

Position Statement on Meal Replacement Approaches in the Management of Overweight and Obesity

Introduction

There is increasing recognition that no single dietary treatment suits all overweight and obese individuals instead treatments are best matched to suit personal preference, lifestyle factors and previous dieting experience. However it is essential that any dietary treatment considered an option in the management of overweight and obesity is supported by evidence for its efficacy and safety.

Despite extensive ‘over the counter’ availability of meal replacements and their apparent popularity among the general population, health professionals have given little attention to the potential of these approaches in the management of overweight and obesity. This may relate to concern about the value of meal replacements in long term weight management.

Over recent years a number of randomised controlled trials have been published that support the longer term efficacy of meal replacements but it is unclear to what extent this research has filtered through and influenced practitioner’s opinions on the use of meal replacements in the management of overweight and obesity.

This paper aims to

- Summarise the recent evidence on the use of meal replacements in the management of overweight and obesity
- Highlight areas of uncertainty in relation to their use in practice.

Definition of a Meal Replacement Approach

There is no official definition of the meal replacement approach and this may go some way towards explaining the uncertainty among practitioners about the use of this treatment. However a recently devised working definition states that meal replacements are generally considered to be ‘portion controlled products that are vitamin and mineral fortified and replace one or two meals in the day allowing one low calorie meal using

standard foods [and snack/s]¹. This combination of food based meals and portion controlled liquid shakes, bars and other replacement products may sometimes be referred to as a partial meal replacement plan.

A meal replacement approach will usually provide in the region of 1200-1600kcal per day and should not be confused with very low calorie diets that provide less than 800kcal/day. Very low calorie diets are used as a sole source of nutrition replacing all food based meals and snacks and can only be used for a short period of time. Meal replacements are not designed to be a complete source of nutrition and therefore are not usually recommended for use without the inclusion of foods in the diet.

Summary of Key Findings

- *Randomised controlled trials with meal replacements used as part of a well-supported programme run by specialist obesity research/university departments.*

Ditschuneit² and Flechtner-Mors³ undertook a long term, prospective randomised trial in 100 subjects with a mean BMI 34kg/m² comparing a conventional dietary treatment with a meal replacement approach over the short term [3 months] with progress monitored for the next 4 years. For the first 3 months group A [n=50] was treated with a conventional low calorie diet of 1200-1500kcal/day and group B [n=50] was advised to replace two of their three meals each day with liquid shakes and eat one self selected meal of 600-900kcal. Both groups were asked to keep food diaries, given food exchange lists and monitored monthly by a nutritionist. For the next four years both groups were given meal replacements and asked to use these in place of one meal and one snack each day. After the three month weight loss phase group A [conventional diet group] lost 1.5±0.4% whereas group B lost 7.8±0.5% [meal replacement group][p<0.001]. Over the next four years weight loss was maintained in both groups with a mean weight loss of 3.3±0.8% and 8.4±0.8% for groups A and B, respectively. This study suggests that meal replacements may encourage weight maintenance and in this instance produced better weight loss over 12 weeks.

Yip⁴ ran a short-term [12 weeks] randomised controlled trial in obese subjects with type 2 diabetes. One group was advised according to the American Diabetes Association's diet exchange plan and the other two groups given either a standard liquid meal replacement or an isocaloric liquid shake with sucrose and fructose replaced with maltodextrins. All subjects were advised to reduce energy intake by 500kcal per day. No difference was found between the two types of meal replacements in terms of weight loss, glucose, insulin, HbA1c and lipid changes. Meal tolerance testing, designed to compare the glucose and insulin response of meal replacements to that of foods, showed that meal replacements had the same effect on glucose levels as a standard food based breakfast. At 3 months the meal replacement groups lost 6.10±4.4kg compared to 4.2±4.7kg [p=0.009] in the exchange diet group. It was concluded that meal replacements were a safe and effective strategy for use in obese patients with type 2 diabetes⁴. The recent publication of 12-month findings from this study show a continued difference in weight loss between

the meal replacement group $[-4.35 \pm 5.28 \text{kg}]$ and the standard diet group $[-2.36 \pm 4.92 \text{kg}]$ ⁵. However a second 12-month study in obese diabetic patients found no significant difference in weight or glycaemic control with mean weight loss of 1.7kg in the conventional diet group compared to 2.1kg loss in the meal replacement group⁶. Nevertheless they concluded that meal replacements offered an alternative dietary treatment to more conventional approaches.

- *Research evaluating meal replacements in primary care*

An interesting study by Ashley⁷ explored the outcome of using meal replacements in a primary care setting. One hundred and thirteen women took part in a one year study and were randomly assigned to one of three groups; 1] a dietitian led group, 26 sessions, each session lasting 1 hour 2] dietitian led group, 26 sessions each session lasting 1 hour plus meal replacements 3] physician or nurse visits [10-15 minutes] plus meal replacements. Greatest weight loss was achieved by the dietitian led group using meal replacements with a mean change of $-9.1\% \pm 8.9\%$ compared to the dietitian led group where no meal replacements were incorporated. This difference remained at the 2 year follow up study⁸. The physician or nurse sessions lasting 10-15 minutes were as effective as the longer dietitian led groups where no meal replacements were incorporated $[4.3\% \pm 6.5\% \text{ vs } 4.1\% \pm 6.4\%, \text{ respectively, } p < 0.05]$.

- *Community based interventions with minimal study related support or education*

In a rural community in the USA, Rothacker⁹ set up a self managed, minimal intervention weight control programme where free meal replacement products were provided to overweight men and women $[n=158]$ and weights were checked twice a year over a five-year period. It was suggested that participants replace two meals per day with liquid shakes during the weight loss phase and to help maintain lost weight to either use one meal replacement each day or to weigh on a daily basis. If weight was regained the advice was to restart using 2 meal replacements each day. Three control subjects were selected from the surrounding area to match each meal replacement participant for age, BMI, race and gender. After 5 years mean weight change in the men using meal replacements was $-5.8 \pm 5.4 \text{kg}$ and in the women $-4.2 \pm 6.9 \text{kg}$. By comparison male controls had gained $6.7 \pm 10.2 \text{kg}$ and the females gained $6.5 \pm 10.7 \text{kg}$ illustrating the high level of background weight gain and escalating obesity. Although this is not a randomised study, it is unclear how meal replacements were used, and weight was self reported rather than measured in control subjects it does demonstrate the potential of this approach in the management of obesity within this type of community.

In an Australian 6-month study designed to evaluate over the counter usage of meal replacements with minimal health professional input this strategy was found to have a similar magnitude of effectiveness compared to a structured low fat diet¹⁰. Sixty-six subjects were randomised to receive either 2 meal replacements each day plus information on healthy food choices or were given information on a structured low fat diet plus food vouchers of an equivalent financial value to the meal replacement products

provided. At 6 months $9\pm 6.9\text{kg}$ weight loss had been achieved in the meal replacement group compared to $9.2\pm 5.1\text{kg}$ in the structured diet group. The provision of an equivalent financial incentive to the control group is an interesting design element that may have influenced the outcome of this study. Although minimal health professional support was provided it is important to recognise that subjects did have their weight checked on a fortnightly basis by administrative staff.

Efficacy of Weight Loss

A recent meta-analysis by Heymsfield¹ has examined the findings from six randomised controlled trials in which the meal replacement approach was compared to a more conventional food based dietary treatment. Four of the six studies were carried out over a one year period, one for three months and one for four years. The meta-analysis demonstrated significantly greater weight loss in the meal replacement group compared to the conventional dietary treatment. A random effects meta-analysis found a 2.54kg greater weight loss in the meal replacement group at 3 months and a 2.43kg greater weight loss at one year. A pooling analysis of completers found a similar magnitude of greater weight loss using the meal replacement treatment. They concluded that that the use of the meal replacement approach could ‘safely and effectively produce significant sustainable weight loss and improve weight-related risk factors of disease’¹

Interestingly, no difference was found in the dropout rate between the two dietary treatments at 3 months but a much lower dropout rate was observed at one year in the meal replacement group. In those with type 2 diabetes a similar high rate of attrition was observed in both dietary treatments with no significant difference in weight loss between the two dietary treatments. It seemed that type 2 diabetes was linked with greater difficulties in losing weight and particularly in sustaining weight loss at the 12 month time point.

In the recently published Australian Clinical Guidelines on the management of overweight and obesity four studies comparing meal replacement treatment with conventional low calorie diets over a 1-5 year period were evaluated. They found a mean weight loss of 6kg in the meal replacement group compared to a 1.4kg increase in the control group. Their recommendation [level B*] was that ‘clinically significant weight loss can be achieved using meal replacement programs’¹¹

Possible Mechanisms for Weight Control

It has been suggested that part of the efficacy of the meal replacement approach may relate to the structured nature of the plan and the emphasis on regular eating¹¹. The ‘pressure’ of food selection is lessened at least for two meals while maintaining an element of food choice and if supported by sufficient education can allow individuals to develop their skills in the selection of food types and portion sizes. The convenience of this strategy may prove to be very important to some individuals.

Limitations of the evidence

- The majority of clinical trials have provided meal replacement products free of charge. It is unclear what effect the purchasing of products would have on programme compliance and attrition particularly among lower socio-economic groups. There is a need for research to determine outcome when products are not freely available
- There is limited evidence relating to ‘off the shelf’ usage of meal replacements. The characteristics of people who buy and use these products, whether they seek additional support and the outcome of their use on weight loss and/or maintenance is relatively unknown
- The majority of the research that has evaluated the efficacy of meal replacements has been based in the USA and Germany with no large long-term randomised controlled trials undertaken in the UK. It is unclear to what extent these clinical trial findings will translate into the UK health care and community settings.

Conclusion

A number of randomised controlled trials do support the efficacy and safety of this dietary treatment in the management of overweight and obesity. However there is a need to undertake long term trials in the UK and particularly to evaluate the ‘real life’ outcome of using this approach within standard UK healthcare settings with the limited resources and time that are usually evident in these situations. Meanwhile DOM[UK] does support the use of meal replacements, as one of a range of dietary treatment options, in comprehensive weight management programmes. It offers an alternative to the more conventional dietary treatments and may prove beneficial for some patients.

Summary of DOM [UK] position

1. We consider that there is sufficient evidence to support the inclusion of meal replacement approaches as one of a range of possible dietary treatments for the management of overweight and obesity.
2. A number of studies have demonstrated the short-term effectiveness of meal replacements showing them to be at least as effective as conventional dietary treatments.
3. Uncontrolled studies with longer term follow up suggest that meal replacements may encourage weight maintenance
4. Most studies have used meal replacements as part of a comprehensive management programme with support and education from health professionals. Less is known about the value of ‘off the shelf’ unsupported usage.

5. More information is needed about which type of patient does best with this dietary treatment and how to integrate meal replacements within the management of overweight and obesity in the UK health care and community settings
6. Studies do support the safety of using meal replacements in overweight and obese people with type 2 diabetes although, as with weight management in general, outcome tends to be poorer compared to those without diabetes
7. Little is known about how effective this dietary treatment will prove in obese people with a BMI >45kg/m² as studies to date have included subjects in lower BMI categories.

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* Level B: Evidence obtained from at least one properly designed randomised controlled trial

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