Cambridge® Weight Plan

Real people, real support, real results.

The formula for effective weight loss

Safe, effective weight loss and maintenance with sustained health benefits using formula low-calorie and very low-calorie diets

A digest of recent research using Cambridge Weight Plan

By Anthony R. Leeds

What is Cambridge Weight Plan?

Now a flexible series of dietary Steps based on the use of nutritionally complete formula foods, the programme was originally known as the 'Cambridge Diet'. However despite this range and flexibility, Cambridge Weight Plan is still synonymous in the minds of some healthcare professionals with very low-calorie diets (VLCDs).

Developed by Dr Alan Howard as a formula VLCD, this does remain the greater part of its present-day usage. However, about 10 years ago it evolved into a more flexible series of dietary energy intake levels (1500, 1200, 1000, 810, 615, 440kcal/d), allowing titration of energy intake against the client or patient's response.

This is interesting historically, because in the late 19th century a step-wise titration upwards of dietary energy was offered to people with diabetes, following a fast to clear the urine of reducing sugars. Now, this remarkably precise titration process (precise because it includes formula food products rather than non-formula foods alone) can be applied with a step-wise reduction or increase of energy intake according to need.

Very low-calorie diets (VLCDs) give the most effective weight losses, but sometimes a part-formula and part-food diet can achieve remarkable weight loss. Dietary adherence tends to be poorer at the higher energy intake levels and patients tend to be hungrier, but nevertheless energy intake levels above 800kcal/d can give good results.

The gradually accumulating scientific literature on the efficacy of VLCDs indicates that it is highly likely that the potential applications of VLCDs and part-food, part-formula food low-calorie diets (LCDs above 800kcals/d) and total diet replacement (TDR formula diets of 800kcals/d) will be more widely accepted.

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Anthony R Leeds is Medical Director of Cambridge Weight Plan. He practises in NHS clinics at the Central Middlesex and Whittington Hospitals in London, England, and holds visiting posts at the University of Copenhagen, Denmark; the University of Surrey, England; and at Frederiksberg Hospital, Copenhagen, Denmark.

Introduction: The formula for effective weight loss

The requirements for weight loss and maintenance need to be defined in terms of degree of obesity, both in terms of whole body fat and local fat in target organs, age, demographic and health characteristics of the subject group, proven amount of change needed for given health or cosmetic benefit, type and setting of the intervention and an analysis of the costs and benefits.

Formula diet programmes have been under-investigated, underused and undervalued since they were dismissed on flimsy grounds and without adequate evidence by some scientists, especially in the United Kingdom in the 1980s. Elsewhere, especially in Scandinavia, formula diets have been used in practice to a greater degree.

The rising prevalence of obesity and obesity-related diseases and a recognition that morbid (>40) and super obese (BMI>50) patients are increasing in numbers and need more than conventional dietary and lifestyle advice to correct their problems, has prompted innovative surgery and renewed investigations of potential use for formula diets in this group too.

As manufacturers of one of the world's most successful formula food brands, Cambridge Weight Plan has embarked on a significant medical research programme.

The Cambridge Weight Plan medical research programme is based on clearly defined needs and objectives and has been constructed to provide evidence for:

- Effective weight reduction in specific groups (defined by disease state, gender, age) in specific settings (secondary care research clinic, primary care, community programme, etc).
- Effective weight maintenance in specific groups and settings.
- Health benefit by measurement of accepted disease endpoints by accepted methods.
- Sustained health benefit with weight maintenance.
- Nutritional status changes with evidence of maintenance of changes with weight maintenance.
- Change of cardiovascular risk factors with weight loss and maintenance.
- Body composition changes with weight loss and maintenance, especially lean mass loss.
- Retention rates (or drop-out rates).
- Cost of interventions in defined settings.

The research work described here has not been 'commissioned' as such but has taken place following negotiation and facilitation, and has been undertaken with an absolute understanding that data ownership remains with research teams, there must be full transparency with all evidence (all adverse events published) and funding (all interests declared), and results must be published promptly to fully inform the next round of research work.

What is the distinctive mechanism of action of formula diet programmes?

- Formula diet programmes can provide a range of energy intakes from just over 400kcal/d to 1500kcal/d.
- Use of formula products at the lower end of the energy intake scale is the only way to ensure adequacy of intake of micronutrients on a daily basis.
- Lower energy intakes result in a greater decifit between energy requirement and dietary energy intake resulting in greater rates of weight loss.
- Rates of weight loss greater than a half to one kilogramme per week result in rapid improvement in symptoms, such as reduction of pain, decreased shortage of breath, improved mobility, and often reduction of medication use, than after conventional diet programmes.
- Rapid weight loss and symptom improvement is highly motivating and this is likely to improve compliance.
- The physiological ketosis developed at lower energy intake levels may facilitate compliance through suppression of appetite and enhancement of euphoria.

Summary of effects

Weight loss rates of 1 to 2kg per week can be achieved. This can give a 15kg weight loss, which is associated with a symptomatic response in osteoarthritis, sleep apnoea, psoriasis and diabetes, in 8 to 12 weeks.

Weight loss can be maintained in compliant individuals and maintenance of more than 10kg or more than 10% of initial body weight is possible, following a VLCD or low calorie liquid diet, by using partial replacement of conventional food with formula food, by following a high protein diet or by use of drug therapies.

Health benefits following weight loss in osteoarthritis, sleep apnoea and psoriasis have been demonstrated and maintenance of these benefits has been demonstrated in some cases.

Cardiovascular risk factor profiles are improved and some aspects of these can be maintained with weight maintenance.

Lean mass loss associated with weight loss has been shown to be lower than expected in obese people with osteoarthritis.

There is some evidence for improved vitamin D status and bone health in the elderly obese with osteoarthritis.

Drop out rates in clinical trials have been shown to be lower than expected.

Osteoarthritis in obese people

Obesity and osteoarthritis both reduce mobility. Obesity is a risk factor for osteoarthritis. Osteoarthritis causes people who are overweight and obese to exercise less and possibly eat more than is appropriate for their low activity levels.

Women with osteoarthritis have slightly reduced lean mass relative to their body weight. Thus, losing and maintaining weight is difficult for people with osteoarthritis. Many individuals may have complicating factors such as cardiovascular disease, which may mean that bariatric surgery may not be an option even if they are otherwise eligible. Thus a new solution for weight issues in osteoarthritis is needed.

The evidence relating to obesity and osteoarthritis is reviewed in: Bliddal H, Leeds AR, Christensen, R Osteoarthritis and Weight Loss: Hard facts, hypotheses and Horizons: a scoping review. Obesity Reviews 2014; 15(7):578-86. doi: 10.1111/obr.12173. Epub 2014 Apr 22.

Weight loss with formula diet VLCD and LCD in older obese people with knee osteoarthritis

Christensen P, Bliddal H, Riecke B F, Leeds A R, Astrup A, Christensen R. Comparison of a low-energy diet and a very low-energy diet in sedentary obese individuals: a pragmatic randomised controlled trial Clinical Obesity Article first published online: 21 MAR 2011 I DOI: 10.1111/j.1758-8111.2011.00006.x.

Riecke BF, Christensen R, Christensen P, Leeds AR, Boesen M, Lohmander LS, Astrup A, Bliddal H. Comparing two low-energy diets for the treatment of knee osteoarthritis symptoms in obese patients: a pragmatic randomised clinical trial. Osteoarthritis and Cartilage 2010; 10/1016/j.joca.

One hundred and ninety two patients were treated with a VLCD (415 to 540kcal/d) or LCD (810 kcal/d) liquid diet for eight weeks, then a 1200kcal/d diet (which included two formula diet portions) for eight weeks, combined with group education given weekly to groups of eight subjects delivering a total of 17 sessions.

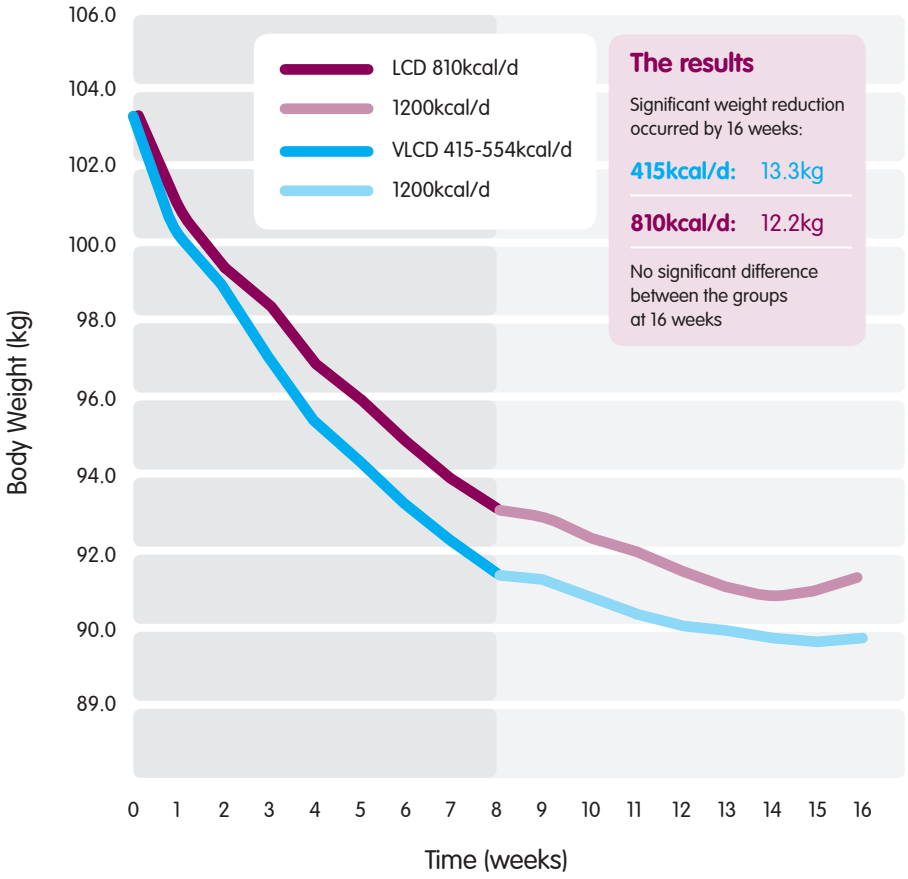

Figure 1. Mean drop in body weight from baseline. Blue/pale blue lines: very low energy diet for eight weeks followed by eight weeks 1200kcal/d diet. Dark red/ pale red lines: low-calorie diet for eight weeks followed by eight weeks 1200kcal/d diet.

More than 12% of initial body weight was lost in both groups with 60% having a good symptom response also in both groups.

Eight out of 96 dropped out of the VLCD group, 6 out of 96 dropped out of the LCD group.

Thus for this group of individuals there appeared to be no advantage in terms of weight loss to using a VLCD over an LCD.

Figure 1. Redrawn from: Christensen P, Bliddal H, Riecke B F, Leeds A R, Astrup A, Christensen R. Comparison of a low-energy diet and a very low-energy diet in sedentary obese individuals: a pragmatic randomised controlLCD trial Clinical Obesity Article first published online: 21 Mar 2011 I DOI: 10.1111/j.1758-8111.2011.00006.x

Weight maintenance with formula diet in older obese people with knee osteoarthritis

Christensen P et al 'Comparison of three different weight maintenance programs on cardiovascular risk, bone and vitamins in sedentary older adults. 2013 Obesity published on-line 20 March 2013 'Accepted article' doi: 10.1002/oby. 20413.

This paper reports the 'secondary' endpoints of the one-year maintenance phase of the Copenhagen trial of weight loss in older obese people with knee osteoarthritis. Patients were re-randomised into one of three groups for a maintenance phase of 52 weeks. The three groups were:

- Diet maintenance (in which one formula product was used in place of one conventional meal each day and dietary messages were reinforced at a monthly meeting with a dietitian).
- Knee exercises (in which patients were trained to do knee exercises by a physiotherapist under direct supervision in hospital and also at home).
- A control group (in which subjects received no further contact, advice or intervention until recalled at 68 weeks).

In both the preparation (weight loss) phase and during maintenance the primary end-points were symptoms and body weight. Variables relating to body composition (fat mass, lean body mass), cardiovascular risk (blood pressure, blood lipids, blood glucose) and nutritional status (vitamin D, bone density, bone mineral, vitamin B12 and blood ferritin) were classified as secondary variables.

The primary overall purpose of the whole trial was to determine whether or not diet maintenance was superior to a knee exercise intervention in maintaining a symptom benefit after weight loss.

The paper published in 'Obesity' shows that there were some very statistically significant differences which demonstrated the advantages of following the dietary maintenance programme.

Dietary maintenance led to greater changes than the knee exercises programme, in the following variables (at 68 weeks, that is after one year of maintenance):

- Body weight (11kg weight loss after diet, 6.3kg weight loss after knee exercises) Significant p=0.0023.
- Waist circumference (down 8.4cm after diet, down 4.6cm after knee exercises) Significant p=0.0073.
- Fat Mass (down 5.1kg after diet, down 2.4kg after knee exercises) Significant p=0.001.
- Vitamin D3 (up 28.5 nmol/L after diet, up 18.7 nmol/L after knee exercises) Significant p=0.035.
- Proportion of participants who were vitamin D3 deficient (down to 8% after diet, down to 24% after knee exercises) Significant p=0.054.
- Parathyroid hormone PTH (down 1.02 pmol/L after diet, down 0.03 pmol/L after knee exercises) Significant p=0.0006.
- Proportion of participants with high PTH (down to 12.5% after diet and down to 28% after exercises) Trend but not significant p=0.09 (thus there was a trend towards dietary maintenance reducing the secondary hyperparathyroidism more than knee exercises).

The effect of weight loss followed by weight maintenance in all groups was associated with:

- A reduction and maintenance of lowered systolic and diastolic blood pressure reduction to a degree that would appreciably reduce cardiovascular risk.
- An improvement in vitamin B12 blood levels (trend towards greater rise in the diet treated group).
- A reduction of bone mineral loss to levels much less than expected according to body weight (and relative to fat mass loss).
- Low lean mass losses of between 9% to 13% of body weight lost (no significant difference between groups).

Four year (1 + 3 years) weight maintenance

Christensen P, Bliddal H, Bartels EM et al. (2014) Long-term intervention with weight loss in patients with concomitant obesity and knee osteoarthritis: the LIGHT study – a randomised clinical trial. T5: S25.54 Obesity Reviews 15 (S2): 152 (2014) doi/10.1111/obr.12151/

- 153 of 175 subjects who had completed the one year weight maintenance randomised controlled trial were then re-randomised either to a regular substitution of one formula product each day or to intermittent use of 5 weeks Low Energy Liquid Diet (LELD) (800kcal/d) three times each year for three years. The average weight loss (from the original baseline weight of 102.5kg) of those 153 subjects at the start of the three year weight maintenance phase was 11.3kg.
- 108 completed the three year maintenance study. Those who used one product per day regained 1.78kg (they had maintained 9.5kg weight loss this being 68% of their original 14kg weight loss), those who used intermittent LELD regained 0.71 kg on average (they had maintained 10.6kg weight loss this being 76% of their original 14kg weight loss. There was no statistically significant difference between the weight changes in the two groups.
- The initial start weight was 102.5kg, so the weight loss maintenance at four years was approximately 9 - 10% of the original weight (9.5/102.5 = 9.3%, and 10.6/102.5 = 10.3%).
- Of the weight lost initially (14kg) between 68% and 76% of that weight loss was maintained in those who completed the programme.

Implication of these results

A good weight loss and maintenance method for obese people with osteoarthritis is one which gives sufficient weight loss to reduce symptoms, especially pain, and improve mobility, while maintaining or improving body composition (losing fat, retaining lean tissue), improving cardiovascular risk and improving or maintaining vitamin D status and bone health status (during and after weight loss bone-remodelling usually results in mineral loss).

Thus the approach to weight loss with formula diet programmes described in this paper has been proven to deliver a package of health benefits rather than simply weight loss and weight maintenance.

Obstructive sleep apnoea in obese people

Sleep apnoea can be due to problems in the part of the brain that controls breathing. In obstructive sleep apnoea (OSA) it is caused by blockage of the airway by collapse, due to extra amounts of fat tissue next to the airway and failure of the muscles to hold the airway open.

Obstructive sleep apnoea is said to be present when the airflow through the mouth and nose stops for more than 10 seconds at least 30 times during a seven-hour sleep. Some surveys suggest that one in four people with diabetes mellitus may have OSA, others that four out of five obese people with diabetes may be affected. There is uncertainty about the rate of OSA in the general population; perhaps one in 25 is affected, perhaps more. Obstructive sleep apnoea can be a factor in causing raised blood pressure. Those who have suffered from but survived a stroke often give a history showing that they had sleep apnoea before they had their stroke. Sleep apnoea is thus a condition which is best avoided.

Does sleep apnoea matter?

OSA causes snoring interrupted by pauses in breathing, choking and gasping during sleep, restless sleep and excessive daytime sleepiness and perhaps falling asleep at work or while driving a motor vehicle. Quality of life may be seriously impaired by general fatigue, poor concentration, irritability, forgetfulness, morning headaches, depression and sexual dysfunction.

What causes sleep apnoea?

Factors linked to OSA include variations in the shape and size of the upper airway, being overweight and obese and having a family history of OSA. Scientific studies have shown that in OSA the airway is narrowed and that there is more fat next to the airway in those who are overweight and obese. The muscles supporting the airway may be less good at holding the airway open, allowing it to collapse and obstruct.

Weight loss in mild obstructive sleep apnoea

A recently published study reports a randomised controlled trial undertaken in Finland by Tuomilehto et al (2009) of a Very Low-Energy Diet with supervised lifestyle modification compared to routine counselling in 72 overweight patients with mild OSA.

At the end of one year, the group treated initially with VLCD (n=35) lost an average 10.7kg body weight, compared to a loss of 2.4kg in the routine counselling group (n=37). The number of apnoea-hypopnoea episodes was reduced significantly in the VLCD group by four, compared to a slight rise in the routine counselling group. Other measures of severity of sleep apnoea were also improved significantly in the VLCD group, compared to the routine counselling group.

A recently published study from the USA has shown that people with diabetes and sleep apnoea who lose more than 10kg with formula diet and who maintain that weight loss for one year, also maintain the improvement in sleep apnoea (Foster et al 2009). What was lacking until December 2009 was good high quality research in the form of a randomised controlled trial of weight loss in people with moderate or severe sleep apnoea.

The Swedish study on moderate and severe obstructive sleep apnoea.

Johansson K, Neovius M, Lagerros YT, Harlid R, Rossner S, Granath F, Hemmingsson E. Effect of a very low-energy diet on moderate and severe obstructive sleep apnoea in obese men: a randomised controlled trial. BMJ 2009; 339: b4609 doi 10.1136/bmj.

Johansson and colleagues at the Karolinska Institute in Stockholm reported that 63 obese Swedish men with moderate and severe OSA were allocated to one of two groups. Thirty men followed a seven-week Cambridge VLCD (554 kcal/d) followed by two weeks of rising dietary energy intake in preparation for a one-year maintenance programme, and 33 men (the control group) received no treatment and followed their usual diet.

In the Cambridge VLCD treated group:

- Average weight loss was 18.7kg (average baseline weight was 113.4kg).
- There was a 3.8cm reduction in neck circumference (baseline was 45.1cm).
- A little over one quarter of body fat (30.1 percent at baseline) was lost by nine weeks.
- 22 out of 30 were not obese (BMI under 30) after nine weeks.
- Five improved sufficiently to be classed as 'cured' of their OSA.
- 26 out of 30 saw improvement in their OSA.
- No-one dropped out from the VLCD treated group [in contrast, two subjects out of 33 dropped out from the control group].

In the control group:

- There was a small weight gain of 1.1kg (average) and very slight increases in neck circumference and body fat.
- Four subjects saw improvement in their OSA, five deteriorated and 24 out of 33 stayed unchanged.
- The differences between the VLCD group and the control group were highly significant.

This paper is important because:

- It is the first published randomised controlled trial of VLCD in moderate and severe sleep apnoea.
- It provides high quality evidence that a relatively short period of VLCD diet can result in effective weight loss and improve OSA in a majority of male patients.

After nine weeks those who had been in the control group then followed the nine-week diet programme. All subjects were then offered a maintenance programme with continued support from a dietitian and an option to use formula product to maintain weight for one year.

After one year the apnoea – hypopnea index had improved by 17 compared to baseline and body weight was 12kg less than at baseline. Thirty out of 63 no longer required CPAP and 6 out of 63 had total remission. Those who lost the most weight or had the most severe sleep apnoea at baseline benefitted most.

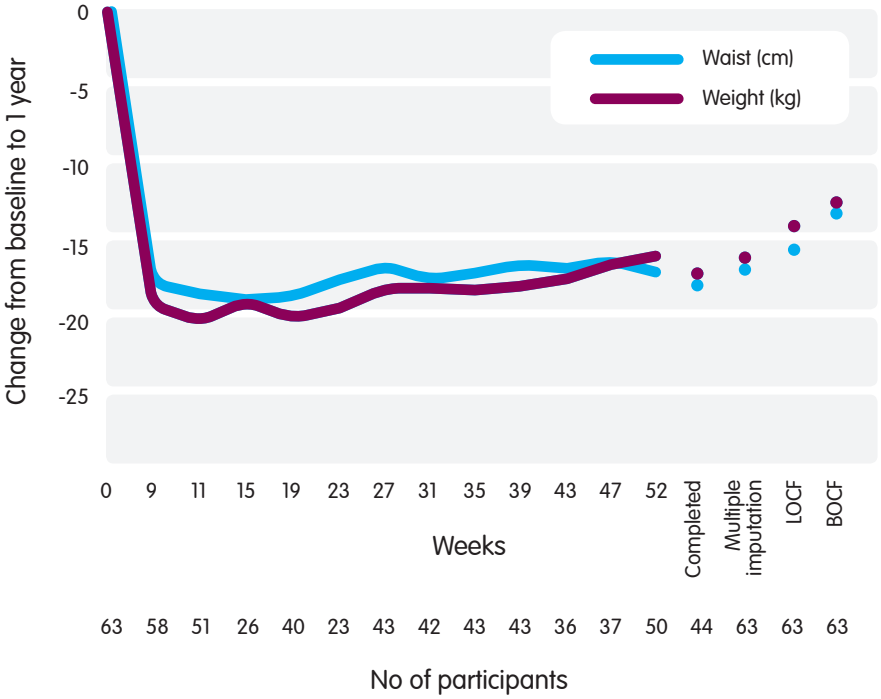

Figure 2. Mean change from baseline in weight, waist circumstances during and after treatment with very low energy diet for patients completing weight loss maintenance programme (n=44) and sensitivity analysis for missing data with multiple imputation (n=63), last observation carried forward (LOCF; n=63), or baseline observation carried forward (BOCF; n=63). Attendance was low at 15 and 23 weeks because of summer holidays.

References:
Johansson K, et al Longer term effects of very low energy diet on obstructive sleep apnoea in cohort derived from randomised controlled trial prospective observational follow-up study. BMJ 2011: 342:d3017 doi: 10.1136/bmj.d3017.

Foster DG, Borradiale KE, Sanders MH, et al., Randomised study on the effect of Weight loss in obstructive sleep apnea among obese patients with type 2 diabetes. Arch Int Med 2009; 169 (17): 1619-1626.

Tuomilehto HPI, Seppä JM, Partinen MM et al Lifestyle intervention with weight reduction: first line treatment in mild obstructive sleep apnoea. Am J Respir Crit Care Med 2009; 179: 320-327.

Figure 2. Redrawn from Johansson K, et al BMJ 2009; 339: b4609 doi10.1136/bmj.b4609.

Weight maintenance after weight loss with VLCD or formula LCD

A popular belief has been that weight regain occurs rapidly after weight loss with VLCD or formula LCD, probably reflecting the failure of practitioners to put in place effective maintenance strategies. How best to maintain a lower dietary energy intake (approximately 250kcal/d for every 10kg body weight lost) and a higher physical activity level for many years are the subject of ongoing investigations.

Effects of anti-obesity drugs, diet and exercise on weight loss maintenance after a very low-calorie diet or low-calorie diet: a systematic review and meta-analysis of randomised controlled trials Johansson K, Neovius M, Hemmingsson E Am J Clin Nutr 2013 published online 30 October 2013.

This meta-analysis was designed to evaluate the effects of anti-obesity drugs (sibutramine and orlistat), diet or exercise on weight loss maintenance after an initial very low-calorie diet (VLCD) or low-calorie diet (LCD) period (less then <1000 kcal/d). It consisted of a systematic review of English articles using MEDLINE, Cochrane Controlled Trial Register, EMBASE from 1981 to February 2013, and by contacting clinical experts, etc. Included studies were randomised controlled trials specifically evaluating weight loss maintenance strategies after an initial VLCD/LCD period.

Twenty studies with a total of 27 study arms and 3017 participants were included. These were studies on anti-obesity drugs (3 arms, n=658), meal replacements (4 arms, n=322), high protein diets (6 arms, n=865), dietary supplements (6 arms, n=261), other diets (3 arms, n=564) and exercise (5 arms, n=347).

During the VLCD/LCD period, the pooled mean weight loss was 12.3kg (median duration: 8wks, range 3-16wks).

Compared with placebo or control the intervention changed weight loss maintenance statistically significantly as follows:

- Anti-obesity drugs by -3.5kg (95%CI -5.5,-1.5: median duration 18mo, range 12-36mo).
- Meal replacements by -3.9kg (95%CI -5.0,-2.8: median duration 12mo, range 10-26mo).
- High protein diets by -1.5kg (95%CI -2.1,-0.8: median duration 5mo, range 3-12mo).

In contrast the differences in the following groups were not significant: Exercise (0.8kg: 95%CI -2.8,1.2: median duration 10mo, range 6-12mo) and dietary supplements (0.0kg: 95%CI -1.4,1.4: median duration 3mo, range 3-14mo).

Thus anti-obesity drugs, meal replacements, and high protein diets were associated with improved weight loss maintenance after a VLCD/LCD-period.

Conclusion

Since sibutramine has now been withdrawn from use in Europe, the only interventions currently proven to result in significantly better weight maintenance after weight loss with VLCD or LCD are orlistat, partial replacement of conventional food with formula meal replacement product and use of a high protein diet.

Figure 3. Body weight change during the VLCD or LCD period followed by the weight loss maintenance period. The thin lines represent the control subjects in each category, while the thick lines represent the active intervention.

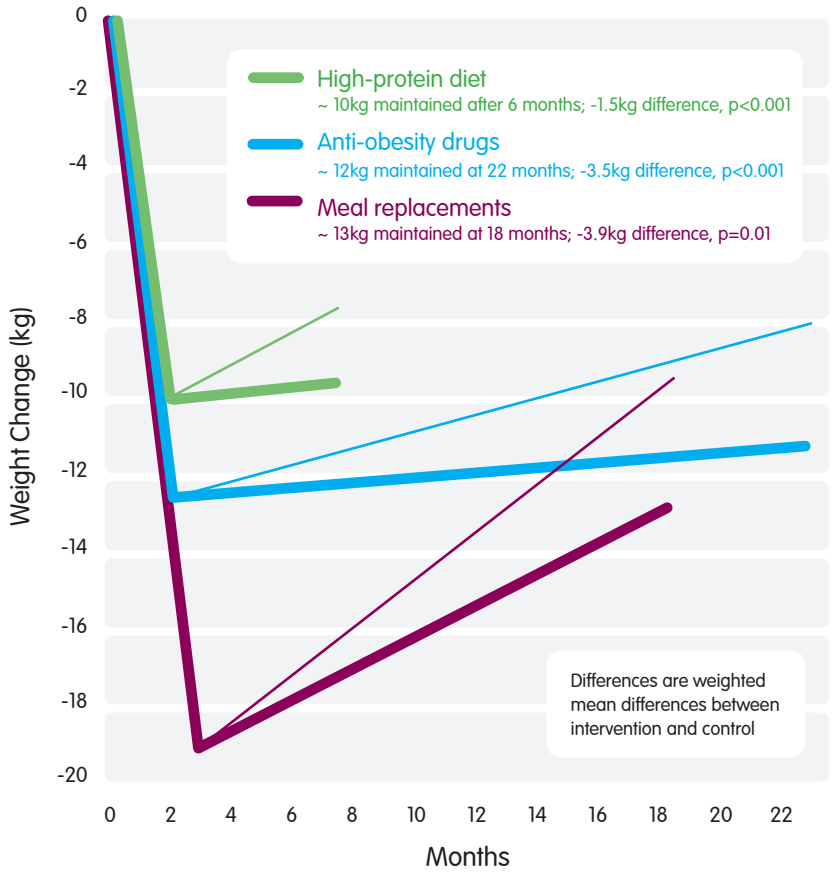

Figure 3. Redrawn from Effects of anti-obesity drugs, diet and exercise on weight loss maintenance after a very low-calorie diet or low-calorie diet: a systematic review and meta-analysis of randomised controlled trials Johansson K, Neovius M, Hemmingsson E Am J Clin Nutr 2013 published online 30 October 2013.

Translation into primary care

A care package which included an initial weight loss with a Cambridge Weight Plan total diet replacement (TDR, 810-833kcal/d liquid diet comprised of soups and shakes) followed by food re-introduction and weight maintenance (the Counterweight programme) delivered more than a 15kg weight loss after one year in one third of participants in a primary care setting.

Weight loss and maintenance with formula diet now feasible in primary care. Lean M, Brosnahan N, McLoone P, McCombie L, Bell-Higgs A, Ross H, Mackenzie M, Grieve E, Finer N, Reckless J, Haslam D, Sloan B, Morrison D. Feasibility and indicative results from a 12-month low-energy-liquid-diet treatment and maintenance programme for severe obesity. Br J Gen Pract 2013; DOI: 10.3399/bjgp13X663073.

The study, reported in February 2013 in the British Journal of General Practice by Professor Mike Lean and colleagues from the University of Glasgow and the Counterweight programme team, described the results of the weight loss intervention in 91 people with BMI >40 living in rural and small-town Scotland (Lean et al 2013). Severe obesity is increasing rapidly in Scotland: 6% of men and 11% of women have BMI over 35, and for those over 55 years 3% of men and 5% of women have BMI over 40. Potentially eligible for surgery, many of these people with BMI in excess of 40 are unlikely to get that treatment in today's circumstances and yet the 15 to 20kg weight loss needed to correct the metabolic derangement in type 2 diabetes cannot be achieved by conventional dietary regimens. Formula diet programmes, providing a nutritionally replete diet, achieve a higher energy deficit than conventional reducing diets, resulting in 1 to 2kg weekly weight loss, in turn giving the weight losses needed. These higher rates of weight loss have been shown to be safe (adverse event profiles are fully published, Johansson et al 2011) and lean mass losses were reported as remarkably low in older Danes with osteoarthritis (Christensen et al 2011).

In the Counterweight total diet replacement weight loss and maintenance programme, 91 patients (mean BMI 48) entered the programme and 58 completed the liquid diet phase (82 initially chose the commercial programme over the 'home-made' version). The mean weight loss during the liquid diet was 16.9kg, and during food re-introduction was 2.1kg.

Fifty-two patients commenced the maintenance phase, 27 achieving a loss of more than 15kg at one year. Forty-four had accepted use of orlistat to facilitate maintenance at some point during the year and those taking orlistat showed a weight loss of 20.1kg at one year while those not taking it showed an average loss of 14.1kg at one year.

The cost, carefully calculated to include all components, including practice nurse time and cost of product and telephone calls, was estimated at £861 per participant or, since three participated in order for one to lose 15kg, the cost (given in the paper) was £2611 per patient with a documented 15kg weight loss.

A qualitative analysis showed that participants were 'very satisfied' with the rate and degree of weight loss with the formula diet. Transient constipation and dizziness occurred in some people but there was more concern over social and occupational consequences such as difficulties at family meal times.

The participants in this feasibility trial were largely non-diabetic patients, so there is now a need to undertake a similar study in those with type 2 diabetes. Strategies for reducing drop-out need to be devised and methods to enhance weight maintenance beyond one year need to be tested. In the weight loss trial in elderly Danes with osteoarthritis (Christensen et al 2011, see page 5), at the end of the first year of maintenance patients were re-randomised to one of two active intervention programmes. The first allowed the daily use of one formula product to substitute for one meal to help achieve the daily reduction of dietary energy intake of about 400kcal/d needed after a 15kg weight loss, with tight monitoring of weight and a short-term use of an 800kcal/d liquid diet if weight rose by 2kg. The second provided an opportunity for a five week 800kcal/d liquid diet every four months. This three-year randomised controlled trial will determine whether or not weight maintenance is possible and which of these two interventions gives the best outcome.

Psoriasis

Psoriasis is a chronic recurring inflammatory skin condition characterised by patchy red, thick and scaly skin, which varies in severity from time to time. Environmental and genetic factors play a part in the causation of psoriasis. It is associated with obesity, it is not seen in very slim individuals, may become more severe with increasing body weight and in some people seems to respond to weight reduction. Until the publication of the work described below, there was no good clinical trial evidence that weight loss could be helpful.

Effect of Weight Loss on the severity of Psoriasis Jensen, P., et al JAMA Dermatol doi: 10.1001/jamadermatol.2013.722 (published on line 29th May 2013).

Sixty obese patients with psoriasis were randomised to either usual management (control) or an 800-1000kcal/d Cambridge Weight Plan diet programme for eight weeks followed by a 1200kcal/d diet for eight weeks in preparation for a maintenance programme. The diet-treated group lost 15.4kg more than the control group at 16 weeks. The dermatology life quality index (DLQI) improved significantly after the formula diet compared to control and the Psoriasis Area and Severity Index (PASI) showed a trend towards improvement. The results after one year of follow-up will be available towards the end of 2014.

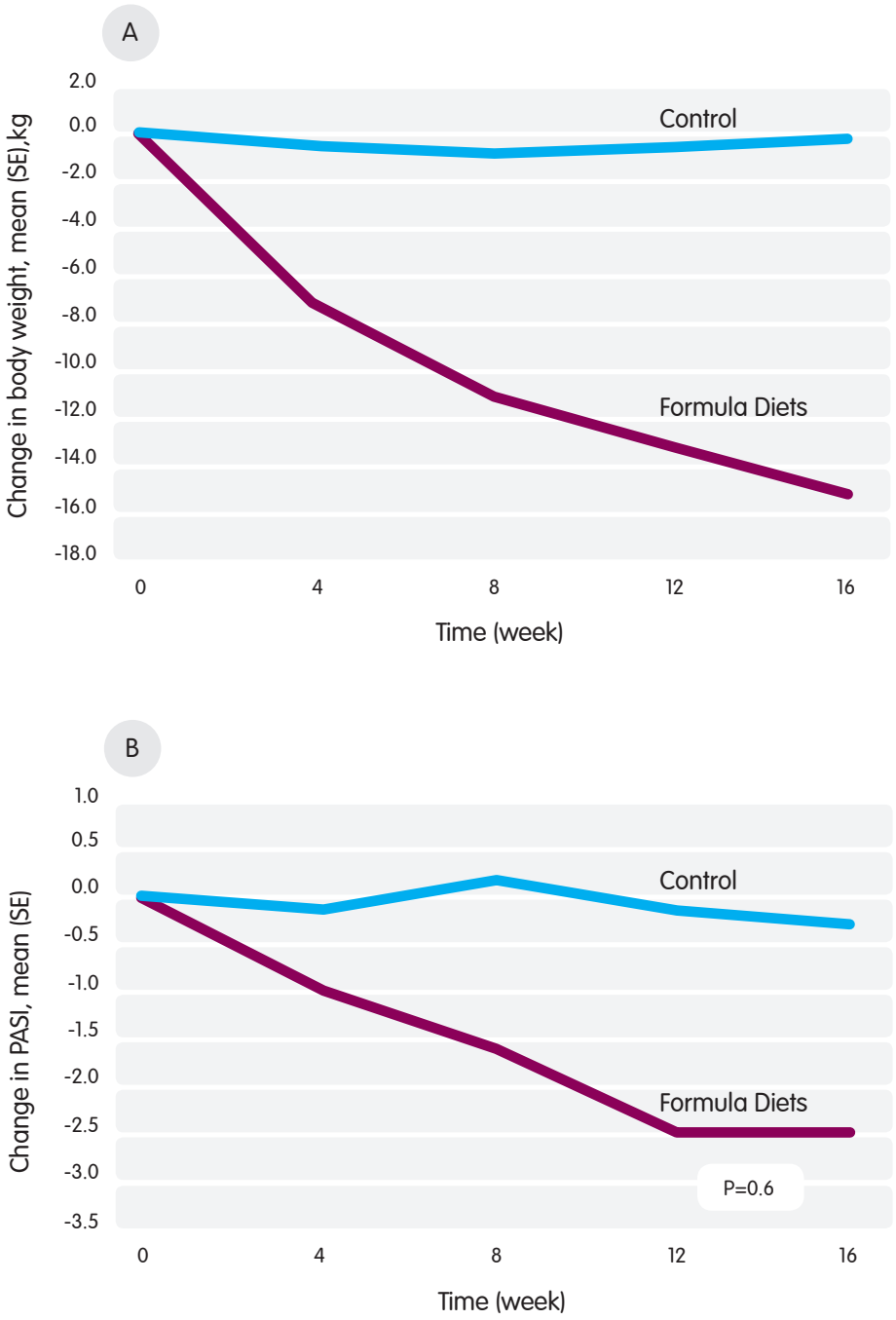

Figure 4 Mean changes over time from baseline body weight (A) and Psoriasis Area and Severity Index (PASI) (B). The dark red line represents low-calorie diet group; blue line represents the control group.

Figure 4. Redrawn from: Effect of Weight Loss on the severity of Psoriasis Jensen, P., et al JAMA Dermatol doi: 10.1001/jamadermatol.2013.722 (published on line 29th May 2013).

Cardiovascular risk factors in psoriasis

A recently published meta-analysis of 75 relevant articles (Miller at al 2013) showed that psoriasis is associated with heart disease, diabetes, hypertension, dyslipidaemia, obesity and the metabolic syndrome, but not cardiovascular mortality. In the study reported by Jensen and colleagues described on page 10 cardiovascular risk factors were measured as well as markers of endothelial function.

Miller IM, Ellervik C, Yazdanyar S, et al. (2013) Meta-analysis of psoriasis, cardiovascular disease, and associated risk factors. J Am Acad Dermatol 69: 1014-24.

Jensen P, Zachariae C, Christensen R et al. (2014) Effect of Weight Loss on the Cardiovascular Risk Profile of Obese Patients with Psoriasis. Acta Derm Venereol doi: 10.2340/00015555-1824

Some traditional cardiovascular risk factors (see table right) showed significantly greater reduction following weight loss with formula diet (800 – 1000kcal/d Cambridge Weight Plan) followed by eight weeks of 1200kcal/d diet than after 16 weeks of 'usual care' control treatment.

Endothelial function had been assessed by measurement of soluble markers: intercellular adhesion molecule (ICAM)-1, vascular adhesion molecule (VCAM)-1 and tissue plasminogen activator inhibitor (tPAI)-1. Tissue plasminogen activator inhibitor showed a large fall following weight loss from 5.21 to 2.14 ng/ml after weight loss with formula diet and a slight rise after the control treatment (4.53 to 4.94 ng/ml), the difference between the groups being significant ($p = 0.001$), but (ICAM)-1 and (VCAM)-1 showed no significant change. Microvascular endothelial function was assessed using peripheral arterial tonometry but there was no significant change in the calculated reactive hyperaemia index.

Thus, some components of the cardiovascular risk profile were improved by weight reduction with a formula diet Cambridge Weight Plan programme.

Changes in variables from baseline to 16 weeks:

	Formula diet	Control	Difference	P value
Systolic blood pressure mmHg	-7	-2	-5	0.1
Diastolic blood pressure mmHg	-5	1	-6	0.002
Total Cholesterol mmol/l	-0.4	0.04	-0.5	0.008
LDL-cholesterol mmol/l	-0.2	0.04	-0.1	0.06
Triglyceride mmol/l	-0.58	-0.24	-0.32	0.01
Plasma glucose mmol/l	-0.6	-0.1	-0.5	0.007
Glycated haemoglobin %	-0.7	-0.4	-0.3	0.007

One year follow-up: effect of weight loss on severity of psoriasis.

Following completion of the randomised controlled trial described on page 10, subjects in the control group were offered weight loss with formula diet over 16 weeks. After weight loss, subjects from both groups were offered weight maintenance with replacement of two meals daily with formula diet products and support from a dietitian at eight weekly intervals. Body weight, Psoriasis Area and Severity Index (PASI) and Dermatology Life Quality Index (DLQI) were measured.

Geiker N R W, Jensen P, Zachariae C et al.(2014) Effect of weight loss on the severity of psoriasis: one year follow-up. T5: S41.04. Obesity Reviews 15(S2): 170-1. doi: 10.1111/obr.12151/

Thirty-two out of 38 subjects completed the one year follow up programme. During their initial 16 week weight loss programme they lost on average 15.4kg. After one year they had maintained about 66% of that initial loss – approximately 10kg (a significant change from baseline $p<0.001$). The improvement in PASI seen at 16 weeks was maintained at one year follow up (a significantly lower score compared to baseline, $p<0.001$). The significantly improved DLQI seen at 16 weeks was maintained at one year.

These results suggest strongly that effective weight loss with an 800 to 1000kcal/d formula diet programme can improve the severity of the skin lesions in psoriasis and that this can be maintained by partial use of formula diet in a weight maintenance programme. A full scale multi-centre randomised controlled trial, with weight loss followed by at least a two year weight maintenance programme, should now be undertaken to provide evidence of the strength required for weight loss and maintenance guidance to be incorporated into psoriasis management guidelines. In the meantime clinicians may feel inclined to see whether or not individual obese people with psoriasis benefit from weight loss using formula diet weight reduction and maintenance programmes.

Research in progress

Diabetes

Cambridge Weight Plan is providing product for two studies on weight loss in diabetes and pre-diabetes.

PREVIEW

In the PREVIEW study (work package one) more than 2000 adults with pre-diabetes in eight centres (Denmark, Finland, Holland, Bulgaria, Spain, New Zealand, Australia and the UK) will lose weight using an 800 to 1000kcal/d Cambridge Weight Plan diet and those who achieve 8% of initial weight loss will enter weight maintenance programmes. Designed to determine how best to achieve weight loss and maintenance and subsequent reduced risk of development of diabetes, the study is funded by an EU grant and commenced in August 2013.

For more information see: https://clinicaltrials.gov/ct2/show/NCT01777893

or please scan the QR code:

DiRECT

In the DiRECT (Diabetes Remission Clinical Trial) study about 150 people with type 2 diabetes and who are obese will either follow a usual care pathway or use an 800kcal/d low calorie liquid formula diet provided by Cambridge Weight Plan through the Counterweight Plus programme for eight to 20 weeks. The low calorie diet will be followed by a food reintroduction period over two to eight weeks and then a weight maintenance programme. Participants will be observed for two years and some will participate in studies on liver and pancreatic fat content and tests of metabolic function. The study began in April 2014, with participants recruited and managed in primary care practices, and is jointly run from the University of Glasgow and the University of Newcastle.

For more information see: http://www.diabetes.org.uk/Research/Research-round-up/Research-spotlight/Research-spotlight-low-calorie-liquid-diet/

or please scan the QR code

Weight loss before surgery

Total knee replacement

Patients destined for total knee replacement are often obese by the time surgery is offered and are often set unrealistic weight loss targets by orthopaedic surgeons. The relatively large weight losses needed can be achieved in defined periods and this may influence the peri-operative and post-operative outcomes. A full-scale clinical trial of weight loss with Cambridge Weight Plan with one-year follow up has now been completed in Sønderborg in southern Jutland (Denmark). A preliminary report is expected in 2015.

Heart Disease

Copenhagen study of overweight patients with coronary artery disease undergoing low energy diet or interval training: The randomised CUT-IT trial protocol Pedersen et al. BMC Cardiovascular Disorders 2013, 13:106 http://www.biomedcentral.com/1471-2261/13/106

Overweight women with coronary artery disease will be randomised to an 800-1000kcal/d Cambridge Weight Plan programme or supervised aerobic interval training for 12 weeks and will be followed up for 40 weeks. The primary endpoint is coronary flow reserve.

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