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NUTRITIONAL SCIENCE

Weight loss in a UK commercial all meal provision study: a randomised controlled trial

D. D. Mellor,* C. Whitham,† S. Goodwin,† M. Morris,‡ M. Reid†§ & S. L. Atkin†

*Division of Nutritional Sciences, The University of Nottingham, Leicestershire, UK

†HONEI Project, University of Hull, Hull, UK

‡Clinical Sciences and Nutrition, University of Chester, Chester, UK

§Department of Psychology, University of Hull, Hull, UK

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Correspondence

D. D. Mellor, 49F North Laboratory, Division of Nutritional Sciences, The University of Nottingham, Sutton Bonnington, Loughborough, Leicestershire LE12 5RD, UK.

Tel.: +44 (0)115 951 6098

Fax: +44 (0)115 951 6122

E-mail: duane.mellor@nottingham.ac.uk

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Introduction

Obesity prevalence has reached epidemic proportions to the point that, along with its associated comorbidities, it is becoming considered as a major threat to global and economic development (Alwan *et al.*, 2011). In the UK, 25% of UK adults are obese and a further 44% of men and 33% of women are overweight [World Health Organization (WHO), 2011]. Obesity reduces both quality of life and productivity, and increases morbidity and mortality (Jebb *et al.*, 2007). Consequently, the emphasis has

Abstract

Background: Effective approaches are needed to address the increasing prevalence of overweight and obesity. The present study investigated whether all meal provision was a more effective and acceptable method for weight loss than a self-directed diet.

Methods: This randomised controlled trial recruited 112 men and women with a body mass index in the range 27–35 kg m⁻², who had no comorbidities, from the local area of Hull. Participants were randomised to receive either meal provision or follow a self-directed diet for a 12-week period that resulted in an estimated 2928 kJ day⁻¹ (700 kcal day⁻¹) deficit. A dietitian supervised both dietary interventions.

Results: At 12 weeks [mean (SEM)], percentage weight loss in the meal provision group was 6.6% (0.5%) compared to 4.3% (0.6%) for those on the self-directed diet. In terms of clinically relevant weight loss, 61% of participants lost 5% or more of their body weight with meal provision compared to 22% on the self-directed diet ($P < 0.001$). Weight loss was associated with wellbeing in both groups. Attrition was less apparent with 7% of those participants receiving meal provision withdrawing from the study compared to 41% of those following the self-directed diet ($P < 0.001$).

Conclusions: Meal provision was a more effective and accepted method for weight loss over a 12-week period compared to a self-directed diet. This may in part represent the difference between being given the meal provision food free of charge. However, longer-term maintenance studies need to be undertaken to ascertain their effects on the maintenance of weight loss.

been placed on reducing the incidence and development of obesity, which has become a major public health concern (Nishida *et al.*, 2004; Jebb *et al.*, 2007). This has led to the need to develop weight management strategies that address obesity, including the use of weight management programmes (WHO, 2011).

Previous research has found that structured weight management programmes tend to lead to more weight loss than self-directed dieting, and that this applies across a wide range of commercially available diets in the USA (Tsai & Wadden, 2005). In one UK study, the four tested commer-

cially available diets were all shown to be effective, leading to weight loss (Truby *et al.*, 2006). The Weight Watchers National Health Service (NHS) Referral Scheme database showed that, of the 29 326 people referred to a 12-week course between April 2007 and October 2009, one-third of participants achieved the 5% or more weight loss defined as clinically relevant (Jebb *et al.*, 2011). A comparison of different approaches to community based interventions in the UK also concluded that a 12-week based dedicated programme of weight management can result in clinically useful amounts of weight loss (Jolly *et al.*, 2011).

In other countries, prepared meal provision, with portion sizes and nutritional content being controlled, has been shown to lead to more weight loss than either self-directed dieting or structured weight management programmes without prepared meal provision (Haynes *et al.*, 1999; Hannum *et al.*, 2004, 2006). Typically, two types of prepared meal provision have been used: all meal or partial meal replacement. The replacement meals can be liquid shakes, bars, prepackaged meals or a combination of these. What is referred to here as 'all meal replacement' typically involves the use of packaged meals to replace the main meals of the day, usually supplemented with some additional food according to the individual's nutritional requirements. The majority of studies to date have used specially prepared meals (McCarron *et al.*, 1998; Metz *et al.*, 2000). Only one study looked at a commercial all meal replacement service in combination with dietary and physical activity counselling, reporting a greater weight loss compared to usual care (Rock *et al.*, 2010). To date, the effectiveness of a commercial all meal replacement service alone has not been evaluated and compared with that of self-directed dieting within the UK. The present study aimed to compare commercial all meal provision for weight loss with a self-directed diet where both groups are prescribed a 2928 kJ day^{-1} ($700 \text{ kcal day}^{-1}$) energy deficit.

Materials and methods

Participants were volunteers recruited by advertisement from both the University of Hull and the local area. Recruitment took place between January and March 2011 and the intervention commenced in January 2011 and ended in July 2011. Ethical permission was obtained from the University of Hull, Department of Sport, Health and Exercise Science, where the study was undertaken. The study was conducted in accordance with the Declaration of Helsinki (World Medical Association, 2008) and was registered (ISRCTN29087562). The study was funded by Diet Chef Ltd, in conjunction with Scottish Enterprise, although neither party had any input in the design, conduct or reporting of the study. Inclusion criteria for the study:

- Body mass index (BMI) in the range $27\text{--}35 \text{ kg m}^{-2}$.
- Aged between 30 and 70 years at enrolment.
- No history of diabetes or eating disorders.
- Not taking any medication likely to lead to alterations in weight.
- Not having undergone or planning bariatric surgery.
- Not planning or currently pregnant.
- Not diagnosed with any food allergy.
- Not vegan.
- Willing to attempt to lose weight for 3 months.

After provision of informed consent, participants were randomised and then attended a screening visit. Randomisation was such that participants attended only with other participants assigned to the same intervention. This was to reduce any bias from participants sharing different experiences. Randomisation was undertaken using an online generator (Jolla, 2011). A 1 : 1 treatment allocation was used and the block size of eight was not revealed before analysis of the data. The randomisation included an allowance for a 1 : 2 male : female ratio to ensure that equal numbers of each sex were in each arm of the study. Before enrolment of the first participant, the randomisation code was generated by computer. The visit schedule was arranged to avoid participants from the different intervention arms of the study meeting at the study site because this was considered to be a potential source of participant bias.

Height and weight measurements were taken at screening and those individuals outside the BMI inclusion criteria were excluded from the trial at this point. Weight was taken without shoes and participants were asked to wear similar clothing at each visit. Participants were then asked to complete four psychological questionnaires aimed at assessing the effects of weight on quality of life and psychological approach to weight loss. These were: Impact of Weight on Quality of Life Questionnaire (IWQoL-lite; Kolotkin & Crosby, 2002); The European Quality of Life Questionnaire 5D (EQ-5D; EUROQOL GROUP, 1990); Mental Toughness Questionnaire (MTQ48; Clough *et al.*, 2007); and the Rotter Locus of Control Questionnaire (Rotter, 1966).

Estimated total energy expenditure (ETEE) was calculated for all participants using Harris-Benedict equations (Harris & Benedict, 1918) and an appropriate physical activity level was determined from an activity questionnaire. A 2928 kJ day^{-1} ($700 \text{ kcal day}^{-1}$) deficit was then deducted from the ETEE to provide the recommended energy intake for weight loss, of which all participants were informed. After the estimation of energy requirement, an open disclosure of the dietary intervention was given to the participant. Because of the nature of the study, neither participants, nor researchers could be blind to the assigned intervention.

Those on the meal provision arm were given instruction on how to order their food via the Diet Chef® website (<http://www.dietchef.co.uk>). Meals were provided gratis as part of the study. All meals (vacuum packed) and snacks for a 4-week period were then delivered to the participant. There were two meal plan options [5020 J day^{-1} ($1200 \text{ kcal day}^{-1}$) and 6276 J day^{-1} ($1500 \text{ kcal day}^{-1}$)] and participants were advised by a dietitian how to add fruit, vegetables and dairy food portions to meet their prescribed individual energy intake based upon their ETEE; these additional foods had to be purchased by the participants themselves.

The self-directed arm of the study received the 'So You Want to Lose Weight for Good' booklet, (British Heart Foundation, 2009), which provides information on healthy eating and the portions of foods from each food group needed to make up their prescribed individual energy intake based on their ETEE as previously described. The study dietitian provided advice on how to meet their individual prescribed energy intake using this booklet. No food was provided for this group, and individuals had to meet the cost of their own food.

The study schedule up to 12 weeks is shown in Fig. 1, including the attrition from the study and the numbers included in the analysis.

Participants were asked to attend on four occasions: baseline, 4, 8 and 12 weeks. A dietitian was present at all visits but gave no additional dietary guidance unless considered necessary for participants' healthy nutritional status. Participants were asked to continue their normal daily physical activity, although standard physical activity advice in line with government recommendations was included for both arms. Adherence was assessed using the proxies of weight loss and attrition. It was felt that the use of food diaries or dietary recall might introduce a further source of confounding, which might further increase dropout rates.

Statistical analysis

Analyses were conducted using SPSS, version 20 (IBM, New York, NY, USA). The power analysis was based on a meta-analysis of previous studies, which indicated that a sample size of 42 would be sufficiently large to detect a

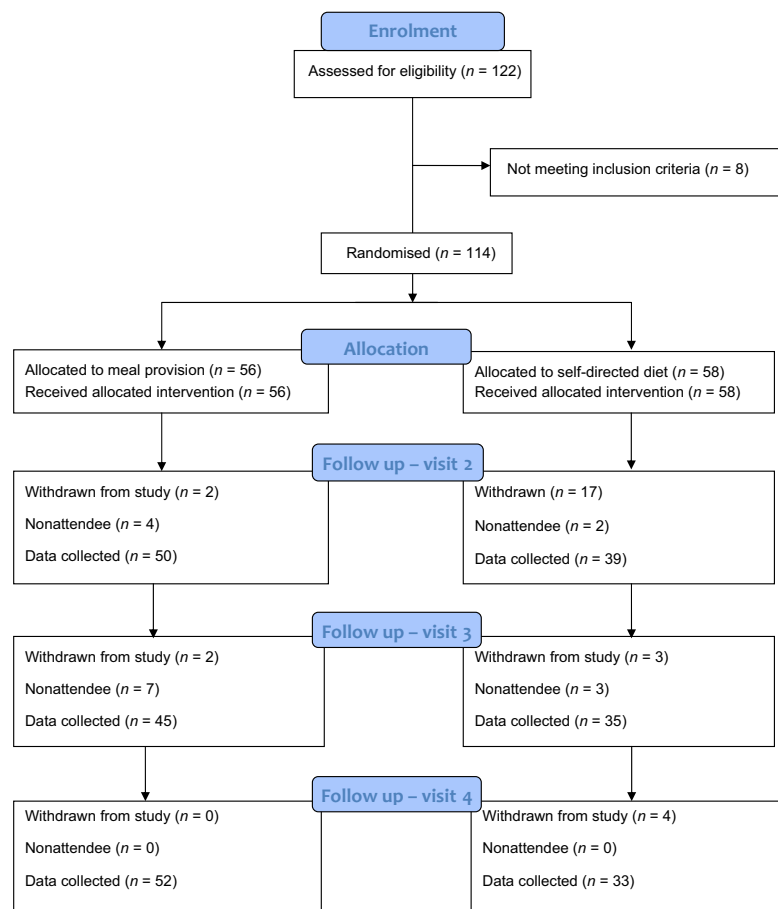


Figure 1 CONSORT statement flow diagram of participants through trial (Schulz *et al.*, 2010).

2% difference in weight loss (Franz *et al.*, 2007). Assuming an SD between groups of 3.2%, this sample size would have 80% power to detect a difference between groups (Rosner, 2010). To allow for the high attrition rate often seen in diet studies, recruitment of 120 participants was planned to allow for a 30% drop out.

All data was tested for normality using Kolmogorov–Smirnov tests, and then continuous normally distributed data were expressed as the mean (SEM). Within each treatment arm, changes in weight, percentage weight loss and BMI were calculated and compared between groups. A two-way mixed model analysis of variance was undertaken to assess effects by intervention and time. This was followed by post-hoc testing where appropriate for significance using multiple independent *t*-tests at each time point with a Bonferroni correction to offset the risk of type 1 error. $P < 0.017$ was considered statistically significant.

Differences between withdrawal rates and the percentage of each arm achieving 5% or greater weight loss were tested using chi-squared. Data for percentage weight loss and questionnaires was undertaken using all available data; carrying of last observation forward or estimations for missing data were not applied. Data from the psychological questionnaires were correlated with weight loss to explore potential interactions with weight loss using Spearman's rho. Attrition and losing at least 5% of body weight were analysed on an intention-to-treat basis to account for all participants entered into the study. Missing data was therefore counted as withdrawing from weight loss, and not achieving at least 5% weight loss.

Results

Subject recruitment, attrition and completion are shown in Fig. 1: of the 122 people enrolled, eight were excluded as a result of a BMI $> 35 \text{ kg m}^{-2}$. Baseline characteristics between groups did not differ (Table 1); although the majority of participants recruited were female, there were no significant differences with respect to sex between the two arms.

At 12 weeks, attrition was 41% in the self-directed arm compared to 7% in the meal provision arm ($P < 0.0001$). In total, 61% of the meal provision arm compared to 22% of the self-directed arm achieved clinically significant $>5\%$ loss of body weight calculated using an intention-to-treat analysis ($P < 0.001$).

A significant difference in percentage weight were seen at all time points between the meal provision and the self-directed arms, which is supported by the significant effect of intervention and time by the two-way mixed model analysis of variance ($P = 0.046$). At 4 weeks, the difference was 1.64% [-4.01% (0.28%) versus -2.37% (0.37%); $P < 0.001$], which increased at week 8 to 2.03% [-5.41% (0.46%) versus -3.38% (0.60%); $P = 0.008$] and at week

12 to 2.31% [-6.55% (0.52%) versus -4.23% (0.66%); $P = 0.007$]. Figure 2 suggests that there is an increase in difference between the groups, which increases over the 12 weeks of the study, with no indication of a plateauing of weight loss. There were no differences in rates of adverse events between groups, with the most common event being respiratory tract infections.

None of the baseline psychological variables were correlated with the percentage of body mass lost at week 12 (Spearman's rho). There were no differences between groups between baseline and 12 weeks; however, weight-related quality of life (IWQoL-lite), mental toughness (MTQ48) and the 100-point health state scale from EQ-5D all improved in participants completing the studies, although these changes did not significantly correlate with weight loss (Table 2). Baseline mental toughness was not predictive of 12-week outcomes and did not vary significantly across the study. The two arms did not differ on any psychological variable at baseline.

Discussion

This is the first study in the UK to demonstrate the effectiveness of all meal provision approach to weight management. From 4–12 weeks, a significant difference was seen in weight loss between the all meal provision group and the self-directed group despite both groups being prescribed a 2928 kJ day^{-1} ($700 \text{ kcal day}^{-1}$) energy deficit. This was accompanied by a significantly lower level of attrition (7% versus 41%) in the all meal provision group. This had the overall effect that three times more of the all meal provision group achieved at least a 5% weight loss compared to the self-directed group. Whether this was influenced by the gratis food provision cannot be discounted.

A modest weight loss of 5–10% of initial body weight has been shown to result in a significant reduction in morbidity and mortality, being associated with improvements in risk markers for heart disease, (Must *et al.*, 1999), along with hypertension (He *et al.*, 2000), diabetes mellitus and insulin resistance (Uusitupa, 1996), and certain cancers (Williamson *et al.*, 1995). In this 12-week study, all meal provision resulted in significantly more

Table 1 Mean baseline characteristics of participants

	Meal provision	Self-directed diet
Male : female (%)	15 : 41 (27 : 73)	19 : 39 (33 : 67)
Age, mean (SEM) (years)	45.11 (1.29)	45.19 (1.29)
Weight, mean (SEM) (kg)	87.9 (1.63)	88.9 (1.51)
BMI, mean (SEM) (kg m^{-2})	31.6 (0.32)	32.0 (0.04)

BMI, body mass index.

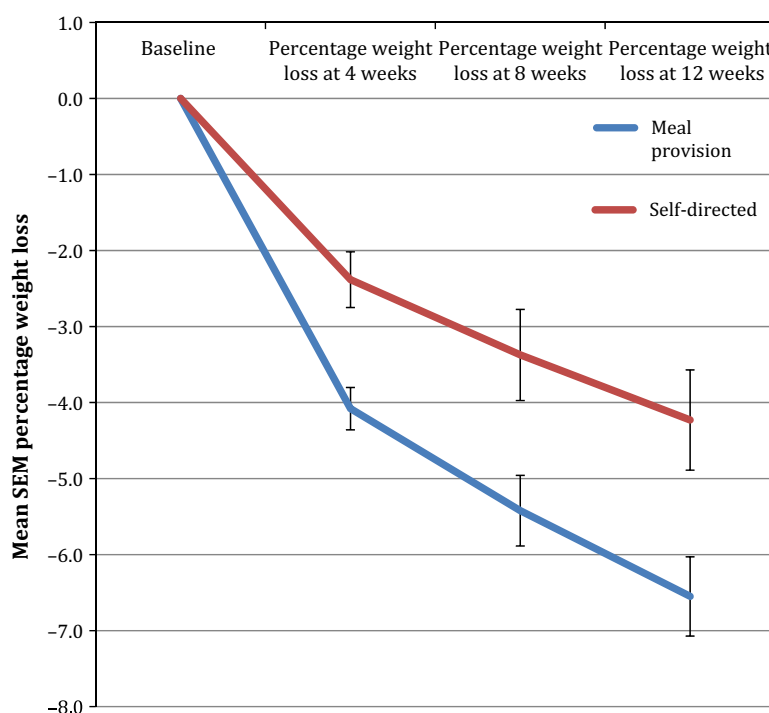


Figure 2 Mean percentage weight loss over 12 weeks.

Table 2 Mean (SEM) data at baseline and 12 week scores for psychological measures

	Diet Chef©		Difference from baseline <i>P</i> value	Self-directed diet		Difference from baseline <i>P</i> value	Difference between groups
	Baseline	12 weeks		Baseline	12 weeks		
IWQoL	75.2 (1.8)	87.6 (1.5)	<0.001	77.7 (1.9)	86.8 (2.4)	<0.001	0.318
Health state (EQ-5D)	54.2 (2.9)	75.3 (2.5)	<0.001	57.0 (2.5)	73.1 (3.5)	<0.001	0.574
Locus of control	12.4 (0.5)	12.3 (0.6)	0.902	11.8 (0.5)	12.6 (0.7)	0.301	0.479
MTQ48	3.55 (0.07)	3.74 (0.07)	<0.001	3.58 (0.04)	3.72 (0.07)	0.041	0.453

EQ-5D, European Quality of Life Questionnaire 5D; IWQoL, Impact of Weight on Quality of Life Questionnaire; MTQ48, Mental Toughness Questionnaire.

participants achieving this weight loss goal. However, to realise these health benefits, the weight loss must be maintained for at least 2 years to be converted into a reduction in morbidity.

The present study also further highlights the issue of attrition in weight management interventions. The all meal provision group had a very low level of withdrawal at 7%, whereas the self-directed group attrition rate was similar to that reported elsewhere (Tsai & Wadden, 2005; Truby *et al.*, 2006; Finley *et al.*, 2007). The majority of the attrition occurred in the first 4 weeks, which is compatible with the hypothesis that this may be an effect of the study design and dissatisfaction of being randomly allocated to the self-directed arm. However, the high level of retention between weeks 4 and 12 suggests that regular

monitoring and support aids retention in weight management programmes.

Commercially provided weight management services can be more effective and cheaper than primary care services (Jolly *et al.*, 2011). The cost of this intervention service was £468 for 12 weeks (at 2011 prices). This is approximately equivalent to the cost of prescribing Orlistat for 1 year (£400: NHS electronic drug tariff, July 2012), although the latter cost does not include the costs of food. Given the huge estimated costs of obesity (approximately 2.5% of the NHS budget; McCormick & Stone, 2007), reducing weight by 5% has an economic saving to the NHS of several hundred pounds.

A caveat of the present study is that additional foods may need to be added to the all meal provision because it

was potentially nutritionally incomplete, and a dietary assessment is required. Nonetheless, it is clear that it is an effective way of achieving clinically important weight loss over a period of 12 weeks. An all meal provision approach therefore may have utility as an intervention for individuals and patients who wish or need to lose 5% body weight in a relatively short period of time.

Conclusions

All meal provision was more effective and led to better retention over a 12-week period compared to a self-directed dieting alone. Weight loss at 12 weeks is promising but a further powered research trial would be needed to clarify this. For prolonged use, vitamin supplementation may be required.

Conflict of interests, source of funding and authorship

All authors have completed the ICMJE uniform disclosure form (http://www.icmje.org/coi_disclosure.pdf) and declare that there are no relationships or activities that would appear to have influenced the submitted work.

The study was funded by Diet Chef Ltd (Newbridge, Scotland, UK). They had no input in the design or conduct of the study; collection, management, analysis or interpretation of the data; or preparation, review or approval of the manuscript.

DM designed the trial, wrote the initial protocol, generated the randomisation sequence, analysed the data and carried out statistical tests. CW, SG and DM coordinated the study, screened and randomised participants, and collected the data. DM, MM and MR analysed the data. CW, MR and DM drafted the manuscript with contribution from SG and SA. DM is guarantor. All authors critically reviewed the manuscript and approved the final version submitted for publication.

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