Amendment 1 (protocol v2.0; 19/08/10)

1. Bio-electrical impedance assessment (BIA) will not now be included as a secondary outcome measure. BMI (primary outcome), waist circumference and waist-to-hip ratio are felt to be sufficient and reliable indicators of body composition.

   Participants suffering from mental health problems will no longer be excluded from the trial (unless unable to comply with the study protocol). However, individuals with cognitive impairment and those who have had bariatric surgery will be excluded.
2. Psychological well-being (GHQ-12) and binge-eating (EDE-Q) have been added to the questionnaire for outcome assessment at 12-months post-intervention (2 years).
3. The protocol has been amended to state that alcohol consumption and smoking status will be assessed at all time-points as outcomes. Measures to assess these health-related behaviours were included in the approved baseline questionnaire, though this was not previously explicitly stated in the protocol.
4. The Treatment Self-Regulation Questionnaire (TSRQ) will be used to measure intrinsic motivation, as it is briefer, validated and more likely to be an accurate measure of motivation in the current population than the previously stated Behavioural Regulation in Exercise Questionnaire (BREQ).
5. The number of contact attempts and length of MI telephone calls will be recorded as part of the process evaluation to facilitate an accurate estimate of the cost of the intervention.
6. Following advice from the TSC and further discussion amongst the TMG, the study team feel it would be valuable to gain control group participants' views of taking part in the trial and explore any lifestyle changes made as a result of participation in addition to, and for comparison with those in intervention groups. If the trial was unsuccessful it would help us to understand why. Also, on further reflection, the team feel that there may be important differences in participant experiences during the intervention period, as well as post-intervention. Therefore participant interviews will now be carried out during the intervention (at approximately 6 months) and at the end of the 12-month intervention period and will include participants from all three trial arms (15 in each intervention arm and 10 controls at each time point or until themes are saturated).

7. The procedure for reporting SAEs has been clarified. Any related and unexpected SAEs will now be reported to the TSC chair within 15 days, in addition to notifying the main REC as previously stated. The protocol has also been amended to highlight that SAEs will be recorded on CRFs at 6 months during the intervention and post-intervention (1 year) (each referring to events in last 3 months). Participants will also now be asked to contact the research directly by telephone if they are hospitalised at any point during the trial, as the research team do not have access to patient records: a member of the research team will then complete an SAE form on behalf of the participant. The patient information sheet has also been amended to reflect this and it has been made explicit that GPs will be asked to report SAEs directly to the study team.

Amendment 2 (v3.0; 27/04/11)

1. The inclusion and exclusion criteria have been modified to maximise inclusivity whilst maintaining the safety of trial participants. Cognitive impairment has been removed from the list of exclusions, although individuals unable to provide informed consent and/or comply with the study protocol will not be recruited. Exclusions now comprise: terminal illness, previous bariatric surgery, living with another trial participant, current pregnancy, difficulty communicating in English/unable to complete study materials and any other conditions/circumstances that render the individual unable to comply with the study protocol. The inclusion criteria have also been amended to specify that weight loss must be intentional due to concerns that we should not be recruiting individuals losing weight due to undiagnosed medical conditions (on screening, individuals who have unintentionally lost weight will be advised to contact their GP as soon as possible).
2. The protocol has been amended to clarify the procedure for dealing with a pregnancy that occurs during the trial in recruited participants. We will ask women of childbearing age to let us know if they become pregnant at any point during the study. Pregnant women will not be excluded from the study once recruited, but will given a leaflet on exercising safely during pregnancy (appended to this amendment).
3. A change to the participant diary for intervention groups has been made to allow participants to record other markers of weight loss/healthy lifestyle maintenance, in

addition to recording diet and physical activity levels (e.g. better fitting clothes or improved fitness).

4. Following the advice of experienced Group Facilitators, the structure and format for the group sessions has been modified to maximise participation and facilitate a supportive group environment. Participants will no longer be weighed at the beginning of the sessions, although tea/coffee is still provided at the start to encourage more informal exchanges between participants. Participants will still be able to invite a friend/family member to this initial part of the session for additional support if this is helpful to them. However, this friend/family member will not now be able to attend the group discussion sections of the session.
5. As participants are randomised individually on study entry, there remains a theoretical possibility of contamination across arms where close relationships exist between participants. In order to address this, individuals who live with another study participant will not be recruited to the trial. This has been added to the list of exclusion criteria. The degree of potential contamination 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.
6. It was stated in a previously approved amendment (modified amendment 1, 19.08.10) that interviews carried out as part of the process evaluation should be carried out during and following the intervention, at approximately 6 and 12 months from randomisation. On further reflection, it is felt that the timeframe for interviews post-intervention should be extended from approximately 12 to 18 months, in order to more effectively assess participants' circumstances post-intervention.

Amendment 3 (v4.0; 08/11/11)

1. The procedure for confirming participant screening appointments has been modified. Once a potential participant has agreed to attend a screening visit (recruitment route 2 only), the appointment will be confirmed via <u>either</u> telephone, text, email or letter,

depending on the time lag between appointment booking and appointment date. Prior to the start of the recruitment period, it was envisaged that all screening appointments would be confirmed by letter and that a copy of the screening information sheet would be sent out in advance by post. However, screening appointments often become available at short notice and in such circumstances we feel it would be helpful to have the option of booking appointments and confirming details by text/email/phone to maximise recruitment and attendance. We also do not feel it is necessary to provide the screening information sheet in advance of a screening session, as the purpose of the visit is explained when booking the appointment and participants have already had chance to read and consider information sheet 1 which outlines the screening process. Participants will however be given the screening information sheet before consenting to height/weight measurement as a reminder of the purpose of the session.

2. Following advice from research network staff recruiting participants, a flow diagram for participants randomised to the control group has now been created to remind participants about the data-collection follow-up time points (participant flow diagrams for the intensive and less intensive groups have previously been reviewed by the committee).

Amendment 4 (v5.0; 27/01/12)

1. The wording of the poster/flyer used to advertise the study has been altered to emphasise that the focus of the study is on *maintenance* of weight loss rather than on weight loss itself (although participants may wish to continue losing weight once they have reached the 5% target and will be encouraged to do so if this fits with their long-term goals). The requirement to produce written verification of weight loss has also been made more explicit and examples of acceptable verification are provided (WILMA poster/flyer v2.0).
2. Given the high number of expressions of interest received from potential participants yet to lose weight, we propose a modification to the screening procedure to ensure we have sufficient capacity to screen participants. The protocol now states that those yet to lose weight and who otherwise meet eligibility criteria will progress through the study in two ways. They will be given the option to either: (a) attend a screening meeting with a researcher locally and consent to have their weight and height

recorded and to be followed up by the research team two months later, 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 written verification).

3. The exclusion criteria have also been modified to allow individuals who have had bariatric surgery reversed (e.g. removal of a gastric balloon) to be recruited to the study if otherwise eligible. Where applicable, individual cases will be referred to a clinical member of the team to verify procedures that constitute bariatric surgery and subsequent reversal.

Amendment 5 (v6.0; 21/05/12)

1. While the use of GP practices as Patient Identification Centres (PICs) has been valuable, we propose identifying pharmacies as additional PICs. This will increase the pool of potential participants who will hear about the study and help with current low recruitment levels. Pharmacies have been added to the list of PICs.
2. The study TMG (with TSC agreement) proposes altering the 6 month assessment (a postal questionnaire) in order to reduce its size thus potentially increasing response rates. This entails excluding the DINE and IPAQ outcomes from the assessment and including three mediators. The 6 month assessment will now comprise of the mediators; social support, self-efficacy and intrinsic motivation along with the EQ5D and health and other resource usage.
3. That, following feedback from the patient representative and potential participants, the control group will now be offered a free 12 week attendance at a local Slimming World or Weight Watchers programme OR £50 in high street vouchers at the end of the follow-up as an additional incentive to complete follow-up.
4. Due to slow recruitment and the fact that the EOP and SW consultants have no incentives to encourage them to recruit people (while GPs have through SSCs) we would like to offer a small token of our gratitude for their time in helping us recruit people. 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 bimonthly 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.

Amendment 6 (v7.0; 31/05/12)

1. We propose to limit the number of times that appointments are rearranged after an individual has not attended, to 3. At which point a letter will be sent out stating that unless the individual gets in contact with the study team, we will assume they are no longer interested in taking part.
2. As specified in section 6.5 of the protocol, participants have the right to withdraw consent for participation in any aspect of this trial at any time. In order to reduce loss to follow-up and to clarify that just because an individual does not want to take part in one particular aspect of the study, it does not mean they have to exclude themselves from the study as a whole withdrawal forms will be completed by the study team. The withdrawal form (v2.0 16/05/2012) clearly shows which aspects of the study the participant does not want to take part in. If participants wish to withdraw from all aspects of the study without giving reason, that is obviously their right however we would assume consent to use data already collected unless otherwise specified.

Amendment 7 (v8.0; 15/08/12)

1. In order to guarantee enough data is collected for the process evaluation element of the trial, more audio recordings than originally specified in previous versions of the protocol will now be collected. The relevant section of the protocol reflects this.

Amendment 8 (v9.0; 10/10/12)

1. We wish to stop the delivery of the group support sessions, therefore all reference to group sessions have been removed from the protocol which is especially applicable to section 7 (Study/Trial Intervention, p20). Having been in discussion with the HTA regarding the feasibility of delivering the intervention as it currently stands, consensus is that the study should focus on the most important and achievable aspect of the

intervention namely the Motivational Interviewing sessions. Group sessions have been poorly attended and in removing them from the intervention, it reduces the burden on those who are currently recruited into the study which has the potential to have an impact on retention rates. This proposal has been approved by the HTA.

Amendment 9 (v10.0; 05/02/13)

The following changes have been made to the protocol

1. Reporting. The study is now being reported as a feasibility study due to fewer numbers being recruited than originally anticipated n=170, compared to the original sample size of n = 950.
2. Follow-up. Instead of carrying out follow up assessments at 1, 2 and 3 years after randomisation, participants will now only be followed up at 1 year post randomisation (after the intervention has been delivered). All references to the 2 and 3 year follow up assessments have been removed from the protocol. In addition, we are submitting the letter (as agreed by the HTA) which will go out to participants to explain the changes in the follow up. We will also send our flow diagram summarising the changes.
3. Incentives. With much lower than anticipated recruitment figures, we are concerned about the dropout rates for the 12 month assessments (1 year post randomisation). We are not currently hitting our predicted targets and hope that by increasing the incentive offered to participants for completing the assessment from £10 to £20 in high street vouchers, the dropout rate will decline. For those who have already had their one year follow-up we will send a voucher for the additional £10, so that everyone gets the same. We hope this might encourage people to complete the follow-ups and we feel this is reasonable given the actual length of time taken to complete the follow-up assessments. We also propose offering £10 in vouchers to those who agree to take part in the process evaluation interviews in recognition of participants time to take part (see next point).
4. Process Evaluation. With a now reduced sample of participants and follow up, we propose conducting fewer interviews and at a slightly altered time point to fit in to the reduced follow up period. We will now interview up to 30 participants in total from the two intervention arms at 6 months and up to 30 from the intervention arms plus up to 10 control participants at 12 months (as opposed to 18 months as planned). In

addition, we would like to conduct these interviews over the telephone rather than face to face as originally intended. However, we use this method of interviewing successfully in other studies, so anticipate no issues. As stated above, we will also offer an incentive (a £10 high street voucher) to those who are approached to take part in the interviews in order to encourage participants to offer their views and thank them for their time. Altered information sheets are being submitted to reflect this change. Due to logistical issues around the curtailment of recruitment and therefore intervention delivery we will still feedback MITI scores to MI practitioners, however the focus of this will no longer be on preventing intervention 'drift'.

5. Health Economics and Statistics. Changes to both the Health Economics and Statistics have been made according to the closedown plan. The relevant sections of the protocol have been amended to reflect these changes.

Amendment 10 (v11.0; 30/07/13)

The following changes have been made to the sections of the protocol detailing the subgroup and qualitative analyses and process evaluation sections:

1. We have been unable to collect sufficient and reliable data regarding speed of weight loss; the subgroup analysis section of the protocol has therefore been amended to reflect this.
2. MI sessions will still be subject to assessment using the MITI scale but it has not been feasible to provide real time verbal and written feedback to counsellors during intervention delivery.
3. The qualitative analysis approach to be used is best described as framework rather than thematic analysis and the protocol has been amended to reflect this.