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Formula food-reducing diets: A new evidence-based addition to the weight management tool box

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Abstract

The changing pattern of obesity-related disease has created a need for a greater range of weight management options for the increasing number of people for whom weight loss and maintenance cannot be addressed by conventional dietary methods.

Formula diet weight loss programmes [very low-calorie diets (VLCDs) (400–800 kcal/day) and low-calorie diets (LCDs) (800–1200 kcal/day)] can deliver weight loss at rates of 1–2 kg/week. This rate of weight loss can result in 10–20 kg weight loss in 8–12 weeks. Many health benefits associated with weight reduction seem to require between 10 and 20 kg weight loss. Formula diet programmes can result in weight loss, reduction of liver volume and reduction of visceral fat before bariatric surgery; weight loss before knee joint replacement surgery has also been shown. The benefit of pre-operative weight loss is still under investigation and such practices before bariatric surgery are variable in surgical units across the UK.

Weight loss with formula diet in obesity-associated conditions where inflammation is an important component, such as osteoarthritis and psoriasis, has been demonstrated. Maintenance of about 10% of initial bodyweight loss, with symptom improvement in elderly obese people with knee osteoarthritis, has been shown over a period of 4 years. In obese people with psoriasis, weight loss with skin improvement has been maintained for 1 year.

Clinical trials are currently underway to examine the merits of an initial weight loss with formula diet in pre-diabetes, in early type 2 diabetes and in insulin-treated type 2 diabetes.

Rapid initial weight loss can result in rapid symptom improvement, such as reduced joint pain in osteoarthritis, improved sleep quality in obstructive sleep apnoea, reduced shortness of breath on exertion, reduced peripheral oedema and rapid improvement in metabolic control in diabetes, all changes that are highly motivating and conducive towards compliance.

There is also some evidence for improved vitamin D status and maintained bone health in elderly obese people with osteoarthritis but more research is needed.

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Rapid initial weight loss was feared to be followed by rapid weight regain. However, provided initial weight loss is delivered in parallel with an intense education programme about nutrition, cooking, shopping and lifestyle for long-term maintenance; and where long-term support is provided, subsequent weight maintenance after VLCDs and LCDs has been shown to be possible. A recent literature review identified high-protein diets, obesity drugs and partial use of formula meal replacements as methods which can result in statistically significantly greater weight maintenance after initial weight loss with VLCDs or LCDs.

Anxiety about serious adverse side effects seems to be unfounded although users need to be aware of both minor and more serious, though very infrequent, adverse events, such as gallstones and gallbladder disease.

Keywords: formula food-reducing diets, low-calorie diets, obesity, very low-calorie diets, weight management

Introduction

Very low-calorie diets (VLCDs) (<800 kcal/day) and low-calorie diets (LCDs) (800–1200 kcal/day) delivered as liquid foods (*i.e.* as soups and shakes) have been available for use in the UK for about 30 years. Developed initially around the concept of creating a near-fasting metabolic response without nutrient depletion, the encouraging initial findings were often dismissed by sceptics and such diets were labelled as hazardous and liable to be followed by rapid weight regain with disproportionate regain of body fat. Thirty years ago, the pattern of obesity in the population was less challenging with only relatively small numbers of morbidly obese individuals [body mass index (BMI) > 40 kg/m^2] in contrast to today's pattern, where 1 in 4 adults in the UK population is obese, and where about 1 in 10 obese people is morbidly obese. Overall, the pattern of obesity-related disease has changed with a rising prevalence of type 2 diabetes and increasing locomotor impairment and disability from osteoarthritis related to an ageing and heavier population. Increasing challenges in obstetric practice due to higher rates for gestational diabetes with premature infant death, trauma during delivery and higher perinatal death can be obesity related. Against this background, the need for a wider range of options for people to choose from, and for professionals to use with confidence, is needed; but the body of scientific evidence has, until recently, been insufficient to support confident use of formula diets.

Formula diets cause weight reduction by creating a greater energy deficit between energy requirement and dietary energy supply than is usual with a conventional food-reducing diet with a 500–600 kcal/day deficit. Formula diets can supply anywhere between just over 400 kcal/day to about 1200 kcal/day and can be composed of mixed formula diet and conventional food at the higher levels. Conventional food diets below 1000 kcal/day cannot be constructed to supply all micronutrients on a daily basis, hence the principle of manufacturing formula food products providing a full 100% Dietary Reference Value (DRV) supply within a defined number of portions (usually 3 or 4). When the evidence for nutritional deficiency in obese people is considered, there may be merit in losing weight using a method that may replete nutrient levels rather than further depleting them. Very low dietary energy intakes result in high levels of blood ketones and these may suppress hunger in many individuals, an effect mediated by suppression of the hunger hormone ghrelin (Sumithran *et al*. 2013). At higher dietary energy intake levels, blood ketone levels may not be so high. The protein level supplied is intended to meet metabolic requirements and limit lean tissue loss – levels in products vary and it is likely that definitive guidance on optimal protein composition will be given by a European Food Standards Agency (EFSA) panel in early 2015.

Conventional reducing diets with a 500–600 kcal/day energy deficit are likely to lead to weight loss rates of around 0.5 kg/week. For individuals who need to lose 15–20 kg of weight for medical reasons (see below), a dietary programme lasting 30–40 weeks may seem daunting. Many individuals can follow such programmes and achieve good weight losses of around 5 kg in completers with maintenance of just over 4 kg at 1

year (Jolly *et al*. 2011), but this may not deliver a tangible medical benefit in all individuals concerned.

Formula diet programmes allow conventional food to be withdrawn from the daily decision-making process. Compliant individuals do not have to worry about portion control and may be more easily able to avoid comfort eating or snacking if they have begun to experience some symptomatic improvement and if they are being sufficiently encouraged and supported. After weight loss, there is a period of gradual food reintroduction with the application of all that has been learned, until a food-based weight maintenance diet is established in association, where possible, with a level of physical activity sufficient to increase the probability of maintaining the new lower weight. The normal natural responses to dietary energy restriction of metabolic adaptation and physical activity reduction may account for some of the reduction of rate of weight loss, which occurs in most people over a 2- or 3-month period; but a sufficient level of physical activity has been shown to counteract these two natural adaptations (Redman *et al*. 2009; Hunter *et al*. 2010).

Meal replacements are usually bars, soups or drinks designed to replace a conventional food meal, containing between 200 and 400 kcal per portion and defined amounts of micronutrients. Usually intended to be used to replace two meals each day, they could contribute to a total energy intake of 800–1500 kcal/day depending on the composition of the conventional food eaten in the third meal. Meal replacements have been used in some very significant clinical trials, such as the *Look AHEAD* trial, which examined just over 5000 overweight/obese adults with type 2 diabetes randomised to usual care or an intensive lifestyle intervention that included use of meal replacements. Fifty per cent of the intensive intervention participants maintained more than 5% of weight loss for 8 years (Look AHEAD Research Group 2014).

Quantitative aspects of weight loss

The amounts of weight loss needed for particular purposes can be defined. In a cosmetic context, a woman who wishes to fit into a particular size of dress knows roughly how much weight loss is needed, from her previous size to weight ratios while gaining weight and from the general relationship of waist circumference to weight (very roughly 1 cm to 1 kg bodyweight). A 20-cm waist reduction requires about a 20-kg weight reduction. In a medical context, it is now known that about 15 kg weight loss will lead to a reduction of the apnea/hypoapnoea index of 20 units, enough to cause a marked symptom improvement in obstructive sleep apnoea (Johansson *et al*. 2009). A 12–15 kg weight loss with 10 kg weight maintenance at 1 and 4 years is associated with symptom improvement (principally pain) and maintenance in elderly obese people with osteoarthritis of the knee (Riecke *et al*. 2010; Christensen *et al*. 2011a, 2013). This trial (Christensen *et al*. 2011a) that was based in a secondary care setting required all subjects to participate in weekly group education sessions run by a dietitian during the weight loss period. The subsequent weight maintenance programme that followed included further, but less frequent, support and education sessions. Such patients not only gain freedom from reduction of knee pain, but also reduced pain as experienced in other joints and improved sleep quality. A 20-kg weight loss in obese people with psoriasis causes a significant improvement of the dermatology quality of life questionnaire (Jensen *et al*. 2013) and this can be sustained with maintenance of 60% of the initial weight loss in completers (Geiker *et al*. 2014). In most of these patient groups, the starting BMIs are in the range of 30–40 and it is to this specific BMI range that the notion of the efficacy of a 20-kg weight loss applies. Few or no clinical trial studies have been done on the morbidly obese or superobese with these conditions, but anecdotal observations in a bariatric surgical service suggest that a 20-kg weight reduction in individuals weighing around 150 kg at baseline (with BMIs typically around 50) can contribute to decreased joint pain, improved mobility, decreased shortness of breath, reduced peripheral oedema, improved sleep quality, decreased depression, and decreased use of analgesic drugs and bronchodilators, along with measureable improvement in blood pressure, blood lipids, and glucose and insulin, if raised initially.

Short-term weight loss

There is very clear evidence from several papers that formula diets, whether VLCDs or LCDs, can cause weight reduction in compliant individuals from a variety of different patient groups. Where the need is a weight loss for a specific (usually surgical) purpose, the potential for using an 8- to 12-week liquid formula diet while awaiting surgery has very clear advantages. One such example is weight loss before total knee arthroplasty (TKA). Surgeons may demand a weight loss before surgery to reduce perioperative risks and facilitate mobilisation post-operatively; however, this demand is difficult to meet by conventional diet and few TKA candidates merit or get bariatric surgery. Heavier people

require a second knee replacement earlier than lighter individuals, and there is a suggestion that longer term outcomes may be better if there has been pre-op weight loss. With this in mind, the team at Aarhus University Orthopaedic Department is currently running a randomised controlled trial (RCT) in Southern Denmark. The efficacy and acceptability of this intervention has been reported in preliminary form and 6- and 12-month post-op outcomes are eagerly awaited (Liljensøe *et al*. 2013, 2014). So-called liver shrinkage diets before bariatric surgery are undertaken in some but not all centres in the UK. A restricted energy intake before surgery rapidly reduces liver fat and liver volume in 2 weeks (Colles *et al*. 2006), rendering the liver less liable to tear and bleed and to be more easily retractable with just one retractor. To achieve reduction of visceral fat (rarely demanded by a surgeon), longer diet duration is needed. Such 12-week diets may be particularly helpful in preparing super-obese people (BMI > 50) but to date no clinical trials have been undertaken. When those are designed, the focus should be on anaesthetic and recovery outcomes as much as the surgeon's subjective perception of surgical difficulty.

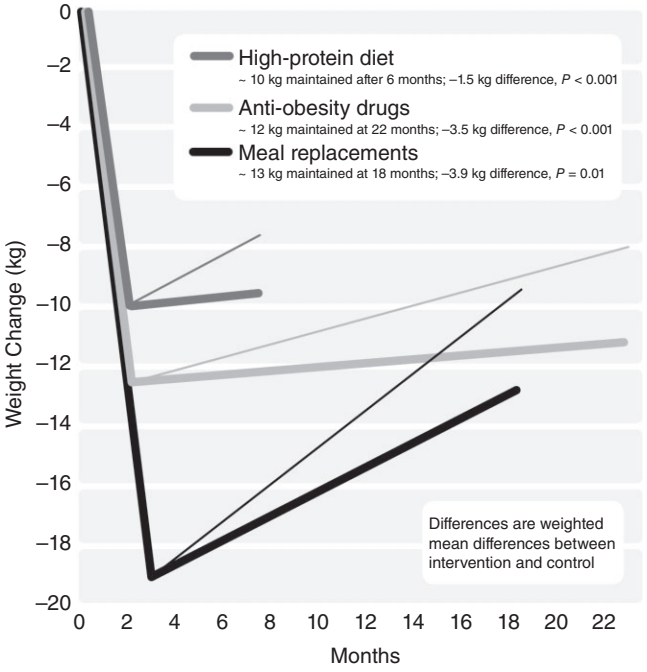

Figure 1 Bodyweight change during the very low-calorie diet or low-calorie diet period followed by the weight loss maintenance period. The thin lines represent the control subjects in each category while the thick lines represent the active intervention. (Adapted from Johansson *et al.* 2013a)

Weight maintenance

One reason often given for not using formula diet weight loss programmes is that any weight lost will be rapidly regained, and early papers have clearly shown that this can be the case (Franz *et al*. 2007). Overall, there was a general failure to incorporate education and interventions to achieve successful weight maintenance. However, maintaining a new lower dietary energy intake and having a consistently higher physical activity level is sometimes possible. Johansson *et al*. (2013a) recently published a meta-analysis of papers reporting RCTs of specific interventions after initial weight loss with VLCDs or LCDs (see Fig. 1). Three interventions showed statistically significantly better weight maintenance with the intervention than in the control group: high-protein diet, anti-obesity drugs (which included sibutramine and orlistat) and partial use of meal replacement formula diet products. The initial weight loss depended on the duration of treatment with the VLCD or LCD and the absolute amount of weight maintained relates to the initial weight loss, but in each of the three cases the intervention gave a significant additional benefit. This opens up the possibility of combining two or three of these interventions in parallel or in sequence. Many weight maintenance diets are already slightly higher in protein than conventional diets based on evidence from trials such as the *DIOGENES* study (Larsen *et al*. 2010).

Weight loss in obesity-associated inflammatory disease

The UK has an ageing heavier population that is increasingly affected by osteoarthritis. The increasing number of knee replacements is an indication of the scale of the problem, but hidden away, often housebound, are countless thousands who suffer from inadequately controlled pain and disturbed sleep. Risk of cardiovascular disease is higher in osteoarthritis and weight reduction with maintenance could deliver a portfolio of benefits: risk factor reduction as well as weight reduction. However, reduced mobility renders this group difficult to help since exercise capacity is limited. Large-scale trials to investigate weight loss in this group have been undertaken. The *Cartilage and Osteoarthritis weight loss trial* (*CarOT*) undertaken in Copenhagen has shown that elderly obese people with knee osteoarthritis can lose 12–15 kg in weight (10% of initial bodyweight) over a 16-week programme of intense weekly education with a dietitian, combined with 8 weeks of VLCD or LCD, followed by 8

weeks of a 1200 kcal/day food reintroduction diet (Riecke *et al*. 2010; Christensen *et al*. 2011a). After weight loss, they were then rerandomised to a diet maintenance, exercise or control programme for 1 year, and although all three maintained some of the weight loss, the best outcomes (weight reduction, body fat reduction) occurred in the diet (one formula product per day) group (Christensen *et al*. 2013). After weight loss, over 60% had achieved a major symptom improvement (mostly pain reduction) (Riecke *et al*. 2010) and a proportion of this was maintained in all three maintenance groups. After 1 year of weight maintenance, participants were then rerandomised again into two weight maintenance programmes for 3 years (one meal per day versus three episodes of a 5-week LCD diet annually). Both groups maintained most of the weight lost, showing that over the whole rather complex sequence, weight loss with symptom improvement and weight maintenance of about 10% of initial bodyweight for 4 years can be achieved in this difficult-to-manage group (Christensen *et al*. 2014). Moreover, blood pressure reduction achieved at weight loss was partially maintained at 1 year (Christensen *et al*. 2013). Preliminary analyses of magnetic resonance imaging (MRI) knee scans suggest that a diet maintenance programme can suppress the progression of signs of the inflammatory component of the disease (Henricksen *et al*. 2014). Bliddal *et al*. (2014) concluded that for all obese patients with osteoarthritis, weight loss should be advocated as a first-line treatment aiming to achieve rapid weight loss of about 10% bodyweight.

Psoriasis is a chronic recurring inflammatory condition characterised by patchy thickened, red and scaly skin. It varies in severity from time to time and is influenced by obesity. It is not seen in very slim individuals; it may become worse with weight gain, and there is evidence that weight loss may be beneficial. A recently published clinical trial, the first of its kind, reported an effective weight loss with an 8-week LCD programme followed by an 8-week 1200 kcal/day food reintroduction programme. The skin improved significantly on the Dermatology Life Quality Index (DLQI), but showed a strong trend towards improvement on the Psoriasis Area and Severity Index (PASI) (Jensen *et al*. 2013). All subjects were invited to maintain weight with a partial meal replacement programme for 1 year (non-randomised), in which participants maintained about 60% of the initial weight lost (Geiker *et al*. 2014). Large improvements in cardiovascular risk factors were also shown after weight loss (Jensen *et al*. 2014). Therefore, with this in mind, weight loss with formula diet as an adjunct therapy in psoriasis should be further investigated with a large-scale multicentre trial.

Weight loss in diabetes and heart disease

Dietary energy restriction causes a reduction in liver synthesis of glucose and prevailing blood glucose. This was ably demonstrated by Lim *et al*. (2011) in Newcastle who used a VLCD in a small number of people with type 2 diabetes. This had already been shown by many other groups over many decades. Indeed, recognition of the effect of energy restriction was confirmed during the Siege of Paris in 1871 when Apollinaire Bouchardat recorded that his (presumably type 2) diabetes patients improved when food was scarce. Others who have shown similar findings with VLCDs include Snel *et al*. (2012) but Lim *et al*. (2011) reported an additional important finding: demonstration of recovery of the first phase of insulin release and a reduction of the high levels of fat accumulated in the pancreas and the liver. Energy restriction, reduced weight, reduced local fat in key abdominal organs (thus decreasing insulin resistance) and reduced liver glucose synthesis had, in effect, reversed diabetes. Some subjects were metabolically normal after weight loss. The question was: could this effect be maintained? With the challenge being to maintain a lower dietary energy intake, Diabetes UK has agreed to fund a two-centre study (Newcastle and Glasgow) to investigate if delivery of a low-energy liquid diet (800 kcal/day) with an intense education programme, followed by an effective weight maintenance programme, can be achieved in a primary care setting. Previously published work undertaken in Scotland showed that weight loss with low-energy liquid diet and weight maintenance, with food reintroduction, education and support, is possible in a primary care setting. Participants who were morbidly obese (BMI > 40 kg/m^2) were able to maintain a ≥15 kg weight loss for 1 year in 1 in 3 cases, and 5–15 kg weight loss in a further 1 in 5 cases (Lean *et al*. 2013).

Weight loss and associated changes improve the cardiovascular risk profile in those with diabetes, and weight loss and maintenance can result in cardiac remodelling (Jonker *et al*. 2014). Coronary flow reserve (CFR) is a measure of cardiac microvascular function and a strong prognostic marker in coronary artery disease. Preliminary evidence from a RCT comparing the effect of a 12-week low-energy liquid diet programme with an aerobic interval training programme showed that both improved CFR significantly, but the greater weight loss in the diet group also improved

insulin sensitivity, reduced insulin resistance and improved blood glucose control (Pedersen *et al*. 2013, 2014; Olsen *et al*. 2014).

Nutritional status

People with obesity may have poor dietary intake and poor nutritional status based on biochemical variables (Xanthakos 2009). Since it is known that micronutrient bioavailability from intact food structures may be reduced, there is a theoretical possibility that substitution of conventional food with a formula diet product incorporating nutrients in readily absorbable forms may result in repletion during a weight loss programme. This has been tested for vitamin D, iron and vitamin B_{12} in the *CarOT* study on elderly people with knee osteoarthritis (Christensen *et al*. 2011b, 2013). Blood vitamin D, ferritin levels and vitamin B_{12}, along with parathyroid hormone (PTH) were measured, and dual energy X-ray absorptiometry (DEXA) scans were performed to measure bone mineral content and density. At the end of the weight loss period, vitamin D_3 had risen significantly and PTH was significantly reduced (54 of 175 subjects had initially raised levels of PTH, reflecting secondary hyperparathyroidism consequent to vitamin D insufficiency), while the number with raised PTH was halved during the formula diet weight loss programme. Fifty-two weeks later in the diet-treated group (one formula product daily) vitamin D was higher, whereas no further rise was seen in the exercise or control group, and raised PTH was seen in smaller numbers in the diet-treated group. Bone mineral content loss in the diet-treated group was less than in the exercise and control groups but not significantly so, but all three groups showed less bone mineral loss than expected 1 year after weight loss. Bone scan data following a further 3 years of bodyweight maintenance will be published shortly. Vitamin B_{12} in blood rose significantly after the initial 16-week weight loss phase, and rose further still by 52 weeks after weight loss in the diet group but not in the exercise and control groups. These results demonstrate a sustained blood level response of micronutrient delivery in a formula food product, and the reduction of PTH suggested that for vitamin D this was having a functional effect. No consistent haematological and ferritin changes were seen and no tests related to vitamin B_{12} and function, such as memory, were undertaken. There was no clear effect of the vitamin D repletion on bone mineral other than that losses of mineral were less than expected in all three groups, based on extrapolation from literature sources relating body fat loss to bone mineral loss. These results therefore suggest that there may be some improvement in some specific aspects of nutritional status, but other published results cast doubt on such benefits (Damms-Machardo *et al*. 2012). Clearly, further investigations of nutritional status during weight loss with formula diet are needed.

Safety, restrictions on use and monitoring

The most common minor side effects occurring while following VLCD and LCD programmes are constipation, flatulence, feeling cold, dizziness, fatigue and headache (Christensen *et al*. 2011a, 2011b). In the Swedish sleep apnoea study, 1 in 30 was affected by acute gout and 1 in 20 subjects had an acute gallstone event in the weight maintenance period after using a VLCD (Johansson *et al*. 2011), whereas in other trials no gallstone events occurred. A survey of 6361 'person-years' of exposure undertaken by the Swedish group showed that the risk of gallstones was low at 44 per 1000 person-years during or after a VLCD and 15 per 1000 person-years after a 1200 kcal/day diet (threefold greater risk after a VLCD than after a 1200 kcal/day conventional reducing diet) (Johansson *et al*. 2013b).

Lean mass loss was 30% of weight lost after 16 weeks of a VLCD in people with type 2 diabetes, but this was reduced to 20% in the VLCD plus intensive exercise group (Snel *et al*. 2012). In the *CarOT* trial, elderly people with knee osteoarthritis had lean losses of about 14% after 8 weeks of formula diet loss, followed by an 8-week 1200 kcal/day diet, and around 10% after a year of diet maintenance (one formula product per day). Thus, suggesting that being freed from the immobilisation caused by arthritis can be as important in limiting lean mass loss as adding exercise for those with full mobility (Christensen *et al*. 2011b).

Formula diet programmes have largely been investigated in younger adults. The *CarOT* trial (Christensen *et al*. 2011a), designed as a 'pragmatic' trial, was the first to set no upper age limit, with some subjects aged over 70 years at entry, and demonstrated lower than expected lean mass losses. Nevertheless, while common sense suggests that the elderly, being at risk of sarcopenia, ought to be treated gently with more generous energy intakes, the *CarOT* trial showed that a VLCD or LCD gave a good initial weight loss with good lean retention and resulted in longer distances walked in the 6-minute walk test. There is little or no research on formula diet use in older adolescents, but with increasing numbers of severely obese adolescents there is a clear need. Formula diet is only used in this group when requested and intensively managed by a paediatrician and specialist dietitian.

The standard diet used in pre-op 'liver shrinkage' diets provides 1000 kcal/day, but for the super-obese this is a big step down from their baseline intake and, though not yet investigated by formal trials, we start the super-obese on 1500 kcal/day, stepping down to 1200 kcal/day after several weeks, then to 1000 kcal/day when necessary. Commercial diet programmes have strict protocols that must be followed to prevent use of VLCDs by adolescents; pregnant and lactating women; those with severe mental illness, and heart, liver or kidney disease; and those using a vast range of drugs with side effects that may theoretically be enhanced by VLCDs.

In the UK, guidance on use of VLCDs is given in Clinical Guideline 43 (NICE 2006), with a recommendation to limit use to a maximum of 12 weeks. Guideline 43 also restated the 'best-practice' standard of aiming for 5–10% weight loss and a maximum rate of loss of 0.5–1 kg weekly, which can mean an unrealistic 40-week diet to lose 20 kg and an insufficient amount of loss to gain clinical benefit for some people. A position statement from the National Obesity Forum (NOF) (2010) did not support the 12-week limit, but neither report considered use of liquid low-energy diets or total diet replacements at 800 kcal/day, which may be as effective as VLCDs. Clinical Guideline 43 recommended that any diet of less than 600 kcal/day should be used only under clinical supervision but did not define what clinical supervision was, and the NOF suggested that a VLCD could be provided 'without GP approval' if delivered by trained and qualified people. While it is not the place of commercial providers to advise general practitioners (GPs) how to supervise those who choose to use a VLCD (Clinical Guideline 43 emphasised the need for doctors to support their patients' weight loss choices), advisory notes are provided (see Appendix 1 for more information). Overall, non-healthcare professional providers of VLCDs and LCDs have strict protocols to follow and clear demarcation of their responsibilities, working with the client/patient's GP or medical specialist when necessary.

Research needs

As the UK and indeed the world face increasing morbidity and healthcare costs from obesity-related disease, the need for a greater number of evidence-based interventions to apply in the widely differing settings – community, primary care, secondary care – requires that large-scale clinical trials incorporating health economics analysis be undertaken. Findings already published show that multi-centre studies are needed in obstructive sleep apnoea (primary care settings), in severe psoriasis (secondary care setting); osteoarthritis (primary care setting); and idiopathic intracranial hypertension (secondary care setting) (Sinclair *et al*. 2010). Areas relatively untouched by weight loss research include: urinary incontinence in women; renal failure with obesity where weight loss is needed before transplantation; post-operative recovery in obese people undergoing common routine procedures; obesity after pregnancy with or without a history of gestational diabetes; uncomplicated depression; asthma; and uncomplicated hypertension. The association of obesity with a number of tumours has prompted the start of studies on weight loss and cancer markers.

Conclusions

Formula diets, with an education and support programme, can deliver weight loss and weight maintenance of 10% of initial weight with sustained health benefit in osteoarthritis, obstructive sleep apnoea and psoriasis. Initial weight losses of 10–20 kg are associated with rapid improvement of symptoms and metabolic variables. Weight maintenance of 10% reduction of initial weight has been demonstrated in a 3-year RCT in elderly obese people with knee osteoarthritis after an initial weight loss with a VLCD or LCD and 1 year of maintenance (thus demonstrating 4 years of weight maintenance). The safety profiles are known, lean mass losses appear to be less than expected, but there is an increased risk of gallstones after VLCDs, and gout can occur. The effect on blood pressure lowering, which can occur rapidly on commencement of weight loss, means that warnings about postural hypotension and blood pressure measurement and medication adjustment need to be followed carefully, especially in older individuals. The possibility of improved nutritional status needs to be investigated in detail, especially as bone health appears to be maintained more than expected in elderly obese people with osteoarthritis. Weight loss with formula diet programmes is an underused option in weight management. However, there is already sufficient published information to justify formula diet weight loss programmes as an option in diabetes, obstructive sleep apnoea, osteoarthritis and psoriasis.

Conflict of interest

Anthony R Leeds is salaried medical director of Cambridge Weight Plan but holds no shares or share options.

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Appendix 1: An advisory note on medical aspects of using very low-calorie diets

Users of VLCDs need to be warned of the risks of gallstones and gout and to be aware of symptoms and signs. A high baseline blood urate may indicate a higher risk of developing clinical gout, but most GPs would not do an ultrasound gallbladder scan unless it was very specifically indicated. Users of formula diets need to know the potential effect on blood pressure; ensure that high blood pressure is carefully monitored; be aware of the risk of postural hypotension; seek immediate GP help if dizzy; and ensure that hypotensive agents are adjusted as necessary. Those with pre-existing constipation, diverticular disease or haemorrhoids need to be given extra dietary fibre (psyllium 3.5 g twice daily is recommended) from the beginning of the diet. Those with a history of hypothyroidism and/or iron deficiency (usually women) may be at greater risk of hair loss, and at the slightest suggestion of this side effect there may be merit in increasing the dietary step level to increase energy and protein intake. Many commonly used medications (*e.g.* statins, aspirin, inhalers, analgesics) can be left in place with reassessment of analgesic and inhaler use after weight loss, but some drug groups need to be adjusted on commencement of the diet (*i.e.* insulin, some oral hypoglycaemic agents) and during weight loss, while for others, repeated blood pressure checking (in treated hypertension) or blood testing and dose adjustment is necessary (anti-coagulant drugs and hypoglycaemic agents). Routine ECG screening, with or without repeated checks, is only recommended when there are specific pre-existing cardiological problems. Routine blood screening of liver function is indicated where there is an existing history of liver disease to establish baseline levels, since 1 in 10 formula diet users can show a transient rise of liver enzymes (Gasteyger *et al*. 2008). Liver function blood tests usually improve with weight loss as excess liver fat is cleared rapidly, and there is no suggestion from the literature, or from experience in practice, that liver function is adversely affected in the long-term. Kidney function blood tests rarely need to be done except where there is pre-existing kidney disease. Rarely, excessive sweating in very hot weather conditions combined with the low salt (sodium) intake on the diet can lead to nausea, headache, muscle cramps and disorientation due to low blood sodium.