UNIVERSITY OF BIRMINGHAM

PROTOCOL FOR NON-IMP STUDY

LIMIT Study

The effectiveness and cost effectiveness of a brief behavioural intervention to promote regular self-weighing to prevent weight regain after weight loss: randomised controlled trial

Trial registration number: ISRCTN52341938

Version 1.1

02/06/15

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Funding

NIHR Public Health Research Programme

This protocol describes the LIMIT study and provides information about procedures for entering participants: it should not be used as a guide for the treatment of other participants. Every care has been taken in the drafting of this protocol, but corrections or amendments may be necessary. These will be circulated to investigators in the study, but centres entering participants for the first time are advised to contact the trials centre to confirm they have the most recent version. Problems relating to this trial should be referred, in the first instance, to the Study Co-ordinator.

This study will adhere to Good Clinical Practice and will be conducted in compliance with this protocol, the Data Protection Act, and other regulatory requirements, as appropriate.

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1 STUDY SUMMARY

1.1 Title

The effectiveness and cost effectiveness of a brief behavioural intervention to promote regular self-weighing to prevent weight regain after weight loss: randomised controlled trial.

1.2 Aims

The primary aim of this study is to evaluate the effectiveness and cost effectiveness of a brief behavioural intervention delivered by non-specialist staff to promote regular self-weighing to prevent weight regain after intentional weight loss. The intervention will be compared with a usual care group.

1.3 Outcome Measures

Primary outcome: difference between groups in weight change from baseline to 12 months.

Secondary outcomes:

1. The proportion of participants in the intervention and usual care groups who have regained less than 1 kg in weight at three and 12 month follow up.
2. Change in weight from baseline to three months follow up (i.e. end of maintenance intervention in the intervention versus the usual care group.
3. The number of adverse events related to the study that occurs during the three month intervention period including the change in uncontrolled eating, emotional eating and weight preoccupation.
4.The cost to the NHS per kg, and per kg/m2, of the additional weight loss maintained for the intervention compared to usual care at 12 months, the cost per quality adjusted life years (QALY) during the intervention period and predicted lifetime QALYs gained.

1.4 Population

Adults who have attended a weight management programme as part of the Lighten Up weight management service in Birmingham, England.

1.5 Recruitment and Management Locations

The University of Birmingham and Gateway Family Services.

1.6 Eligibility

- Aged 18 years or more.
- People who have lost at least 5% of their starting weight at the end of their weight loss programme.
- Own a mobile phone or landline phone that can receive SMS text messages.
- Able to understand sufficient English to complete the study.

1.7 Duration

Total 36 months. Each participant will be enrolled on the day of recruitment and followed up for 12 months.

1.8 Reference Diagram

Please see Appendix B for Consort flow diagram.

2 INTRODUCTION

2.1 Background

Obesity

Obesity is the most common cause of premature mortality in the UK [1] and a significant cause of morbidity in terms of increased risk of type 2 diabetes, cardiovascular disease and many cancers [2,3]. In the UK the rates of obesity have more than doubled in the last 25 years, and being overweight has become the norm for adults[2]. Direct costs of obesity are about £5.1 billion per year, thus placing a significant economic burden on the NHS and society. Given its prevalence and costs obesity is a significant public health priority in the UK, as well as in other developed countries. Although many behavioural weight loss treatments are effective in the short term, long term maintenance remains a critical challenge. The period after initial weight loss is when people are at highest risk of weight gain. Few people (1 in 10) recover from even minor lapses of 1–2 kg of regain in weight [4]. Therefore preventing small regains from turning into larger relapses appears critical to recovery among people who have successfully lost weight. On average people will regain one third to one half of lost weight within the first year following treatment and will return to baseline weight within 3-5 years after treatment[5,6]. These data clearly indicate that weight regain is common and efforts are needed to prevent it[4].

Maintenance of weight loss

Compared to weight loss trials, relatively few studies have focused on weight maintenance and those trials that do exist have tended to evaluate intensive interventions. A recent review of randomised controlled trials of weight loss maintenance interventions for obese adults after clinically significant weight loss identified 34 relevant studies, none of which had been conducted in the UK[7]. Most studies had evaluated interventions such as food supplements, meal replacements or medication (orlistat). The review identified that the greatest need for further research was in the area of lifestyle interventions focused on supporting people to manage their weight in the longer term by regulating food intake and increasing physical activity. While a few trials of lifestyle intervention have shown promise, there was variability regarding intervention content, delivery and the magnitude of effect of interventions. Of importance here, it was intervention content, not intensity, which appeared to be related to effectiveness. There were four important features of effective weight maintenance interventions, all of which are consistent with self-regulation theory[8]; these being goal setting, self-monitoring of weight and behaviour, action plans for weight control through dietary and physical activity behaviours and plans on how to cope with risk factors for weight regain and relapse prevention. The review authors also noted

that thus far most weight maintenance interventions have been resource intensive and consequently not likely to be scalable, most control groups had provided support far beyond what could be considered standard or usual care, which might dilute any effects seen and information on the cost effectiveness of interventions was very sparse.

Self-weighing

Benefits and evidence

Given that weight regain after a successful weight loss programme is the norm, we need cost effective weight maintenance interventions, but there are none in routine use in the UK. As more than half of all adults would benefit from losing weight and sustaining weight loss we need simple, yet effective and cheap interventions. One promising behavioural strategy is regular self-weighing to check progress against a target, a form of self-monitoring. The potential efficacy of self-weighing has been based on the principles of self-regulation theory[8] and the relapse prevention model. Self-regulation has been described as a process that has three distinct stages; self-monitoring, self-evaluation and self reinforcement[8]. Self-monitoring is a method of systematic self-observation, periodic measurement and recording of target behaviours with the goal of increasing self-awareness. The awareness fostered during self-monitoring is considered an essential initial step in promoting and sustaining behaviour change. Self-monitoring in the context of self-weighing can show individuals how their behaviour affects their weight and allows them to adjust their behaviour to achieve their goals. Self-weighing may have other benefits. Regular self-weighing may improve dietary vigilance; documenting weight against a set target may raise individuals' awareness of the behaviours that influence their weight and encourage them to take action. There is observational data that a lower frequency of self-weighing is associated with higher fat intake, increased disinhibition, and decreased cognitive restraint[9], all behavioural features associated with weight gain and regain. Self-weighing may act as a reward to individuals who control their food intake and exercise behaviour who are provided with positive feedback from the scales, thus enhancing motivation and reducing the potential for relapse. Frequent self-weighing may also improve self-efficacy for weight maintenance which in turn could improve body image. It is simple for a health professional or public health communication to advocate self-weighing and it is simple for people to understand and implement and it is the kind of behaviour that could become habitual, thus performed throughout life, in the way that cleaning one's teeth becomes automatic and effortless. Trials have shown that participants can adhere to daily self-weighing[4,10,11]. There are examples of RCTs[4,10] where self-weighing has been included within intensive multicomponent interventions, but our systematic searches revealed only three RCTs where self-weighing was the main element of the intervention[12-14] . One focused on weight loss [12], one on weight maintenance[14], and one on both[13]. All were small (range from n=23-89), contained other methodological concerns such as short follow up and high attrition making it difficult to draw conclusions. Nevertheless, the weight maintenance interventions seemed effective[13,14].

Birmingham Public Health wanted to evaluate an intervention to facilitate weight maintenance and prevent weight regain over the longer term in users of the Lighten Up service (Weight management service). For a year the public were offered a three month

weight maintenance intervention after completing their weight loss programme and 12 month follow up data were collected. The intervention focused on encouraging regular self-weighing. Participants who did not own scales were given a voucher to obtain a free set from a local pharmacy and sent a chart to record their weight and a hints and tips booklet about strategies to facilitate weight management. Participants were asked to weigh themselves weekly and record this on the card sent to them. Participants were called three months later to encourage regular adherence. The intervention was delivered by non-specialist call centre staff from Gateway Family Services, a third sector community organisation, who are contracted by Birmingham Public Health to manage the Lighten Up service. We examined the efficacy of this self-weighing focused weight maintenance intervention16 on weight regain at 12 months by comparing the weight of those offered the intervention (intervention group) (n=3,290) with participants (n=478) in the preceding Lighten Up trial[15] who had not received a maintenance intervention (control group). Using intention to treat analysis, (i.e. regardless of whether participants had lost weight at the end of the weight loss programme or accepted the maintenance intervention), both groups regained weight but the intervention group regained 0.68 kg (95% CI 0.12 to 1.24) less than the control group. In the per protocol analysis, comparing intervention participants who had accepted the maintenance intervention with controls, the mean difference was much larger at 2.96 kg (95% CI -3.67 to -2.25). Whilst our pilot results are encouraging and offer preliminary evidence to support the intervention, participants were not randomised to the groups, the intervention was not optimally configured to encourage behaviour change, follow up data were mostly self-reported and the frequency of self-weighing was not recorded.

2.2 Rationale For Current Study

The effectiveness of the intervention now needs to be tested robustly before it can be implemented. Moreover, commissioning groups throughout England have begun to offer patients weight loss programmes, often provided by commercial weight management providers, but often have no or minimal provision for weight maintenance support thereafter. If effective, the study would provide information to public health agencies who may be considering adopting a similar model. The need therefore for evidence about effective weight maintenance interventions delivered within public health arenas will become even more important in years to come. The need for evidence about effective weight maintenance programmes is also critical to ensure that weight loss is maintained following weight loss interventions as regain is the norm. This study would provide public health agencies with a simple, 'ready to go', low cost weight maintenance intervention that could be implemented immediately, if effective.

The primary aim of this study is to evaluate the effectiveness and cost effectiveness of a brief behavioural intervention delivered by non-specialist staff to promote regular self-weighing to prevent weight regain after intentional weight loss. The intervention will be compared with usual care. The proposed research will test a theoretically informed weight maintenance intervention, following successful completion of standard widely available commercial and NHS weight loss programmes. While complex multicomponent high intensity interventions may be more effective than the one we propose, we have deliberately chosen to test a simple self-weighing unicomponent

intervention, which has not been done before in a high quality trial. There are several advantages of testing simple and cheap interventions. If we test uni-component interventions and show they are effective we can build up to a more complex multicomponent intervention. It is often difficult to go the other way. Most people in the UK would benefit from losing weight, intensive interventions cannot be delivered cheaply to this number of people. Even if our strategy leads to a smaller effect than a complex intervention, the higher reach of the simple cheap intervention would still result in substantial gains to public health. If we have a range of simple evidence-based self-help strategies that may prevent weight regain we can encourage the public to use these outside of formal programmes.

2.3 Interventions

The trial compares two treatments. The usual care group will receive a standard maintenance leaflet, the eat well plate and a list of useful websites. The intervention group will receive support telephone calls at weeks one, two and four that encourage daily self-weighing, recording of weight on a record card, setting a weight target together with reminder text messages. Participants will be given a set of BodyTrace scales and instructed to weigh themselves daily on these scales and record their weight on the weight record card provided. The BodyTrace scales record participants weight and transmit this data to a remote database. A copy of the record cards will be taken at three months follow-up (refer to trial manual for full description, Appendix C).

INTERVENTION GROUP (AKA telephone support group)

Intervention components

The explicit behavioural goal of the intervention will be for participants as a minimum to avoid regaining more than 1 kg of their baseline weight. The main element of the intervention is support telephone calls at weeks zero, two and four, that encourage target setting and daily self-weighing, together with reminder text messages every Tues, Thursday and Sunday for the first four weeks, reducing to twice weekly thereafter. We have purposefully designed the intervention such that the telephone contacts and frequent texts messages occur in the first four weeks because the period after initial weight loss is when people are at highest risk of weight regain and to maximise the possibility that participants develop the habit of regularly weighing themselves.

Telephone calls

Participants will be called three times; at weeks one, two and four of the intervention. The calls will last about 5 min each. The callers are staff of Gateway and not weight loss counsellors. We will train Gateway staff to deliver the intervention in accordance with the intervention manual. We have planned training activities where we will use role play telephone calls with the Gateway staff and the investigators as well as members of the general public, including the PPI group. A summary of the intervention is detailed below.

The intervention will start with the telephonists explaining that weight regain is the norm after weight loss as successful slimmers often feel overly confident in the likelihood of keeping weight off. Then telephonists will encourage participants to set a

weight goal for regain such as '*In a year I aim to weigh no more than I do now',* although the goal chosen will be set by the person. If the person sets an ambitious weight loss goal then the telephonist will remind the participant that the aim of this programme is to prevent weight regain, not to assist weight loss and encourage them to set a goal for weight maintenance. The telephonists will also explain that weight regain is often not apparent initially and that monitoring weight is important to detect early signs of this occurring. Whilst the goal of the intervention is for participants to avoid regaining more than 1 kg of their baseline weight, in a pragmatic trial we have to accept that some participants may have other goals they would like to achieve, as would be the case if this study was implemented in the population. Thus, the telephonists will accept that some participants may have alternative goals, but they will remind them it is important to set goals that are realistic and achievable and get participants to agree that 'at the worst' they will avoid regaining more than 1 kg of their weight loss. The telephonists will explain that weight fluctuates naturally and that variation is normal and does not immediately mean that a person has gained fat, which is what damages health. Thus together, the telephonist and the participant will agree a goal that is somewhere near to weight stability and have agreed that frequent monitoring is important to detect early signs of weight gain and take corrective action. After that, the telephonist will introduce the concept of daily weighing. S/he will explain that it is easier to keep doing something if it becomes a habit, part of the daily routine *'like brushing your teeth*'. The potential benefits of self-weighing for preventing weight regain will also be outlined. The telephonist will ask the participant if they can commit to daily weighing. Assuming that this is achieved, the telephonist will help the participant to make implementation intentions that describe when and where the weighing will take place '*every morning after I have had my shower and before I get dressed'*. The telephonist will encourage the participant to cue this behaviour '*move the scales into your bathroom so when you see them after your shower it will remind you*'.

Participants will be encouraged to weigh themselves at the same time every day wearing similar amounts of clothing or no clothing. The telephonist will then explain that the aim of weighing frequently is to check yourself against the target weight set for weight stability. The telephonist will explain that s/he will send the participant a booklet which is the participant's personal weight record. Each page of the booklet represents a week and at the top of each page there is a box where the participant enters the target weight which they aim to stay within. The telephonist will explain that every day the participant will check their recorded weight against the target weight and will ask whether the participant can do this and ask them to commit to doing it if so. The telephonist will encourage the participant '*remember every time you record your weight you are one step nearer to this becoming a healthy habit"*. Participants will be advised that if their current weight is more than 1kg above target weight then they would be best to restart following the plan they followed for eating and physical activity when they were on their weight loss programme. There will be no specific encouragement however for participants to rejoin the weight loss programme and this will not be available for free until participants have completed their 12 month follow up.

Week two and four calls

The telephone calls in weeks two and four will include a review of the frequency of self-weighing and recording of weight over the previous weeks. Those not weighing themselves daily will be asked about barriers to this and the telephonist who will help with practical solutions/ ideas and strategies of how they might overcome them. The telephonist will remind the participant of their goals, their commitment to them, and the value of self-weighing. Participants will be further encouraged to self weigh daily. The importance of using the weight record to prevent relapse will also be emphasised. The importance of engaging in regular physical activity/healthy eating to prevent relapse will also be emphasised again but the telephonists will not be competent to and will not give advice on energy intake or expenditure.

Text messages

Automated reminder text messages will be three times per week for the first four weeks, reducing to twice weekly for eight more weeks. The goal for the intervention is to encourage self-weighing such that it becomes a habit. We will continue to send reminder texts twice per month as a 'top up' strategy after the 12 week intervention until 12 months follow up. The schedule and content of the texts messages are contained in the intervention manual.

Table 1: Intervention components using the CALO-RE behavioural change taxonomy[16]

Behavioural technique	Definition
Goal setting (outcome)	Then telephonists will encourage participants to set a weight goal for regain such as '*In a year I aim to weigh no more than I do now'*. .
Prompt review of outcome goals	Participants will be instructed to remain within 1 kg of their study baseline weight and to review their weight each day against this target.
Provide information on the consequences of behaviour in general	Telephonists will discuss the benefits of self-weighing with the participant.
Environmental restructuring	The telephonist will encourage the participant to cue this behaviour '*move the scales into your bathroom so when you see them after your shower it will remind you*'.
Provide information on where and when to perform the behaviour	The telephonist will ask participants to describe when and where the weighing will take place. Participants will be encouraged to weigh themselves at the same time every day.
Use follow up prompts	Participants will receive telephone calls at weeks 1, 2 and 4 that encourage daily self-weighing, together with reminder text messages every other day for the 4 four weeks, reducing to twice weekly thereafter.
Barrier identification/ Problem solving	The telephonists will offer practical solutions and give participants ideas and strategies to overcome barriers to daily self-weighing. Participants will be advised that if their current weight is more than 1 kg above target weight then they would be best to restart following the plan they followed for eating and physical activity when they were on their weight loss.
Agree behavioural contract	The telephonist will ask participants if they can commit to a weight change target and to daily weighing.
Provided general encouragement	The telephonist will encourage the participant '*remember every time you record your weight you are one step nearer to this becoming a healthy habit*"
Prompt self-monitoring of behavioural outcome	Participants will be instructed to weigh themselves daily and record it on the record card provided
Prompt social support	Prompt participants to ask someone they care about to support them – tell this person they care about their goal and ask them to remind the participant of this goal every week.

Delivery of the intervention

Gateway Family Services manage the Lighten Up weight loss service which is one service where participants will be recruited from for this study and they will deliver the weight maintenance intervention. Gateway is a community interest company that operates across the West Midlands and is non-profit organisation that works in partnership with local health and social care organisations to support their strategic decisions whilst empowering people in the community to break social, cultural and economic barriers that can cause deprivation. The Gateway call centre is staffed by employees who are trained in call centre management systems and customer relations, but not in nutrition or weight management. Call centre staff will not offer any opinions or undertake any motivational interviewing, but they will listen, offer positive reinforcement about regular self-weighing and setting weight goals, offer advice about intention implementations, give encouragement and pass on factual information.

3 STUDY OBJECTIVES

Primary objective

To examine the effect of a brief weight maintenance intervention focused on regular self-weighing versus usual care on objectively assessed mean weight change at 12 months follow-up.

Secondary objectives

To compare the proportion of participants in the intervention and usual care groups who gain less than 1 kg from their weight at three and 12 month follow-up.

To examine the effect of a brief weight maintenance intervention focused on regular self-weighing versus usual care on mean weight change at three months (post maintenance intervention) follow-up.

To assess the cost to the NHS per kg and per kg/m2, of the additional weight loss maintained for the intervention compared to usual care at 12 months, the cost per quality adjusted life years (QALY) during the intervention period and predicted lifetime QALYs gained.

To assess the occurrence of adverse effects including uncontrolled eating, emotional eating and weight preoccupation.

To examine the differences in weight control strategies used between the intervention and usual care groups.

To examine if higher weight locus of control is associated with greater weight loss at three, six and 12 months follow-up between the groups and in the intervention group only.

To examine if there is a difference in weight control strategies used between the intervention and control groups at three, six and 12 months.

Objectives based on observational data in the intervention group

To assess whether frequency of self-weighing is associated with the prevention of weight regain.

To assess if regular self-weighing leads to the development of conscious energy regulation.

To examine perceptions of daily-weighing.

To examine previous weight loss attempts and the association with weight loss maintenance.

4 STUDY DESIGN

4.1 Plan Of Investigation

An RCT to compare 560 adults who have received a weight loss programme through a Public Health funded weight management service and lost at least 5% of their initial body weight. Participants will either be randomised to a usual care group who will receive the standard weight loss maintenance intervention (leaflet, eat well plate and a list of useful websites) or the intervention group who will receive the same written materials plus a 12 week intervention that promotes daily self-weighing.

4.2 Study Outcome Measures

4.2.1 Primary Outcome:

The difference between groups in weight change from baseline to 12 months.

4.2.2 Secondary Outcomes:

1. The proportion of participants in the intervention and usual care groups who have regained less than 1 kg in weight at three and 12 month follow up.
2. The difference between groups in weight change from baseline to three months follow-up (i.e. end of maintenance intervention.
3. The cost to the NHS per kg, and per kg/m^2, of the additional weight loss maintained for the intervention compared to usual care at 12 months, the cost per quality adjusted life years (QALY) during the intervention period and predicted lifetime QALYs gained.
4. To assess the occurrence of adverse effects including uncontrolled eating, emotional eating and weight preoccupation.

4.2.3 Non-efficacy outcomes

1. The difference in frequency of self-weighing in the control and intervention groups.
2. To assess if regular self-weighing leads to the development of conscious energy regulation[17].

4.2.4 Process Measures

We will collect process measures to monitor recruitment, intervention delivery and potential variables that may influence outcomes. Table 1 documents the process measures collected.

Table 1: Measurements

Recruitment measures		
Number of participants eligible		
Number of participants consented		
Number of participants consented and randomised		
Measures after consent		
	Control group	**Intervention group**
Frequency of recording self-weighing –record cards		X
Frequency of self-weighing (objective scales)		X
Index of habit strength [18]		X
Energy restriction[17]	X	X
Weight locus of control[19]	X	X
Weight control strategies[20]	X	X
Perceptions of self-weighing[21]		
Attendance at commercial weight loss programmes & application of skills learnt at weight loss programme (open ended)	X	X
Thoughts about regular weighing (open ended questions)		X
Non engagement of weight management (open ended questions)	X	X
Intervention delivery of phone calls		X

Descriptive data

Data will be collected about participants' weight management history and weight loss episode in the weight management service at baseline (Tables 2 and Table 3). The weight loss episode refers to all of the information collected as part of their weight loss programme they received.

Table 2: Information from weight loss episode

Variable	GP practice	Start date of weight loss programme/ online programme	Weight loss programme	Use of anti-obesity medication	Weight at start of programme	Weight at end of programme	Weight change at end of programme	Percentage weight change at end of programme
Format	string	Date	0 = online programme 1= weight watchers 2= slimming world 3 = rosemary conley 4= pharmacy	0=no 1=yes	Continuous Kg one decimal place	Continuous Kg one decimal place	Continuous Kg one decimal place	Continuous % one decimal place

Table 3: Information from the LIMIT trial episode

Variable	Phone call at week 1	Phone call at 2 weeks	Phone call at 4 weeks
Format	No = 0 Yes = 1	No = 0 Yes = 1	No = 0 Yes = 1

4.3 Study Timetable

About 3500 free places on the Lighten Up service are commissioned by Birmingham Public Health each year which is likely to be at least the same in the next financial year. Of these, 59% of participants (n=2065) typically complete their weight loss programme (i.e. attend nine or more sessions) and 42% lose at least 5% of their starting weight (n=867). If 65% of these agree to take part and are fully eligible (n=563) we will recruit an average of 37-38 participants per month with 560 participants recruited within 15 months.

We will also recruit via the Solihull weight management service where there are approximately 500 referrals per year. If there are similar proportions completing and agreeing to take part as the Lighten Up service in Birmingham, we will recruit an additional 136 participants over 12 months.

Start date 1st June 2014	1-3 June 2014	4-6 Sept 2014	7-9 Dec 2014	10-12 Mar 2015	13-15 June 2015	16-18 Sept 2015	19-20 Dec 2015	21-23 Mar 2015	24-26 June 2016	27-29 Sept 2014	30-32 Dec 2016	33-36 Mar 2016
Study set up												
Obtain ethics/R&D												
Staff recruitment												
Train Gateway staff												
Recruit 560 participants												
Deliver the intervention												
3 month follow ups												
12 months follow up												
Data cleaning & analyses												
Report writing												

5 PARTICIPANT ENTRY

5.1 Pre-Registration Evaluations

All participants in the Lighten Up service will be sent an invitation letter and information leaflet when they reach week nine of their Lighten Up weight loss programme. This letter will inform participants about this weight maintenance study and notify them that as part of the routine Lighten Up weight maintenance screening call from Gateway Family Services (call centre) they will be asked whether they are willing to take part in a study to prevent them regaining the weight they may have recently lost. At week 11 of the weight loss programme schedule participants will be asked to report their current weight and the total amount of weight loss since starting their weight loss programme will be calculated. Those who have lost at least 5% of their starting weight will be asked to participate in a study about preventing relapse of weight loss. In other Public Health funded weight management services participants will be sent a letter, information sheet, reply form and pre-paid envelope. The research team at the University will contact the participants on receipt of the reply form to assess eligibility and book a baseline visit.

5.2 Sample Size

We will recruit 560 participants, 280 randomised to each group.

5.3 Inclusion Criteria

- Aged 18 years or more.
- People who have lost at least 5% of their starting weight at the end of their weight loss programme (based on self-reported weight at weight maintenance screening call and confirmed at randomisation visit that they had lost at least 4% of initial body weight).
- Own a mobile phone or landline phone that can receive SMS text messages.
- Able to understand English sufficiently to complete the study procedures.

5.4 Exclusion Criteria

- Women who are known to be pregnant or intending to become pregnant during the study

5.5 Withdrawal Criteria

5.5.1 Participant decides to withdraw from having telephone support (intervention)

Participants can withdraw from receiving the telephone support by calling Gateway or by making a request to the University research team. If this happens the participant should be asked if it would be possible to still contact them at three and 12 months follow up to see if they would be willing to complete the follow assessments. It should be emphasised that it is very important for the research in people to be followed up even if they do not wish to continue to receive the intervention. Otherwise we can get an overly optimistic view of a new programme and it is important that programmes are not recommended to people to help with their weight if they are not effective.

5.5.2 Participant decides to withdraw from the trial

Participants can withdraw from the study by contacting the research team at the University. If participant call Gateway to withdraw from the trial they should be asked to call/notify the University research team to discuss their withdrawal. Participants should be asked if it would be possible to still contact them at a later date to complete the follow ups. It should be emphasised that it is very important in research for people to be followed up otherwise we can get an overly optimistic view of a new programme and it is important that programmes are not recommended to people to help with their weight if they are not effective.

6 STUDY MANAGEMENT

The day-to-day management of the study will be co-ordinated by the University of Birmingham.

6.1 Roles And Responsibilities

See *Appendix A* for the roles and responsibilities of trial staff.

7 ADVERSE EVENTS

There is no reason to assume that this study will lead to an excess of adverse events. The treatment consists of prompting target setting and daily weighing, neither of which seem likely to create harm. Some people believe that asking people to weigh themselves daily may make people become obsessive with their weight and thus cause psychological harm. However, there is no evidence from randomised controlled trials that this is the case but it is important to provide evidence of no harm. Thus, we will measure uncontrolled eating, emotional eating and weight preoccupation in both groups. We will also report serious adverse events related to bulimia, anorexia and self-

harm related to body dissatisfaction that result in hospitalisation during the trial to the trial sponsor (University of Birmingham) and the Trials Steering Committee.

We recognise that follow up of participants requires us to behave sensitively and that, in a trial of this size, some participants will suffer serious health events or other misfortunes that will come to light in a follow up telephone call. To ensure that future follow up attempts are appropriate, we will log these events in section 9 of the CRF. The trial manager will also contact participants if they answer yes to two (one of which has to include the first question) of the SCOFF questions: "do you make yourself sick if you feel uncomfortably full", and "do you worry if you have lost control over how much you eat" and "would you say that food dominates your life". We will talk to participants and ascertain if they are currently doing this and would like further help and suggest they contact their GP.

8 ASSESSMENT AND FOLLOW-UP

8.1.1 Baseline:

Participants will have their height and weight measured by the researcher at a home visit. They will complete the baseline questionnaire and prompted to answer the open questions in the CRF before being randomised (cc. CRF and baseline questionnaire). Usual care participants will be given the standard Lighten Up weight loss maintenance leaflets. The intervention group will also be given a set of BodyTrace scales to use to weigh themselves and a weight record card to record their weight in each day. The BodyTrace scales transmit weight data to a remote database. Each participant will be assigned a scale with a unique barcode. Data will be downloaded from the BodyTrace website and linked to the participant by the assigned barcode ID. Data will be downloaded on a monthly basis.

8.1.2 Three month follow-up:

Participants will be mailed the three month follow-up questionnaire prior to being contacted to arrange a visit by the research team. At this visit the questionnaire will be collected and participants will be weighed by the researchers. Participants will be given a £20 voucher for fully completing follow-up. There are two versions of the questionnaire; one for the intervention group and one for the usual care group.

8.1.3 Six month follow-up

Participants will be sent the six month questionnaire and a self-addressed envelope to return in the post. There are two versions of the questionnaire; one for the intervention group (green) and one for the usual care group (blue).

8.1.4 12 month follow-up

Participants will be sent the 12 month follow-up questionnaire in the post prior to being contacted to arrange a visit by the research team. At this visit the questionnaire will be collected and participants will be weighed by the researchers. Participants will be given a £20 voucher for follow-up visit.

9 STATISTICS AND DATA ANALYSIS

9.1 Statistical Plan

We have proposed a sample size based on the likely size of effect we expect to achieve, a 2 kg difference in change in weight at 12 months. A total of 280 participants randomised to each group (n=560) will be sufficient to detect a 2 kg difference in change in weight at 12 months follow up between the intervention and usual care groups, with 90% power and 5% significance level. This estimate is based on our pilot trial where we found the standard deviation of the difference from baseline (i.e. end of weight loss/start of maintenance programmes) to 12 months follow up in those who lost at least 5% of their starting weight was 6.3 kg. 560 participants allows for 25% loss to follow up at 12 months.

9.2 Randomisation and Blinding

We will follow SOP 14-01 for randomisation and blinding (Appendix C). The randomisation list will be developed by an independent statistician within the Primary Care Research and Trials Unit using NQuery. Participants will be randomised to telephone support or booklet support on a 1:1 basis using random permuted blocks of random size. The lists will be stratified by whether participant intends to continue with their weight loss programme or not. Separate lists will be provided to each trial coordinator since recruitment will be undertaken concurrently by more than one person.

Participants will be randomly allocated to either the telephone support or booklet support group at the baseline visit using opaque sealed envelopes. Participants will be allocated to the groups according to the number order of the batched stratification envelopes that should be opened sequentially in number order and following the instructions below.

- If participants indicate they intend to continue to attend their weight loss intervention the next envelope in the **BROWN** batch must be opened.
- If participants indicate they **DO NOT** intend to continue to attend their weight loss programme then the next envelope in the **WHITE** batch must be opened.

Each person conducting baseline visits will have their own unique set of white and brown batched randomisation envelopes to follow sequentially. The envelope must be opened as detailed above and the slip inside shown to the participant which will indicate the group which they have been randomised to receive (i.e. telephone support[intervention group]or booklet support [usual care group]). Participants' name, ID and date of birth, date of visit and name of person opening the envelope should be written on the back of the slip. The randomisation envelope should be put in the participant's home visit data envelope and given back to the trial coordinator as soon possible. The trial coordinator will then record the group allocation on the trial database at UoB and arrange for the CRF data to be entered on to the UoB database.

9.3 Blinding

Participants will not be explicitly told that this is a trial about target setting and daily weighing and will therefore be blinded to group allocation. We will also ensure that research

assistants taking follow-up outcome measures will be blinded to group allocation by providing the CRF in a sealed envelope with a sticker on the front to record the weight of the participant. Weight will be recorded and therefore research assistants will be blinded to the primary outcome before completing the CRF. The research assistant completing the primary outcome will not have randomised and collected baseline measurements. The trial statistician will remain blinded to group allocation until analysis is completed.

9.4 Analysis Plan

Full details can be found in the Statistical Analysis Plan (SAP). In summary, analysis will be conducted using the intention to treat principle. The primary outcome will be assessed by analysis of covariance to compare weight change (baseline to 12 months) between the groups. Baseline weight and intention at baseline to continue to attend a Lighten Up weight loss programme (stratification variable) will be included as covariates. All participants will be included in the primary analysis regardless of whether they have maintained, lost weight, or gained weight. A similar analysis will be used to compare the secondary outcome of change in weight from baseline to three month follow up. Analysis of the proportion of participants in each group who regain no more than 1 kg from their weight at the end of the weight loss programme (i.e. successful maintainers) at three and 12 month follow up will be conducted using generalised mixed modelling.. We will examine the effect of gender and initial weight loss programme on outcomes in subgroup analyses.

9.4.1 Analysis plan for process measures

We will examine the degree to which participants develop automaticity and the regularity of weighing assessed by their objective weighing scales and the degree to which automaticity is associated with weight change. Furthermore, we hypothesise that regular weighing induces participants to develop conscious cognitive restraint over their food intake and we will therefore assess the association between the frequency of weighing and the development of conscious cognitive restraint. As these are repeated measures we will use repeated measures mixed modelling. We will proceed with full mediation analysis using either Baron and Kenny's approach or structural equation modelling.

9.5 Data Handling, Record Keeping And Retention

Gateway Family Services will provide the research team with all the relevant study data collected by them every month and this information will be merged with the main trial study database hosted by the Primary Care Clinical Research Trials (PCCRTU) at the University of Birmingham (see section 4.2.3). All data will be anonymised and participants will be matched by ID numbers. Every attempt will be made to minimise loss to follow up.

9.6 Data Access and Quality Assurance

Data will be kept in accordance with the Data Protection Act and the trial registered with the Data Protection Act website at the University of Birmingham. The standard operating procedures of the trials unit will be followed, which are designed to protect patient confidentiality (SOP 07-04, appendix C). Patient identifiable information will be available to the person conducting follow up as it is important that these data are known to them. Otherwise, confidentiality will be maintained and no one outside the trial team will have access to either the CRFs or the database. Data entry and validation will follow SOPS 07-01, 07-02 and 07-03 (Appendix C).

9.7 Case Report Forms

The secure online database will hold all of the information from the CRF, however there will also be a paper copy of CRFs. The paper CRFs will be kept in a locked cabinet in a locked office in a locked department. Only individuals detailed on the site delegation form will be allowed to complete the CRF forms and will follow SOP 07-05 (appendix C).

10 REGULATORY ISSUES

10.1 Ethics Approval

The Chief Investigator has obtained approval from the University of Birmingham's Research Ethics Committee. The study will be conducted in accordance with the recommendations for physicians involved in research on human subjects adopted by the 18th World Medical Assembly, Helsinki 1964 and later revisions.

10.2 Participant Consent

Participant consent will be taken as set out in the study manual and will follow SOP 12-02 (see appendix C).

10.3 Confidentiality

The Chief Investigator will preserve the confidentiality of participants taking part in the study, and is registered under the Data Protection Act. Confidentiality will be monitored and consent will be sought from participants to access information they have previously given to Gateway Family Services.

10.4 Indemnity

The University of Birmingham holds clinical trials insurance policies, which apply to this study.

10.5 Sponsor

The University of Birmingham will act as the sponsor for this study.

10.6 Funding

The National Institute of Health Research are funding this study.

10.7 Audits

The study may be subject to inspection and audit by The University of Birmingham under their remit as sponsor, and other regulatory bodies, to ensure adherence to GCP and the NHS Research Governance Framework for Health and Social Care (2nd edition).

11 FINANCIAL ARRANGEMENTS

11.1 Participant Payments

Participants who provide objective measures of weight (i.e. researchers visit them) at their three and 12 month follow up visits will be given a voucher of £20 to cover the inconvenience.

The voucher will need to be signed for as evidence of receipt in the appropriate place in the CRF.

12 PUBLICATION

The trial results will be published and all who meet the criteria for authorship will be listed as authors. We will present the results to the TSC prior to publication. All related papers will be discussed with the trial management group and decisions taken on authorship. Members of the TSC will be listed and their contribution acknowledged, as will the funding source. The funders have no contribution to make on decisions on publication.

13 REFERENCES

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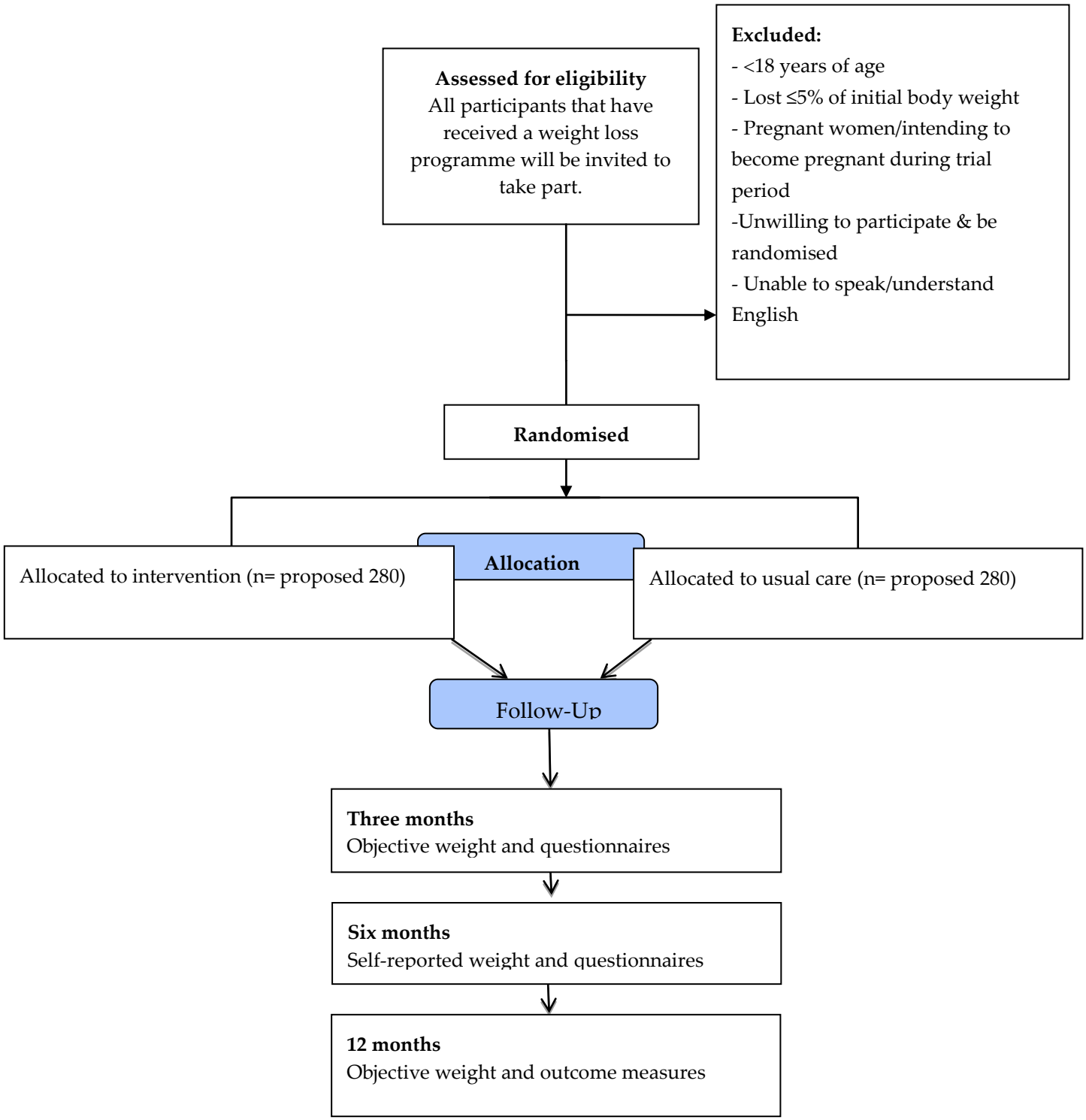
14 PROTOCOL AMENDMENTS

Version 1.1 Approved on 02/06/15

STUDY PERSONNEL CONTACT SHEET

CONSORT Flow Diagram



List of relevant documents

List of SOPS

Title	**SOP**	
Coding of research data	07-01	Available on PCRTU intranet
Manual data entry	07-02	
Validation and cleaning of manual data entry	07-03	
Data protection	07-04	
Case report form completion of clinical trials	07-05	
Obtaining informed consent with adults	12-02	
Randomisation and blinding	14-01	

List of trial documentation

Title	**File name**	
Site delegation form	Site Delegation log_bham Site Delegation log_Gateway	Available in LIMIT folder
CRF	Limit CRF V2 270614	
Information sheet	Information leaflet	
Consent form	Consent form version 2 03042014 Consent form additional sites V1 04032015	
Trial Manual	Limit trial MANUAL 010714	
Baseline questionnaire	LIMIT Baseline questionnaire version 2 250614	
Three month questionnaire INTERVENTION	LIMIT 3 Month Intervention questionnaire Version 3 020714	
Three month questionnaire CONTROL	LIMIT 3 Month Control questionnaire Version 3 020714	
Six month questionnaire INTERVENTION	LIMIT 6 Month Intervention questionnaire Version 3 020714	
Six month questionnaire CONTROL	LIMIT 6 Month Control questionnaire Version 3 020714	
12 month questionnaire INTERVENTION	LIMIT 3 Month Intervention questionnaire Version 3 020714	
12 month questionnaire CONTROL	LIMIT 12 Month Control questionnaire Version 3 020714	