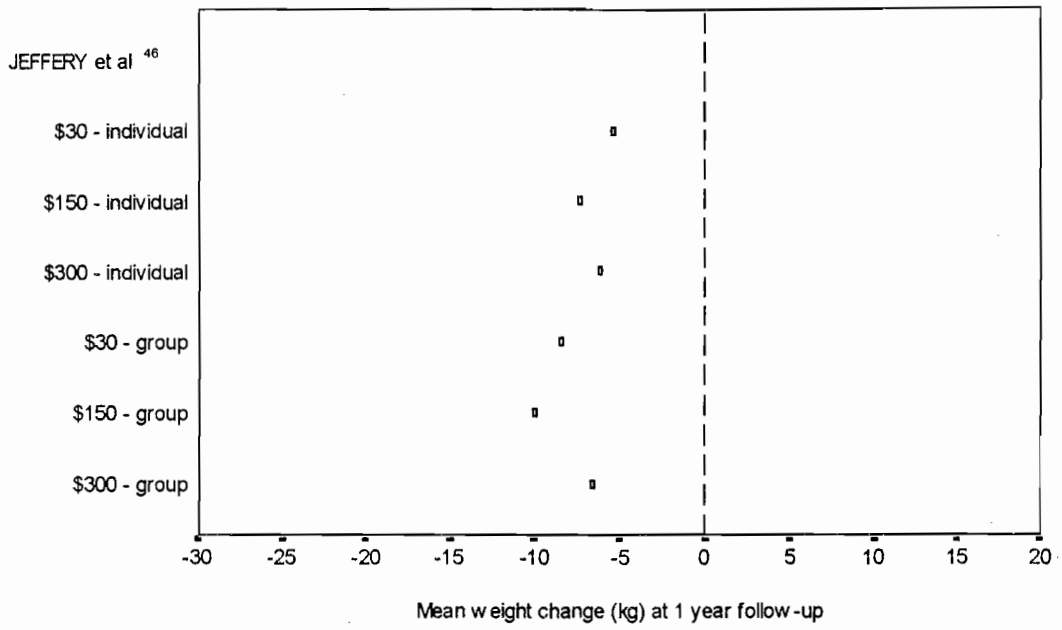

Figure 10: ***Study examining the effectiveness of monetary contracting as part of a behavioural intervention for weight loss.***

3.4.4 Behavioural treatment by correspondence

Cameron et al[47] examine the effects of different elements of a correspondence programme for weight loss. Healthy adults, overweight by between 9 and 23kg, were allocated to different combinations of printed lessons, weekly homework, interim weigh-ins and payment of a deposit. The printed lessons were mailed weekly to participants and presented material on nutrition, exercise, and behavioural strategies to modify eating behaviours. Homework assignments entailed participants summarising in writing any changes in behaviour, plus the record of body weight. Interim weigh-ins involved therapists checking the patients' weight, providing encouragement, and answering any questions that the participants may have about the programme. The final element under study was a participation deposit of Can$21, to be refunded contingent on returning homework and/or attending interim weigh-

ins as required. The only statistically significant result at one year follow-up was that women who received the combination of lessons and homework had a greater mean weight loss relative to the lessons only group (3.93±4.88kg and 1.45±1.76kg respectively).

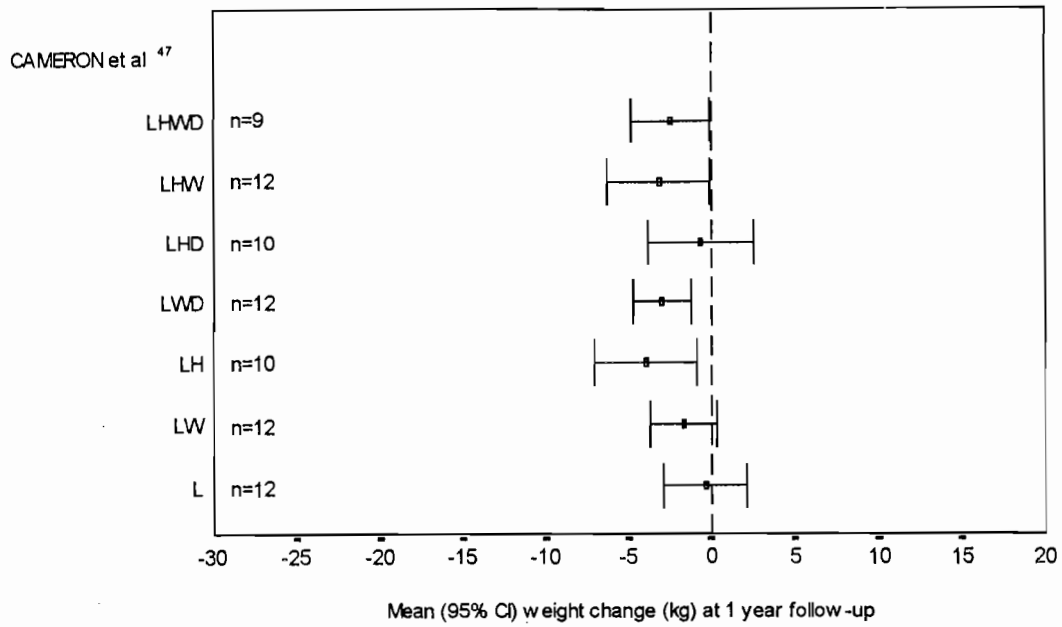

Figure 11: ***Study examining behavioural treatment of obesity by correspondence. (L - printed lessons; H - weekly homework; W - interim weigh-ins; D- payment of deposit).***

3.4.5 Daily weight charting

Fujimoto et al[48] examined the effects of behavioural therapy plus daily weight charting versus behavioural therapy alone as interventions for weight loss in moderately obese women. Results showed that although there was no statistically significant treatment effect at the end of the seven month intervention (mean weight losses of 15.4kg and 17.9kg respectively), there was a statistically significant between group difference at the two year follow-up in favour of daily charting (14.8kg versus 8.8kg respectively, $p<0.05$). These results suggest that the practice of daily weight charting may be of value as a weight loss maintenance intervention.

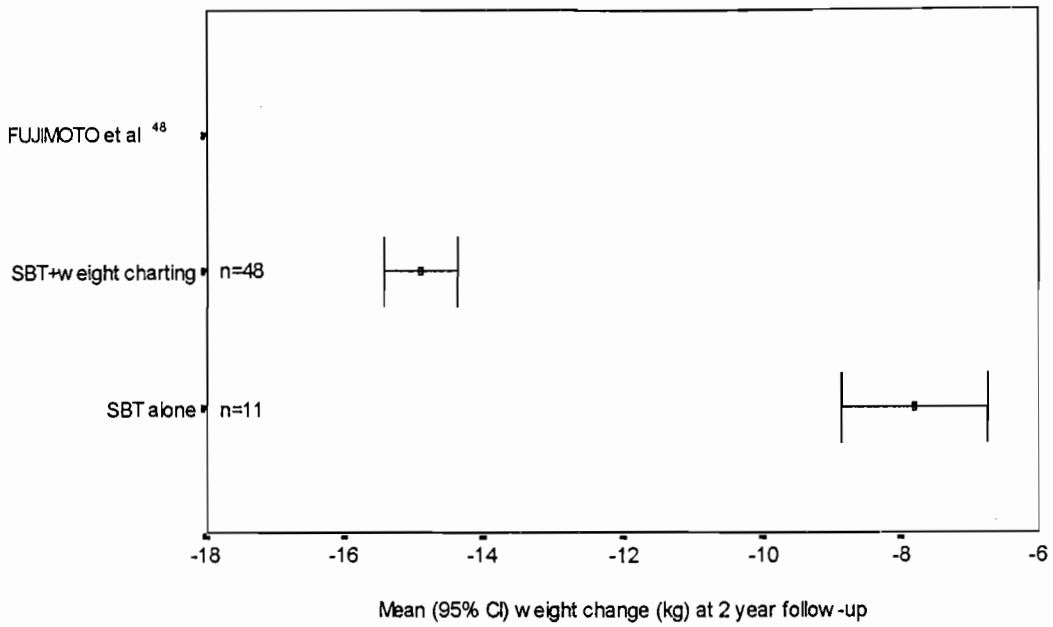

Figure 12: ***Study assessing the effectiveness of adding daily weight charting to standard behavioural therapy (SBT).***

3.4.6 Summary

The effectiveness of spouse involvement in the treatment of obesity is unclear. The findings of studies presented here are conflicting and are based on small sample sizes. Treatment groups included 15 participants or less for the four studies reviewed in this category. Out of the cognitive strategies studied, cue avoidance was the only technique with some evidence of effectiveness. Extending the length of behavioural therapy also appeared to be more effective when compared to an intervention of shorter duration. There was no evidence to suggest that monetary contracting as an individual versus group is of value in the weight loss process. It is possible that some elements of a weight loss programme by correspondence may be useful, for example, the provision of lessons and homework. The practice of daily weight charting may be helpful for both weight loss and maintenance of weight loss. Interventions designed to maintain weight loss will be discussed in more detail in section 5.8.

3.5 Behavioural therapy combined with specific dietary components (see table 4)

3.5.1 Interventions for obese patients with non insulin dependent diabetes

There were five studies focusing on participants with non insulin dependent diabetes (NIDDM). Wing et al[49] compared a behaviour modification group and a nutrition education group to the standard treatment for NIDDM as a 16 week weight loss intervention. The behaviour modification group were given information on exercise, nutrition, diabetes, and a variety of behavioural strategies such as contingency contracts and stimulus control. The nutrition education group received basic information on nutrition, exercise and diabetes, but were not taught any behavioural modification strategies. Both of these groups met weekly for the period of the intervention. The standard care condition met monthly for the duration of the 16 weeks, and apart from this, their treatment was identical to that of the nutrition education group. At the twelve month follow-up there were no statistically significant

differences between the three treatment groups in terms of weight loss, or any of the physiological measures taken.

In a study carried out by Pascale et al[50] all subjects received a 4 month behavioural programme. Two different types of diet (calorie restriction versus calorie and fat restriction) were analysed in participants either suffering from NIDDM or with a family history of NIDDM. All participants underwent a 16 week behavioural weight loss programme with training in diet, exercise and behaviour modification. For the duration of this period participants were assigned to a 1000-1500 kcal/day diet, either restricting calorie intake alone, or both calorie and fat intake. NIDDM participants achieved a mean weight loss of 5.2±7.3kg (±sd) with the calorie and fat restricted diet at the end of the eight month follow-up, compared to a loss of 0.96±3.7kg (±sd) for those assigned to calorie restriction alone. This difference was statistically significant. For those with a family history of NIDDM, there were no significant differences with respect to the diet received.

Wing et al[51] compared 12 months of a low calorie diet (LCD), consisting of 1000 -1200 kcals/day, to a low calorie diet with intermittent periods of a very low calorie diet (VLCD), providing 400-500 kcals/day. At both one and two year follow-up there was no significant difference between the two groups for weight loss, and weight regain occurred in both groups. Those patients who had initially lost more weight, later regained more weight ($r=0.70$, $p=<0.001$). The final measurements at two years showed a mean weight loss of -5.7±7.9kg in the LCD group and -7.2±8.0kg in the VLCD group.

An earlier study, Wing et al[52] compared obese diabetic subjects treated alone to obese diabetic subjects treated at the same time as their overweight spouses. The weight control package consisted of 20 weeks of behavioural therapy, 12 weekly sessions initially, followed by 4 biweekly sessions. Follow-up sessions were held at weeks 24, 28, 40 and 72. Mean weight loss did not differ significantly between treatment conditions at post-treatment or at one year follow-up (5.26±10.39kg and 3.17±5.31kg for alone and together conditions respectively).

The fifth paper looking at weight control in non-insulin dependent diabetics compared a liquid supplement diet providing 800kcal/day with a diet consisting of a combination of liquid supplements, providing 320kcal/day, and conventional foods to the value of approximately 500kcal/day.[53] Both groups also received weekly behavioural education sessions. After twelve weeks of treatment all participants received individual meal plans that gradually introduced conventional foods over a period of 4-6 weeks. Both groups had lost statistically significant amounts of weight by the end of the 12 week weight loss phase. Those on liquid supplement alone had lost 15.3% of their initial weight and those receiving both liquid supplement and conventional foods had lost 14.1% of their initial weight. The loss did not differ significantly between groups. At the one year follow-up, the two groups combined sustained statistically significant weight losses over time ($p<0.0001$), but between group differences were not analysed at this point.

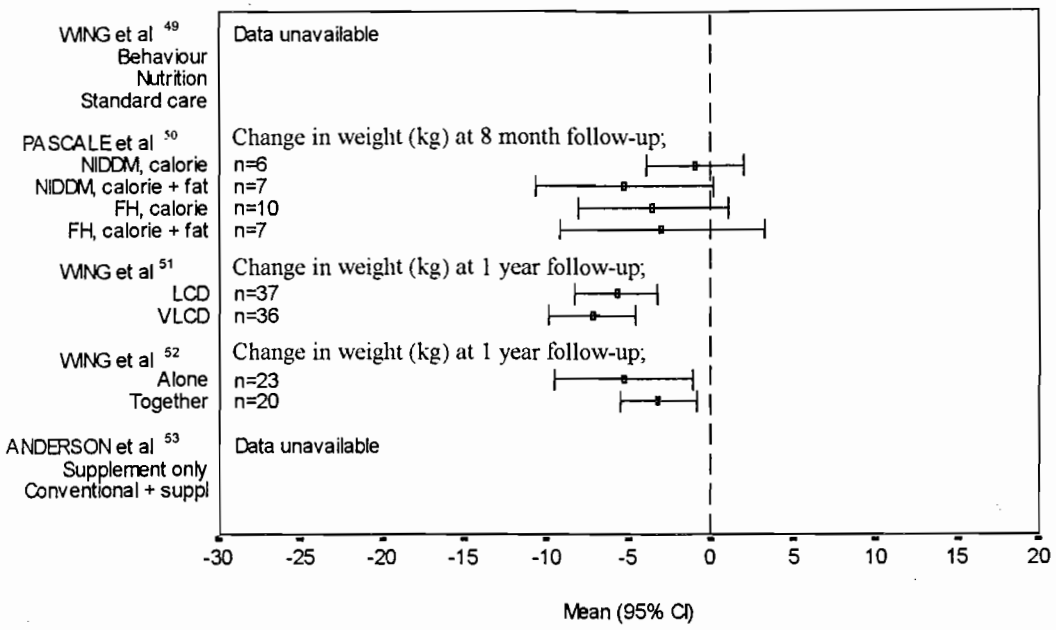

Figure 13: ***Studies examining weight loss interventions for patients with non insulin dependent diabetes (NIDDM). (FH - family history of NIDDM; LCD - low calorie diet; VLCD - very low calorie diet).***

3.5.2 Very low calorie diets

Two studies by Wadden et al investigated the value of adding periods of VLCD to behavioural therapy.[54,55] In the earlier of these studies, a comparison of either VLCD or standard behaviour therapy (SBT) alone to VLCD and SBT combined was undertaken.[54] The VLCD programme lasted for four months. During the first month, participants were prescribed a 1000-1200 kcal/day balanced diet. The following two months saw a reduction in the calorie intake, down to 400-500 kcal/day, with a return to conventional foods in the fourth month. Participants undergoing SBT only were prescribed a 1000-1200 kcal/day diet for the duration of the 6 months of therapy. During this period subjects were taught traditional behavioural techniques, such as stimulus control, modification of self-defeating thoughts, recording of eating behaviour and increasing lifestyle activity. The third group received a combination of the VLCD programme and the SBT programme.

At post-treatment mean weight change for the combined therapy was -19.3±8.3kg compared to -14.1±5.1kg and -14.3±6.7kg for the VLCD alone and the SBT alone respectively. This difference was statistically significant. At one year follow-up, however, participants in all three groups had regained comparable amounts of weight. The mean changes in weight from baseline were -12.9kg for the combined treatment, -4.6kg for those receiving diet alone, and -9.5kg for those receiving SBT alone. The weight loss achieved by the combined therapy group remained significantly greater than that of the VLCD group.

In a later study, three similar treatment groups were compared.[55] The results at one year showed that the two groups undergoing behavioural treatments achieved a statistically significant greater mean weight loss (6.6kg for those receiving behaviour therapy alone and 10.6kg for those receiving VLCD

and behaviour therapy) compared to the diet alone group (mean weight loss 4.7kg). At five years there were no longer any significant differences between treatment groups.

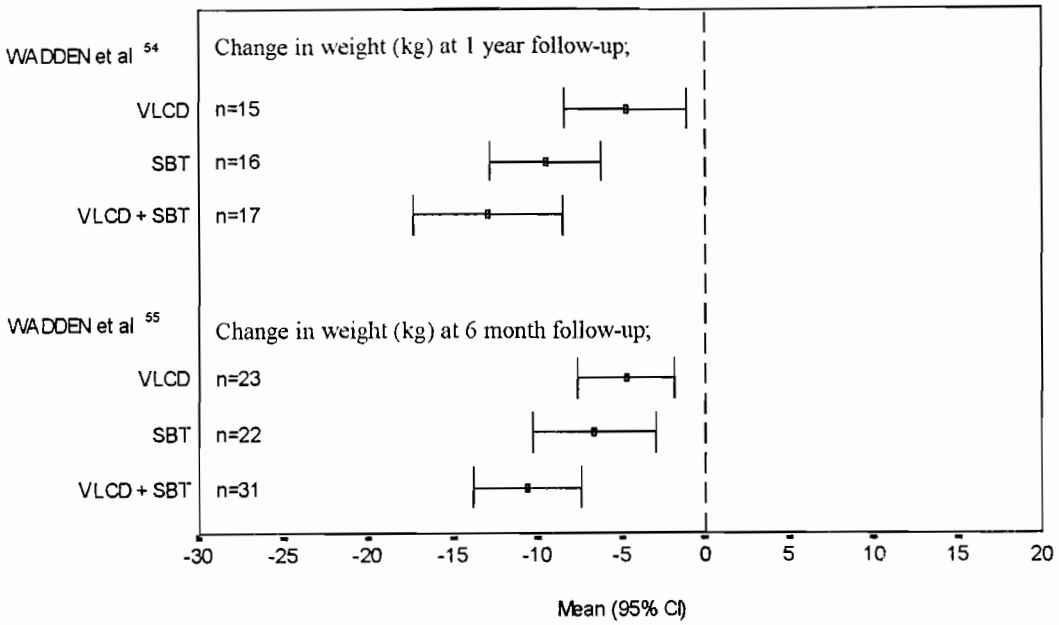

Figure 14: ***Studies examining the addition of very low calorie diets (VLCD) to standard behavioural therapy (SBT).***

3.5.3 Fat restriction versus fat and calorie restriction

Schlundt et al[56] studied fat restriction alone versus fat plus calorie restriction in adults who were at least 20% overweight. The fat restriction only group were encouraged to eat carbohydrate based foods according to their appetite, whilst fat plus calorie restricted subjects consumed these types of foods with reference to a prescribed restriction. All subjects were trained in the use of food diaries and food counters, and attended weekly group sessions where they received a behaviour modification programme for weight loss. This included instruction on self-monitoring, skills development, lifestyle change, regular exercise, improving self-esteem and enhancement of body image. There was a statistically significant greater baseline BMI for those in the fat plus calorie restriction group compared to the fat restriction alone group, namely 37 versus 31kg/m^2 for male subjects and 33 versus 30kg/m^2 for female subjects. However, there were no statistically significant between group differences for the other baseline variables of age, height or weight.

At the end of the intervention (16-20 weeks), subjects restricting fat and calories had a statistically significant greater weight loss compared to those restricting fat alone. The mean (±sd) weight losses were 8.8±4.7kg and 4.6±3.7kg respectively. Both groups had lost statistically significant amounts of weight compared to baseline values. Although the statistically significant effect for time was maintained for both groups at the 9-12 month follow up, the significant between group difference was lost. Mean weight losses were 2.6±4.7kg for the fat restriction only group and 5.5±5.5kg for the fat and calorie restriction group.

Fat restriction versus calorie restriction was also examined in a later study by Jeffery et al.[57] Women, aged between 25 and 45 years, between 120% and 140% of ideal body weight, but otherwise healthy, were recruited through newspaper advertisements. They were randomised to receive either counselling in fat consumption or counselling in calorie consumption. The sessions were given by an experienced dietician and health educator, and included prescriptions for daily calorie or fat intake.

Mean weight losses during the period between baseline and six month follow-up were 4.6kg for the fat counselling group and 3.7kg for the calorie counselling group. By the 12 month follow-up, both groups had regained some of the lost weight (cumulative mean weight losses were 2.1kg and 0.5kg respectively), and by the 18 month follow-up, the mean weight for both groups was greater than the baseline values. The mean weight gains were 0.4kg and 1.8kg respectively. There were no statistically significant between group differences for weight loss or weight gain at any point during the study.

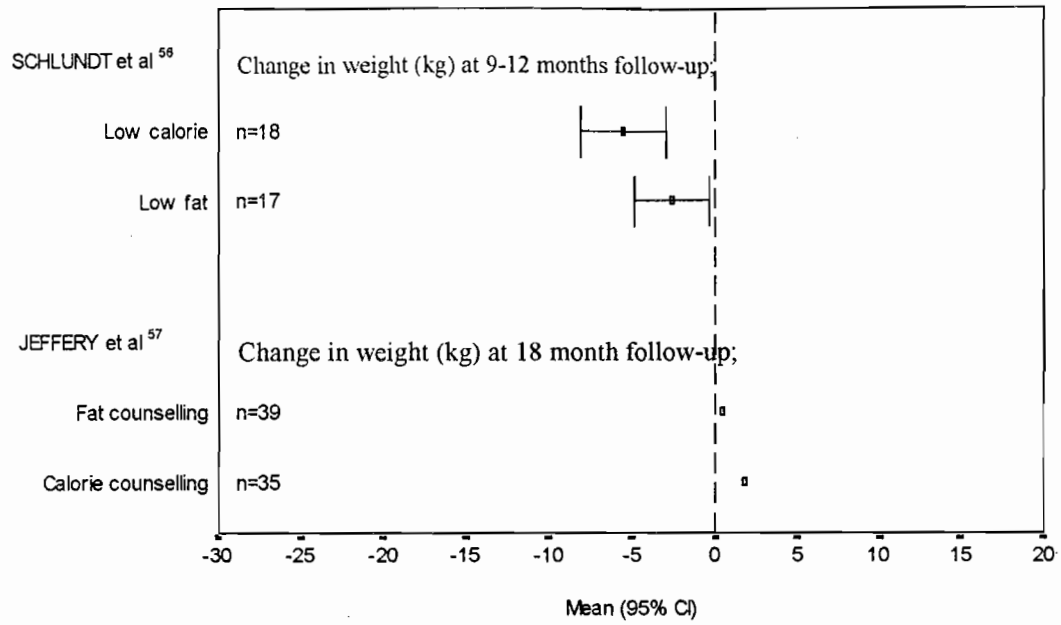

Figure 15: ***Studies examining the effectiveness of fat and calorie restriction.***

3.5.4 Provision of Food and Meal Plans

Jeffery et al[58] recruited adults aged between 25 and 45 years, overweight by 14-32kg but otherwise healthy. These subjects were allocated to receive one of five treatment conditions during an 18 month weight loss intervention. Individuals in the first group served as no treatment controls, and were instructed to use whatever methods they wished to lose weight on their own. Participants in the second group received SBT, which included individual calorie goals, weight goals, and an exercise programme. The third group was provided with two pre-packaged meals a day, five days a week in conjunction with SBT. The fourth group received SBT plus an incentive schedule, whereby a weekly cash payment was made according to the amount of weight they had lost. The fifth group received a combination of food provision, incentive and SBT.

The two groups that were provided with food had the largest weight loss at all time points studied. The mean weight loss across all the treatment groups excluding control was 7.7kg during the time between baseline and 6 month follow-up. The corresponding figure for groups provided with food was 10.1kg. The respective values were 4.5kg and 9.1kg for the 12 month follow-up, and 4.1kg and 6.4kg at 18 months. Analysis of BMI also demonstrated that food provision groups had statistically significant losses when compared to the non-food provision groups. Moreover, the active treatment groups had statistically significant reductions in BMI when compared to the control group. However, the superiority of the food provision observed at 12 months was not maintained at 18 month post-intervention follow-up.[59] There were no statistically significant effects for the financial incentive conditions. There were statistically significant different drop-out rates between the study groups but it is not stated between which groups these differences occur.

In a later study, Wing et al[60] allocated healthy overweight women to receive one of four interventions. The first group were assigned SBT only. The second group received SBT in conjunction with detailed written meal plans and weekly grocery lists. The third group received the same intervention as group 2, with the added provision of a food box containing all the items described on the meal plans. Participants shared the cost of food provision by paying US$25 per week, and food provision was discontinued if co-payments were not made. The fourth group underwent the same treatment as group 3, except that their food was provided to them free of charge.

At the end of the 6 month intervention, the mean (±sd) weight loss in the group receiving SBT alone was 8.0±6.2kg. This was a statistically significant smaller loss when compared to data from the other three groups, which were 12.0±7.2kg, 11.7±5.4kg and 11.4±6.5kg respectively. A similar pattern was maintained at the one year follow-up, although all groups had regained some of the lost weight. The mean weight losses compared to baseline were, 3.3kg for group 1, 6.9kg for group 2, 7.5kg for group 3, and 6.6kg for group 4. These results suggest that the provision of meal plans and grocery lists to overweight patients may be effective as a weight loss intervention, but the provision of food does not provide additional benefit.

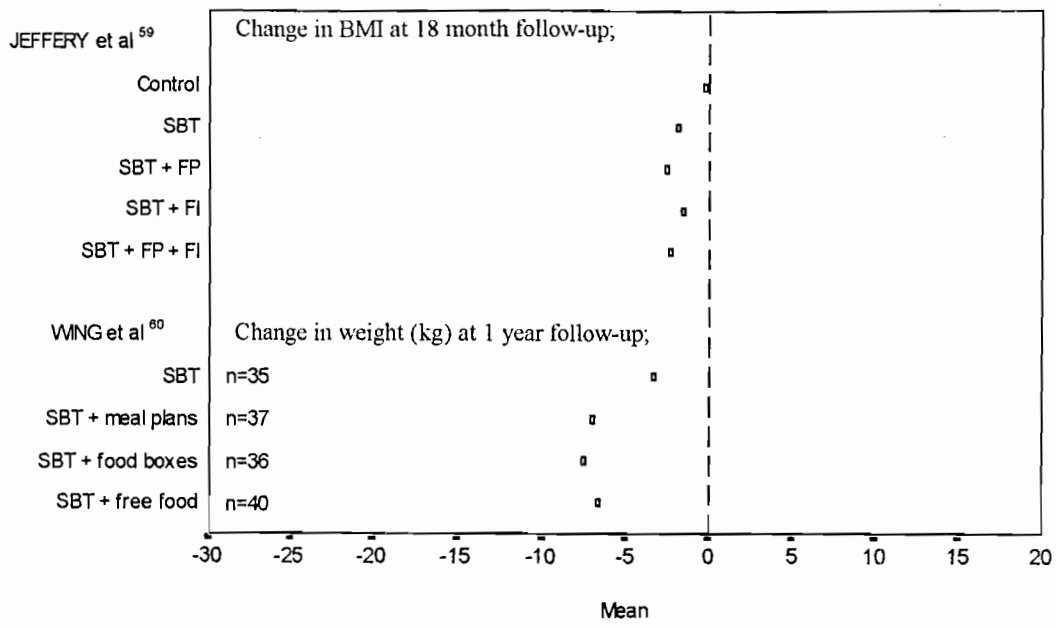

Figure 16: ***Studies examining the effectiveness of food provision and meal plans for weight loss. (SBT - standard behaviour therapy; FP - food provision; FI - financial incentive).***

3.5.5 Inpatient versus outpatient treatment

Hakala[61] allocated adults, aged 20-54 years, and at least 54% overweight, to receive a weight loss intervention based on dietary, exercise and behavioural strategies delivered in either an inpatient or an outpatient setting. The outpatient group attended a local health centre where they underwent a ten week course for weight loss led by specialist nurses. This course included lectures by general practitioners, a psychologist and a physiotherapist. Those receiving the inpatient treatment stayed at a rehabilitation centre for three weeks, where they underwent nutrition counselling, food preparation advice, social counselling, exercise training, occupational therapy, and a prescribed calorie reduced diet. Both groups received written information on diet and exercise advice.

A statistically significant greater mean weight loss of 13.8±8.6kg was observed for the inpatient group at six months compared to a mean weight loss of 7.5±10.0kg for the outpatient programme. Moreover, both groups had lost statistically significant amounts of weight compared to baseline. At the two year follow-up, the mean weight loss in the inpatient group was 7.5±9.5kg versus 3.1±11.1kg for the outpatient group. There were no statistically significant between group differences at this point. The weight loss over time, compared to baseline values, remained statistically significant for the inpatient group only. At the five year follow-up, the mean weight change from baseline was -6.8kg for men and +0.3kg for women in the inpatient group. In the outpatient group, the mean weight had returned to baseline levels for both sexes.

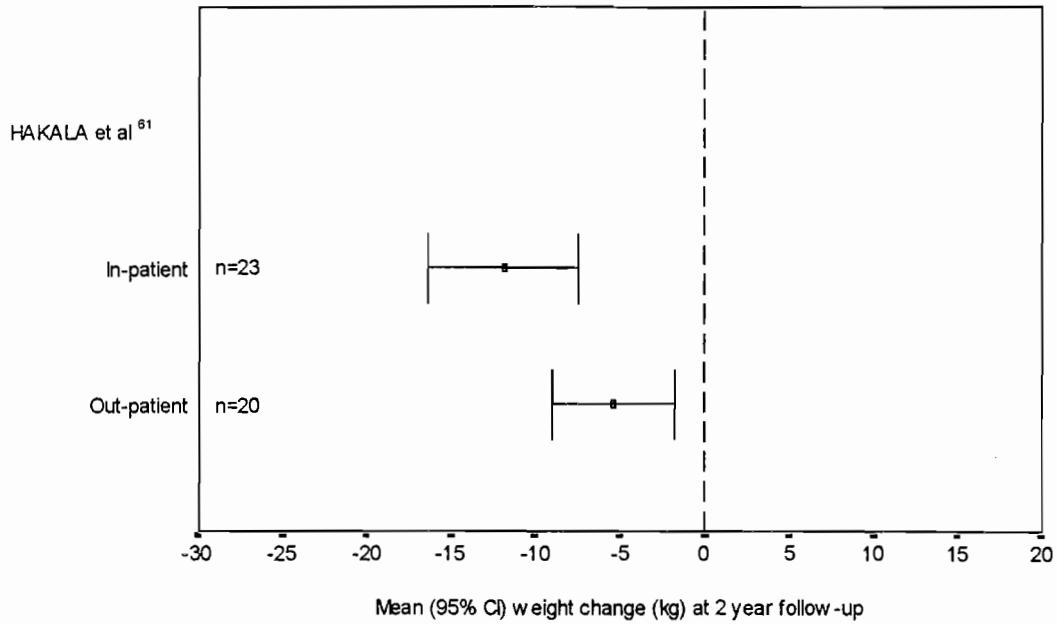

Figure 17: ***Study examining inpatient versus outpatient treatment of obesity***

3.5.6 Summary

Fat and calorie restriction may be more beneficial than calorie restriction alone when targeting NIDDM patients for weight loss. Combining VLCDs with behavioural therapy appears to be more effective than treating obese adults with either VLCD or behaviour therapy alone. There is no difference in the effectiveness of fat restriction alone compared to fat and calorie restriction in the longer term (i.e. at one year follow-up) in non-diabetic participants. The restriction of both fat and calories may be helpful in the shorter term. There is conflicting evidence regarding the benefit of food provision. However, the provision of meal plans and grocery lists may be of benefit as a weight loss intervention. There is no demonstration of the superiority of either inpatient or outpatient management of obesity.

3.6 Behavioural interventions combined with specific exercise components (see table 5)

The four studies in this section evaluated the effectiveness of behavioural interventions used in conjunction with exercise programmes, as a treatment for weight loss.

3.6.1 Moderate exercise versus placebo/no exercise

Wing et al[62] undertook two studies evaluating the role of exercise as a weight loss intervention in overweight non-insulin dependent diabetics. Subjects were greater than 20% overweight and aged between 30 and 65 years. The first study compares moderate exercise, based on walking, with placebo exercise, based on light callisthenics and flexibility exercises. All participants received dietary guidelines with daily calorie goals, and sessions providing instruction in behavioural strategies for weight loss.

At the end of the ten week weight loss intervention, both groups had lost statistically significant amounts of weight compared to baseline values ($p<0.001$). The moderate exercise group lost 8.5±0.8kg (mean ± sem) and the placebo group lost 7.3±0.7kg. There were no statistically significant differences between the groups with respect to weight loss. At one year follow-up, the statistically significant intra-group differences had been maintained, but there was still no significant difference between the two groups.

In the second study, the treatment procedures utilised were similar to study one except that a group receiving the dietary guidelines and behavioural intervention were compared to another group receiving an exercise programme, based on walking, in addition to the above. There was a statistically significant between group difference, in favour of the group receiving exercise, for mean weight loss at both post-treatment (9.3kg versus 5.6kg), and at one year follow-up (7.9kg versus 3.8kg).

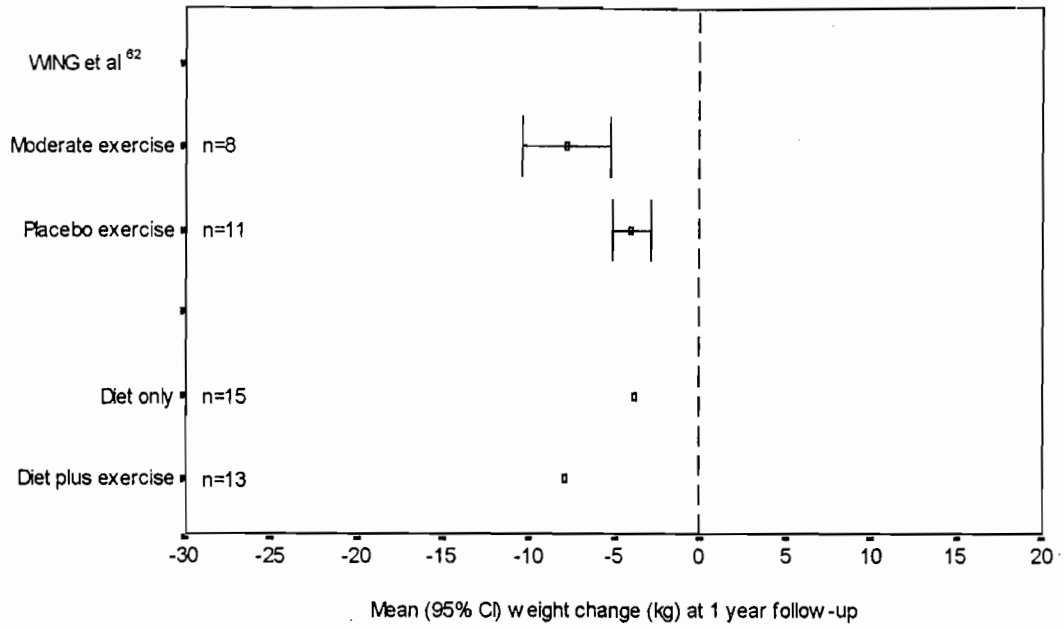

Figure 18: ***Studies examining the effect of moderate exercise compared to placebo exercise or no exercise.***

3.6.2 Supervised exercise versus exercise education

Pavlou et al[63] recruited overweight males aged 26-52 years, who were members of the Boston Police Department and the Metropolitan District Commission. The participants attended educational sessions for 8 weeks within a 2x4 factorial design study. This was used to evaluate four different diets: a balanced caloric deficit diet (BCDD) of 1000 kcal/day, a protein sparing modified fast (PSMF) of 1000 kcal/day, a powdered protein carbohydrate mix of 420 kcal/day (DPC70), and a formula diet of 800 kcal/day (DPC800). Each diet was combined with either supervised exercise sessions, or exercise education with no additional exercise activity. The exercise sessions were of 90 minutes, 3 times per week, and consisted of aerobic activity, callisthenics, and relaxation exercises. Those receiving the exercise education condition were asked to continue normal daily activity, and not participate in any form of additional exercise.

All groups had lost statistically significant amounts of weight by the end of the ten week intervention, ($p<0.001$). However, the BCDD exercise education group, and the DPC800 exercise education group, had lost significantly less weight (7.1kg and 9.6kg respectively) in comparison to the other groups ($p<0.001$). The range of weight loss across the other groups was 10.6kg to 13.2kg. For groups receiving exercise, there were no statistically significant time effects between baseline and 6 and 18 month follow-up measurements. All non-exercise groups had regained weight at the 6 and 18 month follow-ups, although it is not stated whether the rates of regain were statistically significant over time, or between groups. The number of participants treated with exercise who continued to exercise at the 6 and 18 month follow-ups was significantly greater ($p<0.001$) than for those receiving exercise education.

3.6.3 Supervised exercise versus dietary education

In a study undertaken by Bertram et al,[64] obese women were randomly assigned to one of three sixteen week treatment conditions. The first of these was an exercise condition involving thrice weekly one hour aerobic training sessions. The second group received lectures on nutrition and behavioural strategies to modify eating behaviour, and the third group, which served as a control, did not participate in any group activity. All participants received a 1200 kcal/day diet.

All three treatment groups showed statistically significant decreases ($p<0.01$) in body weight and BMI at post-treatment measurement compared to baseline. No statistically significant differences were demonstrated between the groups. However, when the latest available data were included for seven subjects who had dropped out of the control group, it was observed that the average reduction in body weight for this group was 5%, compared to 8% and 9% for the exercise and lecture groups respectively. These values also matched the respective mean reductions in BMI. By the end of the sixteen week intervention, the overall attrition rate was 20%.

Follow-up assessments were carried out one year after the completion of the weight loss programme. At this stage, the attrition rate was 70% and therefore there were insufficient data for meaningful between group comparisons. However, the data that were available indicated that, overall, subjects maintained a statistically significant lower body weight compared to baseline level, although some weight regain had occurred.

3.6.4 Exercise and contingency management

Contingency management is concerned with the reinforcement of desirable behaviours through the use of rewards, and the elimination of adverse behaviours through the use of punishment. It is important that the reward or punishment takes place as soon as possible after the behaviour has occurred. Clinical psychologists, parents, teachers, or spouses may take on the role of contingency manager, meaning that they take the responsibility for identifying, and acting upon the relevant behaviours. However, it is also possible for the patient or client to act as his or her own contingency manager, and this is often the case when this technique is employed as part of a behavioural programme for weight loss. However, the spouse of the overweight person may also fulfil this function. Reinforcers of

desirable behaviour may be material, social or activity based. Material reinforcers may take the form of money, or a type of prize or gift. Social reinforcers involve verbal praise, or non-verbal messages of praise such as facial expressions or physical contact. Activity reinforcers are concerned with the permitted increase of a desired pastime in response to desirable behaviour.

Johnson et al[65] evaluated the effectiveness of contingency management as a strategy for weight loss and compared this to, and combined it with, stimulus control and exercise. The study was carried out using a 2x2 factorial design. Adults who were, on average, 40% overweight, were allocated to four different treatment conditions. All participants were trained in the use of stimulus control, and the first group received this alone. A second group was provided with stimulus control combined with exercise. The third group received stimulus control in conjunction with contingency management, and the fourth was treated with stimulus control, exercise, and contingency management.

All groups demonstrated statistically significant ($p<0.001$) weight losses at the end of the ten week intervention, first group 4.7kg, second group 5.9kg, third group 4.5kg, fourth group 4.3kg. However, there were no statistically significant differences between groups at this time.

At one year follow-up, the groups exposed to exercise and/or contingency management maintained statistically significant weight losses compared to baseline, second group 7.4kg ($p<0.05$), third group 5.2kg ($p<0.001$), fourth group 5.9kg ($p<0.01$). The group that had received stimulus control alone had regained half of the weight lost at the end of the intervention and the net weight loss at this stage amounted to 2.4kg, non significant difference compared to baseline. No statistically significant differences were demonstrated between the effect of exercise and contingency management because the main effect for exercise failed to meet statistical significance.

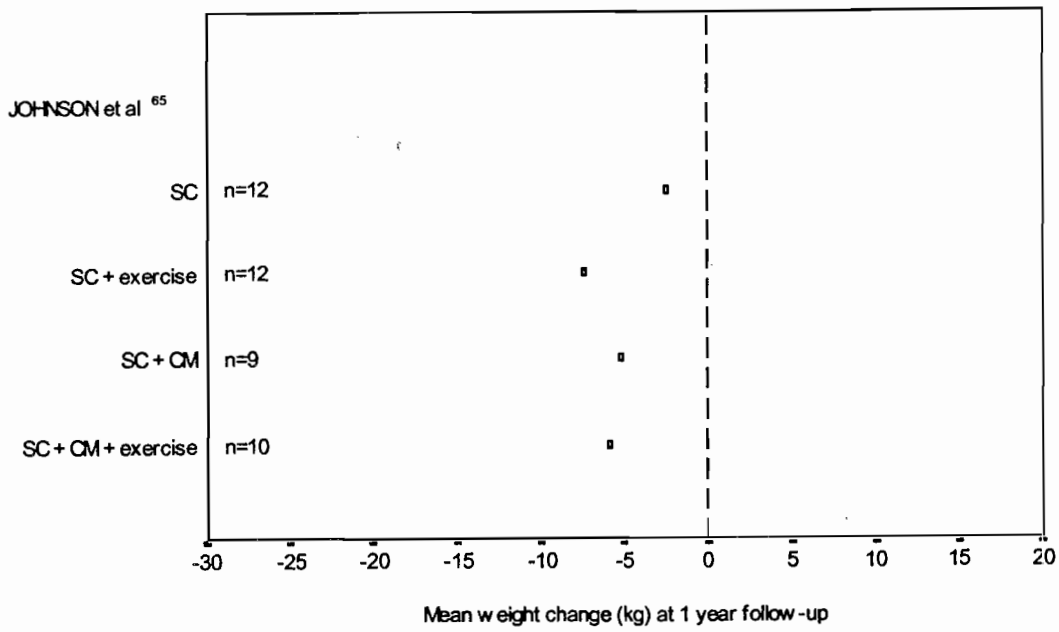

Figure 19: ***Study examining the effectiveness of contingency management (CM) compared to and combined with stimulus control (SC) and exercise.***

3.6.5 Summary

There is one paper to suggest that moderate exercise such as walking, is no more effective than light exercise, such as callisthenics and stretching, as part of a weight loss programme. However, exercise did appear to be of benefit when compared to a group receiving no exercise. When exercise was compared to exercise education, results suggested that the former may be the more useful strategy to help prevent regain of lost weight. The evidence for the effectiveness of exercise versus dietary education remains unclear, although both these treatment conditions had superior weight losses at the end of the weight loss intervention compared to a no-treatment control. The role of exercise and contingency management, both alone and in combination, remains to be clearly determined.

3.7 Dietary interventions (see table 6)

3.7.1 The role of fibre in weight loss

Two papers focused purely on dietary interventions, by examining the role of fibre in promoting weight loss. Baron et al[66] compared three months of a low fibre/low carbohydrate diet with three months of a high fibre/low fat diet, each providing approximately 1000 kcals per day. Participants in this study ranged from barely overweight to obese. It was thought that this range of overweight reflected those attending diet clubs. The low fibre/low carbohydrate group had a greater mean weight loss at one month, three months and one year follow-up. The paper fails to demonstrate the advantage of fibre in promoting weight loss.

In the second paper, Rytigg et al[67] evaluated fibre supplements, compared to placebos, in addition to a calorie restricted diet. All participants were placed on a diet providing 1200 kcals per day, and randomised to receive either a fibre supplement of 7g per day or placebo for 11 weeks. This was followed by 16 weeks on a diet providing 1600 kcals/day and either a fibre supplement of 6g per day, or a placebo. After this period, all participants remaining in the study were given a 6g supplement of fibre with an *ad libitum* diet for the remaining 25 weeks. A statistically significant weight reduction was seen in both groups at eleven weeks ($p<0.01$), with the supplement group demonstrating a significantly greater mean weight loss of 4.9kg compared to 3.3kg for the placebo group. The difference between groups remained statistically significant at the end of the one year intervention ($p=0.03$), even though the control group received fibre supplements from week 27 onwards.

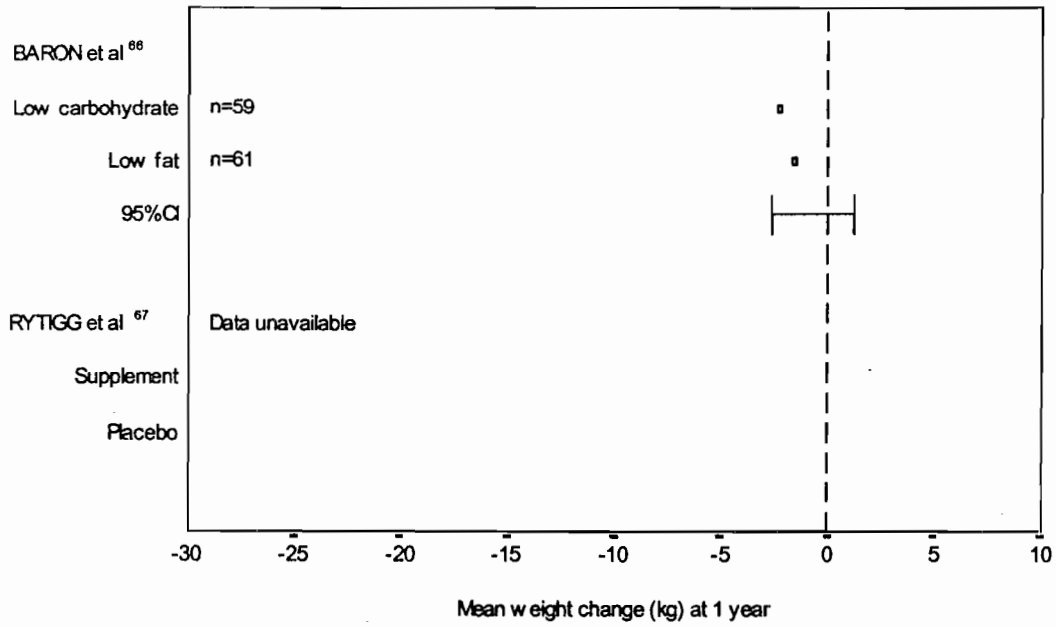

Figure 20: ***Studies examining the role of fibre in promoting weight loss.***

3.7.2 Summary

The evidence regarding the effectiveness of increased fibre intake for weight loss is conflicting. Increased dietary fibre does not appear to show a greater mean weight loss when compared to a low fibre/low carbohydrate diet. However, fibre supplements appear to be more effective than placebo at increasing weight loss for subjects receiving a 1200 kcal/day diet.

3.8 Diet and exercise combined (see table 7)

Skender et al[121] evaluated the relative and combined benefits of diet and exercise as weight loss interventions. The first study group was prescribed a low energy diet, the second received an exercise regime based on walking, whilst the third group underwent the combination of these interventions.

At the end of the one year intervention all groups had lost weight relative to baseline but there were no statistically significant differences between groups. At the end of the one year follow-up, all groups had regained some of the lost weight. Although no statistically significant differences were reported between groups, it was observed that the groups with a dietary component had a tendency to regain more weight, and exercise alone appeared to produce better maintenance of weight loss. However, small sample sizes and high rates of attrition mean that these results should be considered cautiously.

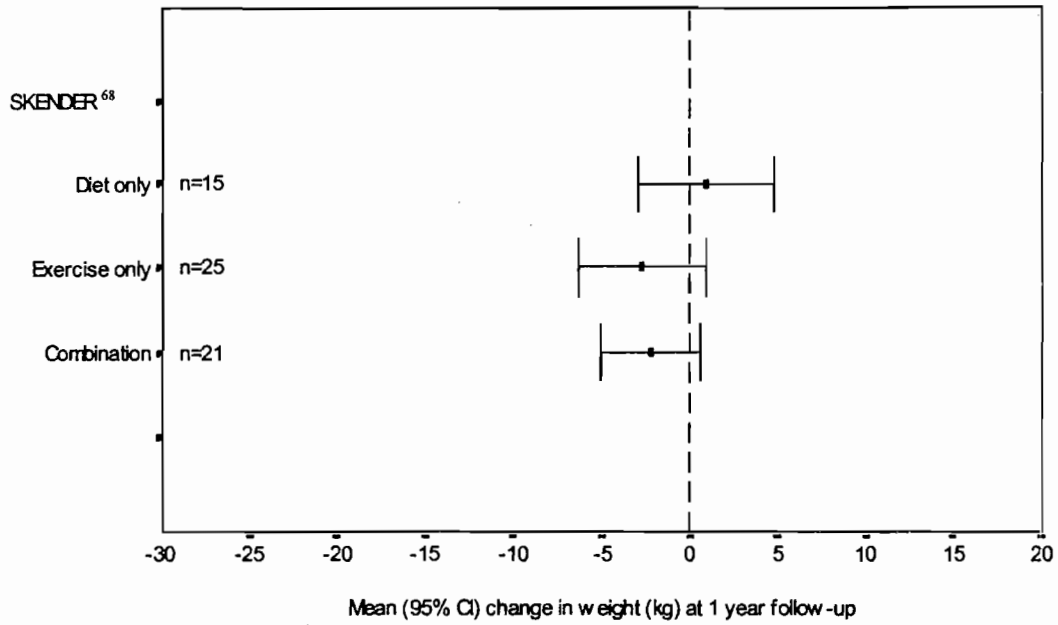

Figure 21: ***Study examining the role of diet and exercise for weight loss***

3.9 Pharmacological interventions (see table 8)

This section will review the effectiveness and adverse events of pharmacological interventions in obesity. Please refer to addendum (page141)

Searches for studies assessing the effectiveness of pharmacological interventions in the treatment of obesity identified 111 references in total. Of these, 11 studies were not RCTs, and were excluded. One hundred RCTs were identified, and of these, 87 were excluded because they did not observe patients for at least one year. Thirteen studies were therefore included in the review and are discussed below.

3.9.1 Studies evaluating dexfenfluramine (dF)

In the thirteen studies satisfying the inclusion criteria, the most commonly studied drug was the selective serotonin agonist dexfenfluramine (dF) (Isomeride®, Adifax®) the dextro-isomer of racemic dl-fenfluramine. Five papers compared dF (15 mg twice daily in all trials) against placebo capsules.[69-73] All participants were prescribed a calorie restricted diet. The largest of the studies, a multi-centre study (the INDEX study – 24 centres in 9 European countries, n=822), demonstrates a statistically significant greater weight loss for the dF group than for the placebo group at the end of the 1 year intervention (9.82 kg versus 7.15 kg).[69] During the last 6 months of intervention, the placebo group showed a tendency to regain weight, whereas the body weight of those taking dF remained relatively stable.

One centre included in the Index trial extended the follow-up to three years.[70] At the three year follow-up, the placebo group had maintained weight loss compared to baseline, whereas the dF group had gained weight.

Mathus-Vliegen et al[71] ran a study following the INDEX trial protocol, (n=75). Both placebo and dF were equally effective in reducing weight up to 7 months, after which there was a similar trend for weight regain in the two groups, even though the intervention continued for a further five months.

Two other trials demonstrated the effectiveness of dF, but only for a 6 month period.[72,73] Participants in the study by O'Connor et al[72] received treatment for 6 months only. Dexfenfluramine produced a statistically significant greater weight loss than placebo at 6 months, 9.7 kg versus 4.9 kg respectively. However, no difference was seen at 5 months post-intervention follow-up. Mathus-Vliegen[73] continued to give dF for a total of 12 months. After the first six months weight began to rise, and by 12 months those receiving dF showed a statistically significant increase in body weight relative to peak weight loss compared to those receiving placebo.

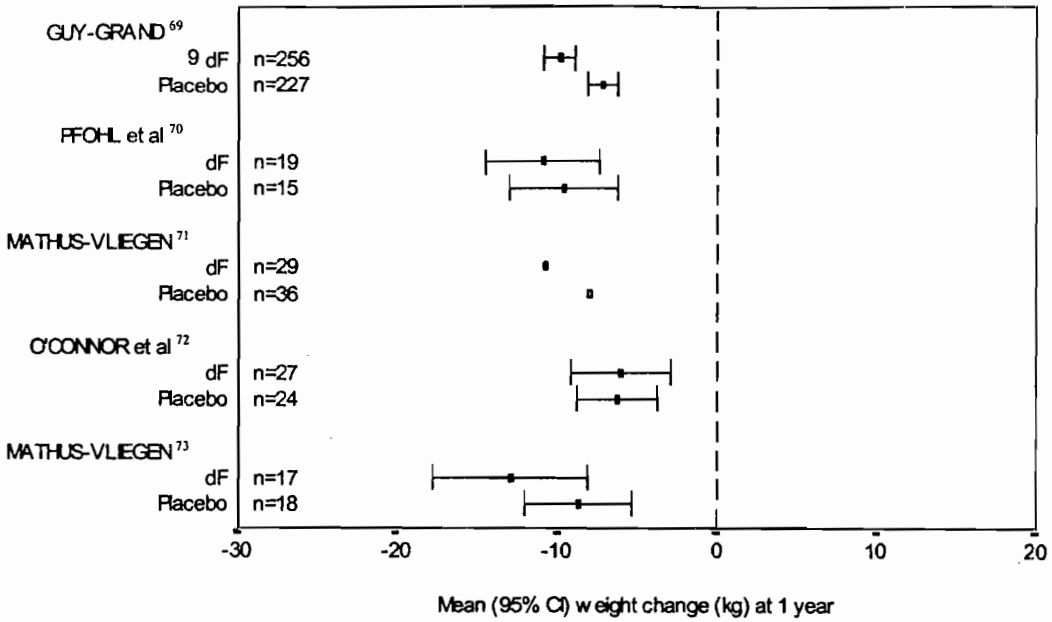

Figure 22: ***Studies evaluating dexfenfluramine (dF) versus placebo for weight loss***

Three of the above studies were pooled (Figure 23) using a fixed effects method.[69,71-72] This found an overall weighted mean difference between treatment and control groups of -2.5kg (95% CI -3.7, -1.2). No significant heterogeneity was found between the studies. The findings of the analysis indicate that dexfenfluramine is more effective than placebo at 12 months, however, the trend for weight regain after approximately 6 months remains a concern.

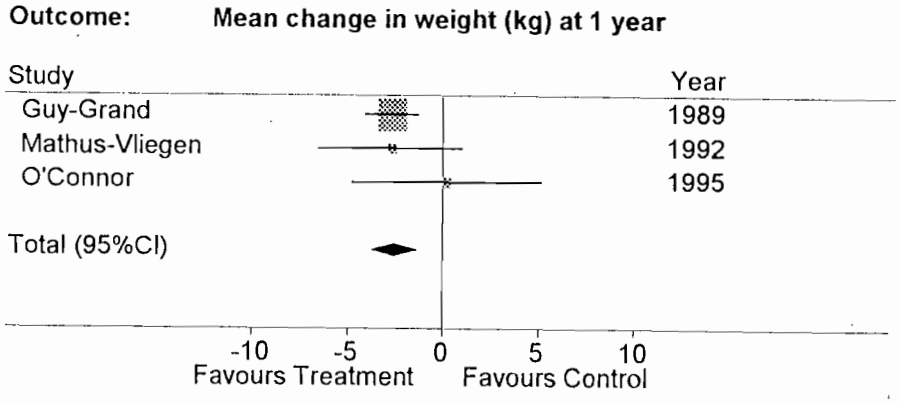

Figure 23: ***Pooled estimate (fixed effect) of weight change at 1 year for studies examining dexfenfluramine versus placebo***

The findings of the meta-analysis suggest that dexfenfluramine is more effective than placebo at 12 months, however, the trend for weight regain after approximately 6 months remains a concern.

One study evaluated dF (15mg twice a day for three months) as part of a year-long weight loss intervention programme, combined with individual dietetic consultations at a clinic.[74] Three other groups were examined. One group received individual dietetic consultations at the clinic, without the addition of dF. A further group underwent the same consultations, but with a selection of the visits taking place in the patients' own home. The final group underwent group behavioural therapy at fortnightly intervals for 3 months and then 2-monthly for the remainder of the year. All patients received the same dietary advice. At 3 months, all groups had lost weight, the only statistically significant between group differences occurring between those undergoing dietetic consultations at the clinic, either with or without dF (mean weight change: -3.40kg versus -1.59kg respectively). By the end of the intervention (1 year), no significant differences were seen between groups. The mean weight change for all groups ranged from -1.14kg to -2.75kg post-intervention.

3.9.2 Studies examining fenfluramine

Ôst and Götestam[75] compared the effectiveness of fenfluramine, an amphetamine derivative, (60 mg twice daily) with a behavioural intervention and a third group consisting of patients on a waiting list, not receiving treatment. Those in the behaviour therapy group achieved a statistically significant greater weight loss compared to the control group. However, there was no significant difference in weight loss between behavioural and fenfluramine, or between fenfluramine and the waiting list control group.

Weintraub et al[76] compared the role of fenfluramine plus phentermine, a sympathomimetic drug, given as a continuous dose or intermittent regime, as part of a larger, complex RCT. No statistically significant difference in weight loss was found.

3.9.3 Studies evaluating selective serotonin re-uptake inhibitors (SSRIs)

Two studies were concerned with the effect of fluoxetine (Lovan®, Prozac®) (60 mg daily), a selective serotonin re-uptake inhibitor (SSRI), compared to placebo.[77,78] One of the activities of serotonin in the central nervous system is to modulate feeding behaviour, and by increasing the level of serotoninergic synaptic activity it is anticipated that food intake will be reduced. Goldstein et al[77] report the findings of a multi-centre (ten-site) study assessing the effects of fluoxetine in conjunction with dietary advice, nutrition and behavioural counselling. The comparison group received the same advice and counselling, with placebo capsules rather than fluoxetine. Fluoxetine was shown to produce a statistically significant greater mean weight loss from weeks 2-28. After this period, the difference in weight loss between the treatment group and the placebo group was no longer significant, both groups commencing weight regain even though treatment continued. The second trial carried out on fluoxetine focused on non-insulin dependent diabetics.[78] In this smaller study, fluoxetine produced a statistically significant fall in median body weight between 3 and 12 months when compared to placebo. However, weight regain commenced at 9 months.

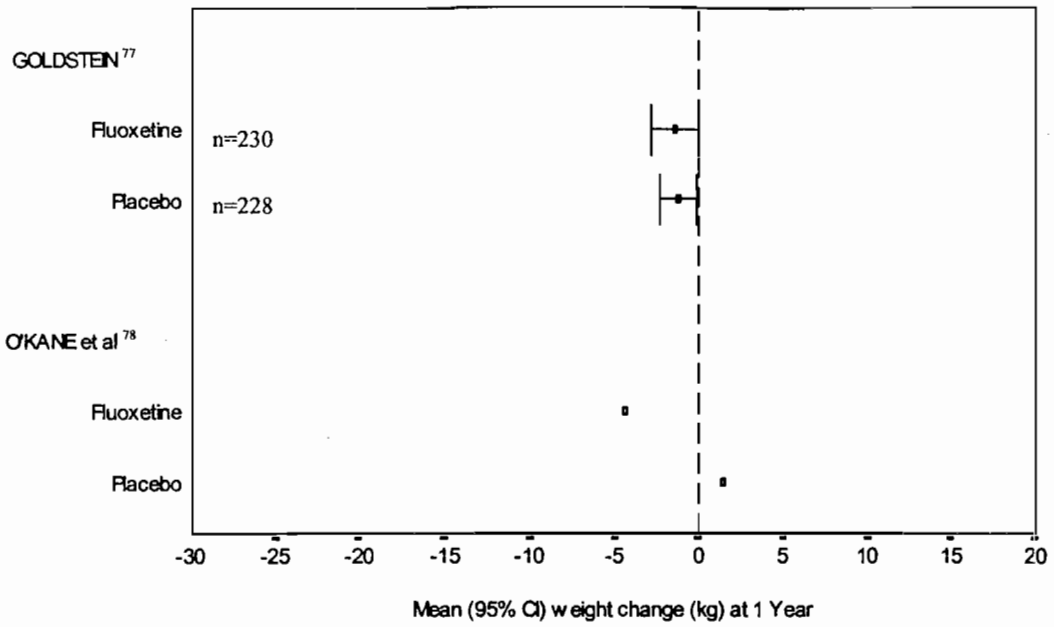

Figure 24: ***Studies evaluating fluoxetine versus placebo***

Another serotonin re-uptake inhibitor examined was femoxitine.[79] Patients were advised to restrict their daily intake to approximately 1200-1600 kcal/day, and randomised to receive either 600 mg of femoxetine or identical placebo. Overall results show no statistically significant benefit of femoxetine.

3.9.4 Studies examining mazindol

Vernace[80] compared the effectiveness of mazindol (Sanorex®, Teronac®) with a standard anorexiant, d-amphetamine and a placebo. Mazindol is a central nervous system stimulant, prescribed solely for the treatment of obesity. Both drug arms showed significantly greater weight loss than the placebo during the 12 weeks of treatment but weight regain occurred post-treatment. There was no statistically significant difference between the three groups at 1 year follow-up.

3.9.5 Drugs currently under study

Two new drugs presently under study in the treatment of obesity are sibutramine (a noradrenergic and serotonin reuptake inhibitor) and Orlistat (a lipase inhibitor). A multicentre double blind RCT of sibutramine (10mg and 15mg once daily for one year) showed weight loss during the first six months, with weight remaining stable for the following six months. At 12 months, average weight loss was 1.6kg for the placebo group, and 3.3kg and 4.4kg for the 10mg and 15mg sibutramine groups respectively.[81]

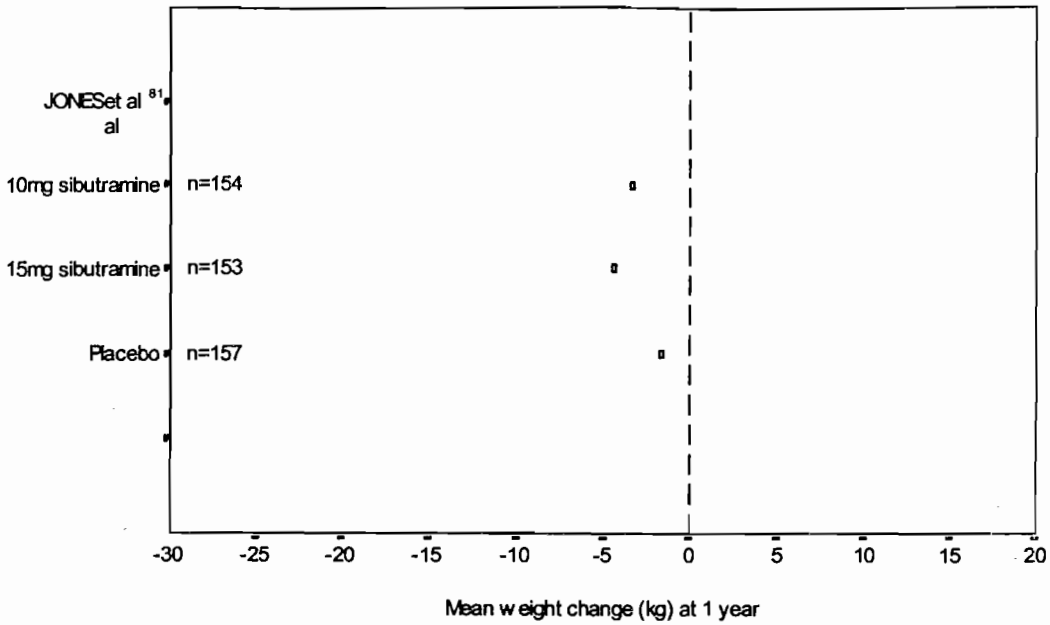

Figure 25: ***Study assessing the effectiveness of sibutramine at varying doses.***

3.9.6 Adverse effects

Four of the five dF versus placebo trials reported on adverse effects. Two studies reported no major events, only initial temporary complaints. Two further studies reported a statistically significant higher incidence of adverse events in the dexfenfluramine groups.[69,72] These events included fatigue, dizziness, dry mouth, nausea, diarrhoea, and polyuria. The risk of pulmonary hypertension has been shown to increase when treatment with df is used for a total period of > 3 months. However the absolute risk is still very low.[130]

Of the two studies assessing fluoxetine versus placebo, one reported more frequent adverse effects in the active drug groups. These effects include gastrointestinal symptoms, sleep disturbances, sweating, tremor, amnesia, and thirst. By contrast, O'Kane et al[78] did not demonstrate any statistically significant inter group differences regarding the frequency of adverse events.

Bitsch and Skrumsager[79] observed that 3 (4%) patients receiving femoxitine withdrew due to the incidence of side effects during weeks one to five of the trial. Ôst and Götestam[75] reported no statistically significant differences in the occurrence of adverse effects in the groups receiving the active drug. Adverse events associated with taking femoxitine include fatigue, dizziness, diarrhoea, and constipation.

Weintraub et al[76], reported fewer adverse effects for those receiving continuous fenfluramine and phentermine compared to those undergoing intermittent medication. Sleep disturbance, fatigue, dizziness, gastrointestinal symptoms, palpitations, nervousness, and changes in libido were among the effects observed.

Vernace[80] noted more side effects in the active drug groups when compared to placebo. Headache, dry mouth and nausea were associated with taking mazindol, whereas insomnia was the principal complaint among those taking amphetamine based drugs. Jones et al[81] report sibutramine as being well tolerated, the commonest adverse events being headache, infection, constipation, dry mouth and pharyngitis.

3.9.7 Summary

The results of studies of dexfenfluramine versus placebo are conflicting. Although one trial demonstrated the superior performance of the active drug at one year follow-up, three others showed that weight initially lost had been regained, sometimes despite continuation of treatment. A further study failed to demonstrate statistically significant between group differences at follow-up. The meta-analysis (Figure 23) suggests that dexfenfluramine is more effective than placebo for weight loss at 12 months. However, weight regain is a concern, and follow-ups of greater than 12 months are required to establish the true, long term effects. Dexfenfluramine enhances weight loss achieved by dietetic consultations.

The findings of papers evaluating the effects of SSRIs also require further clarification. The administration of fluoxetine was associated with an initial statistically significant weight loss compared to placebo. However, regain occurred at later follow-up (9 months), despite the continuation of treatment at this point.

A study of femoxitine versus placebo failed to show any statistically significant between group differences. When the drug fenfluramine was compared to a behavioural intervention, the latter achieved superior results. The study of fenfluramine combined with phentermine did not demonstrate any statistically significant differences between groups receiving continuous and intermittent medication. Regain of initial weight loss occurred after taking mazindol, with no statistically significant between group differences shown.

3.10 Surgical interventions (see table 9)

This section will cover patient selection, key results of surgical studies, mortality and other complications of surgery and quality of life following surgery.

Patients undergoing surgical interventions for obesity have different characteristics to those receiving medical treatments in that they are usually morbidly obese. Although the selection criteria for patients considered for surgery vary slightly between studies, they usually define a minimum measure of obesity. For example, Payne and DeWind[122] and Kral[123] stipulate that patients should be greater than 100 pounds or 100% above ideal body weight, as defined by standard life insurance tables. The National Institutes of Health Consensus Development Conference Statement[124] consider a selection criterion of BMI greater than 40kg/m^2 as suitable. In general, all patients should have undergone previous non-surgical weight reduction programmes, surgical treatment only being considered when all other attempts at weight loss have failed.

Fifteen papers met our inclusion criteria for surgical interventions.[82-96] These covered gastric bypass, gastroplasty, jejunoileal bypass, gastrogastrostomy and gastric balloons.

3.10.1 Gastric bypass versus gastroplasty

Seven papers examined the efficacy of gastric bypass compared to gastroplasty.[82-88] The purpose of the gastric bypass is to produce a small upper pouch in the stomach with a narrow outlet.[88] The pouch, usually constructed by employing a double row of surgical staples, drains into the proximal jejunum, bypassing most of the stomach and all of the duodenum. Although pouch size may vary, the most common size of pouch utilised in the included studies was approximately 30 ml. There are several techniques by which gastric bypass are undertaken. Six of the papers identified in this review look specifically at the Roux-en-Y technique (Fig. 26a), where the jejunum is divided, the distal end anastomosed to the side of the stomach, and the proximal end to the side of the jejunum at a lower level.

MacLean et al[83] and Sugerman et al[82] both compared the Roux-en-Y gastric bypass to vertical banded gastroplasty (VBG). The aim of the gastroplasty is, again, to produce a small upper pouch. Techniques used in the production of this pouch vary slightly. Gastroplasty (Fig. 26b) differs from gastric bypass in the way the pouch drains. Instead of bypassing most of the stomach, the natural passage of the food is maintained, with the upper pouch draining into the lower gastric compartment via a narrow outlet. Again, there are various types of gastroplasty. Vertical banded gastroplasty refers to the direction in which the upper pouch is constructed.

Sugerman et al[82] demonstrated a statistically significant difference between groups, the Roux-en-Y gastric bypass group losing 25% more of their excess weight than the gastroplasty at 1 year. It should be noted that entry to this trial ceased after forty patients had been assessed because a statistically significant result, with regard to weight loss, had been demonstrated for the gastric bypass group. It is unclear whether this was appropriate for this type of study. The difference remained statistically significant for three years post surgery.

MacLean et al[83] did not demonstrate a significant difference between the two groups, although there was a trend towards the Roux-en-Y gastric bypass having a greater success rate. Several patients from both study arms were later converted to isolated gastric bypass due to failure to lose weight (see discussion of morbidity below for more details). The participants in this part of the study were not randomised. However, it may be worth noting that this procedure was found to be more successful for weight loss than either of the original procedures, with a success rate of 83% versus 39% for the vertical banded gastroplasty and 58% for the Roux-en-Y gastric bypass ($p=0.003$). In this study, individual success was defined as a reduction to less than 50% of excess weight.

Three studies compared the Roux-en-Y technique to undefined gastroplasty.[84-86] Hall et al[84] also included a third study group which received gastrogastrostomy (the surgical anastomosis of one portion of the stomach with another, the portions being separated by a staple line). All three papers

showed statistically significantly better results for gastric bypass. At 3 year follow-up Hall et al[84] reported 66% of gastric bypass patients achieving greater than 50% loss of excess weight versus 44% for gastroplasty and 16% for gastrogastrostomy. Laws and Piantadosi[85] showed a 35% loss of initial weight in gastric bypass patients compared to 16% for those undergoing gastroplasty at 12 months post surgery. A mean weight loss of 45.2kg was demonstrated for gastric bypass surgery by Lechner and Callender[86] at 12 months, compared to 33.5kg for gastroplasty.

Two further papers examined undefined gastric bypasses compared to gastroplasty.[87,88] Both papers demonstrated statistically significant long term improved weight loss with the gastric bypass, 60% losing greater than 75% of excess body weight with the gastric bypass compared to 18% with the vertical banded gastroplasty.[87] In the trial by Näslund et al,[88] gastric bypass patients demonstrated a mean weight loss of 42.9kg at 24 months, compared to 27.6kg for gastroplasty patients.

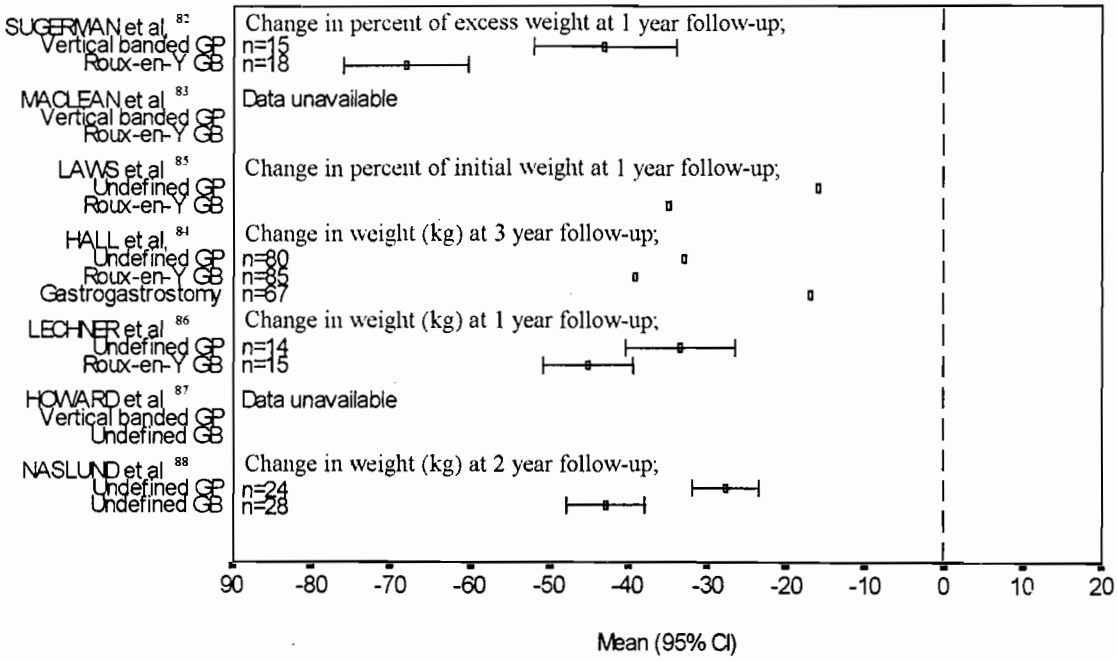

Figure 26: ***Studies examining gastroplasty (GP) versus gastric bypass (GB).***

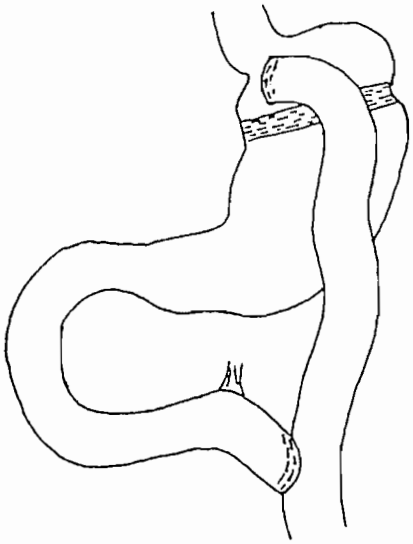

Figure 26a: *Gastric bypass (Roux-en-Y technique, adapted from Brolin et al[89])*

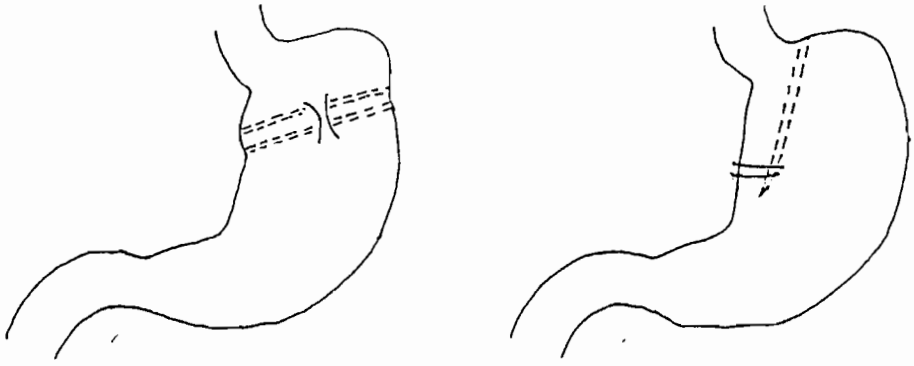

Figure 26b: *Gastroplasty. i) Horizontal banded, ii) vertical banded (adapted from Näslund[88] and Hall et al[84])*

3.10.2 Standard Roux-en-Y gastric bypass versus modified Roux-en-Y

A study by Brolin et al[89] compared the standard Roux-en-Y procedure (75cm defunctionalised jejunum) to modified Roux-en-Y (150 cm defunctionalised jejunum). All patients were recommended to take a daily multivitamin supplement and instructed to follow a liquid diet for the first four weeks, followed by a diet of soft solid foods. The modified gastric bypass resulted in a significantly better post-operative weight loss at 2-3 years follow-up. However, by four years follow-up, this difference was no longer significant, the standard and modified procedures both losing weight (63.5±28.6kg and 72.1±31.8kg respectively). It should be noted that the numbers available for assessment fluctuate over the four years, with only 33.3% of the patients originally randomised being available at the final assessment.

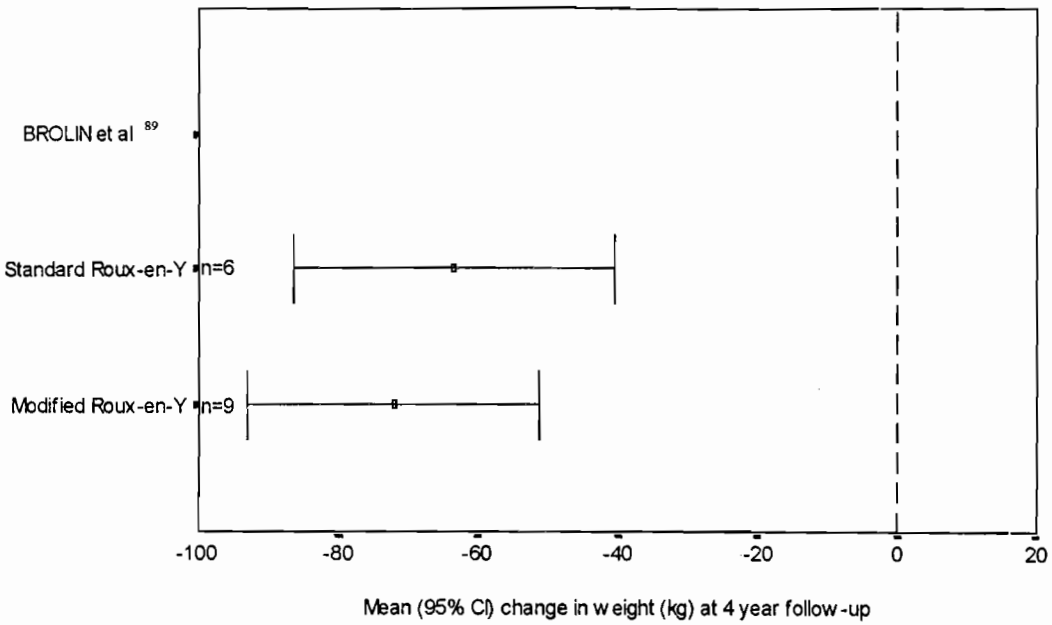

Figure 27: ***Study comparing standard Roux-en-Y gastric bypass with modified Roux-en-Y gastric bypass.***

3.10.3 Horizontal versus vertical banded gastroplasty

Andersen et al[90] compared two modes of gastroplasty, horizontal banded versus vertical banded (Figure 26b). Prior to randomisation, all patients underwent repeated 8-week periods of a very low calorie diet (388kcal/day formula). Every 8 weeks the VLCD was replaced by a diet of 900kcal/day for 2 weeks. This pattern was repeated until 40% of the initial overweight had been lost, when patients were randomised ready for surgery. At the 12 month follow-up, the vertical banded gastroplasty demonstrated a statistically significant greater weight loss (9.7kg versus a gain of 1.0kg). However, weight regain was already commencing at this point and a longer follow-up would be necessary to establish a long term effect.

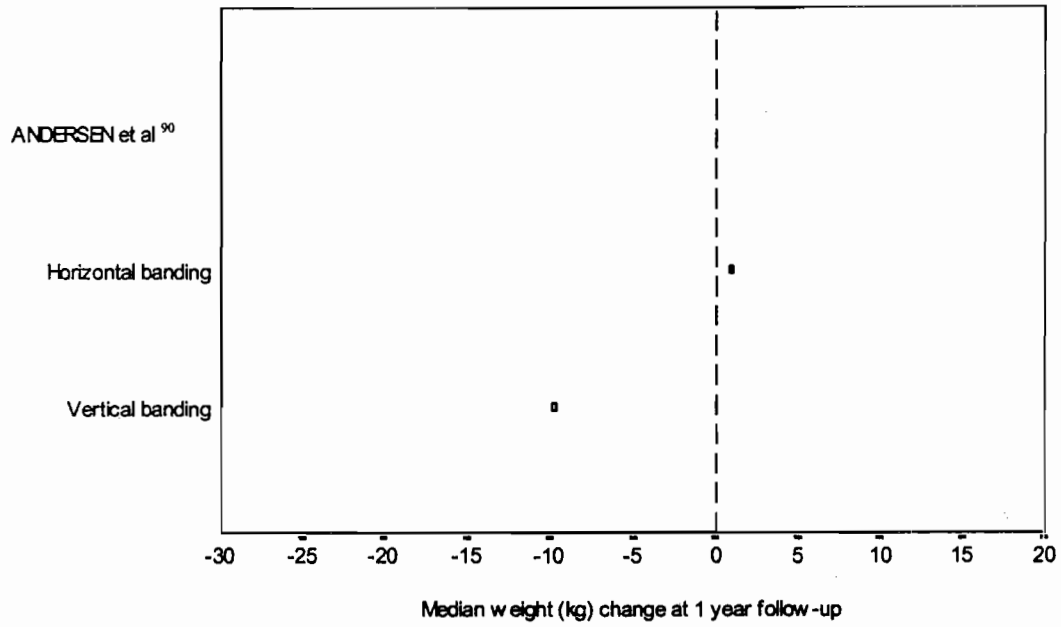

Figure 28: *Study comparing horizontal versus vertical bandedgastroplasty.*

3.10.4 Gastroplasty versus very low calorie diet (VLCD)

In a later study, Andersen et al[91] compared horizontal gastroplasty to a very low calorie diet. Although both groups lost weight, the differences were not reported as being statistically significant when compared to baseline, and there were no significant inter group differences observed throughout the study. It should be noted that the duration of the very low calorie diet was not stated.

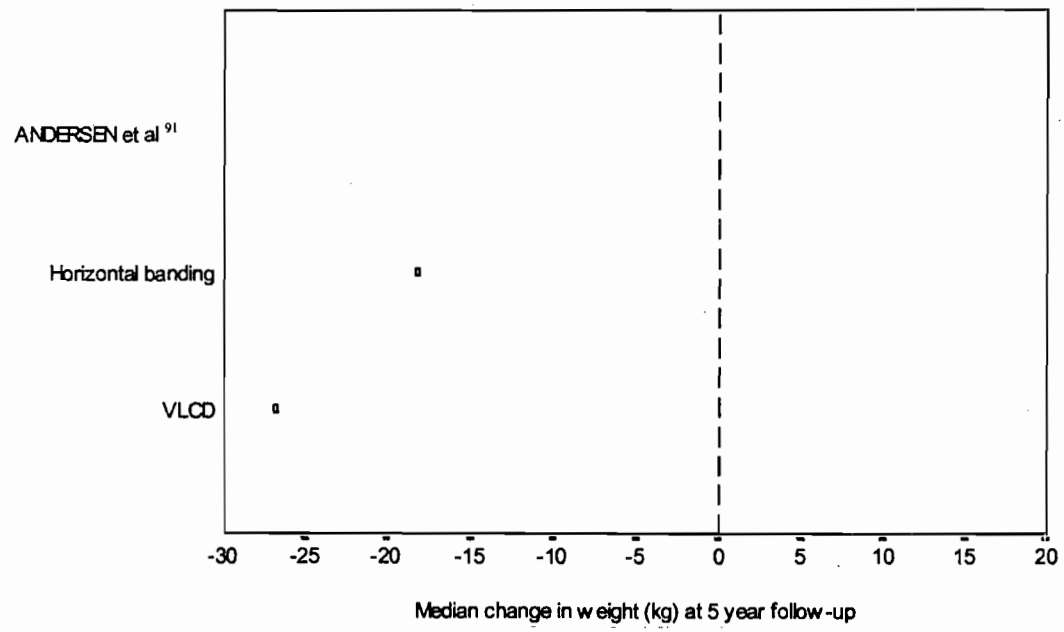

Figure 29: *Study comparing the effectiveness of gastroplasty with that of a very low calorie diet (VLCD).*

3.10.5 End-to-end versus end-to-side jejunoileostomy

A comparison of end-to-end with end-to-side jejunoileostomy (Fig. 30a) was made by Viddal.[92] This was a small study which showed no statistically significant difference between the groups in terms of weight loss. However, it was observed that more patients receiving the end-to-end procedure suffered from post-operative electrolyte deficiencies than those receiving end-to-side jejunoileostomy.

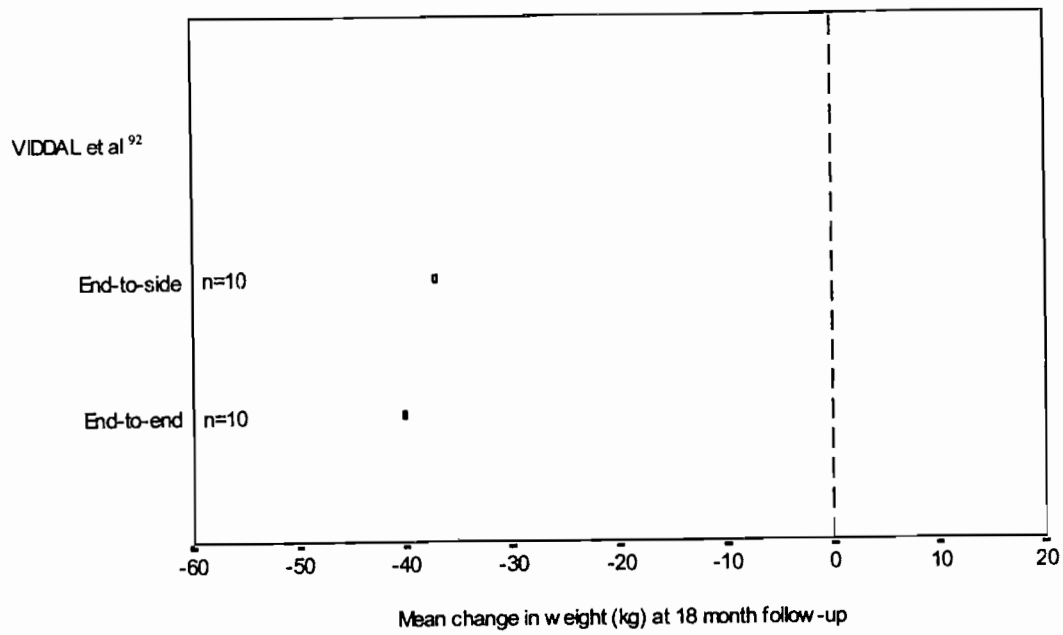

Figure 30: ***Study comparing end-to-end jejunoileostomy with end-to-side jejunoileostomy.***

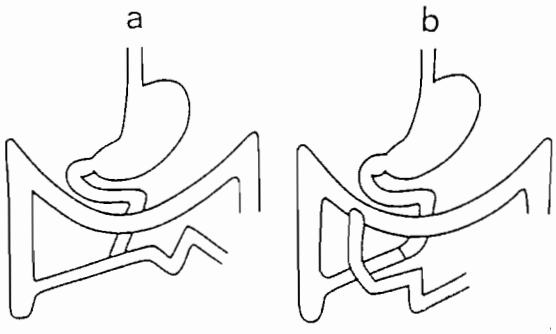

Figure 30a: ***Schematic drawing of (a) end-to-side jejunoileal bypass and (b) end-to-end jejunoileal bypass.***[92]

3.10.6 End-to-side jejunoileostomy versus medical treatment

The Danish Obesity Project[93] compared patients receiving the end-to-side jejunoileostomy with patients undergoing unspecified medical treatment. There was a statistically significant difference in weight loss at 2 years, with median weight losses of 42.9kg for jejunoileostomy patients versus 5.9kg for those receiving medical treatment.

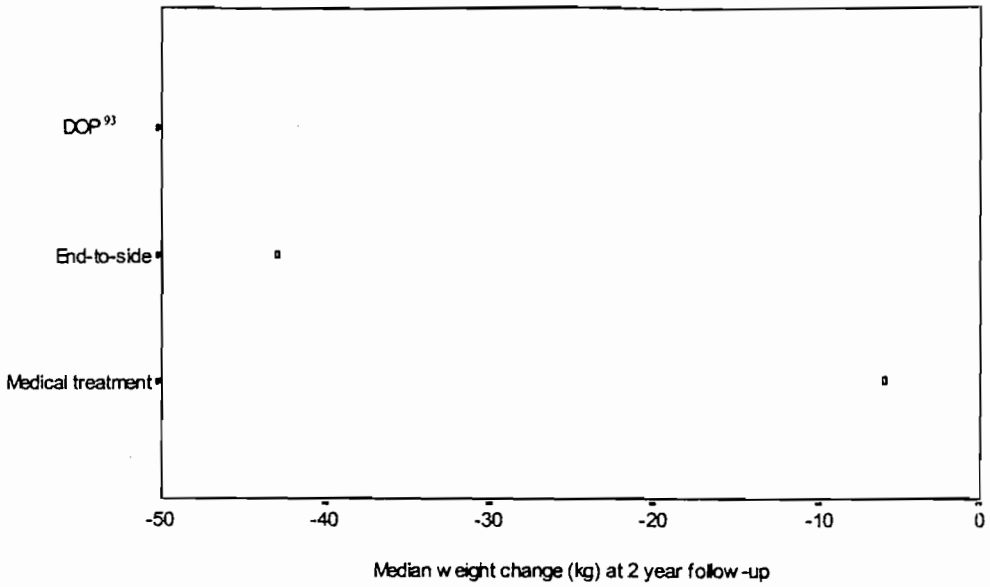

Figure 31: ***Study comparing end-to-side jejunoileostomy with medical treatment of obesity.***

3.10.7 End-to-end jejunoileostomy versus gastric bypass

A RCT of 38 morbidly obese patients was carried out by Buckwalter.[94] All participants were to be followed up for 2 years. However, at the time of publication only 6 patients in each group had undergone 12 months of follow-up. Both groups achieved significant mean weight loss by 12 months (31.5kg following jejunoileostomy, and 43.0kg following gastric bypass). However, few meaningful conclusions can be drawn due to the small number of participants analysed.

A further RCT examining the effectiveness of the gastric bypass in comparison to end-to-end jejunoileostomy also showed significant mean weight loss in both groups by 12 months (57.9kg following jejunoileostomy, and 51.0kg in the gastric bypass group).[95] There was no statistically significant between group difference with regard to weight loss.

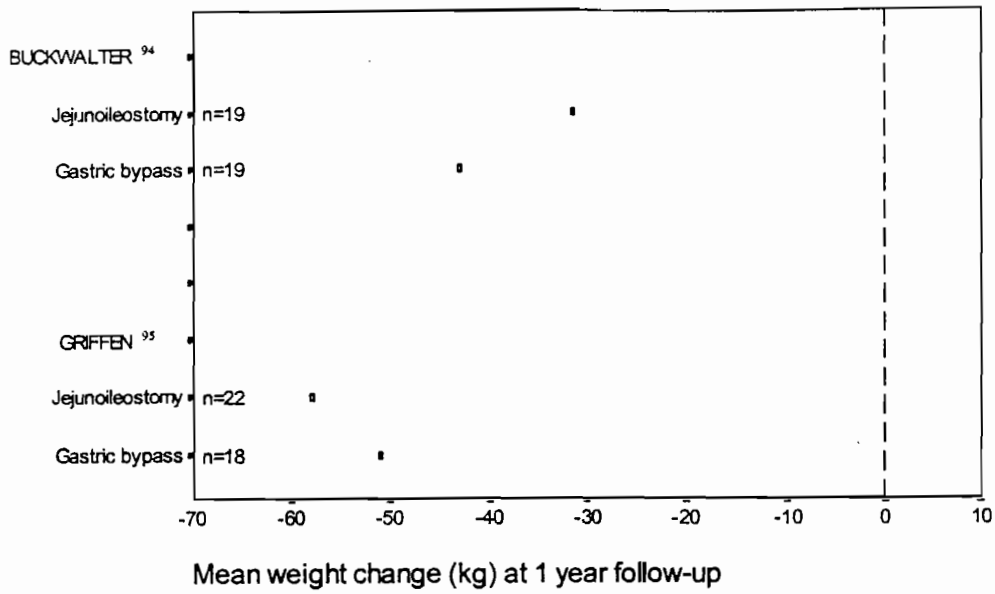

Figure 32: ***End-to-end jejunoileostomy versus gastric bypass***

3.10.8 Garren-Edwards gastric bubble versus placebo

Hogan et al[96] studied the effect of the Garren-Edwards gastric bubble in comparison to a sham placement. The Garren-Edwards bubble is a free floating, intragastric balloon. The balloon was endoscopically inserted and filled with 200ml of air. No statistically significant differences were demonstrated. However it was noted that greater weight losses occurred in the group which had received a sham placement. This group had a significantly higher drop-out rate, which may have led to bias in the results.

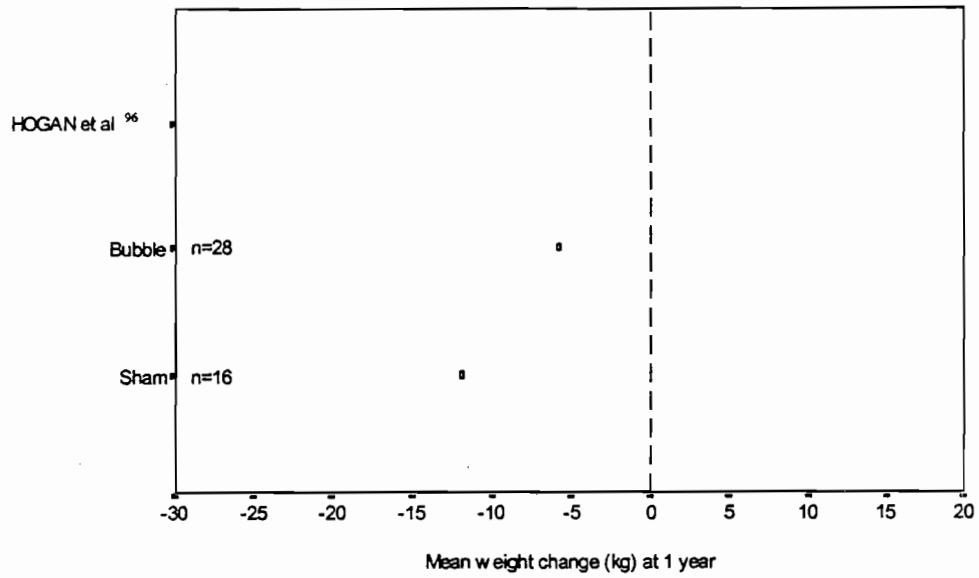

Figure 33: ***Study examining the effectiveness of the Garren-Edwards gastric bubble in comparison to placebo.***

3.10.9 Mortality following surgical interventions in obesity

Of the 8 studies comparing gastric bypass to either gastroplasty or an alternative method of gastric bypass, six reported no early deaths, with no data available for later mortality,[83-85,87-89] Sugerman et al[82] reported one death 3 days post Roux-en-Y gastric bypass, thought to be due to cardiac arrhythmia. The same study described two later deaths: one patient died one year post Roux-en-Y gastric bypass, the cause again attributed to cardiac arrhythmia, and another patient died two years post gastroplasty, and the cause of death was unrelated to surgery. Lechner and Callender[86] report one death 6 days post Roux-en-Y gastric bypass which arose from an anastomotic leak.

For the remaining seven surgical articles, no deaths are reported for 2 of the studies.[90,91] Hogan et al[96] describe one fatal myocardial infarction occurring several months following the mock removal of a sham gastric bubble. Following The Danish Obesity Project,[93] no deaths were observed in the surgically treated group whereas two were noted in the group that had received medical treatment for obesity. One of these deaths was due to a series of complications subsequent to liver biopsy and the other was related to cirrhosis of the liver. Viddal[92] reports a death six weeks after end-to-end jejunoileostomy arising from peritonitis due to anastomotic leak. One death occured 21 days after gastric bypass surgery, due to an embolus to a brachial artery.[94] Finally, Griffen et al[95] report two

deaths (one in each group). The death following jejunoileostomy occured ten months postoperatively after the patient had lost 114kg. The patient refused reanastomosis despite severe liver disease and died in hepatorenal syndrome.

3.10.10 Other complications associated with surgical treatments for obesity

Six papers reported the need for re-operation or surgical conversion to the other procedure in some cases, and this was normally due to a failure to lose weight post-operatively.[82,83,86,88,92,95] The re-operation rates of patients undergoing gastroplasty ranged from 12% to 33%. Surgical conversion after gastric bypass occurred in 2% of the patients examined by Lechner and Callender.[86] Forty percent of those undergoing end-to-end jejunoileostomy required further surgery.[92] Jejunoileostomy also appeared to be associated with a greater number of cases of kidney stones, cholithiasis and fatty metamorphosis in the liver than gastric bypass.[94,95]

It is sometimes asserted that the onset of the "dumping syndrome" subsequent to gastric bypass surgery is at least partly responsible for the superiority of this surgical procedure with regard to weight loss when compared to the gastroplasty. Dumping syndrome relates to a feeling of fullness, dizziness and a desire to lie down after eating. Symptoms can also include faintness, nausea and vomiting, which may be particularly associated with the ingestion of simple carbohydrates, and therefore it is sometimes claimed that the presence of the syndrome will provoke decreased food intake and superior weight losses.

Sugerman et al[82] reported that 10 (50%) patients who had undergone the Roux-en-Y gastric bypass procedure experienced dumping syndrome post-operatively, and this type of surgery produced significantly greater weight losses when compared to gastroplasty, after which there were no complaints of similar symptoms. Similarly, Lechner and Callender[86] presented results on 4 (8%) patients who had dumping syndrome following the Roux-en-Y gastric bypass, which was also found to be significantly more effective than the alternative treatment, gastroplasty. Näslund et al[88] noted that 4 (14%) gastric bypass patients experienced dumping syndrome. In this study, although patients receiving gastric bypass had significantly better results than those receiving gastroplasty, the presence of the syndrome was not associated with greater weight loss.

A further possible consequence of surgery for the treatment of obesity is a deficiency of vitamin B_{12}, due to a decrease in available intrinsic factor. Sugerman et al[82] demonstrated 2 year post-operative vitamin B_{12} levels of less than 300 pg/dl in 7 (35%) gastric bypass patients and 3 (15%) gastroplasty patients. This difference was statistically significant ($p<0.05$). The authors stated that the majority of these patients were successfully treated with oral supplements or injections. Brolin et al,[89] who compared two versions of the Roux-en-Y gastric bypass, found that 5 (23%) patients undergoing the conventional procedure (75 cm defunctionalised jejunum) suffered a vitamin B_{12} deficiency, and a similar proportion, 5 (22%), sustained the same complication in the modified procedure group (150 cm defunctionalised jejunum). In addition, a similar pattern was noted with respect to the general post-operative incidence of vitamin and mineral deficiencies, 16 (73%) and 17 (74%) patients respectively.

3.10.11 Quality of life assessments

Some of the studies included quality of life assessments for patients undergoing surgical treatment for obesity, and this sometimes comprised an assessment of the marital situation. In a study carried out by Lechner and Callender,[86] it was reported that 80% of gastric bypass and 75% of gastroplasty patients felt that their marital situation had remained the same or improved since having surgery. However, half of those whose marriages got worse believed that this was related to the operation. The Danish Obesity Project[93] reported statistically significant greater post-operative satisfaction in the group receiving intestinal bypass than in medically managed patients, 76% versus 52% respectively for social satisfaction, and 82% versus 48% respectively for sexual satisfaction. Viddal[92] showed that six out of ten patients who had undergone end-to-side jejunoileal bypass experienced a post-operative improvement in social well-being, assessed with an unspecified questionnaire, whilst for the group receiving the end-to-end procedure, the figure was nine out of ten. This difference was not statistically significant.

3.10.12 Summary

Jejunoileal bypass, vertical banded gastroplasty and gastric bypass have all been found to produce a significant weight loss. Gastric bypass appears to be the most effective of these surgical intervention in terms of maintained weight loss, and appears to have a low early (within 30 days of surgery) mortality rate. Postoperative complications for this surgical procedure include dumping syndrome. Although this is sometimes proposed as a mechanism for post-operative weight loss, it is unpleasant and may affect the patient's quality of life. Gastric bypasses may also result in both vitamin and mineral deficiency, however, these can be overcome by supplementation. The implications for further research are discussed in Section 6.

3.11 Maintaining weight loss (see table 10)

Ten studies in this category met the review's inclusion criteria.[97-106]

3.11.1 Continued therapist contact

Five studies evaluated different aspects of client-therapist contact as a maintenance intervention.[97-101]

In an early study conducted in two phases, Ashby and Wilson[97] varied the frequency and content of behavioural therapy sessions for maintenance. Female subjects aged 18 to 69 years, who were at least 10% overweight, were recruited through newspaper advertisements. All participants received the same initial 8 week weight loss programme which consisted of a prescribed calorie reduced diet of 1200 kcal/day, guidelines for exercise, and instruction in behavioural techniques. These included self-monitoring, stimulus control, self-reinforcement, relaxation training and the use of imagery. At the end of the treatment period, subjects were stratified according to initial percentage overweight and percentage overweight lost during treatment, and then randomly assigned to receive one of five different maintenance conditions. These were based on either structured behavioural booster sessions or unstructured non-specific booster sessions, held either every two weeks or every month during a 12 month maintenance phase.

The structured behavioural booster sessions served as an extension of the initial 8 week intervention, in that techniques already covered were reviewed. The sessions continued to be therapist-led. By contrast, the unstructured non-specific booster sessions involved the therapist only as a relatively passive facilitator of discussion during meetings. Subjects were advised to continue applying the techniques learnt during the initial intervention, but these were not reinforced or reviewed during the maintenance period.

There was a statistically significant weight loss in all participants, for both phases of the study, during the initial treatment period. For the first phase of the maintenance study, the groups receiving two weekly sessions had a greater mean weight loss than those receiving four weekly sessions at the 3 month follow-up (7.4kg versus 5.0kg). However, the former group regained more weight between the 3 month follow-up and the one year follow-up (mean regain of 4.5kg versus 1.6kg). None of these differences were statistically significant. An overall progressive weight increase was noted between the 3 month and one year follow-ups.

Data analysis from the second phase of the maintenance study revealed no statistically significant differences between group results in terms of weight loss or regain at any point during the study.

A study by Hall et al[98] investigates the benefits of continued therapist contact in weight loss maintenance programmes. Subjects were female, aged between 18 and 65 years, not pregnant, at least 20% overweight, but otherwise healthy. All the women participated in a 10 week behavioural weight loss programme that entailed food and weight monitoring, the application of cognitive techniques, and group support. Following this, they were allocated to one of three maintenance interventions: minimal contact, monitoring/minimal contact, or continued contact.

Minimal contact meant that participants were asked to maintain weight loss through their own efforts, and they did not have contact with a therapist apart from post-treatment measurement sessions. The second condition, monitoring/minimal contact was the same as the first group except that subjects were asked to continue with food and weight monitoring during the maintenance period. The third group, who received continued contact, attended group meetings, led by a therapist, every 2 weeks. Techniques introduced during the initial treatment phase were reinforced during this time, but no new techniques were added.

The mean overall weight loss over time at the end of the 10 week intervention was statistically significant, with a mean of around 3.5kg. At 18 weeks following the commencement of the treatment programme, there was a statistically significant difference in weight loss between the continued contact and minimal contact groups, 5.4kg versus 2.1kg respectively ($p<0.05$). However, this difference was not maintained at the one year follow-up.

A later study also addressed the issue of continued therapist contact versus minimal contact.[99] All participants received the same initial 12 week weight loss programme. This involved weekly sessions

comprising presentations, group discussions, review of self-monitoring records, practice of newly learned skills, and a supervised low-impact aerobic training class. Eligibility for entry to the maintenance programme is not defined, but this appears to be completion of the 12 week weight loss intervention.

At the end of the weight loss programme, pairs of subjects were matched according to their weight loss and were randomly allocated to receive either a therapist-support or minimal support as a maintenance condition. The former consisted of four relapse prevention booster sessions during the 3 month period following the end of the initial treatment phase, therapist-client contact by mail and telephone during the same period, and written feedback about changes in weight after each of the follow-up assessment sessions at 3, 6, and 12 months following the completion of treatment. The minimal support condition involved the same postal contact, and follow-up assessment sessions with written feedback as provided to the other group. However, there were neither relapse prevention booster sessions nor therapist telephone contact in this case.

There was a statistically significant difference with respect to weight loss for all subjects at the end of the initial treatment period versus baseline value: 4.0±3.6kg (mean±sd). At the 12 month follow-up assessment, patients receiving the therapist support condition were observed to be more successful at maintaining weight loss than the minimal contact group: mean weight loss (±sd) at 12 month follow-up compared to baseline was 3.6±9.8kg versus 1.5±6.5kg. However, this difference was not statistically significant.

Perri et al[100] introduced the idea of peer group support to therapist led maintenance programmes. They recruited adult subjects, aged between 21 and 60 years, who were 20 to 80% overweight, but otherwise healthy. All participants received a 14 week behavioural weight loss programme, consisting of instruction in cognitive strategies and exercise management, before being allocated to one of two maintenance conditions. The first group received standard behavioural therapy plus 6 bi-weekly booster sessions. The purpose of the booster sessions was to review and reinforce previously learnt weight loss strategies. Following this, there was no further pre-arranged contact with therapists, or with other group members, apart from 5 follow-up assessment meetings.

The second group received behavioural treatment which incorporated 6 bi-weekly sessions concentrating on strategies to enhance weight loss progress during the follow-up period. Moreover, the formation of self-help peer groups was encouraged. These groups met regularly during the year following treatment and utilised problem solving approaches, mutual monitoring of weight loss, and reinforcement of favourable weight loss outcomes in order to aid maintenance. Participants in this condition also continued to have contact with therapists by post and telephone.

At the end of the weight loss intervention, all groups had lost statistically significant amounts of weight over time (overall mean of around 6.0kg), but there were no statistically significant between group differences. However, at the 9 month follow-up session, participants in the second group

demonstrated statistically significant superior weight losses to the first group, 7.7kg versus 3.1kg. This level of difference was maintained at the 15 month and 21 month follow-ups. However, as the maintenance programme concluded, both groups had regained some of the weight they had lost.

In a later study, Perri et al[101] varied the components of behavioural interventions for weight loss maintenance. Adults aged 22 to 59 years and who were between 20 and 100 percent overweight were recruited. All participants underwent an initial 20 week behavioural weight loss programme. This involved weekly sessions during which subjects were trained in the following techniques: self-monitoring, stimulus control, self-reinforcement, and cognitive restructuring. Participants were also instructed regarding an aerobic exercise regime, and the weekly sessions included a period of supervised exercise. On completion of the behavioural programme, subjects were allocated to one of five 18 month maintenance conditions.

The first group served as a control, and had no further contact with therapists after the completion of the 20 week weight loss programme. The second group continued to attend fortnightly behavioural sessions during which a problem solving approach was adopted to resolve any problems encountered with weight loss maintenance. The third group underwent the same conditions as the second group with the addition of a social influence maintenance programme. This entailed monetary group contingencies for programme adherence, participant led lectures on weight loss maintenance, and the learning and implementation of principles to generate peer support. Individuals in the fourth group received the same maintenance intervention as group 2, with the addition of an aerobic exercise maintenance regime. This included the prescription of exercise goals, and sessions of therapist led exercise activity. Finally, the fifth group received the same intervention package as the fourth group, with the addition of the social influence maintenance programme.

At the end of the initial weight loss intervention, there was an overall statistically significant mean weight loss over time of 12.5kg. At the 6 month follow-up, the four groups who were receiving post-treatment maintenance programmes had achieved statistically significant superior weight losses when compared to the control group. This performance was maintained at the 12 and 18 month follow-ups.

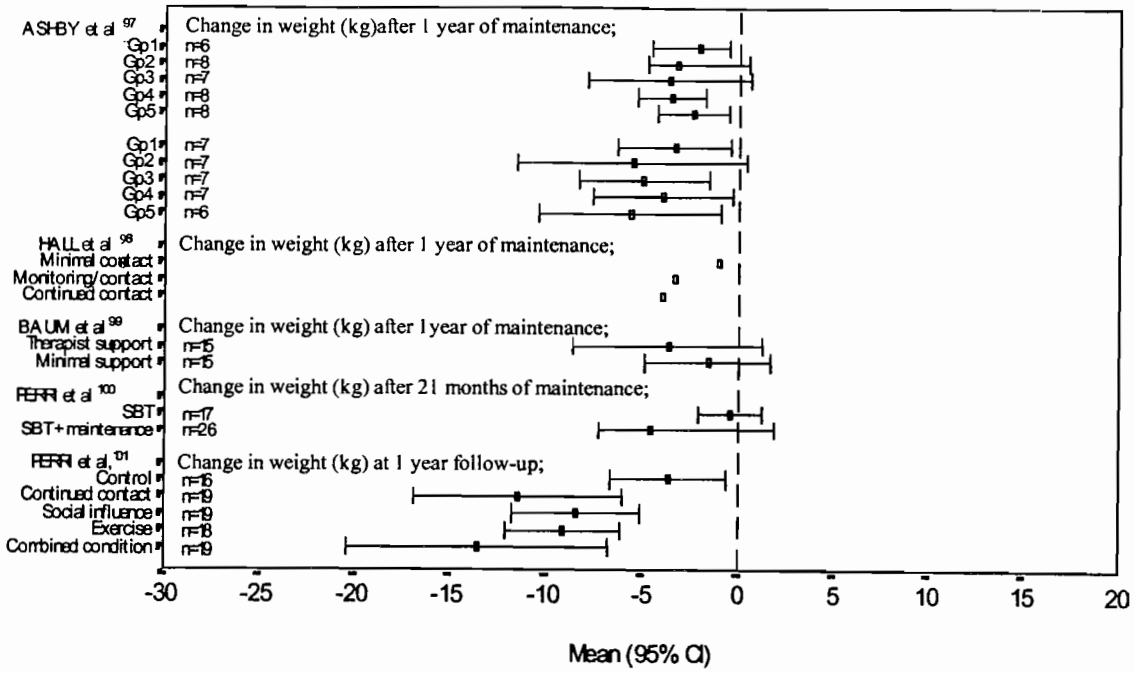

Figure 34: ***Studies examining different aspects of client-therapist contact as a maintenance intervention. (Gp1 – fortnightly structured booster sessions; Gp2 – monthly structured booster sessions; Gp3 – fortnightly non-specific booster sessions; Gp4 – monthly non-specific booster sessions; Gp5 – no contact control; SBT – standard behavioural therapy).***

3.11.2 Skills focus versus weight focus

Kramer et al[102] delivered a fifteen week behavioural weight loss intervention followed by a one year maintenance programme in the form of either a skills focus condition, a weight focus condition, or a no treatment control condition. Only those subjects who had lost at least 10% of their baseline body weight were eligible for inclusion in the maintenance phase. The authors do not state what proportion of the original sample went on to receive one of the maintenance interventions.

The skills focus condition entailed monthly meetings for the whole of the one year maintenance period, during which subjects were trained in dietary and exercise behaviours compatible with maintaining weight loss. The weight focus condition also involved monthly meetings for one year but the emphasis of these was to discuss weight loss maintenance progress and problems, and address any difficulties using a non-specific problem solving strategy. The control group had no contact apart from the assessment at one year and an interim reminder letter. Financial incentive contracts were used in all groups, during both the weight loss and maintenance phases.

All groups regained approximately 40% of initial weight losses at the end of the one year maintenance period. No significant differences were found between the groups for either weight regain or the percent of patients successfully maintaining their original weight loss. However, the percent of subjects maintaining initial weight loss for one year was greatest among the weight focus group, 32%, compared to 14% for the skills focus group, and 18% for the control subjects. Patients in the control

group showed a statistically significant greater variability in the percent of weight loss maintained, when compared to the two active treatment groups.

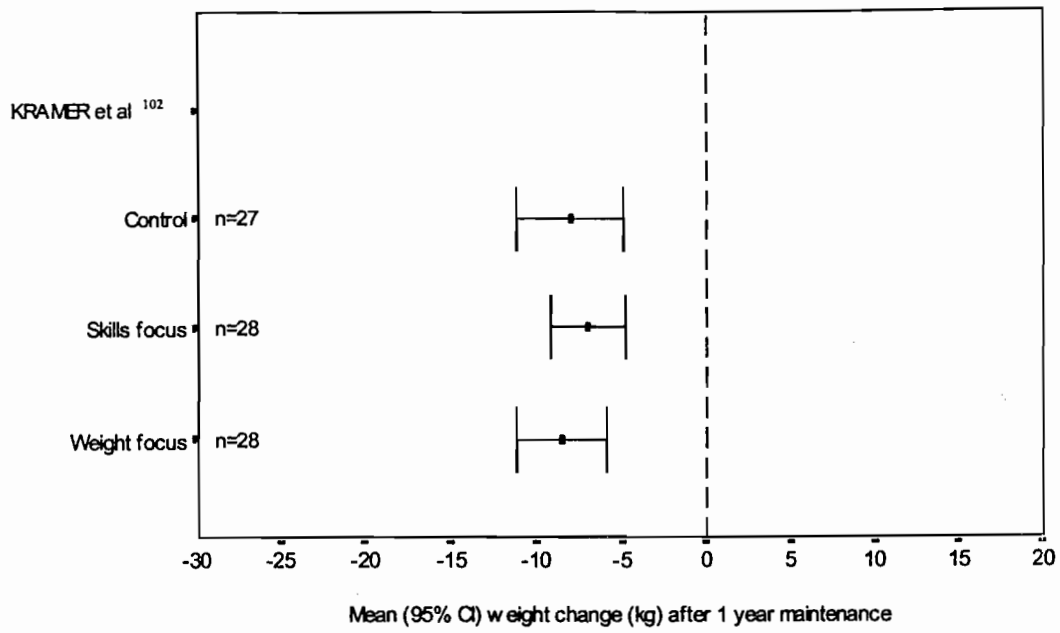

Figure 35: ***Study examining the effectiveness of skills focus versus weight focus for the maintenance of weight loss.***

3.11.3 Conventional foods, pre-packaged foods, and formula diets

Rytigg et al[103] investigated the use of dietary restriction as a maintenance intervention. A twelve week weight loss programme consisting of a very low calorie diet (VLCD), 330 kcal/day, in the form of Cambridge sachets, was prescribed to obese, but otherwise healthy participants. Following this, subjects received a one year maintenance condition which comprised of either a balanced diet consisting of conventional foods to a total of 1,600 kcal/day, or as above but with 220 kcal of the daily intake provided by Cambridge sachets.

Analysis of data from the whole sample demonstrated a statistically significant weight loss of 20.8±7.0 kg ($p<0.0001$) at the end of the twelve week treatment period when compared to the baseline measurement.

At one year follow-up, the group receiving the supplement had a statistically significant lower mean body weight, 93.7±18.1kg (±sd), compared to 109.9±23.8kg (±sd). However, at the start of the maintenance intervention, this group was significantly lighter than the other group: 85.7±14.7kg versus 97.6±19.1kg (mean±sd).

Both groups regained statistically significant amounts of weight during the latter eight months of the maintenance period: the group who received a combination of formula diet and conventional foods regained a mean (±sd) of 8.0±8.2kg (difference between pre-maintenance weight and end of

maintenance weight) whilst the group who received conventional foods regained 12.3±9.7kg. During the maintenance programme the former group regained a lower percentage of weight lost, 39.3±35.7% versus 54.0±38.5%, although this difference was not statistically significant.

Agras et al[104] studied overweight women. All participants received a 12 week dietary regime consisting of a formula diet which provided 800kcal/day, this was combined with behavioural therapy. Participants were eligible to be allocated to one of the four maintenance conditions only if they had lost 5% of their initial weight during the weight loss programme. The maintenance conditions were refeeding with standard food or pre-packaged food, either on a time or weight dependent basis. Time dependent meant that conventional food gradually replaced the formula diet in stages. Weight dependent meant that the patient did not progress to the next stage unless body weight was stable or declining. There were no statistically between group differences at any point (graph shows data at end of 9 month maintenance programme). All groups experienced regain of lost weight.

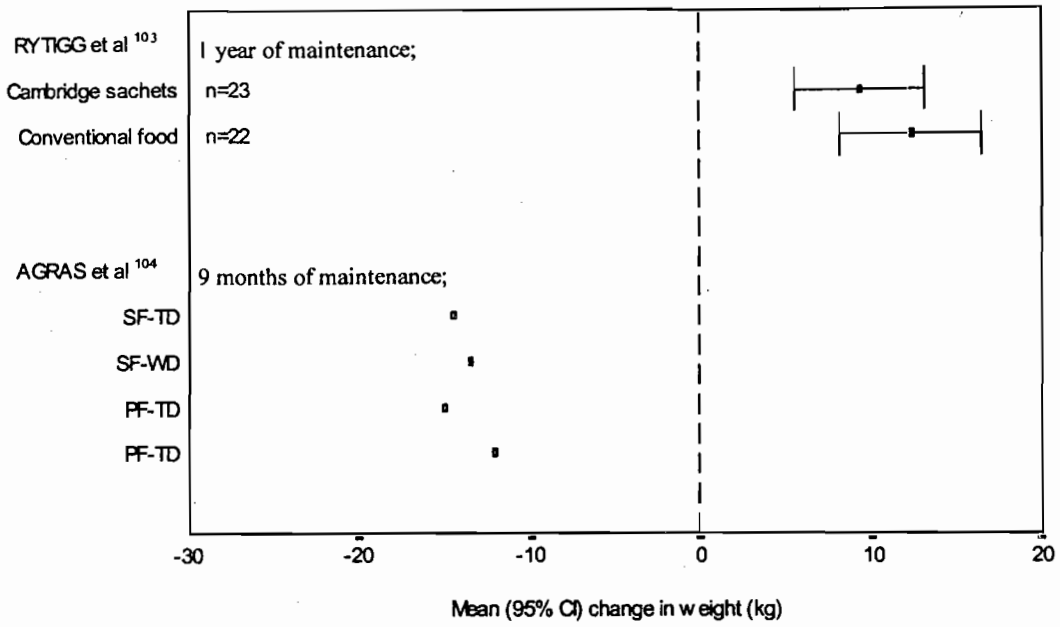

Figure 36: ***Studies assessing the use of conventional foods, pre-packaged foods, and formula diets (SF – standard food; PF – pre-packaged food; TD – time dependent; WD – weight dependent)***

3.11.4 Maintenance of weight loss following surgery

One study examined the effectiveness of a 6 month behavioural intervention following gastric bypass or vertical banded gastroplasty.[105] Fifteen patients received the behavioural intervention, which consisted of 12 sets of written material posted every 2 weeks and monthly behavioural consultations and medical follow-ups. Seventeen patients were allocated to a minimal intervention group, receiving only monthly medical follow-ups following surgery. Both groups achieved significant weight loss (46.6kg and 36.4kg respectively at 12 months post-surgery). However, the weights at both 12 and 24 months were not significantly different, suggesting that the behavioural intervention did not enhance the weight loss produced by surgery alone.

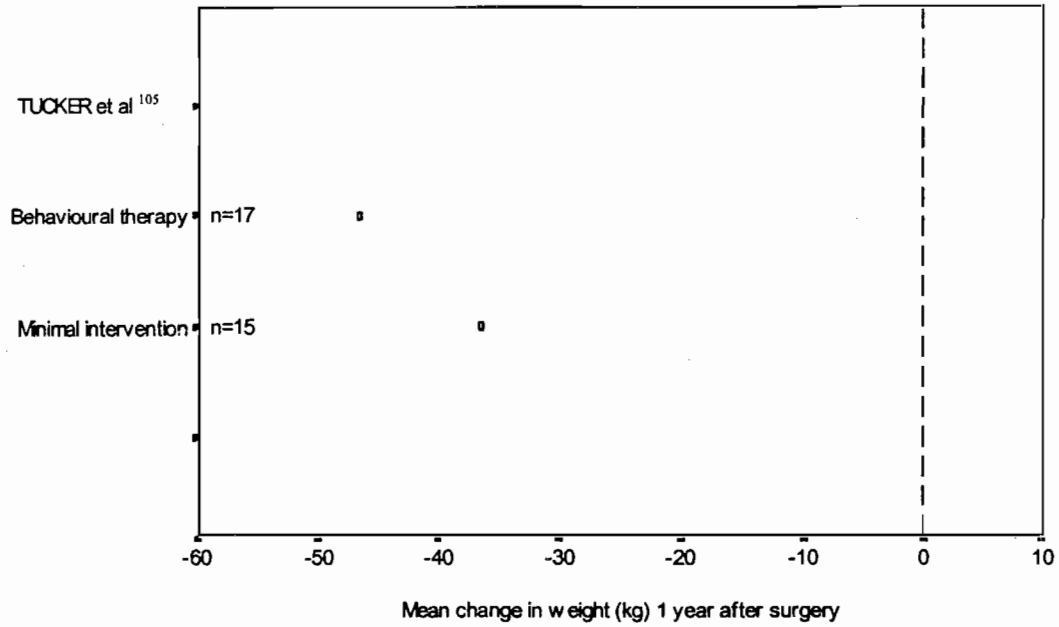

Figure 37: ***Maintenance of weight loss following surgery***

3.11.5 Pharmacological interventions as a maintenance strategy

Only one study investigated the role of pharmacological interventions in the maintenance of weight loss.[106] Wadden et al provided VLCD combined with behavioural therapy to female subjects during a 26 week weight reduction programme. Subjects were required to have lost at least 10% of their initial weight before they could enter the maintenance programme. The 54 week maintenance programme consisted of either sertraline (50-200mg/day) or placebo. At the end of the 54 weeks, there were no statistically significant differences.

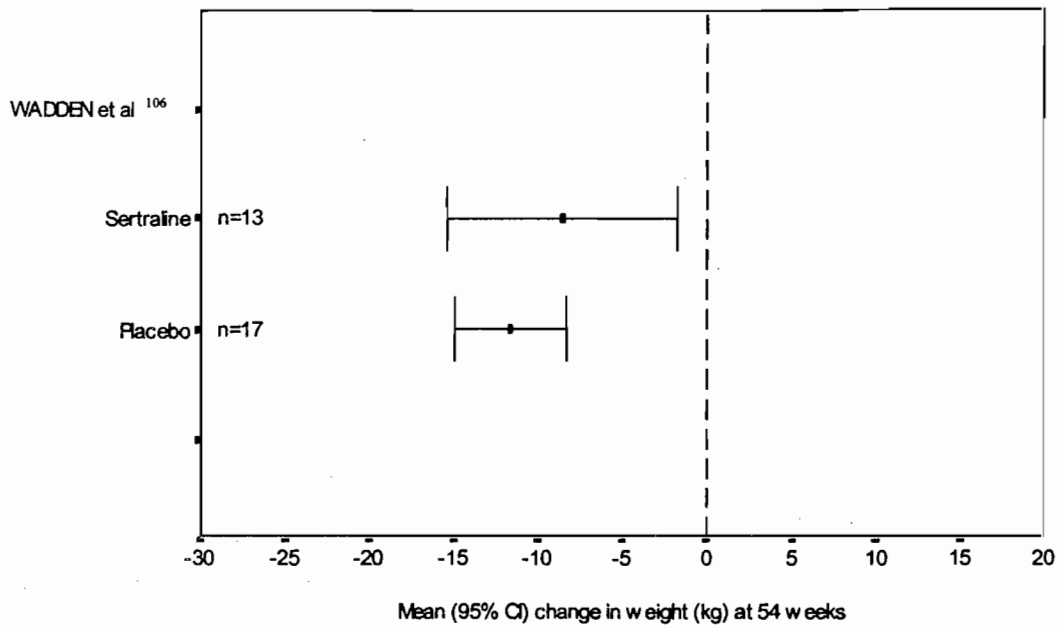

Figure 38: ***Study investigating the role of a pharmacological intervention in the maintenance of weight loss***

3.11.6 Summary

Seven out of ten studies (5 behavioural, 1 dietary, and 1 pharmacological) reported overall mean statistically significant weight losses at the end of the initial weight loss intervention. The other studies did not report these results.

The effectiveness of continued therapist contact as a maintenance intervention remains unclear. This type of intervention may be delivered in varying formats and frequencies. The use of peer group support may be useful. Effectiveness was demonstrated with statistically significant results at 21 month follow-up, although some regain of lost weight did occur. It is possible that problem solving approaches (e.g. weight focus) are effective, however, results in favour of this were not statistically significant. The inclusion of formula diet sachets within a calorie restricted diet appeared to be effective at one year follow-up.

3.12 Comprehensive interventions (see table 11)

This section on comprehensive interventions concerns studies where both treatment and maintenance phases are examined as part of an integrated intervention. There were eleven studies in this category.[107-117]

3.12.1 Different types of post treatment contact

Perri et al[107] examined three different treatment conditions and two different maintenance conditions in a 3 x 2 factorial design. The treatment conditions were non-behavioural therapy (dietary and exercise guidelines in conjunction with non-behavioural therapy sessions), behaviour therapy, and behaviour therapy plus relapse prevention training. The behaviour therapy consisted of training in self-monitoring, stimulus control, self-reinforcement, relaxation and exercise management, whilst the relapse prevention training helped identify high risk situations and how to cope with them. Participants undergoing relapse prevention training were also trained in cognitive strategies to cope with the sense of failure in the event of a relapse. Treatment was carried out for a period of 15 weeks, after which two maintenance conditions were examined. The first of the post-treatment conditions was no further contact with therapists except for follow-up assessments, occurring at 3, 6 and 12 month follow-up meetings. The second condition enabled the participants to remain in contact with the therapists by mail and telephone. They received 22 postcards to be returned weekly to their therapist, recording their daily weight related information. On receiving the postcard, the therapist would telephone the client to discuss briefly the information required. At 6 months post-treatment, mail and telephone contact was discontinued. Although all groups had achieved weight loss at the post-treatment assessment, there were no significant inter group differences. The effects of post-treatment contact varied over the follow-up year according to the initial type of treatment. At the twelve month follow-up, five of the groups gained weight significantly when compared to post-treatment levels. The behavioural therapy plus relapse prevention training and post-treatment contact was the only treatment condition to maintain its post-treatment weight loss (10.31±11.39kg, mean±sd).

The issue of client-therapist contact was also examined in a later study.[108] All participants underwent 20 weeks of behavioural therapy and were then randomised to one of three maintenance conditions: a peer self-help group maintenance programme; therapist contact maintenance programme; no maintenance programme. All groups had lost significant amounts of weight after 20 weeks of treatment ($p<0.0001$), but there were no significant differences between groups. From post-treatment to the seven month follow-up, the therapist contact group had a significantly greater weight loss (11.54kg) than the peer support and control groups (9.31kg and 7.82kg respectively). However, this difference was not sustained between the seven and eighteen month follow-ups, with weight regain occurring in all groups after the end of the maintenance period.

The nature of the therapeutic contact offered to obese patients is also explored by Hakala et al.[109] Participants received either group counselling following a two week inpatient weight loss programme, or individual counselling during the entire two year treatment period. Female participants undergoing group counselling lost significantly more weight than the comparison group during the first three months of treatment (-15.6±5.0kg versus -8.4±5.5kg respectively). No further statistically significant differences were demonstrated for women at any time point over five years. This pattern was not repeated in the male participants who appeared to benefit much more from individual counselling than group counselling, showing a statistically significant difference between the two groups from 8 months (-24.4±8.9kg versus -12.4±6.9kg), through to two years (-15.6±12.0kg versus -1.8±7.4kg). Weight regain had occurred in both groups by the end of the 2 years of treatment. However, the mean weights remained below baseline figures for men and women in both groups at 5 years.

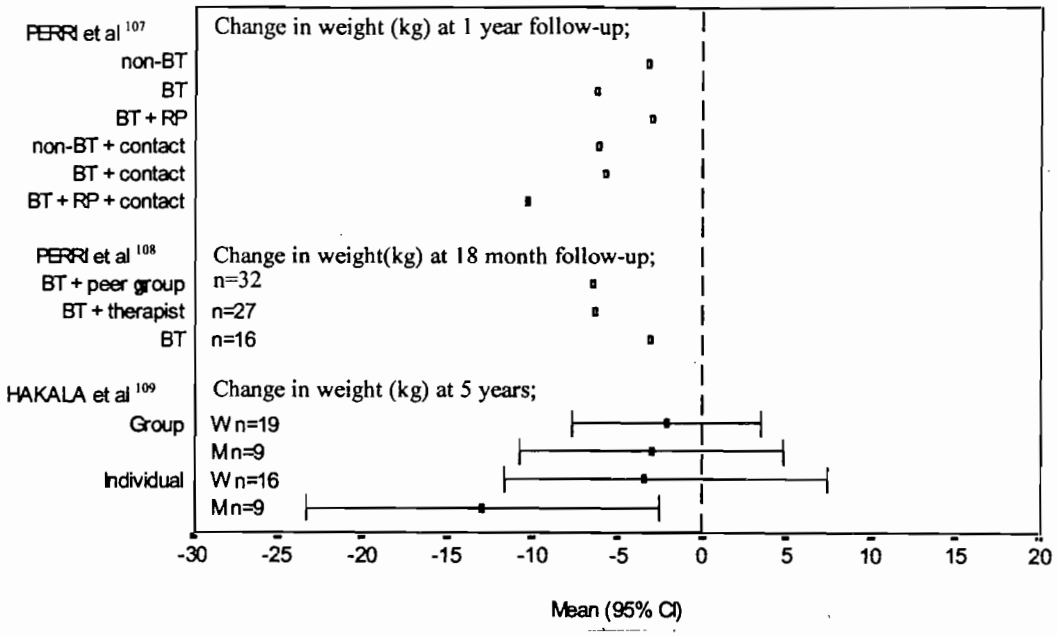

Figure 39: ***Studies examining different types of post-treatment contact following a weight loss intervention. (BT – behavioural therapy; RP – relapse prevention).***

3.12.2 The role of exercise and diet

King et al,[110] conducted a study assessing the effect of a minimal intervention on the maintenance of weight loss through either diet or exercise in 39-50 year old males. Participants were randomised to a moderate energy restriction, an increase in physical activity or a no treatment control for 1 year. At the end of the first year control subjects were provided with dietary and exercise information, and the two experimental groups were randomised within each condition to either a telephone contact maintenance condition or to an assessment only control group. The diet group lost significantly more weight at post-intervention than the exercise group. During the second year, the amount of weight regain in the telephone contact maintenance group was less in the exercisers than in the dieters (0.79±3.1kg versus 3.20±2.9kg respectively). The weight regain in the two control groups was 3.9±2.8kg for the exercisers and 2.6±2.8kg for the dieters. Care has to be taken in the interpretation of these findings as the study was not initially designed to examine weight maintenance but the physiologic effects of 1 year weight changes achieved through diet or exercise.

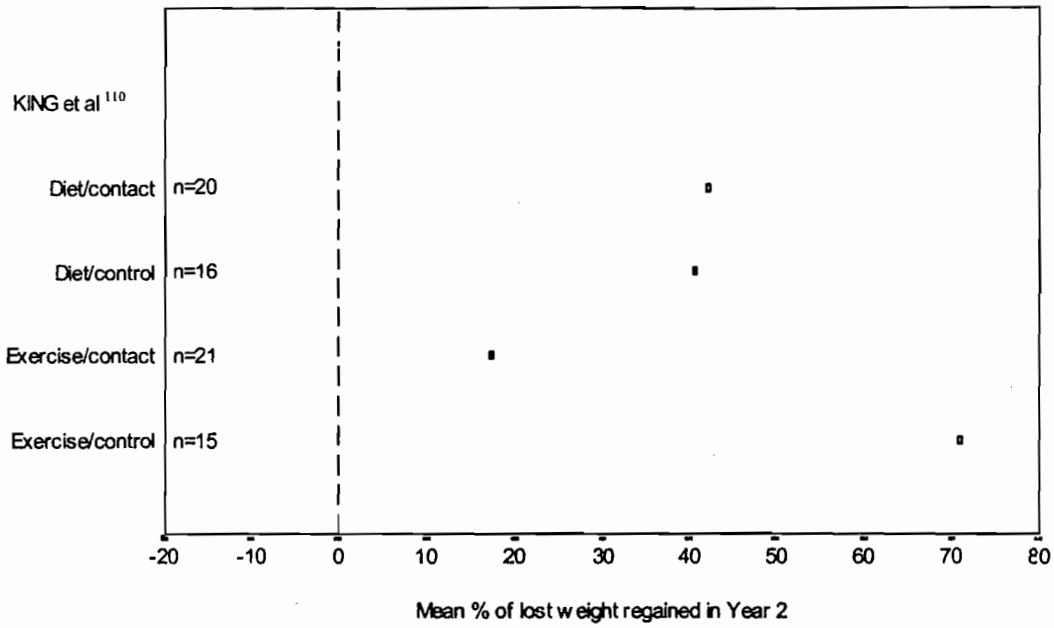

Figure 40: ***Study assessing the effect of post-intervention contact on the maintenance of weight loss through either diet or exercise.***

3.12.3 Behaviour therapy with diet

With regard to maintenance of weight loss following dietary interventions, Wadden et al[111] compared the short term use of a VLCD during treatment phase versus a standard balanced deficit diet (BDD) (1200kcals/day). Both groups underwent the same maintenance programme of bi-weekly sessions during 26 weeks post intervention. The sessions provided instruction in weight charting, exercise, preparing low-fat meals and how to prevent dietary and exercise relapses. Although the weight loss between the two groups differed after 16 weeks of severe caloric restriction in the VLCD group (-20.50kg in the VLCD group versus -9.14kg in the BDD group), after 52 weeks of treatment the weight loss was not significantly different between the two groups (-17.33kg versus -14.43kg). Both groups

regained weight during the maintenance period. However, the BDD subjects gained 2.2kg compared to a significantly greater gain of 6.3kg in the VLCD subjects.

Toubro and Astrup[112] evaluated two types of dietary regime as an initial weight loss programme. Participants were randomised to receive either a low energy formula diet for 8 weeks, or a hypocaloric diet consisting of conventional foods for 17 weeks. After this, subjects remaining in the study were randomised again to produce comparability regarding anthropometry and weight loss, and were assigned to one of two one year maintenance programmes. The first was an ad libitum low fat high carbohydrate diet, and the second was a fixed energy intake diet. All subjects attended behavioural therapy sessions both during the initial weight loss intervention, and during the maintenance programme.

There were no statistically significant between group differences at the end of the initial weight loss intervention, with both groups experiencing a loss of 12.6kg. The rate of weight loss for those receiving the formula diet was approximately twice that of subjects prescribed conventional foods as part of a hypocaloric regime.

At the end of the one year maintenance programme both groups had regained weight. For the group receiving the fixed energy intake diet, the regain was significant (4 kg) compared to measurements taken at the end of the weight loss intervention. At the end of the one year follow-up (commencing from the end of the maintenance intervention) both groups showed further regain. The low fat, high carbohydrate group had regained 5.4kg relative to the end of the weight loss intervention, and the fixed energy intake group had regained 11.3kg. The difference between the groups at this point was statistically significant. The results of this study suggest that the ad libitum low fat, high carbohydrate diet appeared to be superior to a fixed energy regime for maintaining weight loss. However, the fact that the study was undertaken with small sample sizes, combined with an attrition rate of 35% by the end of follow-up, mean that these findings should be regarded with caution.

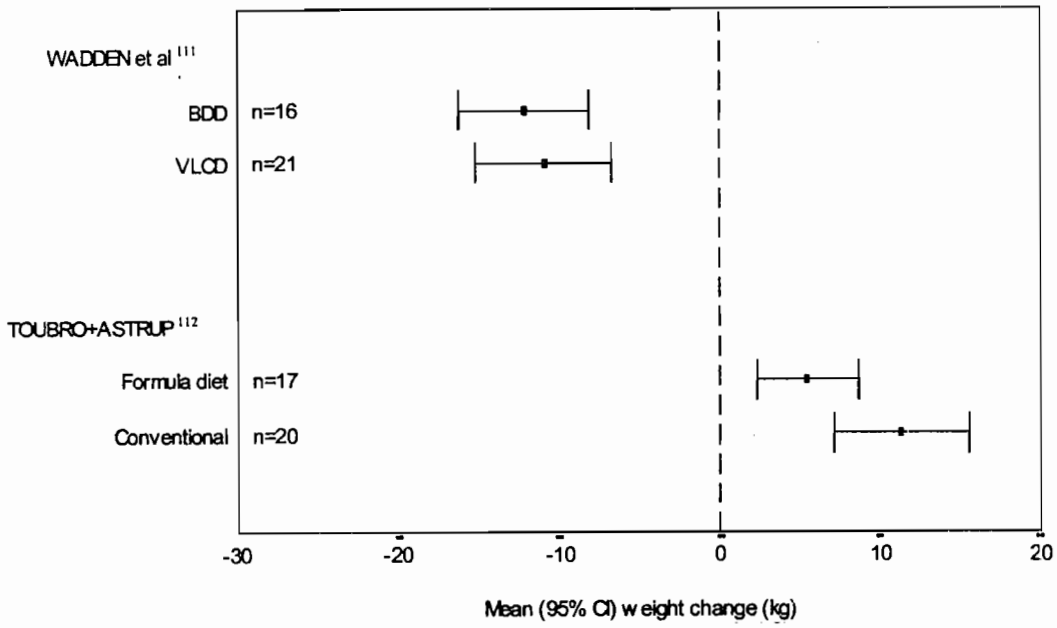

Figure 41: ***Behaviour therapy with diet (VLCD – very low calorie diet; BDD – balanced deficit diet).***

3.12.4 Spaced versus massed booster sessions

Wing et al[113] allocated patients to either a behavioural weight control programme or an intermittent low-calorie regimen. All participants received weekly support sessions for 10 weeks. Following this, the participants received one of two maintenance conditions. The first maintenance schedule was termed "spaced", in which 6 booster sessions were held at monthly intervals. The second was a "massed" condition in which four of the six meetings were held during the third month. Both conditions were seen again 12 months after initial treatment. For the treatment phase of the study, there were no significant inter group differences, but there was a significant effect for both groups combined over time ($p<0.001$) from baseline to the end of the 10 week treatment period. No statistically significant differences in maintenance of weight loss were observed between the two maintenance conditions. All clients regained substantial amounts of weight during the year following the initial treatment.

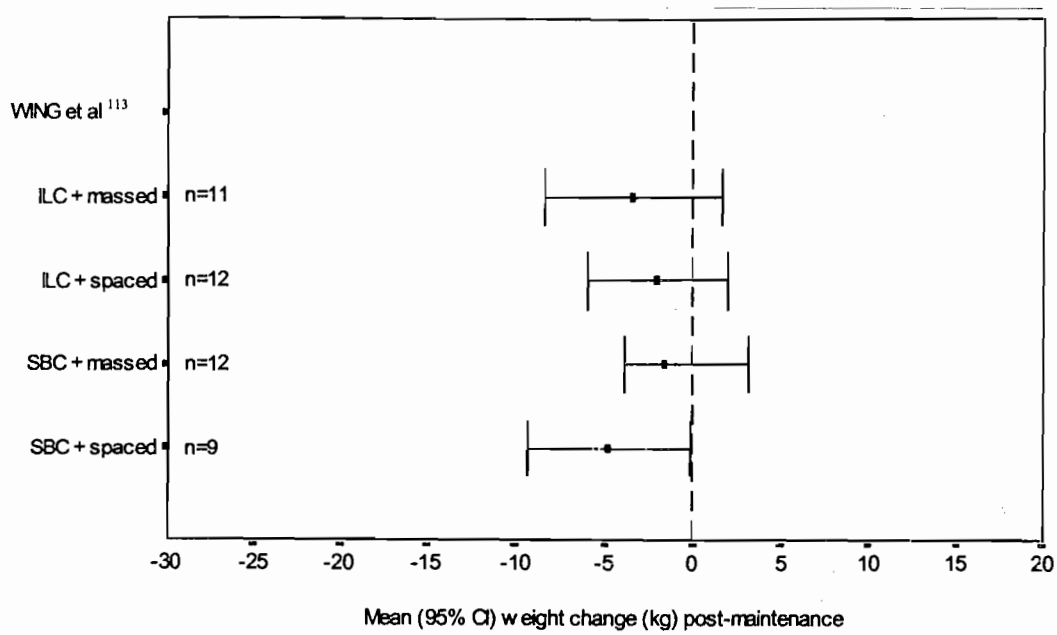

Figure 42: ***Study evaluating spaced versus massed booster sessions following either an intermittent low calorie regime (ILC) or a standard behavioural condition (SBC).***

3.12.5 The role of spouse involvement in maintenance sessions

Cousins et al[114] studied the effect of behavioural sessions and nutrition advice on weight loss in Mexican American women. All participants received a nutrition manual and were randomised to no further intervention, behavioural treatment with maintenance sessions, or modified behavioural sessions, whereby the patient's spouse and family were encouraged to attend the sessions. Following the twelve month treatment/maintenance intervention, the latter two groups lost a statistically significant greater amount of weight than the group receiving the nutrition manual only. Mean weight loss at 12 months was 2.1kg for those undergoing behavioural therapy alone, 3.8kg for those undergoing therapy with their spouse or family, and 0.7kg for those only receiving the nutrition manual. Although analysis revealed a trend for family intervention to be more effective, there was no statistically significant difference between the two behavioural therapy groups.

Murphy et al[115] studied the effects of spouse involvement on weight loss and maintenance. The weight loss intervention was of 10 weeks duration, the maintenance phase lasting 2 years. Spouse attendance and contract condition were varied within a 2x2 factorial study design. The contract conditions differed according to whether the spouse was actively involved in encouraging and reinforcing weight loss activities. Two control conditions, a supportive group and a waiting list control group, were also included in the study. Participants in the supportive group attended treatment sessions without their spouses and contracts were not used. The purpose of this group was to control for therapist contact, group support and other non-specific factors. The waiting list control group did not receive any treatment.

At the end of the 10 week treatment period, there were weight losses of around 7.5kg across the five active treatment groups when values were compared to baseline, no statistically significant differences were demonstrated between these groups. However, these groups did differ significantly from the waiting list control ($p<0.0002$), who had lost 0.4kg at this point. There were 8 maintenance sessions during the two year follow-up occurring at 2, 5, 8, 12, 19 and 26 weeks, and at one and two years post-treatment. Thus, contact between participant and therapist gradually faded during this time. At the 1 and 2 year follow-ups, subjects who had attended sessions with their spouses, and whose spouses had been actively involved in the weight loss process (Couple-2 party, see table 11), had lost more weight than the other groups. This group was significantly superior to the subject alone condition with two-party contracts for actual weight loss at the 2 year follow-up. Analysis comparing the three subject-alone conditions with the two couples conditions demonstrated a greater weight maintenance in the couples condition at both 1 and 2 year follow-up. The type of contingency contract was non-significant for all weight loss variables. It should be noted, however, that the sample sizes are extremely small by the 2 year follow-up.

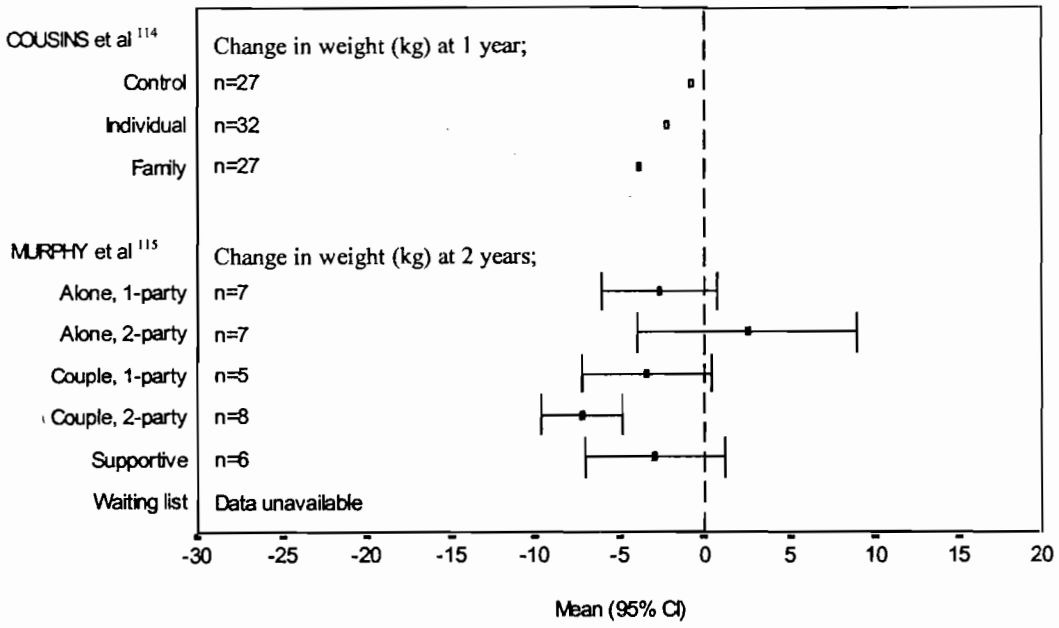

Figure 43: ***Studies examining the role of spouse involvement in maintenance sessions following weight loss. (1-party – subject only contract; 2-party – subject plus spouse contract).***

3.12.6 Self-management techniques and lifestyle changes

Stevens et al[116] investigated the effects of an eighteen month weight loss intervention (14 weeks treatment, the remaining time maintenance), versus a usual care control condition as part of the Trials of Hypertension Prevention (TOHP). Participants were aged 30 to 54 years, and were obese with a high-normal diastolic blood pressure. Those randomised to the 18-month weight loss programme received training in behavioural self-management techniques and were required to make life-style changes aimed at reducing energy intake and increasing physical activity. Weight loss in the intervention group was significantly greater than the control at all time points. The difference in

weight loss between the intervention and control groups (mean±se) at 18 months was 3.9±0.4kg. The average treatment effect remained significant when weight loss was expressed as a percentage change from baseline weight, or as the change in body mass index.

A further study looking at people who were overweight with high-normal diastolic blood pressure found that self-management techniques used in conjunction with moderate exercise, followed by relapse prevention training produced a small sustained greater weight loss (2kg) at 3 years when compared to no active treatment.[117]

3.12.7 Summary

Continued therapist contact following a successful weight loss programme appears to be effective at maintaining weight loss when combined with behavioural therapy and relapse prevention training. There is no evidence to suggest that the use of a balanced deficit diet is more effective than a very low calorie diet when followed by the same maintenance programme. Likewise, there is no evidence to promote the use of massed booster sessions during a maintenance programme when compared to spaced booster sessions. There is a trend suggesting an improved effectiveness of weight loss interventions and maintenance strategies when spouses and families are involved in the interventions, however, the evidence is not strong. Lifestyle change programmes can produce small, sustained weight loss.

3.13 Alternative therapies

3.13.1 Identification of studies

The database Allied and Alternative Medicine (AMED) was searched together with that of the Research Council for Complementary Medicine (RCCM). The search strategy and search terms used are presented in appendix 4.

Altogether, 66 references were generated from these searches, 53 from AMED and 13 from RCCM. Following review of the titles and, where available, abstracts, 16 papers were considered for inclusion in the systematic review. Interventions identified included hypnotherapy (3 papers), acupuncture (3 papers), traditional Indian medicine (1 paper), and ascorbic acid supplementation (1 paper).

Although the above searches were performed with the intention of identifying articles evaluating alternative and complementary therapies, a number of references dealing with other types of treatments were identified. These included exercise (3 papers), diet programme (1 paper), group therapy (2 papers), correspondence programme for weight loss (1 paper), and drug therapy using phenylpropanolamine (1 paper). These papers were reviewed with the intention of including them in the appropriate section of the review, since they more favourably fitted the categories of exercise, diet, behavioural intervention (for group therapy and correspondence programme), and pharmacology, as opposed to being classified as alternative therapies. All retrieved articles are referenced at the end of this document.

3.13.2 Inclusion criteria

Since complementary therapies are rarely evaluated using RCTs, the inclusion criteria were relaxed in order to identify promising interventions which need further research. For this section of the review, it was decided to include prospective studies with a concurrent control group, preferably though not necessarily randomised, with a minimum observation period of 12 months. Due to the high relapse rate often observed in obese subjects who have successfully lost weight, a minimum follow-up or observation period of one year is recommended in order to obtain an idea of the endurance of the effect of treatments. However, despite this relaxation of the general inclusion criteria, the papers evaluating hypnotherapy, acupuncture, Indian medicine, and ascorbic acid were excluded from the review because they were of a non-comparative design and/or comprised an observation period of less than 12 months. One of the hypnotherapy papers was a non-systematic literature review and therefore could not be included as a primary study.

Examination of the studies on exercise, diet, behavioural and pharmacological interventions revealed that these were not eligible for inclusion. Inclusion in the earlier sections of the review meant that the more rigorous criteria of a RCT with at least 12 months observation had to be upheld. None of these studies complied with these criteria.

4. DISCUSSION AND IMPLICATIONS FOR FUTURE RESEARCH

4.1. Prevention of Obesity

Although the difficulties in treating obesity and maintaining weight loss are well documented, little rigorous evaluation has been carried out in the area of primary prevention. The present systematic review identified a total of four studies addressing this problem.[21,33-35]

Family therapy produced promising results in preventing the progression to severe obesity in children, when compared to no treatment.[21] The target group was Swedish children aged 10 to 11 years, and it would therefore be useful to replicate this research in alternative age groups and settings, using larger sample sizes.

The prevention of adult-onset obesity was addressed by three community studies.[33-35] Community based education programmes linked with financial incentives may be effective. However, this is an area where further research is required since it is still unclear whether targeting specific 'at risk' groups, or the population as a whole, would be more effective.

One proposal to aid the prevention of obesity is to improve food labelling in order to help consumers make informed choices. However, the effectiveness of this type of policy would be dependent upon a good level of literacy and prior knowledge of nutrition among consumers.

4.2 Treatment of obesity

4.2.1 Childhood obesity

When targeting obese children, the reduction of sedentary behaviour appeared to be the most effective intervention for both achieving and maintaining weight loss.[31,32] Both studies were of good quality, although sample sizes were small. Since both were carried out in the USA, it may be of value to study the same interventions, using larger sample sizes, in other settings. The reduction of sedentary behaviour in adult populations should also be examined. This view is supported by Prentice and Jebb[4] who suggest that the increasing prevalence in obesity in Britain is due to both high intake of fat and low levels of physical activity. These authors suggest that public health strategies should aim to promote both a reduction in dietary fat intake, and a reduction in sedentary behaviour.

The role of parental involvement in the treatment of childhood obesity remains uncertain.[25-27] Although Epstein et al[26] suggest there may be some benefit of behavioural therapy when parents are involved in the child's weight loss efforts, Brownell et al have shown that behavioural therapy is most effective when the child and parent attend support sessions separately.[25] No difference was demonstrated between the effectiveness of parental and child responsibility for weight loss by Israel et al.[27] All three studies were carried out on small sample sizes.

Further evaluation of the parents' role needs to be undertaken before its true benefit can be established. One explanation of the differences in study results may be the ages of the participants. Brownell et al[25] studied children aged 12 to 16 years, whereas Israel[27] and Epstein[26] recruited children from a younger age group, 8 to 13 years, and 5 to 8 years respectively. It may be argued that adolescent subjects are generally less likely to comply with their parents' wishes compared to younger children, and this tendency may be reflected in the effectiveness of family based interventions for obesity. However, these trends need to be explored and clarified through future research programmes.

The targeting of parents and children together for weight loss showed a statistically significant benefit, when compared to targeting children alone, at five year follow-up.[22] Insufficient data were presented on sample size and baseline characteristics to draw firm conclusions. It is important to note that the three studies reviewed in this section were conducted by the same North American research group. It would therefore be useful for other authors to replicate the research, particularly in a non US setting. The targeting of parents and children together may be examined further by its incorporation into trials evaluating other treatments.

Researchers working in the area of childhood obesity should ensure that the change in the degree of obesity in children is expressed in an appropriate way. For those children still growing, even modest reductions of weight are of importance. This difficulty may be overcome if baseline values and measures of treatment outcome are expressed as the percentage overweight.

4.2.2 Adult obesity

Much uncertainty remains over the most effective interventions for the treatment of adult obesity. However, there are certain areas that show promise and require further research. Jeffery et al demonstrated that the provision of food to participants produced a significantly greater reduction in BMI at 18 months follow-up when compared to a no treatment control.[58] However, this difference was not maintained at 12 month post-intervention follow-up.[59] Moreover, it is likely that this type of intervention is not practical in the long term. Wing[60] demonstrated that the provision of meal plans and grocery lists to obese women also produced significant weight loss benefits. Although weight regain occurred during the one year follow-up, weight loss associated with the provision of meal plans and grocery lists still remained significantly superior to standard behavioural therapy alone. The design of these studies was good, but the value of the provision of meal plans and shopping lists needs to be assessed in other populations.

The effectiveness of increasing dietary fibre as a weight loss intervention is unclear.[66,67] The role of fibre needs to be clarified through investigation of the most appropriate method of fibre provision (by conventional foods or by supplement), and the duration of the intervention.

Exercise was studied in conjunction with behavioural programmes. Its effects were compared with exercise education, dietary education, callisthenics, stimulus control, contingency management, and no treatment. There is some evidence that exercise may be useful in the prevention of weight regain[63]

although its benefit over dietary education remains unclear. The combination of diet and exercise in conjunction with behavioural treatment, however, does appear to be more beneficial for weight loss than diet alone.[62] When diet and exercise were combined in the absence of behavioural treatment, the combination was no more effective than diet and exercise as single interventions.[68]

Only one paper[46] was concerned with examining group versus individual therapy. Although participants undergoing group therapy lost significantly greater weight post-intervention, there was no evidence to suggest that group therapy would be beneficial in the long term once treatment had finished. Group therapy may be of some use if followed by a successful maintenance programme.

Promising approaches which need further research include cue avoidance (avoidance of situations that provide the temptation to overeat),[41] daily weight charting,[48] behavioural therapy by correspondence[47] and extension of the intervention period for behavioural therapy.[44] It is possible that these interventions may be of value when used in conjunction with other weight loss strategies, such as prescribed diet programmes.

Very low calorie diets, when studied in conjunction with behaviour therapy produced a statistically significant greater weight loss post-intervention, and after 6 and 12 months, compared to VLCDs or behavioural therapy alone.[54,55] However, weight regain had commenced post-intervention. The effect of providing maintenance following an initial weight loss programme consisting of both VLCD and behaviour therapy needs to be studied.

The effectiveness of involving a spouse in weight loss programmes cannot be fully established from the studies included in the present review. Results were conflicting and sample sizes were small in all four studies.[36-39]

No evidence was available from the studies included in the review to suggest that the restriction of fat intake was superior to the restriction in calorie intake for weight loss in non-diabetic participants.[56,57]

The issue of identifying and targeting specific groups who are at risk of developing obesity may be of importance both in terms of policy, and future research agendas. If this approach is taken, as opposed to targeting the general population, studies should be undertaken to determine the optimum interventions for each of the identified groups.

4.2.3 Pharmacological interventions (please refer to addendum, page 141)

Pharmacological interventions did not appear to be effective in producing sustained long term weight loss. Recent guidelines produced by the Scottish Intercollegiate Guidelines Network Working Party on Obesity state that 'drug therapy under medical supervision should be continued long term where necessary'.[125] However, the definition of "long term" is unclear, as are the criteria for prescription. Recent guidelines produced by the Royal College of Physicians[130] state that drug use should be limited to one year, and any patient failing to lose 10% of their weight by 3 months should discontinue the

prescription. A meta-analysis of trials examining dexfenfluramine (dF) versus placebo showed a significant difference between groups at 1 year in favour of dF. However, a more qualitative assessment of the pharmacological studies showed that weight regain begins by 6-9 months, independent of whether treatment is continued or not. It is of great importance that the follow-up in such trials is of sufficient length to enable the long term patterns of weight loss, maintenance of weight loss, or regain, to be studied. This pattern of short term weight loss and long term weight regain justifies the use of a minimum 12 month observation period as an inclusion criteria for the current review.

A study conducted by Ôst and Götestam[75] compared fenfluramine with a behavioural programme. No significant differences were observed between the two intervention types at one year follow-up. However, further comparisons between intervention types, for example pharmacological versus behavioural, dietary or exercise programmes, or combinations of such intervention types, should be explored.

Given the apparent short term effectiveness of pharmacological interventions, future research should investigate the combination of these with a maintenance strategy. For example, drug therapy could be given for a period of 6 months in combination with behavioural support, which would continue after the pharmacological intervention had stopped, in order to promote maintenance of weight loss. Behavioural support is effective for the maintenance of weight loss, although further research is required into the frequency and type, for example, peer group support or client therapist contact.[98-100]

The role of diet and exercise following pharmacological interventions should also be evaluated as a long term strategy for continued weight loss/maintenance. As there is some evidence to support the effectiveness of exercise, diet, behavioural support and pharmacological interventions, further research should address the best combination of these therapies, which may differ between different categories of obese patients.

4.2.4 Surgical interventions

There is good evidence to indicate the effectiveness of gastric bypass in the treatment of morbidly obese patients (those with BMI>40). Seven studies compared gastric bypass (Roux-en-Y or undefined technique) with gastroplasty (vertical banded, horizontal banded or undefined procedure). Six of these showed significantly greater post-operative weight loss in favour of gastric bypass. Typical weight loss one year after gastric bypass was 45-65 kg compared to 30-35 kg after gastroplasty. MacLean et al also showed a greater weight loss in the gastric bypass group although this difference was not statistically significant when compared to results for the gastroplasty group.[83] Isolated gastric bypass may have good results in patients failing to lose weight post Roux-en-Y and post VBG[83], however, this procedure should be evaluated as part of a RCT, with long term follow-up.

The silicone band gastroplasty provides an alternative procedure to the vertical banding method. No identified RCTs evaluating the silicone band gastroplasty met the review's inclusion criteria. RCTs, with long term follow-up, are therefore required.

Only one study examined the role of a gastric bubble.[96] No evidence was found to support this technique. However, as this is a less invasive procedure, it perhaps warrants further examination.

It should be noted that, in general, weight loss in surgical patients is greater when compared to those receiving less invasive methods. Given the higher levels of maintained weight loss with surgery it may also be useful to study the cost- effectiveness and effectiveness of gastric bypass surgery for obese patients who are not morbidly or super obese and who have failed to lose weight using other approaches. However, surgery is associated with complications. These include revision of the initial surgery, dumping syndrome, deficiencies of vitamins and minerals due to the modification in gut absorption processes, and associated mortality. Due to the complexity of the techniques used, only surgical teams which can show experience and a good record (using data from long term follow-up) should be allowed to conduct this type of surgery. The jejunoileal bypass procedure is associated with long term complications, arising as long as ten or fifteen years subsequent to the surgery, and is no longer recommended as an intervention for the treatment of obesity.

At present, a large non-RCT is being undertaken in Sweden, that will evaluate and compare different interventions for obese subjects. Outcomes relating to mortality and morbidity for those receiving surgery will be compared to patients undergoing non-invasive interventions such as prescribed diet, exercise programmes, behavioural therapy and pharmacological interventions. A nation-wide registry of potential subjects for the trial is being compiled, that, together with the intervention studies, is entitled "Swedish Obese Subjects" (SOS).[126] No current publications arising from this project complied with the review's inclusion criteria. However, since the findings will include long term follow-up of weight loss, comorbidity, quality of life and costs, future results are awaited with interest.

4.3 Maintenance

The majority of the studies included in the present review demonstrate weight regain either during treatment or post-intervention. It is imperative, therefore, that effective maintenance strategies are built into any weight loss programme.

Five studies included in the present review examined continued contact, and although not all showed statistically significant differences in favour of such contact, a trend was noticeable.[97-101] The addition of self-help peer groups in addition to therapist led booster sessions was shown to be effective in maintaining weight loss.[107] However, after the maintenance programme ended, weight regain occurred. Combining other promising maintenance strategies such as weight focus[102] and the use of formula diet preparations,[103] with continued contact, may enhance effectiveness. It is unclear whether a maintenance strategy of standard food or pre-packaged food provided on either a weight dependent or

time dependent basis, is effective.[104] Further research would need to be undertaken in order to establish the value of this type of intervention. The drug sertraline did no better than placebo when administered alongside relapse prevention training, as a strategy to maintain weight loss.[106]

A selection of support services may need to be developed in order to suit individual requirements, for example telephone hotlines, access to additional therapy sessions and regular refresher courses in weight management.[127] Any maintenance strategy has to be seen as a long term intervention and must be an integral part of any weight loss programme. Successful maintenance therapy is vital to the long term success of weight loss interventions. Future research in this area should aim to either develop weight loss treatments that have longer lasting benefits, or develop new, more effective maintenance programmes.

4.4 Comprehensive interventions

Eleven studies were classified as comprehensive interventions, studying different combinations of treatment and maintenance conditions. One of the most effective combinations was a programme consisting of behavioural therapy and continued therapist contact by mail and telephone.[107] Post-intervention weight loss was maintained throughout the 12 month follow-up period.

The results of a study of overweight hypertensive participants demonstrated the effectiveness of self-management techniques and lifestyle changes followed by continued therapist contact during the maintenance phase.[116] When compared to a usual care control condition, the treatment group showed significantly greater weight loss at all time points.

The involvement of the family or spouse in both weight loss and maintenance phases appeared to be of some benefit, although the differences in treatment effect were not statistically significant.[114,115] The latter of these papers had a high drop-out rate by the end of the 2 year programme. The role of spouse involvement requires further research before its value can be fully established.

It is possible that an optimally effective programme for the treatment of obesity and maintenance of weight loss may involve a more focused way of combining existing interventions. It is likely that the constituents of such a programme will vary according to the requirements and characteristics of individual patients. Important characteristics may include body weight, gender, motivation level, and levels of other psychological variables, such as dietary restraint. It is possible that these variables may be of value in predicting the effectiveness of treatment packages, as opposed to the treatment itself. Very few of the papers included in the current review provided detailed profiles of participants. For future research, there are two recommendations. First, those undertaking evaluations of interventions, should, where possible, include information relating to the psychological profile of patients, using appropriate and validated outcome measures. Secondly, studies should be undertaken to identify the patient related variables that are most likely to predict the effectiveness of interventions.

4.5 Alternative therapies

The role of alternative or complementary therapies in the treatment of obesity remains uncertain due to the absence of reliable evidence of effectiveness in this area. Due to the high relapse rate often observed in obese subjects who have successfully lost weight, a minimum follow-up or observation period of one year is recommended in order to obtain an idea of the endurance of the effect of treatments. Future research should feature at least a prospective comparative design with a concurrent control group comprising subjects receiving either an identical placebo or a different treatment. The preferred design would be a RCT.

4.6 Further considerations for future research

4.6.1 The role of health care professionals

Obesity is a frustrating condition for both the patient and the professional due to the long term nature of successful treatment. Health care professionals may have negative attitudes towards the overweight and obese and may benefit from education to modify negative beliefs about obesity, and interventions that train health care professionals in methods for improving the delivery of weight loss/maintenance programmes. Silagy et al,[128] in a systematic review assessing the effectiveness of training health professionals to provide smoking cessation interventions, state that constraints imposed by the conditions in which health care professionals practise must also be addressed if training is to be an effective use of resources.

4.6.2 Methodological quality

Investment should be made in trials of sound methodological quality, conducted in a relevant local setting. This will necessitate a major improvement in the standard of conduct of trials (e.g. *a priori* calculation of sample size, better randomisation, and intention to treat analysis). Patients should be followed-up for long enough to be able to judge the long term effectiveness of interventions. Future studies should include the collection of data on the psychological profiles of obese and overweight patients, particularly variables relating to dietary restraint. Moreover, information concerning gender differences, ethnicity, sociocultural features, and genetic profiles, should be included. The cost-effectiveness of obesity-related interventions also needs to be addressed.

4.6.3 Predictors of treatment outcomes

Psychological and sociodemographic factors, as mentioned above, may serve as barriers to successful weight loss, or may act as predictors of treatment outcome. Research should be conducted to establish the relationship of these types of variables with treatment outcomes. The supervision of treatment may be another factor that determines the degree of success of interventions. Future trials should therefore include detailed information relating to this. The current review did not identify any controlled studies evaluating the effectiveness of commercial weight loss programmes. Good quality research concerning these types of interventions may be extremely useful, and could provide valuable insight into the best methods of supervision of weight loss.

4.6.4 Investment in future research

Despite the national importance of obesity and cost to health services around the world, high quality research is relatively scant. Nationally co-ordinated strategies for research and development in this area are needed. In addition, an effort to encourage health care professionals to become more active in preventing and treating obesity in the long term is needed.

It is possible that population approaches based on national policies, for example tax on food products, would be effective.[129] These would aim to influence the key variables influencing obesity (principally calorie intake and exercise). However, no studies were identified that evaluated policy initiatives, such as the taxation of high fat foods.

5. CONCLUSIONS

This review has identified several potentially effective interventions for the management of obesity. Family therapy may be effective in the prevention of obesity in children. For the treatment of obesity in children, interventions aimed at reducing sedentary behaviour may be useful. Community based education strategies, especially when combined with financial incentives, may help prevent obesity in adults. Behavioural interventions, such as cue avoidance, combined with diet and/or exercise appear to be effective. These may be more effective if of longer duration. Pharmacological interventions, for example dexfenfluramine and SSRIs, are effective for up to 9 months, (please refer to addendum, page 141). Surgical interventions especially gastric bypass and vertical banded gastroplasty have been shown to be effective for people with morbid obesity. Since weight regain is common in people who do successfully lose weight, long term follow-up maintenance strategies (such as self-help groups) should be an integral part of any weight loss programme. Due to problems with methodological quality, it is recommended that research findings indicative of promising interventions are replicated. In addition, the optimum role for the primary health care team needs to be defined and supported by the appropriate resources. The increasing prevalence of overweight and obesity in many western countries represents an important public health problem. Therefore this area deserves greater investment, both in terms of good quality research and service provision.

6. TABLES

Table 1: ***Studies focusing on children and adolescents***

Author (year), country of origin, design	Participants, interventions, sample size	Key long term results
Flodmark et al[21] Sweden RCT, 14-18 month intervention	Swedish children (10-11 years old) identified in a school screening programme for obesity (BMI of >23kg/m^2, mean = 25.1kg/m^2). Gp1. Family therapy - conventional treatment (diet, counselling + encouragement to exercise) and family therapy (n=25). Gp2. Conventional treatment (n=19). Gp3. Untreated control group (n=50). Groups BMI comparable at baseline.	**At 1-year post-intervention follow-up;** Family therapy group showed smaller increase in BMI than control group (5.1% Vs 12.0%, p=0.02) and fewer children with severe obesity (5% Vs 29%, p=0.02). No differences between conventional and control groups were statistically significant. **Attrition;** No data on drop-outs recorded. Analysis carried out on an intention to treat basis.
Epstein et al[22], Study 1 USA RCT, weekly meetings 8-12 weeks, monthly meeting 6-12 months, 10 year follow-up.	6-12 year olds (10.4 years mean age), 20-100% overweight (mean = 45% overweight), one obese parent. All groups received Traffic Light Diet and underwent contingency management. The target for the contingency management differed between groups. Gp1. Parent and child both targeted for weight loss. Gp2. Child alone targeted for weight loss. Gp3. Non-specific target. Sample sizes and comparability unknown.	**At 5 year follow-up;** Children in Gp1 showed a 15.3% decrease in percentage overweight, compared to increases of approximately 1% (figure taken from graph) for Gp2 and 7.6% for Gp3. **At 10 year follow-up;** The percentage overweight for children in Gp1 was stable from 5 years, remaining significantly better than Gp3. However, the difference between Gp1 and Gp2 was no longer statistically significant, with Gp2 demonstrating a decrease in percentage overweight from baseline. **Attrition;** No data given
Epstein et al[22], Study 4 USA RCT, weekly meetings 8-12 weeks, monthly meeting 6-12 months, 10 year follow-up.	6-12 year olds (10.4 years mean age), 20-100% overweight (mean = 45% overweight), one obese parent. All groups received Traffic Light Diet. Parents and children had reciprocal reinforcement contingencies. Gp1. Aerobic exercise. Gp2. Lifestyle exercise. Gp3. Callisthenics control. Sample sizes and comparability unknown.	**At the 10 year follow-up;** Children undergoing lifestyle or aerobic exercise achieved a statistically significant greater change in percentage overweight compared to the callisthenics control group (-19.7%, -10.9% and +12.2% respectively). **Attrition;** No data given

Table 1: *Studies focusing on children and adolescents (Cont'd)*

Author (year), country of origin, design	Participants, interventions, sample size	Key long term results
Epstein et al[23] USA RCT, 6 month intervention, 18 month follow-up.	Families recruited by referral from physicians and public service announcements. 8-12 year olds (10.2 years mean age) 20-100% overweight (mean weight = 56kg), no parent >100% overweight. Both groups received same written material and lectures on behavioural management of obesity, Traffic Light Diet and exercise programme. Gp1. Parents and children had to master behavioural skills. Praise used to reinforce mastery and weight loss (n=17). Gp2. No requirement to master skills, no praise for achievement (n=22). %-over BMI calculated using 50th BMI percentile, based on population standards, as reference. Groups were comparable at baseline.	**Mean change in %-over-BMI at 6 months follow-up;** Gp1. -26.5% Gp2. -16.7% ($p<0.05$) **Mean change in %-over-BMI at 18 months follow-up;** Gp1. -15.4% Gp2. -10.6% At 18 months follow-up the experimental group still had more change but the difference was no longer significant. Analysis for the obese parents showed a similar pattern to above. **Attrition;** 11.4%, these families not included in the analysis.
Epstein et al[24] USA RCT, families stratified on children's weight. 6 month intervention, 6 month follow-up	8-12 years old recruited by physician referral and in response to media adverts. Both child and participating parent 20-80% over ideal body weight. Parents had to attend sessions. Treatment groups received 15 sessions for the first 8 weeks, and then 7 sessions over the following 20 weeks. Families were seen as groups with individual attention for behaviour change. Gp1. Traffic light diet (n=18). Gp2. Traffic light diet and a lifestyle change exercise programme (n = 18). Gp3. Waiting list control (n = 17).	**Changes in % overweight of children;** The two treatment groups were significantly lighter than the control ($p<0.01$), who had gained weight. The ANOVA comparing the two treatment groups at 2, 6 and 12 months showed that, although the children were lighter at 6 and 12 months than baseline, there was no differential effect of the treatment. For adults, similar pattern at 6 months with both treatment groups being significantly lighter than control ($p<0.01$). At 1 year there was a significant treatment differential with superior effect of diet plus exercise at 6 months ($p<0.01$) and greater stability of loss from 6 months to 1 year ($p<0.01$). **Attrition;** Gp1. 16% Gp2. 0% Gp3. 18% 53 families began the study and at 6 months results were available for 47 (89%). Following this controls were offered treatment. Drop-outs were not included in the analysis.

Table 1: ***Studies focusing on children and adolescents (Cont'd)***

Author (year), country of origin, design	Participants, interventions, sample size	Key long term results
Brownell et al[25] USA RCT, children stratified according to % overweight prior to randomisation. 16 week intervention, 1 year follow-up.	12-16 year olds, ≥ 20% overweight (mean = 55% overweight), recruited by newspaper articles and referral by physicians or schools. All subjects received the same programme of behaviour modification, nutrition education, exercise instruction and social support. Gp1. Mother and child attended separate weekly sessions (n=14). Gp2. Mother and child attended sessions together (n=15). Gp3. Mothers did not take part in any sessions (n=13). Groups were comparable at baseline for weight and BMI.	**Mean weight change at 1 year follow-up (mean±SEM);** Gp1. -7.7±4.1kg Gp2. +2.9±2.1kg Gp3. +3.2±1.7kg The results for Gp1 were significantly better than those for Gp2 and Gp3, $p<0.01$ **Attrition;** Gp1. 14% Gp2. 20% Gp3. 8% Drop-outs were excluded from analysis.
Epstein et al[26] USA RCT, 6 week intervention, 46 week maintenance/follow-up.	Obese female (mean = 40% overweight, 25.5kg/m^2 BMI) aged 5-8 years, recruited by referral by health worker and response to media exposure. Both groups received equal education and attention. The groups had 6 weekly meetings plus 9 monthly maintenance sessions. Gp1. Behavioural orientated programme emphasising parent management. Gp2. Control with no behavioural principles. 24 families entered the study. Groups were comparable for all measured parameters.	**Mean change in % overweight at 1 year;** Gp1. -26.3% Gp2. -11.20% There was a significant interaction of treatment x time observed for the children's % overweight ($p<0.005$) indicative of better weight loss for the children receiving behavioural treatment. Post hoc analysis revealed significant differences between groups for % overweight at 8 and 12 months. **Attrition;** Overall rate was 20.8%. Drop-outs were excluded from analysis.
Israel et al[27] USA RCT, 26 week intervention, 3 year follow-up.	8 -13 years old (11 years mean age), at least 20% overweight (mean = 47% overweight), recruited through newspaper ads and letters to paediatricians and school nurses. One parent willing to attend sessions. Common behavioural programme including cue avoidance, monitoring Gp1. Standard treatment condition emphasising parental responsibility for motivation of children (n=18). Gp2. Enhanced child involvement - less emphasis on parental responsibility (n=16). Groups were comparable at baseline with regard to %-overweight.	**Mean % overweight at 1 year (26 week follow-up);** Gp1. 45.15±23.87% Gp2. 42.32±22.50% **Mean change in % overweight at 1 year;** Gp1. +6.4% Gp2. -4.8% No significant treatment or treatment x time effects; however 44% of Gp1 Vs 0% of the Gp2 were below post treatment overweight level at 3 year follow-up ($p=0.026$) **Attrition;** Gp1. 38.9% Gp2 . 43.8% Drop-outs were excluded from analysis.

Table 1: *Studies focusing on children and adolescents (Cont'd)*

Author (year), country of origin, design	Participants, interventions, sample size	Key long term results
Epstein et al[28] USA RCT, children were stratified according to their age, %-overweight and physical work capacity. 8 week intervention, 10 month maintenance period.	Obese girls, 8-12 years of age, ≥ 20% overweight, referred by doctor, school nurse or self referral. All subjects were given identical information on diet and behavioural management techniques. 23 children from 22 families were recruited. Gp1. Exercise 3 times a week for the first 6 weeks of the intervention Gp2. Baseline information Groups were comparable with regard to weight at baseline.	**Mean change in weight at 1 year;** Gp1. -3.86kg Gp2. -1.36kg Gp1 showed a significant decrease in body weight from 0-12 months, $p<0.01$ Gp2 significant decrease from 0-6 months, $p<0.01$, but at 12 months weights were not significantly different from baseline. These changes were related to significant differences ($p<0.05$) in body weight between the 2 groups at 6 months. **Attrition;** No data on drop-outs recorded.
DeWolfe et al[29] Canada RCT, 8 week intervention, 1 year follow-up.	Teenage girls aged 14-20 years (15.6 years mean age) who responded to advertisements in schools and were ≥ 5lbs above ideal body weight. All subjects (n=29) had the same 8 weeks of weight loss programme (including exercise + behaviour modification) before assignment to maintenance programme. Gp1. Monthly follow-up with reinforcement of the programme elements. Gp2. Monthly follow-up, physical measurement only. Gp3. Annual follow-up only. Comparability of groups at baseline unknown.	**Mean weight change during the follow-up;** Gp1. -3.65kg Gp2. -1.9kg Gp3. +3.44kg **Attrition;** Overall rate was 48%. Drop-outs were excluded from analysis.
Figueroa-Colon et al[30] USA RCT, 10 week intervention, 1 year follow-up.	Obese children and adolescents with weight 40% above average (approx. 80% overweight) and in good health. Average age was 11.4 years. All subjects underwent exercise, behavioural and parental involvement components. Subjects were seen monthly during the follow-up Gp1. Protein sparing modified fast (PSMF) 600-800 calories/day for 10 weeks (n=10). Gp2. Hypocaloric balanced diet (HBD) 800-1000 calories/day for 10 weeks (n=9). Groups were comparable with regard to weight, % overweight, and BMI at baseline.	**At 1 year follow-up ;** Mean weight in both groups had returned to baseline levels. Decreases in % overweight and BMI remained due to the children's height increase. The decrease in % overweight in the PSMF group (Gp1) compared with baseline was significant ($p<0.02$) **Attrition;** Gp1. 30% Gp2. 56% Drop-outs were excluded from analysis.

Table 1: *Studies focusing on children and adolescents (Cont'd)*

Author (year), country of origin, design	Participants, interventions, sample size	Key long term results
Epstein et al[31] USA RCT, 4 months weekly treatment, followed by bimonthly meetings up to 1 year.	Obese 8-12 year olds (10.1 years mean age), 20% - 100% overweight (mean =52%), recruited through radio announcements, TV commercials, and direct referrals. Neither parent >100% overweight, one parent willing to attend meetings. A traffic light diet was used with children and parents (1000- 1200 kcals/day). 61 families entered treatment. Gp1. Sedentary group - reinforced decreasing the amount of time they engaged in certain sedentary activities Gp2. Exercise group - reinforced increasing physical activities. Gp3. Combined group - both of the above. Groups were comparable at baseline.	**Mean change in %-overweight at 1 year;** Gp1. -18.7% Gp2. -10.3% Gp3. -8.7% Statistically significant reductions in body fat between the sedentary (-4.7%) and exercise groups (-1.3%) at 1 year ($p<0.05$). **Attrition;** Overall rate was 9.8%. Drop-outs were excluded from the analysis
Mellin et al[32] USA RCT, 3 month intervention, 1 year follow-up.	12-18 year olds (15.6 years mean) recruited through local papers and notices to physicians and schools (mean weight = 78kg). Gp1. SHAPEDOWN programme - self-directed change format encouraging adolescents to make sustainable small modifications in diet, exercise, lifestyle and attitudes (n=37, relative weight 136.5%). Gp2. No treatment control (n=29, relative weight 129.5%). Groups comparable with regard to relative and actual weight at baseline.	**Relative weight loss (±sd) at 1 year follow-up compared with baseline;** Gp1. -9.9±14.98% ($p<0.01$) Gp2. -0.1±13.2% (ns) **Attrition;** Overall rate was 16%. Data were analysed on an intention to treat basis.

Table 2: ***Preventive Interventions***

Author (year), country of origin, design	**Participants, interventions, sample size**	**Key long term results**
Taylor et al[33] USA 4 surveys of random households & a cohort in reference and intervention cities. 6 year intervention.	Participants in the Stanford 5 cities project aged 12-74 years. Gp1. Two intervention cities - an extensive education programme using mass media, direct mailing, classes, seminars, and school curricula. Mean BMI=25.2kg/m^2 (n=885). Gp2. Two control cities - no intervention. Mean BMI=24.8kg/m^2 (n=784). Mean baseline BMI significantly lower in the control cities (p=0.03). Groups also differ with regard to ethnicity.	**Survey results;** BMI change (±se), baseline to year 6: Gp1. 0.57±0.22 Gp2. 1.25±0.23 **Cohort results;** No significant effects of treatment on BMI. All groups gained weight. Cohort response rates 56-70%.
Forster et al[34] USA RCT, 1 year community based intervention.	Participants < 115% of ideal weight from the Minnesota Heart Health Programme. Gp1. Monthly newsletter including information relevant to weight control, participants recorded weight each month, financial incentive. Optional education course. (n=108). Gp2. No treatment control (n=111). Groups comparable at baseline except for the proportion involved in previous weight control programmes (18% in treatment group and 30% in control group).	**Mean weight change adjusted for height (±se) 1 year post-treatment;** Gp1. -0.95±0.27kg Gp2. -0.14±0.27kg (p=0.03) 82% of the treatment group and 56% of the controls maintained or lost weight over the 1 year intervention (p<0.0001). Estimated annual net cost of the programme was $35 per participant. **Attrition;** Gp1. 6.5% Gp2. 2% Drop-outs were excluded from the analysis.
Jeffery et al[35] USA 3 matched pairs of communities - cross sectional surveys and cohort surveys conducted. 10 year intervention.	Minnesota Heart Health Programme, examining 3 pairs of matched communities from different states in the US (mean BMI = 25.7kg/m^2). Gp1. 3 Intervention communities - programme components were based on multiple theoretical orientations including social learning, communications and communications and community organisational theory, and diffusion of innovations (n=3527). Gp2. 3 control communities - no intervention (n=3445).	BMI rose over time, approx. 1 BMI unit on average over a ten year period. The intervention did not produce a significant effect in either the cross sectional or the cohort survey. **Attrition;** Overall rate was 32.9%

Table 3: ***Behavioural Interventions***

Author (year), country of origin, design	Participants, interventions, sample size	Key long term results
Black & Lantz[36] USA RCT, 10 week intervention, 1 year follow-up.	Married women recruited through newspaper ads and referrals, aged between 23 and 53 years, > 10% overweight (mean = 37% overweight), with a husband who agreed to attend sessions and support wife. All subjects received the same 10 week behavioural programme. Gp1. Husband contracting: husband attends treatment sessions and actively encourages wife in her weight loss efforts (n=12). Gp2. Husband not contracting: husband attends treatment sessions but does not provide active encouragement to wife for weight loss (n=12). Gp3. Husband absent: wife attends treatment sessions alone (n=12). Groups comparable with regard to baseline weight and %-overweight.	**Mean weight change at 1 year follow-up compared to baseline;** Gp1. -7.0kg Gp2. -4.2kg Gp3. -7.4kg Gp3 lost significantly more weight than Gp2 (p=0.05). No significant difference between any other groups. All groups demonstrated significant weight change from baseline to 1 year (p< 0.02). **Attrition;** Drop out rate at 1 year 0% but 4 subjects excluded from the analysis because of use of other methods of weight control.
Dubbert & Wilson[37] USA RCT, 19 week intervention, 1 year follow-up.	Volunteers recruited from newspaper ads and public service radio commercials. Subjects ≥7kg overweight, otherwise healthy, with a spouse willing to attend meetings. All subjects received instruction in self monitoring, exercise, and problem solving for relapse prevention. They were allocated to groups according to whether the spouse was involved in the weight loss process (couples conditions) and whether goals associated with weight loss activities were prescribed on a daily or weekly basis. Gp1. Couples/weekly goals (n=10). Gp2. Couples/daily goals (n=11). Gp3. Individuals/weekly goals (n=14). Gp4. Individuals/daily goals (n=12). Groups comparable at baseline.	**Mean weight change at 1 year follow-up;** Results are not reported per group. There was a mean overall weight regain of 1.2kg during this time. **Mean weight change at 30 month follow-up;** Results not reported per group. There was a mean overall weight regain of 2kg, giving a mean overall weight loss of 5.8kg compared to baseline measurement. **Attrition;** Overall rate was 18% at one year follow-up and 27% at 30 month follow-up. Drop-outs were excluded from the analysis.

Table 3: ***Behavioural Interventions (Cont'd)***

Author (year), country of origin, design	Participants, interventions, sample size	Key long term results
Rosenthal et al[38] Canada RCT, patients stratified according to % overweight. 16 week intervention, 3 year follow-up.	Subjects ≥10% over ideal body weight (average weight = 76kg). Both husband and wife had to be willing to attend a meeting, and a $10 deposit was required. All subjects were provided with copy of text which outlined the basic programme for achieving weight loss. Subjects participated in eight 75 minute treatment sessions that convened twice monthly. Gp1. No husband involvement, basic treatment only, as described above. Gp2. Husband involvement, husbands attended all 8 meetings with their wives and were instructed as to how to aid their wives Gp3. Partial husband involvement. Husbands attended only the first four sessions in order to learn specific techniques for aiding their wives. Total of 43 couples started the treatment, the pre-treatment breakdown by conditions not stated. Groups were comparable at baseline with regard to weight.	**Mean weight change at 3 year follow-up compared to baseline;** Gp1. -3.62kg Gps 2&3 combined: - 4.37kg No statistically significant differences between groups, and no reports of overall significant weight loss over time. **Attrition;** Overall rate was 53%.
Pearce et al[39] Canada RCT, 10 week intervention, 12 month follow-up.	Subjects recruited by newspaper ads, ≥90.9kg and 20% overweight (mean = 41% overweight), willing to place a $50 deposit, and with a husband willing to participate in the programme. Gp1. Co-operative Spouse - Subject and spouse attended 10 weekly behavioural treatment sessions. Spouse asked to participate fully to help partner to lose weight. Mutual monitoring of eating behaviour by subjects and spouses (n=14). Gp2. Wives alone - Identical to Gp1 except that the spouse did not attend any of the treatment sessions, no monitoring of eating behaviour (n=13). Gp3. Non-participating Spouse - Wives attended treatment sessions alone. Spouses requested to remain detached from wives' weight loss efforts without sabotaging them. Wife monitored husband's eating habits (n=14). Gp4. Alternative Treatment - Focus of treatment directed at the hypothetical and underlying causes of overeating (n=13). Gp5. Delayed treatment control (n=14). Groups comparable at baseline with regard to weight and %-overweight.	**Mean (±sd) weight change at one year follow-up compared to baseline;** Gp1. -8.3±5.4kg Gp2. -2.2±6.0kg Gp3. -5.6±5.9kg Gp4. +0.3±5.3kg Gp3 lost a statistically significant greater amount of weight than Gp2 or Gp4 ($p<0.005$). Gp1 lost significantly more weight than Gp4 ($p<0.0005$). **Attrition;** Overall rate was 9%. Drop-outs were excluded from data analysis.

Table 3: ***Behavioural Interventions (Cont'd)***

Author (year), country of origin, design	Participants, interventions, sample size	Key long term results
Schwartz et al[40] Israel RCT, 2 month intervention, 1 year follow-up	Mean weight at baseline = 85.7kg. Mean % deviation from ideal weight 26.8%. Gp1. Value self confrontation - attended 3 group sessions separated by one month intervals (T1, T2, T3). T4 is 12 months after T3 T1: Subjects ranked 18 values on their importance as guiding principles in the subject's lives. Subjects were then invited to compare their own values with those of successful and unsuccessful weight losers T2: Subjects received same treatment given to the discussion group in T1 T3: Subjects repeated the discussion treatment given them at T2 T4: Current weight obtained Gp2. Group discussion - attended 3 group sessions as for VSC group. T1: Subjects ranked the 18 values and then discussed their own ideas about relations between values and eating and about barriers to dieting and ways to overcome them. T2: Repeated their T1 treatment. T3: Received the same treatment given VSC subjects at T1 T4: Current weight obtained Gp3. Non-treatment control - contacted by phone at T1 and attended a single session at T3, when they received the same treatment given to VSC subjects at T1. T4: current weight obtained. Groups were comparable at baseline with regard to weight and % overweight.	**Mean weight change at one year follow-up compared to baseline;** Gp1. -2.92kg Gp2. -1.59kg Gp3. -2.28kg No statistically significant differences reported. **Attrition;** Overall rate was 38%. Drop-outs were younger and disproportionately male. Drop-outs were excluded from analysis.
Bennett[41] UK RCT, patients stratified according to whether they were high losers or low losers in terms of initial weight loss. 16 week intervention, 1 year follow-up.	Females, 18-60 years of age, ≥6.8kg overweight (mean weight = 81.7kg, mean BMI = 32.6kg/m^2) All subjects received a common diet providing 1000 kcals below expected requirements. After 3 weeks of dieting, subjects were classified as either high or low losers, (classified on the basis of a median split of their weight loss during this time) and these were then randomly assigned as follows. Gp1. Low losers trained in cue avoidance techniques. Gp2. High losers trained in cue avoidance techniques. Gp3. Low losers trained in cognitive rehearsal techniques. Gp4. High losers trained in cognitive rehearsal techniques. Gp5. Low losers who received social support. Gp6. High losers who received social support. 53 subjects were randomised, but initial breakdown by groups is not given. Groups were comparable at baseline.	**Mean (±sd) weight change at one year follow-up compared to baseline;** Gp1. -3.2±10.9kg Gp2. -5.3±5.5kg Gp3. -0.2±3.4kg Gp4. -5.4±3.7kg Gp5. -0.4±3.6kg Gp6. -4.3±5.2kg The only statistically significant effect was for all groups over time ($p<0.001$). **Attrition;** Overall rate was 24%.

Table 3: ***Behavioural Interventions (Cont'd)***

Author (year), country of origin, design	Participants, interventions, sample size	Key long term results
Bennett[42] UK RCT, 16 week intervention, 1 year follow-up.	Females, 18-60 years of age, ≥6.8kg overweight (mean weight = 83.9kg, mean BMI = 32.7kg/m^2). All groups received core programme of nutritional advice and prescribed diet providing 1000 kcals less than expected requirements. Gp1. Trained in cognitive rehearsal techniques (n = 19). Gp2. Trained in insight control techniques (n = 17). Gp3. Individual contact: therapist contact sessions during which innate self control was encouraged (n = 19). Gp4. Group contact - received the core programme only (n = 19). Group comparability at baseline unknown.	**Mean (±sd) weight change at one year follow-up compared to baseline;** Gp1. -3.4±5.3kg Gp2. -1.8±4.9kg Gp3. -2.3±4.3kg Gp4. -2.2±5.7kg Overall: -2.4±5.0kg Overall statistically significant weight loss ($p<0.001$), no statistically significant between group differences. **Attrition;** Overall rate was 32%. Drop-outs were excluded from analysis.
Jones et al[43] UK RCT, 2x2x2 factorial design. 20 week intervention, 1 year follow-up.	Adult females, overweight (mean %-over weight of 52%, mean BMI 35.1kg/m^2), not diabetic or pregnant. All subjects were asked to consume 1000kcal below expected requirements with 1000kcals as a minimum daily intake. Gp1. Received leaflets (including advice on reducing exposure to food cues), kept food diaries, attended group treatment sessions led by dietician. Gp2. Received leaflets, kept diaries, attended individual treatment sessions with dietician. Gp3. Received leaflets, attended group treatment sessions led by dietician. Gp4. Received leaflets, attended individual treatment sessions with dietician. Gp5. Kept diaries, attended group treatment sessions led by dietician. Gp6. Kept diaries, attended individual treatment sessions with dietician. Gp7. Attended group treatment sessions led by dietician. Gp8. Attended individual treatment sessions with dietician. A total of 160 individuals started the study, no breakdown by groups. Comparability of groups at baseline unknown.	**Mean (±sd) weight change at one year follow-up compared to baseline;** Gp1. -3.3±5.9kg Gp2. -2.5±3.6kg Gp3. -7.8±5.2kg Gp4. -5.1±7.9kg Gp5. -6.3±5.6kg Gp6. -2.1±2.6kg Gp7. -2.3±5.1kg Gp8. -3.1±5.3kg Overall. -4.0±5.4kg No statistically significant results. **Attrition;** Overall rate was 64%. Drop-outs were excluded from analysis..

Table 3: ***Behavioural Interventions (Cont'd)***

Author (year), country of origin, design	Participants, interventions, sample size	Key long term results
Perri et al[44] USA RCT, 20 and 40 week interventions, 52 and 32 week respective follow-ups.	Subjects were to be 21-60 years of age, 25%-100% overweight (mean = 53% overweight), free of obesity-related medical disorders. Behavioural treatment techniques were identical in both groups (training in self-monitoring, stimulus control, self-reinforcement, cognitive modification, problem solving, and programmed aerobic exercise), but the procedures were introduced in a more gradual manner in the extended treatment condition (40 weekly sessions compared to 20 weekly sessions) Gp1. 20 week intervention (n=24). Gp2. 40 week intervention (n=24). Groups were comparable at baseline with regard to body weight.	**Mean (±sd) weight change at post treatment (20 weeks) compared to baseline** Gp1. -8.89±4.75kg Gp2. -10.09±5.53kg **Mean (±sd) weight change at post treatment (40 weeks) compared to baseline** Gp1. -6.41±5.99kg Gp2. -13.64±9.00kg Statistically significant between group difference ($p<0.05$), and overall statistically significant effect over time ($p<0.05$). **Mean (±sd) weight change at 72 week follow-up compared to baseline** Gp1. -4.61±5.16kg Gp2. -9.85±8.21kg Statistically significant between group difference ($p<0.05$), statistically significant effect over time for Gp2 ($p<0.05$). **Attrition;** Overall rate was 33%, with similar rates both study groups. Drop-outs were excluded from analysis.
Meyers et al[45] USA RCT, 8 week intervention, 15 month follow-up	Adults (18-60 years of age), ≥20% overweight but otherwise healthy, recruited via media announcements. Gp1. Live contact (n=18). Gp2. Videotaped live contact (n=13). Gp3. Viewed the videotaped group from their homes (TV delivered) (n=14). Gp4. Waiting list control (n=11). Groups 1-3 received a cognitive-behavioural treatment programme for weight reduction, including training in problem solving and relapse prevention. Additionally a $55 deposit was paid, to be refunded according to attendance and compliance with the programme directives. The groups were comparable at baseline for body weight and percentage overweight.	**Mean weight change at end of 15 month follow-up;** Gp1. +0.3kg Gp2. +4.0kg Gp3. -0.6kg NB: Figures taken from graph. Significant weight regain for Gp2. For Gps 1 and 3, pre-treatment weights were significantly higher than at 15 month follow-up. The television delivered group (Gp3.) was significantly more cost effective than the videotaped group (Gp2) or the live contact group (Gp1). **Attrition;** Overall rate was 39%.

Table 3: ***Behavioural Interventions (Cont'd)***

Author (year), country of origin, design	Participants, interventions, sample size	Key long term results
Jeffery et al[46] USA RCT, 3x2 factorial design. 15 week intervention, 1 year follow-up.	Male subjects, aged 35-57 years, at least 120% of ideal body weight (mean weight = 100.24kg, mean BMI = 31.8kg/m^2). All subjects received a 15 week educational programme including many routine aspects of behavioural therapy. Three levels of monetary deposits were made, refundable in increments according to weight lost. Participants in the individual contract groups received refunds based on individual weight loss. Those in the group contract conditions received refunds based on the average weight loss of their group. The stated programme goal was 13.6kg loss. Patients were weighed weekly. Individual contracts; Gp1. $30 (n=16). Gp2. $150 (n=15.) Gp3. $300 (n=14). Group contracts; Gp4. $30 (n=17). Gp5. $150 (n=14). Gp6. $300 (n=13). Study groups were not comparable at baseline. Those in the larger monetary contract conditions were heavier and taller than those in the smaller monetary contract conditions. This difference is not adjusted for in the analysis.	**Mean weight change at one year follow-up compared to baseline;** Gp1. -5.4kg Gp2. -7.4kg Gp3. -6.2kg Gp4. -8.5kg Gp5. -10.0kg Gp6. -6.6kg At 12 months all groups had regained statistically significant amounts of weight ($p< 0.001$). Neither the type or size of contract was of statistical significance. **Attrition;** Overall rate was 3% . Drop-outs were excluded from analysis.
Cameron et al[47] Canada RCT, 15 week intervention, 1 year follow-up.	Adults overweight by 9-23kg (mean weight = 79.52kg, mean BMI = 29.5kg/m^2), otherwise healthy, not pregnant or breast feeding. All participants received a set of 15 printed lessons mailed weekly (L). These presented information on nutrition, exercise and behavioural strategies. The other features of the programme were weekly homework (H), interim weigh-ins (W) and participation deposit of CA$21 (D). Gp1. LHWD Gp2. LHW Gp3. LHD Gp4. LWD Gp5. LH Gp6. LW Gp7. L Gp8. Delayed treatment group control group. Results for this group are not available beyond the post treatment assessment. 185 participants began treatment. Breakdown by treatment group not given at start of the study. Groups comparable at baseline.	**Mean (±sd) weight change at one year follow-up compared to baseline;** Gp1. -2.4±3.5kg Gp2. -3.2±5.3kg Gp3. -0.6±5.0kg Gp4. -2.9±3.0kg Gp5. -3.9±4.9kg Gp6. -1.6±3.6kg Gp7. -0.3±4.5kg Group 5 had statistically significant greater weight losses compared to Group 7 ($p<0.05$). **Attrition;** Overall rate was 58%. Drop-outs were excluded from analysis.

Table 3: ***Behavioural Interventions (Cont'd)***

Author (year), country of origin, design	**Participants, interventions, sample size**	**Key long term results**
Fujimoto et al[48] Japan RCT, 7 month intervention, 2 year follow-up.	Moderately obese adult females attending obesity hospital clinic (mean weight = 81kg). Gp1. Treated by behavioural therapy plus daily weight charting (n=55). Gp2. Treated by behaviour therapy alone (n=17). Groups were comparable at baseline.	**Mean weight change at two year follow-up compared to baseline;** Gp1. -14.8kg Gp2. -8.8kg Group 1 had statistically significant greater weight losses compared to Group 2 ($p<0.05$). **Attrition;** Gp1. 12.7% Gp2. 35.3%. Drop-outs were excluded from analysis.

Table 4: ***Behavioural Interventions with Dietary Component***

Author (year), country of origin, design	**Participants, interventions, sample size**	**Key long term results**
Wing et al[49] USA RCT, 16 week intervention, 12 month follow-up.	Subjects were 30-70 years of age, ≥20% above ideal body weight (mean weight = 96.4kg), and all had NIDDM. Recruited from newspaper ads. Patients in all treatments were given a calorie goal calculated as (pre-treatment weight x12) - 1,000, with a minimum goal of 1,000 calories per day. Gp1. Behaviour Modification Condition - including information on nutrition, exercise, diabetes and a variety of behavioural strategies to help patients change their behaviour. Met weekly. Gp2. Nutrition Education Condition - basic information on diabetes, nutrition and exercise, but included none of the behavioural techniques to improve compliance. Met weekly. Gp3. Standard-Care Condition - used to approximate the schedule of contact usually provided to patients with Type II diabetes. Met monthly. Total sample size = 53. Size of each group unknown. Groups were comparable at baseline.	**Mean weight change (±sd) at 1 year follow-up;** During the follow-up year subjects regained an average of 1.4±0.8kg with greater weight regain in the behaviour group. The overall weight change from pre treatment to 16 months averaged -2.8±0.8 ($p<0.01$). The overall changes were not significantly different for the 3 treatment conditions. **Attrition;** Overall rate was 6%. Drop-outs were excluded from analysis.

Table 4: ***Behavioural Interventions with Dietary Component (Cont'd)***

Author (year), country of origin, design	Participants, interventions, sample size	Key long term results
Pascale et al[50] USA RCT, 16 week intervention, 8 month follow-up.	Obese women with NIDDM and those at risk of developing NIDDM (family history). Subjects to be more than 20% above ideal body weight (average weight approx. 94kg, BMI approx. 36kg/m^2). All subjects: receive 16 week behavioural programme. Gp1. NIDDM subjects assigned to calorie restriction (n=23). Gp2. NIDDM subjects assigned to calorie and fat restriction (n=22). Gp3. Family history subjects assigned to calorie restriction (n=23). Gp4. Family history subjects assigned to calorie and fat restriction (n=22). Groups were comparable at baseline.	**NIDDM subjects;** Mean weight change (±sd) (baseline to end of follow-up); Gp1. -0.96±3.7kg Gp2. -5.2±7.3kg p<0.05 Decrease in BMI (±sd); Gp1. 0.38±1.4 Gp2. 2.02±2.8 p<0.05 **Family history subjects;** Mean weight change (±sd) (baseline to end of follow-up); Gp3. -3.5±7.4kg Gp4. -3.0±8.4kg ns Decrease in BMI (±sd); Gp3. 1.3±2.8 Gp4. 1.1±3.1 ns **Attrition;** Gp1. 26.1% Gp2. 31.8% Gp3. 43.5% Gp4. 7/22 (31.8%) No significant baseline differences were observed between drop-outs and completers. Drop-outs were excluded from analysis.

Table 4: ***Behavioural Interventions with Dietary Component (Cont'd)***

Author (year), country of origin, design	Participants, interventions, sample size	Key long term results
Wing et al[51] USA RCT, 1 year intervention, 1 year follow-up.	NIDDM adults, 30-70 years of age, >30% overweight (average BMI approx. 37.9kg/m^2), recruited through newspaper ads. Subjects were excluded if they had health problems that would preclude use of a VLCD. All patients paid deposit of $150 which was only returnable if behavioural goals reached. Gp1. LCD, 1.000-1,200 kcals daily (n= 48). Gp2. VLCD. Weeks 1-12, 400-500 kcals, followed by gradual increase to 1,000-1,200 kcals during weeks 12-16. Weeks 16-24, 1,000-1,200 kcals, 400-500 kcals for weeks 24-36, then same increase pattern as before for weeks 36 onwards (n = 45). Groups were comparable with respect to al baseline variables.	**Mean weight change at 1 year follow-up;** Gp1. -5.7±7.9kg Gp2. -7.2±8.0kg These weight changes differed significantly from baseline (p<0.001), but not between groups. The 2 groups had a comparable amount of weight regain over the year of follow-up. Patients who initially lost more weight later regained more weight (r=0.70, p=<0.001). **Attrition;** Gp1. 22.9% Gp2. 20% Drop-outs were excluded from analysis.
Wing et al[52] USA RCT, 20 week intervention, 1 year follow-up.	NIDDM adults 30 -65 years of age, >20% overweight (mean = 155%, with overweight spouse. Recruited through newspaper ads. Both groups underwent a 20 week behavioural weight control programme with 12 weekly sessions and 4 bi-weekly sessions. Follow-up meetings, weeks 24, 28, 40, 72. Groups of 8-10 subjects. Refundable deposit of $100. Gp1. Alone condition - 1200-1500kcal/day; stress on decreasing fat and simple carbohydrates, increasing complex carbohydrates and fibre. Walking programme, goal of expending at least 1000 kcal/week on exercise. Subjects taught behavioural techniques. Spouses did not attend treatment meetings. $50 Deposit refunded if 25lb weight lost ($2/lb) & $50 for patient and spouse attending post assessment and 1 year follow-up (n=25). Gp2. Together condition - both diabetic subject and spouse participated in behavioural weight control programme. No distinction made between patient and spouse. Importance of spouse support for modifying habits emphasised. Subject and spouse paid a deposit $75 each, to be earned back by losing weight and attending 1 year assessment. (n=24). Groups were comparable at baseline.	**Weight loss (±sd) at 1 year follow-up;** Gp1. 5.26±10.39kg Gp2. 3.17±5.31kg Differences not significant, although main effect of time p<.001. No differences between conditions in any variables (diet, exercise, behavioural) - even though only spouses treated together had been taught behavioural skills, spouses alone used them equally. Spouses in both conditions reduced calorie intake, reduced fat intake, and increased exercise. **Attrition;** Gp1. 8% Gp2. 16.7% Drop-outs excluded from analysis.

Table 4: *Behavioural Interventions with Dietary Component (Cont'd)*

Author (year), country of origin, design	Participants, interventions, sample size	Key long term results
Anderson et al[53] USA RCT, stratified according to gender, BMI and insulin use. 12 week intervention, 1 year follow-up.	Adults with NIDDM for greater than 1 year, BMI 30-40 (mean weight = 104.7kg), 40-70 years of age. Both groups received weekly behavioural education sessions Gp1. Liquid supplement diet (800kcals) (n=20). Gp2. Supplement + meal (800kcals) (n=20). Groups were comparable at baseline with regard to weight and BMI.	**At 1 year follow-up (results for groups combined)** Mean weight (±sd) = 95.9±2.3kg ($p< 0.0001$ Vs initial weight) **Attrition;** Overall rate was 7.5%. Drop-outs were excluded from analysis.
Wadden et al[54] USA RCT, 6 months, 12 months follow-up.	Subjects at least 25kg overweight recruited by newspaper ads. Gp1. Very low calorie diet (VLCD) alone. Month 1, 1000-1200kcal. Months 2 &3, 400-500kcal. Month 4, return to conventional foods (n=15). Gp2. SBT alone. 1000-1200 kcal diet throughout. Taught traditional behaviour methods of weight control (n=16). Gp3. VLCD + SBT. As for Gp1 plus an additional two months of 1000-1200 kcal diet. Extensive behaviour therapy, as before, was given throughout (n=19). Groups were comparable at baseline with regard to weight and % overweight.	**Mean weight change (±sd) at 1 year follow-up;** Gp1. -4.7±7.3kg Gp2. -9.5±6.7kg Gp3. -12.9±9.3kg Weight loss for the combined treatment was significantly greater than that for diet alone ($p<0.05$). Post treatment weight loss correlated significantly with initial weight loss but not with % over weight. Men lost more than women both at post treatment and at one-year follow-up **Attrition;** Gp1. 0% Gp2. 0% Gp3. 10.5% Drop-outs were excluded from the analysis

Table 4: ***Behavioural Interventions with Dietary Component (Cont'd)***

Author (year), country of origin, design	Participants, interventions, sample size	Key long term results
Wadden et al[55] USA RCT, 6 months intervention and 1 and 5 year follow-ups.	Adult women (mean weight = 106kg, mean BMI = 39.4kg/m^2), screened to eliminate any contraindications to VLCD. Gp1. VLCD alone (n=23). Gp2. Behaviour therapy alone (n=22). Gp3. VLCD plus behaviour (n=31). Gps 1 & 3 were given a 400 - 500 kcal/day diet for 2 months and 1000 - 1200 kcals for the remainder of treatment. Gp2 received 1200kcals diet for the entire 6 months. Comparability of groups unknown.	**Mean weight change at 1 year;** Gp1. -4.7kg Gp2. -6.6kg Gp3: -10.6kg. Conditions effect significant (p<.05), with the two behavioural treatments superior to diet alone. **Mean weight change at 5 years;** Gp1. +1.0kg Gp2. +2.7kg Gp3. +2.9kg No significant differences between conditions. No effect of treatment apparent at 5 years. 64% regained all weight lost. 5% maintained all weight loss. **Attrition;** Overall rate was 14.6%. Drop-outs were excluded from analysis.
Schlundt et al[56] USA RCT, 2 cohorts, 20 weeks and 16 weeks, 9-12 months follow-up.	Adults, ≥20% above ideal body weight (mean BMI = 32.8kg/m^2), recruited through advertisements in the local paper. Both groups underwent restricted total fat intake to 25g per day, received a group behaviour modification programme, were encouraged to exercise, trained to keep a food diary, and use food counters to calculate the macronutrient composition of each meal. Gp1. Low calorie group. Also limited total energy consumption to 1200 kcal/day for women and 1500 kcal/day for men (n=30). Gp2. Low fat group. Intervention as for both groups (see above) (n=30). Groups were comparable at baseline with regard to weight and height. However, BMI was significantly higher in the fat plus calorie restriction group.	**Mean (±sd) weight change at 9-12 month follow-up compared to baseline** Gp1. - 5.5± 5.5kg Gp2. -2.6± 4.7kg There was statistically significant time effect (P<0.0001) but there were no statistically significant between group differences, nor gender differences. **Attrition;** Overall rate was 42% No statistically significant differences in drop out rates between groups. Drop-outs were excluded from analysis.

Table 4: ***Behavioural Interventions with Dietary Component (Cont'd)***

Author (year), country of origin, design	Participants, interventions, sample size	Key long term results
Jeffery et al[57] USA RCT, 18 month intervention.	Women, 25-45 years of age, 120% - 140% of ideal weight (mean weight = 80kg), recruited via newspaper advertisement. Both groups received counselling sessions held weekly for 6 weeks, then bi-weekly for 20 weeks, and finally monthly until the end of the 18 months. Gp1. Fat counselling, restricted to 20g of fat daily (n=61). Gp2. Calorie counselling, restricted to 1000-1200 kcals/day, depending on initial weight (n=61). Groups were comparable at baseline.	**Mean weight change between baseline and 12 month follow-up** Gp1. -2.1kg Gp2. -0.5kg **Mean weight change between baseline and 18 month follow-up** Gp1. +0.4kg Gp2. +1.8kg There were no statistically significant differences between groups in weight loss or regain at any point during the study. **Attrition;** Overall rate was 39%. Drop-outs were excluded from analysis.
Jeffery et al[58,59] USA RCT, 18 month intervention.	Adults 25-45 years of age, 14-32kg overweight (mean weight = 89.8kg, mean BMI = 31kg/m^2), otherwise healthy, recruited via newspaper advertisements, radio announcements, and postal invitation. Gp1. No intervention control group. Advised to lose weight using whatever methods they wished (n= 40). Gp2. Standard behavioural therapy (SBT). Group meetings for first 20 weeks then monthly. Assigned individual calorie goal 1000 or 1500kcals. Subjects selected a weight goal and had an exercise programme. Behavioural components included stimulus control and problem solving strategies (n = 40). Gp3. SBT (as above) plus food provision. Participants were given 5 prepacked breakfasts and dinners each week for the programme. Meals were at the calorie level of the individual (n = 40). Gp4. SBT+ financial incentives. Weekly cash payment based on the amount of weight they had lost (n= 41). Gp5. SBT plus food provision plus financial incentives (n= 41). Groups were comparable at baseline.	**Mean change in BMI between baseline and 18 month follow-up** Gp1: -0.2 Gp2: -1.8 Gp3: -2.5 Gp4: -1.5 Gp5: -2.3 The mean weight loss across all the treatment groups excluding controls was 4.1kg, and 6.4kg for groups with food provision. Analysis of BMI change showed statistically significant greater changes in the food provision variations (Gps 3 and 5) than in control ($p < 0.0001$). There was no effect for financial incentives or for the interaction of food provision and incentives. **Attrition;** Gp1. 30% Gp2. 35% Gp3. 10% Gp4. 15% Gp5. 17% There was a significant difference between drop-out rates. Drop-outs were excluded from analysis

Table 4: ***Behavioural Interventions with Dietary Component (Cont'd)***

Author (year), country of origin, design	Participants, interventions, sample size	Key long term results
Wing et al[60] USA RCT, 26 week intervention, 1 year follow-up.	Women 15-55 years of age, overweight by 13.5-31.5kg (mean weight = 86.4kg, mean BMI = 32.2kg/m^2), otherwise healthy, not pregnant, recruited via newspaper advertisements. Gp1. SBT only. SBT involved 26 weekly group sessions, dietary guidelines, recording own intake, exercise guidelines, and behavioural strategies including self-monitoring, stimulus control, pre-planning, changing cognitions, problem solving and social support (n=40). Gp2. SBT plus written meal plans and weekly grocery list (n=41). Gp3. As for Gp2 plus food provision. Subjects received a box of food containing all of the items described on the meal plans. Participants shared the cost of the food provision (n=41). Gp4. As for Gp3 except that the food was provided free of charge (n=41). Groups were comparable at baseline.	**Mean weight change at 1 year follow-up compared to baseline** Gp1. -3.3kg Gp2. -6.9kg Gp3. -7.5kg Gp4. -6.6kg Weight losses for Gp1 were significantly smaller ($p<0.02$) than those in Gps 2-4. **Attrition;** Overall rate was 12%. Drop-outs were excluded from analysis.
Hakala et al[61] Finland RCT, 3 and 10 week interventions, 5 year follow-up.	Adults, 20-54 years of age, ≥54% overweight (mean weight for women = 104kg, mean weight for men = 121kg), with no participation in a weight reduction programme during the previous two years, were recruited through local newspaper advertisements. Both groups received leaflets on diet and exercise. Gp1. In-patient group. Three week intervention. Subjects were resident at a rehabilitation centre where they underwent an intensive weight loss programme, including a prescribed diet of 1200 kcals daily plus intensive counselling on nutrition and physical activity (n = 23). Gp2. Out-patient group. Ten week intervention. Subjects attended treatment sessions at a local health centre (n =20). Groups were comparable for all baseline measurements.	**Mean (±sd) weight change between baseline and 1 year follow-up;** Gp1. -11.9±10.8kg Gp2. -5.4±8.2kg Both groups showed statistically significant weight loss over time (Gp1: $p<0.01$, Gp2: $p<0.05$). Non significant between group difference. **Mean (±sd) weight change between baseline and 2 year follow-up;** Gp1. -7.5±9.5 kg Gp2. -3.1±11.1kg Statistically significant weight loss over time for Gp1 ($p<0.05$). Non significant between group difference. **Mean (±sd) weight change between baseline and 5 year follow-up;** Gp1. Men -6.8±5.0kg Women +0.3±-8.7kg Gp2. Men -0.2±12.0kg Women +0.5± 9.6kg The only statistically significant results at this point was the effect over time for men in Gp1. ($p<0.05$). **Attrition;** Overall rate was 10%. Drop-outs excluded from analysis.

Table 5: ***Behavioural Interventions with Dietary and Exercise Components***

Author (year), country of origin, design	**Participants, interventions, sample size**	**Key long term results**
Wing et al[62] USA Study 1. RCT, comprising 10 week intervention and 1 year follow-up.	Diabetics (type 2), 30-65 years, >20% overweight, (mean baseline weights were around 101kg for Study 1 and 104kg for Study 2). All participants received SBT and a daily calorie goal to produce 1kg/week weight loss. Those in the exercise groups exercised 3 x weekly for 1 hour. **Study 1;** Gp1. Moderate exercise group (walking) (n=12). Gp2. Placebo exercise group (callisthenics & stretching) (n=13). Comparability of groups is unclear.	**Study 1; mean (±sem) weight change from baseline to 1 year follow-up** Gp1. -7.8±3.7kg Gp2. -4.0±1.9kg Statistically significant weight losses for both groups over time ($p<0.01$), but no statistically significant differences between groups. **Attrition;** Overall rates was 24%, drop-outs excluded from the analysis.
Wing et al[62] USA Study 2. RCT, comprising 10 week intervention and 1 year follow-up.	Diabetics (type 2), 30-65 years, >20% overweight, (mean baseline weights were around 101kg for Study 1 and 104kg for Study 2). All participants received SBT and a daily calorie goal to produce 1kg/week weight loss. Those in the exercise groups exercised 3 x weekly for 1 hour. **Study 2:** Gp3. Diet only (n=15). Gp4. Diet plus exercise (walking) (n=15). Comparability of groups is unclear.	**Study 2; mean weight change from baseline to 1 year follow-up** Gp3. -3.8kg Gp4. -7.9kg Statistically significant weight loss over time for both groups ($p=0.001$) and statistically significant between group difference ($p<0.01$). **Attrition;** Overall rate was 7%, drop-outs were excluded from the analysis.

Table 5: ***Behavioural Interventions with Dietary and Exercise Components (Cont'd)***

Author (year), country of origin, design	Participants, interventions, sample size	Key long term results
Pavlou et al[63] USA RCT, 8 week intervention, 18 month follow-up.	Overweight, male members of the Boston Police force, 26 -52 years (mean baseline weights were around 100kg for Study 1 and 102kg for Study 2). All participants attended 8 weekly educational sessions that included instruction in behaviour modification, diet, general nutrition, and exercise. **Study 2; (mean baseline weight around 102kg)** Gp1. Exercise as above plus BCDD (1000 kcal/day) (n=10). Gp2. Exercise as above plus PSMF (1000 kcal/day) (n=16). Gp3. Exercise as above plus formula diet DPC70 (420 kcal/day) (n=10). Gp4. Exercise as above plus formula diet DPC800 (800 kcal/day) (n=18). Gp5. Exercise education plus BCDD (1000 kcal/day) (n=11). Gp6. Exercise education plus PSMF (1000 kcals/day) (n=16). Gp7. Exercise education plus DPC70 (420 kcals/day) (n=13). Gp8. Exercise education plus DPC800 (800 kcals/day) (n=16). Both studies: groups were comparable at baseline for age, height and weight.	**Mean (±sem) weight change at end of intervention compared to baseline;** Gp1. -12.0±1.0kg Gp2. -12.5±1.4kg Gp3. -12.3±1.1kg Gp4. -12.1±1.0kg Gp5. -7.1±0.5kg ($p<0.01$ compared to the other groups) Gp6. -10.6±1.2kg Gp7. -13.2±0.8kg Gp8. -9.6±1.0kg **Results at end of 18 month follow-up;** Gps 5-8 had returned to baseline weight, Gps 1-4 maintained loss. **Attrition;** Overall rate was 31%, drop-outs excluded from analysis.

Table 5: ***Behavioural Interventions with Dietary and Exercise Components (Cont'd)***

Author (year), country of origin, design	Participants, interventions, sample size	Key long term results
Bertram et al[64] South Africa RCT, 16 week intervention, 1 year follow-up	Female volunteers, BMI >30 (mean baseline weight around 94kg). All participants were prescribed 1200 kcal/day diet. Gp1. Exercise group (3 one hour aerobic training sessions per week) (n=15). Gp2. Diet lecture group (weekly lectures on nutrition) (n=15). Gp3. Control group, received prescribed diet only (n=15). Groups were comparable at baseline for age, height, weight, and BMI.	**Weight change from baseline to end of intervention** Gp1. -7.0kg Gp2. -8.1kg Gp3. -9.3kg Statistically significant weight loss for all groups over time ($p<0.01$), but no statistically significant differences between groups. However, when data was included from control group drop-outs, this showed average reduction of body weight of 5% for controls, compared to 8% for Gp 1 and 9% for Gp 2. **Weight change from baseline to one year follow-up** Overall: -7.2kg, data per group not reported. Statistically significant weight loss over time ($p<0.01$). **Attrition;** Overall rate was 73%. Drop-outs excluded from analysis, except for % reduction of body weight analysis.
Johnson et al[65] USA RCT, 10 week intervention, 1 year follow-up.	Age at least 15 years, 20-100% overweight (average 40% overweight at baseline). All participants attended 10 weekly sessions and received training in stimulus control. Gp1. Stimulus control only (n=12). Gp2. Stimulus control plus exercise (n=10). Gp3. Stimulus control plus contingency management (n=12). Gp4. Stimulus control plus exercise plus contingency management (n=10). Groups were comparable at baseline for percentage overweight and level of exercise.	**Weight change from baseline to 1 year:** Gp1. -2.4kg Gp2. -5.2kg Gp3. -7.4kg Gp4. -5.9kg Statistically significant weight losses for all groups over time except Gp 1 (Gp 2: $p<0.001$, Gp 3: $p<0.05$, Gp 4: $p<0.01$). Gp1 regained weight between programme end and follow-up. All other groups continued to lose weight up to 3 months. At 1 year only Gp2 was still losing weight. Main effect for exercise did not quite reach statistical significance.($p <0.1$) **Attrition;** Overall rates was 12%. Drop-outs were excluded from analysis.

Table 6: *Dietary Interventions*

Author (year), country of origin, design	Participants, interventions, sample size	Key long term results
Baron et al[66] UK RCT, 12 week intervention, 9 month follow-up	Overweight subjects, 16-70 years (mean baseline weight around 78kg, 85% women in sample). Both groups received 1000 -1200 kcals/day and attended weekly meetings. Gp1. Low carbohydrate/low fibre diet (n=66) Gp2. Low fat/high fibre diet (n=69) Groups were comparable for age, weight, height, sex, social class and fibre intake.	**Mean weight change from baseline to 1 year;** Gp1. -2.3kg Gp2. -1.6kg 95% CI of difference between means: (-1.2, 2.6) **Attrition;** Overall rate was 12% Drop-outs excluded from analysis.
Rytigg et al[67] Denmark RCT, 52 week intervention.	Females, 18-55 years, 10-30% overweight (mean baseline weight around 77kg). Gp1. Received fibre supplement for 52 weeks, with prescribed diet for first 27 weeks and free diet thereafter (n=62). Gp2. Received identical placebo with prescribed diet for first 27 weeks. Then received fibre supplement with free diet for 25 weeks (n=35). Groups were comparable for age, weight and height.	**Weight change from baseline to 27 weeks;** Gp1. -3.8±0.5kg Gp2. -2.8±0.9kg ($p<0.05$) **Weight change from baseline to 52 weeks;** Gp1. -6.7kg Gp2. No data reported **Attrition;** Gp1. 8% Gp2. 14% It is stated that an intention to treat principle was applied, however, 5 drop-outs from each group were excluded from the analysis because they attended only at the start of the trial.

Table 7: ***Dietary and exercise interventions***

Author (year), country of origin, design	**Participants, interventions, sample size**	**Key long term results**
Skender et al[68] USA RCT, 1 year intervention, 1 year follow-up.	Adults, 25-45 years, at least 14kg overweight (mean baseline weight = 97.1kg) Gp1. Prescribed diet only, to produce 1kg/week weight loss (n=42). Gp2. Exercise only, comprising walking programme (n=43). Gp3. Diet and exercise combined (n=42). All groups attended 12 weekly instructional sessions, relevant to the intervention given, followed by 3 bi-weekly and 8 monthly meetings. Each subject made a deposit of $100, to be refunded in increments according to the number of instructional sessions attended. Groups were comparable at baseline with regard to initial weight.	**Mean (±sd) weight change at end of 1 year follow-up;** Gp1. +0.9±7.7kg Gp2. -2.7±9.2kg Gp3. -2.2±6.7kg **Attrition;** Rates differed between groups at 1 year follow-up Gp1 64%, Gp2 42%, Gp3 50%. Drop-outs were excluded from analysis.

Table 8: ***Pharmacological Interventions***

Author (year), country of origin, design	Participants, interventions, sample size	Key long term results
Guy-Grand et al[69] France RCT, 1 year intervention (multi-centre INDEX trial).	Healthy adults, ≥ 18 years, at least 20% overweight, were recruited from 24 centres in 9 European countries (baseline weight around 97kg). Gp1. Dexfenfluramine, 15 mg twice daily (n=404) Gp2. Identical placebo, twice daily (n=418) Both groups were prescribed a calorie restricted diet and received an educational programme, of which the regime varied slightly according to each centre. Groups were comparable for body weight and extent of overweight, but there was a statistically significant difference between groups for age. However , this is unlikely to be of clinical significance (40 years versus 42 years).	**Mean (±sem) weight change at 1 year;** Gp1. -9.8±0.50kg Gp2 -7.2±0.49kg Statistically significant between group difference ($p<0.001$). **Adverse effects;** Significantly more dF patients had transient side-effects such as tiredness, diarrhoea, dry mouth, polyuria, and drowsiness. **Attrition;** At 1 year Gp1. 37% Gp2. 45%. Drop-outs excluded from analysis.
Pfohl et al[70] Germany RCT, 1 year intervention, 3 year follow-up. (Part of INDEX trial. Data from this part of the study have been reported separately due to extended follow-up).	Healthy adults, ≥ 18 years, at least 20% overweight, recruited as part of the INDEX trial (see above), mean baseline weight around 97kg). Gp1. Dexfenfluramine, 15 mg twice daily (n=24) Gp2. Identical placebo, twice daily (n=24) Both groups were prescribed a calorie restricted diet of 1200-1500 kcals/day, and attended fortnightly group therapy sessions. Groups were comparable for age, sex, height, weight, and percentage over ideal body weight.	**Mean (±sem) weight change at 1 year;** Gp1. -10.9±1.8 kg Gp2. -9.6± 1.7kg Overall significant effect over time ($p<0.001$), but no significant between group differences. **Mean (±sem) weight change at 3 years;** Gp1. +1.5±1.3 kg Gp2. -2.1± 1.2kg Overall significant effect over time ($p<0.001$), but no significant between group differences. **Adverse effects;** Not reported. **Attrition;** Overall rate was 29% at 12 months, 54% at 3 years. Equal rates of attrition between groups. Drop-outs excluded from analysis.

Table 8: *Pharmacological Interventions (Cont'd)*

Author (year), country of origin, design	Participants, interventions, sample size	Key long term results
Mathus-Vliegen et al[71] The Netherlands RCT, 1 year intervention, then 2 months follow-up. This study follows the INDEX trial protocol, but the data is not reported within the INDEX study.	Adults, ≥ 18 years, at least 20% overweight (mean baseline weight around 111kg). Gp1. Dexfenfluramine, 15 mg twice daily (n=36) Gp2. Identical placebo, twice daily (n=39) Both groups were instructed to either halve the number of calories normally consumed or to consume 1000 kcal/day less than usual. All subjects had monthly consultations with dietician and doctor.	**Mean weight change at end of treatment (12 months);** Gp1. -10.7kg Gp2. -8.0kg No statistically significant between group differences. **Mean weight change 2 months after termination of treatment;** Gp1. +2.8kg Gp2. +1.0kg Statistically significant between group difference ($p<0.001$). **Adverse effects;** Abdominal discomfort, diarrhoea, and dry mouth were initially and transiently more frequent in the dF group. **Attrition;** Overall rate was 13%. Drop-outs excluded from analysis.
O'Connor et al[72] Australia RCT, 1 month run in, 6 month intervention, 5 months follow-up.	Adults, 18-64 years, BMI 30-40kg/m^2 (mean baseline % overweight around 62%). During the first month all subjects received placebo capsules and a standard weight loss programme. This was followed by the 6 month intervention: Gp1. Dexfenfluramine, 15 mg twice daily. For the first 8 days and last 15 days of treatment, the dose was 15 mg once daily (n=30). Gp2. Identical placebo, dose as for dexfenfluramine (n=28). At baseline the groups were comparable for age, BMI and percentage over ideal body weight. There were significant differences, however, between the groups for waist hip ratio (lower in Gp1.), percentage body fat and ratio of females to males (both greater in Gp1.)	**Mean (±sem) weight change during 6 months treatment compared to baseline** Gp1. -9.7±1.1kg Gp2. -4.9±0.9kg Statistically significant between group difference ($p=0.002$). Mean BMI was also significantly lower in Gp1, although there was no significant change in waist-hip-ratio. **Mean (±sem) weight change at 5 month follow-up compared to baseline;** Gp1. -6.0±1.6kg Gp2. -6.2±1.3kg No statistically significant between group differences. **Adverse effects;** During treatment, Gp1 reported a significantly greater increase of nausea, dry mouth and dizziness ($p<0.05$). No withdrawals due to side effects. **Attrition;** Post-treatment: Gp1. 10%. Gp2. 14%. At follow-up: Gp1. 33%, Gp2. 50%. Drop-outs excluded from analysis.

Table 8: *Pharmacological Interventions (Cont'd)*

Author (year), country of origin, design	Participants, interventions, sample size	Key long term results
Mathus-Vliegen[73] Netherlands RCT, 1 year intervention, up to 2 year follow-up.	Adults, at least 20% overweight (mean baseline weight around 109kg). Gp1. Dexfenfluramine, 15 mg twice daily (n=21) Gp2. Identical placebo, twice daily (n=21) Both groups received dietary advice, and the consumption of ample fluids and fibre-enriched low fat foods was encouraged. Groups were comparable at baseline for age, sex, height and overweight.	**Mean (±sem) weight loss at 12 months compared to baseline;** Gp1. -12.8±2.5kg Gp2. -8.6±1.7kg By the end of the study Gp1 was showing statistically larger increases ($p<0.01$) of body weight than Gp2. **Adverse effects;** Sleep disturbances, abdominal discomfort, diarrhoea and dry mouth were initially and transiently more common in Gp1. **Attrition;** Overall rate was 17% during treatment, 69% by the 2 year follow-up. Data on 5/7 drop-outs were included in the 12 month analysis.
Manning et al[74] UK RCT, 1 year intervention.	Diabetic patients (insulin-dependent and non-insulin dependent), with BMI 28-45kg/m^2, 16-70 years (mean baseline weight around 89kg). Gp1. Individual dietetic consultations (clinic based) every 6 weeks for 6 months, then 2 monthly for the rest of the year (n=37). Gp2. Group behavioural therapy every fortnight for 3 months and then 2-monthly for the rest of the year (n=38). Gp3. As for Gp1 plus dF 15mg twice daily for the first 3 months (n=37). Gp4. As for Gp1 but with the first and fourth visit taking place in the patients home (n=35) Groups were comparable at baseline with regard to age, sex, BMI, weight and diabetic treatment.	**Mean weight (95% CI) change at 1 year;** Gp1. -1.21 (0.06, -2.48) Gp2. -1.82 (-1.51, -2.13) Gp3. -2.75 (-1.42, -4.08) Gp4. -1.14 (0.13, -2.41) No significant between group differences. **Attrition;** Gp1. 39% Gp2. 43% Gp3. 21% Gp4. 29% Drop-outs included in the analysis.
Ôst and Götestam[75] Sweden RCT, 16 week intervention, 1 year follow-up.	At least 15% overweight (baseline weights: Gp1. 87kg, Gp2. 87kg, Gp3. 82kg). Gp1. Behavioural treatment. Trained in control of overeating and provided with a diet and exercise management programme (n=15). Gp2. Fenfluramine. Prescribed to a maximum of 60 mg twice daily, also advice on nutrition and exercise (n=15). Gp3. Waiting list controls (n=15). There were significant differences between groups at baseline for weight and percentage overweight. To adjust for this data were analysed with analysis of covariance, with subsequent t-tests.	**Mean weight change at 1 year follow-up compared to baseline;** Gp1. -4.6kg Gp2. -0.9kg Gp3. -2.5kg No statistically significant between group differences. **Adverse effects;** Greater frequency and duration of adverse effects in Gp2 compared to Gp1. **Attrition;** Overall rate was 27% . Drop-outs excluded from analysis.

Table 8: ***Pharmacological Interventions (Cont'd)***

Author (year), country of origin, design	Participants, interventions, sample size	Key long term results
Weintraub et al[76] USA RCT, 6 weeks run-in, 28 weeks continuous treatment for all subjects, then 70 week comparative study (part of 4 year study).	Adults, 18-60 years, 30-80% overweight (mean baseline weight prior to randomisation around 75kg). All participants underwent 6 week run in of behaviour modification, caloric restriction and exercise, followed by 28 weeks treatment with fenfluramine (60 mg daily) plus phentermine (15 mg daily). Those achieving a loss greater than 10% of initial weight were then randomised to receive one of the following conditions. Gp1. Intermittent drug therapy. Periods on medication as described above were alternated with periods off medication as follows: 2 weeks tapering, 10 weeks off medication, 14 weeks on medication, 2 weeks tapering, 10 weeks off, 15 weeks on, 2 weeks tapering, 11 weeks off, 4 weeks on (n=23). Gp2. Continuous drug therapy, as described above, given for 9 months (n=23). Group comparability at baseline is unclear.	**Mean (±sem) weight change at end of randomised study compared to baseline;** Gp1. -10.9±1.8kg Gp2. -11.3±1.0kg **Adverse effects:** Some participants complained of dry mouth, but no reports of severe adverse events. **Attrition;** Gp1. 26% Gp2. 17% Drop-outs excluded from analysis. Tests of statistical significance were not reported in this study.
Goldstein et al[77] USA RCT, 1 year intervention (multi-centre study).	Adults, >18 years, BMI ≥25kg/m^2 (mean baseline weight around 100kg). Gp1. Fluoxetine 60 mg daily for one year (n=230) Gp2. Identical placebo (n=228) Both groups were given dietary advice, nutrition and behavioural counselling (multi site trial, so the exact nature of the advice/counselling varied between sites). Patients returned to the clinic for scheduled visits, initially every two weeks, then decreasing in frequency to every eight weeks by the end of the study. Groups were comparable at baseline.	**Mean (±sd) weight change at 1 year, compared to baseline;** Gp1. -1.4±7.1kg Gp2. -1.2±5.7kg No statistically significant between group differences. **Adverse effects;** 87% Fluoxetine patients and 85% placebo patients reported one or more adverse events. Significant (p<=0.05) group differences occurred in the incidence of asthenia, diarrhoea, nausea, sweating, insomnia, somnolence, bronchitis, nervousness, nausea and vomiting, tremor, amnesia, thirst and allergic reaction. All events, except allergic reaction, occurred with greater frequency in the Fluoxetine-treated patients. **Attrition;** Gp1. 57% Gp2. 53%. Drop-outs included in analysis.

Table 8: ***Pharmacological Interventions (Cont'd)***

Author (year), country of origin, design	Participants, interventions, sample size	Key long term results
O'Kane et al[78] UK RCT, 1 year intervention.	Obese type 2 diabetic patients (diagnosed for at least 1 year) weight reducing diets as part of their therapy (mean baseline weight around 98kg). Gp1. Fluoxetine 60 mg daily (n=9) Gp2. Identical placebo (n=10) Groups appear to be comparable for weight.	Median (range) weight change at 12 months compared to baseline; Gp1.-4.3(-11.1--3.6)kg Gp 2. +1.5(-2.3-+4.4)kg at 12 months Statistically significant between group difference ($p<0.05$). Adverse effects; Overall number of complaints was small, with no statistically significant between group differences. **Attrition;** Overall rate was 16% Drop-outs excluded from the analysis.
Bitsch and Skrumsager[79] Denmark RCT, 16 week intervention, 8 month follow-up.	Adults, 20-75 years, at least 20% overweight (baseline weights not reported). Gp1. Femoxetine 600mg daily (400mg in week one) (n=36). Gp2. Identical placebo (n=37). All participants were asked to restrict their daily intake to approximately 1200-1600 kcal/day. Groups were comparable at baseline.	**Median change in weight at follow-up compared with baseline;** Gp1. -6.6kg Gp2 -8.8kg Statistically significant between group difference ($p>0.05$). **Adverse effects;** Three patients in Gp1 withdrew due to side-effects (tiredness, dizziness, diarrhoea, constipation) between weeks 1 and 5. No patients on placebo were withdrawn due to side-effects. **Attrition;** Post treatment: Gp1. 25%, Gp2. 30%. By the end of follow-up 49%. Drop-outs excluded from analysis.
Vernace[80] USA RCT, 12 week intervention, minimum of 2 years follow-up.	Adults, 18-60 years, at least 15% overweight (mean baseline weight around 86kg). Gp1. Mazindol, 1 mg 3 times daily (n=32). Gp2. D-amphetamine, 5 mg 3 times daily (n=33). Gp3. Placebo, 1 tablet 3 times daily (n=33) All participants were prescribed a 1000 calorie per day diet. The groups were comparable for weight, percent over weight, ideal weight and duration of obesity.	**Mean weight change at follow-up (average 138 weeks) compared to baseline;** Gp1. +6.1kg (18 patients increased, 4 decreased in weight) Gp2. +8.3kg (14 patients increased, 5 decreased in weight) Gp3. +5.4kg (13 patients increased, 3 decreased in weight) No statistically significant between group differences. **Adverse effects;** The incidence of side effects was greater in Gps 1&2 compared to Gp3. The side effects were mild and transient. **Attrition;** Overall rate was 38% at 138 week follow-up. Drop-outs excluded from analysis.

Table 8: *Pharmacological Interventions (Cont'd)*

Author (year), country of origin, design	Participants, interventions, sample size	Key long term results
Jones et al[81] UK Multicentre RCT, 1 year intervention	Patients with a BMI of 27 - 40kg/m^2 Gp1. 10mg sibutramine once daily (a.m.) Gp2. 15 mg sibutramine once daily (a.m.) Gp3. Placebo once daily (a.m.) 485 patients were enrolled. Groups were comparable a tbaseline for weight and BMI.	**Mean weight change (kg) at 1 year;** Gp1. -3.3kg Gp2. -4.4kg Gp3. -1.6kg ($p<0.001$ sibutramine vs placebo) **Attrition;** Overall rate was 52.8%. Only 13 % of patients withdrew due to adverse events, with no significant differences between the groups. Drop-outs included in analysis.

Table 9: ***Surgical Interventions***

Author (year), country of origin, design	Participants, interventions, sample size	Key long term results
Sugerman et al[82] USA RCT, 3 year follow-up.	Morbidly obese, weighing more than 100lbs above the ideal body weight as determined by the 1959 height/weight tables of the Metropolitan Life Insurance Company (mean % of ideal body weight = 219). Patients accepted for surgery if they 1) failed to lose weight by supervised dietary programmes, 2) had a significant medical problem related to obesity. Gp1. Vertical banded gastroplasty (VBGP) (n=20). Gp2. Roux-en-Y gastric bypass (RYGBP) (n=20). Prior to operation, patients were classified as either sweet eaters or non-sweet eaters. Gastric pouch approx. 30ml. Groups were comparable with regard to ideal body weight and % of ideal body weight at baseline.	**% excess weight lost (±sd) at 1 year;** Gp1. 43±18% Gp2. 68±17% (p<0.001) This difference remained significant for the 3 years. By 3 years, although 3 VBGP patients had been converted to RYGBP, 11 still weighed more than 150% of their ideal body weight, in contrast to 5 patients with RYGBP. At 1, 2 or 3 years after surgery, patients identified as sweet eaters who had undergone VBGP were noted to have lost significantly less excess weight (p<0.05) than non-sweet eaters with the same operation. There was no significant difference at 1 year between sweet eaters and non sweet eaters who had undergone RYGBP. The difference in loss of excess weight between sweet eaters with VBGP Vs RYGBP was highly significant (p<0.0001). **Attrition;** Gp1. 25% Gp2. 10% Drop-outs were excluded from analysis.
MacLean et al[83] Canada RCT, approx. 3 year follow-up.	66 of the patients randomised were morbidly obese (BMI 40-50)(mean BMI = 49kg/m2), 40 were super obese (BMI>50). Participants were randomised immediately after surgery had commenced to receive either: Gp1. Vertical banded gastroplasty (VBG) not dependent upon staples (n=54). Gp2. Roux-en-Y gastric bypass (GB) (n=52). Gastric pouch approx. 15ml Groups were comparable at baseline.	23/54 (43%) of the VBG group required reoperation. Of these, 18/23 (78%) were converted to isolated gastric bypass (IGB). 12/52 (23%) of the patients who underwent GB initially were converted to IGB. Thus, a total of 54 VBG operations and 82 GB or IGB were performed. The success rate in the combined bypass group was 67% compared with 39% for the VBG group (p=0.003, OR 3.1; 95% CI = 1.45, 6.87). IGB was significantly more successful than the original 2 procedures, with a success rate of 83% compared with 39% for VBG and 58% for GB. Excluding the reoperation data, the overall success (a score of excellent/good as defined by the Reinholt classification) and failure rates for the two groups at final assessment were: Gp1. VBG 39% success, 33% failure (28% reoperations) Gp2. GB 58% success, 42% failure (p=0.08) **Attrition;** Overall rate was 0.9%

Table 9: *Surgical Interventions (Cont'd)*

Author (year), country of origin, design	Participants, interventions, sample size	Key long term results
Laws and Piantadosi[85] USA RCT, 1 year follow-up.	Adults, usually under the age of 50. Minimal acceptable weight was considered to be twice ideal weight for medium frame individuals from the Metropolitan Life Insurance scale. Exclusions: patients with aortic stenosis, ischemic heart disease, reflux esophagitis, or unrealistic expectations. Gp1. Gastric partitioning procedure after Pace et al (n=26) Gp2. Gastric bypass with Roux-en-Y gastrojejunostomy (n=27) Gastric pouch approx. 30ml. Groups were comparable at baseline with regard to weight.	**Proportion of initial weight at 12 months;** Gp1. 0.84 Gp2. 0.65 (p=0.0001) **Attrition;** No data on drop-outs recorded.
Hall et al[84] Australia RCT, 3 year follow-up.	Participants had to be > 160% of their ideal weight, > 18 years of age, no prior abdominal surgery for obesity, had undergone vigorous attempts at weight reduction by conservative means, resided in the Adelaide area. Gp1. Gastroplasty (n=106). Gp2. Gastric bypass (Roux-en-Y)(n=99). Gp3. Gastrogastrostomy (n=105). Gastric pouch less than 50ml. Power calculation undertaken. Groups were comparable for all demographic variables.	**Mean weight change at 1 year follow-up compared to baseline;** Gp1. -36kg Gp2. -42kg Gp3. -29kg **Mean weight change at 3 year follow-up compared to baseline;** Gp1. -33kg Gp2. -39kg Gp3. -17kg **Number of subjects achieving more than 50% loss of excess weight at 3 years;** Gp1. 47(44%) Gp2. 65(66%) Gp3. 17(16%) (p<0.001) **Attrition;** Gp1. 24.5% Gp2. 36.2% Gp3. 14.1% Patients classified as failures excluded from analysis.

Table 9: *Surgical Interventions (Cont'd)*

Author (year), country of origin, design	Participants, interventions, sample size	Key long term results
Lechner and Callender[86] USA RCT, 24 month follow-up (results reported for 12 months only)	Participants weighed ≥100lbs over Metropolitan Life Insurance's desirable weight table minimum for height (mean % excess weight = 151). Participants were included if they had been obese for 5 years or longer, were 18-65 years of age, and were free of evidence of endocrine cause for obesity. Gp1. Gomez type gastric partitioning (GP) (n=50). Gp2. Gastric exclusion (GE), Roux-en-Y procedure (n=50). Behavioural modification and dietary instructions were emphasised for all subjects. Patients were urged to keep soft food diet with two very small high protein meals daily, and take a multivitamin and mineral tablet daily. Gastric pouch approx. 30ml. Groups were comparable with regard to weight and mean ideal weight at baseline.	**Mean weight change (±sd) at 12 months;** Gp1. -33.48±13.34kg Gp2. -45.18±11.29kg ($p<0.01$) Reoperation for staple line breakdown or inadequate weight loss were done in 2 patients in Gp2 and in 6 patients in Gp1. **Attrition;** Gp1. 72% Gp2. 70% Drop-outs were excluded from analysis.
Howard et al[87] USA RCT, 5 year follow-up.	Patients with a BMI greater than 40kg/m^2, less than 50 years of age, with a history of at least one and usually several attempts at weight loss. All patients were managed conservatively for 3 months prior to surgery to allow for adequate education about the procedures, and encourage pre-operative weight loss. Gp1. Vertical banded gastroplasty (VBG) (n=22). Gp2. Gastric bypass (GB) (n=20). Follow-up involved routine post-operative care and dietary counselling Gastric pouch approx. 30ml. Groups were comparable with respect to the proportion of super obese at baseline.	Gp2 demonstrated a significantly greater postoperative weight loss ($p<0.05$), apparent from 6 months onwards. **Percentage of subjects losing >75% of excess weight at 12 months;** Gp1. 18% Gp2. 60% **Loss of excess weight at 5 years;** Gp1. No patient had sustained an excess weight loss of over 50%, slow weight regain appeared to be occurring. Gp2. All patients had lost Ú 50% of their excess weight, weight appeared to be stable. **Attrition;** Gp1. 72.7% Gp2. 70% Drop-outs were excluded from analysis.

Table 9: *Surgical Interventions (Cont'd)*

Author (year), country of origin, design	Participants, interventions, sample size	Key long term results
Näslund et al[88] Sweden RCT, 2 year follow-up.	Participants had a Broca's index >1.50 (mean % overweight =105), were less than 55 years of age and did not suffer from overt alcoholism or severe psychiatric disorders. Gp1. Gastroplasty (n=28). Gp2. Gastric bypass (n=29). Both groups were instructed to consume only liquid diet during the first 6 postoperative weeks, and the importance of improving eating habits emphasised. Groups were comparable with regard to weight and overweight at baseline.	**Mean weight (±sd) change at 12 months;** Gp1. -29.9±10.0kg Gp2. -42.3±10.9kg ($p<0.001$) **Mean weight (±sd) change at 24 months;** Gp1. -27.6±10.7kg Gp2. -42.9±13.6kg ($p<0.001$) There were no deaths and few serious complications. Four gastroplasties were converted to gastric bypass after 18-24 months because of failure to lose weight. **Attrition;** Gp1. 14.3% Gp2. 3.4% Drop-outs were excluded from analysis.
Brolin et al[89] USA RCT, mean follow-up 43 months.	Super obese patients, minimum weight 200lbs above ideal body weight as defined by standard life insurance tables (mean BMI = 62.5kg/m^2). Gp1. Conventional Roux-en-Y gastric bypass in which the length of the defunctionalised jejunum measured 75cm (n=22). Gp2. Modified Roux-en-Y gastric bypass in which the length of the defunctionalised jejunum measured 150cm (n=23). All patients were recommended to take a daily multivitamin supplement and instructed to follow a liquid diet for the first 4 weeks, followed by a diet of soft solid foods. Gastric pouch 20±5ml. Groups were comparable at baseline with regard to weight and BMI.	**Postoperative weight change and BMI (±sd) at 1 year;** Gp1. -118±35lbs, 44±8 Gp2. -140±41lbs, 40±9 **Postoperative weight change and BMI (±sd) at 4 years;** Gp1. 63.5±28.6kg, 43±10 Gp2. 72.1±31.8kg, 37±11 **Attrition;** Gp1. 72% Gp2. 61%

Table 9: *Surgical Interventions (Cont'd)*

Author (year), country of origin, design	Participants, interventions, sample size	Key long term results
Andersen et al[90] Denmark RCT, 12 month follow-up.	Morbidly (undefined) obese patients (median weight = 115kg) aged 18-54 years. Prior to randomisation for surgery, all participants underwent repeated 8-week periods with VLCD (388kcal formula) as sole source of nutrition. Every 8 weeks the VLCD was replaced by a 'pause diet' (900kcal) for two weeks. Once 40% of initial overweight had been lost, participants were put on a waiting list for surgery. The diet consumed whilst on the waiting list consisted of normal food items only (1000kcal). Gp1. Horizontal gastroplasty (n=22). Gp2. Vertical gastroplasty (n=23). Groups were comparable at baseline.	**Median weight change following surgery at 12 months;** Gp1. +1.0kg (range -15.0, 36.5) Gp2. -9.7kg (range -28.2, 28.7) ($p<0.001$) Although weight regain had also occurred among patients in Gp2 by 12 months, there was a significant ($p<0.01$) reduction in weight by time. Occasional vomiting was reported more frequently after vertical GP than after horizontal GP ($p<0.02$) **Attrition;** Gp1. 9.1% Gp2. 8.7% Drop-outs were excluded from analysis.
Andersen et al[91] Denmark RCT, 5 year follow-up.	Median weight = 125.1kg Gp1. Gastroplasty and diet (500kcal and 34g of protein daily). Mineral, trace elements and vitamin supplements were also given. Gastric pouch approx. 50ml (n=27). Gp2. VLCD. For 8 week periods the sole source of nutrition was a formula to be taken with orange juice. Between 8 week periods, a 2 week, 900kcal diet was prescribed (n=30). It is unclear how long the VLCD is maintained. Comparability of groups at baseline unknown.	**Weight loss maintenance at 5 years;** Gp1. 30% (95% CI: 14%, 50%) had not relapsed Gp2. 17% (95% CI: 6%, 35%) had not relapsed. The median weight losses of these patients was 18.2kg (Gp1) Vs 26.8kg (Gp2). This difference was not statistically significant. **Attrition;** Overall rate was 1.75% Drop-outs were excluded from analysis.
Viddal[92] Norway RCT, 18 month follow-up.	Morbidly obese patients (average weight around 111kg). Gp1. End-to-side (ES) jejunoileostomy (n=10). Gp2. End-to-end (EE) jejunoileostomy (n=11). Groups were comparable at baseline with regard to weight.	The body weight for both groups stabilised after 12-18 months, after initial rapid decline. **Mean weight change at 18 months;** Gp1. -37kg (33% of preoperative body weight) Gp2. -40kg (37% of preoperative body weight) ($p=0.26$) **Attrition;** Gp1. 0% Gp2. 9.1% Drop-outs were excluded from analysis.

Table 9: *Surgical Interventions (Cont'd)*

Author (year), country of origin, design	Participants, interventions, sample size	Key long term results
Danish Obesity Project[93] Denmark RCT, approx. 3 year follow-up.	Participants were at least 80% overweight for several years (median weight = 125.3kg, median BMI = 45.1kg/m^2), resistant to medical and dietary treatment. Gp1. End-to-side jejunoileostomy (with either 1/3 or a 3/1 ratio between jejunum and ileum left in continuity) (n=133). Gp2. Medically treated patients (unspecified treatment) (n=69). Groups were comparable at baseline with regard to weight and overweight.	**Median weight change at 2 year follow-up;.** Gp1. -42.9kg (20.5-108kg) Gp2. -5.9kg (-11.9-40.4kg) ($p<0.01$) Beyond 24 months only minor changes in weight were observed. The differences in weight loss between Gp1 and Gp2 were highly significant ($p<0.001$). Adverse effects: No deaths in surgical group, 2 deaths in the medical group. Surgical group: 3% had pulmonary complications, 6% had wound complications. **Attrition;** Overall rate was 11%. Drop-outs were excluded from the results.
Buckwalter[94] USA RCT, 1 year follow-up.	Patients weighed twice their normal body weight (mean excess weight = 86.5kg), with a history of unsuccessful weight loss through dieting under adequate physician supervision. Gp1. Jejunoileostomy (n=19). Gp2. Gastric bypass (n=19) Groups were comparable at baseline with regard to excess weight.	**Weight change (kg) at 1 year follow-up;** Gp1. -31.5kg Gp2. -43.0kg **Attrition;** At time of publication only 31% of patients had been followed up for 1 year.
Griffen[95] USA RCT, 1 year follow-up.	Patients were >50kg over their ideal body weight. Gp1. Jejunoileostomy (n=27). Gp2. Gastric bypass (n=32). Groups were comparable at baseline with regard to weight.	**Weight change at 1 year follow-up;** Gp1. -57.9kg Gp2. -51.0kg **Attrition;** Gp1. 18.5% Gp2. 43.8% Drop-outs were excluded from analysis.

Table 9: ***Surgical Interventions (Cont'd)***

Author (year), country of origin, design	Participants, interventions, sample size	Key long term results
Hogan et al[96] USA RCT, 3 month intervention, 9 month follow-up.	Participants were > 50lb over their ideal body weight, and had not succeeded in losing weight through prior dietary therapy. Gp1. Garren-Edwards gastric bubble (GEGB) (mean BMI=39.8kg/m^2) (n=34). Gp2. Sham placement (mean BMI=37.1kg/m^2) (n=25). Both groups underwent standard weight loss programme along side the GEGB or sham placement. Treatment was concluded with either the sham or bubble being removed at the end of three months. Groups were comparable at baseline with regard to weight and BMI.	**Mean cumulative weight change (kg);** Months Bubble Sham 3 8.48 7.80 6 6.62 14.56 9 5.62 10.89 12 5.85 11.88 No significant difference in weight loss when measured in kgs, % decrease of initial body weight or change in BMI. Significantly more cases of nausea, vomiting and abdominal pain, in the sham placement group. This difference was no longer significant by the end of the three months. **Attrition;** Gp1. 18% Gp2. 36% Drop-outs were excluded from analysis.

Table 10: ***Maintenance***

Author (year), country of origin, design	Participants, interventions, sample size	Key long term results
Ashby et al[97] USA RCT, 8 week intervention, 1 year maintenance programme. This study was carried out in 2 phases.	At least 7kg or 10% overweight (mean weights not reported at baseline, for at start of maintenance programme). **Initial weight loss intervention for all participants;** Eight weekly sessions of behavioural group therapy, exercise guidelines and prescribed diet (1200 kcal/day). **Maintenance programmes;** Gp1. Fortnightly structured behavioural sessions involving revision of material presented during the initial intervention. (Phase 1: n=8. Phase 2: n=9). Gp2. Sessions as for Gp1, delivered every 4 weeks. (Phase 1: n=8. Phase 2: n=7). Gp3. Fortnightly unstructured discussion sessions, original material not reviewed. (Phase 1: n=7. Phase 2: n=7). Gp4. Sessions as for Gp3, delivered every 4 weeks. (Phase 1: n=8. Phase 2: n=7). Gp5. Controls receiving no contact except for assessment. (Phase 1: n=8. Phase 2: n=6). The scheduling of the active treatment conditions was as stated above for the first four months, frequency of sessions decreased during the second four months, and there were no maintenance sessions during the final 4 months. At the start of the maintenance programme, groups were comparable for initial percentage overweight, and percentage excess weight lost during weight loss intervention.	**Mean weight change from baseline to end of weight loss intervention** Phase 1: -4.8kg, statistically significant difference compared to baseline ($p<0.001$) Phase 2: -3.6kg, statistically significant difference compared to baseline ($p<0.001$) **Mean (±sd) weight change during 1 year maintenance programme** Phase 1: Gp1. -2.0±3.1kg Gp2. -3.2±2.3kg Gp3. -3.6±5.8kg Gp4. -3.5±2.6kg Gp5. -2.3±2.7kg No statistically significant between group differences. Phase 2: Gp1. -3.3±4.0kg Gp2. -5.6±8.1kg Gp3. -4.9±4.6kg Gp4. -3.9±4.9kg Gp5. -5.6±5.9kg No statistically significant between group differences. **Attrition;** Overall rate was 7% during treatment, 9% during maintenance. Drop-outs excluded from analysis.

Table 10: *Maintenance (Cont'd)*

Author (year), country of origin, design	Participants, interventions, sample size	Key long term results
Hall et al[98] USA RCT, 10 week intervention, 1 year maintenance programme.	Women, 18-65 years, at least 20% overweight (mean baseline weight around 87kg, mean group weights at start of maintenance Gp1 85kg, Gp2 82kg, Gp3 85kg). **Initial weight loss intervention for all participants** Ten week behavioural programme comprising food and weight monitoring, training in cognitive techniques, and group therapy. **Maintenance programmes;** Gp1. Minimal contact. No contact with therapist, except assessments at 18, 26, 34 and 52 weeks, advised to maintain weight loss using own means (n=23). Gp2. Monitoring/minimal contact. As for Gp1, but also asked to continue with food and weight monitoring. (n=25). Gp3. Continued contact. Attended therapist led group meetings every 2 weeks until 34 weeks, then advised to continue practising learnt techniques, with no further therapist contact until the 52 week assessment (n=24). The 3 groups lost comparable amounts of weight during the initial intervention.	**Mean weight change from baseline to end of weight loss intervention;** Gp1. -3.6kg Gp2. -3.3kg Gp3. -3.8kg Overall statistically significant difference compared to baseline ($p<0.001$). **Mean weight change at end of 1 year maintenance programme;** Gp1. -1.0kg Gp2. -3.3kg Gp3. -3.9kg No statistically significant between group differences. **Attrition;** Overall rate was 11% during treatment, 21% by the end of the maintenance intervention. No statistically significant between group differences. Drop-outs excluded from analysis
Baum et al[99] RCT, 12 week intervention, 1 year maintenance programme.	Adults, 25-50 years, 20-70% overweight, (mean baseline weight around 81kg, paired subjects matched on amount of weight lost during the initial intervention were allocated to the maintenance groups). **Initial weight loss intervention for all participants;** Weekly sessions comprising presentations, groups discussions, review of self-monitoring records, practice of newly learned skills, and supervised aerobic exercise. **Maintenance programmes;** Gp1. Therapist support condition. Subjects attended 4 relapse prevention sessions in the 3 months after initial treatment, had contact with therapist by mail and telephone during the same period, and received written feedback concerning weight change following assessment sessions at 3, 6, and 12 months following completion of treatment (n=16). Gp2. Minimal support condition. No booster sessions or telephone contact with therapists. Same postal contact with therapists, follow-up assessment sessions and written feedback as for group 1 (n=16). Groups were comparable for amount of weight lost during initial intervention.	**Mean (±sd) weight change from baseline to end of weight loss intervention;** Gp1. -3.9±4.4kg Gp2. -3.9±3.2kg Overall statistically significant result compared to baseline ($p<0.0001$). **Mean (±sd) weight change at end of 1 year maintenance programme;** Gp1. -3.6±9.8kg Gp2. -1.5±6.5kg No statistically significant between group differences. **Attrition;** Overall rate was 6% Drop-outs excluded from analysis.

Table 10: *Maintenance (Cont'd)*

Author (year), country of origin, design	Participants, interventions, sample size	Key long term results
Perri et al[100] USA RCT, 14 week intervention, 21 month maintenance programme.	Adults, 21-60 years, 20-80% overweight (mean baseline weight around 88kg). **Initial weight loss intervention for all participants;** Training in cognitive strategies and exercise management provided over 14 weekly group sessions. A deposit of $80 was paid, return dependent upon attendance during both intervention ($40) and maintenance ($40). **Maintenance programmes;** Gp1. Standard behavioural treatment plus booster sessions. Six bi-weekly booster sessions to review and reinforce weight loss strategies learnt during initial intervention. Then, no further contact with therapists or group members, except for the 5 follow-up assessment meetings (n=26). Gp2. Behavioural treatment plus multicomponent maintenance programme. Six bi-weekly sessions comprising strategies to enhance weight loss progress. The formation of supportive peer groups was encouraged. These groups utilised problem solving approaches, mutual monitoring of weight loss and reinforcement of desirable outcomes. Subjects continued to have contact with therapists by post and telephone (n=30). Groups were comparable at baseline for weight and percentage overweight	**Mean (±sd) weight change from baseline to end of weight loss intervention;** Gp1. -5.6±3.5kg Gp2. -6.1±3.3kg Overall statistically significant results compared to baseline ($p<0.001$). **Mean (±sd) weight change at end of 21 month maintenance programme;** Gp1. -0.4±3.6kg Gp2. -4.5±7.0kg Statistically significant between group difference ($p<0.01$). **Attrition;** Overall rate was 14% during weight loss intervention (equal attrition rates between study groups), 23% by the end of the 21 month maintenance programme (all drop-outs were from Gp 1, statistically significant between group difference, $p<0.05$). Drop-outs excluded from analysis.
Perri et al[101] USA RCT, 20 week intervention, 26 weeks maintenance programme, 12 month follow-up.	Adults, 22-59 years, 20-100% overweight (mean baseline weight around 95kg). **Initial weight loss intervention for all participants;** 20 weekly 2 hour sessions providing training in self-monitoring, stimulus control, self-reinforcement, cognitive restructuring, and aerobic exercise. **Maintenance programmes;** Gp1. Controls. No further contact with therapists on completion of the above intervention (n=21). Gp2. Continued contact. Fortnightly behavioural sessions utilising a problem solving approach (n=25). Gp3. Social influence. As for Gp 2 with addition of monetary group contingencies for programme adherence, participant led lectures, and peer support (n=25). Gp4. Exercise. As for Gp 2 with addition of an aerobic exercise maintenance regime (n=26). Gp5. Combined programme. Combination of continued contact, social influence and exercise (n=26) Groups stated to be comparable at baseline.	**Mean (±sd) weight change from baseline to end of weight loss intervention;** Gp1. -10.8±7.6kg Gp2. -13.2±5.4kg Gp3. -11.3±3.1kg Gp4. -13.0±4.8kg Gp5. -13.7±5.9kg Overall statistically significant weight loss compared to baseline (mean loss 12.5kg, $p<0.01$). No statistically significant between group differences. **Mean (±sd) weight change at end of 12 month follow-up;** Gp1. -3.6±6.2kg Gp2. -11.4±12.1kg Gp3. -8.4±7.5kg Gp4. -9.1±6.4kg Gp5. -13.5±15.2kg Gps 2-5 achieved superior maintenance of weight loss compared to Gp 1 ($p<0.01$). **Attrition;** Overall rate was 26% by the end of the follow-up. Drop-outs excluded from analysis.

Table 10: *Maintenance (Cont'd)*

Author (year), country of origin, design	Participants, interventions, sample size	Key long term results
Kramer et al[102] USA RCT, 15 week intervention, 1 year maintenance programme.	Adults, 30-50% overweight (median percentage overweight 39%). **Initial weight loss intervention for all participants;** Fifteen week behavioural treatment. To be eligible for the maintenance programme, subjects had to have lost at least 10% of their body weight. **Maintenance conditions;** Gp1. Controls. No contact with therapists except for assessment at 1 year (n=28). Gp2. Skills focus. Attended monthly meetings for one year, during which subjects were trained in dietary and exercise behaviours to produce weight loss maintenance (n=28). Gp3. Weight focus. Attended monthly meetings for one year, during which subjects were trained in the use of problem solving strategies (n=29). Financial incentive contracts were used in all groups, both during the weight loss and maintenance phases, whereby money was refunded at different stages in accordance with successful weight related outcomes. Groups comparable for weight at the start of the maintenance programme.	**Mean weight change from baseline to end of weight loss intervention;** No results reported. **Mean (±sd) weight change at end of 1 year maintenance programme;** Gp1. -8.0±8.2kg Gp2. -7.0±5.9kg Gp3. -8.5±7.0kg All groups had regained approximately 40% of initial weight loss by the end of the maintenance intervention. No statistically significant between group differences. **Percentage of subjects maintaining original weight loss;** Gp1. 18% Gp2. 14% Gp3. 32% **Attrition;** Two participants dropped out and their data were not included in the analysis.
Rytigg et al[103] Sweden RCT, 12 week intervention, 1 year maintenance programme.	Adults, 19-65 years, BMI ≥ 30kg/m^2 (mean baseline weights Gp1 108kg, Gp2 120kg, p=0.07). **Initial weight loss intervention for all participants;** Twelve week VLCD consisting of Cambridge sachets to a limit of 330 kcal/day. **Maintenance programmes;** Gp1. Prescribed balanced diet of 1600 kcals/day, of which 220 kcals/day was provided by Cambridge sachets (n=31). Gp2. Prescribed balanced diet of 1600 kcals/day consisting of conventional foods only (n=29). Groups were significantly different with regard to weight at the start of the maintenance programme, Gp1. 85.7±14.7kg Gp2. 97.6±19.1kg (p=0.02).	**Mean weight change from baseline to end of weight loss intervention;** Overall statistically significant weight loss of 20.8±7.0kg (p< 0.0001). **Mean weight change at end of 1 year maintenance programme;** Gp1. +8.0±8.2kg Gp2. +12.3±9.7kg Statistically significant between group difference (p<0.0001). **Attrition;** Overall rate was 25% by the end of the 1 year maintenance programme, no statistically significant between group differences. Drop-outs excluded from analysis.

Table 10: *Maintenance (Cont'd)*

Author (year), country of origin, design	Participants, interventions, sample size	Key long term results
Agras et al[104] USA RCT, 12 week intervention, 9 months maintenance programme, 6 months follow-up.	Overweight women, mean age 44 years, (mean baseline weight around 100kg). **Initial weight loss programme for all participants** All participants (n=201) received behavioural therapy and 800 kcal/day formula diet (Optifast 800) for 12 weeks. Participants were allocated to a maintenance programme if they had lost at least 5% of their initial weight. Participants were stratified according to BMI and percentage weight loss during the VLCD. **Maintenance programmes;** Gp1: Refeeding with standard food - time dependent. Regular food gradually replaced the VLCD in stages, during a 1 month period. Gp2: Refeeding with standard food - weight dependent. As above, except that the patient did not progress to the next stage unless body weight was stable or declining. Gp3. Refeeding with pre-packaged food - time dependent. As for Gp1 except that a limited number of selected pre-packaged foods were used to replace the VLCD. The aim of this was to reduce the number of stimuli in connection with food. Gp4. Refeeding with pre-packaged food - weight dependent. As for Gp2 except that selected pre-packaged foods were used instead of standard food. 194 participants entered the study, initial sample size per groups not given. Group comparability at baseline not reported.	**Mean (±sd) weight change during initial weight loss intervention;** Gp1. -15.2±4.8kg Gp2. -15.0±4.8kg Gp3. -14.9±4.5kg Gp4. -14.2±4.1kg No statistically significant between group differences. **Mean (±sd) weight change after 9 month maintenance programme;** Gp1. -14.5±11.0kg Gp2. -13.5±11.0kg Gp3. -15.0±10.1kg Gp4. -12.1±9.9kg No statistically significant between group differences. **Mean (±sd) weight change at 6 month follow-up;** Gp1. -8.2±12.3kg Gp2. -8.6±11.4kg Gp3. -6.0±11.1kg Gp4. -2.8±18.3kg No statistically significant between group differences. **Attrition;** Overall rate was 13% by the end of follow-up. Drop-outs excluded from analysis.
Tucker et al[105] USA RCT, 6 month intervention following surgery, 2 year follow-up	Patients underwent gastric surgery (mean preoperative weight = 142.56kg) prior to randomisation to maintenance programme. All subjects received instruction on how to keep an eating diary and asked to do this for one week prior to surgery and one week during each of the first 6 months following surgery. Gp1. Behavioural treatment - subjects received 12 sets of written material mailedevery 2 weeks covering various behavioural approaches to weight management (n=17). Gp2. Minimal intervention - monthly medical follow-ups (n=15). Groups were comparable for BMI and %-overweight.	**Mean weight change at 12 months post surgery;** Gp1. -46.6kg Gp2. -36.4kg **Attrition;** No data reported.

Table 10: *Maintenance (Cont'd)*

Author (year), country of origin, design	Participants, interventions, sample size	Key long term results
Wadden et al[106] USA RCT, 54 week maintenance programme.	Female subjects who had completed a 26-week weight reduction programme (VLCD with behavioural therapy). Subjects were required to have lost at least 10 % of their initial weight. Gp1. Sertraline, titrated from 50 to 200mg/d during the first three weeks of the study, remaining at this dose for the duration of the trial. (n=26) Gp2. Placebo (n=27). Groups were comparable at baseline.	**Mean (±sd) change in weight from pre-VLCD baseline to 54 weeks;** Gp1. -8.5±12.6kg Gp2. -11.6±6.9kg No statistically significant between group differences. **Adverse effects;** A statistically significant number of patients in Gp1 reported experiencing fatigue, nausea, difficulty concentrating, and micturition ($p<0.05$). **Attrition;** Gp1. 50% Gp2. 37% Drop-outs excluded from analysis.

Table 11: ***Comprehensive Interventions***

Author (year), country of origin, design	Participants, interventions, sample size	Key long term results
Perri et al[107] USA RCT, 15 week intervention, 1 year follow-up.	Subjects were at least 15% overweight, (mean baseline weight around 89kg). Gp1. Non-behavioural therapy + no further contact. Gp2. Behavioural therapy + no further contact. Gp3. Behavioural therapy + relapse prevention training + no further contact. Gp4. Non-behavioural therapy + post-treatment contact by mail and phone. Gp5. Behavioural therapy + post-treatment contact by mail and phone. Gp6. Behavioural therapy + relapse prevention training + post-treatment contact by mail and phone. 129 participants were recruited but the breakdown per group was not given. Groups comparable at baseline for weight and percentage over ideal body weight.	All groups achieved weight loss at post-treatment, mean±sd 8.5±5.2kg, no significant between group differences. **Weight change at 1 year follow-up;** Gp1. -3.15±4.76kg Gp2. -6.27±6.1kg Gp3. -2.96±3.60kg Gp4. -6.15±5.00kg Gp5. -5.76±4.16kg Gp6. -10.3±11.39kg **Attrition;** Overall rate was 22%. Attrition rates did not differ significantly between groups. 21/28 drop-outs agreed to a telephone interview. 57% of those interviewed gave slow rate of weight loss as the major reason for dropping out. Subjects who dropped out did not differ from subjects who completed treatment. It was assumed that all dropout subjects had relapsed to pre-treatment weights at the 12 month follow-up.
Perri et al[108] USA RCT, 20 week intervention, 7 month maintenance programme, 11 month follow-up.	Adults, 21 -60 years old and 20-100% overweight (mean baseline weight around 91kg). Gp1. Behaviour therapy plus peer self-help group maintenance programme (n=46) Gp2. Behaviour therapy plus a therapist contact maintenance programme (n=41) Gp3. Behaviour therapy only (n=22) Groups were comparable at baseline for weight and percentage overweight.	**Mean weight change from baseline to end of initial weight loss intervention;** Overall mean loss was 10.69kg ($p< 0.0001$ over time), but no significant between group differences. **Mean weight change at 7 month follow-up;** Gp1. -9.31kg Gp2. -11.54kg Gp3. -7.82kg All groups regained significant amounts of weight between 7 month and 18 month follow-up (overall mean=4.08kg), but no significant between group differences. **Mean weight change (±sd) at 18 month follow-up;** Gp1. -6.47kg Gp2. -6.39kg Gp3. -3.07 **Attrition;** Gp1. 30% Gp2. 34% Gp3. 27% Drop-outs excluded from analysis.

Table 11: ***Comprehensive Interventions (Cont'd)***

Author (year), country of origin, design	Participants, interventions, sample size	Key long term results
Hakala et al[109] Finland RCT, 2 year intervention, 5 year follow-up.	Adults, 22-54 years, at least 50% overweight (mean baseline weights 120kg for women, 141kg for men). Gp1. Group counselling: 2 weeks inpatient treatment including 1200kcal diet, then group sessions weekly for 6 weeks, fortnightly for 10 months, then monthly for the second year. (n=30) Gp2. Individual counselling: monthly medical consultations for the first year and every 4th month during the second year. 1200kcals/day for first 6 months (n=30) Groups were comparable for weight and BMI.	**Mean (±sd) weight change at 1 year;** Gp1. Women -15.7±9.0kg Men -13.1±8.8kg Gp2. Women -11.9±10.4kg Men -26.2±10.3kg **Mean (±sd) weight change post-intervention (2 years);** Gp1. Women -5.4±10.9kg Men -1.8±7.4kg Gp2. Women -10.4±13.4kg Men -15.6±12.0kg **Mean (±sd) weight change at five years;** Gp1. Women -2.1±12.4kg Men -3.0±11.9kg Gp2. Women -3.4±16.7kg Men -12.9±15.8kg **Attrition;** Gp1. 7% Gp2. 17%
King et al[110] USA RCT, 1 year intervention, 1 year maintenance programme.	Adults, 30 -59 years, 20-60% overweight (mean baseline weight around 93kg). **Initial weight loss intervention;** Diet only (n=51) Exercise (n=52) Control (n=52) At the end of the year subjects randomly assigned from within these groups to either minimal intervention (telephone/mail contact) or to an assessment only control. Gp1. Diet/minimal (n=24) Gp2. Diet/control (n=20) Gp3. Exercise/minimal (n=24) Gp4. Exercise/control (n=22) Gps 1 & 2 were comparable for initial weight loss, and weight at beginning of year two. Gps 3 and 4 were also comparable for these measures.	**Weight change at 1 year (mean ±sd);** Gp1. -7.6±3.9kg Gp2. -6.4±5.0kg Gp3. -4.6±3.8kg Gp4. -5.5±2.7kg **% of lost weight regained at 2 years;** Gp1. 42.1 Gp2. 40.6 Gp3. 17.4 Gp4. 70.9 **Attrition;** Gp1. 17% Gp2. 20% Gp3. 13% Gp4. 32% Subjects who completed the 2 years were not different from drop-outs with respect to baseline weight, energy intake or activity. Drop-outs excluded from analysis.

Table 11: *Comprehensive Interventions (Cont'd)*

Author (year), country of origin, design	Participants, interventions, sample size	Key long term results
Wadden et al[111] USA RCT, 12 month intervention, 6 month maintenance programme.	Women at least 25kg overweight (mean baseline weight of around 106kg). Gp1. Behaviour therapy combined with 1200 kcal BDD (n=21). Gp2. Behaviour therapy combined with 16 week VLCD (n=28). All subjects attended weekly group sessions for the first 52 weeks and then bi-weekly maintenance sessions for the next 26 weeks. All began walking programme at week 8. The two treatment groups were comparable at baseline.	**Mean (±sd) weight change from baseline to end of modified fast (week 17);** Gp1. -9.14kg, Gp2. -20.5kg (p<0.001). **Mean (±sd) weight change at 1 year;** Gp1. -14.43±9.46kg Gp2. -17.33±9.86kg **Mean weight change during maintenance programme;** Gp1. +2.2kg Gp2. +6.3kg **Attrition;** Overall rate was 25% Drop-outs excluded from analysis.
Toubro & Astrup[112] Denmark RCT, either 8 week or 17 week weight loss intervention, followed by 1 year maintenance programme, then 1 year follow-up.	Obese adults, otherwise healthy, were recruited from an outpatient waiting list (mean baseline weight around 98kg). **Initial weight loss intervention** Gp1. Low energy formula diet for 8 weeks (n=21). Gp2. Conventional, hypocaloric, high protein diet for 17 weeks (n=22). Both groups were prescribed ephedrine 20mg and caffeine 200 mg thrice daily. All subjects attended weekly sessions where they received nutritional instruction and behavioural therapy. **Maintenance programme** Subjects remaining in the study were re-randomised to receive the following: Gp1. Ad libitum low fat, high carbohydrate diet (n=17). Gp2. Fixed energy intake diet (n=20). All subjects attended sessions consisting of nutritional instruction and behavioural therapy, twice monthly for 6 months, then once monthly for 6 months. Groups were comparable at baseline and were re-randomised for the maintenance programme to produce 2 groups, comparable for amount of weight lost.	**Mean (95% CI) weight change at end of weight loss intervention compared to baseline;** Gp1. -12.6 (10.9, 14.3)kg Gp2. -12.6 (9.9, 15.3)kg No statistically significant between groups difference. The rate of weight loss in Gp1 was approx twice that in Gp2: 1.6 (1.4, 1.8)kg/week versus 0.8 (0.7, 1.0)kg/week. **Mean (95% CI) weight change at end of maintenance programme;** Groups now re randomised to produce comparability re anthropometry and weight loss. Gp1. +0.3(-3.0, 3.6)kg Non significant weight gain compared to end of weight loss intervention. Gp2. +4.1(1.2, 6.9)kg Significant weight gain compared to end of weight loss intervention (p<0.01), group difference 3.8 (-0.4, 8.0)kg (p=0.08). **Mean (95% CI) weight change at 1 year follow-up compared to end of weight loss intervention;** Gp1. +5.4(2.3, 8.6)kg Gp2. +11.3(7.1, 15.5)kg Group difference 5.9 (0.7, 11.1)kg (p<0.03). The maintained weight loss was also greater in Gp1 compared to Gp2: 8.0 (3.5, 12.6)kg versus 2.5(-1.7, 6.6)kg, group difference 5.6 (-0.3, 11.5)kg (p=0.06). **Attrition;** Overall rate was 35% by the end of follow-up. No significant differences in withdrawal rates between groups at any point. Data was analysed on intention to treat basis.

Table 11: *Comprehensive Interventions (Cont'd)*

Author (year), country of origin, design	Participants, interventions, sample size	Key long term results
Wing et al[113] USA RCT, 10 week intervention, 1 year follow-up.	Adults, 20-65 years, 20% overweight (mean baseline weight around 92kg). ILC regime consisting of 5 days/week prescribed calorie intake (weight x 12 - 1000), 2 days/week self control to less than 750 calories (n=25). SBT regime involved continuous prescribed calorie goal (n=23). Participants in both conditions attended weekly meetings for 10 weeks, and were then assigned to either spaced or massed booster sessions. Spaced groups meet at monthly intervals for 6 months. Massed groups met once at beginning and once at the end of the 6 months, and the other 4 meetings were in the 3rd month Gp1. ILC plus massed booster sessions. Gp2. ILC plus spaced booster sessions. Gp3. SBT plus massed booster sessions. Gp4. SBT plus spaced booster sessions. Comparability of groups at baseline is unclear.	**Mean (±sem) weight change post treatment (10 weeks);** Gp1. -8.83±1.45kg Gp2. -7.89±1.13kg Gp3. -7.32±0.98kg Gp4. -8.55±1.74kg **Mean (±sem) weight change at 1 year follow-up;** Gp1. -3.37±2.57kg Gp2. -2.01±2.01kg Gp3. -1.67±1.10kg Gp4. -4.74±2.35kg Patients regained substantial amounts of weight over the year after the initial treatment (5.31±0.85kg). There was no significant difference between the patients in the massed or spaced booster sessions. **Attrition;** Gp1/Gp2 combined 8%. Gp3/Gp4 combined: 9%. Drop-outs were assumed to have lost no weight and were included on an intention to treat basis.
Cousins et al[114] USA RCT, 1 year intervention	Mexican American women, 18-45 years, 20-100% overweight (mean baseline weight around 76kg). All groups given printed material on nutrition, exercise and behavioural principles for weight loss. Calories limited to 1200/day. Gp1. Control (manual only). Gp2. Patient alone attended 24 weekly classes plus 6 monthly maintenance classes. Gp3. Classes as above modified to include partner or family support. 168 subjects recruited, proportions in each group not stated Groups were comparable at baseline for height, weight and BMI.	**Mean (±sd) baseline weight;** Gp1. 77±11.1kg Gp2. 78.1±13.8kg Gp3. 74.2±12.8kg **Mean (±sd) weight at 12 months;** Gp1. 76.3±12.2kg Gp2. 76±14.3kg Gp3. 70.4±14.6kg **Attrition;** Overall rate was 49% Drop-outs excluded from analysis.

Table 11: ***Comprehensive Interventions (Cont'd)***

Author (year), country of origin, design	Participants, interventions, sample size	Key long term results
Murphy et al[115] USA RCT, 10 week intervention, 2 year follow-up.	Adults, 20-80% overweight, with spouse willing to attend all treatment sessions (mean baseline weight around 86kg). Subjects had 11 sessions spread over 10 weeks. Contracts were written so that specific behaviours relating to diet and exercise would be either rewarded or punished as appropriate (rewards/punishments selected by subjects). Gp1. Alone 1. Programme manual given. Subjects attended and drew up treatment contracts alone (n=13). Gp2. Alone 2. As above except contingency contract signed by both partners (n=13). Gp3. Couple 1. Subject and spouse attended sessions. One party contingency contracts. Manual identical to that of Gp1 (n=13). Gp4. Couple-2. As for Gp3 but two party contingency contracts (n=12). Gp5. Supportive. Subjects attended without spouse. No manual or contracts (n=11). Gp6. Waiting list group (n=13). Groups were comparable at baseline for age, weight, and percentage overweight.	**Mean (±sd) weight change at end of 10 week intervention;** Gp1. -7.08±4.76kg Gp2. -6.85±3.54kg Gp3. -8.16±1.45kg Gp4. -7.62±3.76kg Gp5. -7.48±4.22kg Gp6. -0.36±2.90kg Gps 1-5 lost significantly more weight compared to Gp6 ($p<0.0002$). **Mean (±sd) weight change at 2 year follow-up** Gp1. -2.59±4.54kg Gp2. +2.54±8.71kg Gp3. -3.36±4.35kg Gp4. -7.21±3.45kg Gp5. -2.86±5.13kg Gp4 achieved significantly superior weight loss compared to Gp2 ($p<0.05$). **Attrition;** Gp1. 46% Gp2. 46% Gp3. 62% Gp4. 33% Gp5. 46% Drop-outs excluded from analysis.

Table 11: ***Comprehensive Interventions (Cont'd)***

Author (year), country of origin, design	Participants, interventions, sample size	Key long term results
Stevens et al[116] USA RCT, 18 month programme consisting of 14 week intervention and the remaining time as maintenance.	Adults, 30 to 54 years, 15%-65% overweight, with high to normal diastolic blood pressure (mean baseline weight around 90kg). Gp1. Intervention consisted of 14 weekly group meetings followed by monthly maintenance sessions. Participants were trained in behavioural self-management techniques and were asked to make life-style changes aimed at achieving a moderate reduction in energy intake and an increase in physical activity (n=308). Gp2. Control - no intervention (n=256). There were no significant differences in baseline characteristics, except that the intervention group had a slightly larger proportion of men. NB: The main outcome measure was blood pressure, not weight.	At the end of the 18 months, 45% of the men and 26% of women in the intervention group had met their weight loss goal of 4.5kg, compared with 12% and 18% of the control men and women respectively. The mean weight of the control men did not change, and the mean weight of the control women increased 0.2kg after 18 months. The difference in weight loss between the intervention and control groups (mean±SE) at 18 months was 3.9±0.4kg overall, 4.7±0.5kg for men, and 1.8±0.8kg for women. Weight loss in the intervention group was significantly greater than in the control group ($p<0.001$) at each time point, and the difference in weight loss effect between men and women was also significant ($p<0.01$ at each follow-up observation) **Attrition;** Overall rate was 7%. Unclear if drop-outs included in analysis.
TOHP[117] USA RCT, multicentre 2x2 factorial design. Minimum of 36 months follow-up.	Healthy, moderaltely overweight (average weight around 93.6kg), 30-40 year old men and women with a high-normal diastolic BP. Gp1. Weight loss alone (involving group therapy, moitoring of calorie intake and increased physical activity.(n=595). Gp2. Sodium restriction alone (n=594). Gp3. Weight loss plus sodium restriction (n=597). Gp4. No active intervention (n=596). Groups were comparable at baseline for weight and baseline sodium excretion.	**Mean change in weight at 36 months;** Gp1. -0.2±5.9kg Gp2. 1.7±5.2kg Gp3. -0.3±5.5kg Gp4. 1.8±5.3kg The main effect for weight loss at 36months was -2.0±0.2kg ($p<0.001$). **Attrition;** Gp1. 3.2% Gp2. 2.2% Gp3. 3% Gp4. 3.4%

APPENDIX 1: SEARCH TERMS

OBESITY

obese
obesity/refractory obesity
chronic obesity
overweight/"fat"
inappropriate weight gain
body composition
body weight
adiposity/adipose tissue
obesity in childhood
morbid obesity
weight maintenance
weight change
weight gain
central obesity
hyperphagia
fat cell hyperplasia
metabolic syndrome
energy metabolism
binge eating disorder

RISK OF DEVELOPING OBESITY

risk factor
marker
predictive factor
predictor
caloric intake
physical inactivity
family history
genetic factors
environmental factors
metabolic factors
smoking cessation
parity
pregnancy
social class
risk/critical periods
early adiposity rebound
overweight
diabetes
alcohol
weight cycling

ethnicity/south Asians and Polynesians
insulin resistance
breast v bottle feeding
age
education
hormones
depression/low self esteem

INTERVENTIONS

group interventions
individual interventions
medical supervision
unsupervised
family therapy
behaviour therapy/modification
cognitive therapy
drugs
pharmacological interventions

- anoretic drugs
- noradrenergic drugs
- serotonergic drugs
- thermogenic drugs
- bulking agents

Specific agents

- Dexfenfluramine
- Fenfluramine
- d-Fenfluramine
- Fluoxitine
- Phenylpropanolamine
- Diethylpropion
- Mazindol
- Phentermine

weight reducing diet
dietary composition
low fat diet/high fibre
diet/very low calorie diet
food deprivation
dietary modification
commercial slimming organisations
weight watchers
correspondence programmes
exercise
physical activity
fasting
surgery:

- jaw wiring
- dental splinting
- gastroplasty
- gastric bypass
- intestinal bypass
- intra gastric balloon
- stapling
- vertical banding

primary prevention
secondary prevention
community intervention
health promotion
health education
health protection
population intervention
food policy
school programmes
work site programmes
liposuction
complementary/alternative medicine
acupuncture
hypnotherapy
homeopathy
advertising
randomised controlled trial
hypnotism
maintenance

OUTCOME

weight
weight loss
weight reduction
body mass index (BMI)
ponderal index
skin fold thickness
weight control
weight maintenance
fat free mass
waist-hip ratio
fat loss
waist size
abdomen hip ratio

APPENDIX 2: SEARCH STRATEGY FOR EVALUATIONS OF OBESITY INTERVENTIONS MEDLINE

001	randomized controlled trial.pt.	21602
002	randomized controlled trials/	3454
003	random allocation/	22300
004	double-blind method/	17048
005	single-blind method/	362
006	clinical trial.pt.	46291
007	exp clinical trials/	34544
008	(clinical$ adj5 trial$).tw.	11341
009	((singl$ or doubl$ or trebl$ or tripl$) adj5 (blind$ or mask	16276
010	placebos/	2208
011	(placebo$ or random$).tw.	54040
012	research design/	5960
013	comparative study/	239093
014	exp evaluation studies/	77884
015	follow-up studies/	50481
016	prospective studies/	25520
017	(animal not (human and animal)).ti,ab,sh.	542960
018	*obesity/	4960
019	*obesity, morbid/	401
020	*pickwickian syndrome/	33
021	*prader-willi syndrome/	187
022	*weight gain/	288
023	obesity.ti.	2672
024	obese.ti.	2026
025	overweight.ti.	194
026	hyperphagia/	636
027	*bulimia/	744
028	or/18-27	7716
029	or/1-16	388188
030	29 and 28	1650
031	30 not 17	1429
032	exp behavior therapy/	5766
033	(behavior adj (therapy or modification)).tw.	425
034	exp appetite depressants/	3808
035	(appetite adj (suppressant? or depressant?)).tw.	39
036	diet, fat-restricted/	0
037	diet, reducing/	1313
038	(dieting or (low adj calorie) or diet?).tw.	27902

039	food deprivation/	1071
040	(food adj3 (deprivation or depriving)).tw.	523
041	exercise/	3042
042	exercise therapy/	1987
043	exertion/	11679
044	(exercise or (physical adj therapy) or fitness).tw.	22243
045	fasting/	3397
046	fasting.tw.	6957
047	(jaw adj3 (wiring or wired)).tw.	14
048	surgical staplers/	978
049	surgical stapling/	0
050	(stomach adj2 (stapling or banding or bypass)).ti,ab,sh.	23
051	gastric bypass/	62
052	(gastric adj bypass).tw.	182
053	health promotion/	3695
054	health education/	6862
055	(prevent or prevention or preventing).tw.	50965
056	nutrition policy/	0
057	(food adj policy).tw.	18
058	food habits/ and health policy/	11
059	(program or programs or programme$ or intervention$).tw.	58155
060	lipectomy/	253
061	liposuction.tw.	221
062	(guar adj gum).ti,ab,sh.	172
063	exp alternative medicine/	11402
064	(acupuncture or hypnotism).tw.	1336
065	advertising/	1157
066	((diet or dieting or slimming) adj club?).tw.	1
067	weightwatcher?.tw.	1
068	or/32-67	186886
069	31 and 68	652
070	69	652

APPENDIX 3: DATABASES SEARCHED

Medline
EMBASE
DHSS-Data
Current Research in UK
BIDS information service which offers
- Science citation index
- Social Science citation index
- Conference Proceedings index

SIGLE (Grey lit db)
Dissertation Abstracts
Sport
DRUG INFO
DRUG database
Psychlit
AMED (Allied and alternative medicine)
ASSI (abstracts and indexes)
CAB (Commonwealth agricultural board)
H PA
NTIS (National technical information dB)
Directory of Published Proceedings (Interdok)
Purchasing Innovations Database
Health promotion database S.S.R.U.
DARE (CRD - data base of systematic reviews)
NEED (CRD - data base of health economic reviews)

APPENDIX 4: SEARCH DETAILS FOR PAPERS ON ALTERNATIVE THERAPIES

D-S/AMED/ALLIED & ALTERNATIVE MEDICINE'85 - SESSION 543

COPYRIGHT BY Medical Information Service, British Library

The RE-SEARCH facility is not available in this database

D-S SEARCH MODE - ENTER SEARCH TERMS

AMED 1_:obese or obesity or overweight or adipos$3 or overeating or overnutrition

SEARCH TERM 'OVEREATING' NOT IN THIS DATABASE

RESULT 238

AMED 2_:(eating or appetite or metabolic) with disorder $1

RESULT 71

AMED 3_: binge with eating

RESULT 1

AMED 4_:feeding with (behavior or behaviour)

RESULT 39

AMED 5_: metabolic with syndrome

RESULT 2

AMED 6_: weight with (gain or maintenance)

RESULT 15

AMED 7_:body with weight

RESULT 195

AMED 8_:(increased or excessive) with weight

RESULT 5

AMED 9_:hyperphagia

SEARCH TERM 'HYPERPHAGIA' NOT IN THIS DATABASE

RESULT 0

AMED 10_:body adj fat

RESULT 25

AMED 11_:eating adj habit$1

RESULT 2

AMED 12_:body with composition

RESULT 95

AMED 13_:appetite

RESULT 15

AMED 14_:1 or 2 or 3 or 4 or 5 or 6 or 7 or 8

RESULT 517

AMED 15_:9 or 10 or 11 or 12 or 13

RESULT 126

AMED 16_:14 or 15

RESULT 599

AMED 17_:anorexia or bulimia

RESULT 85

AMED 18_:16 not 17

RESULT 576

AMED 19_:(blind or crossover) with procedure$1

RESULT 0

AMED 20_:(comparative or clinical or intervention or multicentre or evaluation or prospective) with (trial$1 or stud$3)

RESULT 2334

AMED 21_:follow adj up

RESULT 424

AMED 22_:meta adj analysis

RESULT 44

AMED 23_:metaanalysis

SEARCH TERM 'METAANALYSIS' NOT IN THIS DATABASE

RESULT 0

AMED 24_:random or placebo$

RESULT 702

AMED 25_:control $3with (trial$1 or stud$3 or group$1)

RESULT 593

AMED 26_:(singl$ or doubl$ or trebl$ or tripl$) with (blind$ or mask$)

SEARCH TERM 'TREBL$' NOT IN THIS DATABASE

RESULT 244

AMED 27_:19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27

RESULT 3446

AMED 28_:18 and 28

RESULT 53

AMED 29_: ..save

APPENDIX 5: DATA EXTRACTION SHEET TREATMENT AND PREVENTION OF OBESITY

<<Author>>

<<Article Title>>

<<Source e.g. Journal, conference proceeding, etc.>>

Year

Vol

Chapter

Pages

Language if not English

<<Stated aim of the study>>

<<Type of intervention (pharmacological, surgical, alternative...)>>

<<Description of intervention package >>

<<Setting e.g. Hospital clinic or work place>>

<<Duration of intervention (weeks)>>

<<Design of study>>

<< Method of randomisation>>

<<Units of randomisation (e.g. individuals, practices etc etc)>>

<<Study population - population to which the study should generalise>>

<<Sampling method >>

<<Entry and exclusion criteria >>

<<Characteristics of participants; >>

<<Age (average)>>

<<Ethnicity>>

<<Class>>

<<Average weight>>

<<Other information>>

<<On what were the intervention and control groups comparable? >>

<<Is the sample representative of the study population?>>

<<Size of intervention group>>

<<Size of control group>>

<<Was an *a priori* estimate made for the sample size?>>

<<If yes what was the anticipated power of the study>>

<<What was measured as baseline?>>

<<What was measured after the intervention?>>

<<Who carried out the measurement?>>

<<How was the measurement done? (e.g. what instrument)>>

<<How was the measurement validated?>>

<<What was the duration of follow -up>>

<<Statistical techniques used>>

<<Did they adjust for confounding?>>

<<How did they deal with attrition?>>

<<Was analysis carried out on intention to treat?>>

<<Quantitative results; estimate of effect size (include CIs and P values)>>

<<Qualitative results>>

<<What was the drop out rate from the study?>>

<<Estimate of cost effectiveness *(NB if present in the study set paper aside for separate analysis)*>>

<<Effectiveness of intervention (author's conclusions)>>

<<Reviewers commentary>>

REVIEWER'S DECISION

36. Is this paper to be included Yes No

Reasons for rejection

ADDENDUM

Since this review was completed the centrally acting appetite suppressants fenfluramine and dexfenfluramine have been withdrawn from use in the UK and the USA in the light of new evidence on possible significant side-effects associated with the use of these drugs.

In addition to an increased risk of primary pulmonary hypertension linked with the use of fenfluramine and its derivatives (Abenhaim et al 1996), a recent series of 24 case reports on women suggests that there may also be an association between valvular heart disease and the use of the combination therapy fenfluramine-phentermine, as used in the USA (Connolly, 1997). The Food and Drug Administration (FDA) has received additional reports of heart valve disease, mainly associated with the use of fenfluramine and phentermine in combination, but there have also been reports of cases where fenfluramine or dexfenfluramine have been used as single agents.

It is anticipated that further research will be carried out to explore possible associations more clearly.

The Medicine Control Agency has requested that doctors and hospital pharmacists report any suspected cases to the Committee on Safety of Medicines.

References:

Abenhaim L, Moride Y, Brenot F et al. Appetite-suppressant drugs and the risk of primary pulmonary hypertension. *New Engl J Med.* 1996; 335: 609-16.

Connolly H, Crary J, McGoon M et al. Valvular heart disease associated with fenfluramine-phentermine. *New Engl J Med.* 1997; 337: 581-8.

REFERENCES

1 The Nutrition and Physical Activity Task Forces. Obesity: Reversing the increasing problem of obesity in England. Department of Health, 1995.

2 Colhoun H, Prescott-Clarke P, eds. *Health Survey for England, 1994. A survey carried out on behalf of the Department of Health.* . Vol. 1:. 1996, HMSO.

3 Knight I. *The heights and weights of adults in Great Britain*: HMSO 1994.

4 Prentice AM, Jebb SA. Obesity in Britain: gluttony or sloth? *British Medical Journal* 1995;311:437-438.

5 Guillaume M, Lapidus L, Beckers F, Lambert A, Bjorntorp P. Familial trends of obesity through three generations: the Belgian-Luxembourg child study. *Int J Obes Relat Metab Disord* 1995;19:55-59.

6 Grio R, Porpiglia M. Obesity: internal medicine, obstetric and gynecological problems related to overweight. *Panminerva Med* 1994;36:138-141.

7 Kahn HS, Williamson DF, Stevens JA. Race and weight change in US women: the role of socioeconomic and marital status. *Am J Public Health* 1991;81:319-23.

8 NHS CRD Report Number 5. Ethnicity and health; reviews of literature and guidance for purchasers in the areas of CVD, mental health, and haemoglobinopathy. University of York, 1996.

9 Eisen SA, Lyons MJ, Goldberg J, True WR. The impact of cigarette and alcohol consumption on weight and obesity. An analysis of 1911 monozygotic male twin pairs. *Arch Intern Med* 1993;153:2457-2463.

10 Flegal KM, Troiano RP, Pamuk ER, Kuczmarski RJ, Campbell SM. The influence of smoking cessation on the prevalence of overweight in the United States. *N Engl J Med* 1995;333:1165-1170.

11 Health Education Authority. *Obesity in primary health care. A literature review* London: HEA 1995.

12 Deegan PC, McNicholas WT. Pathophysiology of obstructive sleep apnoea. *Eur Repir J* 1995;8:1161-1178.

13 Grunstein RR, Wilcox I. Sleep-disordered breathing and obesity. 1994;8:601-628.

14 Richman RM, Elliott LM, Burns CM, Bearpark HM, Steinbeck KS, Caterson ID. The prevalence of obstructive sleep apnoea in an obese female population. *Int J Obes Relat Metab Disord* 1994;18:173-177.

15 Rossner S, Lagerstrand L, Persson HE, Sachs C. The sleep apnoea syndrome in obesity: risk of sudden death. *J Inter Med* 1991;230:135-141.

16 Lee I, Paffenbarger RS. Change in body weight and longevity. *JAMA* 1992;268:2045-2049.

17 Hamm P, Shekell RB, Stamler J. Larger fluctuations in body weight during young adulthood and twenty-five-year risk of coronary death in men. *Am J Epidemiol* 1989;129:312-8.

18 Lissner L, Odell PM, D'Agostino RB, Stokes J, Kreger B, Belanger A, Brownell K. Variability of body weight and health outcomes in the Framingham population. *N Engl J Med* 1991;324:1839-1844.

19 Blair SN, Shaten J, Brownell K, Collins G, Lissner L. Body weight change, all-cause mortality, and cause-specific mortality in the Multiple Risk Factor Intervention Trial. *Ann Intern Med* 1991;119:749-757.

20 Jeffery RW. Does weight cycling present a health risk? *American Journal of Clinical Nutrition* 1996;63(suppl):452S-5S.

21 Flodmark CE, Ohlsson T, Ryden O, Sveger T. Prevention of progression to severe obesity in a group of obese schoolchildren treated with family therapy. *Pediatrics* 1993;91:880 -884.

22 Epstein LH, Valoski A, Wing RR, McCurley J. Ten year outcomes of behavioural family based treatment for childhood obesity. *Health Psychol* 1994;13:373-383.

23 Epstein LH, McKenzie SJ, Valoski A, Klein KR, Wing RR. Effects of mastery criteria and contingent reinforcement for family-based child weight control. *Addict Behav* 1994;19:135-145.

24 Epstein LH, Wing RR, Koeske R. Effects of diet plus exercise on weight change in parents and children. *J Consult Clin Psychol* 1984;52:429-437.

25 Brownell KD, Kelman JH, Stunkard AJ. Treatment of obese children with and without their mothers: changes in weight and blood pressure. *Pediatrics* 1983;71:515-523.

26 Epstein LH, Wing RR, Woodall K, Penner BC, Kress MJ, Koeske R. Effects of family based behavioural treatment on obese 5 to 8 year old children. *Behaviour Therapy* 1985;16:205-212.

27 Israel AC, Guile CA, Baker JE, Silverman WK. An evaluation of enhanced self-regulation training in the treatment of childhood obesity. *J Pediatr Psychol* 1994;19:737-749.

28 Epstein LH, Wing RR, Penner BC, Kress MJ. Effect of diet and controlled exercise on weight loss in obese children. *J Pediatr* 1985;107:358-361.

29 DeWolfe JA, Jack E. Weight control in adolescent girls: a comparison of the effectiveness of three approaches to follow-up. *J Sch Health* 1984;54:347-349.

30 Figueroa-Colon R, von Almen TK, Franklin FA, Schuftan C, Suskind RM. Comparison of two hypocaloric diets in obese children. *American Journal of Diseases of Children* 1993;147:160-166.

31 Epstein LH, Valoski AM, Vara LS, McCurley J, Wisniewski L, Kalarchian MA, Klein KR, Shrager LR. Effects of decreasing sedentary behaviour and increasing activity on weight change in obese children. *Health Psychol* 1995;14:109-115.

32 Mellin LM, Slinkard LA, Irwin CE. Adolescent obesity intervention: validation of the SHAPEDOWN program. *J Am Diet Assoc* 1987;87:333-338.

33 Taylor CB, Fortmann SP, Flora J, Kayman S, Barrett DC, Jatulis D, Farqhar JW. Effect of long term community health education on body mass index: the Stanford Five City Project. *Am J Epidemiol* 1991;134:235-249.

34 Forster JL, Jeffery RW, Schmid TL, Kramer FM. Preventing weight gain in adults: a pound of prevention. *Health Psychol* 1988;7:515-525.

35 Jeffery RW, Gray CW, French SA, Hellerstedt WL, Murray D, Luepker RV, Blackburn H. Evaluation of weight reduction in a community intervention for cardiovascular disease risk: changes in body mass index in the Minnesota Heart Health Program. *Int J Obes Relat Metab Disord* 1995;19:30-39.

36 Black DR, Lantz CE. Spouse involvement and a possible long term follow-up trap in weight loss. *Behav Res Ther* 1984;22:557-562.

37 Dubbert PM, Wilson GT. Goal setting and spouse involvement in the treatment of obesity. *Behav Res Ther* 1984;22:227-242.

38 Rosenthal B, Allen GJ, Winter C. Husband involvement in the behavioural treatment of overweight women: initial effects and long term follow-up. *Int J Obes* 1980;165-173.

39 Pearce JW, LeBow MD, Orchard J. Role of spouse involvement in the behavioural treatment of overweight women. *J Consult Clin Psychol* 1981;49:236-244.

40 Schwartz SH, Inbar-Saban N. Value self-confrontation as a method to aid in weight loss. *J Pers Soc Psychol* 1988;54:396-404.

41 Bennet GA. Cognitive rehearsal in the treatment of obesity: a comparison against cue avoidance and social pressure. *Addict Behav* 1986;11:225-237.

42 Bennet GA. An evaluation of self-instructional training in the treatment of obesity. *Addict Behav* 1986;11:125-134.

43 Jones SE, Owens HM, Bennett GA. Does behaviour therapy work for dietitians? An experimental evaluation of the effects of three procedures in a weight reduction clinic. *Human Nutrition* 1986;40:272-281.

44 Perri MG, Nezu AM, Patti ET, McCann KL. Effect of length of treatment on weight loss. *J Consult Clin Psychol* 1989;57:450-452.

45 Meyers AW, Graves TJ, Whelan JP, Barclay DR. An evaluation of a television-delivered behavioural weight loss program: are the ratings acceptable. *J Consult Clin Psychol* 1996;64:172-178.

46 Jeffery RW, Gerber WM, Rosenthal BS, Lindquist RA. Monetary contracts in weight control: Effectiveness of group and individual contracts of varying size. *J Consult Clin Psychol* 1983;51:242-248.

47 Cameron R, MacDonald MA, Schlegal RP, Young CI, Fisher SE, Killen JD, Rogers T, Horlick L, Shepel L. Towards the development of self help behaviour change programs: weight loss by correspondence. *Can J Public Health* 1990;81:275-279.

48 Fujimoto K, Sakata T, Etou H, Fukagawa K, Ookuma K, Terada K, Kurata K. Charting of daily weight pattern reinforces maintenance of weight reduction in moderately obese patients. *Am J Med Sci* 1992;303:145-150.

49 Wing R, Epstein LH, Nowalk P, Koeske R, Hagg S. Behaviour change, weight loss improvements in type II diabetics. *J Consult Clin Psychol* 1985;53:111-122.

50 Pascale R, Wing RR, Butler B, Mullen M, Bononi P. Effects of a behavioural weight loss program stressing calorie restriction versus calorie plus fat restriction in obese in individuals with NIDDM or a family history of diabetes. *Diabetes Care* 1995;18:1241-1248.

51 Wing R, Blair E, Marcus M, Epstein L, Harvey J. Year-long weight loss treatment for obese patients with type II diabetes: does including an intermittent very-low-calorie diet improve outcome? *The American Journal of Medicine* 1994;97:354-362.

52 Wing RR, Marcus MD, Epstein LH, Jawad A. A 'family-based' approach to the treatment of obese type II diabetic patients. *J Consult Clin Psychol* 1991;59:156-162.

53 Anderson JW, Brinkman-Kaplan V, Hamilton CC, Logan JE, Collins RW, Gustafson NJ. Food-containing hypocaloric diets are as effective as liquid-supplement diets for obese individuals with NIDDM. *Diabetes Care* 1994;17:602-604.

54 Wadden TA, Stunkard AJ. Controlled trial of very low calorie diet, behaviour therapy, and their combination in the treatment of obesity. *J Consult Clin Psychol* 1986;54:482-488.

55 Wadden TA, Sternberg JA, Letizia KA, Stunkard AJ, Foster GD. Treatment of obesity by very low calorie diet, behaviour therapy and their combination: a five year perspective. *Int J Obes* 1989;13:39-46.

56 Schlundt DG, Hill JO, Pope-Cordle J, Arnold D, Virts KL, Katahn M. Randomised evaluation of a low fat ad libitum carbohydrate diet for weight reduction. *Int J Obes Relat Metab Disord* 1993;17:623-629.

57 Jeffery RW, Hellerstedt WL, French SA, Baxter JE. A randomised trial of counselling for fat restriction vs calorie restriction in the treatment of obesity. *Int J Obes Relat Metab Disord* 1995;19:132-137.

58 Jeffery RW, Wing RR, Thorson C, Burton LR, Raether C, Harvey J. Strengthening behavioural interventions for weight loss: a randomized trial of food provision and monetary incentives. *J Consult Clin Psychol* 1993;61:1038-1045.

59 Jeffery RW, Wing RR. Long-term effects of interventions for weight loss using food provision and monetary incentives. *J Consult Clin Psychol* 1995;63:793-796.

60 Wing R, Jeffery R, Burton L, Thorson C, Sperber Nissinoff K, Baxter J. Food provision vs structured meal plans in the behavioural treatment of obesity. *Int J Obes Relat Metab Disord* 1996;20:56-62.

61 Hakala P. Weight reduction programs at a rehabilitation centre and a health centre based on group counselling and individual support: short and long term follow-up study. *Int J Obes Relat Metab Disord* 1994;18:483-489.

62 Wing R, Epstein LH, Paternostro-Bayles M, Kriska A, Nowalk MP, Gooding W. Exercise in a behavioural weight control program for obese patients with type 2 (non-insulin dependent) diabetes. *Diabetologica* 1988;31:902-909.

63 Pavlou KN, Krey S, Steffee WP. Exercise as an adjunct to weight loss and maintenance in moderately obese subjects. *Am J Clin Nutr* 1989;49:1115-1123.

64 Bertram SR, Venter I, Stewart RI. Weight loss in obese women - exercise versus dietary education. *S Afr Med J* 1990;78:15-18.

65 Johnson WG, Stalonas PM, Christ MA, Pock SR. The development and evaluation of a behavioural weight reduction program. *Int J Obes* 1979;3:229-238.

66 Baron JA, Schori A, Crow B, Carter R, Mann JI. A randomised controlled trial of low carbohydrate and low fat/high fibre diets for weight loss. *Am J Public Health* 1986;76:1293-1296.

67 Rytigg KR, Tellnes G, Haegh L, Boe E, Fagerthun H. A dietary fibre supplement and weight maintenance after weight reduction: a randomized, double blind placebo controlled long term trial. *Int J Obes* 1989;13:165-171.

68 Skender ML, Goodrick K, Del Junco DJ, Reeves RS, Darnell L, Gotto AM, Foreyt JP. Comparison of 2-year weight loss trends in behavioural treatments of obesity: diet, exercise, and combination interventions. *J Am Diet Assoc* 1996;96:342-346.

69 Guy-Grand B, Apfelbaum M, Crepaldi G, Gries A, Lefebvre P, Turner P. International trial of long-term dexfenfluramine in obesity. *Lancet* 1989;2:1142-1145.

70 Pfohl M, Luft D, Blomberg I, Schmulling RM. Long-term changes of body weight and cardiovascular risk factors after weight reduction with group therapy and dexfenfluramine. *Int J Obes Relat Metab Disord* 1994;18:391-395.

71 Mathus-Vliegen EMH, Van de Voorde K, Kok AME, Res AMA. Dexfenfluramine in the treatment of severe obesity: a placebo-controlled investigation of the effects on weight loss, cardiovascular risk factors, food intake and eating behaviour. *J Inter Med* 1992;232:119-127.

72 O'Connor HT, Richman RM, Steinbeck KS, Caterson ID. Dexfenfluramine treatment of obesity: a double blind trial with post trial follow-up. *Int J Obes Relat Metab Disord* 1995;19:181-189.

73 Mathus-Vliegen EMH. Prolonged surveillance of dexfenfluramine in severe obesity. *Neth J Med* 1993;43:246-253.

74 Manning RM, Jung RT, Leese GP, Newton RW. The comparison of four weight reduction strategies aimed at overweight diabetic patients. *Diabet Med* 1995;12:409-415.

75 Öst LG, Götestam KG. Behavioral and pharmacological treatments for obesity: an experimental comparison. *Addict Behav* 1976;1:331-338.

76 Weintraub M, Sundaresan PR, Madan M, Schuster B, Balder A, Lasagna L, Cox C. Long term weight control study. *Clinical Pharmacological Therapy* 1992;51:581-646.

77 Goldstein DJ, Rampey AHJ, Enas GG, Potvin JH, Fludzinski LA, Levine LR. Fluoxetine: a randomized clinical trial in the treatment of obesity. *Int J Obes Relat Metab Disord* 1994;18:129-135.

78 O'Kane M, Wiles P, Wales J. Fluoxetine in the treatment of obese type II diabetic patients. *Diabet Med* 1994;11:105-110.

79 Bitsch M, Skrumsager BK. Femoxitine in the treatment of obese patients in general practice. A randomized group comparative study with placebo. *Int J Obes* 1987;11:183-190.

80 Vernace BJ. Controlled comparative investigation of mazindol, D-amphetamine, and placebo. *Obesity/Bariatric Medicine* 1974;3:124-129.

81 Jones S, Smith I, Kelly F, Gray J. Long term weight loss with sibutramine. *Int J Obes Relat Metab Disord* 1995;19:41.

82 Sugerman HJ, Starkey JV, Birkenhauer R. A randomised prospective trial of gastric bypass versus vertical banded gastroplasty for morbid obesity and their effects on sweets versus non-sweet eaters. *Ann Surg* 1987;205:613-24.

83 MacLean LD, Rhode BM, Sampalis J, Forse RA. Results of the surgical treatment of obesity. *Am J Surg* 1993;165:155-160.

84 Hall JC, Watts JM, O'Brien PE, Dunstan RE, Walsh JF, Slavotinek AH, Elmslie RG. Gastric surgery for morbid obesity. The Adelaide Study. *Ann Surg* 1990;211:419-427.

85 Laws HL, Piantadosi S. Superior gastric reduction procedure for morbid obesity: a prospective, randomized trial. *Ann Surg* 1981;193:334-340.

86 Lechner GW, Callender AK. Subtotal gastric exclusion and gastric partitioning: a randomized prospective comparison of one hundred patients. *Surgery* 1981;90:637-644.

87 Howard L, Malone M, Michalek A, Carter J, Alger S, Van Woert J. Gastric bypass and vertical banded gastroplasty - a prospective randomised comparison and 5-year follow-up. *Obesity Surgery* 1995;5:55-60.

88 Näslund I, Wickbom G, Christoffersson E, Ågren G. A prospective randomized comparison of gastric bypass and gastroplasty. *Acta Chir Scan* 1986;152:681-689.

89 Brolin R, Kenler H, Gorman J, Cody R. Long-limb gastric bypass in the superobese. *Ann Surg* 1992;215:387-395.

90 Andersen T, Backer OG, Astrup A, Quaade F. Horizontal or vertical banded gastroplasty after pretreatment with very-low-calorie formula diet: a randomized trial. *Int J Obes* 1987;11:295-304.

91 Andersen T, Stokholm KH, Backer OG, Quaade F. Long-term (5 year) results after either horizontal gastroplasty or very-low-calorie diet for morbid obesity. *Int J Obes* 1988;12:277-284.

92 Viddal K. Intestinal bypass. A randomized, prospective clinical study of end-to-side and end-to-end jejunoileal bypass. *Scand J Gastroenterol* 1983;18:627-634.

93 Danish Obesity Project. Randomised trial of jejunoileal bypass versus medical treatment in morbid obesity. The Danish Obesity Project. *Lancet* 1979;2:1255-1258.

94 Buckwalter JA. A prospective comparison of the jejunoileal and gastric bypass operations for morbid obesity. *World J Surg* 1977;1:757-768.

95 Griffen W, Young V, Stevenson C. A prospective comparison of gastric and jejunoileal bypass procedures for morbid obesity. *Ann Surg* 1977;186:500-509.

96 Hogan RB, Johnston JH, Long BW, Sones JQ, Hinton LA, Bunge J, Corrigan SA. A double-blind, randomized, sham-controlled trial of the gastric bubble for obesity. *Gastrointestinal Endoscopy* 1989;35:381-385.

97 Ashby W, Wilson TG. Behavior therapy for obesity: booster sessions and long term maintenance of weight loss. *Behav Res Ther* 1977;15:451-463.

98 Hall SM, Bass A, Monroe J. Continued contact and monitoring as follow-up strategies: a long term study of obesity treatment. *Addict Behav* 1978;3:139-147.

99 Baum JG, Clark HB, Sandler J. Preventing relapse in obesity through posttreatment maintenance systems: comparing the relative efficacy of two levels of therapist support. *J Behav Med* 1991;14:287-302.

100 Perri M, McAdoo G, Spevak P, Newlin D. Effect of a multicomponent maintenance program on long-term weight loss. *J Consult Clin Psychol* 1984;52:480-481.

101 Perri MG, McAllister DA, Gange JJ, Jordan RC, McAdoo WG, Nezu AM. Effects of four maintenance programs on the long term management of obesity. *J Consult Clin Psychol* 1988;56:529-534.

102 Kramer FM, Jeffery RW, Snell MK, Forster JL. Maintenance of successful weight loss over 1 year: Effects of financial contacts for weight maintenance or participation in skills training. *Behaviour Therapy* 1986;17:295-301.

103 Rytigg KR, Rossner S. Weight maintenance after (VLCD) weight reduction period and the effects of VLCD supplementation. A prospective, randomized, comparative, controlled long term trial. *J Inter Med* 1995;238:299-306.

104 Agras WS, Berowitz RI, Arnow BA, Telch CF, Marnell M, Henderson J, Morris Y, Wilfley DE. Maintenance following a very-low-calorie diet. *J Consult Clin Psychol* 1996;64:610-613.

105 Tucker J, Samo J, Rand C, Woodward E. Behavioural interventions to promote adaptive eating behaviour and lifestyle changes following surgery for obesity: Results of a two year outcome evaluation. *Int J Eat Disord* 1991;10:689-698.

106 Wadden TA, Bartlett SJ, Foster GD, A GR, Wingate BJ, Stunkard AJ, Letizia KA. Sertraline and relapse prevention training following treatment by very-low-calorie diet: A controlled clinical trial. *Obes Res* 1995;3:549-557.

107 Perri MG, Shapiro RM, Ludwig WW, Twentyman CT, McAdoo WG. Maintenance strategies for the treatment of obesity: an evaluation of relapse prevention training and posttreatment contact by mail and telephone. *J Consult Clin Psychol* 1984;52:404-413.

108 Perri MG, McAdoo WG, McAllister DA, Lauer JB, Jordan RC, Yancey DZ, Nezu AM. Effects of peer support and therapist contact on long term weight loss. *J Consult Clin Psychol* 1987;55:615-617.

109 Hakala P, Karvetti RL, Ronnemaa T. Group v individual weight reduction programmes in the treatment of severe obesity - a five year follow-up study. *Int J Obes Relat Metab Disord* 1993;17:97 -102.

110 King AC, Frey Hewitt B, Dreon DM, Wood PD. Diet vs exercise in weight maintenance: the effects of minimal intervention strategies on long-term outcomes in men. *Arch Intern Med* 1989;149:2741-2746.

111 Wadden TA, Foster GD, Letizia KA. One year behaviour treatment of obesity: comparison of moderate and severe caloric restriction and the effects of weight maintenance therapy. *J Consult Clin Psychol* 1994;62:165-171.

112 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 intake. *BMJ* 1997;314:29-34.

113 Wing R, Epstein LH, Marcus MD, Koeske R. Intermittent low calorie regimen and booster sessions in the treatment of obesity. *Behaviour Research Therapy* 1984;22:445-449.

114 Cousins JH, Rubovits DS, Dunn JK, Reeves RS, Ramirez AG, Foreyt JP. Family versus individually oriented intervention for weight loss in Mexican American women. *Public Health Rep* 1992;107:549-555.

115 Murphy JK, Williamson DA, Buxton AE, Moody SC, Absher N, Warner M. The long term effects of spouse involvement upon weight loss and maintenance. *Behaviour Therapy* 1982;13:681-693.

116 Stevens V, Corrigan S, Obarzanek E. Weight loss intervention in phase one of the trials of hypertension prevention. *Arch Intern Med* 1993;153:849-858.

117 The Trials of Hypertension Prevention PI. Effects of weight loss and sodium reduction intervention on blood pressure and hypertension incidence in overweight people with high-normal blood pressure. *Arch Intern Med* 1997;157:657-667.

118 Rimm DC, Masters JC. *Behaviour therapy. Techniques and empirical findings* New York: Academic Press 1974.

119 Hawton K, Salkovskis PM, Kirk J, Clark DM. *Cognitive behaviour therapy for psychiatric problems. A practical guide* New York: Oxford University Press 1989.

120 Harré R, Lamb R. *The dictionary of physiological and clinical psychology* Oxford: Blackwell 1986.

121 Skender M, Goodrick G, Del Junco D, Reeves R, Darnell L, Gotto A, Foreyt J. Comparison of 2-year weight loss trends in behavioural treatments of obesity: Diet, exercise, and combination interventions. *J Am Diet Assoc* 1996;96:342-346.

122 Payne JH, DeWind LT. Surgical treatment of obesity. *Am J Surg* 1969;118:141-149.

123 Kral JG. Morbid obesity and related health risks. *Ann Intern Med* 1985;103:1043-1047.

124 National Institutes of Health Technology Assessment Conference Statement. Methods for voluntary weight loss and control. *Nutr Rev* 1992;50:340-345.

125 Scottish Intercollegiate Guidelines Network. Obesity in Scotland. Integrating prevention with weight management. Scottish Intercollegiate Guidelines Network, 1996.

126 Sjostrom L, Larsson B, Backman L, Bengtsson C, Bouchard C, Dahlgren S, Hallgren P, Jonsson E, Karlsson J, Lapidus L. Swedish obese subjects (SOS). Recruitment for an intervention study and a selected description of the obese state. *Int J Obes Relat Metab Disord* 1992;16:465-479.

127 Perri MG, Sears SF, Clarke JE. Towards a continuous care model of obesity management. *16* 1993;1:200-209.

128 Silagy C, Lancaster T, Gray S, Fowler G. Effectiveness of training health professionals to provide smoking cessation interventions: systematic review of randomised controlled trials. *Quality in Health Care* 1994;3:193-198.

129 Brownell KD. Get slim with higher taxes. *The New York Times*. 1994: New York. p. A29.

130 Royal College of Physicians. *Overweight and obese patients.* Royal College of Physicians, 1996