Health Technology Assessment Programme

National Institute for Health Research

NIHR HTA Programme

11 November 2013

The NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC), based at the University of Southampton, manages evaluation research programmes and activities for the NIHR

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Wei**g**ht **L**oss **M**aintenance in **A**dults (WILMA)

Sponsor:	**Cardiff University** **30-36 Newport Road** **Cardiff** **CF24 0DE**
Sponsor ref:	**SPON 757-09**
Funder:	**NIHR Health Technology Assessment**
Funder ref:	**08/44/04**
REC ref:	**10/MRE09/8**
ISRCTN ref:	**ISRCTN35774128**

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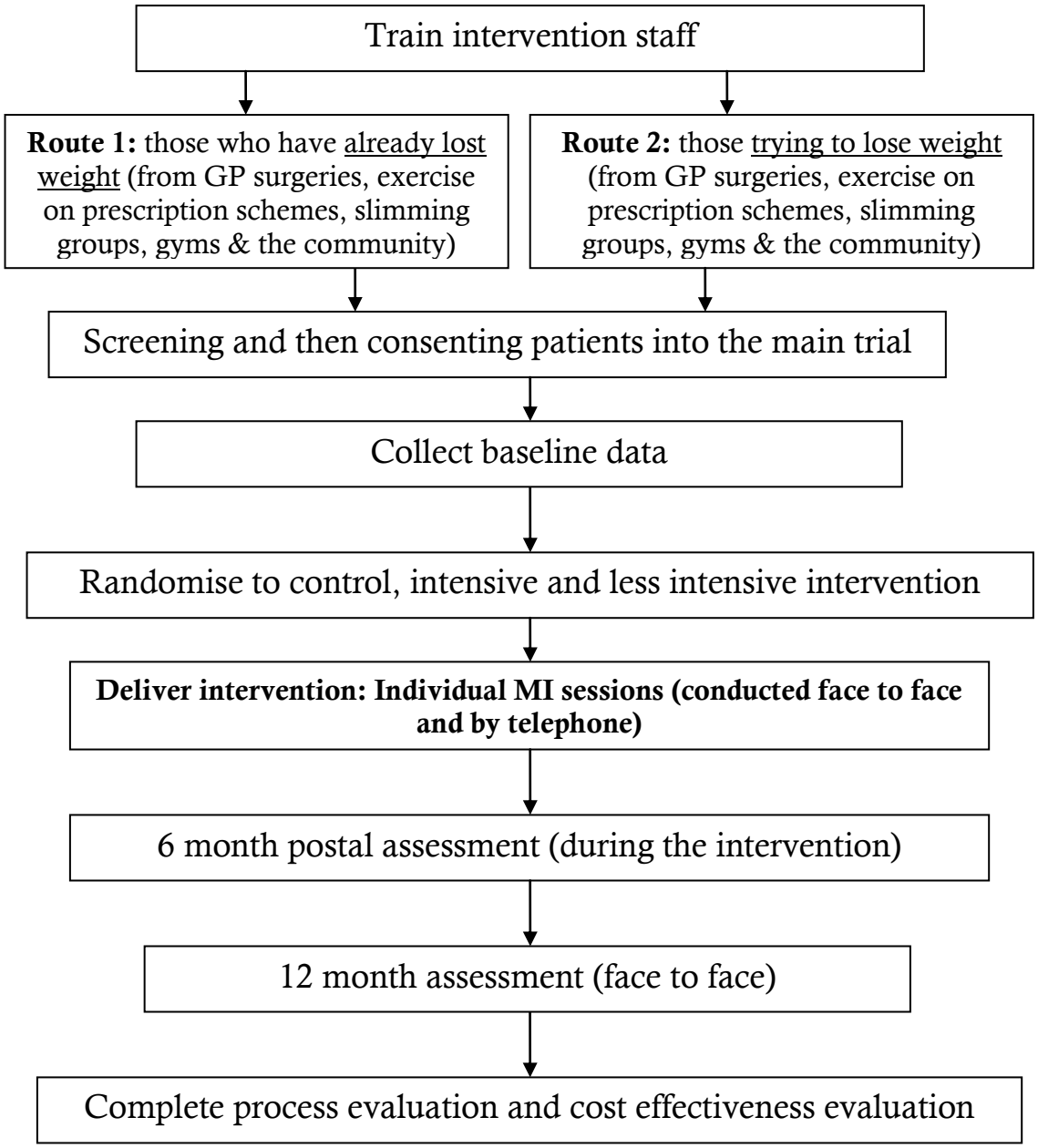
Glossary of abbreviations

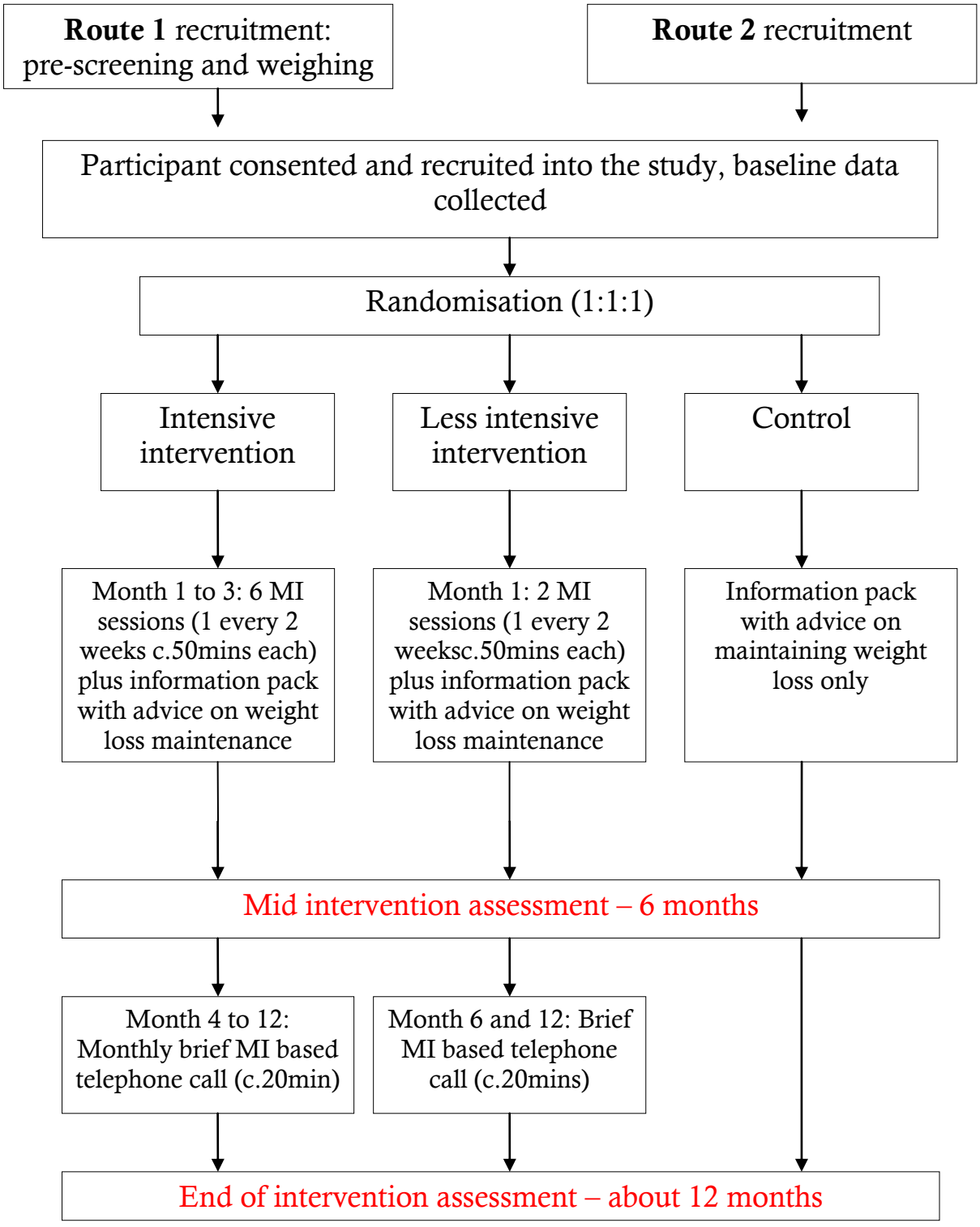
AE	Adverse Event
BMI	Body Mass Index
CI	Chief Investigator
CRF	Case Report Form
DMEC	Data Monitoring and Ethics Committee
GP	General Practitioner
MI	Motivational Interviewing
MITI	Motivational Interviewing Treatment Integrity Scale
NICE	National Institute for Health and Clinical Excellence
NIHR HTA	National Institute for Health Research Health Technology Assessment
PI	Principal Investigator
QALY	Quality Adjusted Life Year
RCT	Randomised Controlled Trial
SAE	Serious Adverse Event
SCT	Social Cognitive Theory
SDT	Self Determination Theory
SEWTU	South East Wales Trials Unit
TMG	Trial Management Group
TSC	Trial Steering Committee

1 Trial summary & study schema

1.1 Study schema



1.2 Participant flow diagram



MI - Motivational Interview

1.3 Trial summary

Background
Studies of weight loss maintenance have had limited effectiveness with weight regain common. Reviews have identified issues important for maintenance including: physical activity; low calorie/low fat diet; self regulation; tailoring; social support; internal motivation and self efficacy. These are central to the intervention being evaluated in this trial.

Aim
The main aims of this feasibility study are to assess the feasibility, acceptability, compliance and delivery of a12 month multi-component intervention, as well as recruitment and retention into the study. We will also evaluate the intervention or a less intensive version on participants': Body Mass Index (primary outcome); waist circumference; waist to hip ratio; physical activity levels and diet around one year from randomisation. This will give an indication of effect sizes for a larger trial. These data would be essential for a future trial of this intervention or a variant of it and also for other trials of weight loss maintenance.

Design
Feasibility study of a 3 arm (intensive, less intensive, control) individually randomised controlled trial. During the trial those allocated to the intensive or less intensive groups will receive a 12 month individually tailored intervention based on two key features; MI and self regulation. The focus will be on maintaining the gains participants have already made. The control group will receive an information pack detailing lifestyle changes for weight maintenance.

Population
We will recruit 170 obese adults aged 18-70 (current or previous BMI 30+) who have lost at least 5% body weight (independently verified) from GP surgeries, exercise on prescription schemes, commercial weight loss groups, community based groups and gyms. We will also approach people trying to lose weight who will be consented into the study as soon as they have lost 5% of their body weight. Exclusion criteria include; living with a trial participant, pregnancy, previous bariatric surgery (unless subsequently fully reversed), terminal illness or inability to comply with the study protocol.

Outcome measures
The feasibility outcomes will be measured using percentages of participants who accepted and complied with the intervention. Numbers recruited and retained will also be presented, as well as data on intervention fidelity. The primary effectiveness outcome is BMI at 1 year post randomisation and the primary contrast will be between the intensive and control groups. Secondary effectiveness outcomes include waist circumference; waist to hip ratio; self report physical activity; proportion maintaining weight loss; self report dietary intake; health related quality of life; health service and weight control resource usage; binge eating, psychological well being and duration of participation and drop out from intervention.

Duration and follow-up
The trial will start after participants are recruited and consented, and they have lost at least 5% of their body weight. Participants will be assessed at 6 months during the intervention

and followed up at the end of the intervention (about 12 months from randomisation with a 3 month window allowing for delays).

2 Introduction

2.1 Background

Whilst there is a large body of literature examining weight loss, there are few randomised controlled trials specifically exploring maintenance.[1-3] One RCT of weight loss maintenance found that at 18 months in the intervention group average weight gain was 2.5kg whereas in the control group average gain was 4.9kg.[4] Another study with a longer follow-up found that at 30 months those in the intervention group had a mean regain of 4kg compared to 5.5kg in the control group and 71% remained below entry weight .[2] Although there is some evidence which indicates that maintenance interventions are associated with smaller weight gains compared to no contact,[1, 3, 5] the prevention of weight regain remains a challenge, differences between intervention and controls tend to be small and around a third of the weight lost during an intervention is regained in the following year.[6]

The psychological processes, skills and strategies which are likely to be effective for weight maintenance are potentially different from those that are needed to lose weight.[4, 7] Research examining 5000 people on the National Weight Control Register suggests that the only factor those losing weight have in common is that they combined diet and exercise to lose weight. When examining the maintenance phase however, a number of common factors were identified including low fat diet, eating breakfast, self monitoring and high levels of physical activity. Losing weight requires a negative energy balance whereas weight maintenance requires continued energy balance. This balance needs to be sustained by behaviours which can be continued over the longer term. In reviews of factors associated with weight loss maintenance a number of issues stand out which are central to the current intervention. These are higher levels of physical activity,[8] low calorie and low fat foods, tailoring of advice, self regulation/monitoring, social support, internal motivation and self efficacy.[9, 10]

2.2 Rationale for current study/trial

The proposed study will evaluate an intervention based on 2 main components: **Motivational Interviewing** (incorporating implementation intentions[11]) and **self regulation** (self monitoring). The overarching theme of the intervention is motivation. Motivation is central to many theories seeking to explain behaviour change. Motivation is unlikely to be static and will be a product of internal and external factors related to the individual.[12] Since prolonged intervention contacts have been shown to help sustain weight loss[2], and attrition from longer term programmes is a problem,[4] motivation is likely to be a key factor. Many people are able to become motivated enough in order to lose weight by dieting and/or exercise.[7] However, maintaining these behaviours seems to be challenging and therefore enhancing motivation will be crucial to continued maintenance of healthy behaviours.

Motivational Interviewing will therefore be the key ingredient of the intervention. Motivational Interviewing (MI) is a client-centred technique, emphasizing personal autonomy, which enhances motivation for change. It is based on the well established

concepts of causal attributions, self efficacy and cognitive dissonance. MI has been shown to be effective as an adjunct to a behavioural weight control program.[13, 14] It can be useful in maintaining behaviour change as well as initiating change[15] and it will support participants in an ongoing, tailored way.

RCTs and systematic reviews of MI approaches have shown that it can be used successfully in interventions to change both diet and exercise[16-20] even when delivered by telephone.[21, 22] Brief interventions using MI have been effective in different areas of behaviour change including diet and exercise. There is some evidence that MI can be effective when only one session is given[23] and even when sessions are as short as 15 minutes.[16, 24] One meta analysis examining MI in different areas of disease showed a combined effect of MI on decreasing BMI of 0.72 ($p<0.0001$) and found that longer follow-up increased the chance of an effect from 36% at 3 months to 81% at 12 months or longer.[16]

Self Determination Theory (SDT[25]) provides a theoretical framework for understanding MI. SDT emphasizes the importance of self regulation and autonomy and conceptualises motivation as intrinsic and extrinsic. Thus, people need to believe they have the skills and confidence needed to carry out a certain behaviour (confidence, efficacy, competence) as well as feeling that they have full responsibility for commencing and maintaining that behaviour and that they are doing so freely (autonomous, self-determination, responsibility).[26]

Motivational interviewing addresses these key areas using a variety of techniques like: developing discrepancy, providing information, helping the client develop goals and considering how to implement these, supporting autonomy and self-efficacy, avoiding being overly directive, exploring pros and cons and avoiding blaming or judgment. These will be incorporated in the intervention, and implementation intentions will also be discussed in the MI sessions as these have been shown to be crucial in the link between intention to change behaviour and actual behaviour.[27] There is evidence that implementation intentions are more effective when combined with motivational interventions.[28] Implementation intentions help individuals establish new habits. Making healthy behaviours habitual is critical if they are to be maintained over the long term; hence this is an implicit aim of the proposed intervention. Implementation intentions specify a plan of when, where and how a person is going to, for example, start exercising. This results in the behaviour being elicited automatically by the relevant environmental cue rather than by a more effortful decision-making process. As behaviours are repeated they become increasingly automatic or habitual and hence more resistant to change.

The other component of the intervention has been shown to be important in weight management. Self regulation is successful in weight maintenance[4] and is recommended by NICE.[30] This consists of regular self weighing and monitoring of diet and physical activity.[16] Self-regulation is central to SDT and Social Cognitive Theory (SCT[31]) and there are conceptual overlaps between these two theories. SCT has two core constructs; self efficacy and outcome expectancies. Individuals have to believe that they possess the necessary skills to change their behaviour and believe that their actions will produce certain consequences, e.g. improved health.

The intervention components can be conceptualised in terms of both motivational and volitional aspects. The different components of these and their theoretical links are as follows:

- **Motivational** - self efficacy (SCT and SDT[31, 25]), outcome expectancies (SCT[31]), intrinsic/autonomous motivation (SDT[25]), causal attributions (SDT[25]) and developing discrepancy.
- **Volitional** - goal setting (SCT[31]), implementation intentions, self regulation (SCT/SDT[31. 25]), self efficacy (SCT and SDT[31, 25]) and problem solving (SCT[31])

The intervention will enhance motivation to adhere to behaviours associated with weight maintenance and although the intervention will focus on maintenance rather than weight loss, further weight loss may occur.

The proposed study will evaluate a 12 month, individually tailored intervention based on MI approaches incorporating implementation intentions and self regulation. The main part of the intervention is concentrated in the first five to seven months, which tapers down to less regular support. We feel that this longer term support, although not resource intensive, is important for the likely effectiveness of the intervention. Previous studies that have had success at weight maintenance have had longer term interventions and support.[2, 4, 5] The focus of the intervention will be on maintaining gains already made. It is envisaged that this intervention, if successful, could be rolled out to a wide variety of people who have lost weight using different methods, therefore the participants will be recruited from a variety of settings.

The trial will have three arms; an intensive intervention arm, a less intensive intervention arm and a control arm. We hypothesise that the intensive intervention will be effective and that the less intensive intervention will have an effect somewhere between the control and intensive intervention. This less intensive arm is important because while some studies have emphasised the importance of long term intervention and follow-up, it remains unclear how intensive this should be and how it is best delivered. This has important implications for cost and the feasibility of rolling out the intervention should it be successful. Effectiveness in this trial refers to maintenance of initial weight loss rather than additional weight loss although this is likely to occur for many participants.

3 Study/trial objectives

3.1 Objectives

The main objectives of this feasibility study are to assess the feasibility, acceptability, compliance and delivery of a12 month multi-component intervention, as well as recruitment and retention into the study. We will also evaluate the impact of the intervention or a less intensive version on participants' Body Mass Index (primary effectiveness outcome). Secondary effectiveness outcomes include: waist circumference; waist to hip ratio; physical activity levels, diet, health related quality of life, binge eating, psychological well being and health resource usage one year from randomisation. This will give an indication of effect sizes for a larger trial.

Additionally we will examine the proportion of participants maintaining at least 5% of body weight previously lost. We will also assess mediators and moderators associated with change. Mediators include; self-efficacy, social support, self monitoring and

implementation intentions, habit formation and intrinsic motivation. Key moderators will be explored in relation to weight maintenance, and the intervention which will allow us to elucidate factors associated with success. These will include; demographics, weight loss history, satisfaction with weight loss, current weight loss goals, binge eating and psychological well being. A process evaluation of the intervention will be undertaken to examine participant views, drop out, duration of participation in the intervention and associated factors. An economic evaluation will also be completed.

4 Study/trial design

This is a feasibility study of a three arm individually randomised controlled trial. The three arms are: an intensive intervention arm, a less intensive intervention arm and a control arm that will receive an information pack and usual care (the intervention arms will also receive the information pack). The two experimental arms will receive a 12 month intervention, which will differ with respect to how intensive the intervention is in terms of the amount of contact with the MI therapist. Individuals will be followed up at 6 months during the intervention and at around 12 months – after the intervention has been delivered (one year from randomisation). Obese adults aged 18-70 with a current or previous BMI of 30+ who have lost a minimum of 5% body weight during the previous twelve months will be recruited.

4.1 Treatment period

The intervention period for participants in the two intervention arms of the trial is 12 months.

4.2 Frequency & duration of follow-up

Following baseline assessments participants will be followed up at 6 months during the intervention by postal questionnaire. Participants will be followed up by a researcher at the end of the intervention (approximately 12 months after randomisation with a 3 month window to allow for any delay)..

4.3 Outcomes

The key outcomes are feasibility, acceptability, compliance and delivery of the intervention as well as recruitment and retention. However we will evaluate the impact of the intervention on BMI as well as the outcomes listed below:

- Waist and hip circumferences
- Physical activity (IPAQ[32])
- Diet (DINE[33])
- Health related quality of life (EQ5D[34])
- Health service and other weight control resource usage e.g. slimming groups (recorded on a Case Report Form)
- Binge eating (EDE-Q[35])
- Psychological well being (GHQ-12[36])
- Health-related behaviours (alcohol consumption and smoking status)[37, 38]

Process outcomes

- Proportion maintaining weight loss
- Duration of participation in the intervention & drop out
- Competency in intervention delivery (assessed via audio-recording MI sessions)
- Evidence of self-regulation, goal setting and implementation intentions (assessed via MI counsellor Case Report Forms and frequency of self-monitoring of weight)
- Participant and counsellor experiences of taking part in the study (qualitative interviews and focus groups)

5 Centre/practice and/or participant selection

We will recruit obese adults from GP practices, exercise on prescription schemes, commercial weight loss programmes, gyms and the community. The multiple sources of recruitment should increase the generalisability of the study results. Participants will be recruited throughout Wales, South West England and the East Midlands.

5.1 Inclusion criteria

Obese adults both men and women aged 18-70 years with current or previous BMI of 30+ who have intentionally lost at least 5% body weight (by pharmacological, lifestyle and/or behavioural methods) during the last 12 months and with independent verification of weight loss (method of verification to be documented by referring practitioner/member of research team).

5.2 Exclusion criteria

We want the study to be as generalisable as possible therefore the only exclusions would be those that rendered the person unable to comply with the protocol such as previous bariatric surgery (unless subsequently fully reversed e.g. by removal of a gastric balloon), terminal illness, pregnancy in women, poor competence in English (resulting in an inability to complete study materials) and living with another study participant. We will ask women of childbearing age to let us know if they become pregnant at any point during the trial. Once recruited, pregnant women will not be excluded from the study but will be given a leaflet on exercising safely during pregnancy.

6 Recruitment

6.1 Recruitment process

Independent verification of weight loss will be required for entry into the study. We will utilise two main routes for recruitment (see diagram 1 below). For Route 1 we will recruit people who have already lost weight. Individuals will be approached face to face or via records from GP surgeries, exercise on prescription schemes, slimming clubs, gyms and the community. We will advertise in local newspapers and radio, GP surgeries, community groups, slimming groups and gyms, for people who have lost weight and can provide independent verification. For Route 2 we will recruit people who are trying to lose weight. These again will be approached via GP surgeries, exercise on prescription schemes,

slimming clubs and gyms (from records or face to face) or via advertisement as described above. We will weigh potential participants and contact them to see if they are still willing to take part in the trial once they have achieved 5% weight loss.

The decision to recruit participants into the trial will not be made by the individual delivering the intervention.

Route 1: Those who have lost weight (independently verified)
Within this route we will approach potential participants three ways, either:

- when GP's, nurses, exercise on referral counsellors, slimming club consultants or pharmacists see the person face to face
- where they identify them from their records
- via advertising (in GP surgeries, gyms, community centres, exercise schemes or slimming clubs)

We will ask GP's and practice nurses, pharmacists, exercise on referral counsellors or slimming club consultants to approach potential participants and give them an information sheet and an 'expression of interest' form on which they can register their contact details. This form will then be sent to the research team. We will then contact the potential participant and arrange for them to meet with a researcher who will explain the study and take consent. Participants who are identified from records will be sent a letter about the study and an expression of interest form. Eligible participants may also respond to the research team directly following advertisements in community settings and/or the local media.

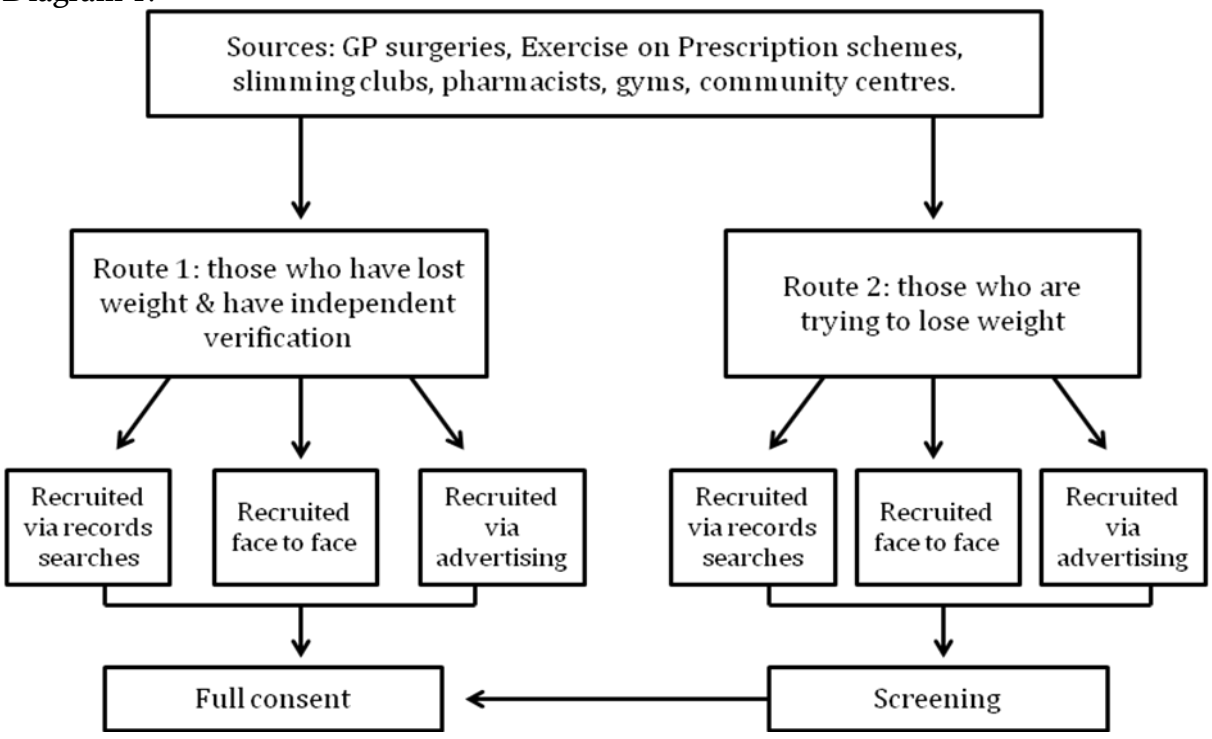
Participants identified in each of these three ways will have independent verification of weight loss (verified by referring GP/nurse, exercise on referral counsellor, slimming club consultant or member of the research team). Participants' current and starting weight (i.e. before 5% loss) will be recorded on the expression of interest form by either the referring practitioner or a member of the research team. If it is not possible to independently verify the participant's weight loss, they will be referred to Route 2 outlined below. Participants will be fully consented when they meet with the researcher.

Route 2: Those trying to lose weight
People who express an interest in the study (following receipt of information sheet 1) via their GP, nurse, pharmacist, exercise on prescription counsellor or slimming consultant will complete an 'expression of interest' form (as Route 1) which will be sent to the research team. We will contact these individuals as well as those who respond to the advertising to either: (a) attend a screening meeting with a researcher locally, or (b) to 'self-screen' by providing documented evidence of starting weight and 5% weight loss within the recruitment window (e.g. a printout from scales in their local chemist/supermarket, slimming club booklet, GP letter or other means of documented weight). Participants attending screening appointments will meet with a researcher locally (e.g. a community centre) where the potential participants will have the study explained to them and be provided with a second information sheet outlining the screening procedure (screening information sheet). At this point they will only consent to their weight and height being recorded and to being contacted in the future to see if they would be interested in taking part in the main trial. Those agreeing to be weighed will provide contact details and we will ask them to call us once they have lost 5% of their body weight. If we haven't heard from them we will phone them after two months to see if they have lost 5% of their body

weight. If they haven't lost enough weight we will call them up to twice more at a time agreed with the potential participant. If they achieve 5% weight loss they will then be invited to meet with a member of the research team who will explain what the trial is about, provide a second information leaflet (main trial information sheet, sent in advance of the meeting to allow sufficient time for the individual to decide whether they wish to participate further) and take consent.

N.B. All participants referred to the research team by a GP/nurse, pharmacist, exercise on referral counsellor or slimming club consultant will be asked to confirm whether they have already lost (Route 1), or intend to lose 5% body weight (Route 2) on the 'expression of interest' form. For participants approached during face-to-face consultations, the referring practitioner will be asked to confirm on the same form whether they can independently verify 5% weight loss for those potential participants who have selected Route 1. Referring practitioners will be provided with a chart detailing 5% weight loss for a likely range of starting weights which they may use with potential participants during face-to-face encounters. Participants approached by letter from records who return a completed expression of interest form will either send verification of weight loss directly to the research team (e.g. by enclosing a copy of their slimming club record) or provide details as to how the research team can access independent verification information (the research team will contact the referring practitioner for verification where applicable/necessary). Participants approached via records searches who are not able to provide independent verification of weight loss will be recruited via Route 2. We will also ask GP/nurses, pharmacists, exercise on referral counsellors and slimming club consultants and to record basic demographic data (anonymised) to comprise age and gender.

Diagram 1:



Slimming World and exercise on prescription scheme staff will be offered High Street vouchers as an incentive to engage with the study and identify potential participants. For the exercise on prescription staff, a £20 voucher will be offered to the best recruiter on a bi-monthly basis. For Slimming World, each staff member will be offered a £20 voucher for

every 5 participants they manage to recruit into the study in a month. In addition, there will also be a £20 voucher for the best Slimming World recruiter each month. This incentive will not be offered to staff at GP surgeries as they are already in receipt of service support costs which cover the time of practice staff.

6.2 Informed consent

Route 1: Those who have lost weight

For those potential participants who have verification of weight loss (they could have been identified face to face, from patient records searches or advertising), once the research team have received the expressions of interest forms (including verification details and current/starting weight) or have been contacted by the potential participants, we will arrange a convenient time and place to meet to discuss the study and an information sheet will be sent to them in advance. When they meet with the researcher she/he will go through the information sheet explaining the study, checking frequently for understanding. They will be given plenty of time to read the material and to ask any questions they have about the study. If the person is eligible for the trial (eligibility will be verified by the researcher using the checklist provided), consent will be obtained from those willing to take part.

We will also approach some of the trial participants to ask them if they would be willing to do a short interview (which will be audio recorded) about their experiences of taking part in the study. Similarly we will also approach the MI counsellors to ask them if they would be willing to be interviewed and possibly take part in a focus group to discuss their experiences (also audio recorded). Separate consent will be taken from both the participants and MI counsellors at the time of these interviews. The person's GP will be informed that they are taking part in the trial and sent a copy of the consent form. All initial contacts with participants (i.e. baseline assessments or screening visits) will be undertaken in public community venues. However, face-to-face MI sessions and/or follow-up appointments may be conducted in participants' homes. Participants' GPs will also therefore be asked to contact the study team and give their assessment of whether this is likely to pose a particular risk to the personal safety of a member of the WILMA team (by returning the form provided or phoning the research team within 1 week of receiving the letter). We would not ask for any details concerning the nature of the risk, only for a recommendation that face-to-face contacts do not take place in the participant's home. Any disclosure of suspected risk will be treated in the strictest confidence. To ensure the personal safety of research and intervention staff carrying out MI, or data collection sessions, particularly those requiring home visits, we will follow the WILMA Lone Worker policy.

Route 2: Those who are trying to lose weight

People expressing an interest in being involved in the study (following receipt of information sheet 1) will be invited to meet with a member of the research team at a convenient time and a place local to the potential participant. Potential participants who agree to be screened will be sent confirmation of the date and time of their appointment and who they will be meeting (confirmed by email/text/phone/letter). The researcher will explain the study and check frequently for understanding, as well as provide the potential participants with a screening information sheet. They will be given plenty of time to read the material and to ask any questions they have about the study. If the person is eligible for

the trial, those willing will agree to their weight being recorded and to being contacted in the future to see if they would be interested in taking part in the main trial. Staff taking consent will be trained in taking consent and in trial procedures. Individuals who have yet to lose 5% body weight and elect to 'self-screen' will be advised of types of verification acceptable to the research team.

Individuals who have successfully lost 5% of their body weight and who are eligible for the trial will either contact us or we will phone them after two months. If they haven't lost enough weight we will call them up to twice more after this at a time agreed with the potential participant. We will make an appointment for them to meet again with a researcher at a convenient time and place and send them the information sheet in advance so that they can consider taking part. When they meet, the researcher will weigh the person to confirm weight loss and then the researcher will go through the information sheet explaining the study, checking frequently for understanding and take consent. The potential participants will be given plenty of time to read the material and to ask any questions they have about the study. If the person is eligible for the trial, consent will be obtained from those willing to take part.

6.3 Registration

Research staff, GPs, pharmacists, exercise on prescription counsellors or slimming club consultants will keep a log of those approached. The researcher will also keep a log of anyone who declined at the pre-trial weighing meeting or at the trial consent meeting. A Case Report Form (CRF) will be completed for all those consented which will include details of nominated persons (e.g. mother or friend) to facilitate participant follow-up.

6.4 Non-registration

Individuals are quite at liberty to decline to consent to taking part in the study and their health care will not be affected in any way.

6.5 Withdrawal & loss to follow-up

Participants have the right to withdraw consent for participation in any aspect of this trial at any time. In order to ascertain which aspect the participant wishes to withdraw from, withdrawal forms will be completed by the study team. If participants wish to withdraw from all aspects of the study without giving reason, consent to use data already collected will be assumed unless otherwise specified. Care from health services will not be affected at any time by declining to participate or withdrawing from the trial. Based on systematic reviews of similar studies we estimate that loss to follow-up will be around 30%[17, 39, 40].

We will make every effort to reduce loss to follow-up using the methods listed below:

1. We will emphasise the importance of getting follow-up data to all participants at baseline and the 4 different follow-up points.
2. Unless they have explicitly requested otherwise, all participants will be invited to complete follow-up questionnaires and attend follow-up appointments.
3. We are seeing people face to face for all the assessments except at six months.
4. We will arrange to complete follow-ups in the participants' homes or somewhere convenient to them so they won't have to travel far.
5. We will have regular contacts in the two intervention arms building relationships with participants. We will also send newsletters and birthday cards with a 'change of address' form to participants in all 3 trial arms.

6. Participants in the control group will be offered £50 in high street vouchers or a free 12 week attendance at a local Slimming World or Weight Watchers programme at the end of the follow-up as an additional incentive to complete follow-up.
7. We will send two reminders to ask participants to return the postal questionnaire and will rearrange follow-ups twice for those who do not attend an arranged appointment.
8. We will obtain participants mobile phone numbers so we can contact them directly to arrange follow-up.
9. We will ask the participants for their GP address as well as alternative contacts.
10. We will look at the choice of outcomes to minimise respondent burden.
11. We will complete over the telephone the key questionnaires for non-responders so we have a minimum data set.
12. We will offer vouchers to thank participants for their time in attending the final outcome assessment (£20, on completion of assessment) as well as to complete and return the questionnaire at 6 months (£5 not conditional on completion/return). There is evidence that this is likely to improve follow-up and we have used this approach in other studies run by SEWTU which has led to much improved follow-up rates. In one study from 35% in the pilot to 82% in the main study.

7 Study/trial intervention

Intensive Intervention Group:
Participants in this group will have 6 one-to-one individually tailored MI sessions. The sessions will be delivered by experienced MI counsellors who will have their skills assessed prior to being employed by the study team. These sessions will be delivered fortnightly for three months and will last approximately 60 minutes. A systematic review of MI as an intervention found an effect in 87% of studies with more than five encounters[16] versus only 40% with one session of MI. For the final nine months of the intervention participants will have monthly MI telephone calls lasting around 20 minutes. This level of monthly contact in the intensive intervention group is based on previous trials.[2] Telephone support has been shown to be effective in weight loss interventions[21, 41] and provides a clear cost advantage over face-to-face sessions. Key aspects of MI will be used including reflective listening, developing discrepancy, participant directed goal setting and consideration of how to implement these, information giving, identification of barriers and supporting participants' self efficacy.

MI session content
MI counsellors will be given a handbook to guide the sessions, comprising the following information: a summary of the client group and their challenges, MI within the context of weight maintenance and intervention 'hot topics': self-monitoring; goal-setting and implementation intentions; habits; emotional eating and coping with relapse; diet; exercise; barriers to maintenance; social support and self-efficacy. Information on study-specific procedures (reporting Serious Adverse Events, lone-working, actual/risk of self-harm to participants and administrative processes) is also included. MI counsellors will keep a written record of each face-to-face and telephone session (including goal setting and implementations intentions) using the appropriate Case Report Form (CRF).

Diet and physical activity will be discussed in the MI sessions in line with current government guidance. Participants will be guided to reflect on their values, goals and current behaviour and to develop their own goals and techniques for implementing and maintaining behaviours. Participants in the intervention groups will be encouraged by researchers at their baseline assessments to self regulate by weighing themselves every week and MI counsellors will encourage the concept of self-monitoring generally. Participants will be able to record all self-monitoring activity, which may include diet, physical activity, other markers of successful maintenance (e.g. clothes fitting better), goals set at sessions and implementation intentions, in a diary provided by the study team: completion is however optional. Diaries provided to participants are intended for their personal use only and will not be collected by the study team for outcome assessment. Participants will however be asked to record their weekly weight and send this information to the study team either via the study website, by text, email or telephone. MI counsellors will be asked to record topics discussed, and goals and implementation intentions set at individual sessions on the MI Case Report Form (CRF) and this information will be collected by the study team. MI counsellors will also complete a brief written summary of the session for the participant to take away (posted to participants by the research team on behalf of the MI counsellor for telephone sessions). This information will also be recorded by the counsellor on the MI CRF and collected by the study team).
MI counsellors will also be provided with summary information relating to each of the intervention 'hot topics' outlined above. This summary information will cover key components of the information provided in the counsellors' handbook in lay language, for the counsellors to use as a reference and share with participants as required during MI sessions.

Less Intensive Intervention Group:
Participants in this group will have two face-to-face tailored MI sessions two weeks apart.[16] This is based on experience from clinical practice as well as evidence from reviews and meta-analyses.[16, 24] They will be encouraged to self-regulate by weekly weighing (to be reported to the study team online, or by text, email or telephone) and will also be given a diary in which they can record self-monitoring activity if they wish (not to be collected by the study team). MI counsellors will document session content on the MI CRF as for the intensive intervention group and participants will be given a summary of the session to take away with them. They will also receive two MI based telephone calls at 6 and 12 months lasting around 20 minutes (N.B. telephone session content also to be recorded by the MI counsellor on the appropriate CRF).

Control Group:
The control group will be given an information pack detailing lifestyle changes for weight maintenance (the intervention groups will also receive this). The content of the information pack is based on useful resources for weight loss and healthy lifestyle, and advice from a user representative, dietician and physical activity specialist specifically on weight maintenance.

All participants in all groups will still be able to access usual care. They may continue, for example to attend a weight loss group and may still be attempting to lose more weight. Participants in both intervention groups will be given the same information pack as the control group with guidance on diet and physical activity. The MI sessions will be held locally to participants. Sessions will be held in suitable rooms, e.g. small meetings rooms in

hotels community centres. Participants will also be offered the MI sessions at home if they prefer.

8 Study/trial outcomes

8.1 Measures/assessment instruments

Measures at all outcome points will be collected face to face except the 6 month assessment which will be a postal questionnaire. Outcome measures are self-report with the exception of weight, waist and hip measurements which will be objectively measured by the researcher at each visit (N.B. the 6-month assessment comprises self-report measures only).. Most of the data, apart from the moderators data (see Table 2) will be collected at baseline and post-intervention. Quality of life, physical activity and dietary data will be collected by questionnaire at 6 months during the intervention. We will also collect resource usage data at this point, since people have difficulty recalling resource use over extended periods of time and we want to be able to identify if individuals treat this as an additional intervention or a substitute e.g. for a slimming club.

With regard to cardiovascular disease, a greater BMI adds to risk prediction beyond traditional risk factor measurements.[42] Visceral fat is independently associated with all-cause mortality[43] and many of the risk factors for CVD, including type 2 diabetes mellitus.[44] As the direct measurement of visceral fat relies on sophisticated imaging technology, most large-scale, community-based studies have relied on anthropometric measurements of the waist and hip circumferences to determine abdominal obesity. Whilst the findings of these studies are not completely consistent, evidence suggests that a measurement of abdominal obesity (waist circumference or waist-to-hip ratio) provides explanatory information in addition to that provided by BMI.[45]

We will therefore measure waist and hip circumferences to assess abdominal obesity. Duplicate measurements of waist and hip circumference will be performed in accordance with standardized procedures.[46]

Table 1 - Outcome Measures
(B=baseline; 6=6 month assessment; 12m = 12 month assessment)

Outcomes	Measure	When	Time to complete
Body Composition			
BMI (weight & height)	Calibrated digital scales & stadiometer	B, 12m	2 minutes
Waist and hip circumferences	Tape	B, 12m	3 minutes
Other			
Physical activity	IPAQ[32]	B, 12m	5 minutes
Diet	DINE[33]	B, 12m	5 minutes
HR quality of life	EQ5D[34]	B, 6m, 12m	1 minute
Health and other resource usage	Case Report Form	B, 6m, 12m	4 minutes

Proportion maintaining weight loss		12m	
Binge eating	EDE-Q[35]	B, 12m	1 minute
Psychological well being	GHQ12[36]	B, 12m	3 minutes
Health-related behaviours (alcohol consumption & smoking status)	AUDIT-C & HSI[37, 38]	B, 12m	2 minutes

8.2 Mediators and Moderators

Although not 'outcomes' as such, assessment of mediators is important in order to identify the processes by which the intervention brings about change. These data will provide important insights into the extent to which the intervention has worked as intended, its theoretical underpinning, and possible ways in which it might be modified in the future to further enhance its efficacy and/or cost-effectiveness. As noted previously, key components of our intervention include (a) encouraging participants to form implementation intentions, in relation to both diet and exercise, (b) encouraging participants to monitor their weight, diet and activity levels, and (c) providing social support for diet and exercise behaviours. We will assess the extent to which the intervention successfully achieves these aims through a series of standardised questionnaires, qualitative interviews and examination of participant diaries and MI therapist records. We will also examine the extent to which these mediators are associated with successful weight maintenance. Additional questionnaire measures will be employed to assess self efficacy for exercise and diet behaviours and intrinsic motivation for diet and exercise behaviours. These were selected since each represents a key mechanism by which MI is believed to bring about change. Finally, given the importance of habit formation for the maintenance of behaviour changes we also include measures of automaticity in relation to both healthy eating and exercise behaviours. Again our analyses will identify both the extent to which the intervention was successful at changing these mediators and the extent to which mediator change was associated with weight maintenance.

Table 2 Mediators (*measures have been adapted and piloted in relation to both diet and exercise)

Outcomes	**Measure**	**When**	**Time to complete**
Social support*	Exercise & Eating Habits Social Support Scales[47]	B, 6m, 12m	6 minutes
Self efficacy*	Weight & Exercise Efficacy Lifestyle Scales[48]	B, 6m, 12m	6 minutes
Intrinsic motivation*	TSRQ [49] (diet and exercise scales)	B, 6m, 12m	4 minutes
Implementation intentions	From MI records and interviews		
Automaticity/Habits*	Self-report habit index[50] (diet and exercise scales)	B, 12m	4 minutes
Self monitoring/regulation*	Short Self Regulation Questionnaire[51]	B, 12m	3 minutes

Demographic information on age, sex, socio-economic status, ethnicity and employment status will be collected in order to characterise the sample but also as potential moderators and factors associated with success in weight maintenance. Whilst a number of studies

have found no differential effects of gender on weight management interventions[52] some have found that the male physiological response to physical activity will impact on weight management interventions.[53] The effects of age are also unclear but older participants have been reported to be more successful in weight maintenance programmes.[54, 55] Prevalence of obesity is higher in some ethnic minority groups and ethnicity has also been associated with weight maintenance in some American studies.[53, 56] This may be confounded by lower socio-economic status, which impacts on food choices resulting from environmental factors and socio-cultural attitudes.[57]

Further moderators related to weight management behaviours will also be measured (see Table 3). Initial percentage weight loss has been found to predict later weight maintenance.[52] This relationship may be a result of the psychological impact of the achievement of predetermined goals and satisfaction with weight lost[58] which has also been reported to predict longer-term maintenance. Success in the weight loss phase will enhance motivation by increasing self-efficacy. Current goals of weight management will be assessed, as the intervention may have differential effects on those wishing to lose weight compared to those who wish to maintain their weight.[55] Finally, binge eating is commonly reported to be a predictor of weight maintenance. It has been suggested that binge eaters are more likely to drop out of treatment prematurely and are more likely to regain weight.[59]

Individual characteristics such as psychological well being will be assessed as a moderator, as negative mood states will make it more difficult for participants to comply with the protocols, but is also measured as a secondary outcome of the intervention. Other factors, such as co-morbidities, medical events and functional disability, which again may impact on ability to carry out the intervention will be recorded. Weight loss medication and any other relevant treatments will also be recorded on CRFs at all outcome assessments. Participants will be asked to bring any medications they are currently taking to all face-to-face outcome assessments (baseline and all follow-up time points apart from the 6-month postal assessment) to maximise the accuracy of self-reported medication use. Members of the team responsible for collecting outcome data will also be provided with a list of medications which may impact on participants' ability to maintain or lose weight (N.B. list to be provided by the clinical member of the study team). Moderators are measured at baseline only, as their purpose is to assess individual characteristics that may impact on people's response to the intervention and, as such, are considered fairly stable traits. However, while variation in psychological distress and binge eating may affect individual responses to the intervention they may, also, be changed by the intervention and so are also measured as secondary outcomes post-intervention..

Table 3 - Moderators

Outcomes	Measure	When	Time to complete
Demographics		B	1 minute
Weight loss history Satisfaction with weight loss Current weight loss goals Reasons for weight loss		B	2 minutes
Binge eating	EDE-Q[35]	B	1 minute
Life events	Qualitative interviews		
Psychological well being	GHQ12[36]	B	3 minutes

Participants in both groups will be reminded of their follow-up appointments and phone calls via text message or a phone call.

9 Trial procedures

Recruitment and follow-up:
Following recruitment into the trial, participants will be randomised to one of three arms; intensive intervention, less intensive intervention and control. Those randomised to the intervention groups will be contacted by either the MI counsellor or a member of the research team to arrange a time to meet for the first session. These sessions will be 60 minutes long and will take place at a convenient place for the participants. Individuals in both groups will be telephoned by the MI counsellor at several time points up until 12 months from randomisation. Those allocated to the control group will receive an information pack on lifestyle changes for weight maintenance (the intervention groups will also receive this). Participants will be assessed at six months (from randomisation) during the intervention period by post. We will send two reminders to improve follow-up rates on these questionnaires. The 12 month assessment will be face to face and will be completed by a researcher. A letter will be sent confirming the appointment as well as a text or phone call on the day of the assessment. We will rearrange the face to face sessions twice more if participants fail to attend. In the case of non-responders we will try to complete the key questionnaires over the telephone so that we have a minimum data set.

Piloting:
Each outcome package (baseline, 6 months and 12) within the trial will be piloted to assess the adequacy of the assessments and presentation. Participant materials (letters, information sheets, posters, leaflets) will also be evaluated. The feasibility and acceptability to participants of materials will be assessed. Piloting will involve lay people acting in an advisory capacity.

MI Counsellor Training:
We will develop a training package for the MI counsellors. A manual will be developed by the team for counsellors to try to ensure that the intervention is delivered in a consistent way. The MI counsellors will initially be assessed for their MI skills using the MITI scale and they will be trained in the MI handbook developed by the study team. This details the way we would like the MI delivered within the study. We will also have discussions on the challenges of running MI sessions over the phone and develop guidance in tandem with the MI counsellors on the best way to approach this. The MI counsellors will be given training on issues around obesity as well as diet and physical activity recommendations. We will discuss with them the challenges of weight maintenance and weight loss and how we might best support participants in this process.

Process Evaluation:
We will conduct a process evaluation of the study which aims to:

- assess the delivery of the intervention to ensure that it is provided in accordance with the protocol and delivered consistently
- establish the level of participant adherence to the requirements of the intervention protocol

- explore participants' views of, and satisfaction with the intervention
- explore MI counsellors experiences of delivering the intervention

The process evaluation will utilise quantitative data from audit of therapist held records and also qualitative data from face-to-face semi-structured interviews with a sample of participants and focus groups with the MI counsellors. We will ask MI counsellors to complete an exit appraisal (included on the MI Case Report Form for the final face-to-face and telephone sessions respectively) for each individual describing what went well and any problems experienced.

1. Assessment of delivery of the intervention

MI counsellors will be asked to audio record as many sessions (face to face and telephone) as possible, with a view to collecting a minimum sample of 6 sessions per counsellor over the course of the study. A random sample of recordings will be assessed using appropriate validated instruments including the MI Treatment Integrity (MITI) coding scale.[60] A stratified sample will include sessions delivered in both intervention arms of the trial and all MI counsellors. Feedback on MITI scores will be given to counsellors. Similarly, recruitment and data collection processes will be audited to ensure standardisation of methods throughout the intervention and data collection periods. Little is currently known about the process of MI and how it relates to outcomes, in particular weight maintenance. Consent will therefore also be sought to use audio-recorded data to examine these relationships, including participant language relating to planning. We propose to qualitatively assess the content of these MI sessions and also to assess how participant/client interactions relate to quantitative outcomes.

2. Participant adherence to the protocols

Overall attendance at MI sessions and success of telephone contact will be monitored (number of contact attempts and length of calls will also be recorded). Participant self regulation will be examined by the frequency of self weighing records; counsellor records of recorded goal setting and implementation intentions will also be examined.

The degree of potential contamination across study arms (arising from friends/family members not living together but recruited to different study arms) will be assessed at the end of the 12-month intervention period. We will ask control group participants whether they have been given any information by another study participant, for details of any information received, and whether or not they used the information given. We will ask intervention participants whether they shared study information with other participants, and for details of any information shared.

3. Participants' views of the intervention

We propose conducting semi-structured telephone interviews with up to 30 participants in total from the two intervention arms at 6 months (during the intervention); and up to 30 from the intervention arms plus up to 10 control participants at 12 months (following the end of the intervention). We will ask for participants consent to the audio recording of the interviews. An interview specific consent form and information sheet will be sent to participants who express an interest in taking part. The interview will only be arranged once a completed consent form has been returned to the study team. In addition to assessing general views of the way the intervention was delivered, views on efficacy, barriers and facilitators (N.B. we will ask about general views of study participation for controls) we will also examine some potential mediators that are not examined elsewhere.

For example, we will explore: the impact of stressful life events on adherence to the interventions; environmental influences; levels and importance of social support from family and friends; impact on their wider social network; weight maintenance challenges; intrinsic and extrinsic motivations for weight maintenance, health value; body image and its impact; strategies, coping mechanisms and responses to relapses. We will compare the three groups as well as those who maintained weight with those putting weight back on. In addition, we will interview a small sample of participants who drop out of the intervention but who are willing to continue to provide data for research purposes, to establish their views of the trial and/or intervention and reasons for discontinuing. Interviews will continue until all the themes are saturated and participants will be offered a £10 high street voucher for their time in taking part in the interviews.

4. Counsellors views of the intervention:
We will also conduct two focus groups of the MI counsellors to gain their views of the intervention, the perceived challenges or barriers in implementing it and ways they think the intervention and/or training could be improved.

The interviews and focus groups will be audio recorded, transcribed and checked by the researcher.

Participants are likely to want to lose more weight as their BMI will still be high, so although the intervention will target maintenance rather than weight loss, participants may continue to lose weight and we will monitor this.

Cost-effectiveness evaluation:
A preliminary cost utility analysis will be undertaken in order to estimate economic parameters and unknowns for future research. (details in section 11.4).

9.1 Data collection/assessment

Baseline and follow-up data will be collected face to face, except for the 6 month assessment which will involve a postal questionnaire. Participants will have their height, weight and waist and hip measured at all time points except the 6 month assessment when just weight will be self assessed. Other data will be collected using paper based methods and researchers will be trained in all aspects of data collection. Data collection at each time point will take 40-50 minutes to complete.

Baseline and outcome data will be collected by the research team and also in Wales by Clinical Studies Officers who are part of the NISCHR Clinical Research Centre and in England the researchers employed by the Comprehensive Local Research Networks. Researchers undertaking the assessment of the outcomes will not have any involvement in the delivery of the intervention. As far as possible they will be blinded to the allocation of the participants, although during interaction with them the group allocation may become apparent. Where this occurs it will be recorded.

9.2 Follow-up

Details of outcomes and follow up time points can be seen in Table 1 and are the same for both experimental and control groups.

9.3 Adverse Events and Serious Adverse Events

Adverse Event (AE): *Any untoward medical occurrence in a study participant.*

Serious Adverse Event (SAE): *Any untoward and unexpected medical occurrence or effect that:*

- *Results in death*
- *Is life-threatening [refers to an event during which the participant was at risk of death at the time of the event; it does not refer to an event which might have caused death had it been more severe in nature]*
- *Requires hospitalisation, or prolongation of existing hospitalisation*
- *Results in persistent/significant disability or incapacity*
- *Is a congenital abnormality or birth defect*

Expected AE/SAE
There are no expected AE's/SAE's. Any planned treatments at the start of the study will not be considered as AE's/SAE's.

Related AE/SAE:
The AE/SAE resulted from administration of any of the research procedures (causal to the research process or intervention).

There are no AE's/SAE's expected to be related specifically to the study intervention, although there may be events related to increased physical activity e.g. cardiovascular/musculoskeletal. However, study recommendations for physical activity are in line with the current, widely publicised UK government guidelines. However, the physical activity leaflet and main trial information sheet given to participants state that any increase in physical activity should be gradual and advises participants to contact their GP if they have any concerns or feel unwell as a result of increased physical activity (including experiencing severe breathlessness, chest pain, fainting or dizziness).

Reporting responsibilities:
Where the adverse event meets one of the above categories for an SAE, an SAE form should be completed by the MI counsellor, GP or research team member and faxed to the WILMA Trial Manager within 24 hours of becoming aware of the event. SAEs will also be recorded on the 6-month follow-up questionnaire and follow-up CRFs (i.e. hospitalisations in the preceding 3 months at each time point). In addition, we will ask patients to contact the research team directly by telephone if they are hospitalised at any point during the trial: a member of the research team will then complete an SAE form on the participant's behalf.
Fax Number: 02920 687612

Evaluating and reporting:
The WILMA Trial Manager and the Chief Investigator and the clinical member of the team (Glyn Elwyn) will assess the nature of the SAE for causality and expectedness. Following the initial report, follow up data may be requested by the WILMA Trial Manager. Where the SAE and is both related and unexpected, the WILMA Trial Manager will notify the Chair of the TSC and the main REC within 15 days of receiving notification of the SAE. All SAEs will be recorded and reported annually to the main REC. A standard template will be used to record SAEs.

Risk of harm

MI counsellors will also be asked to notify the study team directly should they be concerned at any time that a participant has, or is likely to cause significant harm to themselves: the study team will then inform the participant's GP. MI counsellors will be asked to inform the appropriate authorities directly should they become concerned at any time that a participant has, or is likely to cause significant harm to others.

10 Statistical considerations

10.1 Randomisation

Allocation to groups will be by remote telephone randomisation and stratified by region (Primary Care Trust) and minimized by age, gender, ethnicity, source of recruitment (exercise referral scheme, community, etc), % weight loss and current BMI. Whoever is recruiting the potential participants will call the randomisation telephone number and the participant will be given an information pack detailing the next steps.

10.2 Sample size

The sample size for the original study was 950 and based on detecting an effect size of 0.309 with 90% power at a significance level of 5%. Since this is now a feasibility study, the planned sample size will not be derived statistically. Instead the intended sample size is the number of participants it is possible to recruit based on our inclusion criteria over an 18 month period. Since recruitment has now closed our potential sample size is 170. This sample size allows us to estimate a percentage of 50% (the percentage with the greatest associated variability) to within 7.5 percentage points either side for the whole sample (n= 170), or to within 15.7 percentage points for percentages within each study arm (n = 39). These are the precisions that will be achievable for the estimation of the retention rate or any other proportion. As a feasibility study we are not primarily concerned with effectiveness, however we still feel it is informative to present the power we will have to detect differences. With our current sample size (n=170) and assuming 30% attrition, we have 39 in each of the three treatment arms. We will be able to detect a difference of 3.537 BMI points at the 5% significance level with 80% power between any two arms (our primary comparison was between the control group and the intensive arm). This is just over a difference of 9.75kgs between groups.

11 Analysis

11.1 Main analysis

The main outcomes relate to the feasibility of the study. Descriptive statistics relating to the patient recruitment, compliance and retention and well as intervention delivery will be presented.

Given the recruitment issues it is unlikely that we will find a significant difference unless the impact of this intervention is far greater than other types of intervention in this group. So the main analyses will be completed for the study as a feasibility study. We will also examine the point estimates of effectiveness and their confidence intervals for BMI. We

will analyse for key secondary outcomes that are more immediate targets of the intervention (e.g. self-efficacy) to consider the potential of the intervention, as well as assessing if there is a trend from no intervention to the intensive intervention with the less intensive intervention lying between the two. We will undertake mediator analysis to see if the identified pathways to effect measured at six months are associated with maintenance at one year.

An intention to treat analysis will compare the three groups on average BMI using a two level linear regression model to account for clustering within therapist. The main analysis will examine the longest end-point. A secondary analysis will examine the three groups using the interim time point as the end-point. Baseline BMI and previous weight loss will be included as covariates. Both of the intervention groups will be compared to the control in this model. If there is no evidence of clustering, then this will be reduced to a one level model. Secondary outcomes will be analysed similarly using either linear (e.g. diet, waist circumference) or logistic (e.g. probability of return to previous BMI) regression.

Exploratory analysis will consider the impact of demographic factors as well as original weight loss method and theoretical moderators on the intervention effect using interaction terms included in the main analysis models. Exploratory longitudinal analysis will be undertaken to explore the effect of theoretical mediators on subsequent outcomes and interactions with the intervention groups. Individuals lost to follow-up will be compared to those who complete follow up to identify any potential biases.

A sensitivity analysis will be conducted where it will be assumed that all of those lost to follow-up returned to weight levels prior to weight loss (i.e. not baseline, but previous BMI). A Complier Adjusted Casual Effect (CACE) will also be estimated using multi-level mixture analysis.[61] This modelling focuses on estimating the effect of the interventions in the presence of non-compliance, but also incorporates adjustments for loss to follow-up associated with the intervention. CACE approaches have been used in a number of studies of psychological therapies, using either relatively simple corrections through to the more complex multi-level mixture models proposed here. This provides a framework within which to model missingness rather than assuming missing at random (MAR).

11.2 Sub-group & interim analysis

Primary sub-group analyses will investigate associations between weight loss maintenance and age, gender, how much weight participants have lost, method of weight loss, and weight at entry. Exploratory sub-group analyses will investigate the association between weight loss maintenance and smokers, binge-eaters, participants who have been on weight-affecting medications during the trial and ethnicity.

11.3 Qualitative analysis and process evaluation

Data on intervention delivery and duration of participation in the intervention will be examined. The recorded MI sessions will be subject to analyses using the MITI scale to ensure they reach agreed standards. MI Case Report Forms (CRFs) from both face-to-face and telephone sessions (including session summaries given to participants) will be examined for evidence of self regulation, goal setting and implementation intentions. These will be analysed descriptively. The interviews and focus groups will be analysed using framework analysis techniques. This method of analysis is essentially a process of summarisation, categorisation and counting frequency of responses. The transcripts will be

closely examined to identify themes and categories.[62] Codes will be applied to these broad themes which will then be broken down further into sub-codes. Agreement on concepts and coding will be sought between members of the research team in order to ensure reliability. We will seek to identify commonly expressed themes as well as unusual cases. A proportion of the data (10%) will be coded by two different team members to check on reliability of the coding scheme. The interviewing will be iterative; where new themes emerge we will incorporate them into the interviews. Analysis will be supported by the use of computer assisted qualitative analysis software (NVIVO).

11.4 Economic evaluation

There are limitations to undertaking a cost utility analysis within a feasibility study. Although we will not be able to establish definitive cost utility results, we will apply a cost utility framework to estimate parameters and unknowns for future research. Direct costs will include all resources used in the delivery of the interventions (staff time, staff travel, materials, venue, etc.). These will be recorded prospectively in relevant units and valued using standard methods.[63] All resources used in training professionals in motivational interviewing skills will similarly be prospectively recorded and valued. As training is a one off investment which produces a flow of benefits over time, training costs will be amortised similarly to equipment expenditures.

Indirect costs will include differential use of NHS resources. Health service resource use in primary care, secondary care and the community will be collected for participants in all 3 arms of the trial at baseline, 6 months (during the intervention) and at 12 months. Questions will relate to all health service contacts and prescription medicines dispensed in the previous 3 months. Patient recall has been shown to be a valid method for collecting health service resource use data over this period.[64] Health service resource use will be valued using standard sources.[65] All costs relating to weight loss/maintenance activities such as use of gyms will be recorded. It is important to monitor these costs as the intervention may be substituting for some activities, for example weight loss group sessions by participants in the control group. Mean differential costs will be estimated. As cost data are often skewed, tests for normality will be applied. If distributions are shown to be non-normal, non-parametric bootstrapping methods will be used to test for mean cost differences between groups.[66]

The main effectiveness measure in the economic evaluation will be the EQ-5D (EuroQol) quality of life instrument which will be administered alongside the resource use questionnaire.[34] EQ-5D scores allow estimation of quality adjusted life years (QALY). Cost effectiveness will be based on between group differences in costs and EQ-5D scores. This is the method of economic evaluation preferred by NICE as the resulting cost utility estimates can be compared not only with other weight control programmes, but also with unrelated health care interventions. Results will be reported in the form of incremental cost utility ratios (incremental cost/QALY). A cost effectiveness acceptability curve will show the probability of the more costly intervention having an incremental cost utility ratio below a range of acceptability thresholds.[63] A series of one way and multivariate sensitivity analyses will be undertaken to assess how sensitive results are to changes in the assumptions used and these analyses will be key given that this is a feasibility study.

At present, there is a paucity of evidence on how changes in BMI are related to changes in EQ-5D[71]. We will therefore undertake a secondary analysis with BMI as the effectiveness

measure. Difference in the two analyses will contribute to the evidence on the relationship between these two measures.

11.5 Data storage & retention

All data will be kept for 20 years in line with Cardiff University's Research Governance Framework Regulations for clinical research. This data will be stored confidentially on password protected servers maintained on the Cardiff University Network. Files will only be accessible to researchers responsible for the running of the trial and the Chief Investigator (CI). All procedures for data storage, processing and management will comply with the Data Protection Act 1998. All paper records will be stored in a locked filing cabinet, with keys available only to researchers and the Chief Investigator. The Trial Statistician will carry out analysis. All essential documents generated by the trial will be kept in the Trial Master File. Archiving and access to archive will be managed in accordance with the Standard Operating Procedures of the South East Wales Trials Unit (SEWTU).

12 Study/trial closure

The end of the study/trial will be considered as the date on which the last participant has completed their follow-up assessment.

13 Regulatory issues

13.1 Ethical approval

The study will be conducted in accordance with the recommendations for physicians involved in research on human participants adopted by the 18th World Medical Assembly, Helsinki 1964 and later revisions. The study will be submitted to an NHS Research Ethics Committee for approval.

13.2 Consent

Potential trial participants will complete an expression of interest form to indicate their agreement to be approached by a member of the research team or they will contact us to express an interest in the study. We will make an appointment to meet with them and send an information sheet in advance and then during the appointment the researcher will seek consent (if they are eligible) after they have had time to read and understand the information sheet, and had adequate time to ask questions about the study. Participation in the study will involve consent to be randomised to one of the three arms of the study and to data collection (questionnaires and weight, height, waist and hip circumference). Withdrawal of consent will have no detrimental impact on current and future treatment.

13.3 Confidentiality

All data collected from participants during the study will be kept strictly confidential in line with legal and ethical requirements.

13.4 Indemnity

Cardiff University will provide indemnity and compensation in the event of a claim by, or on behalf of participants, for negligent harm as a result of the study design and/or in respect of the protocol authors/research team. Cardiff University does not provide compensation for non-negligent harm.

With regards conduct of the research, the MI counsellors will be sub-contracted to Cardiff University. However, the contract will state that counsellors must hold their own professional indemnity cover.

13.5 Study/trial sponsorship

Cardiff University will act as sponsor for trial.

13.6 Funding

The National Institute for Health Research Health Technology Assessment (NIHR HTA) is funding this trial. To improve follow-up rates participants will be given £20 vouchers at the 12 month follow-up as well as a £5 voucher for returning the questionnaire at the 6 month assessment. After the trial is complete we will offer the control group 12 Slimming World or Weight Watchers sessions or £50 in high street vouchers. Those who take part in the telephone interviews as part of the process evaluation will be offered £10 in High Street vouchers for their time.

13.7 Audits & inspections

The trial is participant to inspection by the NIHR-HTA as the funding organisation. The study may also be participant to inspection and audit by Cardiff University under their remit as sponsor.

14 Study/trial management

Internal Project Group: This group will consist of the co-ordinating team within SEWTU who will meet weekly to discuss the day to day issues that arise from the study. All important discussions will be relayed to the TMG for final decision.

Trial Management Group (TMG): The TMG will consist of the Chief Investigator, Co-applicants and research staff including the Trial Manager and Trial Administrator. The role of the TMG will be to assist in the study set up by providing specialist advice, input to and comments on the study procedures and documents (information sheets, protocol etc). They will also advise on the promotion and the running of the trial and deal with any issues that arise. The group will meet, either face-to-face or using audio-conferencing facilities, bi-monthly throughout the course of the study and if necessary, additional/more frequent meetings may occur particularly at crucial time points during the study.

15 Data monitoring & quality assurance

15.1 Trial Steering Committee (TSC)

A TSC will be established and will meet annually, consisting of an independent chair, and three other independent members. The TSC will be chaired by Dr Jim McCambridge (psychology, MI, trials) and the other members will include Dr Margaret Cupples (general practice, trials, behaviour change), Dr Ruth Pickering (statistician), Dr Janice Thompson (physical activity, nutrition) as well as a user representative. The first meeting will be before the trial commences to review the protocol and arrange the timelines for the subsequent meetings. If necessary, additional/more frequent meetings may occur. The Chief Investigator, Trial Manager and Statistician will attend as observers. The Trial Steering Committee (TSC) will provide overall supervision for the trial and provide advice through its independent chair. The ultimate decision for the continuation of the trial lies with the TSC. The nature of this study makes it unlikely that a Data Monitoring and Ethics Committee *(*DMEC) will be required; however, this will be discussed with the TSC at their first meeting and a DMEC will be set up if deemed necessary.

15.2 Data Monitoring and Ethics Committee (DMEC)

See above (15.1).

16 Publication policy

The publication policy will be drafted and approved by the Trial Management Group. It will state principles for publication, describe a process for developing output, contain a map of intended outputs and specify a timeline for delivery. The publication policy will respect the rights of all contributors to be adequately represented in outputs (e.g. authorship and acknowledgments) and the study to be appropriately acknowledged. Authorship of parallel studies initiated outside of the Trial Management Group will be according to the individuals involved in the project but must acknowledge the contribution of the Trial Management Group and the Study Coordination Centre.

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