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Filling the Intervention Gap: Service evaluation of an intensive non-surgical weight management programme for severe and complex obesity

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Abstract

Background: Weight management including formula total diet replacement is emerging as effective for severe and complex obesity, particularly with type 2 diabetes (T2DM). However, no prospective audit and service evaluation of such programmes are published.

Methods: Following initial feasibility piloting, the Counterweight-Plus programme was commissioned across a variety of healthcare providers. The programme includes: Screening, Total Diet Replacement (formula low energy diet), Food Reintroduction, and Weight Loss Maintenance, delivered by staff with 8 hours training, in-service mentoring, ongoing specialist support and access to medical consultant expertise. Anonymised data are returned centrally for clinical evaluation.

Results: Up to December 2016, 288 patients commenced the programme. Mean (SD) baseline characteristics were: age 47.5 years (SD12.7), weight 128.0 kg (SD32.0), BMI 45.7 kg/m^2 (SD10.1): 76(26.5%) were male and 99(34.5%) had T2DM. On an ITT basis, loss of $\geq$15kg at 12-months was achieved by 48, representing 22.1% of all who started and 40% of those who maintained engagement. For complete cases, mean (95%CI) weight loss(kg) was 13.3(12.1,14.4) at 3-months, 16.0(14.4,17.6) at 6-months and 14.2(12.1,16.3) at 12-months (all $p<0.001$), with losses to follow up of 10.8%, 29.3% and 44.2% respectively. Mean loss at 12-months by ITT analyses was: single imputation -10.5kg (9.5), LOCF -10.9kg (11.6) and BOCF -7.9kg (11.1). The presence of diabetes had no significant impact on weight change outcomes.

Conclusion: This non-surgical approach is effective for many with severe and complex obesity, as an option before considering surgery. The results are equally effective in terms of weight loss for people with T2DM.

Key Words

Obesity, weight management, evaluation, behavior change, formula diet.

Introduction

The rising burden of overweight and obesity on healthcare services, and on personal wellbeing, is well documented, with many obesity related comorbidities including type 2 diabetes (T2DM), hypertension, infertility, sleep apnoea, depression, arthritis and various cancers [1,2]. The Scottish Intercollegiate Guidelines Network guidance on the management of obesity recognises a need to achieve and maintain ≥15kg (≥10%) weight loss with severe and complex obesity [2]. This target is principally justified by the aims of achieving remissions of T2DM initially demonstrated in patients undergoing bariatric surgery [3] and as demonstrated in the Diabetes Remission Clinical Trial (DiRECT) randomised controlled trial [4]. Greater weight loss is also needed to manage sleep apnoea and arthritis optimally, and to allow obese patients to benefit from surgical procedures, for example in gynaecology, fertility services and joint replacement surgery. [5].

Bariatric surgery is widely recommended in evidence-based guidelines for severe and complex obesity (usually BMI>40kg/m^2 or 35kg/m^2 with comorbidities). However, fewer than 1% of those eligible actually access surgery in most countries [6]. As a lower-cost alternative to surgery, randomised controlled trials using 'Total Diet Replacement' low energy formula diets, which provide 100% of the recommended daily intakes for vitamins and mineralshave shown weight losses of 10-15kg, maintained for at least 12-months, with striking clinical benefits among patients with T2DM, sleep apnoea and osteoarthritis[7-9]. Total Diet Replacements provide >800kcal- <1200kcal day and meet nutritional specifications set out in the The Foods Intended for Use in Energy Restricted Diets for Weight Reduction Regulations 1997 implementing Commission Directive 96/8 [10].

The Counterweight Programme initially focused on aiming to establish standard 5-10kg weight loss methods for service provision within the UK National Health Service. However the mean BMI of referrals was consistently 37kg/m^2, with 25% above 40kg/m^2 [11]. Subsequently, with Scottish Government Health Department funding, Counterweight-Plus was developed and established to address the 'intervention gap' before referral to bariatric surgery, and to satisfy clinical weight loss targets for people with severe and medically complex obesity [2,12].The resulting structured, non-surgical programme, aimed at achieving and maintaining >15kg weight loss for as many patients as possible, has been commissioned by a number of UK NHS and

private health agencies. Data from all patients are collected centrally for analysis to inform Continuous Improvement. Here we document the results from a complete prospective audit over the 4-year period after the introduction of Counterweight-Plus, and illustrate how outcomes can be improved using the principles of Continuous Improvement Methodology (CIM), used since 2001 by Counterweight[11]..

Methods

This service evaluation adheres to the SQUIRE reporting guidelines [13]

Following the published feasibility study [12] and Continuous Improvement Methodology review, Counterweight-Plus was made available to public and private healthcare agencies in 2013, through Counterweight Ltd. The service is managed by a small central team of registered healthcare professionals with specialist training in weight management, with access to consultant physician expertise.

Practitioner Training/Support: In order to be certified to deliver Counterweight-Plus, practitioners (mainly Registered Dietitians) complete 2 days training from Counterweight specialists, and a detailed case study. Counterweight Ltd. trainers provide further supervision and mentoring via email, telephone, webinar and annual study days. Competency is reassessed annually from practitioner outcomes or completion of a further case study, with further training and mentoring as necessary.

Target patient population and referral: The service targets patients requiring weight loss of the magnitude of around >15kg or>10% for those with a lower baseline weight. For NHS patients, in areas where funding or part-funding for Counterweight-Plus is available, the service is provided by dietetic department with referral from clinical specialties where weight loss is core to the clinical outcome e.g.T2DM care, bariatric surgery etc. Counterweight-Plus can also be accessed through private health practitioners. On referral, practitioners communicate with general practitioners (GPs) regarding medical management of the patient, particularly over the need to review medications for T2DM and hypertension. Standard protocols support this process.

Programme structure and Implementation

Screening: Initial screening ensures patients meet the entry criteria of age 18-75, BMI>30kg/m^2 or BMI>27kg/m^2 plus associated T2DM, appropriate stage of readiness to change based on the Readiness Ruler [(2)] and to check for exclusion criteria including active mental illness, myocardial infarction or stroke within the previous 3 months, severe or unstable heart failure, porphyria, pregnant until >4 months post-partum; breastfeeding, substance abuse or eating disorder accompanied by purging.

The programme stages are detailed in ***Figure I.*** Appointments are 60 minutes for the initial session of the Total Diet Replacement and Food Reintroduction stages, all other appointments were20 minutes. Counterweight-Plus utilises behaviour change strategies from the CALORE taxonomy, to support long-term lifestyle modification including barrier identification and problem solving, goal setting- action planning and review of outcome goals promts [(14)]. Medical and weight change expectations are also discussed. High-quality patient and practitioner resources are used throughout the programme.

Total Diet Replacement (TDR): The phase consisted of 7 appointments over 12-weeks, or up to 20-weeks if greater weight loss is required, or if 'diet-holidays' are taken. The Total Diet Replacement product provides 825-853kcal/day from nutritionally complete soups and shakes plus 50ml low fat milk for teas and coffees. Macronutrient breakdown is as follows: 61% carbohydrate, 13% fat and 26% protein. The product used is Counterweight PRO800 (Cambridge Weight Plan, Corby, England). Sachets comply with specifications for total diet replacement products [(10)]. Structured discussions supported by written resources around goal-setting, relapse management, planning and physical activity starts during TDR. Advice around potential side effects is discussed and provided in patient materials. Patients are advised to use laxatives with constipation being a common problem due to the low fibre content of the sachets.

Food Reintroduction (FR): This phase consisted of 6 appointments, re-introducing food-based meals stepwise over 6-12-weeks to allow flexibility to accommodate individual needs and time-courses for confident transfer onto normal meals. Increased physical activity is advised aiming for 30 minutes moderate activity per day on at least 5 days per week. Once this is achieved individuals are advised to aim for 45-60 minutes moderate activity per day (monitoring with

step-counters or activity trackers if possible) [15]. Further nutrition and physical activity information is provided, encompassing recognised behavioural strategies [14]. Orlistat is available as an option depending on local prescribing access.

Weight Loss Maintenance (WLM): 7 appointments, to consolidate behavioural change strategies and aim to restrict weight regain to under 2kg at 12-months. A second year of WLM is also available for commissioning depending on local funding.

Relapse management: If there is weight regain above a pre-defined acceptable level of 2-4kg, a 4-8-week 'Rescue Plan' of TDR and/or FR is offered along with a structured weight regain review and associated materials.

Medical and Practitioner Support: Any medical queries from practitioners or GPs are submitted to an experienced consultant weight management physician, using a standard medical query form. Queries and suggestions from practitioners' specific to the programme are dealt with by specialist Counterweight Dietitians. These queries and responses are circulated to all practitioners as 'Frequently Asked Questions' and contribute to CIM.

Evaluation Methods: Practitioners delivering Counterweight-Plus are given an excel database to collect standard anonymised data on each patient enrolled into the programme including reasons for loss to follow up and asked to return the database annually for central analysis. Patients are asked to sign a 'promise agreement' at the first visit where they commit to the programme and related sessions and consent is sought for anonymised data being used for programme evaluation. For patients who had withdrawn from the intervention, data were collected at 12 months (within a pragmatic 'window' of 9-18months), where available, from measurements recorded at routine medical attendances.

Statistics: For analysis purposes, and due to the rolling nature of programme enrollment, predefined rules are applied for eligibility for analysis within time frames and programme stages, and criteria for loss to follow up. Resulting data are then checked for errors. In addition to summary statistics and percentages, formal statistical tests included: t-tests, to assess differences in weight change between groups; univariate and multivariate regressions including sex, diabetes

status, age and BMI, to estimate the effect of continuous variables on weight change and chi-square tests, to determine the significance of the association between categorical variables. Bonferroni adjustment of p-values was performed to account for potential type 1 error in performing repeated t-tests. Twelve-month outcomes are presented for attenders and additional intention to treat (ITT) analyses used single imputation with 12 month weights from GP records available for patients withdrawn from the intervention, last observation carried forward and baseline observation carried forward to allow comparisons with other published studies using similar methodologies.

Ethics: the protocol was previously reviewed for the by West of Scotland Research Ethics Service, which concluded that formal ethical approval was unnecessary, as no new or untested treatment was being offered, and there was no experimentation [12]. This clinical audit of routine care therefore required formal ethical approval.

Results

Between January 2013 and December 2016, 288 patients had enrolled in the Counterweight-Plus programme from nine UK Health Service areas (n=222), one private weight-management service (n=12) and from 8 individual private freelance Counterweight-Plus trained practitioners (n=54). Mean(SD) baseline characteristics were: age 47.5 years (SD12.7), weight 128.0 kg (SD32.0) and BMI 45.7 kg/m^2 (SD10.1), 76(26.5) % were male and 99(34.5) % had diabetes (97% T2DM) (***Table I)***. At the time of analysis 277, 246 and 217 patients were potentially eligible for 3, 6 and 12month weight change analysis respectively, due to the rolling entry into audit. The numbers of eligible patients who attended at these time-points were 247(89%), 174(71%) and 121(56%). In those attending at 12 months, mean number of appointments was 16 (SD4.4).

Data were obtained from GP records for 19 patients who had ceased to attend, showing mean (SD) loss of 6.0 kg (SD8.5) at 12 months.

Mean(SD) weight-losses (kg) in attenders were 12.7(SD8.0), 15.8(SD9.9) and 14.2(SD11.6), at 3, 6 and 12-months respectively. Mean loss at 12-months by ITT analyses was: single imputation -10.5kg (9.5), LOCF -10.9kg (11.6) and BOCF -7.9kg (11.1).

The target weight loss of 15kg at 12-months was achieved by 22%, and >10% loss by 28%, of all patients entering the programme. Among the 56% who continued engagement up to 12-months, 40% maintained a weight loss of >15kg, with mean loss of 14.2kg. In addition to the 15kg target, clinically beneficial weight loss of >5kg was achieved at 3, 6 and 12months by 216(78%), 161(65.4%) and 96(44.2%) respectively on an ITT basis. Summary weight changes are given in ***Table II*** showing follow up and mean loss for attenders and by ITT (single imputation, BOCF and LOCF) at each time point and numbers (%) achieving the defined categories of weight change. ***Figure II*** illustrates the proportion of attenders in each weight-loss category and lost to follow up for each data time point.

Table III outlines through multi-variate regressions that baseline BMI and sex had a significant impact on weight-change at each time point: on average males, and those with higher BMI at baseline, lost more weight. The presence of diabetes and age had no significant impact.

Weight-loss at 12-months was positively related to weight-change that had been achieved at 3 and 6-months. For every 1-kg greater weight-loss at 3 and 6-months, weight loss at 12-months was greater by 0.9kg (95% CI 0.72,1.11) and 1.1kg (95% CI 0.98,1.18) respectively.

Later entry to the programme, over the 4-year observation period, was significantly related to better 12-month retention: 73.8% for those starting after the mid-point (March 2014 – December 2016), as compared to 52.6% in those starting prior to the midpoint of recruitment (January 2013 – March 2014) ($p<0.01$).

For relapse management, brief ‘rescue plans’ were given to 30 of the 217 patients eligible for 12-month follow up (14%).

Longer support beyond 12-months has been offered by some practitioners, and follow-up data at 24-months were available for 46 (35%) of 131 who had started more than 2-years prior to the audit date. Their mean loss at 24-months was 13.5 kg (SD14.8) with 39% maintaining the target loss of >15kg.

Discussion

No previous published evaluation has examined a TDR method outside of a specialist centre setting or clinical trial. Our audit and service evaluation has presented data on all 288 obese patients who entered a structured non-surgical intensive weight-management programme. Patients enrolled had severe and complex obesity at baseline: mean BMI was 46kg/m^2 and 34% had T2DM. This severity and complexity of obesity requires greater weight loss than conventional 'lifestyle only' programmes can achieve, hence there is need for a non-surgical intensive intervention because access to bariatric surgery is limited globally and also holds low appeal for large numbers [16].

The Counterweight-Plus programme achieved weight loss of 14.2kg at 12 months in the attending population reflecting considerably greater maintained weight-loss than is reported with conventional diet and lifestyle interventions, with no worse adherence to this more intensive programme[11].

In this evaluation, baseline characteristics associated with greater 12-month weight-loss included higher baseline BMI and being male. It is notable that the men achieved greater weight-losses, mean 18.8kg even though 58% of men had diabetes, and the results were equally good for people with diabetes contrary to previous published work in weight management [17]. Evidence is accumulating that with weight loss of the order of 15kg, remission of T2DM may be possible for large numbers, bringing major personal, social and medical benefits as well as avoiding the costs of medications prescribed to people with T2DM. Lim et al. showed that remission of T2DM resulted from weight loss c.15kg, using 8 weeks TDR, with loss of the ectopic fat in liver and pancreas, and restoration of first-phase insulin release[8]. The DiRECT randomised controlled trial (RCT) published 12-month outcomes showing T2DM remission rates of 86% with weight loss of $\geq$15kg and 73% with weight loss of $\geq$10kg using Counterweight-Plus[4].

Outcomes for Counterweight-Plus at 12-months in our service evaluation are reassuringly similar to many published high quality RCTs of formula diet interventions[18]. There are no directly comparable routine-service evaluations however published outcomes are available from an Australian specialist tertiary hospital multidisciplinary weight management clinic which used an initial full or partial very-low-energy diet (550 kcal/day VLED) with monthly/bimonthly

attendance, followed by stepped food reintroduction and weight loss maintenance review every 1-3 months [19]. Despite the specialist multi-disciplinary support, 12-month outcomes were better for Counterweight-Plus both in terms of attenders weight change: 12.7kg vs 9.7kg and loss to follow up; 44% vs 58%

The present data add to growing evidence that greater, more rapid, early weight-loss leads to better longer-term outcomes. Weight-loss at 3 and 6-months were positively correlated with outcomes at 12-months. This counters the widespread belief that rapid initial early weight-loss is quickly regained on reverting to a food-based diet[20].The TDR approach was favourably received by patients. Programme retention was exceptionally high during TDR at 89%: motivation is high when weight loss is rapid [20]. The complete step away from usual food and drink allows the opportunity to re-educate and consolidate long-term plans for food choice and weight control, using a range of behavior-change strategies, delivered by a trained health professional.

Loss to follow up is a common problem with weight management and other lifestyle interventions[21]. The use of formula diet in RCT studies have shown retention of rates of 17-21% [22,4] In one, study participants were seen weekly and given ongoing free of charge formula product as part of the weight loss maintenance intervention [22] but this high level of retention may also reflect the population recruited being committed to the research being carried out. However in otherRCTs where patients have volunteered to be part of a scientific study, often with incentives, 12-month loss to follow up is commonly over 40% [23], similar to that seen in the present service evaluation. In non RCT interventions a specialist UK service including psychology, dietetics and exercise therapists, published an 80% loss to follow up at 12-months[24] The results for the Counterweight-Plus service evaluation showed reduced loss to follow up, and also better weight-loss outcomes, for patients who started the programme after the 2-year midpoint date of the 4-year period for enrollment reported here. This improvement may partly represent the success of the Continuous Improvement Methodology integral to Counterweight-Plus, whereby practitioners report problems and ideas for programme refinements, and ongoing central review of the results identifies areas for further training or greater support. However, increased confidence and experience of practitioners would also contribute to the improved

outcomes. Sensitivity analysis on imputed data showed greater weight loss in attenders than those who did not attend (LOCF:10.9kg; BOCF 7.9kg) however we do not have information on those failed to attend at the 12-month point and therefore what their weight change would be. While outcomes on attender cases may overestimate the effect of the programme this conclusion could only be confirmed with actual weight change data for those not attending.

As with all weight management studies, there was some regain from the greatest mean weight-loss of 15.8kg at 6-months, to 14.2kg at 12-months. Rescue plans had been given to 30 of the 217 patients eligible for 12-month follow up (14%). Weight loss at 12-months was no worse for those receiving rescue plans, so this measure was having the intended effect. The data indicate no major rebound weight regain, with mean regain of 1.6kg (10% of total weight loss) between 6 and 12-months. Our limited 24-month data suggest that an important proportion already maintain their weight loss in the longer term.

The main limitations of this service evaluation lie in access around wider data of interest such as details of changes in related clinical conditions such as T2D, recorded information around side effects such as constipation and outcomes for patients who withdraw from the intervention. Improved resource would be needed to address this coupled with systems to automatically access associated patient outcomes and prescribing data such as information on the use of orlistat. Feedback from practitioners suggested very low uptake of orlistat as an option, however without specific details on this the potential influence on weight change should not be discounted. A further limitation is that the focus is on 12-month outcomes however this again is largely driven by the available resource within routine NHS weight management. Finally, there may be recruitment bias and a control arm would add to the conclusions drawn.

In summary, Counterweight-Plus provides a practical option for patients who need to lose more weight than is achieved through conventional lifestyle interventions, but for whom bariatric surgery is unavailable or unacceptable. Unlike many treatments the results are equally good for people with diabetes. Outcomes compare favourably with the DiRECT RCT despite a more medically complex group and non RCT delivery and support structure.Using Continuous Improvement Methods, the programme has been enhanced by providing greater flexibility,

368 which has improved acceptability and in turn improved retention and weight loss. Further
369 improvements to the programme include offering longer-term support for weight loss
370 maintenance with dynamic approaches for prevention of weight regain as well as development of
371 a digital option. Future research to improve longer term weight loss maintenance is warranted,
372 and more high-quality audits of real-life management in routine services should be published [25].

Transparency Declaration:*"The lead author affirms that this manuscript is an honest, accurate, and transparent account of the study being reported. The reporting of this work is compliant with SQUIRE guidelines. The lead author affirms that no important aspects of the study have been omitted and that any discrepancies from the study as planned have been explained."*

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Figure I: Programme Structure

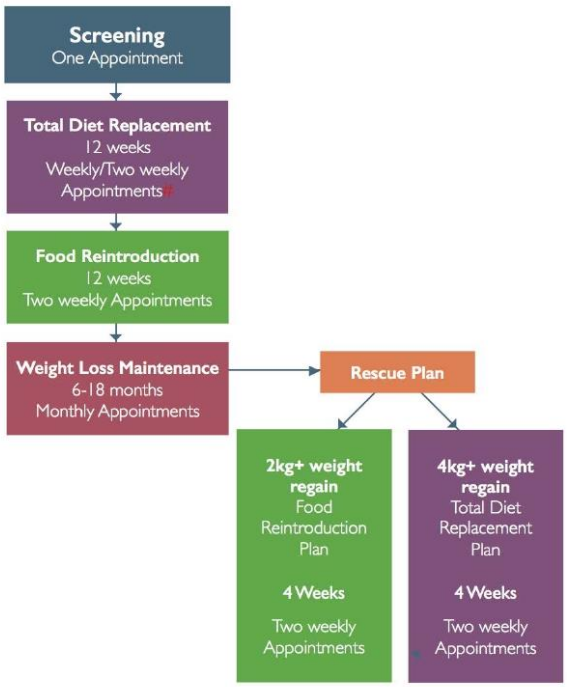

Table I: Baseline Characteristics

Baseline Characteristic	**Service Evaluation Population: Counterweight-Plus**
Total number patients	288
Mean age (years) (sd)	47.5 (12.7)
% males	26.5
Mean BMI (kg/m^2) (sd)	45.7 (10.1)
% with Type 2 diabetes	34.4

Table II: Summary weight change data for 277 patients managed through Counterweight-Plus and eligible for 3-month follow up and beyond.

Data are shown for (a) 'Attenders' who remained engaged in the programme at each time-point; (b) ITT Single Imputation (b) ITT (Last Observation Carried Forward) and (c) ITT (Baseline Observation Carried Forward).

	3 months	6 months	12 months	24 months
a) Attenders				
n eligible	277	246	217*	46**
n (%) with data	247(89)	174	121	46
Mean Weight Change(SD)	-12.7 (8.0)	-15.8 (9.9)	-14.2 (11.6)	-13.5 (14.8)
P value	**<0.01**	**<0.01**	**<0.01**	**<0.01**
b)ITT (imputed weight change -6.0kg)	na	na	-10.5 (9.5)	na
bc)ITT (LOCF)	na	na	-10.9 (11.6)	na
cd) ITT (BOCF)	na	na	-7.9 (11.1)	na
Weight change categories, n(%)				
Weight gain	3 (1.1)	3 (1.2)	3 (1.4)	9(19.6)
0 < 5kg loss	28 (10.1)	10 (4.1)	22 (10.1)	4(8.7)
5kg+loss	216 (78.0)	161 (65.4)	96 (44.2)	33(71)
10kg+loss	150 (54.2)	120 (48.7)	69 (31.8)	26(57)
15kg+loss	82 (29.6)	83 (33.7)	48 (22.1)	18(39)
LTFU****	30 (10.8)	72 (29.3)	96 (44.2)	na**

*the rolling nature of programme recruitment resulted in fewer people being eligible for the latter data capture time points

**because 24m follow up is not routinely provided at this stage so only those followed up at 24m are eligible

***P<0.01 for both one-sample t-test and Wilcoxon signed-rank test at all time points. Weight change at 3m compared to baseline was analysed using 1-sample t-test, with null hypothesis of H0: weight change at 3m = 0. This is equivalent to a paired t-test comparing weight at 3m vs baseline, testing the null hypothesis of H0: weight at 3m = weight at baseline. This test was repeated for 6m and 12m compared to baseline. Bonferroni adjustment had no effect on the significance of the p-values.

****Loss to Follow Up

Table III: Multi-variate regressions of weight change at 3m, 6m, 12m by BMI, age, diabetes and sex at baseline

Variable	Wtloss Coef (95%CI)	P-value	F-value	R-squared
3 months			4.3	0.1396
BMI	0.17 (0.07, 0.27)	<0.01		
Age	0.00 (-0.08, 0.09)	0.95		
Diabetes	-1.82 (-4.02, 0.37)	0.10		
Male	6.16 (3.80, 8.51)	<0.01		
6 months			7.11	0.1594
BMI	0.28 (0.12, 0.43)	<0.01		
Age	0.02 (-0.11, 0.15)	0.78		
Diabetes	-3.04 (-6.35, 0.27)	0.07		
Male	6.96 (3.42, 10.51)	<0.01		
12 months			4.3	0.1396
BMI	0.29 (0.07, 0.51)	0.01		
Age	-0.01 (-0.19, 0.17)	0.88		
Diabetes	-2.46 (-7.01, 2.08)	0.29		
Male	7.44 (2.74, 12.15)	<0.01		