

# clinical information brochure

# LighterLife is a UK industry leader in weight loss and weight management.

- Established, highly successful, holistic approach to significant weight loss and lifetime weight management for patients with BMI  $\geq 25$ .
- LighterLife Lite low-calorie diet or LighterLife Total very-low-calorie diet with behavioural-change facilitation to address the psychological drivers of weight gain, enabling sustainable weight management.
- Proven programmes delivered in small, single-sex groups by a national network of more than 350 qualified weight-management counsellors.
- Supported by a medical advisory board comprising expert healthcare professionals, plus an in-house medical department and support teams, to ensure LighterLife is well researched and complies with best practice, including NICE clinical guideline 43.
- Committed to working in partnership with the NHS to provide an effective solution for overweight and obesity.

For more information, please visit [www.lighterlife.com/clinical](http://www.lighterlife.com/clinical)

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# Overweight and obesity

'In recent years Britain has become a nation where overweight is the norm. The rate of increase in overweight and obesity, in children and adults, is striking. By 2050, Foresight modelling indicates that 60% of adult men, 50% of adult women and about 25% of all children under 16 could be obese. Obesity increases the risk of a range of chronic diseases, particularly type 2 diabetes, stroke and coronary heart disease and also cancer and arthritis.'

Foresight, *Tackling Obesities: Future Choices – Project Report (2nd edition)*, Government Office for Science, October 2007

## The rising cost

- NICE clinical guideline 43 estimates that the current cost of obesity plus overweight in England is £6.6-7.4 billion per year (NICE, *Obesity, clinical guideline 43/full guideline*, December 2006).
- Foresight estimates that, without action, the NHS costs attributable to overweight and obesity will rise to £10 billion per year by 2050, and the wider costs to society and business will reach £49.9 billion per year (at today's prices). (Foresight, *ibid*).
- Obese patients consult their GP at least 30% more often than lean adults, and account for approximately 30% greater prescribing costs (Campbell I, Haslam D, *Obesity*, Churchill Livingstone, 2005).
- 1.28 million prescription items were dispensed in 2008 for the treatment of obesity, which is 10 times the number in 1999 (NHS, *Statistics on Obesity, Physical Activity and Diet: England*, February 2010).
- The relative risk of type 2 diabetes in obese women is 12.7 and of hypertension is 4.2 (NICE, *ibid*).
- It has been estimated that 6.8% of all deaths in England are attributable to obesity (House of Commons Health Committee, *Obesity*, 2004).

classifying overweight and obesity		health-risk assessment			
classification	BMI (kg/m <sup>2</sup> )	BMI classification	waist circumference		
			low	high	very high
healthy weight	18.5–24.9				
overweight	25–29.9	overweight	no increased risk	increased risk	high risk
obesity I	30–34.9	obesity I	increased risk	high risk	very high risk
obesity II	35–39.9				
obesity III	40 or more				

Use BMI to assess weight alongside clinical judgement. For men, waist circumference <94cm is low, 94-102cm is high and >102cm is very high. For women, waist circumference <80cm is low, 80-88cm is high and >88cm is very high.

Source: NICE (*ibid*)

The National Institute for Health and Clinical Excellence (NICE) states that ‘assessment of the health risks associated with overweight and obesity in adults should be based on BMI and waist circumference’.

BMI does not wholly distinguish between lean and fat tissue, and this can yield inaccurate results for adults who are highly muscular. Furthermore, co-morbidity risk factors (such as type 2 diabetes, hypertension, cardiovascular disease and dyslipidaemia) for individuals of Asian and Chinese origin are applicable at lower BMIs.

Waist circumference may be used alongside BMI to assess the health risks for patients with BMI ≤35 (NICE, *ibid*).

- For more information on assessment, see the training resource for healthcare professionals at [www.nationalobesityforum.org.uk](http://www.nationalobesityforum.org.uk).

The rise in obesity and its complications threatens to bankrupt the healthcare system. Early intervention and prevention offer multiple long-term health benefits, and they are the only way towards a sustainable health service.

Haslam D, Sattar N, Lean M. *British Medical Journal* 2006 Sept 23; 333:640-642

# Options for treatment

NICE acknowledges the complexity of managing overweight and obesity.

NICE clinical guideline 43 on the prevention, identification, assessment and management of overweight and obesity is based on the best currently available evidence of effectiveness. It aims to tackle the rising prevalence of obesity in England and Wales, where 37% of English and 36% of Welsh adults are overweight and 24.5% of English and 21% of Welsh adults are classed as obese (NHS, *ibid*; Welsh Health Survey, 2007). The guidance has recently been adopted by Northern Ireland, where 60% of adults are overweight and around one in five are obese (Northern Ireland Department of Health, Social Services and Public Safety).

Current treatment options recommended by NICE:

- Lifestyle changes
- Low-calorie diets (LCDs)
- Pharmacological interventions
- Very-low-calorie diets (VLCDs)
- Surgical interventions

NICE recommends an integrated approach to weight management. It states that primary care organisations and local authorities should recommend to patients, or consider endorsing, commercial weight-management programmes if they follow best practice by:

- Helping people assess their weight and decide on a realistic, healthy target weight.
- Focusing on long-term lifestyle changes.
- Being multicomponent, addressing both diet and activity; offering a variety of approaches.
- Using a balanced, healthy-eating approach.
- Recommending regular physical activity (particularly activities that can be part of daily life, such as walking or gardening) and offering practical, safe advice about being more active.
- Including some behaviour-change techniques, such as keeping a diary and advice on how to cope with 'lapses' and 'high-risk' situations.
- Recommending and/or providing ongoing support.

All of the above recommendations are integral to LighterLife's programmes, through group sessions, literature and online resources, underscored by several fields of expertise which are available through various channels to LighterLife patients.

# NICE clinical recommendations

Both the LighterLife Total very-low-calorie diet (VLCD) and the LighterLife Lite low-calorie diet (LCD) are in line with NICE clinical recommendations, which recommend the use of VLCD and LCD as a suitable treatment option for obesity and overweight.

- *'Low-calorie diets may also be considered, but are less likely to be nutritionally complete.'* The LighterLife Lite low-calorie diet is nutritionally balanced, combining conventional food with fortified formula foods to provide key nutrients during weight loss (see pages 6, 9-10).
- *'Very-low-calorie diets may be used for a maximum of 12 weeks continuously, or intermittently with a low-calorie diet (for example, for two to four days a week), by people who are obese and have reached a plateau in weight loss. Any diet of less than 600 kcal/day should be used only under clinical supervision.'* The LighterLife Total very-low-calorie diet is available for suitably obese patients following GP assessment, is clinically supervised and is followed for no more than 12 weeks continuously (see pages 6, 11-12, 19).
- *'In the longer term, people should move towards eating a balanced diet, consistent with other healthy eating advice.'* LighterLife's weight-management programme is based around healthy, balanced eating principles, according to national guidelines (see pages 7-8).

Source: NICE, *ibid*, pp48-49.

Weight-management programmes should include behaviour-change strategies to increase people's physical activity levels or decrease inactivity, improve eating behaviour and the quality of the person's diet, and reduce energy intake.

NICE, *Obesity, clinical guideline 43*, 2006

# LighterLife: obesity treatment and prevention

LighterLife offers weight-management programmes for patients with BMI  $\geq 25$ .

LighterLife's multi-component programmes address behavioural change, healthy eating and increased physical activity, with the emphasis on identifying personal psychological drivers of obesity and overweight. This enables patients to achieve a healthier and manageable BMI by making sustainable changes to the way they eat, think and live.

## Weight loss

- LighterLife Total – a very-low-calorie diet (VLCD) for obese patients (BMI  $\geq 30$ ) or for women/men with BMI  $\geq 28$ -29.9 and a waist circumference  $>88\text{cm}/102\text{cm}$ , using four nutritionally complete Foodpacks (including soups, shakes, porridge and bars) per day.
- LighterLife Lite – a low-calorie diet (LCD) for overweight patients (BMI 25-29.9), combining three Foodpacks per day with a meal from a portion-controlled selection of specified healthy ingredients to provide key nutrients and energy during weight loss.

The VLCD and LCD are low in carbohydrate. A systematic review found low-carbohydrate diets were more effective at 6 months and as effective, if not more, as low-fat diets in reducing weight and cardiovascular disease risk up to 1 year; furthermore, the attrition rate was higher in low-fat compared with low-carbohydrate groups (Hession et al, 2008).

LighterLife weight-management counsellors work with patients in single-sex, weekly groups (maximum 12) to facilitate TCBT: techniques from transactional analysis (TA) and cognitive behavioural therapy (CBT) developed for behaviour modification in weight management. TCBT enables patients to review their reasons for weight gain, and explore eating patterns, physical activity levels and beliefs about these areas (page 13). This facilitates readiness to adopt change and confidence in making long-term changes. Medically orientated weight-loss programmes involving behavioural interventions, CBT and group support are typically associated with improvements in mood (Foster GD, Wadden TA, 2002; Wadden TA et al, 2002).

LighterLife aims to help people with their relationship with food, regain control of their diet and rebuild a more positive approach to food, weight and life in general.

Lyndel Costain: state-registered dietitian, nutritionist and health writer

- As an organisational member of the British Association for Counselling and Psychotherapy (BACP), LighterLife is bound by its ethical framework for good practice and its ethical guidelines for researching both counselling and psychotherapy.
- LighterLife is a member company of the British Nutrition Foundation and a supporter of the National Obesity Forum and the Association for the Study of Obesity.
- LighterLife is an Investor in People.

### Weight stabilisation

Following weight loss, patients undertake a carefully structured reintroduction to a full range of conventional food to help them stabilise their weight safely and effectively. Research published at the International Congress on Obesity (ICO) 2010 demonstrated that, following a mean 29.2kg weight loss on VLCD, women experienced no significant change in weight or BMI during a 12-week food reintroduction (Hallam C et al, 2010a).

Patients continue to be supported by TCBT in weekly group meetings, and are encouraged to monitor their food intake and reflect on their thoughts and feelings around food. This encourages greater understanding of the motivation to overeat and enables the development of strategies to deal with high-risk situations and lapsing.

### Weight management

When patients have completed the food reintroduction stage, LighterLife's Management programme supports ongoing change, both physical and emotional, to enable sustainable weight management and a reduction in the risk of weight-associated co-morbidities.

A range of support resources is available to weight-maintaining patients, including continued TCBT work in free group meetings and regular weight checks. Literature and internet resources focus on healthy eating, and continue the emphasis on a more active lifestyle and personal-development work to reinforce more helpful patterns of thinking and behaving.

## LighterLife for Men

In England in 2008, 42% of men were overweight and 24% were obese (NHS, *ibid*). However, with most weight-loss programmes designed for and used by women, men demonstrate a marked reluctance to utilise the help they offer. To address this, since 2007 LighterLife has offered LighterLife for Men, with men-only groups. It offers a VLCD or LCD with behaviour-modification work in small groups to enable long-term weight management, with ongoing support after the weight-loss phase. The men-only meetings enable a platform for focus on male-specific weight issues.

What's impressive about LighterLife is that it's not just weight reduction being induced, but behavioural changes being taught, and background information and advice being offered. New habits are formed which will last much longer than the actual programme itself, and that's very important. The results I have seen from my patients on LighterLife are very impressive.

Professor David Haslam, GP and Chair of the National Obesity Forum

### Supporting lifestyle change

Through the use of TCBT, LighterLife aims to help patients make the psychological and emotional shifts that are vital to implementing and sustaining the lifestyle changes necessary to maintain a healthier weight.

The importance of developing a more active lifestyle and undertaking a minimum of 30 minutes of moderate physical activity at least five days a week are emphasised. Formerly obese patients are encouraged to be moderately active for 60-90 minutes a day (Department of Health, 2004) to help avoid weight regain.

Advice and information on how to safely increase levels of physical activity and form new exercise habits is given, and motivational issues are explored. Information is provided on the importance of:

- Setting realistic goals for being more active.
- Developing a more active lifestyle through more everyday movement (such as walking), as well as structured exercise such as swimming or sports.
- Undertaking a combination of stamina, strength, flexibility and mobility exercises.

In the Management programme, the Food Standards Agency's eatwell plate forms the basis of the healthy, balanced, varied and sustainable diet that patients are encouraged to adopt, alongside the government's five-a-day initiative for fruit and vegetable consumption, Dietitians In Obesity Management (DOM UK) servings-size guides for weight management and strategies for healthy shopping, cooking and eating out.

Guidance is given on tailoring choices to individual needs, healthier food choices and preparation, as well as portions for different food groups. This is in line with recommendations in NICE clinical guideline 43 that 'dietary changes should be individualised, tailored to food preferences and allow for flexible approaches to reducing calorie intake' (ibid, pp48).



Just Eat More  
(fruit & veg)

# LighterLife Lite LCD

The LighterLife Lite low-calorie diet (LCD) enables safe, effective weight loss for patients with BMI 25-29.9.

Factors known to hinder successful weight management include:

- Ignorance of portion sizes.
- Frequency of eating.
- Overconsumption of energy-dense foods – some individuals may underestimate energy content by up to 50% (Wal JS et al, 2007).

LighterLife Lite addresses these factors by replacing two main meals with three fortified Foodpacks, with patients selecting their third meal from a range of specified, portion-controlled, healthy ingredients. Three Foodpacks plus the meal provide a daily intake of 800-1200 kcal.

On an energy-restricted diet for weight loss, there is a need to incorporate fortified foods for adequate essential nutrient intake (Ashley JM et al, 2007). On LighterLife Lite, patients have a reduced risk of inadequate vitamin and mineral intake during weight loss, with three fortified Foodpacks providing 75% of recommended daily allowances (RDAs) for key vitamins and minerals, plus a minimum of 37.5g protein, 37.5g carbohydrate and 7.5g fibre, and an average of 11.9g fat. The remaining nutrients are obtained from the daily meal.

The advantages of meal replacements are ease of use, convenience and built-in portion control (Cheskin LJ et al, 2008). Additionally, meal replacements are nutritionally adequate, encourage a regular eating pattern and enable patients to incorporate conventional foods into their diet (National Obesity Forum, 2009). Meal replacements are an approximate form of treatment for inclusion in the practitioner's overweight and obesity 'toolbox' (Heymsfield S, 2010).

## Improved weight loss

Subjects on a meal-replacement diet lost significantly more weight than those on self-selected conventional food diets with comparable macronutrient make-up (Ditschuneit HH et al, 1999). In a study comparing weight loss from meal replacements versus standard food in type 2 diabetics, those on meal replacements had significantly improved weight loss after 8.5 months. They were 6.5 times more likely to lose 10% of their initial body weight at the end of the active weight-loss phase. Therefore, the role of meal replacements may be considered in patients requiring weight loss, such as those with type 2 diabetes (Cheskin LJ et al, 2008).

Traditional and meal-replacement low-calorie diets demonstrate significant long-term weight loss at one year. Meal replacements result in a greater weight loss than observed in traditional reduced-calorie diets: approximately 7-8% compared with 3-7%. They are a safe and effective alternative to promote sustained weight loss and parallel health benefits (Heymsfield S et al, 2003).

Overall, meal replacements have a greater weight loss than that observed in traditional reduced-calorie diets. They are a safe and effective alternative to promote sustained weight loss and parallel health benefits.

Heymsfield S et al, *International Journal of Obesity and Related Metabolic Disorders* 2003;27(5):537-549

### Meal options

Structured meal plans provide simplicity and may also improve compliance. Patients have daily portion-controlled meals from a range of specified ingredient choices to ensure energy and nutrient requirements are met.

Advice on healthier cooking and food preparation is given to facilitate patients' ability to move to a healthy, varied and balanced diet. Salad, vegetables and dairy options can be used as a meal accompaniment and also as a snack. Provision of prepared meal structures enhances success because patients know exactly what to eat, when and how often.

Additional advantages of conventional meal options include:

- Ingredient choices for the conventional structured daily meal can fit into family meals.
- Inclusion of conventional food can alleviate boredom and taste fatigue in comparison to total dietary replacement.

The role of meal replacements in weight management has been evaluated in several studies. When comparing traditional food diets for weight control or reduction, those on meal replacements may experience:

- Better adherence or compliance.
- Greater weight loss.
- Convenience and ease of use.
- Easier portion control.

Dieting for weight control is difficult to adhere to, and some patients have difficulty in the long term. Adherence or compliance is easier on meal replacements compared to standard, self-managed, energy-restricted diets for weight loss, and thus may facilitate greater weight loss. This is very useful for those who have difficulty in achieving weight loss. It may have additional advantages in the control of overweight/obesity co-morbidities, such as type 2 diabetes (Cheskin LJ et al, 2008).

LighterLife research published at ICO 2010 demonstrated a mean weight loss of 7.1kg (9.4%) in 8 weeks for women on the LighterLife Lite LCD (Hallam C et al, 2010b).



# LighterLife Total VLCD

The LighterLife Total very-low-calorie diet (VLCD) enables safe, effective weight loss for patients with BMI  $\geq 30$  or with BMI 28-29.9 and waist circumference  $>88\text{cm}$  (women) and  $>102\text{cm}$  (men).

Despite the development of pharmacological and surgical treatments, dietetic treatment is still the basic therapeutic tool against obesity (Ayyad C, Andersen T, 2000). A VLCD with active follow-up treatment is one of the better treatment modalities related to long-term weight-maintenance success (Saris WH, 2001).

On LighterLife Total, patients replace conventional food with four LighterLife Foodpacks each day. These provide a daily average of 500-600 kcal and 15.9g fat, a minimum of 50g protein and 50g carbohydrate, 10-17g fibre and at least 100% of recommended daily allowances (RDAs) for key vitamins and minerals.

Encouraging patients to abstain from conventional food using a VLCD:

- Ensures the patient receives adequate nutrition whilst losing weight.
- Ensures the patient is depleting energy stores, initially from liver and muscle glycogen stores, then from adipose and visceral fat in the medium term.
- Removes the substance of perceived addiction (as per the addiction/change model), allowing patients a reflective space to enable thinking before automatically following ingrained habits. This enables new self-awareness and the development of new skills and new, healthier habits (page 13).

VLCDs are safe and effective for achieving a significant body-weight reduction. Research published at ICO 2010 showed the mean weight loss for women following 12 weeks on LighterLife Total was 18.9kg, and for men mean weight loss after 8 weeks on LighterLife Total was 19.5kg (Hallam C et al, 2010c,d) (page 16).

It is a common belief that weight loss achieved at a slow rate is better preserved than if the weight is lost more rapidly. However, the literature shows initial weight loss is positively, not negatively, related to long-term weight maintenance.

Astrup A, Rössner S, *Obesity Reviews* 2000 May; 1(1):17-19

There are important advantages to be gained by prescribing a VLCD at the beginning of a weight-loss programme for as long as possible: weight loss is greater, both overall and in the short term, and the spectacular weight loss brought by a VLCD encourages the patients to adhere longer to the ensuing, less energy-restricted diet (Quaade F, Astrup A, 1989).

In line with NICE recommendations, LighterLife Total patients use the VLCD for a maximum of 12 weeks continuously. If they still have weight to lose to reach a healthy BMI, they may return to the VLCD following a short period on a low-calorie diet.



### Clinical improvements

The short-term use of a VLCD is effective in rapidly improving glycaemic control and promoting substantial weight loss in obese, type 2 diabetic patients. Moreover, a VLCD increases insulin sensitivity and reduces substrate for gluconeogenesis. Thus VLCD treatment may improve glycaemic control by factors more than energy restriction alone (Capstick F et al, 1997). 'Considering the effectiveness of VLCDs in promoting fat loss and improving the metabolic syndrome, discounting or condemning their use is unjustified' (Volek JS et al, 2005).

As a general rule, blood pressure (BP) reduces by 1mm systolic and 2mm diastolic for each 1% reduction in weight (Jung RT, 1997). On VLCDs, studies have shown reductions in systolic BP of 8-12% and in diastolic BP of 9-13% (Anderson JW et al, 1992).

Many obese women experience menstrual irregularities. Obesity causes pregnancy complications and is associated with foetal abnormalities, extended labour and postnatal complications; it is strongly associated with fatal, post-menopausal breast cancer. On a VLCD, there can be a return to regular cycles, and weight loss is recommended as the primary intervention in the treatment of infertility and polycystic ovary syndrome for obese women (Pasquali R et al, 2003).

Pre-operative weight loss with VLCDs does not compromise the immune status of patients, and it is suggested that all patients with morbid obesity undergoing elective surgery should be given the opportunity to reduce weight pre-operatively (Pekkarinen T, Mustajoki P, 1997).

**Comprehensive VLCD programmes produce the large and rapid weight losses needed for medically compromised obese individuals, and the combination of monitored VLCDs with intensive lifestyle education is an excellent choice for the treatment of obesity before opting for surgical intervention.**

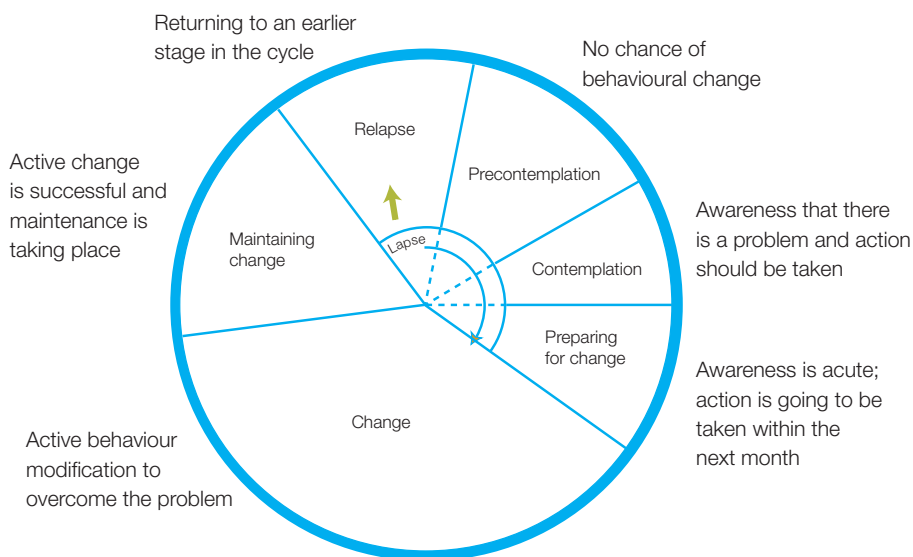
Anderson JW et al, *American Journal of Gastroenterology* 1992 Jan; 87(1):6-15

# Behavioural change

LighterLife group work integrates techniques from cognitive behavioural therapy, transactional analysis and change models (TCBT) to enable patients to change their relationship with food.

An integral part of LighterLife is work in small, single-sex groups with a maximum of 12 patients, led by a LighterLife weight-management counsellor. The group work uses structured activities, based around techniques developed for the treatment of obesity and overweight from cognitive behavioural therapy, transactional analysis and change models (TCBT).

- Cognitive behavioural therapy (CBT) techniques encourage the development of rational, realistic thinking, as opposed to dichotomous thinking, and are well suited to group work.
- Transactional analysis (TA) techniques explain how listening to messages and rules from the past can influence current behaviour, including choices around food and lifestyle.
- LighterLife primarily uses Prochaska and diClemente's cycle of change model, which is the generic model for many addiction therapies, including smoking cessation. LighterLife recognises the importance of maintaining change, with group work focusing on building patients' skills to maintain long-term change.



Interventions [that] simultaneously inform, shift motivation and provide the necessary skills are more likely to lead to behaviour change.

Foresight, Tackling Obesity, October 2007

TCBT gives patients an opportunity to develop awareness of some of the ways in which they have used food (and drink, including caffeine and alcohol) in the past to suppress or avoid difficult emotions. Core concepts include:

- Creation of a reflective space to consider both emotional and behavioural responses in order to interrupt the impulse/action reactions as outlined in change models.
- Goal setting, planning and experiments, and the use of thought logs from CBT. This enables patients to identify irrational thinking patterns that lead to difficult emotional responses and which, in turn, can result in the inappropriate use of food.
- Identification of ego states as outlined in TA that link with overeating responses. Patients are encouraged to use their 'Adult' ego state to enable realistic choices around food.
- Challenging self-fulfilling beliefs, including familial/social messages around the body and food that impact self-esteem and emotional responses, and might lead to overeating.
- Development of self-supporting responses to perceived pressures to eat inappropriately.

## LighterLife weight-management counsellors

LighterLife's programmes are delivered by a national network of more than 350 licensed weight-management counsellors, backed by a central team including a medical advisory board (see right), alongside nursing and nutrition advisors, and psychotherapist support. LighterLife weight-management counsellors:

- Undergo four months' training before being awarded a licence to practise. Each holds a BTEC professional certificate or diploma in Weight-Management Consultancy, awarded by Edexcel and of equal educational standard to a foundation degree. They also undertake continuing professional development courses each year.
- Are trained in working with weight issues through the use of group activities, including: difficulties in knowing the boundaries between physical and psychological hunger; the use of food to manage emotions and/or maintain a large body size as protection; and difficulties in maintaining self/other boundaries.
- Have a coaching role. They use TCBT with basic counselling skills in the groups to facilitate personal development but do not undertake one-to-one counselling.

# Safety and efficacy

To ensure LighterLife is well researched, safe and complies with best practice, we are supported by expert teams.

These include a medical advisory board of experts in obesity, metabolism, endocrinology, clinical nutrition and psychology, chaired by Professor David Haslam, a Hertfordshire-based GP and Professor in Obesity Sciences at Robert Gordon University, Chair of the National Obesity Forum, Physician in Obesity Medicine at the Centre for Obesity Research at Luton and Dunstable, and a member of the Counterweight Board. Professor Haslam took charge of formulating the guidelines for obesity management in primary care and helped develop the guidelines for childhood obesity management in primary care.

LighterLife's Medical Director is Professor Iain Broom, Professor of Clinical Biochemistry at Robert Gordon University and Professor of Metabolic Medicine at the University of Aberdeen. Until his recent retirement from the NHS, Professor Broom was deputy director of the surgical nutrition and metabolism unit in the department of surgery and clinical biochemistry at Grampian University Hospitals NHS Trust. He is chair of the Counterweight Programme and director of the Centre for Obesity Research and Epidemiology at Robert Gordon University.

## VLCD safety

The safety and effectiveness of VLCDs has been assessed by detailed examinations, including:

- NICE** Obesity: guidance on the prevention, identification, assessment and management of overweight and obesity in adults and children, clinical guideline 43, London, 2006
  - SCOOP** Reports on tasks for scientific cooperation. Collection of data on products intended for use in very-low-calorie-diets. Report of experts participating in task 7.3, 2002
  - COMA** Committee on Medical Aspects of Food Policy, The Use of Very Low Calorie Diets in Obesity, Report on Health and Social Subjects No 31, HMSO London, 1987
- 'While patients are on a VLCD, providing they maintain reasonable fluid intake there is no real insult to the kidneys, there is no harmful effect on the liver and there is certainly not an increased CV risk' (Professor Iain Broom).
  - Concern over potential protein loss is addressed by a study that demonstrated no evidence of any significant loss of protein during acute weight loss (Jebb SA et al, 1998).
  - Weight reduction is mainly due to reduction in body fat, and the loss of lean body mass is considered not to be larger than acceptable (Hoie LH et al, 1993) (see also page 16).
  - There were no observed symptoms, arrhythmias or changes in cardiac-condition intervals in obese patients who lost over 20kg on a 16-week VLCD (Doherty JU et al, 1991).

# LighterLife research

LighterLife has an extensive research programme and gathers evidence through service evaluation.

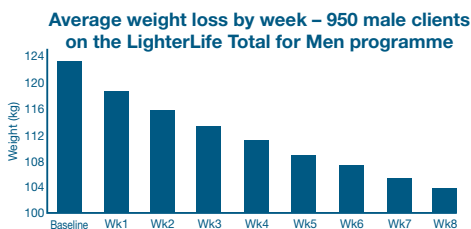
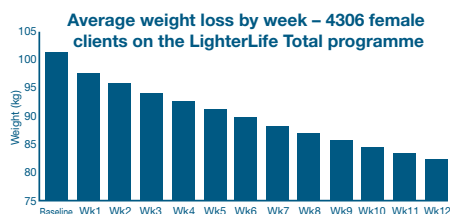
LighterLife regularly presents research at European and international congresses and has recently completed a randomised control trial (RCT) in conjunction with Robert Gordon University, as well as running successful trials in partnership with the NHS.

In a recent randomised clinical trial in patients with BMI >35, greater weight loss and improved cardiovascular risk were achieved with the LighterLife Total VLCD compared with a low-fat, reduced energy diet and a low-carbohydrate/high-protein (LCHP) diet (Rolland C et al, 2009). Significantly greater improvement in total cholesterol, LDL cholesterol, fasting glucose and diastolic blood pressure was seen at three months in patients on the LighterLife VLCD compared with the LCHP, although these differences were no longer significant at nine months, with the exception of fasting glucose.

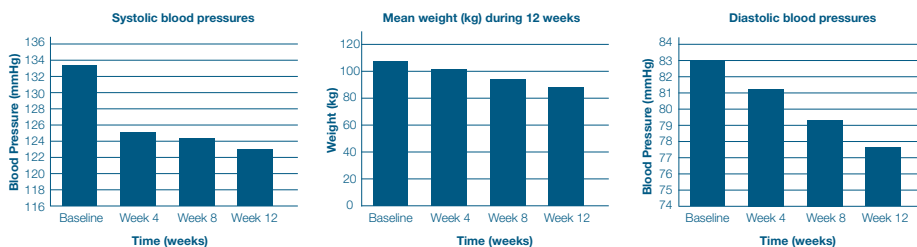
Changes in fat mass and fat-free mass demonstrated that most of the weight loss in both diets was attributed to loss of fat mass while preserving lean body mass. During the screening period prior to randomisation, 85% of participants had failed to achieve >5% weight loss on a low-fat, 600 kcal-deficit diet, which suggests the need for a wide variety of dietary approaches to weight loss.

RCTs examined by NICE from 1990-2005 considered a variety of weight-loss approaches (NICE, CG43 full guideline, 2006, pp425-430). At one year, average weight loss was 0.3-4.4kg. The greatest weight loss reported in any group examined was 11.7kg at 15 months.

LighterLife compares very favourably, with data presented at ICO 2010 demonstrating a mean 19.5kg weight loss achieved by 950 obese men after 8 weeks on the LighterLife Total VLCD and a mean 18.9kg weight loss achieved by 4306 obese women after 12 weeks on the VLCD (Hallam C et al, 2010c,d). With body-weight reductions well in excess of 10% (18.7% for women, 15.8% for men), this will improve health outcomes by decreasing the risk of weight-related co-morbidities.



This is also demonstrated in a LighterLife study published at ECO 2009, looking at the effects of weight loss on hypertension, a known cardiovascular risk factor which is recognised as being secondary to obesity (Sattar N, Lean M, 2007). A cohort of 200 male and female patients participating in the LighterLife Total VLCD underwent monthly blood-pressure checks with their healthcare provider. After 12 weeks on the VLCD, patients had a mean weight reduction of 19kg and a concomitant, significant reduction in systolic and diastolic blood pressure of 8.6% and 6.6% from baseline, which may prevent and/or attenuate co-morbidities, including possible future cardiovascular insults (Salsbury J et al, 2009).



The rapid weight loss associated with a VLCD such as LighterLife Total is also helpful in motivating individuals to start increasing their activity levels. In studies presented by LighterLife at ECO 2008 (Mullins G et al, 2008), self-reported data from a sample of 100 female patients after 12 weeks on LighterLife Total demonstrated significant improvements in ease of climbing stairs and walking one mile.

### Significant weight loss for patients with BMI $\geq 50$

Super-morbidly obese patients (BMI  $\geq 50$ ) represent a significant challenge in terms of weight loss and long-term weight management. NICE recommends bariatric surgery as the first-line treatment for these patients, where surgical intervention is appropriate, as this group is in the most urgent need of rapid weight reduction, yet has difficulties in achieving this by pharmacological agents or calorie-deficient diets. In research published at ICO 2010, LighterLife reported on a sample of 432 super-morbidly obese patients. Following 12 weeks on the Total VLCD, a mean weight loss of 23.5kg was achieved. This represented a BMI reduction of 8.5 and a 15.6% reduction in body weight, and demonstrated that significant and rapid weight loss can be achieved in this group, with LighterLife's group support and behavioural-modification work facilitated in those groups possibly being factors in maintaining compliance with the VLCD (Hallam C et al, 2010e).

A two-year follow-up of 502 formerly obese male and female patients after an initial weight loss of 24.8kg (a mean 24.7% reduction in body weight) on the LighterLife Total VLCD was also presented at ICO 2010. After two years, 86% of patients participating in the LighterLife weight-maintenance programme (page 7) were maintaining a 5% weight loss, 77% were maintaining a 10% weight loss and 32% maintaining a 20% weight loss (Hallam C et al, 2010f).

# Contraindications

LighterLife strives to ensure patient suitability and safety for its weight-loss programmes.

## Absolute contraindications:

- Epilepsy, seizures, convulsions (except febrile convulsions)
- Type 1 diabetes
- Porphyria
- Total lactose intolerance
- Heart failure, arrhythmia, valve disease requiring treatment
- Major depressive disorder, schizophrenia, delusional disorder, psychotic episode, bipolar disorder
- Severe kidney or liver disease
- Current active anorexia, bulimia or other eating disorder currently being treated or awaiting treatment
- Under 16 or over 75 years of age

## After assessment for suitability, and with GP support, patients presenting with the following may be considered for participation:

- Thrombosis requiring treatment
- Cerebrovascular disease
- Cardiac disease, including angina and MI
- Serious illness, injury, trauma and/or surgery in the last three months
- Undergoing/due to undergo any treatment, surgery, investigation and/or referral

## It may be necessary to delay a patient's commencement on LighterLife's weight-loss programmes if they:

- Have had a serious illness, injury, trauma and/or surgery in the last three months
- Are undergoing/due to undergo any treatment, surgery, investigation and/or referral
- Are pregnant
- Have given birth in the last three months
- Are breastfeeding as the baby's main form of nutrition
- Have miscarried at more than 20 weeks' gestation within the last three months

# Clinical monitoring

Supporting your patients if they wish to participate in LighterLife's weight-loss programmes

## Initial assessment

Because of VLCD/LCD contraindications, we review every patient's medical history and seek to exclude those with such medical conditions.

- A patient's self-declared history is assessed by their LighterLife weight-management counsellor and LighterLife's medical department via an initial health questionnaire.
- LighterLife Total VLCD patients who appear suitable after their initial check are then required to complete a brief health questionnaire with their GP, practice nurse or other approved healthcare professional to confirm their self-declared history. This questionnaire examines past medical history for contraindication to VLCD, includes initial BP and pulse, considers the need for medication adjustment as the patient loses weight, and confirms that the patient's GP is willing to undertake such adjustments.
- LighterLife Lite LCD patients can be accepted immediately if they meet LighterLife's initial assessment criteria. For some, this assessment might highlight medical history (such as type 2 diabetes) that would merit further discussion with their GP or practice nurse.

**Signing our health questionnaires confirms that the information provided is true to the best of your knowledge. It does not transfer medical responsibility for the LighterLife Total VLCD or LighterLife Lite LCD to a GP, practice or employer.**

## During LighterLife Total (VLCD)

If the patient is on medication that is likely to require adjustment, a monthly BP check should be carried out by the patient's practice\*. Otherwise, healthy patients can have this check carried out anywhere that provides a BP service: for example, by a practice nurse, pharmacist or other healthcare professional. Many LighterLife weight-management counsellors provide an in-house, clinical-monitoring service for healthy patients, run by registered nurses.

## During LighterLife Lite (LCD)

Patients on medication or with a significant medical history will require support from their GP practice for participation in LighterLife Lite. We would be grateful if you would verify their health questionnaire and make any medication adjustments as required\*.

\*Patients are aware that a charge might be levied for these services and that it is their responsibility to pay this directly.



# Medication adjustment

Because there can be rapid changes to weight, blood pressure and glycaemic control on LighterLife's weight-loss programmes, medication adjustment should be considered.

Medication requirements can reduce dramatically with rapid weight loss; reductions in blood pressure, serum lipids and serum glucose during VLCDs result in significant cost savings due to the substantial number of patients able to discontinue medication (Anderson JW et al, 1992). Similar considerations may need to be taken for patients on the LighterLife Lite LCD.

## Diuretics

Diuretics can alter electrolyte balance, which may result in a medication review, depending on mode of therapy.

## Hypertension

As a general rule, BP reduces by 1mm systolic and 2mm diastolic for each 1% reduction in weight (Jung RT, 1997), thus a review of anti-hypertensive medication may be required.

## Hyperthyroidism

Monitor, as adjustment may be required with weight loss.

## Prescribed weight-loss drugs

Prescribed weight-loss drugs should not be required during VLCD/LCD. Orlistat should be stopped prior to commencement.

## Drugs for angina

Continue as pre-diet; possibly decrease with weight loss.

## Steroids

Continue as pre-diet.



VLCDs have no serious harmful effects and can safely be used in patients with various chronic diseases... In type 2 diabetes it may improve long-term glucose metabolism better than conventional weight-reducing diets.

Mustajoki P, Pekkarinen T, *Obesity Reviews* 2001 Feb; 2(1):61-72

Patients with type 2 diabetes can respond exceptionally well to a reduced-carbohydrate diet and the LighterLife Total VLCD certainly falls into this category. Such alterations in dietary CHO can have a major impact on glycaemic control and on weight loss, which has always proved a major challenge in such patients.

Professor Iain Broom, Robert Gordon University,  
University of Aberdeen, LighterLife Medical Director

### Type 2 diabetes

Overall glycaemic control improves with a VLCD/LCD. Research shows that reduction of hypoglycaemic agents should be considered before or at initiation of the VLCD/LCD, leading to possible discontinuation on assessment of blood glucose results (Anderson JW et al, 1992; Mustajoki P, Pekkarinen T, 2001). Patients with type 2 diabetes can benefit from being on LighterLife's reduced-carbohydrate VLCD or LCD, mainly due to the reduction of visceral fat. Providing there is a problem with patients' weight, and this is hindering their diabetic control, reduced-carbohydrate diets can effect marked changes in their diabetic control: on some occasions this may enable patients to cease all drug treatment and insulin. Substantial weight loss and improvement in cardiovascular risk factors was proven to be maintained for one year in type 2 diabetics by the use of a VLCD (Paisey RB, 1998).

An initial titration management plan should be in place with a patient's diabetologist, GP or diabetic specialist nurse **prior** to commencement of the VLCD/LCD, due to the rapid change in blood glucose which can occur. Secondary care obesity specialist providers prescribing VLCD/LCD intervention for type 2 diabetes recommend an initial titration plan as follows:

### Oral hypoglycaemics

- Sulphonylureas: consider cessation upon commencement of diet.
- Metformin: no change required.
- Thiazolidinediones: consider cessation when HbA1c <7%.
- Newer agents such as gliptins and exenatide can be continued initially but may require reduction in the medium or long term.

### Type 2 diabetes with insulin

- An initial reduction of at least 50% in all forms of insulin is often required.
- In some cases, insulin is discontinued or replaced (for example, by exenatide) at commencement of the VLCD/LCD.
- In addition, it is recommended that self-monitoring of blood glucose is undertaken, and that insulin requirements are managed as appropriate.

## Side effects

Side effects of a VLCD/LCD are temporary. It is important that patients experiencing any side effects are supported, to enable them to finish the short period of VLCD/LCD.

### Potential initial side effects (usually confined to first week of diet)

- Headache or dizziness Due to carbohydrate withdrawal or dehydration. Give analgesic, promote fluids, check BP.
- Hunger Should subside with onset of ketosis. Ketosis is associated with appetite suppression.
- Nausea and diarrhoea Increased supply of vitamins and minerals from Foodpacks may not be initially tolerated; possible lactose intolerance.

### Minor side effects

- Constipation Ensure adequate fluid intake and suggest use of bulking agent.
- Cramps/fatigue May occur during VLCD/LCD.
- Dry mouth/halitosis Common on restricted-carbohydrate, low-fat diets. Use spray breath freshener to lessen effects of ketones on breath.
- Feeling cold May occur during VLCD/LCD due to temporary BMR reduction.
- Hair thinning Hair thinning is possible for patients on VLCD and less likely on LCD. This is a temporary but distressing cosmetic consideration. Normal hair growth resumes when energy intake increases.
- Menstrual cycle changes Some patients may experience temporary menstrual cycle changes whilst on VLCD/LCD, including amenorrhoea.

### More serious side effects

- Gout VLCD/LCD increases serum uric acid. If there is a history of gout, prophylactic treatment with allopurinol may prevent onset.

### For information

- Gallstones Gallstones are more likely to present in females, BMI >30. Any weight loss may initiate attack. If diet contains >7g fat there is no greater risk of gallstones than with other weight-loss methods. The Total VLCD provides an average 15.9g fat and the Lite LCD an average 11.9g. With cholelithiasis history, prophylactic treatment with ursodeoxycholic acid may prevent onset.
- LFTs There is no supportive evidence that LFTs increase during the onset of a VLCD. However, reintroduction of food may cause rebound increase in LFTs in some patients.

## Next steps

LighterLife can work with you to help your patients make a sustainable difference to their health.

### Referring patients

If you would like to refer a patient to LighterLife, please contact our customer care team on **inform@lighterlife.com** or on **0800 2 988 988 (UK) or 1800 927 213 (ROI)**, in order to find your nearest LighterLife weight-management counsellor.

### Programme presentations

Our weight-management counsellors and nationwide team of clinical advisors will be happy to present LighterLife's programmes to you at your practice and to answer any queries you may have.

For further information on using LighterLife to manage overweight or obesity, please contact the clinical team on **medicalcare@lighterlife.com** or on **+44 1279 636998 ext 3006**.

### Working in partnership

LighterLife can support your practice in achieving NHS targets for reducing overweight, obesity and associated co-morbidities.

Our clinical team can also help if you are interested in working with LighterLife in a private capacity to enable patients to access our weight-loss and weight-management programmes.

For further information please contact the clinical team on **medicalcare@lighterlife.com** or on **+44 1279 636998 ext 3006**.

### More information

- For more information on LighterLife's programmes, visit **www.lighterlife.com**.
- For more information on healthcare matters, visit **www.lighterlife.com/clinical**.

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■ All LighterLife's published research can be found at [www.lighterlife.com/clinical](http://www.lighterlife.com/clinical)

# clinical information



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