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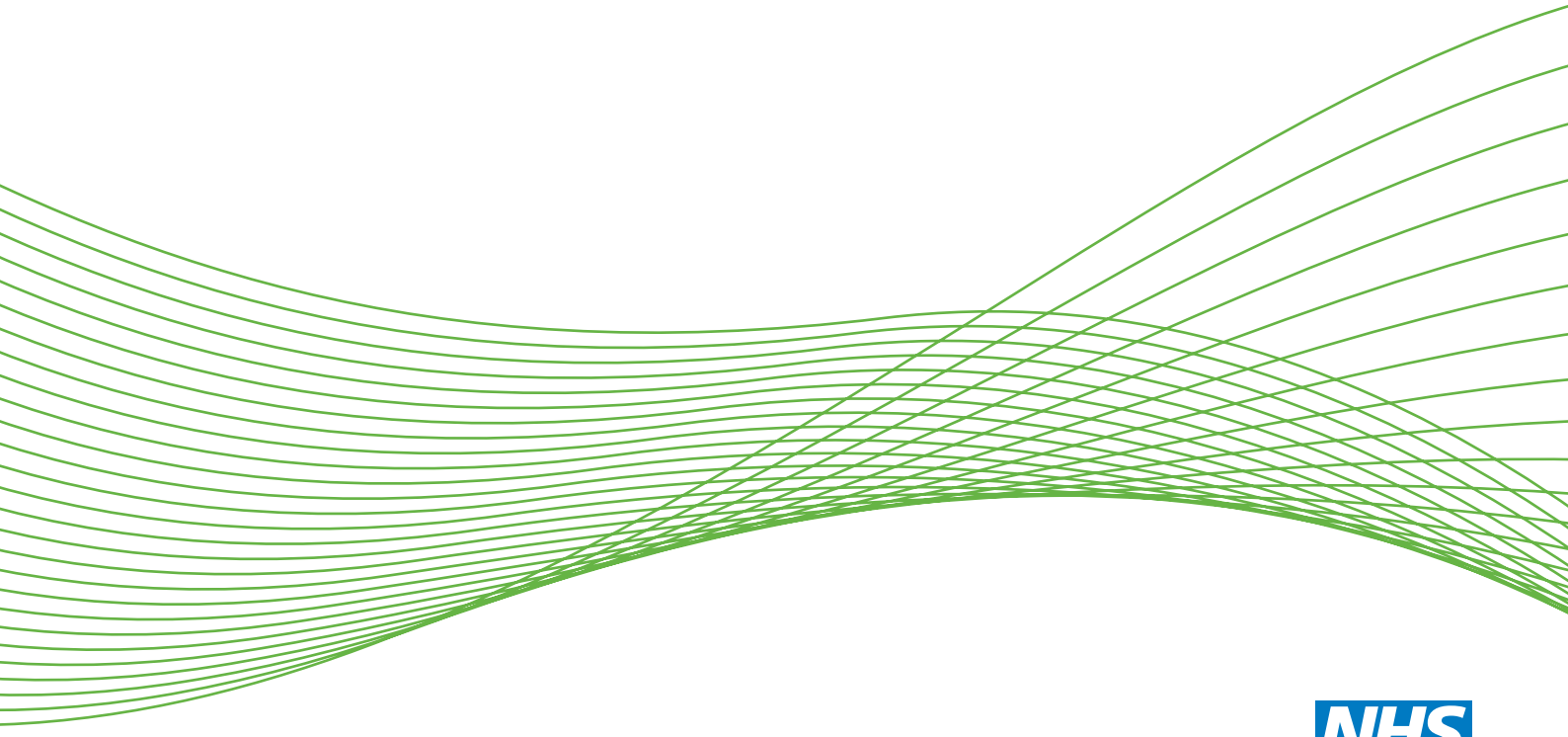
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Sharon A Simpson, Rachel McNamara, Christine Shaw, Mark Kelson, Yvonne Moriarty, Elizabeth Randell, David Cohen, M Fasihul Alam, Lauren Copeland, Donna Duncan, Aude Espinasse, David Gillespie, Andy Hill, Eleri Owen-Jones, Katy Tapper, Julia Townson, Simon Williams and Kerry Hood



NHS
National Institute for Health Research

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Abstract

A feasibility randomised controlled trial of a motivational interviewing-based intervention for weight loss maintenance in adults

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Background: Obesity has significant health and NHS cost implications. Relatively small reductions in weight have clinically important benefits, but long-term weight loss maintenance (WLM) is challenging. Behaviour change interventions have been identified as key for WLM. Motivation is crucial to supporting behaviour change, and motivational interviewing (MI) has been identified as a successful approach to changing health behaviours. The study was designed as an adequately powered, pragmatic randomised controlled trial (RCT); however, owing to recruitment issues, the study became a feasibility trial.

Objectives: To assess recruitment, retention, feasibility, acceptability, compliance and delivery of a 12-month intervention to support WLM. Secondary objectives were to assess the impact of the intervention on body mass index (BMI) and other secondary outcomes.

Design: Three-arm individually randomised controlled trial comprising an intensive arm, a less intensive arm and a control arm.

Setting: Community setting in South Wales and the East Midlands.

Participants: Individuals aged 18–70 years with a current or previous BMI of ≥ 30 kg/m^2 who could provide evidence of at least 5% weight loss during the previous 12 months.

Intervention: Participants received individually tailored MI, which included planning and self-monitoring. The intensive arm received six face-to-face sessions followed by nine telephone sessions. The less intensive arm received two face-to-face sessions followed by two telephone sessions. The control arm received a leaflet advising them on healthy lifestyle.

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Main outcome measures: Feasibility outcomes included numbers recruited, retention and adherence. The primary effectiveness outcome was BMI at 12 months post randomisation. Secondary outcomes included waist circumference, waist-to-hip ratio, physical activity, proportion maintaining weight loss, diet, quality of life, health service resource usage, binge eating and well-being. A process evaluation assessed intervention delivery, adherence, and participants' and practitioners' views. Economic analysis aimed to assess cost-effectiveness in terms of quality-adjusted life-years (QALYs).

Results: A total of 170 participants were randomised. Retention was good (84%) and adherence was excellent (intensive, 83%; less intensive, 91%). The between-group difference in mean BMI indicated the intensive arm had BMIs 1.0 kg/m^2 lower than the controls [95% confidence interval (CI) –2.2 kg/m^2 to 0.2 kg/m^2]. Similarly, a potential difference was found in weight (average difference of 2.8 kg, 95% CI –6.1 kg to 0.5 kg). The intensive arm had odds of maintaining on average 43% [odds ratio (OR) 1.4, 95% CI 0.6 to 3.5] higher than controls. None of these findings were statistically significant. Further analyses controlling for level of adherence indicated that average BMI was 1.2 kg/m^2 lower in the intensive arm than the control arm (95% CI –2.5 kg/m^2 to 0.0 kg/m^2). The intensive intervention led to a statistically significant difference in weight (mean –3.7 kg, 95% CI –7.1 kg to –0.3 kg). The other secondary outcomes showed limited evidence of differences between groups. The intervention was delivered as planned, and both practitioners and participants were positive about the intervention and its impact. Although not powered to assess cost-effectiveness, results of this feasibility study suggest that neither intervention as currently delivered is likely to be cost-effective in routine practice.

Conclusion: This is the first trial of an intervention for WLM in the UK, the intervention is feasible and acceptable, and retention and adherence were high. The main effectiveness outcome showed a promising mean difference in the intensive arm. Owing to the small sample size, we are limited in the conclusions we can draw. However, findings suggest that the intensive intervention may facilitate long-term weight maintenance and, therefore, further testing in an effectiveness trial may be indicated. Research examining WLM is in its infancy, further research is needed to develop our understanding of WLM and to expand theory to inform the development of interventions to be tested in rigorously designed RCTs with cost-effectiveness assessed.

Trial registration: Current Controlled Trials ISRCTN35774128.

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List of abbreviations

AUDIT-C	Alcohol Use Disorders Identification Test
BMI	body mass index
CACE	complier-average causal effect
CDT	cognitive dissonance theory
CEA	cost-effectiveness analysis
CI	confidence interval
CLRN	Comprehensive Local Research Network
CRF	case report form
CVD	cardiovascular disease
DINE	Dietary Instrument for Nutrition Education
EDE-Q	Eating Disorder Examination Questionnaire
EOI	expression of interest
EOR	exercise on referral
EQ-5D	European Quality of Life-5 Dimensions
ETC	excess treatment cost
GF	group facilitator
GHQ-12	General Health Questionnaire – 12 items
GP	general practitioner
HP	health professional
HSI	Heaviness of Smoking Index
ICC	intracluster correlation coefficient
ICER	incremental cost-effectiveness ratio
IPAQ	International Physical Activity Questionnaire
MAP	model of action phases
MI	motivational interviewing
MIP	motivational interviewing practitioner
MITI	motivational interviewing treatment integrity
NICE	National Institute for Health and Care Excellence
OR	odds ratio
PCT	primary care trust
PIC	Participant Identification Centre
QALY	quality-adjusted life-year
RCT	randomised controlled trial
REC	Research Ethics Committee
SAE	serious adverse event
SCT	social cognitive theory
SD	standard deviation
SDT	self-determination theory
WHO	World Health Organization
WILMA	Weight Loss Maintenance in Adults
WLM	weight loss maintenance
WTP	willingness to pay

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Plain English summary

Maintaining weight loss is important for reducing health issues related to obesity. We tested a weight loss maintenance counselling programme for people who had already lost weight. We intended to carry out a larger study with longer follow-up but, owing to recruitment problems, the study became a feasibility study with a 1-year follow-up. We recruited individuals from across South Wales and the East Midlands to take part through general practitioner surgeries, Slimming World, exercise referral schemes and advertising. Participants had a current or previous body mass index (BMI) of ≥ 30 kg/m^2, were aged 18–70 years and provided evidence of having lost 5% of their weight before entering the study. They were randomly allocated to one of three groups: (1) usual care, (2) intensive (more sessions) counselling and (3) less intensive counselling.

Study participants completed questionnaires before, during and after the study to detect any changes and allow for comparisons between groups. Interviews with participants and focus groups with counsellors were carried out to find out their views and experiences of the counselling sessions.

A total of 170 participants took part. Most participants completed the follow-up questionnaires (84%) and attendance at the counselling sessions was excellent. A potential difference in BMI of 1 point (or 2.8 kg) was found between the intensive counselling and usual-care group, a difference which is considered to be important in terms of improving health; however, the small number of participants and short follow-up meant we were unable to predict long-term results. Participants and counsellors spoke positively of the counselling. We recommend that more research be completed to find effective ways to help people maintain their weight.

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Scientific summary

Background

Over one-quarter of adults in the UK are obese. Obesity is associated with increased health risks and reduced life expectancy and has a significant impact on NHS costs. The underlying causes are complex, and tackling obesity is challenging. Evidence suggests that relatively small reductions in weight (5–10% of body weight) can lead to clinically significant health benefits. Interventions tackling lifestyle changes have been effective for weight loss. However, maintaining weight loss in the longer term remains a challenge. Lifestyle and behavioural interventions are likely to be important. Reviews of factors associated with weight loss maintenance (WLM) have identified a number of key features, including physical activity, low-calorie and low-fat foods, tailoring of advice, self-monitoring, social support, internal motivation and self-efficacy.

Motivation is crucial to maintenance of behaviour change. Motivational interviewing (MI) is a counselling technique that emphasises personal autonomy and enhances motivation for change. Some studies have explored MI for weight loss, but none have used it to support WLM. The evidence suggests that relatively brief contact and use of MI in weight loss can be effective. However, we do not know if MI may be useful for WLM or the required treatment intensity.

The intervention tested in this trial comprised MI, incorporating goal-setting, planning and self-monitoring. This study was originally designed as an effectiveness trial with the primary outcome, body mass index (BMI), assessed 3 years post randomisation. However, owing to lower than anticipated recruitment, the trial was closed to recruitment early and became a feasibility study. The results of the feasibility study are reported here in addition to both the original and modified design.

Objectives

The primary objectives were to assess the feasibility, acceptability, compliance and delivery of a 12-month multicomponent intervention based on MI, as well as recruitment and retention. The impact of the intervention on participants' BMI was evaluated 1 year from randomisation. We also assessed the impact of the intervention on a number of secondary outcomes including physical activity, diet, alcohol, smoking status, health-related quality of life, binge eating, psychological well-being and resource use. Furthermore, we aimed to assess key mediators associated with successful change, including self-efficacy, social support, self-monitoring, implementation intentions, habit formation and intrinsic motivation.

Process and cost-effectiveness evaluations were also undertaken.

Methods

Study design

Three-arm individually randomised controlled trial.

Participant recruitment and baseline data collection

Participants were recruited in South Wales and the East Midlands, from general practitioner (GP) practice, exercise referral schemes, a commercial weight loss programme (Slimming World) and the community (via advertising). Individuals were approached either face to face or record searches or self-referred. They were provided with an information sheet and expression of interest (EOI) form. Participants were screened for eligibility, based on age (18–70 years), current or previous BMI (≥ 30 kg/m^2), intentional weight loss of at least

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5% body weight during the previous 12 months and independent verification of weight loss. Participants were not eligible if they had previously undergone bariatric surgery, were terminally ill, had poor competence in English, lived with another study participant or were pregnant. On fulfilment of eligibility criteria, potential participants were invited to a baseline meeting. If participants did not meet or could not provide verification of 5% weight loss, they were invited to recontact the research team when they had achieved this.

Eligibility was confirmed at baseline by the researcher. Participants were consented and randomised to one of three arms: intensive intervention, less intensive intervention or control. Participants completed baseline questionnaires and had their weight, height, and waist and hip circumference measured. On completion of the baseline assessments, intervention participants were invited to the MI sessions and all participants were followed up at 6 months (postal questionnaire) and 12 months (face to face) post randomisation. Those unable or unwilling to attend the 12-month assessment were offered the opportunity to complete a shorter version of the questionnaires over the telephone and self-report their weight.

Trial intervention

Intervention participants received an individually tailored MI counselling intervention. Participants in the intensive arm received six 1-hour face-to-face sessions during the first 3 months followed by nine 20-minute telephone sessions during the remaining 9 months of the intervention period. Participants in the less intensive arm received two 1-hour face-to-face sessions during the first month followed by two 20-minute telephone sessions at 6 and 12 months post randomisation. Originally, the intervention included a group-based peer support element; however, this was not delivered when the study design changed because of feasibility issues relating to recruitment and attendance at the groups. Participants in the control group received a leaflet advising them on healthy eating and lifestyle along with usual care.

Outcome measures

Outcome measures were self-reported with the exception of height, weight, and waist and hip circumference. Secondary outcomes and mediators were measured with validated instruments. All outcomes were recorded on study-specific case report forms (CRFs).

Quantitative analysis

Feasibility outcomes included number recruited, retention and adherence. The main effectiveness analysis was intention to treat and complete case, comparing BMI at 12 months in the intensive intervention arm and the control arm using analysis of covariance controlling for age, gender, ethnicity, source of recruitment and percentage weight lost.

Secondary outcomes included waist circumference, waist-to-hip ratio, physical activity, proportion maintaining weight loss (defined as having a weight at follow-up the same as or lower than their baseline weight), dietary intake, health-related quality of life, health service and weight control resource use, binge eating, alcohol consumption, smoking, psychological well-being, duration of participation and dropout from the intervention. Binary outcomes were analysed using logistic regression and continuous outcomes using linear regression. Mediation analyses were conducted for self-efficacy, social support, intrinsic motivation, habits and self-monitoring as measured at 6 months using a hierarchical model and controlling for baseline randomisation variables. The Consolidated Standards of Reporting Trials – Patient-Reported Outcomes guidelines are referenced for reporting patient-reported outcomes. Exploratory subgroup analyses investigated WLM in binge eaters, gender and source of recruitment.

Process evaluation

We conducted a process evaluation with the aims of assessing delivery of the intervention, establishing the level of participant adherence to the intervention, exploring participants' views of and satisfaction with the intervention, exploring motivational interviewing practitioners' (MIPs) experiences of delivering the intervention and testing the intervention theory. A process evaluation framework was devised to focus on eight key components (context, reach, fidelity, exposure, recruitment, retention, contamination and theory testing). This was used to frame the analysis. Mixed methods were employed.

Audio-recordings of face-to-face sessions were analysed to assess fidelity of intervention delivery and session CRFs were analysed to determine participant adherence. Participants' use of the website for self-monitoring was analysed for frequency of use. Focus groups were conducted with MIPs to gather their views on training received, practicalities of delivering the intervention and suggested improvements. Participants were interviewed to gather their views on the intervention, and barriers and facilitators to weight maintenance. Potential mediators and moderators were also explored, including those specifically being tested in the process evaluation as well as the impact of life events, environmental influences, social support, coping and response to relapse. Focus groups and interviews were analysed using thematic analysis.

Health economic analysis

The change to a feasibility study meant that definitive cost-effectiveness results were unlikely given the reduced sample size and shortened follow-up period. Nevertheless, the costs of delivering the MIP training and intervention delivery were determined, subsequent costs of NHS and non-NHS weight loss/maintenance were estimated and, after adjusting for baseline differences in key variables and for skewness, total costs were assessed against effects in terms of quality-adjusted life-years (QALYs) derived from the European Quality of Life-5 Dimensions health-related quality-of-life data and against BMI.

Results

Quantitative analysis

A total of 1284 EOIs were received and 170 participants recruited. The most common reason for ineligibility was an inability to verify 5% weight loss. The most efficient recruitment route was through the commercial weight loss programme. Adherence to the face-to-face element was excellent in both arms (intensive, 83%; less intensive, 91%). The overall withdrawal and non-responder rates were very low, at 10% and 7%, respectively. The three arms were broadly similar with regard to key demographics and comorbidities. Overall, more women than men ($n = 141$) were recruited.

Although not statistically significant, the between-group difference in mean BMI at 12 months indicated the intensive arm had BMIs 1.0 kg/m^2 lower than the controls [95% confidence interval (CI) –2.2 kg/m^2 to 0.2 kg/m^2]. Mean BMI was also lower in the less intensive group, but the difference was not at a level considered clinically significant. A similar effect was found when considering weight, with the intensive arm weighing an average of 2.8 kg lower than the control (95% CI –6.1 kg to 0.5 kg) and the less intensive group an average of 0.7 kg lower (95% CI –4.1 kg to 2.7 kg). These differences from control were not statistically significant but for the intensive arm would be of clinical importance if shown to be true differences. A difference in waist measurement was also found, with the intensive participants having an average of 0.8 cm lower waist circumference than control (95% CI –4.2 cm to 2.6 cm), while those in less intensive group had an average of 0.2 cm smaller waist circumference (95% CI –3.3 cm to 3.7 cm). In addition, although neither difference was statistically significant, participants in the intensive arm had, on average, a 43% higher chance of maintaining weight loss [odds ratio (OR) 1.4, 95% CI 0.6 to 3.5] than controls, whereas participants in the less intensive arm were, on average, 40% less successful than controls at maintaining weight loss (OR 0.6, 95% CI 0.2 to 1.6).

The other secondary outcomes showed limited evidence of differences between groups. Analysis on the Dietary Instrument for Nutrition Education (DINE) fat scale showed that fat intake was significantly lower in the intensive arm (adjusted mean difference –4.7, 95% CI –7.4 to –2.3). The DINE healthy eating score also showed some evidence of effect in the intensive arm (adjusted mean 4.16, 95% CI –1.8 to 10.1). A statistically significant reduction in binge eating was observed in the intensive arm (mean binge eating rate 0.6 days, 95% CI 0.4 days to 0.9 days). Further analyses controlling for level of adherence indicated that average BMI was 1.2 kg/m^2 lower in the intensive arm than in the control arm (95% CI –2.5 kg/m^2 to 0.0 kg/m^2). The intensive intervention led to a statistically significant difference in weight (mean –3.7 kg, 95% CI –7.1 kg to –0.3 kg) relative to controls.

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The mediation analysis showed that 5 out of the 10 mediators were statistically significantly associated with lower BMI. However, this analysis was largely unable to determine the causal mechanisms underlying these associations. The results do not show any impact of the intervention on the mediators tested.

Process evaluation

The intervention was successfully delivered in the community by trained counsellors. Adherence was good, although there were some issues with telephone delivery, including low acceptability to some counsellors and participants. Use of the website for self-monitoring was quite low, with a median number of 26 logins. The face-to-face MI was delivered with good fidelity, and contamination between arms was minimal.

Motivational interviewing practitioners were positive about the intervention, although they would have preferred the number of sessions to be based on need rather than chance (i.e. randomisation). They preferred face-to-face delivery and felt that participants benefited from the supportive ongoing relationship. They reflected positively on the possibilities of implementing the intervention in 'the real world' and commented on wider social and environmental factors and their impacts.

Participants appreciated the counselling as it provided a safe, caring and non-judgemental environment. They valued the psychological expertise and support of the counsellors. They felt that it provided increased insight into their weight-related behaviours, as well as encouragement to find their own solutions, which helped boost feelings of control in relation to weight management. They also suggested that long-term support was important for maintenance. Most preferred the face-to-face sessions, although telephone sessions were seen as useful for 'checking in'. Some participants reported that they had shared information with family and friends and that, in some cases, this led to behaviour change. Participants described a number of barriers to managing their weight, which included cultural attitudes around food and eating, and significant life events.

The qualitative data provided insights into the mediators of intervention effect. The most important was ongoing motivation, which was strongly influenced by the support of family, friends, peers and professionals. Other factors described as important included positive reinforcement, self-monitoring and habit formation.

Economic analysis

The total cost per person of the intensive and less intensive interventions was £510 and £168, respectively. The cost–utility analysis indicated a small QALY gain for the intensive group (0.001) and a small QALY loss (0.032) for the less intensive group compared with controls, but neither difference was statistically significant. As total NHS costs for both intervention groups were higher than for controls, the less intensive intervention was dominated (i.e. unambiguously not cost-effective) and the intensive intervention produced an incremental cost-effectiveness ratio well above the willingness-to-pay threshold used by the National Institute for Health and Care Excellence. The cost-effectiveness analyses (CEAs) using BMI as the outcome indicated that both interventions were more effective than the control, with the intensive intervention being the most effective, although neither difference was statistically significant.

Conclusions

This is the first trial of an intervention for WLM in the UK. Although recruitment was challenging and problems with verification of weight loss, and governance and infrastructure support issues led to the trial becoming a feasibility study, the results look promising. The intervention is feasible and acceptable, and retention and adherence were high. The qualitative work indicates that both counsellors and participants were happy with the delivery of the intervention and the participants particularly appreciated the support. The effectiveness outcomes showed promising mean differences and CIs for the intensive arm, which would be considered clinically significant; however, the reduced sample size limits our ability to draw

definitive conclusions from the quantitative, mediation and CEAs. Outcomes in the less intensive and control arms appear similar; therefore, we do not recommend the less intensive arm for further investigation. Based on current research evidence, it is likely that more intensive interventions with longer-term support are needed to facilitate long-term weight maintenance.

Motivational interviewing appears to be a promising approach for behaviour modification leading to WLM and, therefore, further testing in an effectiveness trial may be indicated. However, significant resources are required to deliver this intervention at an appropriate level. This intervention could be implemented in a community setting and may prove cost-effective to deliver, particularly if viewed as part of a broader strategy to support healthy choices.

Weight loss maintenance research is still relatively undeveloped. There is a need for future research improving our understanding of WLM and expanding theory to inform the development of interventions, which should then be tested in rigorously designed randomised controlled trials with cost-effectiveness assessed.

Trial registration

This trial is registered as ISRCTN35774128.

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Chapter 1 Introduction

Obesity: the problem

Poor diet, physical inactivity and high body mass index (BMI) have been identified as among the top 10 risk factors for the global burden of non-communicable disease.[1] Worldwide obesity has become a key public health concern, with the prevalence of obesity doubling since the 1980s.[2] Over one-quarter of adults in the UK are obese, and over 63% are either overweight or obese.[3] In 2010, 35% of men and 44% of women were at high or very high risk of health problems based on their BMI and waist circumference.[3] Obesity is associated with a reduced life expectancy of up to 14 years.[4] Obese and overweight individuals are at increased risk of developing type 2 diabetes mellitus, heart disease, osteoarthritis, depression, hypertension and certain cancers.[2] Although in some countries rates of obesity have stabilised, in others obesity rates are projected to continue increasing.[5] Despite efforts taken by many governments to tackle obesity, embracing increasingly comprehensive strategies and involving communities and key stakeholders, little progress has been made in successfully addressing 'the obesity problem'.

The causes of obesity are complex and include biological, social, environmental and psychological influences. The Foresight report *Tackling Obesities: Future Choices*[6] details the complex multidimensional array of influences affecting weight and concludes that tackling the obesity problem will require interventions at multiple levels of influence. Although obesity is associated with a number of potentially important genes, the effect that the genotype has on the development of obesity is strongly influenced by non-genetic factors.[7] Modern lifestyles tend to include low levels of physical activity and high levels of sedentary behaviours, resulting in reduced daily energy expenditure. Recent data, based on self-report, suggest that only 29% of women and 39% of men achieve government recommendations for physical activity in England. When this is based on objective measures, these rates are reduced to only 4% of women and 6% of men reaching government targets.[3] Many occupations have become more sedentary in nature, and easy access to different modes of transportation as well as concerns about safety negatively impact on walking and cycling.[8] Diet in developed countries has moved towards high-fat, energy-dense foods and large portions.[8] In the UK, and many other countries, the balance between energy intake and energy output has tipped in favour of weight gain.

Obesity-related illness represents a significant cost to the NHS, society and individuals. It is estimated that the NHS spends £5B per year[9] treating obesity-related health problems. By 2050, if obesity continues to rise, the combined cost to the NHS and society has been estimated to be almost £50B per year.[6] In primary care, there are limited treatment options with proven effectiveness for weight management. Practice staff are often inadequately trained, and issues such as shortage of referral options, the large number of obese patients, the apparent lack of motivation of patients to change and time constraints compound the problem.[10]

There is evidence that, in overweight or obese individuals, reductions in weight of 2–5 kg can lead to clinically important reductions in key cardiovascular risk factors and prevent progression to type 2 diabetes mellitus.[11–14] Evidence indicates that through various means, including lifestyle interventions and medication, this level of weight loss (and possibly more) can be achieved.[12,13,15–18] National Institute for Health and Care Excellence (NICE) guidance emphasises the importance of interventions that tackle both physical activity and diet and include behaviour change strategies.[19] Systematic reviews have shown that combining diet and physical activity is likely to be more effective than either alone.[20,21]

Studies testing lifestyle interventions for weight loss have been successful in the short term; however, weight regain is common.[13,16] Weight loss interventions will ultimately be cost-effective and have a longer-term impact on health only if weight loss is maintained. Effective interventions that can help people successfully

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manage their weight in the longer term are therefore needed. Although there is some evidence that indicates maintenance interventions are associated with smaller weight gains than no contact, the prevention of weight regain remains a challenge.[20,22] Differences between intervention and controls tend to be small, and around one-third of weight is regained in the year following the intervention,[23] with return to baseline weight within 5–6 years.[16] Helping individuals achieve long-term weight loss or maintenance has proven to be challenging. The skills and techniques used to maintain weight loss may be somewhat different to those required to lose weight. To date, research has provided limited insight into how this can be achieved;[24] however, lifestyle and behavioural interventions are likely to be key to long-term weight loss.

The following two sections explore approaches to weight loss as well as weight loss maintenance (WLM). Evidence related to bariatric surgery was not considered because this group of patients are likely to require different support in terms of the strategies and psychological approaches. Bariatric surgery was also a specific exclusion criterion in the study. As there are few systematic reviews looking specifically at WLM interventions, we have included reviews that examine long-term weight loss (and, therefore, maintenance), with at least 1-year follow-up, as well as those in which the interventions being tested have a distinct focus on maintenance of weight already lost.

Weight loss interventions

A systematic review and meta-analysis of 30 randomised controlled trials (RCTs)[25] of weight loss strategies, most of which included behavioural plus other approaches (13 diet alone, four diet and exercise, four exercise alone, seven meal replacement and two very low-energy diets) found that diet alone, diet and exercise, and meal replacements led to weight loss at 12 months of between 4.8% and 8%, and at 24, 36 and 48 months of between 3% and 4.3%. At 48 months, no groups regained weight to baseline levels. Only two of the studies of meal replacements went beyond a 1-year follow-up, and exercise alone did not appear to lead to successful WLM. When large weight losses were achieved using very low-energy diets, weight regain was rapid, but 5% loss could be maintained at 36 months.[25] A systematic review of six RCTs evaluating diet, exercise, or diet and exercise together indicated some advantage of combined diet and exercise interventions, which achieved a 20% greater sustained weight loss at 1 year than diet alone.[20] There is heterogeneity in the results of trials exploring type of diet and its relation to weight loss. A meta-analysis of five trials found no differences between low-carbohydrate and low-fat diets at 12 months.[26] A systematic review of 14 RCTs found that low-fat, 600 calorie deficit, or low-calorie diets were associated with weight loss at 12, 24 and 36 months.[13]

Obesity medication has also been used to target long-term weight loss. A meta-analysis of 12 RCTs indicated that orlistat (Xenical®, Roche) conferred an advantage above diet alone of 3.1 kg weight loss [standard deviation (SD) 10.5 kg] at 24 months.[25] Another systematic review of 12 clinical trials found that orlistat plus dietary or lifestyle intervention resulted in a 3–10-kg loss after 12–24 months and increased the odds of attaining 5% weight loss or greater at 24 months.[27] However, the included studies suffered from high attrition rates, on average between 30% and 50%, highly selected patient populations, inadequate description of randomisation and few used intention-to-treat analyses.

Weight loss maintenance interventions

In terms of interventions specifically for WLM, there are limited data on diets suitable for WLM. However, evidence from the US Weight Control Registry indicates that those who maintain weight loss in the longer term generally follow low-fat, low-calorie diets, eat breakfast and have consistent eating patterns over weekdays and weekends.[28] A conceptual review of factors associated with WLM also found that eating breakfast and a regular meal pattern are important, as is having a healthier low-fat diet.[29]

Although physical activity is important for maintenance of weight loss,[30] limited evidence exists regarding the type or amount of physical activity required. A systematic review comprising 11 RCTs and 35 prospective or non-randomised studies suggested that higher levels of physical activity may be associated with WLM.[31] Secondary analyses of one well-designed trial found that individuals reporting higher levels of physical activity (275 minutes per week) were better able to maintain 10% weight loss at 24 months.[32] Another review identified that 60–90 minutes of moderate-intensity activity per day is needed to prevent weight regain.[33] The 2008 US Physical Activity Guidelines Advisory Report[34] identified that the currently available evidence has a number of limitations; nevertheless, the report suggests that 'more is better'. The studies included in the report indicated that, to prevent weight regain, individuals should walk for 60 minutes or jog for 30 minutes daily. However, many individuals find this difficult to maintain in the longer term.

A recent systematic review of trials of interventions to maintain weight loss found that behavioural interventions focusing on diet and physical activity led to an average weight difference of –1.56 kg in weight regain in intervention participants relative to controls at 12 months.[35] Orlistat plus behavioural treatment led to a –1.80 kg difference between intervention and control.[35] In addition, a review of RCTs of WLM interventions found that treatment with orlistat or sibutramine (Reductil®, Knoll Abbott) alongside a dietary intervention, caffeine or protein supplementation, physical activity, low-fat diet, ongoing contact, problem-solving therapy, or acupressure was helpful in minimising weight regain.[36] A systematic review and meta-analysis of the impact of extended care on maintenance of weight loss in the longer term found that extended care could lead to an additional maintenance of 3.2 kg at 17.6 months compared with control.[37]

There is some evidence that web- or computer-based interventions may be useful for WLM,[38,39] and they are likely to cost less to deliver. One review suggested that web-based interventions are about as effective as face-to-face interventions and higher website use may be associated with WLM.[40] Another recent review found that computer-based interventions were more successful for WLM than no intervention or minimal intervention.[39] When computer-based interventions were compared with in-person interventions, the weight loss was smaller and weight maintenance was of shorter duration.[39] A recent telephone- and mail-based intervention found that, at the 24-month follow-up, the odds of weight maintenance was 1.37 times greater in the guided telephone intervention than in the self-guided arm.[41] This approach is likely to be more feasible and cost-effective to deliver.

Further research is needed, as the evidence base is limited, because most trials included in reviews are of poor or moderate quality. Many trials of longer-term weight loss or WLM are inconclusive. They are heterogeneous in terms of setting, length of follow-up, type and duration of intervention, many have methodological flaws, including inadequate reporting of randomisation processes or blinding and paucity of intention-to-treat analyses, and findings are often contradictory. High levels of attrition are evident and this is probably associated with WLM failure. This makes it difficult to draw conclusions about what works in WLM. There is a need to develop and rigorously test interventions that are based on evidenced behaviour change techniques which also take contextual factors into account, that can help people with long-term weight loss or maintenance of weight loss. Although there is a lack of research evidence for interventions that can effectively support longer-term weight loss, there have been some notable successes, for example the Finnish Diabetes Prevention programme, in which participants maintained an average weight loss of 3.5 kg at 3-year follow-up.[42] Conducting trials in this area is challenging for a number of reasons: difficulties achieving blinding owing to the nature of the intervention; the difficulty of retaining participants over long-term follow-up; and the cost of running such long-term studies, which makes the production of the required evidence time-consuming and expensive.

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Psychological/behavioural therapeutic approaches

Trials of interventions for long-term weight loss or maintenance of weight loss usually include some aspect of behaviour therapy or counselling as part of the intervention, alongside other elements such as dietary change. Counselling or psychotherapeutic approaches that have been successfully used for weight loss include cognitive–behavioural therapy[43] and motivational interviewing (MI).[44] As well as these particular counselling approaches, many interventions have employed specific behaviour change techniques and, in many cases, the effects of these elements are not teased out. Behavioural techniques that have been specifically assessed in high-quality RCTs and shown to offer significant benefit for WLM include goal-setting,[38] problem-solving,[22,38] relapse prevention,[38] self-monitoring[22,38] and daily self-weighing.[22] Peer or social support[21,22] and frequent continued professional support have also been shown to be important.[22,38]

As noted above, the psychological processes, skills and strategies which are likely to be effective for WLM are potentially different from those needed to lose weight.[22,24,45,46] Research examining 5000 people on the US National Weight Control Registry suggests that the only factor those losing weight have in common is that they combined diet and exercise to do so. However, when examining the maintenance phase, a number of common factors were identified, including low-fat diet, eating breakfast, self-monitoring and high levels of physical activity.[28] Losing weight requires a negative energy balance, whereas weight maintenance requires continued energy balance. This balance needs to be sustained by behaviours that can be continued over the longer term. In reviews of factors associated with WLM, a number of issues stand out: higher levels of physical activity,[32] consumption of low-calorie and low-fat foods, individual tailoring of advice, self-regulation/monitoring, social support, internal motivation and self-efficacy.[28,29]

The WeIght Loss Maintenance in Adults (WILMA) trial tested an intervention that incorporated many of the evidence-based behavioural techniques described above alongside three main components: MI (incorporating action-planning and implementation intentions[47,48]), social support and self-monitoring. These three main elements and evidence for them will be considered briefly in *Motivational interviewing*, *Social support* and *Self-monitoring*. The intervention elements and theoretical approach are described in more detail in *Chapter 2*.

Motivational interviewing

Motivation is a key precursor for behaviour change, and ongoing motivation is important in terms of maintaining behaviour change.[49] As ongoing intervention contacts have been shown to help maintain weight loss,[38] and attrition from longer-term programmes is a problem,[22] motivation is likely to be important. Many people are able to lose weight by dieting and/or exercise.[45] However, sustaining these behaviours seems to be challenging and, therefore, enhancing motivation is likely to be important in terms of maintaining healthy behaviours. MI is therefore the key ingredient of the intervention. MI is defined as:

> *a collaborative, goal-oriented style of communication with particular attention to the language of change. It is designed to strengthen personal motivation for and commitment to a specific goal by eliciting and exploring the person's own reasons for change within an atmosphere of acceptance and compassion.*[50]

The effectiveness of MI has been demonstrated in a wide range of behaviour change contexts including modification of drug use[51] or alcohol consumption[51] and smoking cessation.[52] Weight loss and WLM is a relatively new area for MI, and few studies have been completed.[53] MI has been shown to be effective as an adjunct to a behavioural weight control programme.[53] It can be useful in maintaining behaviour change as well as initiating change and supports participants in an ongoing, tailored way.[53,54]

Brief interventions using MI have been effective in different areas of behaviour change including diet and physical activity. RCTs and systematic reviews of MI approaches have shown that it can be used successfully in interventions to change both diet and exercise.[55–59] It can also effectively be delivered by telephone, which provides a clear cost advantage over face-to-face delivery.[60,61] There is some evidence

that MI can be effective when delivered in just one session[62] and even when sessions are as short as 15 minutes.[57,63] One meta-analysis examining MI in different areas of disease showed a combined effect of MI on decreasing BMI by 0.72 kg/m^2 ($p < 0.0001$) and found that longer follow-up increased the chance of an effect from 36% at 3 months to 81% at 12 months or longer.[57]

A systematic review and meta-analysis identified 11 RCTs examining the effect of MI on weight loss.[64] It found that participants who received MI lost more weight than controls [weighted mean difference −1.47 kg, 95% confidence interval (CI) −2.05 kg to −0.88 kg]. The pooled effect size was 0.51. When weight loss was the primary outcome, treatment was more than 6 months and a treatment fidelity measure was used and the effect of MI on BMI increased. However, most of these studies had a follow-up period of less than 12 months.[64]

No studies have tested MI as a WLM intervention, although a few have investigated longer-term WLM following an MI-based weight loss intervention.[53,54] West *et al.*[53] tested a weight loss intervention consisting of MI (plus a group-based weight control programme) in women with type 2 diabetes mellitus. They found that women in the MI group lost significantly more weight by the 18-month follow-up assessment than those in the control group (3.5 kg ± 6.8 kg loss in MI and 1.7 kg ± 5.7 kg in control subjects, $p = 0.04$). Hoy *et al.*[54] conducted a study with a 5-year follow-up period. They evaluated a dietary intervention with MI techniques and found that, after 1 year, body weight was lower in the intervention group and at 5 years women in the intervention group weighed significantly less than controls [6.1 lb mean weight difference between groups ($p = 0.005$) at 5 years].

Social support

As environmental factors can encourage or impede behaviour change and maintenance, social support has a key role. Social support may operate in a number of ways to promote healthy behaviours, for example through reinforcement, encouragement, motivation, feedback, empathy, role-modelling, increased self-efficacy, instrumental support (help), appraisal (e.g. affirmation), peer pressure for healthy behaviours or access to health information. There is evidence indicating that social support and health are related[65] and that social support can promote better health behaviours when employed alongside goal-setting and self-monitoring. Ferranti *et al.*[66] found that social support is positively correlated with a good diet and increased physical activity.[67,68] Social support can improve WLM,[69] encourage health-promoting behaviours and promote well-being.[70] Conversely, there is also evidence that unhealthy behaviours are correlated with less social support. The current NICE behaviour change draft guidance notes that, across a range of health behaviours (including diet, alcohol and physical activity), social support was present in most of the effective interventions.[71]

Social support tends to be employed and theorised as one of several key elements in behaviour change interventions[72] and has been identified in reviews as one contributing factor to effectiveness, alongside goal-setting and self-monitoring.[21,73] Common intervention elements thought to operate in conjunction with social support are self-efficacy,[74] perceived control[68,74] and social norms.[75] A trial of diet change and weight loss with the inclusion of group-based social support found that those who received social support regardless of the diet they followed lost more weight at years 1 and 2 than those who did not receive support.[76] Other studies also report that participants who received interventions which included social support lost more weight by the end of the study than did controls.[69,77] Continued professional support is also related to better WLM.[21,22,38]

Self-monitoring

Self-monitoring is important for successful behaviour change.[78] In a meta-analysis of behaviour change interventions of physical activity and healthy eating, more effective interventions were shown to combine self-monitoring with at least one other technique derived from control theory (e.g. intention formation, specific goal-setting).[73] Regular self-monitoring is associated with WLM and is recommended by NICE.[19]

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Self-monitoring in this context consists of regular self-weighing and monitoring of diet and physical activity.[57] A systematic review found a consistent association between self-monitoring and weight loss, although the authors suggest caution as the quality of the evidence is weak.[78] One good-quality study found that daily self-weighing was associated with a decreased risk of regaining weight at the 18-month follow-up.[22] Another study exploring WLM among participants in the National Weight Control Registry found that WLM for longer than 5 years was associated with regular self-monitoring of weight.[28]

The trial

The present study evaluated a 12-month, individually tailored intervention based on MI incorporating implementation intentions/action-planning, peer support and self-monitoring. The trial comprised three arms: (1) an intensive intervention arm, (2) a less intensive intervention arm and (3) a control arm. The intervention, which is described in detail in *Chapter 2*, was initially delivered face to face and incorporated follow-on sessions delivered by telephone as well as group-based peer support sessions. The focus of the intervention was on maintaining gains already made. It is envisaged that this intervention, if successful and cost-effective, could be rolled out to a wide variety of people who have lost weight using different methods; therefore, the participants were recruited from a variety of settings.

The original aim of the study was to evaluate the impact of a 12-month multicomponent intervention, or a less intensive version, with a control intervention on participant BMI with follow-up at 3 years from randomisation. However, set-up and recruitment challenges meant that the trial design was changed to a feasibility study. The main objectives of the feasibility study were to assess the feasibility, acceptability, compliance and delivery of a 12-month multicomponent intervention, as well as recruitment and retention, which were assessed as part of the process evaluation. The process evaluation also examined the views of participants and intervention staff. To give an indication of effect sizes for a larger trial, we evaluated the impact of the intensive or less intensive intervention on participants' BMI (primary effectiveness outcome) at 12 months from randomisation.

We examined the effect of the intervention on physical activity, diet, health-related quality of life, binge eating, psychological well-being and health resource use. We also examined the proportion of participants maintaining their baseline weight at the 1-year follow-up (defined as having a weight at follow-up the same as or lower than their baseline weight). To assess abdominal obesity, waist circumference and waist-to-hip ratio were included as outcomes. This is important because visceral fat is independently associated with all-cause mortality[79] and many of the risk factors for cardiovascular disease, including type 2 diabetes mellitus.[80] 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 circumference to determine abdominal obesity. Although 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.[81]

We assessed mediators associated with change and hypothesised mediators include self-efficacy, social support, self-monitoring, implementation intentions, habit formation and intrinsic motivation. Analyses sought to identify the extent to which the intervention was successful at changing these mediators and the extent to which mediator change was associated with WLM (see *Chapter 5*). See *Table 2* for a full description of mediators.

Data on key moderators were collected to examine factors associated with success in WLM. These include demographics (age, gender, socioeconomic status, ethnicity and employment status), binge eating, quality of life, source of recruitment, psychological well-being, gender and socioeconomic status. Although a number of studies have found no differential effects of gender on weight management interventions,[38]

some have found that the male physiological response to physical activity does impact on weight management interventions, although further work is needed.[82–84] The effects of age are also unclear, but older participants have been reported to be more successful in WLM programmes.[85] Prevalence of obesity is higher in some ethnic minority groups, and ethnicity has also been associated with better WLM in some American studies.[86,87] This may be confounded by lower socioeconomic status, which impacts on food choices resulting from environmental factors and sociocultural attitudes.[87] Finally, a cost-effectiveness evaluation was also undertaken.

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Chapter 2 The WeIght Loss Maintenance in Adults trial intervention

Background

There has been a significant focus in recent years on developing behaviour change interventions with a strong theoretical foundation that are clearly described and consequently replicable.[88–92] Furthermore, there are a number of suggested frameworks and taxonomies of behaviour change techniques[88,90–92] which provide a method for defining intervention components and a set of accompanying definitions that facilitate accurate description and replication of these components. Researchers have also indicated which psychological theories some of these techniques map onto, for example goal-setting and social cognitive and control theories.[88] However, there remains a significant amount of uncertainty regarding how best to match behaviour change techniques to theoretical constructs.[90] Based on these recommendations and observations, the approach taken here was to develop a well-described, theory-based intervention and to explicitly test the theorised mechanisms of effect.

Intervention components and theory

As outlined in *Chapter 1*, the WILMA trial intervention was based on three main components: MI (incorporating implementation intentions),[47] social support and self-regulation (self-monitoring).

Motivational interviewing

Motivation is central to many theories seeking to explain behaviour change. Motivation is unlikely to be static and is a product of both internal and external factors related to the individual.[49] As highlighted in *Chapter 1*, motivation is likely to be critical in minimising attrition,[22] which is important as sustained intervention contact is associated with better weight outcomes.[38] For this reason, MI is the key ingredient of the intervention.

Four key processes have been identified as occurring during MI counselling sessions: engaging, guiding, evoking and planning.[50] Engaging is the process whereby the counsellor develops rapport and a collaborative working alliance with the client. Guiding occurs after engagement and is the process in which the counsellor helps guide the client along a particular course in relation to change. Evoking involves prompting the client to think about and describe his or her motivations for change, and this is a key aspect of MI. Planning involves the client developing a plan in order to achieve the change that he or she desires. These processes are ongoing and may need to be revisited at different time points.

The effectiveness of MI has been demonstrated in a wide range of behaviour change contexts[51,52] (see *Chapter 1*). MI in relation to weight loss and maintenance is a relatively new area, although MI appears to be effective as an adjunct to a behavioural weight control programme.[51] MI may facilitate maintenance of behaviour as well as behaviour change. In the context of the WILMA trial intervention, MI supports participants in an ongoing and tailored way.[53,54]

Self-determination theory

Self-determination theory (SDT) provides a theoretical framework for understanding MI.[93] SDT characterises motivation as either intrinsic or extrinsic, with intrinsic motivation being linked to more sustained behaviour change.[94] According to SDT, intrinsic motivation for a behaviour is enhanced when the behaviour is associated with feelings of competence (i.e. confidence or belief that one can accomplish the behaviour), autonomy (i.e. that the behaviour is the individual's choice) and relatedness (i.e. feeling understood and

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valued by significant others). MI supports feelings of competence, autonomy and relatedness and is therefore thought to help promote intrinsic motivation for behaviour change. It achieves this using a variety of techniques such as developing discrepancy, providing information, helping the client develop goals, supporting autonomy and self-efficacy, being non-directive, exploring pros and cons and avoiding blaming or judgement.[49,50] These are central to the WILMA trial intervention.

Motivational interviewing can also be said to draw on cognitive dissonance theory (CDT).[95] This states that when an individual holds conflicting cognitions it produces a state of tension or discomfort. The individual is motivated to reduce this discomfort, usually by rejecting one set of beliefs in favour of the other. MI creates cognitive dissonance by developing discrepancy, that is helping individuals see a mismatch between where they are and where they want to be.

Model of action phases

According to the model of action phases (MAP), behaviour change consists of a motivational phase, in which an individual decides to change his or her behaviour, and a volitional phase, during which the individual decides *how* to implement the change.[96] As such, action-planning/implementation intentions were incorporated into the MI sessions in order to target the volitional phase of behaviour change. Implementation intentions have been shown to be very effective at helping individuals achieve their goals[47,97,98] and, in keeping with MAP, have been shown to be particularly useful in promoting behaviour change when combined with motivational interventions.[99,100] Implementation intentions specify a plan of when, where and how a person is going to, for example, start exercising. This is believed to result in the behaviour being elicited automatically by the relevant environmental cue rather than by a more effortful decision-making process. It also helps ensure that good opportunities to perform the target behaviour are not missed.[101] If the behaviour is repeated over time it may become increasingly automatic or habitual. Turning healthy behaviours into habits is critical if they are to be maintained over the long term as habits tend to be very resistant to change.[102] The promotion of healthy habits is therefore a key aim of the proposed intervention.

Social cognitive theory

Development of the intervention was also strongly influenced by social cognitive theory (SCT),[103] which states that individuals have to believe that they possess the necessary skills to change their behaviour (self-efficacy) and also that their actions will produce certain consequences, for example improved health (outcome expectancies). Furthermore, these beliefs can be modified though observing the behaviour of others (modelling) and/or as a result of positive reinforcement.

Social support

As outlined in the previous chapter, social support can help promote healthy behaviours (e.g. through reinforcement, encouragement, motivation, feedback, empathy, role-modelling and increased self-efficacy), particularly in combination with goal-setting and self-monitoring,[65] and has been identified as a component of the majority of effective behaviour change interventions.[71] Additionally, continued professional support is related to better WLM.[21,22,38]

Self-monitoring

Self-monitoring is a key aspect of self-regulation and is important for successful behaviour change.[78] Regular self-monitoring is associated with both WLM[22,28] and weight loss,[78] and is recommended by NICE.[19] Self-monitoring allows people to track their eating, physical activity and weight, and observe links between patterns of behaviour and changes in body weight. Monitoring weight also allows individuals to identify smaller changes before these escalate and they can then take steps to prevent further weight gain.

The WeIght Loss Maintenance in Adults trial intervention model

The WILMA trial intervention model is detailed in *Figure 1*. The main component of the WILMA trial intervention is MI, incorporating self-monitoring and social support. The intervention utilises a number of techniques and processes central to MI, such as promoting intrinsic motivation using a collaborative and curious style (engaging, evoking), providing tailored support (guiding) and encouraging goal-setting

FIGURE 1 The WILMA trial intervention model. a, MI style/technique; and b, theorised mediators.

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(action-planning). Providing feedback and positive reinforcement and enabling clients to develop discrepancy between behaviours and desired outcomes are also techniques that are key to MI and the current intervention. The concept of self-monitoring was generally encouraged during MI sessions: participants were also asked to record their weight weekly and submit these weekly weights to the study team. An optional component of self-monitoring and behavioural regulation was also provided, in the form of an online and/or paper diary; these data were not collected by the study team. MI practitioners (MIPs) provided professional support and encouraged peer support; additionally the group session component described here (see *Peer group support sessions*) was intended to provide peer support and encourage information sharing and modelling of behaviour.

It was hypothesised that the intervention components detailed in *Figure 1* would be associated with specific variables and that these, in turn, may mediate relationships between the intervention and outcomes. Specifically, it was hypothesised that the intervention would increase intrinsic motivation, action-planning, self-efficacy, self-monitoring behaviours and boost/provide a source of social support. These variables were theorised to increase physical activity and healthy diet behaviours that would eventually become habitual, ultimately leading to successful WLM and, in some cases, further weight loss.

The components of the WILMA trial intervention and their suggested theoretical links are outlined in *Table 1*.

TABLE 1 The WILMA trial intervention and theoretical links

Intervention component/outputs	Relevant theory
Promoting intrinsic motivation	SDT[93]
Providing positive feedback/reinforcement	SDT, SCT[103]
Developing discrepancy between current behaviours/weight and ideal behaviours/weight	CDT[95]
Goal-setting/forming implementation intentions/action-planning	SCT (GS), MAP (II)[96]
Self-monitoring	SCT (self-regulation)
Encouraging/providing social support	SCT, SDT
Encouraging problem-solving	SCT
Promoting self-efficacy	SCT, SDT

The Weight Loss Maintenance in Adults trial intervention

The WILMA trial comprised an individually tailored intervention based on MI, incorporating implementation intentions, social support and self-monitoring. The main part of the intervention was concentrated in the first 2 (less intensive) to 6 months (intensive), tapering down to less regular support. It was felt that this longer-term support, although not resource intensive, would be important for the effectiveness of the intervention. Previous studies that have had success with WLM have had longer-term interventions and support.[22,38,104] The trial comprised three arms: (1) an intensive intervention arm, (2) a less intensive intervention arm and (3) a control arm. We hypothesised that the intensive intervention would be effective and that the less intensive intervention would have an effect somewhere between the control and intensive intervention. This less intensive arm is important because, although 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 the latter may occur for many participants.

Individual motivational interviewing sessions

Participants in the intensive intervention group had six one-to-one individually tailored MI sessions. Sessions were delivered by experienced MIPs and were delivered approximately fortnightly for 3 months, lasting around 1 hour. For the final 9 months of the intervention participants received monthly MI telephone calls lasting approximately 20 minutes. This level of monthly contact in the intensive intervention group is based on evidence from previous trials.[38] Participants in the less intensive intervention group received two face-to-face tailored MI sessions 2 weeks apart. This was based on experience from clinical practice as well as evidence from reviews and meta-analyses.[57,63] Participants also received two MI-based telephone calls at 6 and 12 months lasting around 20 minutes.

Motivational interviewing session content

Motivational interviewing practitioners were given a handbook to guide the sessions (see *Appendix 1*). This comprised the following information: a summary of the client group and their challenges, MI within the context of the WLM trial and intervention 'hot topics'. Hot topics comprised self-monitoring, goal-setting and implementation intentions, habits, emotional eating and coping with relapse, diet, physical activity, barriers to maintenance, social support and self-efficacy. The purpose of this section of the handbook was to summarise, in non-expert language, the key research evidence suggesting that these components are likely to be effective for WLM. Information on each topic was provided in the following format: (1) description of the topic ('what is it?'), (2) summary of research evidence ('why is it important?') and (3) suggestions on how to use the information during individual sessions in an MI-consistent (i.e. non-directive) way ('what do I need to do?'). MIPs were also provided with summary information relating to each of these intervention hot topics on laminated sheets. This summary information covered key components of the detail provided in the practitioners' handbook in lay language, for them to use as a reference and share with participants as required during MI sessions.

Diet and physical activity were discussed in the MI sessions in line with current government guidance. Participants were encouraged 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 were encouraged by researchers at their baseline assessments to self-monitor by weighing themselves weekly and MIPs encouraged the concept of self-monitoring generally. Participants were able to record all self-monitoring activity, including 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 (paper-based and brief online version); however, completion was optional. Diaries provided to participants were intended for their personal use only and were not collected by the study team for outcome assessment. However, participants were asked to record their weekly weight and send this information to the study team via the study website or by text, e-mail or telephone. MIPs kept a written record of each face-to-face and telephone session (including goal-setting and implementation

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intentions) using the appropriate case report form (CRF) and this information was collected by the study team. MIPs also completed a brief written summary of the session for the participant to take away.

Information on study-specific procedures [reporting serious adverse events (SAEs), lone working, actual/risk of self-harm to participants and administrative processes] was also included in the handbook.

Peer group support sessions

Professional-led peer group support sessions were planned to take place monthly, lasting 1.5 hours, for 4 months, to follow on from the face-to-face MI sessions. The group sessions were the same for both intervention arms. The number of sessions chosen was felt to provide a cost-effective method of reinforcing the main messages of the intervention as well as allowing people to share their experiences and increasing their social support. The group sessions were to be led by a facilitator with the aim of providing participants with the opportunity to share problems, techniques and tips with peers. The sessions were designed around four themes: (1) barriers to maintenance, emotional eating and coping with relapse, (2) diet, (3) physical activity and (4) intervention-related tasks and activities such as self-monitoring, goal-setting and implementation intentions, social support and habit formation. Each session was structured around a series of interactive tasks, intended to provide an opportunity to share tips and increase knowledge in these key areas. Participants were to be given a summary sheet at the end of each session to take away with them and asked to complete a brief feedback sheet aimed at gauging the extent of knowledge of topics prior to sessions and what they found most useful.

A handbook was also prepared for group facilitators (GFs) (see *Appendix 2*) to guide the content of sessions. Information covered the following: a summary of the study, intervention and client group, WLM issues, key intervention components (self-monitoring, goal-setting, habits, social support, self-efficacy), group facilitation skills, overview of group sessions, individual session structure and content. Information on study-specific procedures was also included.

Motivational interviewing practitioner and group facilitator training and ongoing support

Training packages were developed for both the MIPs and GFs to cover and expand on key information detailed in the handbooks. For MIPs, specific guidance was developed regarding the challenges of delivering MI in just two sessions and over the telephone. Guidance was developed in consultation with MIPs during training. Both the MIPs and GFs were given training on issues around obesity as well as diet and physical activity recommendations. We discussed with them the challenges of WLM and weight loss and how we might best support participants in this process. The GFs were additionally given training on group facilitation skills. Training was delivered face to face over 2 days by experienced MIPs and key members of the study team involved in intervention development. Training for GFs comprised a 1-day face-to-face session and was delivered by the study team. All MIPs were required to have experience of delivering individual MI in health-care settings. All GFs were required to have experience of group facilitation. The GFs were trained to deliver sessions in a MI-consistent manner and many had experience of delivering face-to-face MI counselling; however, the group sessions were not group MI sessions.

We planned to run four peer support sessions for MIPs in which they would get together in small groups to share their experiences, listen to recordings of sessions and discuss any challenges or issues in MI delivery. These sessions were designed to give WILMA trial intervention-specific support in addition to that which the MIPs arranged as part of their own supervision. We also planned to run four workshops on specific WILMA trial intervention-related topics spaced out across the intervention delivery period, to support the MIPs and discuss difficulties.

Summary

The WILMA trial intervention comprises a number of behaviour change techniques which have been shown to be effective in other domains,[90] namely MI incorporating goal-setting and action-planning, self-monitoring and social support. The purpose of the current chapter and the intervention handbooks appended to this report is to describe the components and theoretical underpinnings of the WILMA trial intervention and provide sufficient detail about how it was operationalised to allow replication or modification. *Chapters 5* and *8* will seek to explore and describe relationships between the behaviour change techniques used and associated intervention functions as well as outcome.

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Chapter 3 Methods

As noted previously (see *Chapter 1, The trial*), this study was originally designed as an effectiveness trial of a multicomponent intervention, with the main outcome (BMI) assessed 3 years post randomisation. However, owing to significant problems in set-up and recruiting, the trial was closed early and is therefore reported as a feasibility study. We feel it is nonetheless important to detail the methods as originally designed (see *Design* through to *Cost-effectiveness analysis*), prior to describing changes made following conversion to a feasibility study. The changes to the trial design are described in detail in *Feasibility study methods*; however, the key changes were that primary outcomes were feasibility outcomes, the follow-up was shortened to 12 months and the group-based aspect of the intervention was no longer delivered because of feasibility issues.

Design

The study was a three-arm individually randomised controlled trial comprising an intensive intervention arm, a less intensive intervention arm and a control arm. The two experimental arms received a 12-month intervention based on three key elements – (1) MI, (2) self-monitoring and (3) social support – which differed only in amount of contact with the MIP. The control arm received an information pack and usual care. Follow-up was planned at 6, 12, 24 and 36 months post randomisation. The aim was to recruit 950 adults aged 18–70 years with a current or previous BMI of ≥ 30 kg/m^2 who had lost a minimum 5% body weight during the previous 12 months. Ethics approval was given by the Research Ethics Committee (REC) for Wales.

Objectives

The primary objective was to evaluate the impact of the intervention on participant BMI 3 years post randomisation. Secondary objectives were to examine the effect of the intervention on waist circumference, waist-to-hip ratio, physical activity, diet, health-related quality of life, binge eating, psychological well-being and health resource use. Additionally, we planned to examine the proportion of participants maintaining their baseline weight and mediators and moderators associated with change (see *Mediators and moderators*). A process evaluation examined intervention delivery, participant and practitioner views, dropout, adherence and retention. A cost-effectiveness evaluation was also planned.

Participants

Participant Identification Centres selection

Participants were recruited from general practitioner (GP) practices, exercise referral schemes, a commercial weight loss programme (Slimming World) and the community. The aim was to recruit participants throughout South Wales, South West England and the East Midlands. A sample of research-active GP practices across four health boards in South Wales were approached to participate (approximately 15 practices per region in Cardiff and Vale, Cwm Taf, Aneurin Bevan and Abertawe Bro Morgannwg University Health Boards), with a view to recruiting 20–25 practices. All exercise referral and Slimming World schemes within these geographical areas, as well as within the boundaries of Derby City, Derby County and Nottingham Primary Care Trusts (PCTs), were identified and approached to act as Participant Identification Centres (PICs).

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Identifying participants

Individuals were approached either face to face or via record searches from GP surgeries, exercise referral schemes and Slimming World, and provided with an information sheet and an expression of interest (EOI) form to return to the research team. Participants also self-referred from the community via poster and local media advertisements. Once an EOI form was received, two main routes for recruitment were employed.

- Route 1: 5% weight loss achieved. Individuals able to provide independent verification of weight loss (e.g. from a referring practitioner) were invited to a baseline visit at which the researcher confirmed eligibility, provided further details about the study and took consent prior to completing assessments. Current and starting weight (i.e. pre-5% loss) were recorded on the EOI form by the referring practitioner or researcher. If it was not possible to verify weight loss, participants were referred to route 2.
- Route 2: yet to achieve 5% weight loss. We contacted these individuals to either (1) attend a screening meeting with a researcher or (2) self-screen by providing documented evidence of starting weight and subsequent 5% loss (e.g. a printout from scales in their local chemist/supermarket, slimming club booklet, GP letter). At locally held screening appointments, participants were provided with a second information sheet outlining the screening procedure. They then consented to have their weight, height and contact details recorded and were asked to contact us once they had achieved the 5% target. If no contact was made after 2 months, potential participants were followed up by telephone at agreed time intervals. On reaching the 5% target, participants were invited to a baseline visit.

All participants referred by a GP/nurse, pharmacist, exercise referral professional or slimming club consultant were asked to confirm on the EOI form whether they had lost (route 1), or intended to lose (route 2), 5% body weight. Referring practitioners were asked to verify 5% weight loss for those approached during face-to-face consultations and who selected route 1. Participants approached by letter who returned an EOI form either sent verification directly to the research team or provided details as to how we could access verification, for example by contacting the referring practitioner. Participants approached by letter and unable to provide verification were recruited via route 2. Referring practitioners were asked to record how many patients were approached (face to face or via letter) as well as basic anonymised demographic data (age and gender).

Inclusion criteria

Adults aged 18–70 years with a current or previous BMI of $\geq 30\ kg/m^2$ were eligible for inclusion if they had intentionally lost at least 5% body weight (by pharmacological, lifestyle and/or behavioural methods) during the previous 12 months and this weight loss had been independently verified.

Exclusion criteria

Exclusion criteria were factors rendering potential participants unable to comply with the protocol, such as previous bariatric surgery (unless fully reversed, e.g. by removal of a gastric balloon), terminal illness, poor competence in English (i.e. inability to complete study materials), living with another study participant or, in the case of women, pregnancy (note: women who became pregnant after recruitment were not excluded, but given a leaflet on exercising safely during pregnancy).

Assessment of risk

Participants' GPs were informed of their trial participation and sent a copy of the consent form. All initial contacts with participants were in public community venues. However, some face-to-face MI sessions and/or follow-up appointments were conducted in participants' homes. Participants' GPs were asked to contact the study team to give an assessment of the level of risk posed to individuals undertaking home visits and a study-specific lone worker policy was developed.

Withdrawal and loss to follow-up

Participants were free to withdraw at any time; however, consent to use data already collected was assumed unless otherwise notified. The following measures were taken to maximise retention:

- The importance of obtaining follow-up data was emphasised to participants.
- All assessments were conducted face to face (except at 6 months which was by post) and in locations convenient to participants.
- Newsletters and birthday cards (including a change of address form) were sent to all participants.
- Participants in the control group were offered £50 in high-street vouchers or free 12-week attendance at a local commercial weight loss programme at the end of follow-up to minimise unequal dropout.
- Two reminders were sent to participants requesting that they return the postal questionnaire.
- Follow-up appointments were rearranged for those who did not attend appointments.
- Mobile telephone numbers were obtained in order to contact participants directly for follow-up.
- Participants were asked for their GP's address as an alternative contact.
- Outcomes were carefully chosen to minimise respondent burden.
- Key questionnaires were completed by telephone when possible for non-responders to ensure a minimum data set.
- Although we did not offer travelling expenses, participants were offered vouchers for attending follow-up outcome assessments (£10 per time point on completion of assessment) and completing and returning the questionnaire at 6 months (£5 not conditional on completion).

Interventions

Intensive intervention arm

Participants received six one-to-one individually tailored MI sessions, delivered by experienced MIPs. These sessions were delivered face to face, approximately fortnightly for 3 months, and lasted about 60 minutes. During the final 9 months of the intervention, participants received monthly MI telephone calls lasting approximately 20 minutes.

Less intensive intervention arm

Participants received two face-to-face tailored MI sessions 2 weeks apart and two MI-based telephone calls at 6 and 12 months only. All other aspects of intervention delivery were as described for the intensive intervention arm (see *Chapter 2*).

Peer group sessions

Participants in both the intensive and the less intensive arms had the opportunity to attend four professional-led peer group support sessions which were planned to occur monthly lasting 1.5 hours for 4 months and following on from face-to-face MI sessions (see *Chapter 2*). Allocation to group sessions was on a rolling basis; participants did not necessarily attend sessions in the same order.

Control arm

The control group were given an information pack also sent to participants in both intervention arms. The content of the information pack was based on useful resources for weight loss and healthy lifestyle, and advice on WLM. Participants in all arms were able to access usual care, for example attending a slimming club.

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Trial procedures

Adverse events and serious adverse events

No adverse effects or SAEs were expected as recommendations for physical activity were in line with current and widely publicised UK government guidelines. However, the possibility of cardiovascular/musculoskeletal events occurring related to increased physical activity was acknowledged in the protocol and the physical activity leaflet, and the main trial information sheet stated that any increase in physical activity should be gradual. Participants were advised to contact their GP if they felt unwell as a result of increased physical activity (e.g. experiencing severe breathlessness, chest pain, fainting or dizziness). Safety reporting procedures are outlined in *Appendix 3*.

Risk of harm

Motivational interviewing practitioners were asked to notify the study team directly if they became concerned that a participant had caused, or was likely to cause, significant harm to him- or herself. Provision was also made to inform participants' GPs when appropriate. MIPs were asked to inform the appropriate authorities directly if concerned that a participant had caused, or was likely to cause, harm to others.

Training

All intervention staff (MIPs and GFs) were trained as per the appropriate manual (see *Chapter 2*). All staff undertaking randomisation and data collection visits were trained in study-specific procedures.

Outcomes

Primary and secondary outcomes

Outcome measures were self-reported with the exception of height, weight and waist and hip measurements, which were measured by the researcher at each visit. Outcome assessors were given video training in measuring weight, height, waist and hip circumference to ensure consistency. Height was measured to the nearest 0.1 cm using a Seca 213 stadiometer (Seca, CA, USA). Weight was measured to the nearest 0.1 kg with calibrated Seca 877 weighing scales (Seca, CA, USA). Participants were weighed wearing a single layer of clothing (having removed shoes, belts, heavy items). Waist circumference was measured at the midpoint between the superior iliac crest and the lowest rib at the end of a normal expiration; hip circumference was measured at the maximal level of the maximal circumference around the buttocks with a Seca 201 measuring tape (Seca, CA, USA). A number of secondary outcomes were also assessed (*Table 2*): physical activity, diet, waist-to-hip ratio, health-related quality of life, health and other resource use, binge eating, psychological well-being, health-related behaviours and proportion maintaining weight loss. Maintenance of weight loss is defined as successful when the participant's weight at the end of the trial is less than or equal to their weight at baseline. All outcomes were recorded on study-specific CRFs (see *Appendix 4*). For both height and hip measurements, the average across both time points was used. If a follow-up height or hip measurement was missing, then the baseline measurement alone was used.

Mediators and moderators

We measured a number of potential mediators and moderators associated with change. Mediators included self-efficacy, social support, self-monitoring, implementation intentions, habit formation and intrinsic motivation. Moderators included demographics, weight loss history, satisfaction with weight loss, current weight loss goals, binge eating and psychological well-being.

TABLE 2 Outcome measures

Outcome	Measure	Type	Time point	Modifications	Number of items
Anthropometric measures					
BMI (weight, height)	Calibrated digital scales, stadiometer	Primary	Baseline, 12-month follow-up	N/A	–
Waist and hip circumferences	Tape	Secondary	Baseline, 12-month follow-up	N/A	–
Secondary outcomes/moderators					
Physical activity	IPAQ[105]	Secondary	Baseline, 12-month follow-up	Wording change to reflect UK population ('house and yard work' changed to 'housework and gardening')	Seven
Diet	DINE[106]	Secondary	Baseline, 12-month follow-up	(a) Wheat-type cereals now includes oat type (b) Milk now includes soya (c) Bread, added chapattis/wraps and 'other' (d) Removed 'St Ivel Gold' (e) Added fruit/vegetable items (f) Added sugar and fizzy drinks items	39
Health-related quality of life	EQ-5D[107]	Secondary	Baseline, 6- and 12-month follow-up	None	Six
Proportion maintaining weight loss	Participants whose weight at 1 year is less than or equal to their weight at baseline were defined as maintainers	Secondary	12-month follow-up	N/A	N/A
Alcohol and smoking status	AUDIT-C[108] and HSI[109]	Secondary	Baseline, 12-month follow-up	None	Three per scale
Health and other resource usage	Medication, health service contacts, other weight control resources used	Secondary	Baseline, 6- and 12-month follow-up	N/A	16
Binge eating	EDE-Q[110]	Secondary; moderator	Baseline, 12-month follow-up	None	Six
Psychological well-being	GHQ-12[111]	Secondary; moderator	Baseline, 12-month follow-up	None	12

continued

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TABLE 2 Outcome measures (*continued*)

Outcome	Measure	Type	Time point	Modifications	Number of items
Demographics	Age, gender, socioeconomic status, ethnicity, employment status	Moderators	Baseline	N/A	10
Mediators					
Social support	SSEH and SSEX[112]	Mediator	Baseline, 6- and 12-month follow-up	Eating: shortened from 10 items to three on two themes – encouragement (two items) and discouragement (one item) Exercise: shortened from 10 items to three on two themes – family and friend participation (one item) and family rewards and punishments (one reward item; one punishment)	Six
Self-efficacy	WEL[113]	Mediator	Baseline, 6- and 12-month follow-up	None	20 weight, 10 exercise
Intrinsic motivation	TSRQ diet and exercise[114]	Mediator	Baseline, 6- and 12-month follow-up	None	15 diet, 15 exercise
Automaticity/habits	Self-reported habit index (diet and exercise)[115]	Mediator	Baseline, 12-month follow-up	None	12 diet, 12 exercise
Self-monitoring/ regulation	SREG[116]	Mediator	Baseline, 12-month follow-up	Subset of eight questions comprising positive and negative statements selected from full SREG	Eight
Implementation intentions	From MI records and interviews	Mediator	All sessions	N/A	–

AUDIT-C, Alcohol Use Disorders Identification Test; DINE, Dietary Instrument for Nutrition Education; EDE-Q, Eating Disorder Examination Questionnaire; EQ-5D, European Quality of Life-5 Dimensions; GHQ-12, General Health Questionnaire – 12 items; HSI, Heaviness of Smoking Index; IPAQ, International Physical Activity Questionnaire; N/A, not applicable; SREG, Short Self-Regulation Questionnaire; SSEH, Social Support for Eating Habits; SSEX, Social Support for Exercise; TSRQ, Treatment Self-Regulation Questionnaire; WEL, Weight Efficacy Life-Style Questionnaire.

Statistical methods

Sample size

To give 90% power at the 5% significance level to detect a difference in mean BMI of 1.7 units (SD 5.5 units) between the primary contrast of the intensive intervention and control, 221 participants per group would be required. This assumes a baseline mean BMI of 32.5 kg/m^2 and a mean of 34.2 kg/m^2 prior to 5% weight loss. Allowing for 30% attrition,[20,27,55] a total of 950 participants would be required.

Randomisation

Allocation to groups was by remote telephone randomisation, stratified by region and minimised by age, gender, ethnicity, source of recruitment (GP, exercise referral, slimming club, community), percentage weight loss and current BMI. The service was provided by the Bristol Randomised Trials Collaboration randomisation service. This used a bespoke system written in the programming language C++.

Blinding

It was not possible to blind participants to arm allocation given the complex procedural and interactive nature of the intervention. Outcome assessors were also involved in recruitment and randomisation and were therefore not blind to allocation.

Main analysis

The planned main analysis was intention to treat comparing the three groups on average BMI using a three-level linear regression model to account for clustering within MIP and groups. The main analysis was intended to examine the longest end point. A secondary analysis was planned to examine the three groups using the interim time point as the end point, with baseline BMI and previous weight loss as covariates. Both intervention groups were to be compared with the control (reduced to a one-level model if no evidence of clustering is observed). Secondary outcomes were to be analysed using linear or logistic regression or Poisson as appropriate. The analyses of BMI and weight were repeated including the self-reported weights as a sensitivity analysis. There is evidence that single-item measures are more likely to be biased than multiquestion measures.[117] We do not feel that the results for the other questionnaires are likely to be biased.

Exploratory analyses were proposed to consider the impact of demographic factors, original weight loss method and theoretical moderators on the intervention effect, using interaction terms included in main analysis models. Exploratory longitudinal analyses were proposed to explore the effect of theoretical mediators on subsequent outcomes and interactions with intervention groups. These were to be conducted in a similar manner to the primary analyses, with outcomes predicted using a hierarchical model and controlling for baseline randomisation variables and in accordance with the 1986 Baron and Kenny guidelines.[118] This analysis was used to check the postulated logic model produced by the WILMA trial team. Individuals who failed to respond would be compared with those who completed follow-up to identify potential biases. The planned sensitivity analysis assumed that those non-responders would return to weight levels prior to weight loss (i.e. not baseline, but previous BMI). A last observation carried forward assumption would not be conservative for WLM and so was not used. Self-report weight was added to objectively assessed weight to account for some loss to follow-up. A complier-average causal effect (CACE) analysis was proposed, using multilevel mixture analysis[119] to focus on estimating intervention effects in the presence of non-compliance.

Subgroup and interim analysis

Primary subgroup analyses were proposed to investigate associations between WLM and age, gender, method of weight loss and weight at entry. Exploratory subgroup analyses were planned to investigate associations between WLM and smokers, binge eaters, weight-affecting medications and ethnicity.

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Process evaluation

We conducted a process evaluation, the aims of which were to:

- assess delivery of the intervention to ensure it was provided in accordance with the protocol and delivered consistently
- establish the level of participant adherence to the intervention
- explore participants' views of, and satisfaction with, the intervention
- explore MIPs' and GFs' experiences of delivering the intervention
- test the logic model.

Intervention delivery

Motivational interviewing practitioners were asked to audio-record as many sessions (face to face and telephone) as possible, with a view to collecting a minimum sample of six sessions per MIP over the course of the study. A random sample of recordings from face-to-face sessions was assessed using the motivational interviewing treatment integrity (MITI) coding scale.[120] A stratified sample included sessions delivered in both intervention arms and by all MIPs. Skill in MI delivery was assessed prior to study entry (via audio-recorded mock consultations with trained actors). In order to be recruited as a practitioner, individuals were required to reach the MITI proficiency threshold (see *Chapter 6*). We planned to observe group sessions to assess fidelity of intervention delivery.

Participant adherence

Data on intervention delivery and exposure to the intervention were examined. Overall attendance at intervention sessions and success of telephone contact were monitored (number of contact attempts and length of calls was recorded). MI CRFs from face-to-face and telephone sessions were examined for evidence of self-regulation, goal-setting and implementation intentions and analysed descriptively. Participant self-regulation was examined by the frequency of self-weighing records/reports of self-weighing.

Participants' views of the intervention

Semistructured telephone interviews were carried out with participants in all arms, during the intervention (at approximately 6 months) and following the end of the intervention period (see *Chapter 8*). Participants were purposively sampled across key factors including trial arm, gender, age, recruitment route and attendance levels. In addition to assessing general views around intervention delivery, views on efficacy, barriers and facilitators, we also examined potential mediators not examined elsewhere such as the impact of life events on adherence; environmental influences; levels and importance of social support from family and friends as well as the professional support provided as part of the intervention; impact on their wider social network; WLM challenges; intrinsic and extrinsic motivations for WLM; health value; body image; and strategies, coping mechanisms and responses to relapses (see *Appendix 5*). In addition, we planned to interview a small sample of participants who dropped out of the intervention to establish their reasons for discontinuing. Interviews continued until themes were saturated. Interviews were audio-recorded, transcribed and checked by the researcher.

Intervention staff's views of the intervention

All MIPs, apart from one who took part in an interview, contributed to two focus groups designed to enable us to elicit their views of the intervention, the perceived challenges or barriers in implementing it and how they thought the intervention and training could be improved. Separate focus groups with GFs were also planned. The MIP focus groups and interview took place following recruitment closure. At this point the majority of MIPs had completed their face-to-face sessions and were mid-way through their telephone sessions. A focus group guide was developed to explore the MIPs' experiences. This comprised 18 items and spanned four main topics (see *Appendix 6*). Up to three members of the research team were present during the focus groups, one of whom facilitated the session, and the interview was conducted by one member of the research team. The focus groups lasted around 2 hours, while the interview lasted 1 hour.

Qualitative analysis

All interviews and focus groups were audio-recorded and transcribed for analysis. Transcripts were checked and uploaded into QSR International NVivo10 software version 10 (QSR International, VIC, Australia) and analysed using thematic analysis. Thematic analysis is a systematic approach in which the data are initially coded and then collated into themes.[121] Themes are then analysed in more detail to map out the overall data and examine relationships between them. Finally, themes are refined to produce an overall story of participants' views and experiences.[121,122] As outlined by Braun and Clark[121] thematic analysis consists of five defining phases: (1) familiarisation, (2) initial coding, (3) creation of themes, (4) reviewing themes and (5) defining and naming themes. Our analysis followed each of these phases and is described in relation to these below. Data collection and analysis of interview data were conducted simultaneously and the analyses informed data collection in terms of changes to the interview schedule, for example adding new questions to probe particular areas of interest. Data collection continued until data saturation was reached. Analysis of the focus group data was conducted after data collection, but followed the same process.

Phase 1: familiarisation

During the familiarisation phase, a coding scheme was devised by the team to inform the coding procedures. Separate schemes were developed for the participant interview and MIP focus group (plus one interview) analysis, as they had differing aims and different questions were asked accordingly. Therefore, it was not appropriate to analyse all data across a common coding scheme. The coding schemes were developed by initially reading and rereading a few of the early transcripts. Codes were mapped out by three researchers (for the participant analysis: SS, YM and CS; for the MIP analysis: SS, YM and LC) during two face-to-face meetings (following independent coding of two interviews/focus groups) and these initial codes were pulled together into a coding scheme. Following development of the initial coding scheme, it was then applied to other interviews/focus groups independently by two coders. Each of the schemes was then further refined as new codes emerged from the data during the initial coding procedure.

Phase 2: initial coding

Following the coding scheme development, the initial coding of participant interviews was completed by CS and YM, while the focus group coding was completed by YM and LC. Transcripts were closely examined and indexed according to the coding scheme. During the coding phase, the coders had regular discussions concerning any new codes identified and sought common agreement on any further amendments needed to the scheme. This ensured consistency between coders. An analysis log was kept to record coders' discussions and track any changes made to the coding scheme as well as to record further thoughts and developments of the analysis process. A total of 10% of the interview transcripts were double coded to ensure reliability of the coding scheme and any discrepancies discussed and resolved. Both MIP focus groups and interviews were read and reread by YM and LC in preparation for the scheme development and were therefore not double coded.

Phase 3: searching for themes

Once all transcripts were coded, codes were examined in detail and broken down further into subcodes where appropriate. Moreover, some extracts were recoded where necessary. This phase was both data driven (i.e. bottom up) and theory driven as we sought to answer specific process evaluation questions and look at mediators not measured elsewhere. Commonly expressed themes, as well as unusual cases, were identified. Relationships between codes were explored by carrying out queries to identify text common to two (or more) related codes. This analysis led to the development of overarching themes.

Phase 4: reviewing themes

The themes developed in the previous phase were reviewed by the coders, who remained in close contact to further discuss and develop their thoughts. During this phase, coders referred to the key questions identified in the process evaluation model to support the final analysis. The initial codes were examined for any instances that were inconsistent with the emerging themes. The themes were further examined across groups (arm/gender/age) to explore their differences and similarities. A thematic map was developed for both the participant interview and practitioner focus group analysis to further inform this phase.

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Phase 5: defining and naming themes

During the final phase, coders examined themes in detail ensuring they accurately represented the data and captured the overall story. Themes were mapped out in order to explore broader links and relationships within the overall data and analysis. As themes were explored, a detailed narrative was written for each, which provided the structure for the final reporting of results. The qualitative findings then fed into the overall process evaluation.

Cost-effectiveness analysis

The original intention was to undertake (1) a within-trial cost–utility analysis assessing between-group differences over 3 years in total costs against differences in quality-adjusted life-years (QALYs) [derived from European Quality of Life-5 Dimensions (EQ-5D) quality-of-life data], (2) a lifetime cost–utility analysis using an economic Markov model and (3) a within-trial cost-effectiveness analysis (CEA) assessing between-group differences in total costs against differences in BMI at 3 years. All analyses were from a NHS perspective. In pursuit of this, all direct intervention costs were recorded prospectively in relevant units and valued using standard methods.[21] These included all resources used in intervention delivery (staff time, staff travel, materials, venues). All resources used in training professionals in MI skills were similarly prospectively recorded and valued. As training is a one-off investment producing a flow of benefits over time, training costs would be amortised similarly to equipment expenditures and expressed on an equivalent annual cost basis. Indirect costs would include differential use of health service resources from recruitment to end of follow-up.

Health service resource use in primary and secondary care and the community was collected for all participants at baseline and follow-up time points. Resource-use data collected at baseline, that is relating to the period prior to recruitment, would not be included in total costs but used as a covariate if shown to be different between groups. Resource-use questions related to all health service contacts and prescription medicines dispensed in the previous 3 months. The 12-month follow-up data cover resource use over a period of 6 months, based on two CRFs delivered at 6- and 12-month time points. Health service resource use would be valued using standard sources.[123] All costs relating to non-NHS weight loss/maintenance activities such as use of gyms were recorded. It was important to monitor these costs as the intervention may have substituted for some activities but these would be reported separately and not included in the cost-effectiveness ratios. Baseline BMI, age and gender might have resource implications, so all resource-use variables and costs at 12 months were to be analysed controlling for these patient-level characteristics. The analysis also involved a regression-based adjustment for any potential baseline difference in resource use and costs.[124] Analyses were planned to assess mean differential costs and resource use using tests for normality where appropriate; however, as many resource-use variables and costs are unlikely to be normally distributed, a non-parametric bootstrap method was used,[125] first performing the adjustment procedure and then bootstrapping with the adjusted data. All costs are in 2012 prices.

The effectiveness measure for the cost–utility analyses was the EQ-5D[107] quality-of-life instrument, administered at baseline and all follow-up time points. EQ-5D scores allow estimation of QALYs. It was planned to assess cost-effectiveness based on between-group differences in costs and QALYs, reported in the form of incremental cost–utility ratios (incremental cost/incremental QALY). 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. Other planned analyses included a series of one-way sensitivity analyses to assess how sensitive results were to changes in assumptions used. A probabilistic sensitivity analysis would be used to assess uncertainty in the cost–utility ratio and to generate a cost-effectiveness acceptability curve showing the probability that the intervention is being cost-effective at a range of willingness-to-pay (WTP) thresholds.

It was intended to assess long-term cost-effectiveness using a decision-analytic Markov model (given uncertainty in long-term weight patterns among obese individuals).[126] The model would comprise seven health states: 'normal', three states reflecting increased cardiovascular disease risk [cardiovascular disease (CVD); hypertension, type 2 diabetes mellitus, hypercholesterolaemia], two states reflecting CVD risk (coronary heart disease, stroke) and a 'death' state. It was also our intention to model lifetime health-care costs and health effects for a hypothetical cohort of 10,000 adults in the 'normal' state receiving either of the interventions or standard care. The base-case assumption was that the effect of the interventions on CVD risk factors and weight loss is maintained for a period of up to 6 years, after which participants regain weight linearly for a period of 4 years, that is in 10 years' time weight will revert to the initial weight. This assumption is in line with that used in economic evaluations of weight loss interventions[127,128] and is based on observations from clinical trials.[19]

We calculated mean BMI by age and gender from the trial data but, in order to assess the effect of different levels of weight loss, we planned to define two cohorts reflecting lighter and heavier trial participants. A variety of secondary sources for parameter estimates were to be used in the model. We planned to use a risk equation from the Framingham cohort study[129] to estimate the risk of developing the three CVDs from 'normal', 'hypertension', 'diabetes' and 'hypercholesterolaemia' health states. We intended to use trial data on utility measures and costs of interventions in the model and to obtain costs of obesity-related complications in the UK from the published literature.[130] As a generic measure, it was considered that EQ-5D may not be sufficiently sensitive to capture differences in health-related quality of life in these essentially healthy participants. A within-trial cost-effectiveness study was therefore also planned with BMI at 3 years as the effectiveness measure.

Feasibility study methods

In September 2012, the decision was taken to close the trial to recruitment owing to the difficulties described in detail in *Chapter 4*. At this point we were 15 months into the trial and we had recruited 170 individuals. A closedown plan was devised to consider ethical issues and to maximise the scientific value of the trial. It was agreed with the funder that recruitment would cease immediately, but that included participants would still receive the intervention that they were randomised to and be followed up to 1 year. This meant that the whole study would finish in January 2014 and would now be considered a feasibility study. The methods for the feasibility study are similar to those described for the original trial with some key alterations. These are summarised in *Table 3* followed by more detail on key components.

TABLE 3 Summary of design changes

Study component	Changes to design
Sample size, recruitment and retention	Sample size reduced from 950 (90% power at 5% significance level: mean BMI difference of 1.7 kg/m^2) to 166[a] (80% power at 5% significance level: mean BMI difference of 3.5 kg/m^2)
	Incentives offered to participants for completing assessments increased from £10 to £20. Incentives (£10 vouchers) also offered to interview participants
Length of follow-up	Reduced from 3 years to 1 year post randomisation
Intervention	Group sessions discontinued
Analysis of primary and secondary outcomes	Planned subgroup analyses (age, amount of weight lost, method of weight loss, satisfaction with weight loss) not undertaken; some exploratory analyses carried out (gender, binge eating, source of recruitment), but others (smoking, weight-affecting medication) dropped. Implementation intentions not included as a mediator. CACE estimated using two-stage least squares instrumental variable regression and not multilevel mixture analysis
Process evaluation	Group component of intervention dropped therefore GF focus group not run. Participants who withdrew from the intervention not willing to be interviewed
Economic evaluation	Estimation of long-term cost–utility (economic Markov modelling) not undertaken

a Actual number recruited minus exclusions.

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Objectives

The main objectives were to assess the feasibility, acceptability, compliance and delivery of a 12-month multicomponent intervention, as well as recruitment and retention. To give an indication of effect sizes for a larger trial, we evaluated the impact of the intensive or less intensive intervention on participants' BMI (primary effectiveness outcome) at 12 months from randomisation.

Design

This was a feasibility study of a three-arm individually randomised controlled trial. The population recruited was as described in *Participants*. As described in the *Scientific summary*, the intervention changed as we stopped delivering the group element. Outcome measures used were as described in *Table 2* with the exceptions noted in *Table 3*. After completing baseline assessments, participants were followed up at 6 months, during the intervention, by post and at the end of the intervention (approximately 12 months post randomisation, with a 3-month window to allow for any delay in receiving the intervention). A 1-year follow-up was conducted face to face in most cases, although a few were conducted by telephone with self-reported weight.

Sample size

The original sample size of 950 was based on detecting an effect size of 0.309 with 90% power at a significance level of 5%. Given that the study was now a feasibility study, the sample size was not derived statistically but based on actual recruitment at the time of closure ($n = 166$). This allows us to estimate a percentage of 50 (the percentage with the greatest associated variability) to within 7.6 percentage points either side for the whole sample, or to within 15.9 percentage points for percentages within each study arm ($n = 38$). These are the achievable precisions for estimation of the retention rate (or any other proportion). Although not primarily concerned with effectiveness, we still feel that it is informative to present power to detect differences. With our current sample size of 166 (four participants from the original 170 recruited were ineligible and randomised in error and subsequently withdrawn) and assuming 30% attrition, we have 39 in each of the three arms. We are therefore able to detect a difference in BMI of 3.537 kg/m^2 at the 5% significance level with 80% power between any two arms (primary comparison between the control and intensive arms). This is a difference of about 9.75 kg between groups based on average height.

Analysis of primary and secondary outcomes

The main feasibility outcome was the proportion of participants remaining in the study for a year. A secondary feasibility outcome was the proportion of participants who adhered to the intervention in each treatment arm. Comparisons were made between those who completed the study and those who dropped out, to highlight any biases. The main effectiveness analysis was intention to treat and complete case comparing the intensive intervention arm with the control on average BMI using a three-level linear regression model to account for clustering within therapists and groups (reduced to a one-level model where there is no evidence of clustering). The main analysis examined the latest end point (12 months), controlling for individual patient characteristics (baseline BMI, age, gender, ethnicity, source of recruitment, current BMI and percentage weight loss). Both intervention groups were compared with the control. We completed augmented analyses for BMI and weight, for which self-reported follow-up weights were included with verified follow-up weights. The statistical analysis plan specified that if the primary outcome was missing for more than 10% of cases then multiple imputation would be used.

Secondary outcomes included waist circumference, waist-to-hip ratio, self-reported physical activity, proportion maintaining weight loss (defined as successful when the participant's weight at the end of the trial is less than or equal to his or her weight at baseline), self-reported dietary intake, health-related quality of life, health service and weight control resource use, binge eating, alcohol consumption, smoking status, psychological well-being, duration of participation and dropout from the intervention. All analyses controlled for individual patient characteristics. Binary outcomes were analysed using hierarchical logistic

regression and continuous outcomes (appropriately transformed if necessary). Mediation analyses were conducted on self-efficacy, social support, intrinsic motivation, habits and self-monitoring as measured at 6 months using a hierarchical model and controlling for baseline randomisation variables in accordance with Baron and Kenny guidelines.[118] Consolidated Standards of Reporting Trials – Patient Reported Outcomes guidelines are referenced for reporting patient-reported outcomes.[131] Exploratory subgroup analyses investigated WLM in binge eaters, gender and source of recruitment.

Sensitivity analyses

A sensitivity analysis was conducted assuming that non-responders returned to weight levels prior to weight loss (i.e. not baseline but previous BMI). A CACE was estimated using two-stage least squares intrumental variables regression.[119] This modelling focuses on estimating the intervention effects in the presence of non-compliance, but also incorporates adjustments for loss to follow-up. Compliance was defined as follows: for the intensive arm, attending five of the six face-to-face MI sessions; for the less intensive arm, attending both face-to-face MI sessions. Potential differences on basic demographics and the primary outcome between full responders and those providing a minimum data set were described and all models were tested for adequate fit using appropriate diagnostics.

Process evaluation methods

Minor changes to the process evaluation are listed in *Table 3*.

Economic evaluation

There are limitations to undertaking economic evaluations alongside a feasibility study. In particular, the change in design meant (1) the within-trial analyses would only reflect short-term (12-month) differences in costs and effects, (2) the study was less likely to have sufficient power to detect statistically significant differences in costs or effects and (3) the absence of data on longer-term WLM or costs made estimation of lifetime cost–utility through economic modelling unfeasible. Although it would not be possible to establish definitive cost–utility/effectiveness results, we nevertheless applied as far as possible the methods described in *Cost-effectiveness analysis* to estimate parameters and unknowns to inform future research. Specifically, (1) methods to determine costs of training and intervention delivery were unchanged; (2) methods for collecting resource use and EQ-5D data were unchanged apart from the final data collection being at 12 not 36 months; and (3) the planned estimation of long-term cost–utility was dropped.

Patient and public involvement

Kirby[132] proposes that service user involvement can occur at three different levels: consultation, collaboration and user-controlled research. In the WILMA trial, user representation was at the level of collaboration. We sought to address patient and public involvement at all stages of the WILMA trial, including the design of the study and funding application as well as the subsequent running of the trial. In the research design stage we recruited a participant representative (CB) to help us to design the study and she subsequently became a co-applicant on the grant. In particular, she contributed to three things at the design stage: (1) discussions about outcome measures and follow-up, (2) recruiting potential participants and (3) intervention design. At this stage we also recruited a lay representative to the Trial Steering Committee, who helped oversee the trial and particularly advised and commented on the study materials and recruitment.

Once the study was up and running, CB attended monthly trial management group meetings and contributed to the discussions and decisions made in relation to managing the trial. In particular, she helped the team focus on the key measures that we needed, as initially the outcome assessment was overly long. She helped pilot the questionnaire with other lay people and commented on clarity, ordering of questionnaires in the booklet, etc. She also helped design the questionnaire pack and the patient

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information to be appealing to potential participants. She helped to ensure that the patient information was written in a clear, concise and participant-friendly way. All data collection materials were piloted with members of the public with regards acceptability and feasibility prior to being finalised. When the study ran into problems with recruitment, she helped develop the detailed recruitment strategy and, along with other team members, actually went out to try and facilitate recruitment in the community. Now that the trial is over she has been advising on possible future approaches to dissemination, for example the study website, newsletters, as well as other means and she is helping us to develop a strategy for dissemination to participants.

Chapter 4 Implementation challenges and implications for future trials

The purpose of this chapter is to describe the main challenges experienced by the WILMA trial team, in order to highlight the practical issues that could potentially impact on the successful set-up and delivery of similar pragmatic trials of complex public health interventions delivered in community (i.e. non-NHS) settings. Challenges relating to governance, recruitment and intervention delivery are summarised below.

Governance

Defining and accessing NHS costs for public health interventions

We experienced a number of issues relating to the definition of NHS costs for the WILMA trial intervention, given that there is currently no standard treatment for obesity. A great deal of regional variation in interpretation of attribution and liability of excess treatment costs (ETCs) was apparent at the time, and for this reason we experienced significant difficulties and delays in securing ETCs in England in excess of 12 months, despite the involvement of the Department of Health and the relevant Strategic Health Authorities. It is acknowledged that significant changes to guidance on attribution of NHS costs have since been implemented, as have changes to the mechanism of distribution for ETCs in England. However, there remain a number of grey areas in attribution of costs for interventions delivered by non-NHS staff, that is community public health interventions, even if it were feasible for these interventions to be delivered or commissioned by the NHS if proven to be effective. In Wales, there is a centralised budget and decision-making for primary care and public health studies, and approvals regarding ETCs were gained at the same times as research governance in all regions of Wales with no delays.

Participant Identification Centres compared with research sites

When the WILMA trial was set up, PICs were a relatively new concept in research governance and, as such, there was a degree of regional variation in terms of what constituted appropriate PIC responsibilities. Given the large number of WILMA trial sites, including non-NHS settings such as slimming clubs and exercise referral schemes, we felt it most appropriate to set up participating GP surgeries as PICs rather than full sites. In addition, general practice staff were not actively involved in any aspect of the study, other than helping to identify potential participants. However, in some English regions this model was not acceptable to participating Comprehensive Local Research Networks (CLRNs), because the costs of doing so would not be reimbursed as part of the activity-based funding model, and so a research site model was adopted for GP surgeries in England. However, we experienced significant delays in reaching this agreement, which, in addition to difficulties accessing ETCs, meant that, in England, recruitment in one region got under way only approximately 4 months prior to closing recruitment completely and not at all in three other PCTs.

Differences in infrastructure support between devolved nations at the time – specifically, the capacity of research network staff to recruit participants and undertake assessments – also had an impact on feasibility of delivery and resulted in different models of working in England and Wales and substantially different timeframes. Centralisation of systems in Wales at the time facilitated faster recruitment and set-up of PICs. However, differences in the implementation of infrastructure support between devolved nations still exist and may still present practical challenges that require a flexible approach to set-up for research teams recruiting in more than one of the devolved nations. It is in the interests of research teams looking to conduct similar trials to ensure that they are fully aware of these different approaches and systems and the impact that these are likely to have on feasibility at the study design stage.

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Recruitment

Participant recruitment was open for 15 months from July 2011 to September 2012 (although in England the study was open for only 4 months of this time). By the end of the trial, we had received 1284 EOI forms from individuals who had heard about the study from various sources – the main ones being via an approach from their GP, Slimming World consultant or exercise referral practitioner. We gave each of these main sources 'approach logs' to keep track of and report the number of approaches made to individuals. However, these logs were poorly completed and very few were returned. As a result, data regarding sample representativeness are not presented in this report.

The EOI forms tended to capture details only of those who had received information about the study through a PIC site. Those who contacted the team to request more information in response to adverts/posters were asked how they heard about the WILMA trial, but gathering this information was less formalised and not always consistently collected. As described previously (see *Chapter 3*), there were two routes for entry into the study – it was always anticipated that the majority of participants would enter through route 1 with available evidence of their 5% weight loss from their GP, exercise referral or Slimming World record.

Of the 1284 who expressed an interest in the study, only 241 were initially eligible via route 1, that is were able to provide verification of a minimum 5% weight loss. For the 170 eventually recruited, 151 (88.8%) met the inclusion criterion for verifiable weight loss at the EOI stage and 19 (11.2%) were initially eligible via route 2 and subsequently met the 5% weight loss criterion. For all recruited participants, evidence mostly came in the form of slimming club record cards. It became apparent that we were attracting significantly more individuals via route 2, which was creating a substantial delay in progression through to being fully recruited into the study. The majority of route 2 individuals were either not able to lose 5% of their weight or did not maintain interest or contact with the study. We decided to revise our recruitment strategy and look at different ways of targeting those who were more likely to fall into the route 1 category.

We drafted a recruitment strategy implementation plan (*Table 4*) to describe and prioritise ways in which our current recruitment could be improved, expanded and monitored as well as who was to take the lead in implementing each activity. The plan was laid out according to priority and timescale, ease of implementation with the resources available and impact based on current evidence.[133,134]

TABLE 4 Summary of the recruitment strategy implementation plan

Task	Priority	Actions taken
Section 1: PICs		
Expansion of recruitment territory	High	Expand to recruit GP and exercise referral PICs in Cwm Taf. Two GPs and two exercise referral practitioners were recruited
Incentives	High	For exercise referral staff, a £20 high-street voucher for the best recruiter every second month. For Slimming World consultants, a £20 voucher for every five participants recruited per month. There was also a £20 voucher for the best Slimming World recruiter each month (note that GP PICs were reimbursed via NHS support costs)
Presenting to Slimming World	High	Attend Slimming World groups to present study to clients, 47 meetings attended. Attend Slimming World regional consultants meetings, 11 meetings attended
Increased Slimming World HQ involvement	High	Advert placed in Slimming World magazine and e-mail from Head of Nutrition Research at Slimming World to consultants encouraging involvement
Increased contact with PICs	High	Monthly telephone contact with all PICs ($n = 75$), PIC newsletters every second month, repeat training sessions
Engage with slimming club on referral from GP practices in South West England	Medium	Not implemented as study closed to recruitment before opening in South West England
Monitoring PICs	Medium	Monitor poor recruiters for support. Decided against closing them

TABLE 4 Summary of the recruitment strategy implementation plan (*continued*)

Task	Priority	Actions taken
Section 2: advertising		
Study website	High	Website live
Poster displays	High	Posters in non-PIC GP surgeries, local gyms and classes, hospital corridors, community centres
Local pharmacies	High	Posters displayed in pharmacies in Tesco ($n = 26$) and Sainsbury's ($n = 27$) in South Wales and local independent pharmacies
Large local employers and universities	High	21 companies and six universities advertised study via intranet
Press releases	Medium	Local newspapers printed two articles. Item aired on local radio
Social media: Facebook® (CA, USA; www.facebook.com) and Twitter® (CA, USA; www.twitter.com)	Medium/ low	Accounts live and linked to Slimming World pages and other relevant sites
Section 3: other		
Alter emphasis to target route 1	High	Altered posters and recruitment drive to focus on route 1 only
Close monitoring of recruitment rates and monthly recruitment targets	High	Figures examined weekly
Research network support	High	Area-specific strategies given to network staff to implement locally. CLRN nurse in Trent trained and engaged with CLRN in South West England
Establish links with other health professionals	High to medium	Trial Management Group members presented at dietetics meetings as well as to gym managers and fitness club managers. Specialist weight management clinic advertising study
Collaborate with other weight loss studies	Medium	Unsuccessful owing to lack of studies
Maximise use of flagging systems on practice databases	Medium	Unsuccessful owing to complexities of various practice systems
Manage screening process and follow-up of route 2 participants	Medium	Contact maintained with route 2 participants but emphasis that they must contact the study team with evidence of their weight loss
Attend and present at local health events	Low	Two events attended but little impact on recruitment
Section 4: actions not pursued		
Use pharmacies as PICs	High	Not pursued owing to resource implications involved in training sites
Complete database searches for PICs	High	Not pursued owing to lack of REC approval
Visit PICs to problem solve	Low	Not pursued owing to lack of resource and likely low impact on recruitment rates
Link in with relevant patient groups	Low	Not pursued as study closed to recruitment
Target discussion forums/threads on the internet	Low	Not pursued as study closed to recruitment
Create links with other slimming groups	Low	Not pursued owing to Slimming World involvement
Placing adverts	Medium	Attempted to advertise on relevant internet sites but they were not appropriate/willing. Paper, TV and radio – cost proved too expensive
Identify a local celebrity to champion the study	Medium	Attempted but unsuccessful

HQ, head quarters; TV, television.

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The first section of the plan focused on how we could maximise the impact/success of our PIC sites in reaching potential participants. High-priority strategies included increasing the geographical area of recruitment. We gained research governance approval from another health board in South Wales, and enlisted a further two GP practices and two exercise referral practitioners. Based on what we had learned from the way in which existing PICs approached patients, we trained staff at these new sites to approach only those who fulfilled the criteria for recruitment via route 1, thus not adding to the already substantial 'pool' of individuals potentially entering the study via route 2.

We examined how best to maximise Slimming World's involvement and engagement in the study as its clients would be most likely to have lost weight and be able to provide evidence. An advert placed in both its magazine and on its website proved very successful. A large number of enquiries, and subsequently participants, heard of the study in this way. In addition, a senior member of the central Slimming World team e-mailed consultants directly, inviting them to encourage their clients to read about the study. The study team were also permitted access to various Slimming World meetings and classes. While attending classes and speaking directly to clients was useful, there were also a number of barriers, including logistical issues such as time constraints. It was found to be more effective to attend the local consultants' meetings where between 5 and 10 consultants were present and we could speak directly about the study to a number of those who lead the classes (often several classes).

Potential participants were more likely to respond to the consultants' backing for the study than an unfamiliar member of the study team attempting to recruit them. Advertising was also an area that was to prove effective. The use of posters and e-mail adverts was a low-cost, time-efficient and potentially far-reaching option. Our posters gave brief information about the study including eligibility criteria and contact details. They were placed in a number of local GP practices as well as pharmacies – including those based in large supermarket chains in recruiting areas. Along with adverts circulated to employees of large companies and universities in South Wales, this relatively simple approach to disseminating information to a large audience proved moderately effective.

Social media were also utilised to increase the visibility of the study; however, it became apparent that this method would not lend itself to recruitment as we had hoped. Those linking in with the study via Facebook and Twitter tended to be other weight loss organisations or health professionals (HPs) rather than potential participants.

Having worked through various alternative strategies it was apparent that linking in with a weight loss intervention or programme was a highly effective and resource-efficient way of recruiting eligible individuals. Although we did recruit significant numbers of participants via the GP route, this was significantly more resource intensive in terms of staff time and cost (note that this avenue of recruitment was also open for significantly longer). Having the backing of the Slimming World programme and being invited to approach its clients and consultants was the most direct way of targeting potentially interested and eligible individuals. Those attending exercise referral schemes were not necessarily interested in weight loss, and engagement from exercise referral staff was generally quite low. GP practices did not have the capacity to effectively screen those who might be eligible, or did not record sufficient information for verification purposes (e.g. if weight was recorded only once in a 12-month period no information about weight loss could be obtained). Practices could reach a large number of individuals but unrefined database search tools and/or a lack of information to assess eligibility meant that the majority fell into the route 2 category. GPs also made few opportunistic (i.e. face-to-face) approaches, possibly owing to lack of time during consultations and a need to focus on more acute issues requiring immediate management.

A key learning point from our experience is that careful consideration needs to be given to the viability of entry criteria at the outset. Furthermore, early piloting of the recruitment process and proposed routes (including a formal review process and associated timelines) could have identified problems earlier and ensured that resources were appropriately directed. Shifting our emphasis and resources to those who were eligible via route 1, for example, proved the more effective strategy. Mass advertising allowed us to do this without incurring significant costs or increasing workload.

Intervention delivery

The individual components of the intervention (face-to-face and telephone MI) proved feasible to deliver and compliance rates were high, particularly for the face-to-face element (see *Chapter 6*). However, the group sessions proved extremely challenging to deliver for logistical reasons, predominantly relating to the low recruitment, creating a challenge with establishing groups and poor uptake by recruited participants. For this reason, it was decided to remove the group component from the intervention.

Summary

The current feasibility trial highlights a number of issues important to consider at the design stage of pragmatic trials of any community-based complex intervention. First, governance issues relating to NHS (in particular excess treatment) costs and the PIC model could have a significant impact on feasibility of delivery, particularly where no standard treatment currently exists, and/or when interventions are delivered by non-NHS staff in a trial setting, even if they would ultimately be delivered or commissioned by the NHS if effective and rolled out at a later date. Second, differences in accessibility and delivery of infrastructure support between devolved nations and regional variation in England need careful consideration as early as possible, in terms of their potential impact on feasibility of recruitment and associated timelines.

There is convincing evidence that social support is an important component of successful weight loss and maintenance interventions.[21,22,38,69,76,77]

However, we were not able to assess the impact of group-based peer support in this instance for the reasons described in *Chapter 3, Feasibility study methods*. Delivery of locally led group sessions on a rolling basis does not appear to be feasible, particularly when recruitment is lower than expected. Other, less resource-intensive and logistically challenging, approaches to providing social support that do not depend on a minimum recruitment rate should therefore be considered in future WLM studies.

For similar trials for which written verification of weight loss is a requirement for inclusion, recruitment routes linked to current or recent weight loss programmes (slimming clubs or concurrent weight loss trials) are likely to be most effective. Therefore, strategies designed to engage or maximise the involvement of such schemes as research partners are worthy of investment, particularly given that very few participants otherwise eligible for the WILMA trial who wanted to lose at least 5% body weight appeared able to do so within a 12-month period. We also identified a number of targeted advertising strategies with minimal resource implications that proved effective in this setting.

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Chapter 5 Main results

Baseline

In total, 1284 EOI forms were received. These are summarised in a flow diagram (*Figure 2*). The greatest number of EOIs were from primary care (71.7%); however, these were least likely to translate into eligible recruits, with only 7% ($n = 66$) being randomised into the trial. The most common reason for ineligibility in this population was not having achieved the required 5% weight loss (or not having evidence of having achieved it). The most successful recruitment route in terms of EOIs that were translated into actual recruits was Slimming World. Clear and consistent recording of weight and, therefore, evidence of weight loss was key to this. Such clear recording should have also been available from the exercise on referral (EOR) scheme; however, there were logistical issues which made this route less successful at translating EOIs into recruits (see *Chapter 4*).

A total of 170 people were fully recruited and randomised; however, four were subsequently shown to have been inappropriate recruits and were therefore excluded. These were recruited early in the study before recruiter retraining was undertaken. The characteristics of those randomised to the three arms were broadly comparable and are given in *Table 5*. The majority of participants were over 30 years of age, non-smokers, female and white with an average BMI of just under 35 kg/m^2.

Feasibility outcomes

The primary feasibility outcomes of the trial relate to recruitment, retention and adherence (see *Chapter 3*).

Recruitment

A total of 170 participants were recruited to the trial over a period of 15 months. Four participants were ineligible and randomised in error and were subsequently withdrawn. These participants were excluded from the feasibility outcomes results.

Retention

Once recruited, the vast majority of participants stayed in the study for 12 months, with only 10% (16/166) overall withdrawing, as shown in *Table 6*. Participants in the control group were the least likely to actively withdraw, with only one individual doing so (2%, 1/58). Participants in the less intensive arm were most likely to withdraw (17%, 9/54). The proportion of non-responders was similarly modest, at only 7% overall (11/166). Participants in the control group were the most likely to fail to respond (10%, 6/58). The combined total of 27 participants (16%, 27/166) dropping out of the study was below the 30% attrition predicted in the original sample size calculation, albeit this referred to a longer follow-up period (3 years). The overall dropout rate was 12% (7/58), 20% (11/54) and 17% (9/54) in the control arm, the less intensive arm and the intensive arm, respectively. At both the 6- and 12-month follow-up assessments, the overall retention was 83.7% (139/166) (albeit some who were present at 6 months were not at 12 months and vice versa).

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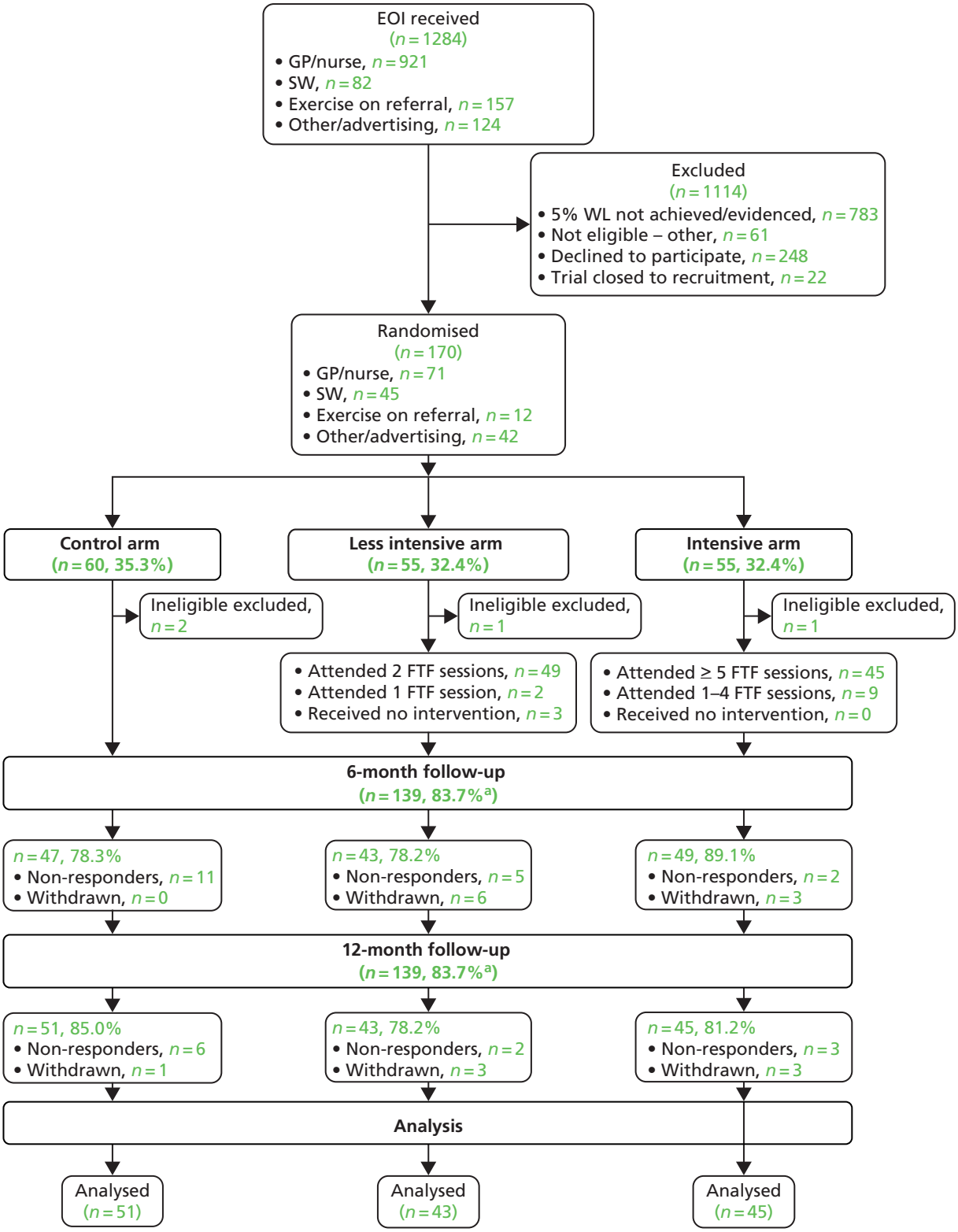


FIGURE 2 Recruitment flow chart. a, 83.7% were successfully followed up at 6 months and 12 months after excluding the four ineligible subjects. FTF, face to face; SW, Slimming World; WL, weight loss.

TABLE 5 Baseline demographics of all randomised participants by group ($n = 166$)

Demographics	Control ($n = 58$)	Less intensive ($n = 54$)	Intensive ($n = 54$)	Total ($n = 166$)
Age (years)				
< 30, *n* (%)	6 (10.3)	5 (9.3)	5 (9.3)	16 (9.6)
30–59, *n* (%)	36 (62.1)	33 (61.1)	32 (59.3)	101 (60.8)
≥ 60, *n* (%)	16 (27.6)	16 (29.6)	17 (31.5)	49 (29.5)
Gender				
Male, *n* (%)	9 (15.5)	8 (14.8)	9 (16.7)	26 (15.7)
Female, *n* (%)	49 (84.5)	46 (85.2)	45 (83.3)	140 (84.3)
BMI (kg/m^2), mean (SD)	33.3 (5.2)	34.8 (6.2)	34.4 (6.2)	34.2 (5.9)
Waist-to-hip ratio, mean (SD)	0.9 (0.1)	0.9 (0.1)	0.9 (0.1)	0.9 (0.1)
Smoker				
No, *n* (%)	52 (89.7)	48 (88.9)	50 (92.6)	150 (90.4)
Yes, *n* (%)	6 (10.3)	6 (11.1)	4 (7.4)	16 (9.6)
AUDIT-C score, mean (SD)	3.3 (3.0)	3.1 (2.8)	3.4 (2.9)	3.3 (2.9)
IPAQ score, median (25–75% percentiles)	1572.0 (0.0–2692.5)	2088.0 (0.0–3999.0)	1460.5 (198.0–3172.5)	1632.0 (0.0–3172.5)
EQ-5D health status score, mean (SD)	82 (24)	78 (27)	82 (21)	81 (24)
% weight lost, mean (SD)	12.0 (7.4)	11.4 (5.9)	12.6 (7.0)	12.0 (6.8)
Ethnicity				
White, *n* (%)	53 (91.4)	50 (92.6)	54 (100.0)	157 (94.6)
Non-white, *n* (%)	5 (8.6)	4 (7.4)	0 (0.0)	9 (5.4)
Method of recruitment				
Practices, *n* (%)	21 (36.2)	25 (46.3)	23 (42.6)	69 (41.6)
EOR, *n* (%)	3 (5.2)	3 (5.6)	4 (7.4)	10 (6.0)
Slimming World, *n* (%)	18 (31.0)	14 (25.9)	13 (24.1)	45 (27.1)
Other, *n* (%)	16 (27.6)	12 (22.2)	14 (25.9)	42 (25.3)
Comorbidities[a]				
Heart disease, *n* (%)	3 (5.2)	0 (0.0)	2 (3.7)	5 (3.0)
Diabetes mellitus, *n* (%)	8 (13.8)	9 (16.7)	13 (24.1)	30 (18.1)
Depression, *n* (%)	19 (32.8)	20 (37.0)	21 (38.9)	60 (36.1)
Stroke, *n* (%)	0 (0.0)	2 (3.7)	0 (0.0)	2 (1.2)
Arthritis, *n* (%)	17 (29.3)	13 (24.1)	18 (33.3)	48 (28.9)
Hypertension, *n* (%)	26 (44.8)	16 (29.6)	23 (42.6)	65 (39.2)
High cholesterol, *n* (%)	15 (25.9)	9 (16.7)	14 (25.9)	38 (22.9)
Asthma, *n* (%)	11 (19.0)	8 (14.8)	10 (18.5)	29 (17.5)
Chronic obstructive pulmonary disorder, *n* (%)	1 (1.7)	0 (0.0)	1 (1.9)	2 (1.2)
Back pain, *n* (%)	21 (36.2)	18 (33.3)	20 (37.0)	59 (35.5)

AUDIT-C, Alcohol Use Disorders Identification Test; IPAQ, International Physical Activity Questionnaire.
a Participants were asked if they had ever been diagnosed with any of these health problems.

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TABLE 6 Withdrawals and non-responders at 12 months and adherence levels of eligible recruits split by treatment group

Feasibility outcome	Control ($n = 58$)	Less intense ($n = 54$)	Intense ($n = 54$)	Total ($n = 166$)
Withdrawals	1	9	6	16
Percentage (95% CI)	2 (0 to 10)	17 (8 to 30)	11 (5 to 23)	10 (6 to 15)
Non-responders	6	2	3	11
Percentage (95% CI)	10 (4 to 22)	4 (1 to 14)	6 (1 to 16)	7 (4 to 12)
Adherence		49	45	
Percentage (95% CI)		91 (79 to 97)	83 (70 to 92)	

Adherence

Adherence was defined as attendance at five out of six face-to-face sessions for the intensive group and two face-to-face sessions for the less intensive group. Adherence to the intervention was excellent, with both treatment arms achieving adherence in excess of 85% in those who had not withdrawn. Detailed qualitative exploration of recruitment, retention and adherence is presented in *Chapters 6–8*.

Effectiveness outcomes

Table 7 summarises the continuous outcome variables at baseline and follow-up.

Primary effectiveness outcome

The primary effectiveness outcome was BMI (see *Chapter 3*). A three-level hierarchical model (with participants clustered within MIPs and groups) was proposed in the statistical analysis plan; however, the peer support groups could not be included as a third level as not enough were run. The two-level hierarchical model was fitted, but there was no evidence of clustering [intracluster correlation coefficient (ICC) < 0.000], so a linear model is reported. Each of the intervention arms was compared with the control arm. Transformations of BMI (such as square, square root and log) were investigated but did not appreciably improve model fit as measured by the adjusted R^2 and so results are presented for the untransformed BMI. This is based on 129 individuals who were weighed. All results are summarised in *Table 8*.

The analysis of the primary outcome of BMI shows that the intensive arm had a non-significant difference in BMI of –1.0 kg/m^2 (95% CI –2.2 kg/m^2 to 0.2 kg/m^2) (i.e. mean BMI was 1 kg/m^2 lower in the intensive arm than in the control group), whereas mean BMI in the less intensive arm showed a non-significant difference from the control group of –0.2 kg/m^2 (95% CI –1.4 kg/m^2 to 1.0 kg/m^2). A difference in mean BMI of 1 kg/m^2 would be considered clinically important in a fully powered RCT, but is not statistically significant in this feasibility study. However, this magnitude of difference (and the 95% CI excluding substantial weight differences in the direction of harm) does suggest that the intensive intervention is worthy of further investigation. The difference of –0.2 kg/m^2 achieved by the less intensive intervention compared with the control group is unlikely to be of clinical relevance. The effect sizes associated with these results are –0.140 for the intensive arm and –0.029 for the control arm. Allowing for the inclusion of self-reported weight for missing values in BMI did not change the conclusion.

TABLE 7 Comparison of primary and secondary continuous outcome variables at baseline and 12-month follow-up

Outcome	Baseline				12-month follow-up			
	Control, mean (SD)	Intensive, mean (SD)	Less intensive, mean (SD)	Total, mean (SD)	Control, mean (SD)	Intensive, mean (SD)	Less intensive, mean (SD)	Total, mean (SD)
BMI (kg/m^2)	33.3 (5.19)	34.4 (6.19)	34.8 (6.20)	34.2 (5.86)	33.0 (5.22)	33.3 (6.50)	33.4 (6.03)	33.2 (5.89)
BMI augmented[a] (kg/m^2)	N/A				33.0 (5.39)	33.3 (6.50)	34.1 (6.22)	33.5 (6.00)
Weight (kg)	90.2 (15.41)	92.5 (20.02)	93.8 (17.66)	92.1 (17.70)	89.6 (17.21)	90.1 (21.00)	91.6 (17.19)	90.4 (18.49)
Weight augmented[a] (kg)	N/A				90.1 (17.28)	90.1 (21.00)	94.3 (19.97)	91.4 (19.34)
Waist circumference (cm)	102.5 (11.96)	104.3 (15.51)	105.4 (14.10)	104.1 (13.86)	102.7 (14.63)	102.8 (16.33)	103.2 (13.56)	102.9 (14.84)
Waist-to-hip ratio	0.9 (0.08)	0.9 (0.09)	0.9 (0.09)	0.9 (0.09)	0.9 (0.10)	0.9 (0.10)	0.9 (0.09)	0.9 (0.10)
IPAQ (MET minutes per week)	1902 (1517)	2805 (3412)	2506 (2239)	2386 (2500)	2346 (2457)	3017 (3343)	3594 (4548)	2956 (3521)
GHQ-12 score	2.3 (3.52)	1.8 (2.82)	2.4 (3.38)	2.2 (3.25)	2.6 (3.81)	2.3 (3.31)	3.0 (3.70)	2.6 (3.60)
DINE fibre score	32.7 (10.50)	34.7 (8.91)	33.7 (8.64)	33.7 (9.38)	31.2 (8.85)	34.0 (7.06)	32.4 (9.79)	32.5 (8.56)
DINE fat score	14.9 (4.82)	17.7 (5.41)	16.7 (4.95)	16.3 (5.11)	17.3 (4.83)	17.0 (3.99)	17.5 (4.99)	17.3 (4.56)
DINE healthy eating score	17.7 (9.71)	17.4 (9.34)	16.3 (5.76)	17.1 (8.34)	14.9 (8.34)	17.2 (7.97)	15.9 (9.56)	16.1 (8.57)
EQ-5D score	0.8 (0.24)	0.8 (0.21)	0.8 (0.27)	0.8 (0.24)	0.8 (0.18)	0.8 (0.18)	0.8 (0.32)	0.8 (0.23)
EDE-Q number of days binge eating	2.4 (4.04)	2.2 (4.92)	2.7 (4.02)	2.4 (4.32)	2.5 (4.14)	1.4 (2.61)	4.1 (6.06)	2.6 (4.54)
AUDIT-C score	3.3 (2.95)	3.4 (2.85)	3.1 (2.79)	3.3 (2.85)	3.1 (2.78)	3.3 (2.68)	3.0 (2.67)	3.1 (2.70)

AUDIT-C, Alcohol Use Disorders Identification Test; DINE, Dietary Instrument for Nutrition Education; EDE-Q, Eating Disorder Examination Questionnaire; GHQ-12, General Health Questionnaire – 12 items; IPAQ, International Physical Activity Questionnaire; MET, metabolic equivalent; N/A, not applicable.

a Self-reported follow-up weights are included with verified follow-up weights in these analyses. There were four self-reports in the control group: four in the less-intensive and none in the intensive group.

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TABLE 8 Summary of adjusted mean differences comparing the less intensive and intensive treatment arms with the control arm for primary and secondary outcomes

		Less intensive[a]		Intensive[a]	
Outcome	***n***	**Mean**	**95% CI**	**Mean**	**95% CI**
Primary outcome					
BMI (kg/m^2)	129	–0.21	–1.44 to 1.03	–0.96	–2.16 to 0.23
BMI augmented[b] (kg/m^2)	137	–0.23	–1.38 to 0.93	–0.94	–2.09 to 0.21
Secondary outcomes (continuous)					
Weight (kg)	129	–0.70	–4.10 to 2.70	–2.82	–6.09 to 0.45
Weight augmented[b] (kg)	137	–0.69	–3.88 to 2.50	–2.73	–5.87 to 0.41
Waist (cm)[c]	129	0.15	–3.34 to 3.65	–0.84	–4.21 to 2.59
Waist-to-hip ratio	129	–0.001	–0.030 to 0.027	–0.012	–0.039 to 0.016
IPAQ MET minutes per week (transformed)	111	6.33	–5.33 to 17.98	0.85	–10.61 to 12.32
GHQ-12 score	Not fitted				
DINE fibre score[c]	96	–0.60	–4.32 to 3.12	0.47	–3.20 to 4.14
DINE fat score[c]	54	–1.80	–4.50 to 0.54	–4.68	–7.44 to –2.28
DINE health eating score[c]	46	–0.30	–5.73 to 5.12	4.16	–1.80 to 10.14
EQ-5D score	Not fitted				
EDE-Q number of days binge eating	Not fitted				
AUDIT-C score	Not fitted				
		Less intensive		**Intensive**	
Outcome	***n***	**OR**	**95% CI**	**OR**	**95% CI**
Secondary outcomes (binary)					
Maintaining weight lost	129	0.61	0.23 to 1.56	1.43	0.59 to 3.54
Maintaining weight lost augmented	137	0.69	0.28 to 1.71	1.45	0.61 to 3.49
AUDIT-C categorised	134	0.34	0.08 to 1.28	1.53	0.42 to 5.63
GHQ-12 case ≥ 3	133	1.07	0.39 to 2.98	1.12	0.40 to 3.09
GHQ-12 case ≥ 12		Not fitted			
EQ-5D (< 100, 100)	139	1.39	0.49 to 3.94	0.85	0.29 to 2.46
EDE-Q recurrent	Not fitted				
EDE-Q compensatory behaviour	Not fitted				
Heaviness of smoking	Not fitted				
Sensitivity analysis assuming non-responders failed to maintain	166	0.64	0.27 to 1.47	1.34	0.60 to 3.01
		Less intensive		**Intensive**	
Poisson regression	***n***	**Expected rate**	**95% CI**	**Expected rate**	**95% CI**
EDE-Q number of days binge eating	135	1.01	0.78 to 1.31	0.60	0.42 to 0.86

AUDIT-C, Alcohol Use Disorders Identification Test; DINE, Dietary Instrument for Nutrition Education; EDE-Q, Eating Disorder Examination Questionnaire; GHQ-12, General Health Questionnaire – 12 items; IPAQ, International Physical Activity Questionnaire; OR, odds ratio.

a The primary outcome is based on an analysis controlling for baseline BMI, age (less than 30 years, 30–59 years, ≥ 60 years), gender and minimisation variables of ethnicity (white vs. non-white), source of recruitment (practices, EOR, Slimming World, other), and percentage weight lost ($\leq 10\%$ vs. $> 10\%$). All other analyses control for the baseline measurement of the outcome variable as well as a dichotomised baseline BMI variable (BMI < 40 kg/m^2 or ≥ 40 kg/m^2).

b Self-reported follow-up weights are included along with verified follow-up weights in these analyses (four in the control group, four in the less-intensive and none in the intensive group).

c Hierarchical model results presented.

Weight

Weight measured in kilograms (kg) was formally investigated in a similar way to the primary outcome, controlling for the same covariates, but replacing baseline BMI with baseline weight. Again, no clustering was found in the hierarchical model fitted, so linear regression results are presented. Weight in the intensive treatment arm was not statistically significantly different from that in the control arm, participants in the intensive treatment arm weighing, on average, 2.8 kg less than control participants (95% CI –6.1 to 0.5 kg); participants in the less intensive arm weighed only 0.7 kg less than controls (95% CI –4.1 to 2.7 kg). The 95% CI shows that participants in the intensive arm were unlikely to be appreciably harmed by the intervention and a difference of 2.8 kg would be clinically important if shown to be a true difference. The less intensive arm is less likely to be producing an effect of clinical importance. The analysis was repeated with self-reported weight, but the results did not change appreciably.

Waist measurements

There was some indication of clustering in waist measurement, so hierarchical methods were used. The ICC was 0.040. The results show little evidence of a large effect on this outcome, with the intensive arm having an average waist measurement 0.8 cm lower than the control group (adjusted mean difference –0.8, 95% CI –4.2 to 2.6), while mean weight circumference in the less intensive arm was 0.1 cm lower than in the control group (95% CI –3.3 cm to 3.7 cm). The size of difference between groups would not be considered clinically important and there were some large and potentially implausible individual differences between baseline and follow-up waist circumference measurements (range –26.5 cm to 18 cm), which may be attributable to measurement error.

Waist-to-hip ratio

There was no evidence of a treatment effect on waist-to-hip ratio with an adjusted mean difference of –0.01 comparing the intensive with control group (95% CI –0.04 to 0.02) and an adjusted mean difference of –0.001 comparing the less intensive group with the control group (95% CI –0.03 to 0.03).

International Physical Activity Questionnaire

The International Physical Activity Questionnaire (IPAQ) follows a very skewed distribution, which is shown, split by group, in *Figure 3*. Transformations of the IPAQ score were investigated in our analysis. The square

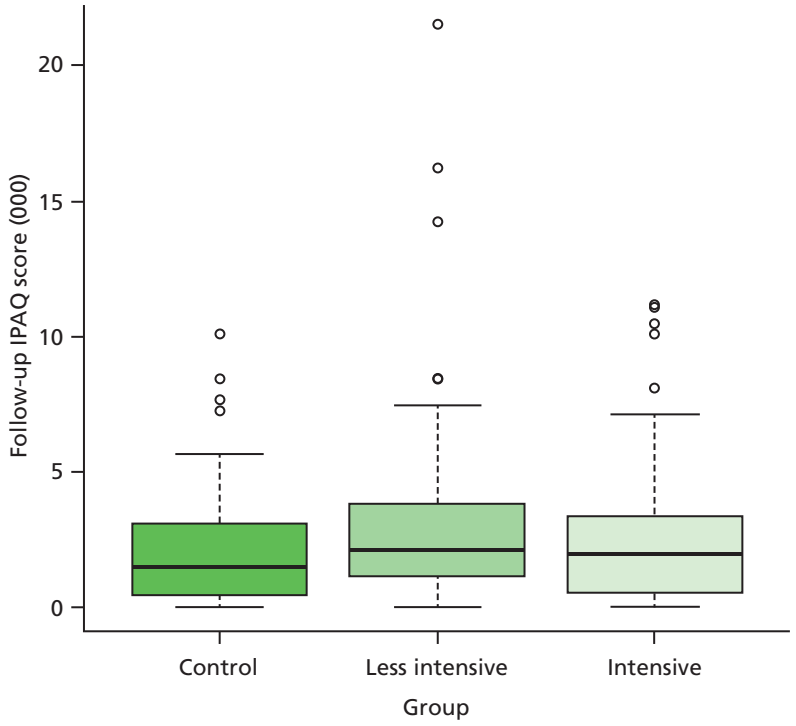


FIGURE 3 Distribution of follow-up IPAQ scores between groups.

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root performed the best (based on visual inspection of fitted versus residual plots). There was no evidence of clustering, so linear regression is reported. There was no evidence of any impact of treatment group on this outcome, with the intensive arm having a square root IPAQ score of 0.9 greater than that of the control group (95% CI –10.6 to 12.3) and the less intensive arm having a square root IPAQ score 6.3 greater than that of the control group (95% CI –5.3 to 18.0).

Maintaining weight lost

A binary assessment of whether or not the participants had gained weight since baseline was performed and logistic regression was used to compare groups, controlling for the same covariates used in the primary analysis. There was no evidence of clustering, so a non-hierarchical logistic regression is reported. *Table 8* shows that, while mean weight in neither treatment arm was statistically significantly different to that in the control group, participants in the intensive arm had, on average, a 43% higher chance than those in the control group of maintaining weight loss (OR 1.43, 95% CI 0.6 to 3.5). In contrast, participants in the less intensive arm were, on average, 40% less successful than the control group at maintaining weight loss (OR 0.6, 95% CI 0.2 to 1.6). This analysis was repeated using self-reported weight, but the results were similar (see *Table 8*). The proportion of maintainers was highest in the intensive arm (56%, $n = 25$) and lowest in the less intensive arm (37%, $n = 14$) (*Table 9*).

General Health Questionnaire: continuous score

The General Health Questionnaire – 12 items (GHQ-12) scores were not distributed normally (*Figure 4*). Standard transformations were investigated, but the model fit was not improved. The score was dichotomised using the standard cut-off point of 3 or more to indicate a case. There was no evidence of clustering, so non-hierarchical results are presented. The odds of scoring 3 or higher on the GHQ-12 was 12% higher for participants in the intensive arm than for those in the control arm (OR 1.12, 95% CI 0.4 to 3.09), while the less intensive arm had an odds of 7% higher than the control (OR 1.07, 95% CI 0.39 to 2.98).

General Health Questionnaire: dichotomised

The GHQ-12 was analysed as a binary variable derived using the World Health Organization (WHO) threshold for evidence of distress (a score of 12 or more). However, in this general population sample there were very few participants who met this criterion (three individuals, *Table 10*) and so we were unable to fit a regression model to this variable.

TABLE 9 Frequencies of maintainers across treatment arms

	Treatment arm		
Weight status	Control	Less intensive	Intensive
Maintained weight lost?			
No	25 (54%)	24 (63%)	20 (44%)
Yes	21 (46%)	14 (37%)	25 (56%)

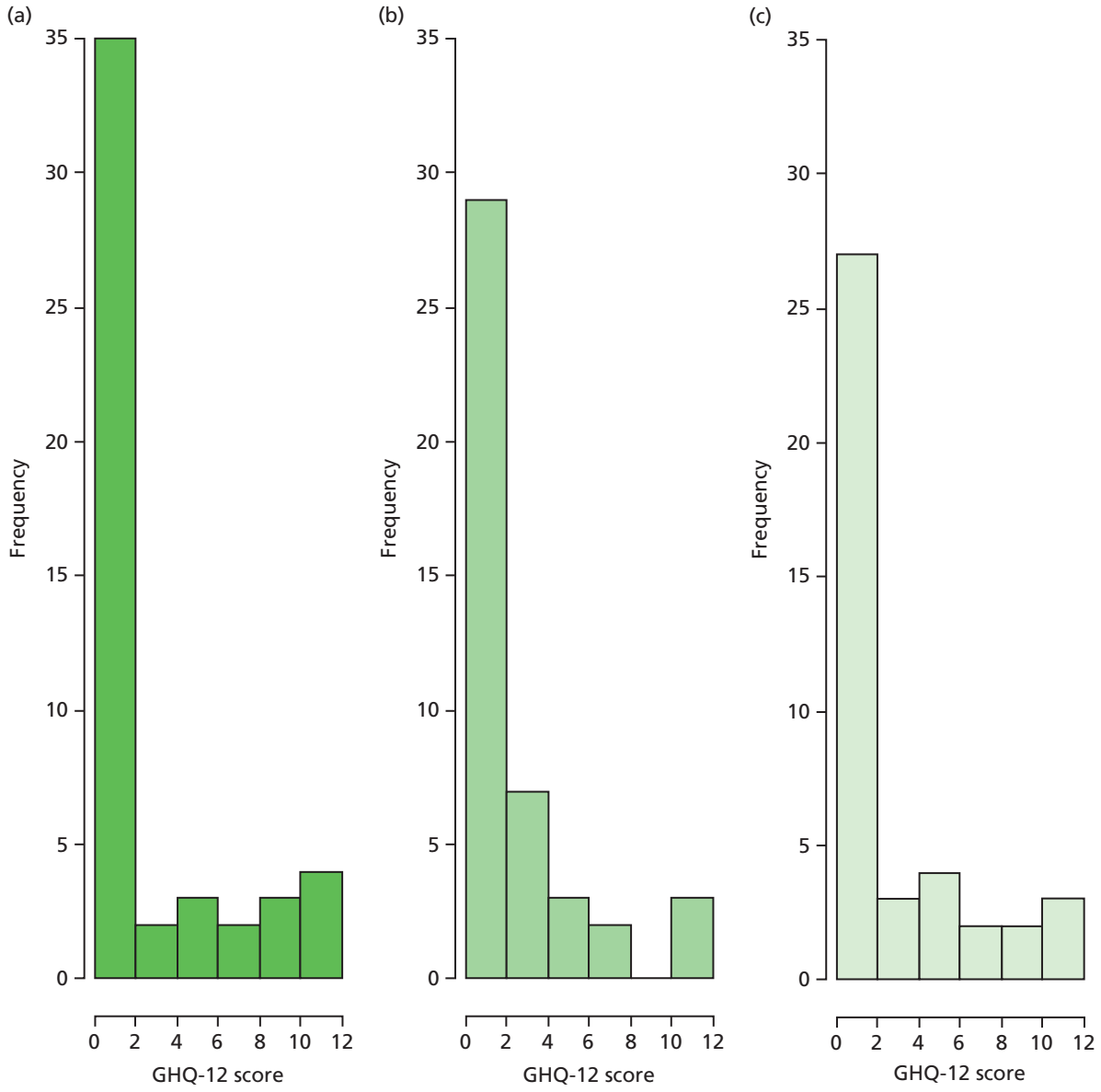


FIGURE 4 Comparison of follow-up GHQ-12 distributions between treatment arms. (a) Control group; (b) less intensive group; and (c) intensive group.

TABLE 10 Numbers of participants meeting the WHO threshold for distress in each treatment arm

	Numbers of participants meeting the WHO threshold for distress	
Arm	No	Yes
Control	49 (100%)	0 (0%)
Less intensive	39 (95%)	2 (5%)
Intensive	43 (98%)	1 (2%)

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Dietary Instrument for Nutrition Education scale

We examined three scales from the Dietary Instrument for Nutrition Education (DINE): the fibre, fat and healthy eating scales.

The Dietary Instrument for Nutrition Education fibre scale

There was evidence of clustering in the DINE fibre scale scores, so the results of the hierarchical model are presented. The ICC was 0.056. Missing DINE fibre scores reduced the number of participants on which this model was run to 96. The adjusted mean difference was 0.5 greater for the intensive arm than for the control arm (95% CI –3.2 to 4.1) and 0.6 lower for the less intensive arm than for the control arm (95% CI –4.3 to 3.1). Both CIs are broadly centred about zero, representing little evidence of a treatment effect.

The Dietary Instrument for Nutrition Education fat score

There was evidence of clustering in the DINE fat score, with a very high ICC of 0.63, and so results from the hierarchical model are presented. Again, however, there were many missing values, resulting in this analysis being performed on only 54 participants. Participants in the intensive arm reported statistically significantly lower fat intake than did participants in the control group (adjusted mean difference –4.7, 95% CI –7.4 to –2.3). There is some evidence that participants in the less intensive arm also reported lower fat intake in comparison with the control group, but the difference was not statistically significantly different (adjusted mean difference –1.8, 95% CI –4.5 to 0.5).

The Dietary Instrument for Nutrition Education healthy eating score

The DINE healthy eating score is the contrast between the fat and fibre scales, so this score is affected by the missing data for dietary fat and fibre referred to above. This reduced the sample size to 46. There was clustering in evidence (the ICC was 0.097) and so the hierarchical model is reported. The intensive arm reported healthy eating scores that were, on average, 4.2 points higher than those reported by the control group (95% CI –1.8 to 10.1), while the less intensive arm reported scores 0.3 points lower than those of the control group (95% CI –5.7 to 5.1). This suggests a small potential effect of the intervention for the intensive arm only; however, the very small numbers make it hard to draw any conclusions.

European Quality of Life-5 Dimensions

The EQ-5D scores were not normally distributed (*Figure 5*). Standard transformations (inverse, log, square root) did not improve the fitted compared with residual plots, so a dichotomised analysis is presented (those with scores below 100, vs. those with scores of 100). There was no evidence of clustering (ICC < 0.000), so non-hierarchical results are presented. The odds of scoring 100 was 15% lower in the intensive arm than in the control arm (OR 0.85, 95% CI 0.29 to 2.46), while in the less intensive arm it was 39% greater than in the control arm (OR 1.39, 95% CI 0.49 to 3.94).

The Eating Disorder Examination Questionnaire

Three measures of binge eating [from the Eating Disorder Examination Questionnaire (EDE-Q)] were investigated: (1) a threshold for recurrent binge eating behaviour (yes/no), (2) the number of days in the last 28 days on which binge eating occurred and (3) the threshold for compensatory behaviour (yes/no). The numbers for the threshold for recurrent binge eating behaviour and for compensatory behaviour were too small for analysis and the results are therefore presented only descriptively (*Tables 11* and *12*).

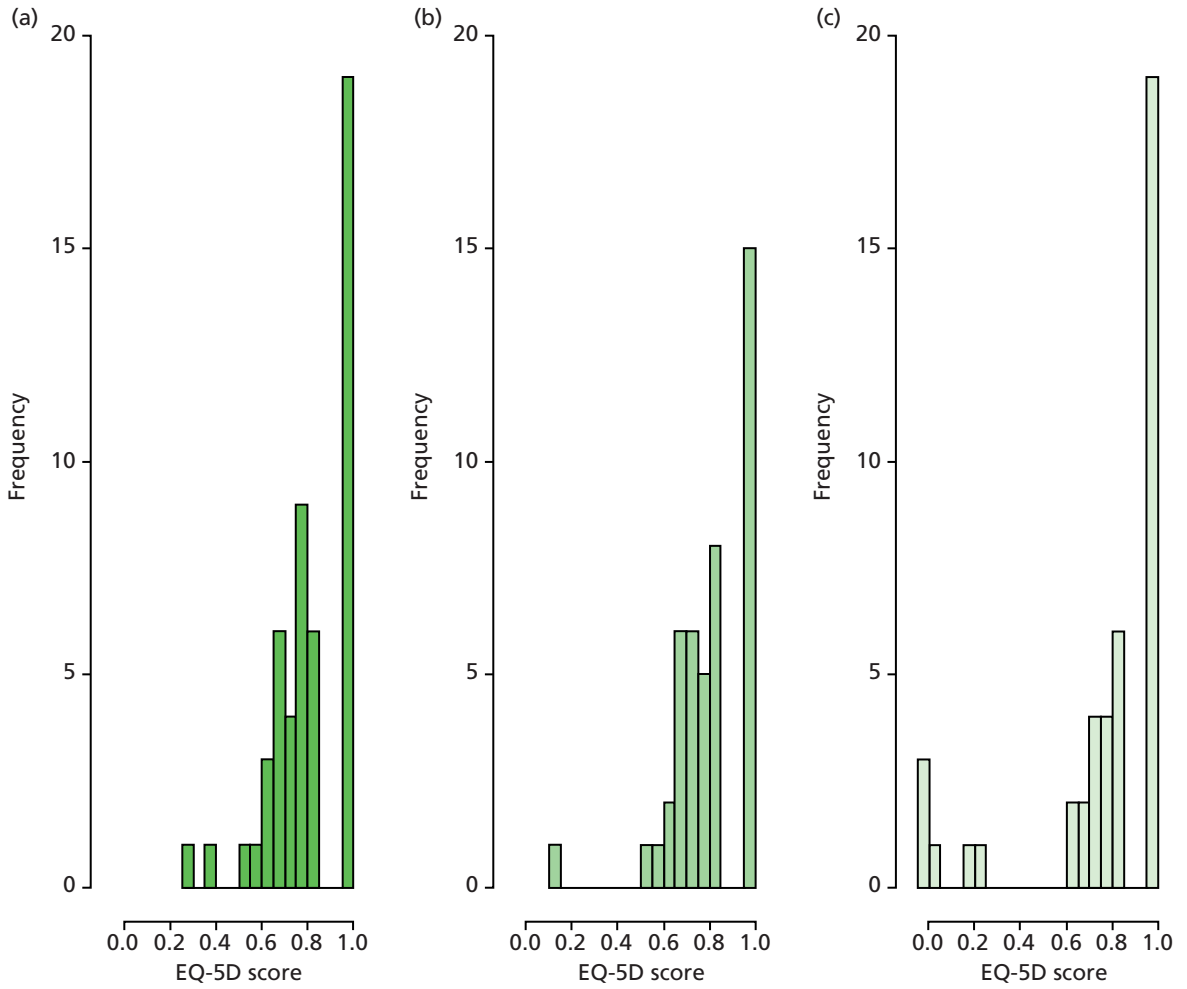


FIGURE 5 Comparison of follow-up EQ-5D scores between treatment arms. (a) Control group; (b) less intensive group; and (c) intensive group.

TABLE 11 Frequency of recurrent binge eating behaviour at baseline and follow-up

	Follow-up recurrent binge eating behaviour	
	No	Yes
Baseline recurrent binge eating behaviour		
No	116 (94%)	7 (6%)
Yes	6 (50%)	6 (50%)

TABLE 12 Frequency of baseline and follow-up compensatory behaviour

	Follow-up compensatory behaviour	
	No	Yes
Baseline compensatory behaviour		
No	126 (98%)	3 (2%)
Yes	3 (60%)	2 (40%)

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Number of days on which binge eating occurred

The number of days on which binge eating occurred was not normally distributed (*Figure 6*). A zero-inflated Poisson regression was fitted to the data and showed that the mean number of days on which binge eating occurred was 40% lower in the intensive arm than in the control arm (expected rate 0.60, 95% CI 0.40 to 0.86), while in the less intensive arm this value was very similar to that in the control arm (rate 1.01, 95% CI 0.78 to 1.31).

Alcohol Use Disorders Identification Test

The continuous Alcohol Use Disorders Identification Test (AUDIT-C) was highly skewed (*Figure 7*) and so only the AUDIT-C categorised for high-risk drinking was analysed using logistic regression. This model suggests that participants in the intensive arm were more likely to develop increasing or higher risks of drinking (OR 1.53, 95% CI 0.4 to 5.6), while those in the less intensive arm were less likely to develop increasing or higher risks of drinking (OR 0.32, 95% CI 0.1 to 1.3). However, the CIs are extremely wide for both arms, so the evidence for a treatment effect is uncertain. *Table 13* shows the frequencies of categorised AUDIT-C scores at baseline and follow-up.

Heaviness of smoking index

The Heaviness of Smoking Index (HSI) is presented in *Table 14*. Very few participants changed over time so this outcome was not analysed.

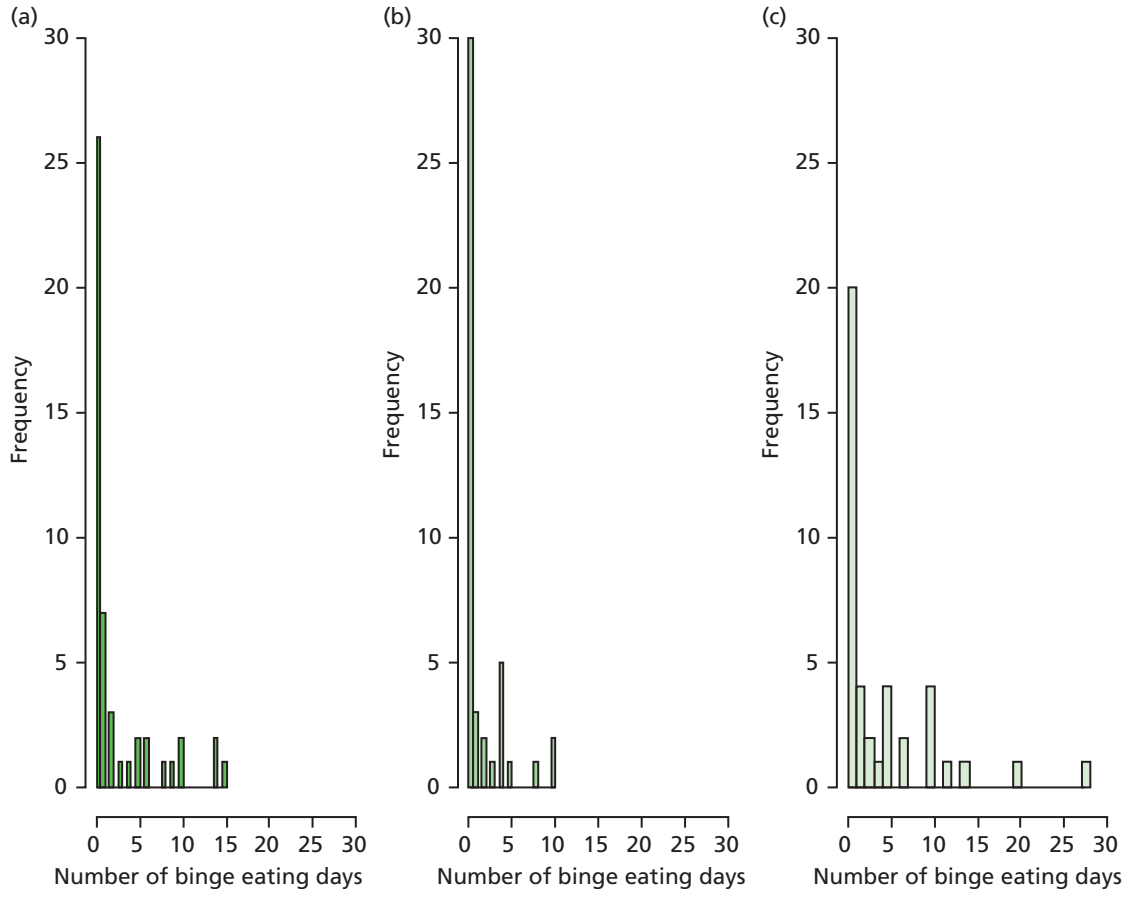


FIGURE 6 Comparison of the number of binge eating days at follow-up across groups. (a) Control group; (b) less intensive group; and (c) intensive group.

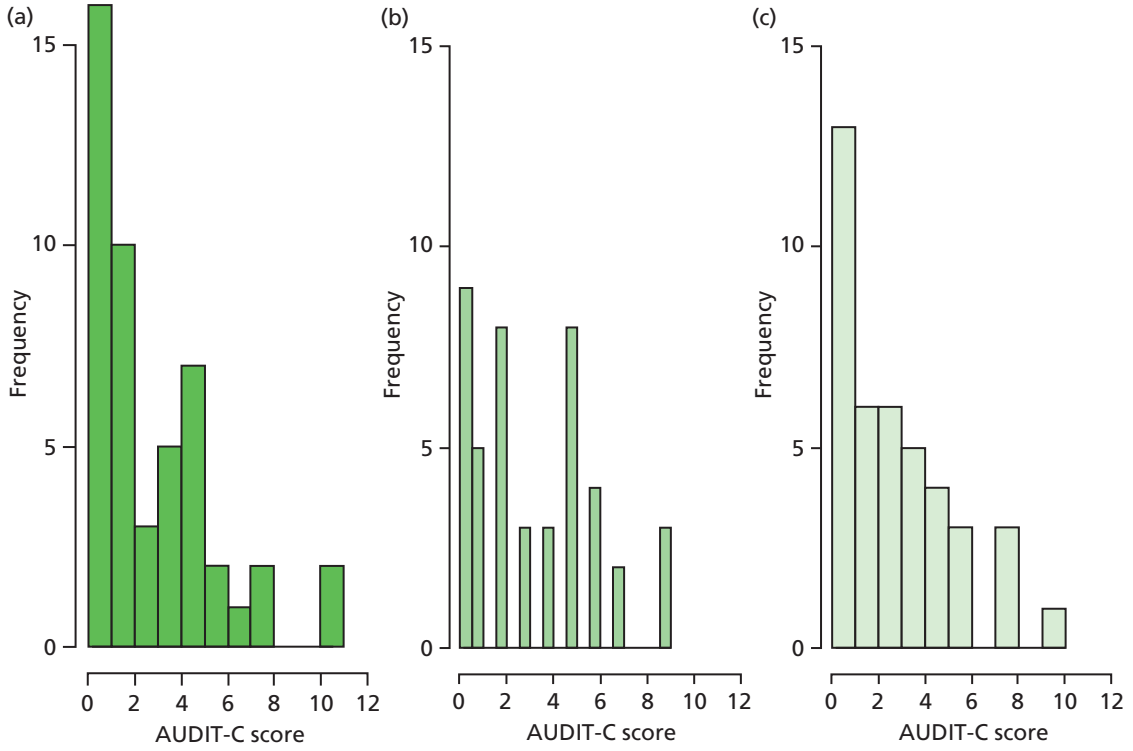


FIGURE 7 Distribution of follow-up AUDIT-C scores across trial arms. (a) Control group; (b) less intensive group; and (c) intensive group.

TABLE 13 Cross tabulation of categorised AUDIT-C scores between baseline and follow-up

	Categorised follow-up AUDIT-C	
	Not increasing/higher risk of drinking	Increasing/higher risk of drinking
Categorised baseline AUDIT-C		
Not increasing/higher risk of drinking	82	12
Increasing/higher risk of drinking	10	30

TABLE 14 Frequencies of baseline HSI with follow-up

	Follow-up HSI	
	Low addiction	Moderate addiction
Baseline HSI		
Low addiction	129	2
Moderate addiction	2	2

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Sensitivity analysis

The analysis of the proportion who maintained their weight loss was performed assuming that the 29 individuals who we were unable to follow up failed to maintain their weight loss. The results did not change dramatically, with the intensive arm having an OR of maintaining weight loss of 1.3 (95% CI 0.6 to 3.0) and the less intensive arm an OR of 0.6 (95% CI 0.3 to 1.5).

Complier-average causal effect analysis

For the purposes of this analysis, a complier will be defined as:

- for a participant assigned to the intensive arm, attending five of the six face-to-face MI sessions
- for a participant assigned to the less intensive arm, attending both of the face-to-face MI sessions.

Compliance with the intervention

The majority of participants (87.0%) attended the number of sessions required to be classified as a complier. Compliance was higher among those allocated to the less intensive arm (90.7%) than for those allocated to the intensive arm (83.3%), which could be expected given the lower threshold for being a complier (two sessions rather than at least five).

Missing outcome data

The majority of participants both complied with the intervention and provided follow-up BMI data (74.1% of participants in the intensive arm and 66.7% of participants in the less intensive arm; *Table 15* and *Figure 8*). Non-compliance did not appear to be associated with dropout; in fact, in the less intensive arm more compliers dropped out than non-compliers.

Intracluster correlation coefficients

There was no evidence of clustering of responses to the primary outcome (ICC 0.00). A small amount of clustering was observed when exploring the relationship between compliance with the intensive intervention and MIP (ICC 0.057), and there is no evidence of compliance with the less intensive intervention clustering by MIP (ICC 0.00). An ICC of 0.057 (5.7% of the total variability in compliance to the intensive intervention was related to differences between MIPs) was not particularly large. For simplicity, our CACE analyses did not take clustering into account.

Adjusting the primary analysis for compliance, we observe a larger difference in post-intervention BMI for the intensive arm, but no observable difference (to two decimal places) for the less intensive arm. This demonstrates that attending the intensive intervention reduced BMI by 1.23 kg/m^2, although the 95% CI ranges from a reduction of –2.49 kg/m^2 reduction to an increase of 0.03 kg/m^2, so the difference was not statistically significant at the 5% level (*Table 16* and *Figure 9*).

TABLE 15 Relationship between outcome data availability and compliance with the intervention in each treatment arm

Level of compliance	BMI outcome data available	BMI outcome data not available	Total
Less intensive arm			
Complied with intervention	36	13	49
Did not comply with intervention	2	3	5
Total	38	16	54
Intensive			
Complied with intervention	40	5	45
Did not comply with intervention	5	4	9
Total	45	9	54

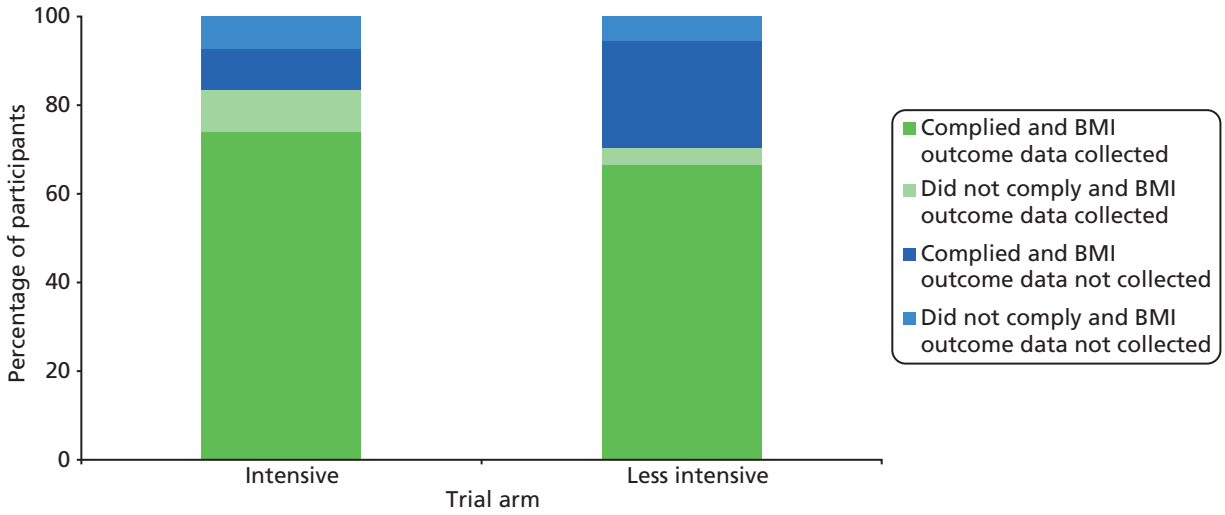


FIGURE 8 The relationship between compliance and dropout/availability of outcome data.

TABLE 16 Comparison of intention-to-treat and CACE estimates for BMI

Comparison	Type of analysis	Adjusted between-group mean difference in post-intervention BMI[a]	Lower 95% CI	Upper 95% CI	*p*-value
Intensive vs. control	ITT (effectiveness)	–0.96	–2.16	0.23	0.114
Intensive vs. control	CACE (efficacy)	–1.23	–2.49	0.03	0.056
Less intensive vs. control	ITT (effectiveness)	–0.21	–1.44	1.03	0.739
Less intensive vs. control	CACE (efficacy)	–0.21	–1.40	0.98	0.733

ITT, intention to treat.
a Analysis adjusted for baseline BMI, and variables balanced on at randomisation (age, gender, ethnicity, method of recruitment and percentage weight loss).

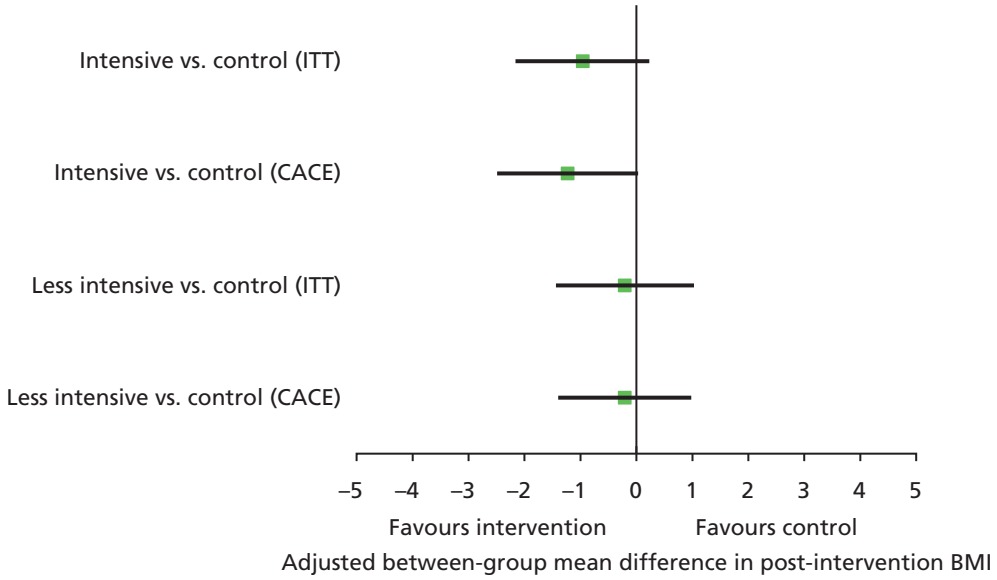


FIGURE 9 The effectiveness and efficacy of treatment on post-intervention BMI. Adjusted mean difference represented by the square point. Associated 95% CIs are represented by the dark bold lines. ITT, intention to treat.

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In a similar way to the BMI outcome, adjusting the analysis for compliance, we observe a larger difference in post-intervention weight and the difference was less pronounced in the less intensive arm than in the intensive arm. We found that attending the intensive intervention reduced weight by, on average, 3.69 kg, with the 95% CI ranging from a 7.08 kg reduction to a 0.31 kg reduction ($p = 0.033$) (*Table 17* and *Figure 10*).

TABLE 17 Comparison of intention-to-treat and CACE estimates for post-intervention weight (kg)

Comparison	Type of analysis	Adjusted between-group mean difference in post-intervention weight[a]	Lower 95% CI	Upper 95% CI	*p*-value
Intensive vs. control	ITT (effectiveness)	–2.84	–6.10	0.42	0.087
Intensive vs. control	CACE (efficacy)	–3.69	–7.08	–0.31	0.033
Less intensive vs. control	ITT (effectiveness)	–0.82	–4.19	2.56	0.632
Less intensive vs. control	CACE (efficacy)	–0.89	–4.16	2.38	0.594

ITT, intention to treat.
a Weight in kg. Analysis adjusted for baseline weight, and variables balanced on at randomisation (age, gender, ethnicity, method of recruitment and percentage weight loss).

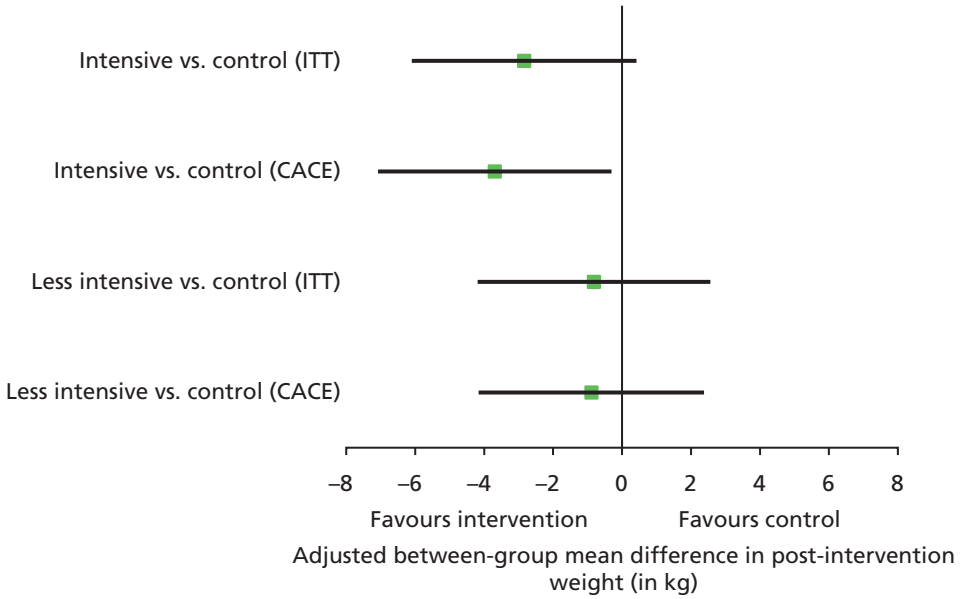


FIGURE 10 The effectiveness and efficacy of treatment on post-intervention weight (in kg). Adjusted mean difference represented by the square point. Associated 95% CIs are represented by the dark bold lines. ITT, intention to treat.

Mediation analyses

Mediation analyses were also conducted on self-efficacy, social support, intrinsic motivation, habits and self-monitoring as measured at 6 months (see *Chapter 3*).

It is important to note here (*Figure 11*) that we have assumed that there are no confounders in the relationship between the mediator(s) and the outcome. Given that mediators are measured post randomisation (by definition), it is likely that there will be some measured and unmeasured confounders that will not be taken into account in our model and, therefore, our estimates will be prone to selection bias.

The outcome was not statistically significant at the 5% level; however, there certainly was some evidence of a treatment effect, which was made more evident by the increasing benefit obtained when the intensity of the intervention was increased (*Table 18*). While, strictly speaking, mediation analysis requires a significant association between exposure and outcome, mediation analyses were still conducted to explore the process/mechanisms by which the intervention may work.

A linear regression model could not be fitted for two of the mediators owing to the high level of skew in the responses. None of the 10 remaining between-group comparisons for the mediators investigated was statistically significant at the 5% level and, for the majority, the 95% CIs were wide (*Table 19*). However, as this was a feasibility study that was not powered to detect differences on any of the above outcomes or mediators, a full mediation analysis will nevertheless be conducted to investigate whether or not the mediators may lie on the causal pathway.

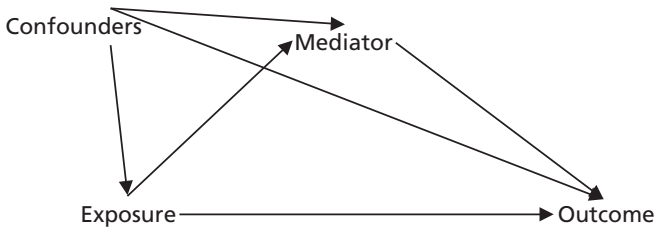


FIGURE 11 Causal-directed acyclic graph illustrating proposed mediation.

TABLE 18 Between-group analysis of outcome

Outcome[a]	Number of participants	Trial arm	Estimate[b]	Lower 95% CI	Upper 95% CI	*p*-value
BMI	129	Intensive	–0.96	–2.16	0.23	0.114
		Less intensive	–0.21	–1.44	1.03	0.739

a Outcome collected at 12-month time point unless specified otherwise.
b Estimate represents the adjusted between-group mean difference (intervention minus control). Mean difference adjusted for the corresponding baseline covariate (e.g. baseline BMI for the BMI outcome) and variables balanced on at randomisation.

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TABLE 19 Between-group analysis of mediators

Mediator[a]	Brief interpretation of scale (higher scores indicate . . .)	Number of participants	Trial arm (compared with control)	Estimate[b]	Lower 95% CI	Upper 95% CI	*p*-value
WEL	Greater confidence to resist eating	139	Intensive	2.33	–9.12	13.78	0.691
			Less intensive	1.90	–9.63	13.44	0.746
ESES	Greater confidence to exercise	138	Intensive	0.19	–0.49	0.88	0.578
			Less intensive	–0.03	–0.72	0.66	0.930
SSEH survey – sabotage domain	Greater perception that friends/family sabotage their attempts to eat healthily	131	Intensive	–0.04	–1.09	1.00	0.935
			Less intensive	0.33	–0.71	1.38	0.531
SSEH survey – encouragement domain	Greater perception that family/friends provide encouragement to eat healthily	128	Intensive	–0.12	–0.77	0.52	0.706
			Less intensive	0.51	–0.14	1.16	0.126
SSEX survey – participation domain	Greater perception that family/friends participate/involve themselves in their exercise routine	127	Intensive	–0.00	–0.77	0.77	0.999
			Less intensive	0.06	–0.73	0.85	0.882
SSEX survey – support domain	Greater perception that family/friends provide support/encouragement for their exercise routine	123	Intensive	0.42	–0.42	1.23	0.331
			Less intensive	0.26	–0.63	1.16	0.565
SSEX survey – punishment domain	Small numbers in some cells (i.e. data were highly skewed). Unable to analyse						
TSRD – relative autonomy	Greater autonomous regulation of their healthy eating	139	Intensive	–0.11	–0.63	0.42	0.687
			Less intensive	–0.17	–0.70	0.37	0.537
TSRE – relative autonomy	Greater autonomous regulation of their motivation to exercise	137	Intensive	0.41	–0.08	0.90	0.099
			Less intensive	0.04	–0.46	0.54	0.876
Self-monitoring regularity	Small numbers in some cells (i.e. data were highly skewed). Unable to fit a linear model						
Self-reported habit index (diet) at 12 months	More positive habits with regards to eating healthy food	133	Intensive	0.04	–0.35	0.44	0.833
			Less intensive	–0.19	–0.59	0.21	0.364
Self-reported habit index (exercise) at 12 months	More positive habits with regards to exercising	135	Intensive	–0.28	–0.89	0.33	0.366
			Less intensive	–0.09	–0.70	0.53	0.781

ESES, Exercise Self-Efficacy Scale; SSEH, Social Support and Eating Habits; SSEX, Social Support and Exercise; TSRD, Treatment Self-Regulation Questionnaire Concerning the Motivation for Eating a Healthy Diet; TSRE, Treatment Self-Regulation Questionnaire Concerning the Motivation for Exercising Regularly; WEL, Weight Efficacy Life-Style Questionnaire.

a Mediator collected at 6-month time point unless specified otherwise.

b Estimate represents the adjusted between-group mean difference (intervention minus control). Mean difference adjusted for the corresponding baseline covariate (e.g. baseline WEL for the WEL mediator) and variables balanced on at randomisation.

As shown by *Table 20*, it was difficult to determine how much of the effect of intervention on BMI was mediated through any of the mediators. Of the 20 comparisons made, two provided a positive value for the percentage of the total effect that was via the mediator and one was zero (the remaining were negative, meaning that including the mediator in the model increased the trial arm coefficients). *Table 21* provides the coefficient for the corresponding mediator from the model that regresses the trial arm, mediator and confounders onto outcome.

Table 21 demonstrates that 5 of the 10 mediators had a statistically significant association with outcome. This indicates that there was a relationship between some of the mediators and BMI, in the expected direction (increases in weight self-efficacy, exercise self-efficacy, perception that family/friends support and encourage positive exercise habits, positive habits related to healthy eating and positive habits related to exercise were associated with decreases in BMI at 12-month follow-up), but the mediation analysis was largely unable to determine the causal mechanisms behind this relationship.

TABLE 20 Mediation for BMI measured at 12 months post randomisation

Mediator[a]	Trial arm (compared with control)	Total effect	Direct effect (not via mediator)	Indirect effect (total – direct)	Percentage of total effect through mediator
WEL	Intensive	–0.96	–0.87	–0.09	9.38
	Less intensive	–0.21	–0.25	0.04	–19.05
ESES	Intensive	–0.96	–1.13	0.17	–17.71
	Less intensive	–0.21	–0.37	0.16	–76.19
SSEH survey – sabotage domain	Intensive	–0.96	–0.99	0.03	–3.13
	Less intensive	–0.21	–0.33	0.12	–57.14
SSEH survey – encouragement domain	Intensive	–0.96	–1.19	0.23	–23.96
	Less intensive	–0.21	–0.56	0.35	–166.67
SSEX survey – participation domain	Intensive	–0.96	–1.07	0.11	–11.46
	Less intensive	–0.21	–0.65	0.44	–209.52
SSEX survey – support domain	Intensive	–0.96	–1.07	0.11	–11.46
	Less intensive	–0.21	–0.48	0.27	–128.57
TSRD – relative autonomy	Intensive	–0.96	–1.11	0.15	–15.63
	Less intensive	–0.21	–0.37	0.16	–76.19
TSRE – relative autonomy	Intensive	–0.96	–0.96	0.00	0.00
	Less intensive	–0.21	–0.44	0.23	–109.52
Self-reported habit index (diet) at 12 months	Intensive	–0.96	–0.92	–0.04	4.17
	Less intensive	–0.21	–0.42	0.21	–100.00
Self-reported habit index (exercise) at 12 months	Intensive	–0.96	–1.02	0.06	–6.25
	Less intensive	–0.21	–0.25	0.04	–19.05

ESES, Exercise Self-Efficacy Scale; SSEH, Social Support and Eating Habits; SSEX, Social Support and Exercise; TSRD, Treatment Self-Regulation Questionnaire Concerning the Motivation for Eating a Healthy Diet; TSRE, Treatment Self-Regulation Questionnaire Concerning the Motivation for Exercising Regularly; WEL, Weight Efficacy Life-Style Questionnaire.
a Mediator collected at 6-month time point unless specified otherwise.

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TABLE 21 Relationship between mediators and BMI

Mediator[a]	Coefficient[b]	Lower 95% CI	Upper 95% CI	*p*-value	Brief interpretation (as mediator increases . . .)
WEL	–0.03	–0.05	–0.02	< 0.001	BMI decreases
ESES	–0.28	–0.51	–0.05	0.015	BMI decreases
SSEH survey – sabotage domain	0.08	–0.08	0.24	0.332	
SSEH survey – encouragement domain	–0.09	–0.37	0.20	0.546	
SSEX survey – participation domain	–0.09	–0.34	0.17	0.491	
SSEX survey – support domain	–0.26	–0.48	–0.04	0.022	BMI decreases
TSRD – relative autonomy	0.06	–0.28	0.40	0.732	
TSRE – relative autonomy	–0.23	–0.56	0.11	0.185	
Self-reported habit index (diet) at 12 months	–0.49	–0.85	–0.13	0.007	BMI decreases
Self-reported habit index (exercise) at 12 months	–0.36	–0.61	–0.12	0.004	BMI decreases

ESES, Exercise Self-Efficacy Scale; SSEH, Social Support and Eating Habits; SSEX, Social Support and Exercise; WEL, Weight Efficacy Life-Style Questionnaire.

a Mediator collected at 6-month time point unless specified otherwise.

b This is the effect per unit increase in mediator on post-intervention BMI, adjusted for baseline BMI, trial arm and variables balanced on at randomisation.

Exploratory analyses

Exploratory analyses were conducted investigating binge eaters, gender and method of recruitment (*Figures 12–14*). Formal exploratory analyses investigated main effects and interaction terms with treatment arm. There was little evidence of effect, except for the group of binge eaters in the less intensive arm, who appear to have higher BMIs at follow-up than non-binge eaters in the less intensive arm; however, this is based on five participants only.

Summary

In summary, there were some promising effects of the intensive arm intervention on both BMI and weight that would be clinically important if they were shown to be true differences. There was less evidence that outcomes in the less intensive arm were different to those in the control arm. The evidence for differences between groups in secondary outcomes was less convincing, except for the DINE fat and healthy eating subscale scores and the number of days of binge eating, on which measures the intensive arm performed better than the control arm. CACE analysis revealed a slightly larger effect than the primary analysis, indicating that those who complied with the intervention had better outcomes. The mediation analysis identified five potential mediators but was not able to determine the causal mechanism behind those relationships.

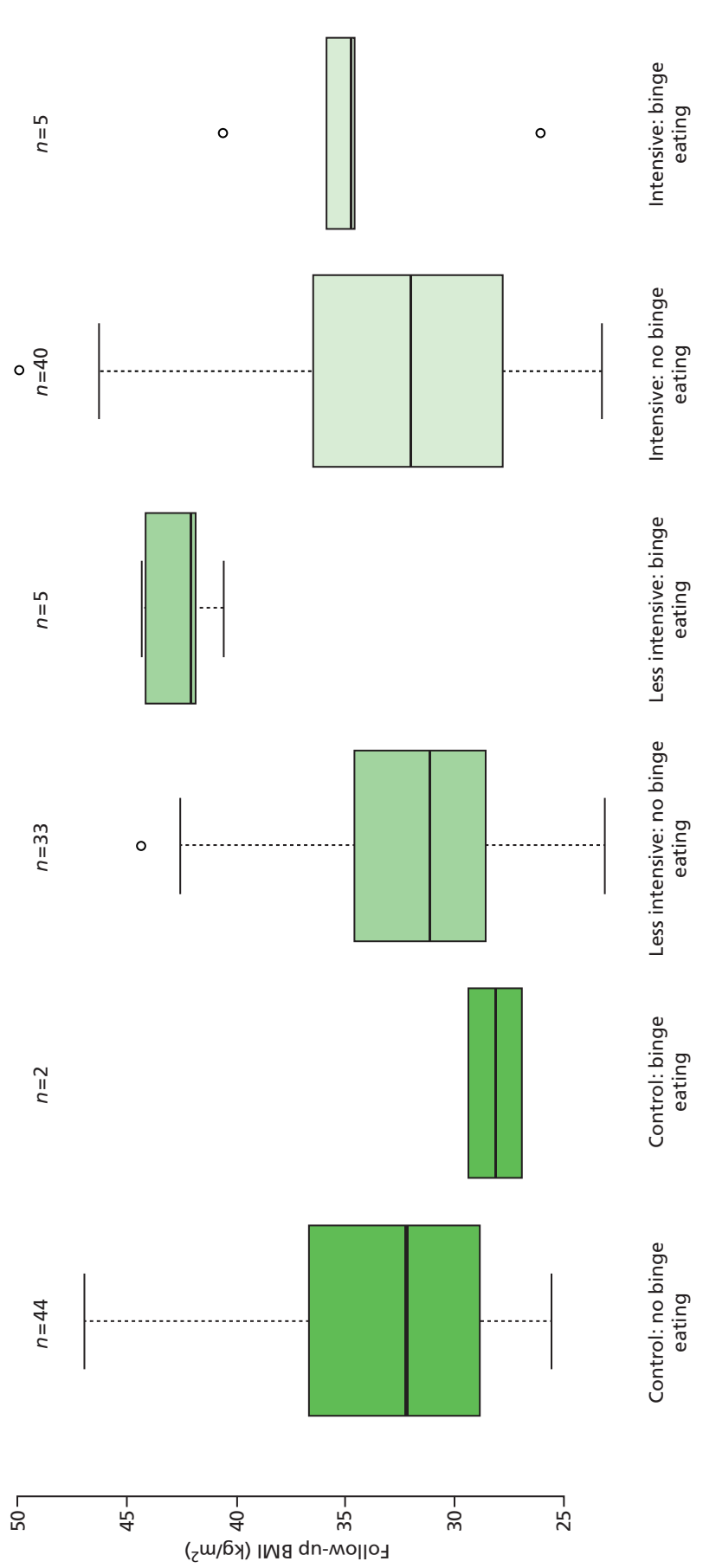


FIGURE 12 Follow-up BMI (kg/m^2) for binge eaters and non-binge eaters split by treatment arm.

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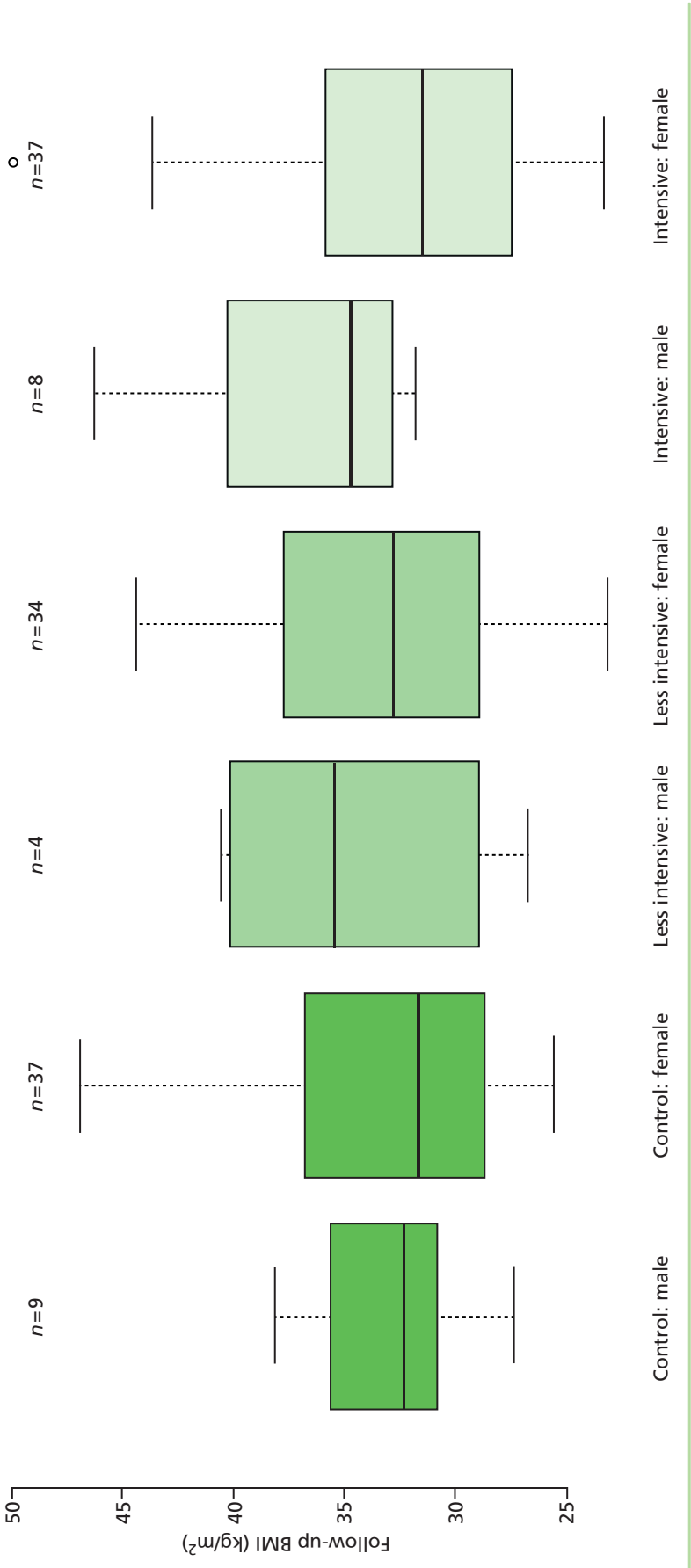


FIGURE 13 Follow-up BMI (kg/m^2) for males and females split by treatment arm.

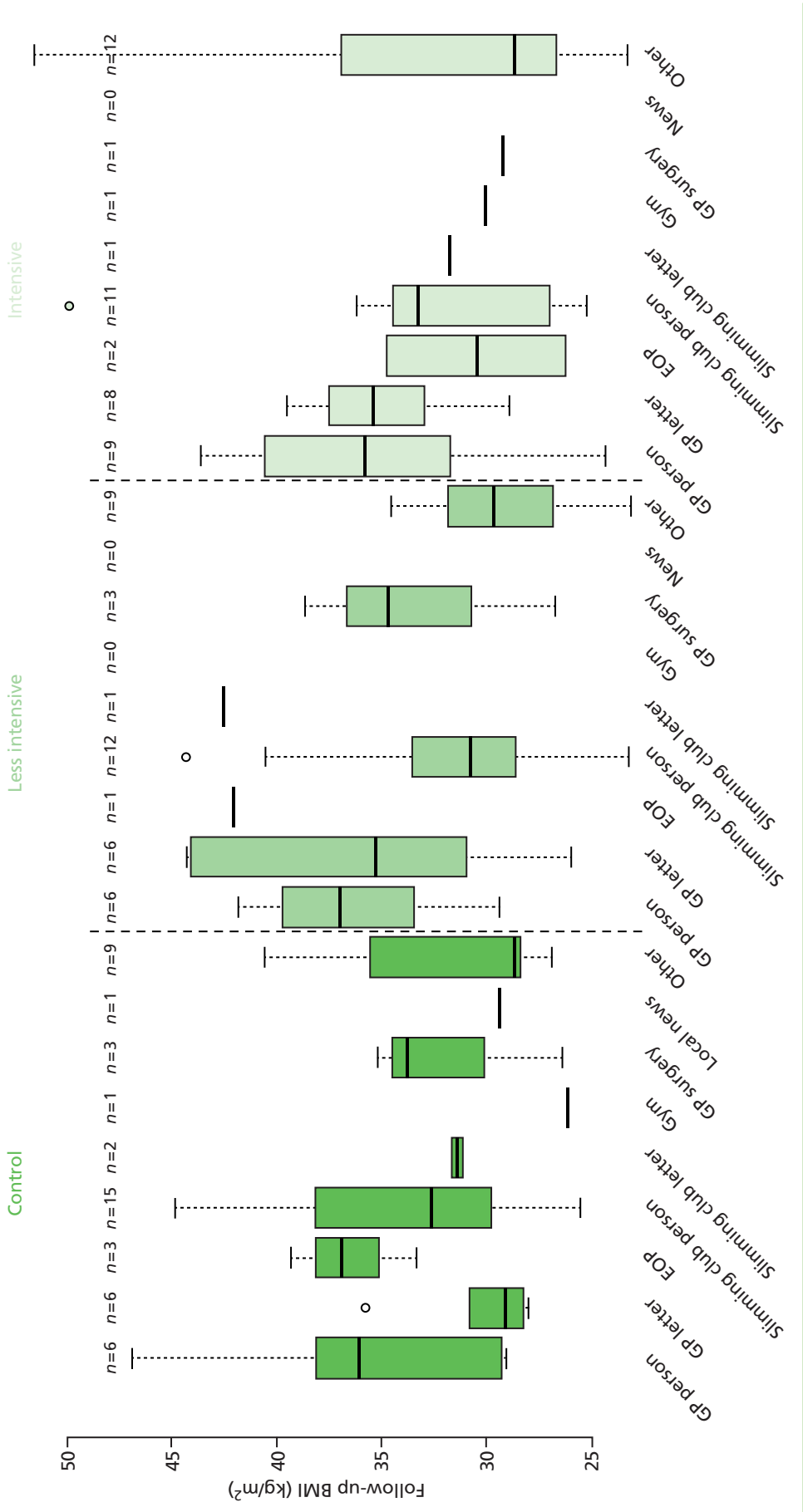


FIGURE 14 Follow-up BMI (kg/m²) for participants recruited via different routes split by treatment arm. EOP, excercise on prescription.

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Chapter 6 Process evaluation: mixed-methods results

Introduction

We conducted a process evaluation, the aims of which were to:

- assess the delivery of the intervention to ensure it was 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 MIPs' experiences of delivering the intervention
- test the logic model.

The process evaluation utilised both quantitative and qualitative data from the practitioner-held records, the website, audio-recordings of sessions and qualitative data from individual semistructured interviews with a sample of participants and focus groups (and one interviews) with MIPs.

Method

The process evaluation was conducted in line with the framework suggested by Steckler and Linnan.[135] We developed a framework (*Tables 22* and *23*) to assess eight key components of process evaluation: context, reach, fidelity, exposure, recruitment, retention, contamination and theory testing. The definition of some components is clearer than others, and there is a degree of overlap between them; each is therefore defined as used in the study in the relevant sections below. *Table 22* summarises the key sources of information used to explore these eight components. Each of these will be considered here, although for some more detailed methods and results are reported elsewhere and this is indicated when relevant.

Context

Context includes information relating to aspects of the context in which the intervention was delivered, as well as the broader context that both the practitioner and client were operating within that may influence intervention effectiveness.

This was explored by addressing who delivered the intervention and where it was delivered. We collected the curricula vitae of MIPs and GFs in order to describe the demographics and experience of intervention staff. We also kept a record of venues used for sessions. In the qualitative work we examined issues relating to circumstances, skills, training, resources, client group and recruitment context (i.e. slimming group, EOR, primary care, community), contextual barriers to attendance and delivery of the intervention, attitudes and contextual issues relating to potential roll-out. We conducted two focus groups and one interview with intervention staff and interviewed 47 participants across the three trial arms. Interviews and focus groups were analysed using thematic analysis and further details of qualitative methods and analyses is given in *Chapter 3*.

In our definition of context we also include details of where participants were recruited from and what services they continued to access throughout the trial.

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TABLE 22 Process evaluation components

Process evaluation component	Sources of information
Context	MIP and GF demographics
	Where MI was delivered
	Contextual issues explored in the focus groups and participant interviews
Reach	Attendance at the intervention sessions
	Demographics of participants compared with those not recruited
	Participant interviews
Fidelity	MITI assessment of recorded consultations at baseline
	MITI assessment of randomly selected recorded consultations
	Delivery of other intervention elements (post-session CRFs)
	Focus groups
Exposure	Attendance at intervention sessions
	MIP post-session CRFs
	Audio-recorded consultations
	Data from the WILMA trial website
	Focus groups and interviews
Recruitment	Demographics of sample compared with those approached but not recruited
	Interviews and focus groups
Retention	Dropout by trial arm
	Demographics of those dropping out compared with those remaining
	Focus groups
Contamination	Participants asked if they shared study information
	Participants asked about other services they utilised
Theory testing	Mediation analyses using questionnaire data
	Participant interviews

TABLE 23 Process evaluation model summary

Process evaluation element	Outcomes	Methods							
		Participant interviews	MIP focus groups	CRF data	QRF data	Session CRFs	MITI analysis	PIC log	MIP demographics
Fidelity	Quality of MI delivery		✓				✓		
	Are MIPs delivering the WLM and theory components?					✓	✓		
	Barriers to delivering the intervention		✓						
	Participant's understanding or experience of the intervention	✓	✓						
Exposure	Participant's satisfaction with the intervention	✓	✓						
	How much intervention exposure did participants get?	✓	✓			✓			
	Did participants implement the intervention?	✓	✓			✓			
Reach	Did the intervention reach and influence people other people?	✓							
	Did the study sample represent the population of interest?							✓	
Context	MIP differences and impact on outcomes	✓		✓	✓				
	MIP characteristics								✓
	Difficulties/issues during intervention delivery		✓						
	MIPs satisfaction with intervention implementation and study procedures?		✓						
	Under what circumstances or in which groups does the intervention work best?	✓	✓	✓	✓	✓			
Contamination	Did control group acquire study materials from intervention participants?	✓	✓						
Theory testing	Quantitative mediators not explored elsewhere			✓	✓				
	Qualitative mediators not explored elsewhere	✓	✓						

QRF, questionnaire report form.

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Reach

Reach is defined as the extent to which the target audience is reached by the intervention, as well as any 'spillover' effects on people not recruited, for example any impact on the family and friends of the participants.

We collected demographic data at baseline for all participants (see *Chapter 5*). Data on attendance at MI sessions and group sessions were collected. We also explored reach in the interviews by asking participants if they had shared any study information and whether or not receiving the intervention had any impact on family and friends such as joining in with diet or physical activities.

Fidelity

Fidelity is defined as the degree to which the MIPs and GFs delivered the intervention as intended.

We planned to improve fidelity as well as provide support for MIPs by running four workshops with specific WILMA trial-related topics and four peer group sessions, in which small groups of MIPs met up to listen to an audio-recording, share their experiences and discuss any issues that they were having. We also intended to provide feedback on four recorded sessions to prevent 'drift' in intervention delivery. For the recorded MI sessions we measured fidelity in two ways: using the MITI to assess delivery of MI and examination of the post-session CRFs to look at whether or not the five key WILMA trial 'hot' topics (diet, physical activity, self-monitoring, goal-setting and planning) were covered. The MITI rating tool comprises a number of count and score variables. 'Global' ratings are given for each of these: 'evocation', 'collaboration', 'autonomy/support', and 'direction and empathy'. These are scored on a scale from 1 to 5. Behaviour count scores are provided for 'giving information', 'MI adherent' behaviours, 'MI non-adherent' behaviours, 'closed questions', 'open questions',' simple reflections' and 'complex reflections'. MIPs can be rated as 'proficient' or 'competent' (the higher level).

A number of composite scores are calculable from these variables, including the 'global spirit' rating (which encompasses scores on evocation, collaboration, direction, empathy and 'autonomy/support'), percentage open questions, percentage complex reflections, ratio of reflections to questions and the percentage MI adherent. There is no overall score to indicate proficiency or competence incorporating all the measures; however, the MITI guidance indicates that, in order to reach proficiency in each of the measures, a practitioner must achieve an average global spirit rating of 3.5, a reflection to question ratio of at least 1, at least 50% open questions relative to all questions, at least 40% complex reflections relative to all reflections and be 90% MI adherent. To reach competency, these values are 4, 2, 70%, 50%, 100%, respectively.

Before the study started, all MIPs were assessed to ensure that they achieved at least 'proficiency' in their delivery of MI according to the MITI scale. They completed a simulated counselling session with a trained actor that was audio-recorded and later assessed independently by two expert raters for proficiency or competency. In order to assess the MI delivery accurately, four raters were trained in MITI rating over 3 days by two expert trainers. The four trained team members each rated 14 MI sessions, and each rater's scores for the 14 MI sessions were compared. The agreement level was summarised for each of the global rating scales using a Fleiss multirater kappa.[136] The behaviour counts were examined in terms of reliability (instead of agreement) using an ICC. As there are no upper limits on counts, this was explored in terms of reliability rather than agreement using an ICC.[137]

During the intervention delivery period, the MIPs were asked to record all sessions, if participants consented, with a view to collecting a minimum sample of six sessions per practitioner over the course of the study. The face-to-face MI recordings were then assessed for fidelity to MI. One MIP had no recordings and two others had only one or two recordings, respectively, so it was not possible to randomly select recordings for those practitioners. Therefore, for 12 MIPs, two recordings each were randomly selected, a stratified sample included sessions delivered in both intervention arms of the trial and across all MIPs. The counselling sessions each lasted around 60 minutes, as per the MITI manual, and 20 minutes of the session was selected for

coding in the MITI. If the consultation lasted 20 minutes or less, then the entire recording was used; if the consultation lasted more than 20 minutes, but less than 30 minutes, the middle 20 minutes were selected; and, if the consultation lasted over 30 minutes, a random 20-minute segment (excluding the first and last 5 minutes) was selected. We selected sessions using a random number generator in the R program, version 3.0.2 (The R Foundation for Statistical Computing, Vienna, Austria) language and workspace (with a seed set for reproducibility). A second random number was then generated to select which minute of the recording the rater should start from. For each of the 12 MIPs, two raters independently rated one individual consultation each for that practitioner. Therefore, each rater assessed 12 MI sessions independently, one for each of the MIPs for whom recordings were available. For the two practitioners who had insufficient sessions recorded to allow random selection, the three sessions available were assessed using MITI with a random start time selected.

The session CRFs (see *Appendix 7*) asked MIPs to rate the extent to which they discussed the different topics in each counselling session (diet, physical activity, implementation intentions or planning, goal-setting or self-monitoring) using a 10-point Likert scale. These data were summarised descriptively.

In the focus groups we explored fidelity in both telephone and face-to-face sessions. We asked MIPs whether or not they delivered the MI with fidelity, covered the hot topics and delivered anything differently or in addition to the guidance in the handbook. If there was a departure from the guidance, we asked for details and the rationale.

Exposure

Exposure is defined as the extent to which participants received and understood the different elements of the intervention and whether or not they implemented these as intended. Their satisfaction with the intervention and barriers to receipt and implementation were also considered.

There is some overlap between data analysed for exposure with those used to assess reach and fidelity. As described in *Table 22*, we collected data on attendance at face-to-face and telephone counselling sessions as well as group sessions and we audio-recorded counselling sessions which facilitated exploration of whether or not the intervention was actually delivered to participants.

We collected data from the online WILMA trial intervention to explore use of the website and the degree to which participants used it for self-monitoring. This was summarised descriptively. In the session CRFs we also asked MIPs to complete an exit appraisal for each participant, describing what went well and any problems experienced. These data were analysed by reading and rereading the practitioner comments and identifying initial themes, which were developed into broader themes that encapsulated the initial coding of the data. Finally, instances of these broader themes were counted.

In the focus groups we explored whether or not the MIPs delivered the different intervention components. In both the interviews and focus groups we asked if participants implemented different aspects of the intervention including goal-setting, making plans and self-monitoring using the website and the diary. We also explored participants' satisfaction with the intervention, attendance and barriers and facilitators to attendance.

Recruitment and retention

Detailed information on methods relating to recruitment and retention can be found in *Chapters 3* and *4*. We also explored these issues in the focus groups and participant interviews. MIPs were asked if there were any issues related to recruitment that impacted on them and also if they had any insights into why people withdrew from the counselling and/or the study. Participants were asked why they took part in the study and about their experiences of the recruitment process. We were able to interview some participants who dropped out of the intervention but, unfortunately, not those who dropped out of the study (see *Chapter 8*).

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Contamination

In the participant CRFs we assessed potential contamination between the intervention and control groups by asking participants if they knew anyone in the study and if they had shared intervention information with them. We also asked about details of all other services that control group participants accessed that might be similar in any way to the WILMA trial intervention, for example a slimming club that offered exercise and diet advice, goal-setting, etc. These data were analysed descriptively.

Theory testing

A final and key aspect of the process evaluation relates to theory testing. We developed a logic model (see *Figure 1*) that details the hypothesised processes by which the intervention brings about change. This was developed from our experiences of delivering MI in practice,[50] as well as the literature describing processes within MI. We also drew on relevant theories of behaviour change (see *Chapter 2*). The key hypothesised mediators are self-monitoring, intrinsic motivation, self-efficacy, habits and social support, which were assessed using questionnaires (see *Chapter 3*). We tested the hypothesised mediators via mediation analyses (see *Chapter 3, Main analysis*, for methods and *Chapter 5*, *Mediation analyses*, for results). We also considered goal-setting, problem-solving and planning to be important (explored below).

The intervention theory was also examined in the qualitative data. We asked participants if they discussed the different intervention elements (e.g. self-monitoring, goal-setting, planning, problem-solving) with the MIP and which aspects of the intervention they perceived as most useful or effective and which they implemented. We asked if they weighed themselves regularly (self-monitoring) and what strategies they used, and enquired about their social support as well as other factors that influenced their success at WLM.

Results

Context

Participants were recruited from primary care, EOR, Slimming World and the community. Both the intervention and control group had access to usual care during the trial. GP surgeries at this time offered variable care for weight management, which could have included lifestyle advice, referral to a dietitian, practice nurse-led clinics, EOR and, in England, referral to Weight Watchers® (New York, NY, USA), or Slimming World in some areas. The majority of our participants who attended slimming clubs attended Slimming World or Weight Watchers, and both of these clubs provide dietary and physical activity advice and social support as well as some motivational elements. The EOR scheme involved attendance at community-based sessions of supervised exercise for 16 weeks with follow-up at 8 and 12 months and did not include any dietary counselling. Participants lost weight by a variety of means in addition to the above: weight loss medication, going to the gym or increasing physical activity, calorie counting and fitness apps.

The intervention was delivered in a community setting by 15 MIPs (24 were trained but some dropped out or never saw participants) and two GFs (22 GFs were trained in total). All were employed specifically to deliver the WILMA trial intervention (see *Chapter 2*) and were trained to do this. MIPs had a variety of different professional backgrounds, including dietetics, addiction and mental health. A summary of key practitioner characteristics is given in *Table 24*. All MIPs had experience of using MI in practice, all but three were currently using MI, all were educated to at least degree level or equivalent and all but four were female.

To encourage attendance, MI sessions were delivered close to where participants lived, in a variety of settings including community centres, churches, sports centres and village halls. Many of the sessions were completed in participants' homes.

The two GFs who delivered sessions were educated to postgraduate level and had training in MI. One was currently using MI in a health-related setting. Both had experience of facilitating groups. Group sessions were also delivered in local community venues.

TABLE 24 Motivational interviewing practitioner demographics

MIP background	%	*n*
Nursing or health background	67	10
Experience of working in the field of obesity, diet or physical activity	40	6
MI trainer (higher-level MI qualification)	67	10
Currently using MI in health-related area	80	12
Counselling qualification	93	14

In the qualitative data, participants and MIPs described contextual factors that influenced the impact of the intervention. Details of this can be found in *Chapters 7* and *8*.

Reach

Participant demographics are reported in *Chapter 5*. At baseline, all but seven participants were either overweight or obese and they represent a broad demographic spread in terms of age and social class, although men and ethnic groups were under-represented. Reach of the intervention for participants was high for the face-to-face MI sessions, the key aspect of the intervention. As attendance was high, the comparison of attenders and non-attenders was not completed. Attendance at the telephone sessions was lower (see *Table 31*). In terms of reach of group sessions, owing to logistical difficulties associated with organising these groups locally, poor attendance and slow recruitment, it was not feasible to run the groups as planned and this element of the intervention was dropped.

Within the qualitative data, there was evidence that participants had shared study information with family and friends and had encouraged them to change their diet and physical activity behaviours. Others described completing dietary changes and physical activity together with friends and family (see *Chapter 8*).

Fidelity

All MIPs assessed on the MITI before commencing the study achieved proficiency, and three achieved competence (the higher level). In terms of the peer group support sessions, some of these did take place but the data we have on these are incomplete. We ran one of the workshops a few months after the MI started being delivered, but this was not repeated. The planned feedback to MIPs on audio-recording did not happen owing to the issues we had with recruitment.

The data reported here are based on the face-to-face MI sessions. There are a number of reasons for this, including that the face-to-face sessions are the heart of the intervention, the audio-recordings are better quality, and few MIPs actually recorded telephone sessions in practice, which does not facilitate selection of a random sample. Information related to group sessions is not reported because so few sessions actually took place and the team had not started the planned session observations for the purpose of assessing fidelity.

Despite much effort to encourage MIPs to record all sessions, we did not achieve the target of six for all practitioners. The reasons included participant non-consent, practitioner resistance, technical issues and practitioner forgetfulness. For the face-to-face sessions, we received 185 recordings out of a possible 393, and for the telephone sessions we received 89 (*Table 25*). Eleven out of 15 MIPs recorded 50% or more of their MI sessions. It was not possible to identify exactly how many telephone sessions MIPs delivered because we had a poor return rate for the paperwork related to the telephone sessions.

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TABLE 25 Number of recordings

MIP	Number of face-to-face recordings	Total number of face-to-face sessions	Number of telephone recordings
1	1	33	0
2	6	8	0
3	2	2	0
4	11	12	11
5	15	18	2
6	8	8	0
7	0	79	0
8	24	27	1
9	14	14	0
10	6	36	0
11	10	10	0
12	15	30	0
13	45	45	45
14	23	30	30
15	5	17	0
Total	185	393	89

We examined MITI ratings of the 14 MI sessions completed by the four members of the study team to explore agreement prior to assessing fidelity. In relation to the global ratings, *Figure 15* shows the raw data split by interview and global rating. Global ratings are in rows and interviews in columns. Each dot represents a rating by one rater. For perfect agreement straight horizontal lines would be seen in each box (lines can be any height). For example, there is perfect agreement for direction in session 12. There appears to be more agreement for some sessions than for others (e.g. for sessions 1 or 6 than for sessions 9 or 10).

Agreement was summarised for each global rating using a Fleiss multirater kappa (*Table 26*). Values further away from 0 indicate better agreement. Guidance indicates that agreement of 0.21–0.40 constitutes fair agreement between raters.[138]

In terms of the behaviour counts, as there are no upper limits, this was explored in terms of reliability rather than agreement using ICCs (*Table 27*). These analyses indicated high reliability overall, with less reliability for MI-adherent and complex reflection ratings.

The agreement and reliability ratings were considered acceptable. The next step was to assess recordings for fidelity to MI. Overall there were few MIPs failing to reach proficiency in the different aspects of the sessions rated. Out of all practitioners and all measures, in only 6% of the ratings did MIPs fail to reach proficiency. For most measures practitioners reached proficiency or competence. The non-proficient ratings were roughly evenly spread between the different measures, with three practitioners not achieving proficiency in 'global spirit', four in 'per cent complex reflections', seven in 'per cent open questions', three in 'reflection to question ratio' and four in 'per cent MI adherent'. The cut-off for per cent open questions was achieved slightly less often than the others. *Table 28* shows the mean scores for each MIP based on the ratings of the four sessions. These indicate that, overall, no MIPs failed to reach proficiency on any measure and that all MIPs reached the cut-off for competent on the globals and per cent complex reflections.

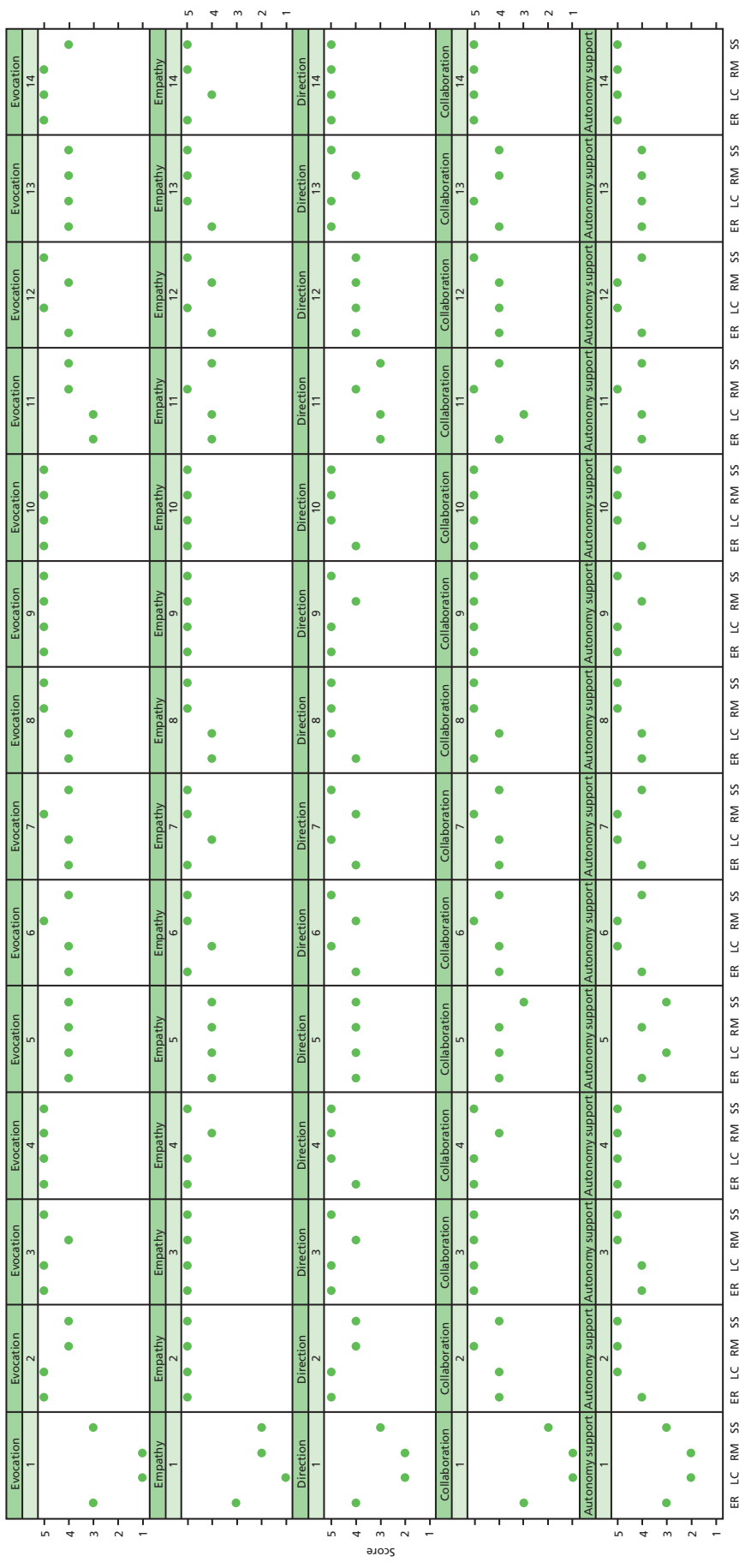


FIGURE 15 Scores for each session for each of the global ratings. Initials on *x*-axis refer to the raters.

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TABLE 26 Global ratings (kappa)

Global rating	Kappa
Evocation	0.359
Empathy	0.267
Direction	0.232
Collaboration	0.315
Autonomy/support	0.192
Overall	0.282

TABLE 27 Intracluster correlation coefficient for behaviour counts

Behaviour count	ICC
Simple reflection	0.507
Open question	0.827
MI non-adherent	0.760
MI adherent	0.218
Giving information	0.468
Complex reflection	0.191
Closed question	0.668
Overall	0.798

TABLE 28 Motivational interviewing treatment integrity ratings of sessions

MIP	Global spirit rating	Per cent complex reflections	Per cent open questions	Reflection-to-question ratio	Per cent MI adherent
1	4.8	66.8	75.5	2.7	97.8
2	4.6	74.7	75.0	2.8	94.5
3	4.1	65.6	70.8	2.2	100.0
4	4.2	57.5	57.4	2.6	100.0
5	4.6	69.3	67.9	1.6	100.0
6	4.5	67.9	68.4	2.1	100.0
7	4.3	56.2	52.4	4.2	100.0
8	4.5	71.4	60.2	1.6	96.5
9	4.3	69.1	57.8	1.8	89.3
10	4.6	59.3	63.4	1.5	100.0
11	4.8	58.9	87.9	5.4	100.0
12	4.2	59.3	67.3	1.6	91.8
13	4.9	83.5	100.0	3.0	100.0
14	5.0	62.0	47.0	1.7	100.0

For each session, practitioners were asked to rate five topics: (1) diet, (2) physical activity, (3) implementation intentions or planning, (4) goal-setting and (5) self-monitoring. This was completed using a 10-point Likert scale going from 'did not discuss' through 'talked a little about' to 'talked in detail about'. Overall, 391 session CRFs were completed. The topics most often discussed were diet, exercise, goal-setting and planning, whereas self-monitoring was discussed least (*Table 29*). However, in all sessions there was some discussion of these topics. For all topics over all sessions, the mean rating was 6 or above, which indicates that coverage of each topic was somewhere between 'talked a little about' and 'talked in detail about'.

In the practitioner focus groups, we explored (1) the extent to which they delivered the intervention according to the WILMA trial manual, (2) barriers and facilitators and (3) ways in which they may have done things differently from the manual and the reasons for this. Details of the findings can be found in *Chapter 7*.

Exposure

Attendance at face-to-face MI sessions was very high. In the intensive group, 83% attended all six MI sessions and in the less intensive arm 91% attended both sessions. Only three participants failed to attend any sessions and, of these, two informed the study team that they wished to withdraw prior to starting the intervention (*Table 30*). Attendance at telephone sessions was lower (*Table 31*), with 72 participants (67%) receiving at least one telephone call, of whom 43% were in the less intensive group and 57% in the intensive group. Overall, 53.5% of telephone sessions that should have taken place did actually take place, and the proportion was higher in the intensive intervention arm (54%) than in the less intensive arm (51%). A number of potential explanations for this lower attendance at the telephone sessions have been identified. Within the MIP focus groups the following were acknowledged: difficulty getting hold of participants, a feeling that the telephone sessions were not as useful, difficulty delivering MI over the

TABLE 29 Ratings of discussion of hot topics

Topic	Median rating	Interquartile range
Goal-setting	7	2
Planning	7	2
Self-monitoring	6	2
Physical activity	7	3
Diet	8	3

TABLE 30 Number of participants attending face-to-face sessions by trial arm

Number of sessions	Less-intensive arm	Intensive arm
0	3	0
1	2	1
2	48	4
3	1[a]	2
4	N/A	2
5	N/A	1
6	N/A	44
Total	54	54

N/A, not applicable.
a This participant received an additional session.

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TABLE 31 Number of participants attending telephone sessions by trial arm

Number of sessions	Less-intensive arm	Intensive arm
0	23	13
1	7	1
2	24	4
3	–	3
4	–	1
5	–	4
6	–	3
7	–	8
8	–	6
9	–	11
Total	54	54

telephone and low MIP motivation owing to the feeling that payment for this element was inadequate. From the participant interviews, we identified disengagement with the telephone sessions, as they were perceived as less useful than the face-to-face sessions. However, it is likely that more telephone sessions were delivered than we have a record of, as the return of paperwork for these was poor.

We defined compliance to the intervention using attendance at the face-to-face sessions, as this is the core aspect of the intervention. In order to comply with the intervention, participants in the less intensive group had to attend both face-to-face sessions and those in the intensive group had to attend at least five out of six sessions. In the less intensive group, 91% complied, and in the intensive group 83% complied, according to this definition. We also explored reasons for non-compliance with the intervention in the qualitative interviews.

Only six group sessions were actually run for a total of 15 participants. Participants were asked to attend four sessions, but only two attended four sessions and most attended two or fewer. The total number of attendances for all 15 participants was 10 in the intensive group and 18 in the less intensive group. We interviewed three participants who actually received the group intervention, two attended two sessions and one attended a single session. Further information on their views of the group sessions can be found in *Chapter 8*.

In terms of participants actually implementing the intervention elements, we asked if they regularly self-monitored their weight at baseline. In response, 90% in the control, 83% in the less-intensive and 87% in the intensive arms indicated they did. At follow-up, this was lower in all arms: 71% in the intensive, 63% in the less intensive and 68% in the control group indicated they weighed themselves at least once a week. This indicated that participants in all three arms of the trial were regularly self-monitoring their weight.

With regards to use of the online WILMA trial website, 78 (71%) participants logged onto the system. The highest number of logins by a single individual was 51; however, the majority of participants who logged in did so 10 times or fewer (51%). The median number of logins was 26 (range 1–51). With regards to self-monitoring of weight, 75 used the weight-logging facility at least once; however, most participants did this 10 times or fewer (52%). The online diary was used less often; 33 used it at least once to record diet and physical activity and the median number of entries was nine (range 1–49). Thirty-three participants in the study chose to send their weight to the study team via text message. Eight people did this only once and the median number of times that weight was sent by text message was five (range 1–37).

As well as self-monitoring, we gained insights into whether or not participants were implementing the other intervention elements (i.e. diet, physical activity, planning and goal-setting) from the qualitative interviews and the session CRFs. At the end of each counselling session the practitioners noted discussion in five key areas in the CRFs. These data are reported in the previous section, *Fidelity*. The final session CRF included a summary of how successful the MIP felt the sessions had been, challenges and barriers, and what had worked well. A summary of the key themes can be found in *Table 32*. In the majority of cases MIPs felt that participants had found the sessions useful. The most common themes were that the sessions increased motivation and provided an opportunity for reflection, feedback and support as well as to be listened to in a non-judgemental way. Issues relating to participants' mental and physical health were considered barriers to behaviour change; other barriers are listed in *Table 32*.

The interview and focus group data indicated that participants were setting goals and making plans in relation to diet and physical activity as well as regularly self-monitoring their behaviour (see *Chapters 7* and *8*).

Recruitment and retention

Data on recruitment are reported in *Chapter 5*. In the interviews we asked participants why they took part and reasons included wanting to learn how to maintain their weight, helping keep them focused on their goals, having an interest in MI and receiving long-term support or supporting research.

We assessed overall study retention by intervention or control and compared those dropping out with those remaining in the trial in terms of demographics (see *Chapter 5*). When participants withdrew from the study, they usually did not give a reason, but those who did cited the following: family illness, time, life events, working away, mental health issues, travel problems and privacy issues related to venues. Two participants felt that they were not getting anything out of the study and another felt that being in the study made her anxious. We also asked the MIPs why people dropped out: they had limited insight as to reasons for dropout, but reported life events and not wanting to complete the telephone MI (see *Chapter 8*).

Contamination

Thirty participants indicated that they knew someone else in the trial, but only 11 (10%) in the intervention arms said that they had shared study information with them (five in the intensive arm, six in the less intensive arm). Only two people in the control group said that the people they knew in the study had shared information with them. The information shared included the food diary, motivational tips and information on diet, portion size and food labelling. Only one control participant reported using this information. We suggest the impact of contamination via this route is likely to be minimal.

Access to services at which the content might overlap with the WILMA trial intervention was checked, for example slimming clubs, health clubs, gyms, swimming pools and exercise classes. We found that, at 6 months, 63% of the controls, 67% of the less intensive group and 58% of the intensive group had paid for these types of services in the previous 3 months. At 12 months, these figures were 65%, 71% and 49%, respectively. Attendance at these services was high among all groups but in the intensive group was noticeably lower at 12 months; it could be that the MI was substituting somewhat for these other services. Although these types of services can offer some elements that overlap with the WILMA trial intervention, including social support, advice on diet and physical activity, goal-setting and monitoring, they lack the key aspect of MI. As these services were frequently accessed across all arms, we feel that this is unlikely to constitute a significant source of bias.

Theory testing

We tested the hypothesised mediators via mediation analyses, the results of which are reported in *Chapter 5*. The mechanism of effect of the intervention was also explored in the participant interviews and focus groups (see *Chapters 7* and *8*).

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TABLE 32 Key themes from the final session CRFs

Theme	How often reported over all MI sessions?
Worked well	
Increased, reinforced/focused on motivation	41
Greater self-awareness/self-knowledge/insight	10
Helped clarify thoughts and feeling about weight and weight loss/renew focus on weight and importance of weight loss/helped with ambivalence	15
Space to talk/being listened to	19
Appreciated positive feedback/support	10
Client engaged well/worked hard	11
WILMA trial intervention components: self-monitoring, increased self-efficacy, client feeling better equipped to deal with lapses/setbacks; focusing on planning/implementation intentions, setting and reviewing goals and problem-solving (knowing MIP will review progress, recognising barriers, keeping goals realistic)	45
MI techniques/counselling techniques: elicit–provide–elicit ($n = 2$), importance and confidence ($n = 6$), challenging self-defeating thoughts ($n = 3$), looking at discrepancies ($n = 1$), empathic listening ($n = 1$), addressing mood ($n = 1$) and agenda setting ($n = 2$)	16
The future (preferred future and planning for the future, aims in life, challenges ahead, focus on improving health)	13
Reflective space/opportunities for reflection/reflecting on what worked well in the past/what is different this time	27
Therapeutic alliance (good rapport)	11
Recognising/reinforcing how well participant has done/focus on the positive and what has been achieved/affirmation, improved self esteem	17
Understanding links between emotions, thoughts and behaviours/underlying issues causing the behaviours/relationship with food/emotional eating	8
Lifestyle changes in diet and physical activity/increased awareness of diet/advice on diet and physical activity helpful, hearing some else's experience	14
Challenges	
Physical problems making it hard to implement diet or physical activity strategies, e.g. diabetes mellitus or joint problems	16
Challenging not being able to explore other issues (e.g. mental health) owing to time restrictions	4
Difficult family/life circumstances/stresses	6
Low mood/depression/emotional eating/other psychological issues often leading to poor control of eating and yo-yoing weight	13
Clients' lifestyle (travelling a lot, eating out)	4
Maintaining motivation	8
Condensing work into only two sessions (often not enough for people)	5
Lack of social support	4
Client time pressures/work pressures difficult to find the time	11
Low self-esteem/low confidence/ambivalence	7
Other barriers: keeping focus, telephone sessions problematic, weather, relationship with food, not enthusiastic about exercise, lack of money for healthy food and activity, difficult to achieve goals	11

Summary

The MI aspect of the intervention was successfully delivered in a community setting with trained MIPs to a group of mostly overweight or obese individuals who had a spread of different demographic characteristics. Attendance was high at the face-to-face MI sessions and overall compliance was high. There were issues with delivery of the intervention over the telephone, which included both MIPs' and participants' concerns with this medium of delivery. The intervention was delivered with good fidelity and participants seemed to have implemented many of the intervention components. The group-based part of the intervention was less successful, and the reasons for this have been outlined above. Recruitment was problematic as outlined in *Chapter 4*; however, the retention rate was high at 12 months and, as there seemed to be no systematic differences between those dropping out and those remaining in the study, it is unlikely this has biased the results. It is also unlikely that contamination was an issue, as few participants in the intervention groups indicated they had shared information with the controls.

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Chapter 7 Process evaluation: focus group results

Overview

One of the aims of the study was to explore what the MIPs' views of the WILMA trial intervention were and to understand their experiences of delivering it. Two focus groups with 11 MIPs and one interview were conducted. The MIP focus groups and interview took place following recruitment closure. At this point the majority of MIPs had completed their face-to-face sessions and were mid-way through their telephone sessions. Further details of participating MIPs' characteristics can be found in *Chapter 6*. Three MIPs were unable to attend. A focus group guide was developed to explore the MIPs experiences. This comprised 18 items and spanned four main topics (see *Appendix 6*). The focus groups lasted approximately 2 hours, while the interview lasted 1 hour. All were audio-recorded and transcribed for analysis. Further details of the methods and analysis can be found in *Chapter 3*. *Figure 16* shows a schematic overview of the analysis and *Table 33* shows an overview of the key themes from the focus groups.

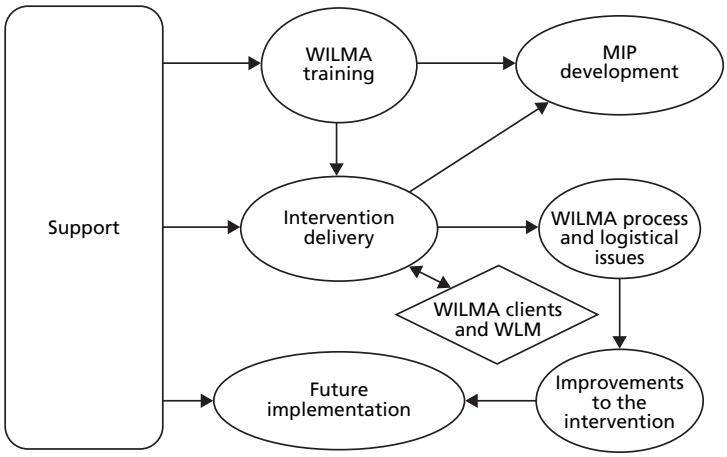


FIGURE 16 Schematic overview of focus group analysis.

TABLE 33 Overview of themes from focus groups

Overarching themes	Subthemes
WILMA trial intervention training and development	Perceptions and experiences of training
	Timing of training
Intervention delivery	Delivering within a set structure
	Intervention content
	Participation, attendance and logistics
	Impact on participants and MI for WLM
Future intervention implementation	Training improvements
	Intervention-specific improvements
	Study process improvements
	Implementation in a real-world context

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Weight Loss Maintenance in Adults trial intervention: training and development

Perceptions and experiences of training

The MIPs were trained to deliver the intervention (see *Chapter 2*). Many said that they enjoyed the training and found it useful. They felt that it was set at an appropriate level and contributed to their personal development, as they had a chance to learn new skills and assess their current skills. Moreover, they appreciated the opportunity to enhance their telephone counselling skills. As part of the training, MIPs were given guidance on delivering telephone counselling and brief (i.e. two sessions) MI. MIPs found this helpful as it differed from their normal practice.

> *The guidance on, if you had an intensive or less intensive participant (. . .), it gave me a really good idea of what was expected of me. Cos, I come from the weight loss field, where I'm not restricted on the number of appointments. Suddenly I was having to do things within a certain time frame, so it really helped me to know where I was gonna go.*
>
> *MIP4*

The WILMA trial intervention incorporated hot topics into the MI session (see *Chapter 2*). The MIPs felt that the training helped them understand how to bring these things together and allowed them to practise delivering the intervention before they saw their first participants. During training, an actor was used to portray a potential participant, MIPs did not feel that this reflected the reality of their clients and did not prepare them for the realities of working with WLM clients.

> *I think what was difficult was that the training didn't necessarily prepare me for the reality. I think that all of the different elements that were covered in the training were certainly things that I used at various points, but actually, there were things that came up in the reality of working with the clients, that I think could only have come up through experience.*
>
> *MIP3*

As part of their training, and during the intervention, the MITI coding scale was used to assess MIPs' MI skills (see *Chapter 6*). This form of assessment was new to many MIPs. They felt that it was useful and liked receiving feedback in this format. The feedback built their confidence in their MI skills and supported their professional development.

> *I've been sort of hankering for someone to do that for a long time for me, so to have the opportunity to do that was brilliant, and then to get the feedback and really specific feedback as well was fantastic.*
>
> *MIP4*

Some MIPs felt that the length of training was appropriate and equipped them with sufficient knowledge to deliver the intervention.

> *It equipped me enough to do all of the things that I needed to do for it. I didn't feel as if I went out there from the training and thought 'I don't know what I'm going to do now, I don't know where to start'.*
>
> *MIP4*

However, some felt that there was too much focus on MI skills and not enough on the weight management aspect of the intervention. Many outlined their inexperience of working with clients dealing with weight loss or maintenance.

MIPs were given a study handbook that outlined the intervention and MI aspects, issues relating to weight loss and maintenance as well as study procedures (see *Chapter 2*). However, many predominantly used the manual to consult on process issues rather than the intervention. More specifically, they referred to it when completing paperwork or answering participants' study-specific questions. It was described as being overcomplicated and could have been simplified.

> *I found it useful if a client would ask me a direct question (. . .) about the programme, what was going on. Umm, but I didn't find that I needed it actually in the sessions as it were.*
>
> *MIP10*

Timing of training

Motivational interviewing practitioner training was delivered early on and helped engage them in the study. However, owing to research governance issues, there was a 10-month delay between MIPs receiving training and seeing participants. This left them feeling less energised when the time came to deliver the intervention. A refresher session was organised; however, this took place after around half of MIPs had begun delivering the intervention.

> *At the end of the training I felt (. . .) energised. (. . .) I certainly felt excited, you know about working on the project and then there was a big gap.*
>
> *MIP3*

Intervention delivery

Delivering within a set structure

Motivational interviewing practitioners were required to deliver the intervention through both face-to-face and telephone sessions (see *Chapter 2*). They were specifically asked about their experience of delivering the telephone element, as this was a new experience for many. One MIP described the challenge of having to juggle many different things during a telephone counselling session.

> *I didn't realise how tricky this could be; listening, processing and then trying to keep it in my angle. Whilst at the same time I (. . .) was thinking 'Ok, I'm interested in finding out where, what's going on with the exercise from our last calls'. So, you know; review last goals, listen, MI, talk and then new goals. So for me that was, yeah . . . and this was my first experience of real telephone counselling.*
>
> *MIP10*

The MIPs showed a preference for the face-to-face sessions and described this style of delivery as more beneficial. It allowed for more personal interaction with the client and they considered it important for building relationships. One MIP said they found it difficult to maintain ongoing relationship over the telephone and, moreover, MIPs explained that face-to-face delivery allowed them to use non-verbal cues, which were seen as vital for counselling. Despite the drawbacks of telephone counselling, MIPs were in agreement that it can be useful under certain circumstances and that this delivery method was better than providing no counselling. One MIP explained that the focus of the telephone sessions was different to that of face to face, in that they saw this as an opportunity for participants to check in rather than deliver the full intervention. Telephone sessions were seen as useful to support participants in reviewing their goals and giving them a timeframe to achieve these.

> *I spoke to a man last week, he's just come back from Australia (. . .) and he's put on some weight, and he's, 'Right, now, by the time you phone me again, this is what I'm going to do'.*
>
> *MIP4*

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One of the MIPs was required to deliver two participants' face-to-face sessions via telephone because the participants struggled to make a face-to-face meeting. Despite acknowledging the aforementioned difficulties, this MIP felt that the 1-hour duration meant that she did not experience the same difficulties in maintaining an ongoing relationship as when delivering the standard 20-minute telephone sessions.

MIP3: *I'm puzzled that the 20-minute phone calls didn't work in the same way*

Interviewer: *oh right*

MIP3: *because when I did the face-to-face, 1-hour slots on the phone*

Interviewer: *Yeah*

MIP3: *. . . it worked like clockwork you know, people were there, they'd pick up we'd set a schedule, we'd set a time. Something about the phone calls, the 20 minute phone calls em just felt like, like an add on.*

Many MIPs found it challenging to work within a set structure and deliver according to the schedule. Some MIPs described experiences whereby they struggled to fill their 1-hour sessions, as participants did not engage fully. In these circumstances MIPs found themselves talking to participants about their wider support needs and even, in some instances, cutting sessions short. The number of sessions participants received depended on which intervention arm they were in. Many MIPs discussed the challenges of delivering a pre-set number of sessions. They expressed frustration with the design as they felt that, in some instances, participants would have benefited more from being in a different intervention arm to the one they were in.

Often it's not matched. So there's people that I've got (. . .) two phone calls over a year that really could do with one a month. (. . .) You know and it's really hard, when you've got people who've got nine that don't need them.

MIP4

The MIPs commonly expressed difficulty in delivering the less intensive intervention, as they were required to be as concise as possible. They felt they did not have time to discuss the root of participants' weight management issues and support their needs fully.

MIP15: *In a way your first session is really sort of listening most of it and trying to give them that sort of opportunity to get it all out, and then the second session would be a lot about sort of really giving them as much tools and information (. . .) ready for them to sort of go and do what they can. (. . .) You'd work (. . .) different with somebody with two than you would with six (. . .)*

Interviewer: *So was it, so more sort of focused in a way then?*

MIP15: *Yeah*

MIP10: *Can I use the word rushed!? (. . .) I'm used to working on the beginning and an ending. So I felt like I'm doing a beginning and then next time I see you I'm doing an ending. So it felt like, there's the beginning quickly saying your bit. And it's almost like 'come on, come on'. And just as the client starts to feel safe and give you stuff and you're working, it's like 'OK thanks a lot I'll speak to you in a couple of weeks'.*

Frequency of telephone sessions differed between intervention arms. For the less intensive group, the two telephone sessions were delivered 6 months apart. This gap was regarded as too long and had an impact on the MIP/participant relationship as well as the MIPs' confidence in delivering the intervention.

> *The telephone counselling, after the two sessions, was in 6 months. (. . .) So that was a long time in a way of touching base. So we felt as if it was too short.*
>
> *MIP15*

A further difficulty MIPs described included the timelines that the intervention needed to be delivered in. As a result MIPs explained the differences between their usual practice and working within a research framework.

> *I didn't stay on time track as closely as I should have…and then I remember I used to get these e-mails back to say (. . .) 'you've kind of missed your deadline'. I got a fright because I didn't actually realise there were deadlines, but of course there were and they described them in the handbook.*
>
> *MIP3*

Intervention content

Motivational interviewing practitioners were provided with a set of hot topics to address during MI sessions (see *Chapter 2*). When asked what they thought of these topics and how they used them, MIPs said that they occurred naturally throughout their sessions and were at the heart of supporting participants' weight management goals. Moreover, MIPs explained that they did not find themselves making a conscious effort to address these owing to their natural occurrence.

> *I covered them but not . . . I didn't sort of consciously work with them. I didn't sort of, you know, take them out and say 'right, today we're going to talk about such and such.'. . . em but we certainly did dip into that because those are things that you know just came up quite naturally in the conversation.*
>
> *MIP3*

However, when they were used, topics provided MIPs with a routine that ensured that all required aspects were covered.

> *You do talk about (. . .) exercise, checking about the diet you know, the self-monitoring. (. . .) There was almost a process, wasn't there?*
>
> *MIP7*

Motivational interviewing practitioners explained that they often structured sessions by revisiting participants' goals and progress since their previous session rather than using the topics specifically, stating that this felt more natural and fitted with their usual practice.

> *We'd always end the sessions with some kind of plan in moving forward (. . .) and then we'd always start the next session with some kind of 'how they'd been getting on since last time' and revisiting em those (. . .) goals that they'd set for themselves.*
>
> *MIP3*

Despite mostly positive feedback, a few MIPs commented on the fact that the information given on some of the topics was too simplistic, for example on binge eating. One MIP raised the difficulty of addressing complex topics like this within the time available to deliver the intervention.

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Participation, attendance and logistics

Participant attendance during the trial was excellent. Only on a few occasions were MIPs able to reflect on participants' reasons for non-attendance. This was mostly because of personal circumstances, a lack of interest in telephone counselling and disappointment with their allocation to the less intensive group, in which they felt they would not receive enough of the intervention to make it worth their while.

> *I had two who withdrew at that stage [phone sessions] as well. (. . .) One just said (. . .) she'd been thinking about it and she didn't want to speak on the phone, she just wasn't comfortable with it. And the other person said that (. . .) there was too much pressure. (. . .) I don't think that was the real reason, I don't know what it was. But you know, two great sessions, really useful and then, just not interested in the phone.*
>
> *MIP8*

The MIPs felt that it was important to build good rapport and relationships with clients to maintain engagement and outlined that those they found difficult to engage from the start were the ones who subsequently withdrew. Although MIPs did not experience low attendance, logistical issues preventing them from delivering sessions were more common. The most widely discussed difficulty was making contact with participants to arrange appointments, particularly for telephone sessions.

The MIPs commonly expressed the feeling that the routine of daily life conflicted with participants' engagement with the study, which was a contributing factor in the difficulties of scheduling sessions.

> *It is tricky to book a phone call and agree a phone call. (. . .) Life happens, so clients are just not there at that particular time or they've got to cancel for whatever reason, so that can be quite tricky.*
>
> *MIP10*

Moreover, one MIP described a participant's unwillingness to book sessions too far in advance. Although sympathetic, MIPs felt having to constantly chase participants to arrange appointments became an effort that was very time-consuming and carried a cost implication.

In terms of engaging participants, MIPs described surprise at their reasons for volunteering for the study. Many participants told MIPs they were taking part to support the project and help the MIPs, rather than for their own benefit, which created an extra barrier for MIPs during delivery.

> *I think one of the things that happened with some clients, [is that they] seemed to have been recruited feeling that they were doing [us] a favour, taking part in a trial. So rather than what they were getting out of it, they were here to offer something.*
>
> *MIP6 (general agreement from the group)*

A further point of discussion was that of venue choice for the sessions, which yielded a mixed response. Some MIPs chose to use local venues such as community and leisure centres recommended by the WILMA trial team, whereas others chose to travel to participants' homes. Although some MIPs provided participants with the choice of home or local venues, others steered away from visiting participants' homes as they felt that they were full of distractions.

Motivational interviewing practitioners who chose to see participants in their homes commented that this supported engagement and attendance levels, as it was innately more difficult for participants not to attend.

> *I ended up seeing nearly all of mine at home. Which, obviously you've got a captive audience then, and you know, I don't think I had any cancellations.*
>
> *MIP7*

The MIPs who used the suggested venues expressed mixed views. They commented on the unsuitability of many of them, particularly for counselling purposes.

> *I think working in sort of like community centres and leisure centres wasn't really working, I mean, my first client I saw in a basement. (. . .) I mean she was a young girl, I felt really safe, but you know when you're thinking, this is not right you know, there's no fire exit, there's no window. (. . .) This person could have an emotional breakdown and where do I go from here?*
>
> *MIP15*

However, some MIPs preferred using these as they felt that it was more appropriate to meet in a neutral environment. Moreover, once familiar with the booking process, they felt it worked well.

Impact on participants and motivational interviewing for weight loss maintenance

The MIPs reported receiving positive feedback from participants with regards to their experience of the intervention and described witnessing participants' positive development throughout sessions. In particular, MIPs commented on participants' increased self-awareness and confidence in their achievements. They described how sessions gave participants the opportunity to speak openly and be listened to. MIPs emphasised the importance of listening to participants, and it was apparent that, to them, giving participants the opportunity to speak to someone was the most important element of the intervention. However, MIPs felt that, although the aim was to deliver MI, the key techniques that participants benefited from and supported them in their goal achievement were good listening and reflection skills.

> *It's a lot about the being with the person and the listening and letting them hear back, you know. The skills of reflective listening I think comes up again and again you know, letting them hear back the type of things that they've been saying and linking everything together and seeing realisation.*
>
> *MIP4*

While MIPs discussed the participants' individual goals and achievements, many agreed that what participants gained as a whole from participation was a realisation and understanding of their achievements. In particular, MIPs discussed participants' realisation that it was OK to maintain their weight and shift their focus from wanting to keep losing weight, as maintaining was an achievement in its own right.

> *Actually happiness to recognise that; actually maintaining weight was OK. Because I think that takes a bit of a mind shift. (. . .) A lot of people have been on losing weight, actually just not gaining weight, was a real (. . .) that really shifted them, the not gaining weight and just keeping, weight, weight constant was actually could potentially be a goal within itself.*
>
> *MIP1*

A key question for the research team was whether or not MI worked within a WLM population. MIPs' responses were mixed in this regard. Some described having witnessed the positive impact of using MI with these participants. Others described participants for whom the intervention did not seem to work as they kept coming back looking for a 'magic bullet'.

> *I think (. . .) she was one of the ones that expected me to go in and tell her something new that she hadn't heard, but actually it's, it's what she knew anyway, it's about moderating your diet and regular movement basically and you know, increasing your exercise. So you know, I think she was a bit disappointed thinking that I, I was going to go there with something she'd never heard of before.*
>
> *MIP7*

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Motivational interviewing practitioners agreed that the success of using MI was reliant on the participant. If participants were already motivated and engaged, then pure MI worked really well, but this was not the case for those not at this stage. Participant engagement and a good relationship with their practitioners were seen as key for progression.

> *So, what I felt made a good session was when people would come thinking 'ooh maybe I could try that, what do you think about that?' (. . .) They were kind of really engaged in working with you. They weren't all like that.*
>
> *MIP5*

A number of MIPs said that they were unsure whether or not they delivered pure MI and that they tended to use MI as part of their overall delivery method.

> *I never do pure MI, so this is very different for me because I'm, I'm a CBT [cognitive–behavioural therapy] therapist so I use MI as part of my whole intervention. So yeah, very different to do a whole 50 minutes of MI. I'm not convinced still that I did. [Laughs.]*
>
> *MIP6*

Future intervention implementation

Training improvements

One of the most common suggestions for training improvement was to increase the number of training sessions, including a refresher session at a later date. This would have allowed more focus on study-related elements to ensure that MIPs knew what data to provide to the study team. Furthermore, it would have enabled MIPs to receive feedback after seeing participants and facilitated discussion of day-to-day issues.

> *[It] would have been good to have another sort of days training to see how we were all doing and to tweak the things that maybe we were struggling with, but it felt as if we didn't get that far.*
>
> *MIP15*

Although MIPs were originally due to receive continual feedback through regular MITI assessments, this did not occur owing to recruitment and other challenges. However, MIPs felt that further assessment and feedback on their skills during the intervention would have been valuable. This would have allowed them to reflect on their development and delivery.

> *Rather than like the first one, which was a judgement call as in 'yay or nay', I would have wanted that to be rolled in to a kind of coaching/supervision.*
>
> *MIP11*

A further suggestion was to have an additional training day for the telephone sessions. MIPs proposed that a 'role play telephone session' would have been beneficial, allowing them to practise delivering this element and adapt their practice to working with participants in the absence of non-verbal cues.

Intervention-specific improvements

In order to gain a better understanding of the strengths and weaknesses of the intervention, MIPs were asked what they thought should be changed. MIPs recognised that participants' needs varied dramatically, and this was particularly influenced by the stage of their weight management journey (weight loss vs. WLM). Owing to this large variation, MIPs felt that it was challenging to design an intervention that would

fit all people. They reiterated the struggles they had whereby some participants in the less intensive arm needed more sessions, while some of those allocated to the intensive arm did not need six face-to-face sessions. MIPs expressed the difficulty in getting at the root of participants' problems within the set number of sessions. In some cases they felt that even six sessions were not enough.

> *You could be touching on what's a much, much bigger issue which you could, you can never really address it in six sessions. It's still there and that bigger issue will come back and in a way be a problem again in the future. But whether you can extend that and talk about just the dieting, it wouldn't really address that bigger issue.*
>
> *MIP8*

They suggested that a more tailored approach is needed, in which each participant's needs are assessed and then the participant is allocated to the most appropriate arm. However, MIPs did acknowledge the difficulty of embedding this design within a randomised trial.

> *Just some degree of matching, and I know that's really hard to do in terms of a design. But I do feel that actually, (. . .) in terms of it being a realistic study, in the real world you wouldn't deliver it [makes 'rigid' sounds to indicate that a rigid approach to delivery cannot always be used and there needs to be some flexibility].*
>
> *MIP9*

It was additionally suggested that two sessions of face-to-face contact as a minimum was not sufficient. One MIP suggested using three sessions as the less intensive intervention because this would provide a better structure, consisting of a beginning, middle and end, which would allow for some progress to be made during the intervention. MIPs also outlined the difficulties of maintaining ongoing relationships when faced with large gaps between delivery time points. Although there were mixed views on the value of telephone sessions, it was suggested that increasing their duration to 1 hour might improve them.

> *The one [participant] I mentioned, I think that would have been enough two sessions and to go to, to telephone would have been fine, but if the telephone had (. . .) the same length of period of involvement, but it's done by phone and not face to face.*
>
> *MIP8*

The MIPs expressed the need for better clinical support for the duration of the project. They outlined how this would have further supported their delivery through the exchange of ideas and ongoing support. It was suggested that experts in MI for weight loss or WLM could have been recruited to the core study team and delivered the intervention to all participants. This would have allowed for a smoother delivery and increased the robustness and fidelity of the intervention as practitioner variation would have been reduced.

> *I kind of felt that I needed somebody there who'd actually tried it, you know who'd really tried it with these people, who'd sort of given it a go, who'd come back and sort of worked through some of the MI principles and said look you're going to come across this, you're going to come across that, you know this is how we, we envisage this working you know.*
>
> *MIP3*

Study process improvements

Some MIPs outlined improvements required to support them in their delivery. This was focused on having easier to use paperwork and more training on how to do this and how to use the equipment they were provided with. It was suggested that some pre-study piloting work could have been done on completing the study paperwork and session recordings.

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Implementation in a real-world context

The MIPs spent some time discussing how an intervention such as WILMA could work in practice. This included discussions around wider contextual factors as well as the practical elements of implementing it within the NHS. More specifically, they were aware of the impact that environmental factors could have on participants' motivation and success in WLM. They felt that it was particularly important to recognise that counselling may work for some but not others owing to wider environmental factors.

One factor that MIPs felt impacted on people's abilities to engage with weight management more generally was financial circumstances, which could act as a barrier or facilitator to engage with support services and activity classes. They suggested that this could have an adverse effect on the individual's motivation and engagement.

One MIP felt that it would be difficult to sustain an intervention such as WILMA on its own as further and more in-depth psychological interventions were needed to really make a difference. However, it was recognised that the issue of obesity is complex and that addressing it effectively is challenging. MIPs suggested that, in order to see real change, obesity needs to be tackled on a broader scale. An example of this was described by one MIP in relation to food banks, at which people are being taught about food to allow them to make healthier choices.

When thinking how weight management interventions might work within the NHS, MIPs recognised that much had changed in recent years. It was highlighted that it will always be difficult to increase session numbers within the NHS, despite the potential benefits.

> *It used to be we had one appointment with people and never see them again, there was no follow-up. Then it was 'oh you can have two or three appointment's' and then it was like 'it's five now'. And actually because my boss was so flexible, she knows that there is huge benefit to be had by having more and more time with these people. So I'm actually spending up to 12 to 14, maybe more than that, months with people. (. . .) It's something that I think the NHS will always want to restrict us to five appointments but with weight management I just don't think that's possible.*
>
> *MIP14*

However, it was suggested that with current NHS restructuring and increased financial autonomy within health boards/Clinical Commissioning Groups there may be some scope to allow for individual decisions to be made to support such interventions taking place.

Summary

Despite experiencing some challenges while delivering the MI sessions, MIPs were overwhelmingly positive about the intervention and they described the encouraging impact it had on participants. MIPs repeatedly highlighted the importance of an ongoing supportive relationship with clients. This allowed them to build good rapport and delve much deeper into participants' weight management issues. Furthermore, it allowed for a supportive environment in which participants could feel safe to speak openly. In terms of the practical aspects of the intervention, MIPs were particularly favourable towards face-to-face delivery; however, they felt restricted by the low number of sessions for the less intensive group and described challenges of working in this way. Furthermore, the large time gap between telephone sessions for the less intensive group was also regarded as problematic.

In terms of improvements, MIPs highlighted the importance of incorporating a further training session at a later date. Furthermore, some logistical issues were discussed, particularly around the required study paperwork and session recordings. MIPs recognised the difficulties of successfully implementing the intervention in the 'real world' as contextual and environmental factors are important influences on people's weight management. They also acknowledged the resource restrictions inherent in working within the NHS. However, they were positive about the importance of implementing such an intervention to address obesity as part of a broader strategy.

Chapter 8 Process evaluation: interview results

Overview

The participant interviews were designed to address some of the issues raised in the process evaluation (see *Chapter 6*), specifically issues pertaining to context, reach, exposure, recruitment and the psychological theory underpinning the intervention (see *Figure 1* and *Table 22*). The interviews also explored participants' views and satisfaction with the intervention as well as their experiences of weight loss and WLM.

Semistructured telephone interviews were carried out at 6 (mid-intervention) and 12 (post intervention) months. An interview schedule (see *Appendix 5*) was developed and regularly reviewed and amended. The interviews lasted between 45 and 60 minutes and were audio-recorded, transcribed and analysed using thematic analysis. There were two parts to the analyses: first, a study-specific analysis (e.g. participants' views and satisfaction with the intervention) and, second, a more general analysis exploring mediators of weight management that explored the data in relation to the underlying theory of the intervention. Further details of the methods are given in *Chapter 3*.

Results

Forty-seven participants were interviewed. Details of their characteristics are given in *Table 34*.

Quotes from participants will be identified according to identification number, group [intensive, less intensive or control (Int/LessInt/Cont)], gender (M/F) and time since randomisation (6mnth/12mnth).
A summary of key themes identified in the participant interviews can be seen in *Table 35*.

Context

Initial motivation

The most commonly reported reason for participants' weight loss was desired improved health. This was either preventative, triggered by serious health events in family members, or a response to their own long-term health issues such as diabetes mellitus, high cholesterol and arthritis. Other participants had been advised to lose weight either prior to or following surgery.

Poor self-image was also reported as a motivation for weight loss, commonly triggered by upcoming social events, such as weddings and holidays, and involved a desire to find better-fitting clothes and avoid embarrassing situations (e.g. requiring a seat belt extension on a plane). Weight loss was also perceived as facilitating a more active role in family social life, such as playing with children or grandchildren. For some participants, a sudden realisation of weight gain prompted their weight loss, which was described by one participant as 'having a light bulb moment' (0073-LessInt-F-12mnth). However, for many this was linked to an awareness of increasing age, particularly when reaching significant milestones, and the health concerns that come with ageing.

Weight loss history

Prior to entering the study, many participants had lost a substantial amount of weight, often significantly more than the required 5% eligibility threshold. Reports of lifelong struggles with weight gain were common, resulting in experiences of yo-yoing, a repeated cycle of weight loss and regain.

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TABLE 34 Characteristics of the participant interview sample

Characteristic	Control	Brief	Intensive	Total
Time of interview				
6 months	0	7	8	15
12 months	7	11	14	32
Gender				
Female	4	17	15	36
Male	3	1	7	11
Age (years)				
≤ 40	1	4	4	9
41–59	2	8	11	21
≥ 60	4	6	7	17
Recruitment source				
Slimming World	2	4	6	12
GP	2	7	5	14
EOR	0	0	1	1
Other (usually advert or poster)	3	7	10	20
Attendance level				
Attended no face-to-face sessions	N/A	0	0	0
Attended two or fewer in the intensive or one in the less intensive	N/A	1	1	2
Attended three or more in the intensive and both sessions in the less intensive	N/A	17	21	38
Total sample	7	18	22	47

N/A, not applicable.

TABLE 35 Overview of key themes from participant interviews

Overarching themes	Subthemes
Context	Initial motivation, weight loss history
Perceptions and satisfaction with the intervention	Counselling sessions
	Length and frequency of sessions
	Telephone sessions
	Session content
	Group sessions
	Online WILMA trial intervention
	Information sharing and impact of family/friends
Mediators of weight management	Ongoing motivation
	Support
	Professional
	Peer
	Family and friends
	Positive reinforcement
	A sense of achievement
	Health benefits
	Control
	Routine/habit formation
	Barriers to maintaining motivation
	Cultural attitudes
	Life events
	Adapting to weight loss

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Participants described using many different weight loss techniques including diet change, physical activity or professional support. Diet strategies included calorie counting, reducing sugar or fat intake, decreasing portion size and making healthier choices, along with various diets such as Slim Fast® (Unilever, NJ, USA). More specifically, participants reported skipping breakfast, eating little but often and having small portions during the day and a large portion for dinner. Physical activity was discussed less often than diet, with the most commonly mentioned strategy being walking. Some participants had sought professional support from their GP or a dietitian.

Perceptions and satisfaction with the intervention

The counselling sessions

The majority of participants in both intervention arms identified the counselling sessions as the best component of the study. The support provided by practitioners was in line with the professional support described in the *Mediators of weight management* section, with an emphasis on the psychological benefits of having a non-judgemental and impartial listener.

> *What was particularly good about it was the non-judgemental element of it.*
>
> *0358-Int-M-12mnth*

Participants felt that the practitioner was caring and concerned for their well-being and that they could tell them anything.

> *Well the best was that somebody was interested in, you know, your well-being and health.*
>
> *0634-Int-F-12mnth*

Participants recognised the psychological expertise provided by practitioners, which was perceived to be a valuable resource.

> *I thought they were very helpful because I know that is what I really need more of. Because as I say, a lot of my problems are psychological, and to talk to somebody who can help you on that score I think is one of the most important things of any study to do with anybody that's obese or big built.*
>
> *0080-LessInt-F-6mnth*

The counselling sessions provided a level of insight and understanding that was not gained from other sources of support such as friends or family.

> *There were a couple of things that, in talking to her, that I got to realise about those patterns of eating, about how I think about food and how I handle both the weight loss and the weight maintenance, so for me those sessions were really, really helpful.*
>
> *0073-LessInt-F-12mnth*

In addition, participants expressed an understanding of the counselling methods in that it drew them to a deeper level of understanding through the use of questioning and probing, and encouraged them to find their own solutions, giving participants greater control (described as a mediator of weight management below).

> *He was very good about not telling me things but asking me things, and asking me to formulate my own plan if you like, of how to maintain or lose more.*
>
> *0647-LessInt-F-12mnth*

Reports of increased awareness and understanding were more frequently offered by those in the intensive group, so promoting awareness and insight likely took time as the therapeutic relationships developed. It was also dependent on whether or not individuals were able to talk freely.

> *In the beginning I found it really hard, because you, you know, you've got to spill your guts, cos you've got to find out why you do what you do and it was really, really hard to do that.*
>
> *0341-Int-F-12mnth*

However, some acknowledged that it just gave them an opportunity to 'off load' (0079-Int-F-6mnth) and to have dedicated time to talk about their weight management issues and they valued the individual attention that counselling provided.

> *When you go [to] the Slimming World group you get a very short amount of time and you have to make an effort to speak to somebody on your own, whereas having that allotted time to yourself, it really helps you to talk through and explore particular issues of mine I might not have brought up in the group.*
>
> *1801-Int-F-6mnth*

Participants reported a perception of accountability on seeing the MIP, which provided additional motivation.

> *. . . that would give me motivation before he [the practitioner] came because if I lose a couple more pounds before he comes or he's going to be phoning this day so I better stick to it this week now, you know like that, like a check-up type of thing.*
>
> *2703-LessInt-F-6mnth*

However, just being part of the study gave some participants more focus on their weight management with a level of accountability inherent in the study measurements, which were, for some, the most useful aspect of the study.

As is described in the *Mediators of weight management* section, an important element of support is encouragement and positive reinforcement, and both of these needs were fulfilled by the MIPs.

> *He gave me quite a lot of help with motivation, you know, encouragement just to keep going.*
>
> *0349-LessInt-F-12mnth*

The encouragement, positive reinforcement and support provided in the counselling sessions boosted participants' confidence and increased their self-efficacy.

> *I think motivation interview made me feel quite strong in my decisions . . . it made me feel even stronger in what I was doing was the right thing for me.*
>
> *0645-LessInt-F-12mnth*

Negative views of the counselling sessions

A minority of the sample did not find the counselling sessions helpful. These tended to be either males or younger women. Some men expected the practitioner to be controlling and to drive and motivate them by setting targets, in the mode of a personal trainer.

> *He was very good for telling you if you were doing well, and 'you're doing really well and keep it going' kind of thing, but he didn't actually say 'right lets set the target'. It was you set the target.*
>
> *0076-Int-M-6mnth*

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Another dissatisfaction expressed was an expectation for more novel information with the complaint that they had not learnt anything new. When asked about the worst aspects of the study, several participants mentioned the location of the counselling sessions and travel difficulties. Conversely, participants did value practitioners making the effort to see them in their own homes.

Length and frequency of sessions

Views on the number and frequency of sessions varied. More people in the intensive group expressed satisfaction with the number of sessions, although there were still a number in the less intensive group who thought they had sufficient sessions. There was a consistent view that the number of sessions should be based on the circumstances or characteristics of the individual, or vary at different stages of the weight management journey.

> *Some people might only need three, some people might need more, it depends how quickly you can identify what your problem is and get it out and then start working your way through it.*
>
> *0341-Int-F-12mnth*

> *What I think would be better is if somebody said like 'well, if you hit crisis and if you get yourself into trouble then you can reaccess this service'. Because I, there would be no point in me having six/eight sessions if in the first few sessions I felt refocused and remotivated.*
>
> *0645-LessInt-F-12mnth*

Views on the frequency of sessions also varied. Some felt monthly sessions would allow for more time to work on their goals compared with every 2 weeks, whereas others felt they needed more regular support. It was also recognised that people attending a weight loss group get weekly support whereas those without this type of support might need counselling more frequently, again reflecting the view that it was dependent on individuals' circumstances.

The need for long-term support was also expressed by participants in the intensive group and one woman tentatively suggested that length of support was more important than frequency of sessions.

> *Maybe once a month was enough, but maybe for a longer period of time? (. . .) There's a lot of people who have lost their weight, you know, they reach goal and they stop going to class [Slimming World] and then 6 months later they're back, and they're back where they were because they've put it all back on.*
>
> *0649-Int-F-12mnth*

Telephone sessions

The majority of participants preferred the face-to-face to telephone sessions because of the availability of non-verbal cues. It was suggested that the client could be less than truthful or at least hide things from the practitioner over the telephone.

> *It's completely different being on the telephone. I suppose when you're face to face with somebody they can read your body language and you can read their body language, so in a way there isn't any hiding.*
>
> *0079-Int-F-6mnth*

It was also felt that compared with telephone calls, face-to-face sessions outside the home environment had fewer competing distractions. However, one participant preferred the telephone sessions as she was more distracted at face-to-face sessions, thinking about competing demands on her time. The acceptability of telephone sessions also depended on participants' expectations and the stage of their counselling. In-depth or very personal discussions were less acceptable over the telephone.

> *I really wasn't keen on doing it over the phone, (. . .) that was so intensely personal to me, that I just felt it was impersonal doing it on the phone.*
>
> *0645-LessInt-F-12mnth*

The fact that the telephone sessions were shorter was also not conducive to more in-depth discussion. Alternatively, if viewed as a progress 'check-in' they gave a further opportunity for accountability (described in the *Mediators of weight management* section).

> *You did look forward to the next one, just to have a check-in . . . [laugh] . . . Because you've got used to the contact and having to be responsible to somebody.*
>
> *0341-Int-F-12mnth*

Acceptability of the telephone sessions was also increased if the participant had previously met the MIP in the face-to-face sessions.

> *If it had been without having met her I'm not sure that would have been as useful (. . .) but carrying on a conversation with someone that you know quite well has been absolutely fine.*
>
> *0361-Int-F-12mnth*

Content of the counselling sessions

The MIPs were advised to address certain issues such as goal-setting, self-monitoring, encouraging social support as well as advice on diet and physical activity. Goal-setting appeared to be addressed with most participants, with varying success.

> *Most of the goals that we tried to set were exercise related (. . .) and they didn't work, and then I fail, because I failed on those. That's very demotivating.*
>
> *0649-Int-F-12mnth*

Participants did not recall self-monitoring being discussed routinely in the counselling sessions, possibly because this was a strategy participants used prior to entering the study. Some discussed frequency of self-monitoring as those who were struggling with weight management found it demotivating to weigh themselves too frequently. Coping with relapse was reported to be a major topic of the counselling sessions, including discussion of planning for occasions that were likely to be difficult.

> *But certainly the sort of the thing that I most discussed with [practitioner] was the bit about don't beat yourself up about it all the time and, sort of accept the positives (. . .) about you know your weight loss and things.*
>
> *2101-LessInt-F-6mnth*

Group sessions

Few participants had attended the group sessions before they were terminated. For those who did attend, some participants found them helpful, whereas others did not.

> *I only had three sessions with, you know, the group, but anything like that, that gets you speaking to other people is always going to be helpful.*
>
> *0051-LessInt-F-6mnth*

> *No I didn't find really anything that they had to say useful because it, there was quite a lot of negativity (. . .) about losing weight and it seemed to me that they weren't looking for a solution as much as someone waving a magic wand.*
>
> *0060-LessInt-F-12mnth*

Those who did not find the groups helpful emphasised the importance of the motivations and attitudes of group members and the facilitation skills of the group leader. This was recognised particularly by those who reported bad experiences in other weight management groups.

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There was variation in the response to cancellation of the group sessions. Some participants were very disappointed and others were disappointed but felt they got peer support through commercial weight loss groups. A minority did not feel comfortable taking part in a group or were unsure how they would feel in a group situation. A few participants pointed out that those taking part in the WILMA trial would have lost their weight using various strategies and so there might have been a good opportunity for exchange of information.

Weight Loss Maintenance in Adults online

Participants already using an alternative website tended not to make full use of the WILMA trial website, although many recorded their weekly weight as requested. There were aspects of commercial websites that participants were using that they preferred, for example they could enter half pounds, they could backdate their weight and there was more information.

However, they did acknowledge the usefulness of the website for anyone who did not use an alternative, as they felt it gave them an opportunity to monitor their progress and increased motivation by having the accountability of entering their weight on a weekly basis. The ability to enter additional comments to explain weight loss/gain was felt to be a useful monitoring tool.

> *You couldn't think 'oh well, I won't bother being careful this week' but it's because I knew I had to go on that site more or less every week and put my weight in so, it kept me on the straight and narrow. (. . .) When I'd weighed myself if I'd put on a couple of pounds I'd put a comment about why I thought I'd put it on (. . .) and you know it was handy to actually look back and see.*
>
> 2706-Int-F-6mnth

A few participants said they did not use the website frequently because of lack of time or because they forgot to use it. Others used it for a short time and then lost motivation and discontinued.

Suggestions for improvements to the website included provision of recipes and food facts, and opportunities to interact with other participants in an anonymised way. One woman had difficulties reading the font and another felt that it was a bit bland but, overall, participants felt that it was well presented.

Information sharing and impact on family and friends

The risk of contamination between groups through sharing of specific study information seemed to be low. Some participants merely disclosed that they were taking part in the study to other participants, while others reported sharing no information at all. Some information was shared with family, friends and colleagues, including information on healthy eating, portion size, food labelling, physical activity strategies, self-monitoring, coping with barriers and relapse, and the importance of looking at the bigger picture rather than short-term weight loss. It was difficult in many cases to distinguish the impact of taking part in the study on family and friends from the impact of weight management more generally. However, positive impacts on family and friends included a healthier diet and in some cases unintentional weight loss owing to the change in diet.

Family, friends and colleagues were often motivated to lose weight when they saw the participants' success, and relaying study information to family members was reported to have had a direct impact on their weight management.

> 0645-LessInt-F-12mnth: *My partner's lost 6 stone.*
>
> Interviewer: *And do you think that that's related to what you've been taking part in?*
>
> 0645-LessInt-F-12mnth: *Absolutely, no question, yeah.*

Interviewer: *And how do you think you've influenced that?*

0645-LessInt-F-12mnth: *I suppose talking to him about the motivation interviewing and making aware of that. But I suppose it's just that kind of interdependent support really.*

Participants' increased physical activity motivated other family members to be more active and produced subtle changes in family attitudes and lifestyle.

> *We'll say to the boys, 'what would you want to do?' [as a reward] And probably before it would've been 'eat something', and now it's well 'can we go out on our bikes'.*
>
> *0045-Int-F-6mnths*

A greater awareness of good nutrition also became part of family culture.

> *She's [daughter] a lovely tall, slim 5-year-old, and I, something clicked in my head and I'm going 'hang on a minute, I wasn't fat as a child, I was slim. She's going to get addicted to sugar' (. . .) and so Monday to Thursday – no chocolate, she can have a yogurt or an apple or a banana or grapes, whatever we've got home, after school. Because it was always a chocolate and can I have crisps, and it was all that kind of, salt/sugar.*
>
> *0364-LessInt-F-12mnth*

Mediators of weight management

The central category in this analysis (i.e. the category that was related to most other categories) was 'ongoing motivation', which is also key in WLM. A model is presented in *Figure 17* of the relationships found between the conceptual categories organising the data and 'ongoing motivation', the central category. Each of these categories will now be discussed in turn.

Ongoing motivation

Ongoing motivation was strongly influenced, both positively and negatively, by the type of support provided by others. Support fulfilled a number of different needs, one of which was positive reinforcement. This also had a direct link to motivation, independent of the support of others (e.g. by self-satisfaction or self-fulfilment). Other influences on motivation were 'changes in lifestyle' and 'barriers' to success (e.g. negative life events and cultural attitudes to food).

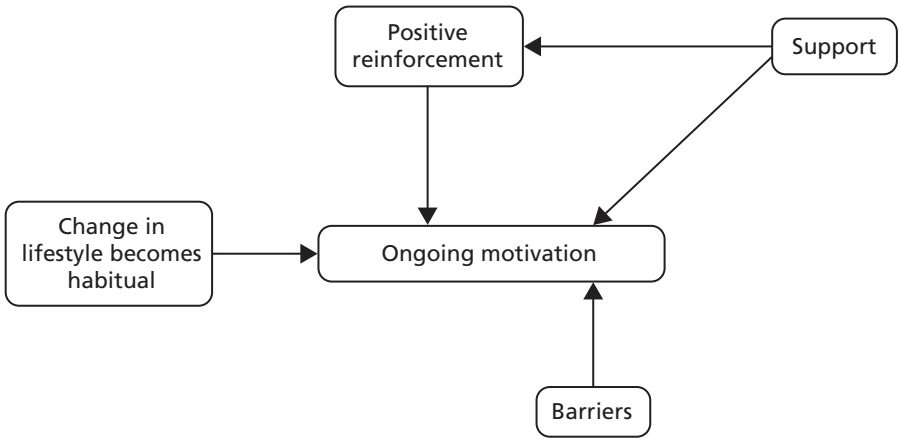


FIGURE 17 Model of mediators identified in participant interviews.

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Support

Support was felt to be important for maintaining motivation, with a view expressed that they could not lose weight 'on their own'. Support came from three different sources: professionals (including the MIPs), peer weight losers, and family and/or friends. Some aspects of support were provided by any or all of these three groups and some were particular to a certain group.

Professional support

Professional support was provided through the WILMA study (see *Chapter 2*), weight management groups such as Slimming World, and from GPs and dietitians. What participants sought from professionals was someone to listen to their issues in a caring, empathic and non-judgemental way, with psychological support being an important component and, as described in *Perceptions and satisfaction with the intervention*, the WILMA trial MIPs fulfilled these needs. Straightforward information giving was felt to be insufficient.

> *I didn't find that the GP, although they're sympathetic and they know exactly what to do, what to say; but I know what to do as well, and as far as eating and activity is concerned, but I think they need to be a lot more rigorous in their approach really and, it wasn't enough for me anyway.*
>
> *0647-LessInt-F-12mnth*

It also gave them reassurance they were not on their own.

> *You felt like, 'Christ I'm not actually on my own'.*
>
> *0068-LessInt-F-6mnth*

What was different from other types of support was the objectivity; having an independent and non-judgemental confidante with whom they could talk honestly about topics they would not address with a family member or friend. A good professional relationship facilitated motivation by instilling in participants a feeling of 'wanting to please', that is by being successful in their weight management. This was related to a need for 'accountability' whereby they were accountable to an independent party for progress. One participant expressed this as needing the 'external discipline'. This was most often provided in the current sample via weight loss groups, but could take place elsewhere, for example entering weekly weight on the website, attending the GP surgery for weigh-ins. However, there could be negative effects resulting in a minicycle of 'yo-yoing', in which participants would eat badly for a few days after their 'weigh-in' but then try and claw back their transgressions immediately prior to the next 'weigh-in'.

Peer support

Peer support was also important. This provided a more immediate source of support on a more frequent basis than that provided by professionals. In addition to weekly meetings, members of slimming groups reported telephoning, texting and e-mailing other members when they needed specific encouragement or advice, thus helping prevent relapses.

> *Everybody that wants to shares phone numbers [does], so there's always support from someone . . . somewhere, by some means. So it's, you know, even if it's (. . .) 'I'm shopping I want to buy this cream cake somebody stop me', and generally somebody does.*
>
> *0053-Cont-F-12mnth*

Again, it alleviated feelings of isolation but was distinct from other types of support because of the shared experience. It also provided a yardstick against which they could measure their own progress. When people were unsuccessful, it was reassuring that others also experienced set-backs and when people were successful, it provided a role model which had the potential to increase self-efficacy, particularly in an

environment that reinforced achievements. Experiencing success and achieving consistent weight loss appeared to be a crucial element for maintaining motivation. Peer comparisons could also be viewed in a competitive light, particularly by male participants.

> *. . . with a bit of competition, when there's like eight or ten of you in the class and I want to do the best and it's a good, good stimulus.*
>
> *0076-Int-M-6mnth*

The caring and supportive environment engendered in a cohesive weight loss group provided a sense of community that went beyond the immediate issue of weight. Members provided support to each other for life events generally, which could indirectly impact on their weight management. Participants were intrinsically motivated to attend the groups because they enjoyed the meetings on a social level and often made friends, but recognised the dual effects of having an activity they enjoyed that had a positive impact on their weight management. Friendships, however, were frequently focused on their weight management support and were not extended into other areas of their life.

Support from family and friends

Weight management provided fewer challenges if family and friends took an active part in helping promote a change in lifestyle. The most helpful scenario was when both husband and wife undertook a weight management programme together, or when a mother or sister started weight loss at the same time. Practically, the logistics of catering for a healthier eating regime was more manageable when the whole family ate the same meals, allowing the change in diet to become integrated into their lifestyle.

> *My husband, you know, will eat the same food as I do. My son actually has taken on board some of the healthier things that I've tried in the past, things like dry roast potatoes (. . .) and it's part of their lives now.*
>
> *0060-LessInt-F-12mnth*

If all the family did not eat healthy food, the participant found it difficult to resist temptation. Additional difficulties were faced if family members lacked understanding of the weight management process.

> *The first week I lost weight he bought me a big bag of Maltesers[®, Mars Inc., VA, USA] to say 'oh well done you've done really well this week', and I was like 'what are you doing, why are you doing this?'*
>
> *0045-Int-F-6mnth*

On the whole, families were supportive and provided encouragement, positive reinforcement and practical help. Friends were, perhaps, less helpful although some did go out of their way to accommodate the participant's diet. However, participants did experience situations where friends and/or family would try to persuade them to eat high-calorie foods. Whether or not participants succumbed to persuasion depended on the individual, the context and how they were feeling at the time. One woman pointed out that the responses of friends would be different if she refused to eat something because she wanted to lose weight rather than if she said she was diabetic.

> *If she'd went 'oh, [name] is dieting' they would have gone 'oh go on, one won't hurt', but because it's medical [diabetes] they went 'oh that's fine then'.*
>
> *0075-LessInt-F-6mnth*

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Positive reinforcement

A sense of achievement

As well as the positive reinforcement received from others, there was also positive reinforcement from a sense of achievement. In this regard, achieving a weight loss at the weekly slimming group 'weigh-in' was crucial in maintaining motivation and conversely seeing a gain in weight was demotivating. One woman likened a weekly weight loss to a pay day.

> *Every week going to a slimming group and losing weight, that was my sense of achievement for the week, and it was like it had all paid off, it's all been worth it, it's almost like a payday.*
>
> *0045-Int-F-6mnth*

A lack of this sense of achievement was blamed for failure to be able to maintain weight losses as the praise given to weight losers is in excess of that given to maintainers.

> *It sounds like its attention seeking but it's not, it's just, you don't feel like you're achieving anything anymore, you don't sort of get any praise for losing a pound or losing two pound (. . .) and psychologically it was harder.*
>
> *0045-Int-F-6mnth*

Health benefits

Improvements in health acted as a positive reinforcement. For some it was the relief of pain in joints from losing weight and increasing exercise, and for others it was just an increased sense of well-being when a healthy diet was maintained.

> *You do notice when you, after a day or two of eating poorly, you wake up and you feel sluggish or you have a headache and you just don't feel very good, because when you eat well you feel good.*
>
> *0355-LessInt-F-6mnth*

Others maintained motivation by reminding themselves of the potential negative health effects of being overweight, which was often reinforced by events like stroke or heart attack in family members.

Control

Having a feeling of being 'in control' was closely linked to diet and successful weight loss and was empowering for individuals and positively reinforcing in itself.

> *But I'm quite happy also not to eat tons and tons of food, in fact I'm much better when I'm in control, I feel happier more you know psychologically, I benefit from it all, I feel wonderful when I'm in control.*
>
> *2101-LessInt-F-6mnth*

Some viewed eating and weight as one thing that they could control, in the face of other more uncontrollable factors in their life, such as losing a job.

The converse of control in relation to food was likened to an addiction, and a loss of control could result in a bingeing experience. However, being too rigid about diet and continually feeling deprived meant that control was very difficult to maintain, so that failure and loss of motivation was more likely.

> *One of the things that I did when I was eating carefully was to hold a sense of, I don't know how to express it, 'I'm not allowed that, I'm depriving myself of that'(. . .) so that when I would remove that restriction (. . .) I would then have a kind of 'I can do anything I like. I can have another chocolate bar. I can have another biscuit'.*
>
> *0058-Cont-F-12mnth*

Control could be maintained by taking a more flexible approach to diet.

> *Yes that's right and cutting it [a cake] in sort of proper sizes you know instead of going and thinking 'oh blow it' and coming back and going into 'sod it' mode and just think you know . . . I'll finish the whole lot (. . .) I don't do that. We might open a bottle of wine between the two of us, but it could take us 2 or 3 days to finish it.*
>
> *0051-LessInt-F-6mnth*

In a WLM phase, continual self-monitoring gave that sense of control.

> *You know, it's a lot easier to lose 2 pound than it is 2 stone, and as long as I keep it in short bites then, I can control it a lot easier.*
>
> *0651-Cont-M-12mnth*

Routine/habit formation

To maintain motivation it was important for some participants to establish a routine with their diet and/or exercise.

> *I do have to motivate myself, but I also know if I get out of a routine it all collapses.*
>
> *0062-Int-F-12mnth*

Any change of diet and exercise required, in the first instance, conscious effort to maintain, and as the participant above (0062-Int-F-12mnth) reported, any disruption to their routine resulted in abandonment of their healthy lifestyle. It was recognised the changes need to become automatic, requiring little or no conscious effort, and to become so ingrained that it would be difficult not to do those activities.

> *On the other hand there are now a couple of ideas and a couple of habits that are so ingrained that it's more difficult to not to do them things like the portion control and like the exercise.*
>
> *0073-LessInt-F-12mnth*

In this way, the need for conscious and effortful ongoing motivation diminished over time and new habits developed.

Barriers to maintaining motivation

Cultural attitudes

Food was viewed as an integral part of peoples' pleasure in life, particularly at times of celebration such as holidays, birthdays and Christmas.

> *Yes, keeping your motivation going is really hard because there are things that happen. For a start there's things get in the way, like birthdays, Christmas, holidays.*
>
> *0068-LessInt-F-6mnth*

Within this context it was felt to be socially unacceptable to refuse food offered. Some participants went along with social expectations and ate whatever they were given, while others tried to choose the healthiest option available. Because of the strong link between food and enjoyment, friends could resent participants who chose healthy options.

> *I've got it sussed what I eat and basically one of the friends in the group turned round and said 'oh don't whinge about the food you're eating now, we're here to enjoy ourselves' (. . .) because I decided not to have a set menu and just eat the healthiest option on the menu (. . .) they made me feel rotten and it just spoilt the whole thing for me.*
>
> *0645-LessInt-F-12mnth*

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Many attitudes to both food and exercise were reported to stem from childhood.

> *I think as a child, and I had two brothers and they were quite sporty, my father used to take them to the rugby as children, take them to rugby clubs to play (. . .) and, they were encouraged to be very sporty and I don't recall as a girl, I remember staying at home with my mum. (. . .) And I don't recall ever being encouraged to be sporty.*
>
> 0355-LessInt-F-6mnth

Female participants reported having an issue with emotional eating, which was less common in males. This was linked to family attitudes because food was a cultural response to both positive and negative events, as well as being used in a nurturing and caring context.

> *If I'm upset or depressed or unhappy, I eat. And if I'm happy, we all have a good meal, you know so whatever it is, it revolves around food! (. . .) And it seems that way with my whole family.*
>
> 0355-LessInt-F-6mnth

Other beliefs, passed on through families, such as 'you should never feel hungry' or 'always eat everything on your plate' also made managing weight challenging.

> *I was taught and conditioned, not to leave anything on my plate and I still find that difficult.*
>
> 0638-Cont-M-12mnth

Some individuals were labelled as 'big' or 'big boned', which served to lower self-efficacy by convincing them that being 'big' was natural for them.

> *[I] think it was probably experience in like growing up and you know my Nan being big (. . .) and always being told by people 'oh you're big boned', and 'you're big built'. And, as a child, you know, puppy fat and you're a chubby baby, and I think you just always think you're a big person so you can't possibly maintain this.*
>
> 0045-Int-F-6mnth

Environmental context is also important here, as participants found that the availability of healthy foods was often limited in shops and restaurants.

Life events

Negative life events could create the stress necessary to trigger comfort eating, or could result in periods of depression making it difficult to focus the emotional energy required for weight management.

> *Even though I wanted to do it, it's just stuff going on in my life and I couldn't bring myself to be dieting on top of it.*
>
> 0043-Int-F-12mnth

Significant changes in life circumstances, such as retirement could either help or hinder weight management. Pregnancy and childbirth figured consistently as a life event that had negative impacts on weight management. However, life events did not necessarily lead to negative impacts on weight management if participants accepted that food was not a necessary coping mechanism.

> *I've made a huge step forward and I think 'What is eating going to do? . . . What problem will that solve?' And I think it's just a realisation that food is not the answer.*
>
> 2103-Int-F-12mnth

Adapting to weight loss

For those who were successful there could be challenges in coming to terms with a changed self-image and also the physical results of extreme weight loss, that is excess skin, which was felt to be more unattractive than fat.

> *. . . so I've got I want to say flabby bits (. . .) and I'm more ugly than seeing a fat person and I know that sounds bizarre but without being awful when I was big all those bits were filled out with fat. Now I'm skinny they jiggle about.*
>
> *0068-LessInt-F-6mnth*

Summary

Participants were generally positive about the intervention and the counselling sessions. Counselling provided support not received from other sources and participants particularly valued the psychological input. The MIPs provided encouragement and positive reinforcement, which helped boost confidence and increase self-efficacy. Face-to-face sessions were preferred over telephone sessions, although telephone sessions were felt to have their place as an opportunity to 'check in' with practitioners. Views on the number and frequency of counselling varied but it was felt that this should be based on individual needs.

In terms of the underlying theory, the central category in this analysis was 'ongoing motivation' which is crucial for WLM. This was facilitated by support from three sources: professionals, peers, and family and friends. Professional support (as given by the study practitioners) needed to be independent, non-judgemental and empathic. Peer support provided more frequent and immediate support from those with shared concerns. Support from family and friends was crucial in facilitating changes in lifestyle, in relation to both diet and exercise.

Positive reinforcement was provided by professionals, peers, and family and friends but was also acquired through a sense of achievement. Continuing success was crucial in maintaining motivation. Weight maintenance did not elicit the same levels of positive reinforcement, which made maintenance difficult. Positive reinforcement also occurred with regards to the health benefits experienced. A sense of control was also perceived as reinforcing and empowering with loss of control sometimes resulting in bingeing. In a maintenance situation, self-monitoring provided a sense of control. Participants felt that it was important for changes in lifestyle to become routine and habitual in order to be maintained. Barriers to weight management included cultural attitudes, environmental context, life events and difficulties adapting to weight loss.

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Chapter 9 Economic evaluation results

Training costs

Motivational interviewing practitioners

A total of 24 MIPs were trained through attendance at one of three seminars. Following the seminars, 20 MIPs were assessed using the MITI scale. Simulated counselling sessions were conducted between each MIP and an actor. Finally, 15 MIPs attended supervision workshops (see *Chapter 2*). The total costs incurred in all aspects of MIP training are shown in *Table 36*. Individual seminar costs varied owing to actors only being trained once and not being used in seminar 3 (other than for the MITI assessment), which was completed in a shorter time as fewer MIPs were trained and the seminar did not include the evening engagement element. Administrative costs of setting up the training seminars were not recorded. Unit costs are given in *Appendix 8*.

TABLE 36 MIP training costs

Aspects of MIP training	Number of units	Unit cost	Cost (£)
Seminar 1 (18.5 hours)			
Venue and refreshments		Amount paid	2233
Materials		Various	62
MIPs	12 × 18.5	Various[a]	6105
Trainers	4 × 18.5	Various[a]	2741
Actors training	4	Fee	800
Actors' performance	6	Fee	1800
Travel expenses (all)		Claims	171
Seminar 2 (18.5 hours)			
Venue and refreshments		Amount paid	1941
Materials		Various	30
MIPs	8 × 18.5	Various[a]	3280
Trainers	6 × 18.5	Various[a]	3935
Actors' performance	4	Fee	1200
Travel expenses (all)		Claim	255
Overnight accommodation	6	3 × 2 nights	595
Seminar 3 (8.5 hours)			
Venue and refreshments		Amount paid	100
Materials		Various	20
MIPs	4 × 8.5	Various[a]	634
Trainers[b]	4 × 8.5	Various[a]	1007
Travel expenses		Claim	0

continued

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TABLE 36 MIP training costs (*continued*)

Aspects of MIP training	Number of units	Unit cost	Cost (£)
MITI individual assessment session 1			
Venue		Amount paid	0
MIPs[c]	16 × 1	Various[a]	391
Actors	2	Fee	574
Assessors[d]	0.5 × 16	Various[a]	255
Travel expenses (all)		Claim	0
MITI individual assessment session 2			
Venue		Amount paid	150
MIPs[c]	4 × 1	Various[a]	98
Actors	1	Fee	144
Assessors[d]	4 × 0.5	Various[a]	64
Travel expenses (all)		Claim	182
MITI individual assessment session 3[e]			
Venue		Amount paid	0
MIPs[c]	2 × 1	Various[a]	49
Actors	1	WILMA trial team member	19
Assessors[d]	2 × 0.5	Various[a]	32
Travel expenses (all)		Claim	0
Supervision meeting (2 hours)			
Venue		Amount paid	0
MIPs[c]	15 × 2	Various[a]	733
Trainers[d]	4 × 2	Various[a]	255
Total MIP training costs (£)			**29,855**
Mean cost per MIP trained (£)			**1244**

a See *Appendix 8*.
b No actors were used in this seminar. One of the trainers played the role of actor.
c Average hourly cost across all MIPs used (£24.44).
d Average hourly cost across all trainers used (£31.84).
e This session was undertaken to reassess two of the MIPs who did not perform adequately on first assessment.

Group facilitators

A total of 22 GFs were trained by attending one of three seminars, which ranged from 6.26 hours to 8 hours (see *Chapter 2*). The costs incurred in GF training are shown in *Table 37*. Unit costs are given in *Appendix 8*.

TABLE 37 Group facilitator training costs

	Number of units	Unit cost	Cost (£)
Seminar 1 (8 hours)			
Venue and refreshments		Amount paid	103
Materials		Various	259
GFs	5 × 8	Various[a]	826
Trainers	3 × 8	Various[a]	760
Travel expenses (all)		Claims	10
Seminar 2 (8 hours)			
Venue and refreshments		Amount paid to venue	206
Materials		Various	49
GFs	10 × 8	Various[a]	1839
Trainers	3 × 8	Various[a]	760
Travel expenses (all)		Claims	436
Overnight accommodation	4	4 × 1 night	228
Seminar 3 (6.25 hours)			
Venue and refreshments		Amount paid	140
Materials		Various	34
GFs	7 × 6.25	Various[a]	794
Trainers	2 × 6.25	Various[a]	311
Travel expenses (all)		Claims	16
Total GF training costs (£)			**6771**
Mean cost per GF trained			**308**

a See *Appendix 8*.

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Apportioning training costs across participants receiving the Weight Loss Maintenance in Adults interventions

The total cost of training the 24 MIPs (£29,855) and the 22 GFs (£6771) was £36,626. As this investment can produce a flow of benefit over time, these costs have been amortised at 3.5% assuming a 5-year training life. The annuitised annual cost of training is £8111.

This can be expressed on a per participant basis. Assuming that all participants receive all intended face-to-face sessions, that each MIP and GF can deliver the intensive intervention to a maximum of 165 participants or the less-intensive intervention to 500 participants per year, the cost per participant attributable to training is £49 for intensive and £16 for less intensive intervention, respectively. The above estimate is based on an assumed maximum of 25 intensive sessions per week per MIP (191 participants per year) conservatively reduced by 15% to 165 participants per year.

As explained in *Chapter 3* the group sessions were shown to be unfeasible and it is recommended they be excluded from the WILMA trial intervention. Without GF training, total WILMA trial training costs are £29,855 (£6611 annuitised) or £40 per intensive participant and £13 per less intensive participant.

Given the magnitude of these costs per participant, no sensitivity analyses on training costs have been performed as they are unlikely to have any effect on overall cost differences between the three arms of the trial.

Costs of delivering the interventions

According to the WILMA trial protocol, the intensive group were to receive six face-to-face sessions, nine telephone interviews and four group sessions. The less intensive group were to receive two face-to-face sessions, two telephone interviews and four group sessions (see *Chapter 2*). All individualised elements were delivered by MIPs and group sessions were delivered by GFs.

In the event, following the change to feasibility study, only six group sessions had been delivered to a total of 15 participants (four intensive, 11 less intensive) and the sessions lasted 1.5 hours. On the same unit cost basis as for face-to-face sessions (see *Table 39*) the cost of delivering a group session was £105 per session or £630 for the six sessions.

Participants attended between one and four sessions as shown in *Table 38*. The total number of attendances by the intensive group was 10 and by the less intensive group was 18 (see *Table 38*). Dividing the total cost of delivering all sessions (£620) by the total number attending (28) produces a cost per attendance of £22.14.

For face-to-face sessions, MIP time was valued at £70 per hour including travel,[123] which is the unit cost for a 1-hour home visit by a community nurse on a salary of £32,600. This was considered appropriate as the face-to-face sessions were 1 hour, involved the MIP travelling and the median salary of the MIPs in the study was £31,248. This figure understates the £90 per face-to-face session that was paid to MIPs and included travel and time taken to write notes. The effect of varying this unit is shown in *Sensitivity analyses*.

The total costs of delivering the WILMA trial interventions are shown in *Table 39*.

On the above basis, the total cost per person receiving the WILMA trial intensive intervention was £510 and £168 for those receiving the less-intensive intervention.

TABLE 38 Numbers attending group sessions

Number of sessions attended	Intensive group	Less intensive group
1	1 × 1	6 × 1
2	1 × 2	4 × 2
3	1 × 3	0 × 3
4	1 × 4	1 × 4
Total	10	18

TABLE 39 Cost of delivering the face-to-face, telephone and group interventions

Intervention delivery elements	Intensive group ($n = 54$)	Intensive group cost (£)	Less intensive group ($n = 54$)	Less intensive group cost (£)
Face-to-face sessions[a]	275 sessions @ 1 hour	19,250	92 sessions @ 1 hour	6440
Cost of hiring the venue per session	275 sessions @ £10	2750	92 sessions @ £10	920
Telephone sessions (value of time)[b]	255 sessions @ 20 minutes	2077	55 sessions @ 20 minutes	448
Telephone (cost)	5100 minutes @ 14 ppm	714	1100 minutes @ 14 ppm	154
Group sessions (cost per attendance)	Four sessions @ £22.14	89	11 sessions @ £22.14	244
Total cost		24,880		8206
Cost per participant (excluding training)		460.74		151.96
Total cost per participant including training	@ £49	509.74	@ £16	167.96

ppm, pence per minute.
a Unit cost = £70/hour including travel.[123]
b Mean hourly unit cost across all MIPs = £24.44.

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Sensitivity analyses

Table 40 below shows the effect of varying the base-case unit costs as follows:

- Face-to-face session unit cost at fee paid to MIPs in the study (£90/hour).
- Face-to-face session unit costs reduced by 15% (£59.50/hour) on basis that lowest salary for an MIP in the study was 15% below median used in base case.
- Telephone sessions valued at median MIP unit costs (£19.84) rather than mean as unit costs for some MIPs were significantly above mean.
- Group sessions at £17.50 per attendance. While, in theory, group sessions could be given to up to 10–15 participants, in practice, this would be unlikely to exceed six given the logistics involved. With full attendance, cost per session would fall to £105 divided by six group sessions = £17.50.
- The cost of GF training and GF delivery removed as feasibility study showed group sessions to be impractical and should not form part of the WILMA trial intervention.

TABLE 40 Sensitivity analyses

Sessions and cost elements	Intensive group ($n = 54$)	Intensive group cost (£)	Less intensive group ($n = 54$)	Less intensive group cost (£)
Face-to-face sessions at amount paid to MIPs				
Sessions	275 sessions @ 1 hour	24,750	92 sessions @ 1 hour	8280
Total cost (including all other elements)		30,380		10,046
Cost per participant (including training)		611.59		202.04
Face-to-face sessions at 15% of base case				
Sessions	275 sessions @ 1 hour	16,362	92 sessions @ 1 hour	5474
Total cost (including all other elements)		21,992		7240
Cost per participant (including training)		456.26		150.07
Telephone sessions at median MIP unit cost				
Telephone sessions (value of time) @ median	255 sessions @ 20 minutes	1686	55 sessions @ 20 minutes	364
Total cost (including all other elements)		24,489		8122
Cost per participant (including training)		502.50		166.41
Group sessions assuming full attendance				
Group sessions	Four sessions @ £17.50	70	11 sessions @ £17.50	193
Total cost (including all other elements)		24,861		8155
Cost per participant (including training)		509.39		167.02
No group sessions				
Group sessions	0	0	0	0
Total cost (including all other elements)		24,791		7961
Cost per participant (excluding training)		459.09		147.43
Cost per participant including training	@ 40	499.09	@ 13	160.43

Using fees paid to MIPs increased total costs by 20% for both groups. Reducing them by 15% has reduced total costs by 10% for intensive and 11% for less intensive groups, respectively. The effect of using median rather than mean MIP unit costs is small. Although the costs of group sessions would be considerable if participants attended as per protocol, the fact that so few group sessions were delivered within the study means that the effect on total costs of removing GF training and the delivery of group sessions is small.

No participants received the full interventions per protocol. The costs reported here are as they were incurred. Although the WILMA trial was only a feasibility study, all outcomes reported here relate to effects of the interventions as received by study participants. Thus, although they cannot be related to any of the outcomes, *Table 41* indicates what it might cost to deliver the complete intensive intervention to 54 participants and the complete less intensive intervention to 54 participants assuming full participation and excluding GF training and group sessions.

TABLE 41 Cost of delivering WILMA trial interventions assuming full compliance and no group sessions

Intervention delivery elements	Intensive group ($n = 54$)	Intensive group cost (£)	Less intensive group ($n = 54$)	Less intensive group cost (£)
Face-to-face sessions	330 sessions @ 1 hour	23,100	110 sessions @ 1 hour	7700
Cost of hiring the venue per session	330 sessions @ £10	3330	110 sessions @ £10	1100
Telephone sessions (value of time)	495 sessions @ 20 minutes	4033	110 sessions @ 20 minutes	896
Telephone (cost)	9900 minutes @ 14 ppm	1386	2200 minutes @ 14 ppm	308
Total cost		31,849		10,004
Cost per participant (excluding training)		589.80		185.26
Total cost per participant including apportioned training	@ £40	629.80	@ £13	198.26

ppm, pence per minute.

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NHS resource use

Complete-case analysis of NHS resource use by the three groups and associated costs at baseline and 12-month follow-up are shown in *Tables 42* and *43*, respectively. Unit costs are shown in *Appendix 8*. Baseline resource-use data are historic and are not included in the 12-month resource-use and cost figures. At baseline, participants in the less intensive group were (historically) higher users of NHS resources. The mean cost of resource use in the 3 months preceding baseline in the less intensive group was more than double that in the control group (£137 and £58, respectively).

Costs at 12-month follow-up are reported in *Table 42*. 'Other services' refers to weight control services paid for by study participants. These data were collected to monitor whether or not the WILMA trial interventions might have been substituting for private sector weight control services. They are not included in the CEA in *Table 43*. The results show that, although the control group and less intensive groups spent roughly the same on non-NHS WLM services at baseline [mean (SD): control = £79 (£86), less intensive = £69 (£89)], expenditure after 12 months of follow-up was much lower for the controls than for the less intensive group [mean (SD): control = £81 (£62), less intensive = £121 (£126)].

Unadjusted mean differences in NHS resource use and costs are shown columns 2 and 5, respectively, in *Table 44*. Bootstrapped mean differences of the same variables adjusted for age, gender, baseline BMI and the baseline value are shown in columns 3 and 6. Bias-corrected bootstrapped 95% CIs are shown in columns 4 and 7. Total NHS costs excluding intervention costs are higher for the less intensive group and lower for the intensive group – both compared with control – but neither difference is statistically significant. When intervention costs are included, total NHS costs are statistically significantly higher for both intervention groups than controls.

TABLE 42 Mean (SD) resource use for the control, less intensive and intensive groups at baseline and 12 months post randomisation

	Control ($n = 43$)		Less intensive ($n = 39$)		Intensive ($n = 44$)	
Services	Baseline	12 months	Baseline	12 months	Baseline	12 months
GP surgery visit	0.81 (0.85)	2.30 (2.60)	2.08 (4.50)	2.28 (2.16)	0.75 (0.92)	1.68 (1.79)
Nurse surgery visit	0.63 (0.87)	1.12 (1.92)	0.51 (1.43)	0.89 (1.31)	0.52 (0.85)	0.75 (1.14)
Other HP surgery visit	0.05 (0.31)	1.09 (2.77)	0.28 (0.76)	0.41 (1.14)	0.11 (0.49)	1.41 (3.38)
GP home visit	0	0.07 (0.34)	0	0	0.05 (0.21)	0
Nurse home visit	0	0	0	0.15 (0.96)	0	0
Other HP home visit	0	0.30 (1.49)	0	0.15 (0.67)	0	0.02 (0.15)
A&E visit	0.05 (0.21)	0.28 (0.98)	0.03 (0.16)	0.21 (0.50)	0.05 (0.21)	0.07 (0.25)
Hospitalisations (number)	0	0.07 (0.26)	0.03 (0.16)	0.05 (0.22)	0.02 (0.15)	0.11 (0.39)
Inpatient days	0	0.09 (0.37)	0.08 (0.48)	0.28 (1.23)	0.02 (0.15)	0.16 (0.68)

A&E, accident and emergency.

TABLE 43 Mean (SD) costs (£) of resource use in the control, less intensive and intensive groups at baseline and 12 months post randomisation

	Control ($n = 43$)		Less intensive ($n = 39$)		Intensive ($n = 44$)	
Services	Baseline	12 months	Baseline	12 months	Baseline	12 months
GP surgery visit	35.00 (36.60)	99.00 (111.63)	89.31 (193.41)	98.13 (93.04)	32.25 (39.48)	72.32 (76.90)
Nurse surgery visit	8.60 (11.95)	15.28 (26.25)	7.02 (19.58)	12.29 (17.98)	7.16 (11.62)	10.26 (15.66)
Other HPs surgery visit	0	4.65 (16.30)	1.22 (5.81)	0	1.16 (7.69)	5.80 (26.14)
GP home visit	0	7.67 (37.15)	0	0	5.00 (23.18)	0
Nurse home visit	0	0	0	2.94 (18.36)	0	0
Other HP home visit	0	0	0	0	0	0
A&E visit	1.91 (8.74)	11.44 (40.34)	1.05 (6.56)	8.41 (19.23)	1.86 (8.64)	2.79 (10.45)
Hospitalisations	0	20.33 (80.02)	16.81 (105.01)	66.07 (289.34)	4.97 (32.95)	35.56 (153.20)
Medicines	12.63 (16.77)	19.16 (26.77)	21.35 (35.29)	40.46 (56.14)	20.01 (37.09)	36.27 (56.69)
Other services	79.00 (86.46)	80.84 (62.10)	69.27 (89.44)	120.87 (126.11)	63.75 (94.37)	79.39 (96.14)
Intervention cost (per participant)				167.96		509.74
Total NHS cost[a]	58.13 (55.36)	177.55 (174.48)	136.77 (243.85)	396.25 (359.15)	72.41 (85.55)	672.75 (233.57)

A&E, accident and emergency.
a Excludes 'other services'.

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TABLE 44 Mean difference in resource use and costs (£) between control compared with less intensive group, and control compared with intensive group at 12-months post randomisation

Services	Control vs. less intensive			Control vs. intensive		
	Unadjusted mean difference (less intensive – control)	Bootstrapped difference[a]	Bootstrapped 95% CI[b]	Unadjusted mean difference (intensive – control)	Bootstrapped difference[a]	Bootstrapped 95% CI[b]
Resource quantities						
GP visit	–0.02	–0.41	–1.55 to 0.65	–0.62	–0.69	–1.71 to 0.26
Nurse visit	–0.22	–0.14	–0.97 to 0.62	–0.37	–0.32	–1.10 to 0.36
Other HP visit	–0.68	–0.89	–2.05 to 0.14	0.32	0.24	–1.04 to 1.63
A&E visit	–0.07	–0.07	–0.54 to 0.23	–0.21	–0.22	–0.65 to 0.05
Hospitalisation (number)	–0.02	–0.03	–0.15 to 0.08	0.04	0.04	–0.14 to 0.20
Inpatient days	0.19	0.16	–0.17 to 0.55	0.07	0.05	–0.15 to 0.30
Resource costs (£)						
GP visit	–0.87	–17.82	–66.80 to 25.88	–26.68	–29.77	–72.95 to 10.04
Nurse visit	–2.99	–1.92	–12.54 to 8.00	–5.01	–4.43	–14.67 to 4.35
A&E visit	–3.03	–3.02	–21.27 to 9.40	–8.65	–9.12	–26.74 to 2.46
Hospitalisation	45.73	38.75	–36.97 to 134.89	15.22	11.76	–33.07 to 66.37
Medicines	21.30	10.76	–0.21 to 22.00	17.11	7.45	–1.89 to 16.68
Other services	40.03	38.61	–0.60 to 75.07	–1.45	1.24	–31.63 to 34.93
Total NHS costs (excludes intervention)	50.75	15.87	–89.31 to 140.19	–14.54	–25.99	–108.62 to 63.37
Total NHS Cost	215.95	183.84	80.59 to 306.72	486.82	483.75	400.96 to 568.19

A&E, accident and emergency.
a Adjusted for age, gender, baseline BMI and the baseline value of the respective variable.
b Bias-corrected 95% CI from 5000 bootstrapped samples.

Health effects and cost–utility analysis

Mean EQ-5D scores are shown in *Table 45*. The control group had slightly higher scores at baseline and this was maintained at both follow-up points.

Bootstrapped between-group differences in mean QALYs, adjusted for age, gender, baseline BMI and baseline EQ-5D are shown in *Table 46*. The adjusted differences between intervention groups and controls are small and not statistically significant.

Difference in costs and QALYs are shown in *Table 47*. The less intensive intervention is less effective and more costly, meaning that it is dominated by the control, with a negative incremental cost-effectiveness ratio (ICER) which falls in the north-west quadrant of the cost-effectiveness plane (see *Figure 18*). The intensive intervention is marginally more effective than control but more costly, producing an ICER of £483,750. These results are subject to considerable uncertainty because the differences in QALYs (see *Table 46*) are not statistically significant.

One-way sensitivity analyses

Two one-way sensitivity analyses on cost-effectiveness were undertaken to reflect two of the sensitivity analyses on costs, that is:

Sensitivity analysis 1: changing face-to-face session unit costs to reflect the amount paid to MIPs increased intervention costs from £509.74 to £662.59 (intensive) and from £167.96 to £186.04 (less intensive).

TABLE 45 Mean (SD) EQ-5D score for control, less intensive and intensive groups at baseline and 6 months and 12 months post randomisation

	Control ($n = 43$)			Less intensive ($n = 39$)			Intensive ($n = 41$)		
Measure	Baseline	6 months	12 months	Baseline	6 months	12 months	Baseline	6 months	12 months
EQ-5D	0.836 (0.18)	0.862 (0.17)	0.816 (0.18)	0.776 (0.29)	0.749 (0.32)	0.751 (0.32)	0.796 (0.21)	0.806 (0.22)	0.813 (0.18)

TABLE 46 Mean QALY gain from baseline to 12 months

	Less intensive minus controls			Intensive minus controls		
Measure	Unadjusted mean difference	Bootstrapped difference	Bootstrapped 95% CI[a]	Unadjusted mean difference	Bootstrapped difference	Bootstrapped 95% CI[a]
QALY	–0.087	–0.032[b]	–0.080 to 0.014[b]	–0.039	0.001[b]	–0.036 to 0.041[b]

a Bias-corrected 95% CI from 5000 bootstrapped samples.
b Adjusted for age, gender, baseline BMI and baseline EQ-5D.

TABLE 47 Difference in costs and QALYs: less intensive and intensive groups compared with controls

Measure	Less intensive minus control	Intensive minus control
Difference in QALYs	–0.032 (less effective)	0.001 (more effective)
Difference in costs	(More costly) £183.84	(More costly) £483.75
Cost-effectiveness	Dominated by control	ICER = £483,750

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Sensitivity analysis 2: changing face-to-face session unit costs to reflect the salary of the lowest paid MIP decreased intervention costs from £509.74 to £459.09 (intensive) and from £167.96 to £160.43 (less intensive).

Hospitalisation is a high-cost item and, as no data were collected regarding the reasons for hospitalisation, a third sensitivity analysis was undertaken.

Sensitivity analysis 3: intervention costs as in baseline analysis but hospitalisation costs removed from NHS costs.

Results of the sensitivity analyses are given in *Table 48*. In all cases the less intensive intervention remained dominated by controls and ICERs for intensive intervention all remained high.

Probabilistic sensitivity analysis

A probabilistic sensitivity analysis was carried out using a non-parametric bootstrap method, which allows both costs and QALYs to be varied from their joint distribution. The scatterplot in *Figure 18* shows the uncertainty surrounding the cost–utility of intensive versus control based on 5000 bootstrapped resamples. All points represent higher costs for the intensive intervention compared with controls, and most show reduced QALYs.

Figure 18 shows the probability of the intensive intervention being cost-effective, that is having an ICER below a range of WTP thresholds. The adjusted curve (*Figure 19*) shows only about a 9% probability that intensive intervention is cost-effective at a WTP threshold of £20,000 per additional QALY, which is the lower threshold used by NICE.

TABLE 48 Difference in costs and QALYs from one-way sensitivity analyses: less intensive and intensive groups compared with controls

Measure	Less intensive minus control	Intensive minus control
Difference in QALYs	–0.032 (less effective)	0.001 (more effective)
Difference in costs: sensitivity analysis 1	(More costly) £201.91	(More costly) £636.60
Cost–utility	Dominated by control	ICER = £636,600
Difference in costs: sensitivity analysis 2	(More costly) £176.30	(More costly) £433.10
Cost–utility	Dominated by control	ICER = £433,100
Difference in costs: sensitivity analysis 3	(More costly) £145.67	(More costly) £472.49
Cost–utility	Dominated by control	ICER = £472,490

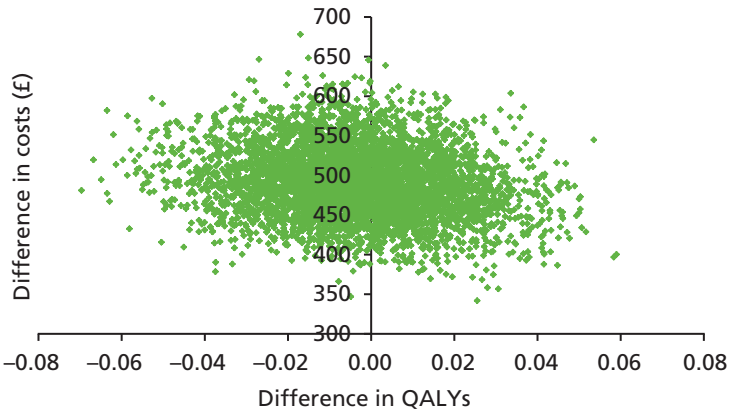


FIGURE 18 Cost-effectiveness plane for intensive intervention compared with control: adjusted QALYs and costs.

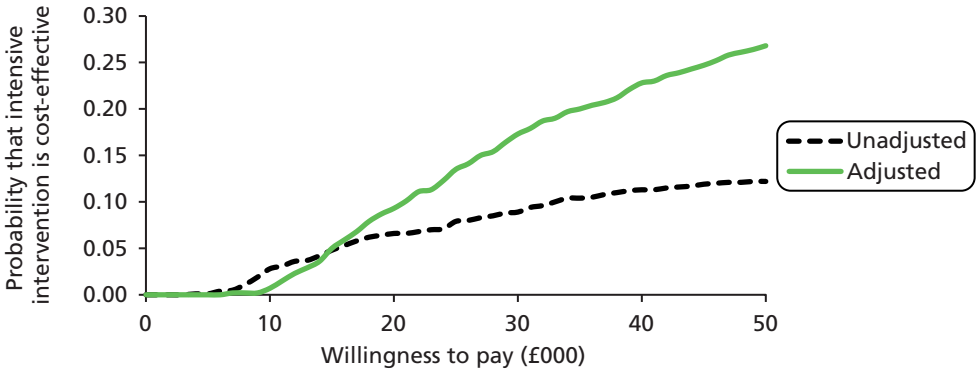


FIGURE 19 Cost-effectiveness acceptability curve for control compared with intensive: unadjusted and adjusted QALYs and costs.

Body mass index effects and cost-effectiveness analysis

Bootstrapped differences between groups in mean BMI scores, adjusted for age, gender and baseline BMI are shown in *Table 49*.

The negative adjusted differences suggest that both intervention groups show decreased BMI compared with controls at 12 months' follow-up, but the differences are small and not statistically significant.

A CEA assessing costs against the primary outcome of the study (BMI) was also undertaken. The results are shown in *Table 50*. In the cost–utility analysis above, higher QALYs reflect greater health gain. A positive effect is thus shown when the difference in QALYs is in favour of an intervention over its comparator. In the case of BMI, however, higher values reflect worse outcomes. In order to produce an ICER in which, as by convention, a positive denominator reflects a positive effect, the figures in *Table 50* are those for control minus intervention.

TABLE 49 Difference in Mean BMI at 12 months post randomisation

	Less intensive minus controls			Intensive minus controls		
Measure	Unadjusted mean difference	Bootstrapped difference	Bootstrapped 95% CI[a]	Unadjusted mean difference	Bootstrapped difference	Bootstrapped 95% CI[a]
BMI	0.75	–0.24[b]	–1.57 to 1.09[b]	0.83	–1.17[b]	–2.47 to 0.11[b]

a Bias-corrected 95% CI from 5000 bootstrapped samples.
b Adjusted for categorised age (< 30 years, 30–59 years, ≥ 60 years), gender, baseline BMI, ethnicity (white vs. non-white), method of recruitment (practices, EOR, Slimming World, other) and initial percentage weight lost (5–10% vs. > 10%).

TABLE 50 Cost-effectiveness analysis (control minus intervention)

Measure	Control minus less intensive	Control minus intensive
Difference in BMI	0.24 (more effective)	1.17 (more effective)
Difference in costs	(More costly) £183.84	(More costly) £483.75
ICER	£766.00 per unit of BMI reduction	£413.46 per unit of BMI reduction

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These results show both interventions to be more effective than controls, with the intensive intervention being more effective than the less intensive intervention. Both interventions were more costly, producing positive ICERs of £766 and £413 per unit reduction in BMI for the less intensive and intensive interventions, respectively. There was much uncertainty around these results because differences in BMI did not approach the traditional level of significance (see *Table 49*). These point estimates fall on the north-east quadrant of the cost-effectiveness plane.

Probabilistic sensitivity analysis

A probabilistic sensitivity analysis was carried out using a non-parametric bootstrap method as in the cost–utility analysis (see *Health effects and cost–utility analysis*). The scatterplot in *Figure 20* shows the joint uncertainty of costs and effects (BMI) for the intensive intervention, based on 5000 bootstrapped resamples. All replications show higher costs for the intensive intervention than for controls, with approximately 95% showing increased effect (lower BMI).

The curve in *Figure 19* shows the probability of the ICER for the intensive intervention being below the NICE WTP threshold of £20,000 per extra QALY. To repeat the exercise here would require us to predict how much the NHS would be willing to pay for a 1-kg/m^2 reduction in BMI. That figure would be only a fraction of the identified WTP threshold for an extra QALY but, in the absence of any guidance on what that figure might be, no attempt has been made here to produce a cost-effectiveness acceptability curve with respect to BMI.

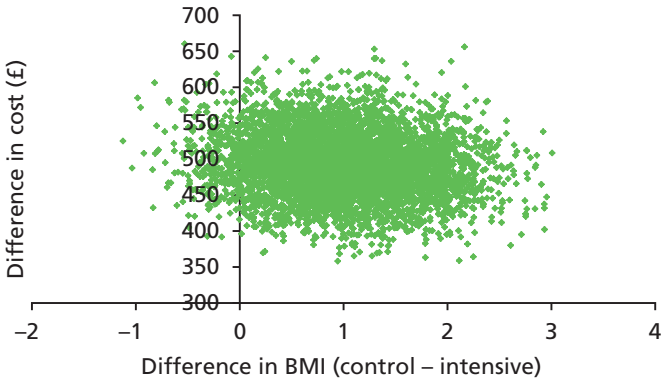


FIGURE 20 Cost-effectiveness plane for control vs. intensive: adjusted BMI and costs.

Summary

It would be inappropriate to conclude that the WILMA trial interventions are not cost-effective on the basis of the data collected in this feasibility study. Apart from the issue of the reduced sample size, the early termination of the study and the change to a feasibility trial meant that no participants received the full intervention as described in the protocol. Moreover, and perhaps more importantly, the WILMA trial is about WLM, which suggests that a much longer follow-up period (as in the initial trial) is needed to establish the effect to which weight loss is maintained in the longer term.

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Chapter 10 Discussion and conclusions

Summary of main findings

This study assessed the acceptability and feasibility of a theory-based intervention at two levels of intensity for WLM in participants who had initially lost at least 5% of their body weight. We also explored the impact of the intervention on BMI and a number of other secondary outcomes at 12 months' follow-up and assessed mediators associated with change including self-efficacy, social support, self-monitoring and action-planning (including implementation intentions), habit formation and intrinsic motivation (see *Chapter 5*). Finally, process and cost-effectiveness evaluations were also conducted.

The trial recruited 166 eligible people and follow-up rates were excellent, 84% at 6 months and 12 months. There were no systematic differences between those dropping out and those remaining in the study. Adherence to face-to-face MI was also high, 87% overall, 83% and 91% in the intensive and less intensive group, respectively. MI sessions delivered by telephone were less successful for a variety of reasons, including the logistics of arranging them and practitioner and participant concerns with this medium of delivery. The key feasibility issues related to the difficulty of delivering the group-based support sessions and also recruitment into the trial.

The three arms were broadly similar in terms of key demographics and comorbidities. More women than men were recruited, which presents a problem for future studies attempting to generalise their results to the male population. The between-group difference in mean BMI at 12 months, controlling for baseline variables, indicated that although not statistically significant, the intensive arm had a difference in BMI relative to the control group, which would be considered clinically important, that is lower by 1 kg/m^2.[11–14] This also excluded a potentially harmful effect (worse BMI than controls). The difference between the less intensive arm and controls would not be considered clinically relevant, but it was in the same direction as the intensive arm, giving some plausibility to a potential dose–response effect as was a priori predicted. The same pattern was seen with weight, with a non-significant difference between both intervention arms and control. The potential size of the effect for the intensive intervention is relatively large and likely to be clinically meaningful.[11–14] To explore the potential efficacy of the interventions, CACE analyses were conducted and indicated, after adjusting the primary analysis for compliance, that average BMI was 1.23 points lower in the intensive arm than in the control group, but this difference was not statistically significant. When using weight as the outcome, the intensive intervention led to a statistically significant lower average weight (3.7 kg).

Waist circumference showed the same pattern of slightly lower values in both intervention groups relative to controls. The proportion of weight maintainers (i.e. those whose 1-year follow-up weight was the same as or lower than their weight at baseline) was not significantly different between the intensive (56%) and control arms (46%), but a smaller proportion of the less intensive group maintained or lost weight (37%). However, the formal analysis of maintenance in this group revealed a wide CI around the odds ratio, which was nearly symmetrical at about 1 (95% CI 0.23 to 1.56), which indicates a very small effect if one exists at all. There was evidence of a statistically significant reduction in the number of days of binge eating in the intensive group (60% less than control). For the other secondary outcomes (IPAQ, GHQ-12, DINE fibre, EQ-5D, AUDIT-C, HSI), there was no evidence of any difference between groups. On the DINE questionnaire there was evidence that participants in the intensive arm reduced fat intake statistically significantly more than controls. There is some evidence that participants in the less intensive arm may have reduced fat intake more than controls, on average, but the difference was not statistically significant. In the case of the DINE healthy eating score, there was some evidence of an effect of the intervention in the intensive arm (non-significant). However, there were a considerable number of missing data for DINE and this finding may, therefore, be subject to bias.

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Interpretation of the mediation analyses results is limited by the small sample size, the absence of a statistically significant effect of the intervention on the primary outcome and the absence of any statistically significant between-group differences in the analyses of mediators. When exploring how much of the effect of the intervention on BMI is mediated by any mediator, two variables – weight self-efficacy and diet habit index – showed positive effects. Five of the 10 mediators had a statistically significant association with outcome, which indicates that there is a relationship between some of the mediators and BMI, in the expected direction (increases in weight self-efficacy, exercise self-efficacy, perception that family/friends support and encourage positive exercise habits, positive habits related to healthy eating and positive habits related to exercise are associated with decreases in BMI at the 12-month follow-up), but the mediation analysis is largely unable to determine the potential causal mechanisms behind this relationship. The intervention does not appear to have influenced these mediators; however, the analyses are likely to be underpowered.

The process evaluation sought to assess the delivery of the intervention, adherence, participants' views of the intervention, MIPs' experiences of delivering the intervention, as well as testing the logic model. The process evaluation framework assessed eight key components: context, reach, fidelity, exposure, recruitment, retention, contamination and theory testing (see *Chapter 6*). The intervention was successfully delivered in the community by trained practitioners. There was good adherence, although there were some issues with the MI delivery by telephone. Use of the website for self-monitoring was also not as high as anticipated. The face-to-face MI was delivered with good fidelity, and participants seem to have implemented at least some intervention components. There did not appear to be any issues with contamination, as few participants in the intervention group indicated they had shared information with the controls.

The MIPs were very positive about the intervention (see *Chapter 7*); however, they felt that two sessions was not enough for some participants while six sessions was too many for others and the MIPs would have preferred the number of sessions to be based on 'need' rather than chance (i.e. randomisation) as in the study. Future studies could look to accommodate this in their design, whereby the intervention arm could receive MI that is tailored by the MIP up to perhaps six sessions maximum and the data are analysed to explore dose and its relationship to outcome. They also suggested that three sessions might be better for the less intensive intervention, that the time delay between telephone sessions in the less intensive group should be shortened and that face-to-face delivery was preferable to telephone delivery. MIPs felt that participants benefited from the supportive ongoing relationship, which allowed people space to open up about their weight management issues as well as develop goals and plans to achieve them. They were very positive about implementing such an intervention in 'the real world'; however, they cautioned that wider social and environmental factors might mitigate the effect of such a brief intervention.

The interviews indicated that participants were satisfied with the intervention. They appreciated the counselling as it facilitated discussion of their weight issues in a safe, caring and non-judgemental environment. They valued the psychological expertise of the practitioners as well as the support and reinforcement, and some liked the accountability provided in seeing the MIP and felt it increased their motivation. Participants said that sessions gave them increased insight and understanding that was different from their other sources of support as well as encouragement to find their own solutions which helped boost their feelings of control in relation to weight management.

More participants in the intensive arm (than in the less intensive arm) were happy with the number of sessions and, like the MIPs, participants felt that the number of sessions should be based on the circumstances of the individual (see *Chapter 8*). The higher overall dropout in the less intensive arm could be interpreted as a lack of acceptability of the less intensive intervention. They also said that long-term support or contact was important for maintenance. Most preferred the face-to-face to the telephone sessions, as some did not like talking about personal or in-depth issues over the telephone; however, the telephone sessions were felt to be useful for 'checking in'. Participants' use of the WILMA trial website was relatively limited and this was owing to lack of time and motivation as well as their previous or ongoing

use of a commercially available alternative such as Slimming World. This type of self-monitoring via either the WILMA trial website or commercial websites was used by most participants and was a popular monitoring resource. However, use of the website tended to decline over time, which could be because either motivation declined or diet and exercise strategies became more habitual.

Some participants said that they had shared information with family and friends, and some reported a positive impact on the behaviour of family or friends. This took the form of unintentional weight losses, uptake of healthier lifestyles and greater awareness of healthy diet and exercise strategies. However, it was difficult to directly attribute the intervention itself to these changes. Reasons for not finding the sessions useful included that they were not directive enough and did not include any new information. Most participants did not get the opportunity to take part in the group sessions, but it was generally felt these would have been an important aspect of the intervention.

The qualitative data provided insights into the mediators of intervention effect. The most important was ongoing motivation, which was strongly influenced positively and negatively by the support of others including family, friends, peers and professionals. The idea of positive reinforcement, which could come from direct reinforcement from peers or family as well as just maintaining or losing weight, was also important. In this regard, self-monitoring in the form of regular self-weighing was seen as useful. Routine and habit formation were described as crucial to longer-term maintenance of healthy behaviours. Participants described a number of barriers to managing their weight, which included enviromental influences, cultural attitudes around food and eating, and significant life events.

The economic evaluation identified the total cost per person of receiving the intensive and less intensive interventions, including apportioned costs of training the MIPs and GFs, to be £510 and £168, respectively (see *Chapter 9*). Subsequent use of NHS resources was reduced in the intensive group compared with controls and increased for the less intensive group, but neither difference was statistically significant. The addition of intervention costs meant that total NHS costs were statistically significantly higher in both groups than in controls.

The cost–utility analysis indicated a small QALY gain for the intensive group (0.001) and a small QALY loss (0.032) for the less intensive group compared with controls, but neither difference was statistically significant. As total NHS costs for both intervention groups were higher than for controls, the less intensive intervention was dominated (i.e. not cost-effective) and the intensive intervention produced a positive ICER of £483,750 per additional QALY gained. Probabilistic sensitivity analysis showed the intensive intervention to have only a 9% probability of being cost-effective at the current lower NICE WTP threshold of £20,000 per extra QALY gained. The CEAs using adjusted BMI as the outcome indicated that both interventions were more effective than control, with the intensive intervention being the more effective although neither difference was statistically significant. As total NHS costs for both intervention groups were higher, both produced positive ICERs (£414 intensive, £766 less intensive) per kg/m^2 reduction in BMI.

Strengths and limitations

This feasibility trial has a number of strengths. It is the first trial of an intervention for WLM for adults in the UK and, as far as we are aware, it is one of only three trials evaluating an intervention for WLM for adults who had already lost weight before entering the study. Most other RCTs have included a weight loss element in their design. It was conducted rigorously, assessed a range of relevant outcomes and included a CEA. We combined both quantitative and qualitative methods, which provided important insights. We achieved excellent retention rates at 12 months, and excellent adherence to the key face-to-face MI element of the intervention. The study recruited a diverse range of participants from different geographical areas in Wales and a few from the East Midlands.

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We were able to conduct in-depth interviews with a large sample of participants that generated rich data on their views of the intervention as well as their general weight management experiences. We also sought the views of those delivering the intervention. Both of these are important in terms of the design of any future trial as well as potential roll-out. We developed a logic model and theory of the intervention, which was tested using both the qualitative data and mediation analyses. The measurement of mediators is rarely completed in intervention research.[91,92] We developed a detailed process evaluation framework and were careful to assess intervention fidelity. The intervention itself was delivered with good fidelity. There also did not appear to be any problems with contamination between study arms. The intervention is safe, as the single SAE reported was related to a pre-existing condition and not to the intervention.

We involved patient representatives at all stages of the trial and this has benefited not only the trial but also the other team members. The involvement of a patient representative early on in the development work proved invaluable and led to the decision to involve her as a co-applicant. Our experience with user involvement throughout the study has been very positive and we feel that it led to an enhanced study design as well as assisting us during the running of the trial. Feedback from our user representative indicated a number of pointers for future patient and public involvement. In terms of positive aspects of her experience, she felt that the team made her feel that her contribution was important and this made it easier to engage with the study and the team. She felt listened to and was asked for her opinion on all aspects of the study. When asked to review documents she felt she was never rushed and that her comments or suggestions were listened to, acted on or acknowledged and, if not instigated, the reasons were explained. She felt that her own experience of yo-yo dieting and weight control problems gave her a unique and valuable perspective on the study. In terms of areas for improvement, she suggested a more formal induction into the trials unit and the research process would be useful, as well as at the beginning a more formal introduction to the members of the trial management team and their areas of expertise. She also suggested that it would have been helpful to have more information on MI and the different behaviour change models.

The original study was an adequately powered, pragmatic RCT which aimed to evaluate the impact of the intervention on BMI at 3 years' follow-up. However, a number of issues impacted negatively on the trial, including governance and challenges related to accessing NHS costs as well as issues related to verification of 5% weight loss. We received 1284 EOIs from individuals who had heard about the study, but the majority of those were unable to provide independent evidence of 5% weight loss. Despite a comprehensive recruitment strategy, we were unable to recruit an adequate number of participants in a reasonable timescale. The governance and NHS costs issues impacted directly on our ability to recruit as we were delayed in opening the study in England by around 12 months.

Because of these difficulties, the study became a feasibility trial with a shortened follow-up of 12 months. Thus, the trial was underpowered to demonstrate effectiveness or cost-effectiveness and we are limited in our ability to draw conclusions from the quantitative analyses. For a future study, based on the results observed in this study (i.e. assuming a difference in BMI between the intensive intervention and control groups of 1 kg/m^2, a SD of 6.5 and a correlation between baseline and follow-up BMI of 0.88) and assuming we test at the 5% significance level and require 90% power, we need 201 per group for analysis. Assuming 30% attrition (over 3 years) we would need 576 in total. If the effect were halved in size over 3 years (to a difference in BMI of 0.5 kg/m^2) we would require 2292 in total for analysis. If it increased by 50% (a difference in BMI of 1.5 kg/m^2) we would require 258 in total for analysis.

The shortened follow-up did not facilitate exploration of longer-term maintenance of weight loss. We were unable to test the full intervention owing to issues with running the groups, which was partly due to slow recruitment rates. There were also some issues with delivery of the telephone MI. We were unable to recruit many men or those from lower socioeconomic groups or of ethnicities other than white British. There are therefore potential limitations to the generalisability of the results. Despite recruiting from a wide range of sources, it is likely that we recruited a non-representative group of participants. Most of the outcome measures used in the study were self-reported, and there are limitations of self-report measures,

including recall bias and under-reporting[139–141] as well as social desirability effects.[142,143] These effects are likely to be strong in these behaviours.[144,145] It is also likely that some of these measures, particularly diet and physical activity as well as some of the mediators, were not sufficiently sensitive to detect small but potentially important changes in behaviour.

Owing to uncertainty about continuation of the study, some of the 6-month follow-up interviews were delayed and were completed quite a while after the face-to-face elements of the intervention were delivered. However, they were all completed within 4–9 months of the last face-to-face MI session. This may have had an impact on the participants' ability to remember the different aspects of the intervention. As is usual in pragmatic trials, it was not possible to blind participants to treatment arm or those completing follow-up.

Although participants had used a range of strategies for their initial weight loss, there was a predominance of people who had attended weight loss groups, probably partly because of our recruitment strategies. This may have impacted on the effect of the intervention since there was overlap in approaches and aims, although those attending weight loss groups were distributed roughly evenly between control and intervention arms. This also made it difficult to attribute weight management activities and attitudes exclusively to the intervention, particularly as some participants relied on Slimming World for maintenance as well as weight loss. There was a predominance of female participants although there was evidence that men also benefited from the intervention. There did appear to be some differences in attitudes and needs between men and women, which needs further exploration. Few participants were in a purely 'maintenance' stage, with many still attempting to lose weight, and, consequently, this may have impacted on the WLM intervention.

Interpretation and comparison with previous studies

The key feasibility issue of slow recruitment is perhaps unsurprising, as issues with recruitment are common in RCTs.[146] A HTA monograph exploring this issue that examined 114 funded trials found that only 31% successfully recruited to target and 45% achieved less than 80% of the original sample size.[147] The authors also noted that it is more to difficult to recruit to target in non-drug trials. Additionally, it is likely that the rather complicated inclusion criteria, in particular the requirement of written verification of weight loss, compounded the issues we experienced with recruitment. Most of the 1284 people who expressed an interest in taking part in the trial were unable to provide written verification. We devoted a significant amount of resource to identifying potential participants with 5% weight loss from primary care and EOR, with limited success relative to effort (although primary care did provide 39% of recruits). This was primarily because records kept by GPs and EOR practitioners were not sufficient for our verification requirements. GPs often record weight but lack systematic monitoring, with the result that a 5% loss within a 12-month period is often not recorded in an easily searchable manner. Therefore, when written verification of weight loss is an entry requirement, recruitment routes linked to current or recent weight loss programmes (slimming clubs or concurrent weight loss trials) are likely to be most effective, although this may limit generalisability. In addition, delays in obtaining treatment and service support costs (particularly in England), as well as governance delays, were related to our recruitment problems. Although the landscape has changed considerably since this trial, consideration should still be given to these issues as well as to obtaining infrastructure support and how this might vary between the devolved nations.

Our reduced sample size and thus reduced power means that we are able to draw only limited conclusions about the impact of the intervention on BMI. This sample size is, however, considerably larger than many trials of WLM interventions.[148–152] In a systematic review of WLM following at least 1 month of intervention and then 1 year of no intervention, the sample sizes of the 12 included studies[152] (with 22 intervention groups)[153–169] ranged from 44[170] to 241,[171–173] with only three studies having a larger sample size than the present study. There are no studies of MI for WLM; however, in a review of studies using MI as an intervention for weight loss, only one-third of the 12 included studies had a larger sample size than the current study and the range was 22–599.[64]

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Our retention rate for the trial is excellent and compares favourably with other trials of complex behavioural interventions for weight loss or WLM, in which dropout rates can be high even at 1 year. A systematic review of long-term weight loss interventions found an average dropout of 29% at 1 year.[25] In the MI review for weight loss,[64] two-thirds of included studies had a higher dropout than the current study with a range of 8–35%; only one study had a longer follow-up than this study (18 months).[53]

With regard to the elements considered in the process evaluation, the intervention was delivered with good fidelity. There was evidence that practitioners covered the topics required by the WILMA study. The participants appeared to receive the intervention as intended because understanding of the purpose and methods of the counselling sessions was demonstrated. However, a couple of men had unfulfilled expectations of the sessions, anticipating a much more directive approach. In terms of adherence to the intervention, we had excellent adherence to the key face-to-face MI, at 87% overall. This compares favourably with adherence in other counselling-type interventions.[53,59,174] However, we did have an issue with the group-based aspect of the intervention. Delivery of local group sessions on a rolling basis did not appear to be feasible, although the low recruitment rates had an impact on the ability to run these as planned. Other, less resource-intensive and less logistically challenging, approaches to providing social support that do not depend on a minimum recruitment rate should be considered in the design of any future trial. Telephone MI sessions were also not as successful as the face-to-face MI. There were a number of reasons for this, some of which could be addressed in future studies, including more training for delivering MI over the telephone, better reimbursement for MIPs to account for time taken in arranging these sessions, longer sessions and possibly sessions closer together, particularly for those in the less intensive arm. However, it was difficult to gauge the adherence rate because of poor return of paperwork. It is likely that more of these were completed than we have records for and participants in many cases found this contact useful. Evidence also indicates the importance of ongoing contact for WLM.[38,175,176]

For a feasibility study, both the qualitative and quantitative results look encouraging. As expected, there are few statistically significant results owing to the analyses being underpowered; however, there are promising mean differences and CIs on important outcomes. The intensive arm has a consistently larger treatment effect and generally in the direction of benefit, representing a clear signal that the intensive treatment potentially leads to improvements on a wide range of health-related outcomes. This leads us to suggest that any future trial should consider comparing only the intensive intervention with a control. Although weight loss in neither treatment arm was statistically significantly different to that in the control group, the odds of maintaining weight loss was 43% higher in the intensive arm than in the control group. According to CACE analyses, the average weight loss was 3.69 kg lower in the intensive arm relative to the control group. In the case of BMI, average BMI was 1.23 kg/m^2 lower in the intensive arm relative to the control group. This compares well with other trials, and this degree of difference is likely to be clinically significant in this group of individuals, many of whom are probably at increased risk of cardiovascular disease. Several studies indicate that loss of 2–5 kg weight can lead to reductions in cardiovascular risk factors.[11–14,177] In a trial of MI delivered in five sessions in primary care, the mean difference in BMI between the intervention and control groups was 0.36 kg/m^2 at 12 months (from end of intervention) and 0.1 kg/m^2 at 6 months.[178] A recent systematic review of trials of behavioural interventions (focusing on diet and physical activity) to help individuals maintain weight loss found an average weight difference of –1.56 kg in weight regain relative to controls at the 12-month follow-up.[35] If the findings in this study were true differences, then this compares favourably with other trials. The Barte *et al.*[152] systematic review of 12 studies found that the percentage of initial weight loss that was maintained after 1 year's unsupervised follow-up ranged from 25% to 88% and the average was 54%. Four of these studies had an intervention period of 3 months or less, so were similar in length of follow-up to this study. This percentage maintenance has also been found in other systematic reviews[20,149] that have reported 50% maintenance at 1 year post intervention.

With regard to the other secondary outcomes, there are few indications of an effect from the intervention, with the exception of the DINE fat and healthy eating scores and the number of days of binge eating. However, there are issues with the sensitivity of the measures to detect an effect, and measuring physical activity and diet accurately are particularly problematic.[179,180]

With regards to the theory testing and the mediation analyses, we are limited in what conclusions can be drawn from the analyses because they are underpowered. There does appear to be a relationship between a number of the mediators and outcomes, but we cannot say whether or not changes in these are influenced by the intervention. In terms of studies using mediation analyses to look at the impact of MI, the evidence base is limited; however, there is mixed evidence of the impact of MI on self-efficacy.[181–184] An impact of MI on self-monitoring was found in one study[53] while another that explored the link between MI and motivation found that MI is related to increased autonomous motivation.[183] One study found that an intervention using the core principles of MI led to improved planning as it generated more detailed action plans and longer duration of physical activity than the control.[99] One other study has noted the importance of some of these mediators in WLM, including self-efficacy and intrinsic motivation.[185] A recent systematic review looking at mechanisms of MI within health behaviours found that MI 'spirit' and motivation were the most promising mechanisms of MI but concluded that there is a dearth of research exploring this issue, and more studies need to be completed.[184]

Another potential concern with the assessment of mediators is that the measurement tools we used may not have been sufficiently sensitive to detect a change. In addition, the timing of the measurement of the mediators could be important. If assessment does not occur at the critical time, then this could affect our ability to detect the impact of the intervention on these mediators and, thus, on outcome. We had originally planned a 6-month time point for assessment of mediators as we estimated this would be after all the face-to-face sessions would have been delivered and, therefore, participants would have had a full dose of intervention to influence these mediators. In the majority of cases this did happen, and 39 out of 54 participants in the intensive arm received five or six sessions of MI before their 6-month assessment.

There is some support in the qualitative data for the theoretical underpinning of the intervention and thus the different elements of the logic model. Ongoing motivation was seen as central; however, other aspects, such as self-monitoring, self-efficacy, habit formation and social support, were all seen as important by participants. Ongoing motivation was strongly influenced positively and negatively by the support of others including family, friends, peers and professionals. Participants reflected on the MIPs' skills in MI of providing an empathic, non-judgemental environment in which they allowed individuals to control and direct their own plans for weight management. Professional support that was caring, objective and non-judgemental and provided psychological support was thought to be important. A good professional relationship helped with motivation because participants wanted to please their practitioner; it also provided the checking in or accountability elements that participants found useful.

Social support was discussed in detail by participants and was seen as key for WLM. Peer support was considered important because it provides accessible, regular opportunities for support, reduces isolation and provides opportunities for reinforcement, encouragement, feedback, role-modelling, instrumental support and comparison as well as learning from each other. Peer support is distinct from other support because of the shared experience, and it also provides opportunities to improve self-efficacy, which is integral to the psychological theories underpinning the intervention. Support from family and friends was also deemed important, particularly if these individuals were committed to maintaining a healthy lifestyle. If they were not, then often this led to temptation; for example, some family and friends deliberately tempted participants or, less directly, had a negative influence by bringing unhealthy foods into the house. Positive reinforcement was a crucial aspect of support and could come from direct reinforcement from peers or family. It also appeared to work independently to facilitate self-efficacy and maintain motivation, particularly the reinforcement acquired through continued weight loss or maintenance. Improvements in health also acted as a positive reinforcer.

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Control was seen as important, and participants indicated that feelings of control were reinforcing and were important in relation to motivation. Conversely, loss of control could lead to bingeing and thus demotivation and feelings of failure; however, if the diet was too rigid and participants felt deprived, then failure was more likely. Participants suggested that control could be retained by taking a more flexible approach to their diet. Self-monitoring was seen as important to both weight loss and maintenance, in the form of regular weighing. Self-monitoring was described as helping people to feel in control. This was something that the majority of participants were carrying out prior to entering the study and was recognised by many as an important tool. The importance of control and not feeling deprived has been noted in other research.[185,186]

Routine and habit formation were described as important to longer-term maintenance of healthy behaviours, and the development of 'good habits' in relation to WLM was also part of the theory underlying the WILMA trial intervention. Those who failed to develop healthy lifestyle habits continued to struggle with their weight management. There is evidence from the psychological literature about the importance of developing healthy habits, which are not effortful to maintain, and enhance maintenance of behaviour changes.[187–189]

The analyses also revealed some of the potential barriers faced by weight loss maintainers, including environmental and cultural barriers and the important role that food has within our society. The issues identified by participants make maintaining weight loss particularly challenging as so much of our lives revolve around food. There are inherent tensions in dealing with food, which is simultaneously a source of pleasure but is also at the heart of participants' struggles. It is not a behaviour that we can stop doing: we need to eat to live. Our environment presents a number of challenges, including the ready availability of high-fat unhealthy food relative to healthier options, which can make weight management difficult. Other people can help or hinder weight management through various direct and more subtle routes, as noted earlier.

There are few qualitative studies exploring WLM; however, those that have been completed have described many similar findings to the present study. Studies have indicated the importance of realistic goal-setting, use of routines, self-monitoring, avoiding deprivation and effective coping skills.[186,190] Another study emphasised the importance of support during maintenance, problem-solving skills and motivation.[191] Evidence from the qualitative literature on MI indicates that participants found monitoring to be useful when losing weight. They felt that being accountable to someone was helpful, especially when they struggled with self-monitoring, and they also mentioned increased motivation to change and an increased feeling of personal control.[192] A Swedish study[193] found that WLM was seen as a 'tightrope walk' and the strategies that participants found useful in this regard were finding things to enjoy about WLM, such as nice foods and focusing on well-being rather than body weight; routine was seen as important, as was the support of significant others. Participants described the importance of being in control, and this included using self-monitoring.[193] In another study, the respondents described the presence of saboteurs as well as the lack of positive reinforcement during the maintenance stage as a particular challenge.[194]

Although the cost-effectiveness results suggest that the interventions may not be cost-effective, we must again bear in mind that this feasibility study had a reduced sample size and was therefore underpowered to fully explore these issues. Moreover, the trial is about WLM, and a much longer follow-up period is needed to establish whether or not weight loss is maintained in the long term and thus whether or not the intervention is cost-effective at meeting its intended aim.

The main cost-effectiveness study focused on QALY gains based on EQ-5D scores. Although there is evidence to suggest that higher BMI is associated with lower EQ-5D scores,[195] obesity is largely considered a health problem because of its association with raised risk factors for conditions including type 2 diabetes mellitus and cardiovascular disease. Therefore, success in terms of reduced BMI ought to produce long-term health gains in terms of reductions in the incidence and severity of these conditions and consequent reductions in health service treatment costs. An original aim of the WILMA study was therefore to estimate lifetime costs and

QALYs via economic modelling using trial-based data on BMI, EQ-5D and costs. This was dropped when the WILMA trial became a feasibility study.

The overall benefits of the interventions are nevertheless likely to be observed over a far longer time period, while the intervention costs are more short term and weighted to the early stages. The short-term nature of this analysis is therefore likely to be a lower bound for the potential cost-effectiveness of these interventions. Few trials of WLM or long-term weight loss have looked at cost-effectiveness. A HTA monograph suggests that there is some evidence that weight loss management interventions may be cost-effective; however, the authors suggest caution owing to methodological limitations of the two included studies.[196]

Generalisability

In terms of the participants recruited, we were unable to recruit many men or those of ethnic groups other than white British. Fewer men than women generally engage with weight loss research[197,198] and recruiting different ethnicities into trials has proven difficult.[198,199] One qualitative study found that men want weight loss programmes that include individual-level feedback and involve others with whom they identify.[200] It is likely that in order to engage men and non-white ethnic group in trials, interventions may have to be specifically targeted.[201] A recent trial of recruiting men into a group-based intervention delivered at football grounds was successful in helping men lose weight.[202] In terms of increasing the representation of non-white ethnic groups in trials, suggestions have included training recruiters in greater cultural sensitivity, employing advocacy workers and using outreach approaches.[199]

Although we did manage to recruit from diverse sources, we are likely to have recruited a fairly motivated group of participants. This is often an issue where research study participants are not necessarily representative of the general population. Therefore, the intervention is tested out in a tightly controlled trial with motivated participants and the subsequent roll-out in the 'real world' is much less effective. However, if this were delivered in practice it is likely that those participating would also be fairly motivated, having already lost a significant proportion of their body weight. Given the challenges we faced with recruitment, any future trial will need to consider carefully how best to recruit participants who have already lost weight. We did consider an initial weight loss intervention followed by the maintenance intervention and follow-up; however, we felt this would limit the generalisability of the findings.

Conclusions

Recruitment into the trial was much lower than originally anticipated, and this was caused by problems with obtaining independent verification of 5% weight loss as well as delays in opening the trial in England because of issues with research governance and infrastructure support leading to the study becoming a feasibility trial. We tried many different approaches to improve recruitment, but these two issues were key to the recruitment challenges we faced. For any future trial, consideration of different approaches to verification would be prudent as well as to infrastructure support and governance issues. The trial tested an intervention based on MI to support individuals who had previously lost at least 5% of their body weight. As a feasibility study the results look very promising; however, we are limited in what can be concluded from the quantitative, mediation and CEAs owing to the reduced sample size as well as the shortened follow-up. As expected, there are few statistically significant results, but there are encouraging mean differences and CI on important outcomes. The intensive arm seems to consistently have the biggest treatment effect and generally in the direction of benefit. Data from the qualitative work also suggest that increased awareness and understanding were more frequently described in the intensive group, so it is likely that developing insight took time as the therapeutic relationship developed.

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We included a less intensive arm as we thought that this might be more feasible to deliver within the NHS. However, the impact of this brief intervention does not look encouraging and the results look very similar to the control group, which is in keeping with the available evidence. A systematic review of MI as an intervention across a range of health behaviours found an effect in 87% of studies with more than five encounters, compared with only 40% with one session of MI.[57] Two large studies of successful long-term weight loss indicate that intensive and, therefore, costly interventions may be necessary to help people lose weight over a longer-term period and maintain their weight loss. The Finnish Diabetes Prevention Study[42] and the Look AHEAD study[203] found positive results at 3 and 8 years, respectively. In the Look AHEAD trial, the intervention consisted of both group and individual sessions up to the 6 months time point, the participants attended group sessions for the first 3 weeks of each month then on the fourth week they had an individual sessions instead. In months 7–12, they had monthly individual sessions but group sessions were only delivered twice per month. The average weight loss was 8.5% in the intervention group. In years 2–8, the focus was on maintenance, but individuals still received monthly face-to-face sessions, monthly telephone calls and monthly group sessions for 8 years. The average weight loss from baseline at 8 years was 4.7% relative to 2.1% in the controls. This trial is the largest and longest evaluation of a lifestyle intervention. A few trials have found less intensive interventions effective for WLM at shorter follow-up; however, these are few and far between and are still not 'light touch' as they still involve quite a lot of contact.[41,204] This and other evidence indicates that trying to identify brief interventions as a 'quick fix' for the problem may not be appropriate. Brief interventions should be recommended in the NHS only when they have proven efficacy, and at present there is a dearth of evidence for WLM interventions, intensive or otherwise. Obesity should be viewed as a chronic condition for which longer-term support, and probably quite intensive support, is needed.

Weight loss maintenance is extremely challenging; individuals faced with their own motivational struggles are also confronted with an obesogenic environment, which does not facilitate making healthy choices. Their efforts can also be undermined by friends and family as well as by the central role food has in our lives and society. This intervention may help some individuals with their WLM, but it can only be part of a broader strategy to support healthy choices. The House of Lords Scientific and Technology Committee Report on Behaviour Change[205] highlighted that no single approach is likely to be effective in tackling priority health behaviours and that complex interventions addressing multiple levels of behavioural determinants are likely to be needed to bring about sustained change.[205]

One observation we have from the work completed here is that there is scope for confusion in defining successful WLM. This has also been noted by Stevens *et al.*,[206] who have pointed to a range of definitions of WLM. Successful long-term weight loss has been described as losing at least 5% for at least 1 year.[207] Patterns of weight loss and regain are complex, and most individuals tend to regain some weight over time, even in successful interventions. Stevens *et al.*[206] point out that most definitions of WLM allow for some regain of weight. RCTs tend to focus on the differences in weight regain as an outcome rather than maintenance. Long-term weight loss and WLM are terms that are sometimes used interchangeably, and systematic reviews often include studies of long-term weight loss, that is maintenance following a weight loss intervention, as well as those specifically testing WLM interventions. We have defined successful WLM as being successful when the participant does not exceed their pre-weight loss weight at the end of the trial. This includes both those who simply maintained as well as those who lost more weight.

There is also confusion over whether or not interventions for initial weight loss, which then lead to long-term weight loss, are suitable to support WLM. In addition, although strategies for WLM have been proposed as different from those for weight loss, this may not be the case. A recent systematic review concluded that, in order to achieve WLM, the strategies that had led to the initial weight loss had to be continued over the longer term.[208] It is likely that this may at least be partly true, although clearly there will have to be some adjustment to behaviours used for initial weight loss or participants would continue to lose weight. Evidence from the National Weight Control Registry[29] indicates that for successful weight maintainers, using approaches such as dietary restrictions, physical activity and self-monitoring are

important in WLM. Psychological theories of behaviour change often do not clearly differentiate between initiation of a behaviour change and maintenance.

A minority of our participants were actually in the 'maintenance stage', in which they were consolidating and reflecting on how to maintain the weight loss that they had already achieved. Most (92% at baseline and 76% at follow-up, split roughly equally between arms) were seeking to lose further weight. Although this intervention was designed to help individuals with WLM, many participants wished to continue their weight loss and were supported in this. While we sought to help participants maintain weight loss, the idea that people hit their target weight and then adopt maintenance behaviours was not what emerged from the qualitative work. Participants reported that it was an ongoing process, and the battle was never won – they still had to put the work in to prevent weight regain; however, if they could get to the stage at which their weight fluctuated around a certain point, which could be managed, then this could be considered maintenance. Patterns of weight loss and gain are complex, and future interventions need to consider that many participants will still be planning further weight loss.

Weight loss maintenance research is still relatively undeveloped. There is a need for the enhancement of theory which will help inform the development of interventions to be tested in rigorously designed RCTs with cost-effectiveness assessed.

Implications for health care

Obesity is a significant contributor to diseases such as cardiovascular disease, diabetes mellitus and cancer. Treating obesity and the consequences of it represents a significant and growing cost to the NHS and society. The causes of obesity are multifold and complex[209] and, therefore, our response to it will have to be multifaceted, including individual-level approaches and wider public health approaches. Interventions will have to tackle multiple levels of influence.

There is good evidence that lifestyle interventions can promote weight loss;[18,25,176] however, long-term maintenance of weight loss is a challenge. This intervention may provide one approach to tackling this issue. The development of healthy habits is crucial for WLM, and weight loss can be maintained only by behaviours that fit with individual lifestyles, motivations and preferences. MI looks like a promising psychological approach for WLM; however, significant resources are required to deliver this level of intervention, including training and support for those delivering MI in practice, including regular supervision. This intervention could be rolled out in a primary care setting by trained health-care staff and may prove cost-effective to deliver in a larger trial with longer follow-up. It is possible that the intervention could have a wider impact on health as those who are successful weight maintainers may influence others in their social circle, as we found in the present study. In addition, individuals' own experience of MI and their enhanced motivation might influence them in relation to other health behaviours, for example smoking.

Obesity is one of the key public health challenges of our time. Costs to the NHS and society have been estimated at £49.9B by 2050 if the trends in obesity remain unchecked.[209] There is a need for interventions to support individuals with WLM. The stakes are high with potentially large health benefits and cost savings to the NHS and society as a whole.

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Recommendations for future research

This work has identified a number of key areas for future research in WLM.

There is a need for well-designed RCTs, which include cost-effectiveness evaluations, testing interventions to support individuals with WLM, as many studies to date have had significant methodological limitations. We also need more research to help improve our understanding of the cost-effectiveness of WLM over different time periods.

- Based on the findings of this feasibility study, an intervention focusing on MI and self-monitoring looks promising for helping people who have already lost weight to maintain their weight loss. We therefore recommend that a fully powered RCT of the intensive intervention compared with control be conducted. This would enable a proper evaluation of this intervention using dose–response curves to explore what level of MI is needed to produce a clinically significant effect and trial-based data would facilitate the use of economic modelling. The intervention and trial design would be informed by the findings of this feasibility study. Given the likely importance of social support for behaviour initiation and maintenance, an additional component would seek to facilitate effective social support, as originally proposed; however, alternative ways of providing this would be considered including utilising new technologies to mobilise social support.
- Our qualitative data suggest that ongoing support is likely to be important, as does other work in this area.[210] However, research is required on intervention intensity and effectiveness in terms of both total contact time as well as number of contacts required and over what time period. Given the resource issues with providing ongoing contact, further work needs to be completed on delivering interventions by telephone, internet, smartphones, etc. With regard to the challenges we experienced in running the groups, these methods could also be explored to deliver the social support element of the intervention.
- Further development of psychological theory in relation to both maintenance and interventions is required.[211] Presently, most theories do not address 'maintenance of behaviours' directly, and most seem to assume that the psychological processes needed for initial behaviour change are, in essence, the same as for maintenance. The majority of interventions tested are not based on psychological theory, and few measure psychological determinants or behavioural outcomes. There is a clear need for better description of theory and the behavioural components of interventions. In order to build and test theories and to identify potentially useful behavioural techniques, behavioural outcomes and theorised mechanisms of the effect of interventions should be measured. Based on current evidence, a number of potential approaches are likely to be important in WLM, including habit formation, intrinsic motivation and social support.[21,28,29,69,74,185] More exploration of how to encourage or support these is needed. MI may be a useful strategy for improving intrinsic motivation.
- Given that our sample included few men and people from ethnic minorities, thereby limiting the generalisability of our results, further research needs to be completed on interventions that are targeted specifically at men and ethnic minorities as well as more effort to recruit these groups into trials.
- In our qualitative data and our other work, we identified that defining WLM and understanding the associated processes is complex. Future research needs to look at transitions from weight loss to maintenance and to unpick people's experiences of 'maintenance' and the processes needed to maintain.
- Finally, there is limited evidence on the type of diet or amount or type of exercise required for WLM and more work needs to be completed.

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Contributions of authors

Dr Sharon A Simpson (Senior Research Fellow, psychology) led the design of the trial and the intervention as well as the implementation of the study. She led the writing of the report.

Dr Rachel McNamara (Research Fellow, psychology) contributed to study and intervention design. She also managed the trial and led the writing of several chapters.

Dr Christine Shaw (Reader, qualitative methods) was key to the design of the trial and the intervention. She also led the qualitative components of the study and contributed to drafting and revising the report.

Dr Mark Kelson (Research Fellow, statistics) contributed to study design and led the quantitative analyses and contributed to drafting and revising the report.

Yvonne Moriarty (Research Assistant, qualitative methods) conducted the qualitative interviews, led the analyses of the focus groups and contributed to the analyses of the interviews. She also contributed to drafting and revising the report.

Elizabeth Randell (Research Associate, psychology) was involved in analysing and interpreting the data as well as drafting and revising the report.

Professor David Cohen (Professor, health economics) led the health economics analyses and contributed to drafting and revising the report.

Dr M Fasihul Alam (Senior Research Fellow, health economics) conducted the health economics analyses and contributed to drafting and revising the report.

Lauren Copeland (PhD student, psychology) was involved in the analyses of the focus groups as well as revising the report.

Donna Duncan (Deputy Head of Nutrition and Dietetics) was involved in the design of the trial and contributed to revising the report.

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Aude Espinasse (Research Assistant, data management) was the data manager and contributed to interpretation of the results. She also contributed to revising the report.

David Gillespie (Research Associate, statistics) conducted some of the quantitative analyses and contributed to drafting and revising the report.

Professor Andy Hill (Professor, medical psychology) was involved in the design of the trial and contributed to revising the report.

Dr Eleri Owen-Jones (Research Associate, trial management) was involved in the design of the trial and contributed to revising the report.

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Professor Kerry Hood (Professor, statistics) oversaw the quantitative analyses and was involved in the design of the trial and contributed to drafting and revising the report.

All authors approved the final version of the report.

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Appendix 1 Motivational interviewing practitioners' handbook









THE WILMA MI PRACTITIONERS HANDBOOK

By

Sharon Simpson, Rachel McNamara, Chris Shaw, Sue Channon and Steve Rollnick

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Part 1: 'Setting the Scene'

1.1 Who are the clients?

The clients will be a mix of people from all sorts of backgrounds. We will be recruiting them from primary care, exercise on prescription schemes, slimming groups and gyms. These individuals will have lost at least 5% of their body weight and have had a previous or current BMI of 30+. We are recruiting both men and women aged 18-70, although it's likely we will recruit many more women. This is because men don't tend to volunteer to take part in research as much as women and although the numbers of men and women who are obese is roughly similar, men do not tend to seek help to lose weight.

Some of these people will want to maintain the weight loss they have already achieved, but many will want to continue to lose weight and we wish to support them in doing both of these things, but most importantly in maintaining the gains that they have already made (5% or more weight loss). You will likely encounter individuals who have lost weight for many different reasons, cosmetic, family or peer pressure and also for health reasons. Some may have lost weight just to be healthier generally, others because they are awaiting an operation or because they have been diagnosed with a serious health condition, like heart disease or diabetes. Many clients will have what could be called 'normal' weight gain (of for example up to 2 to 3 stones), who have experienced being 'normal' weight but have gained weight perhaps after the birth of a child. Others will have a lifetime problem with weight and weight loss might have resulted in a total change in their perceptions about themselves.

You will encounter individuals who have psychological difficulties associated with their weight, some who have a very high previous or current BMI, as well as those who "just wanted to lose a bit" for example after the birth of a baby. Some of these individuals will have a very dysfunctional relationship with food. The methods for achieving weight loss will also be very variable and include calorie counting, increasing exercise levels, both diet and exercise changes, prescribed obesity medication, crash diets, slimming plans or groups like 'Lighter Life' or Slimming World. We won't be including anyone who has had bariatric surgery. It is likely given what the research evidence says that many of these individuals will have lost weight and put it back on again in a repeating pattern over the years.

Below are some quotes from volunteers that have been involved in the study, one of whom is trying to maintain weight loss after having lost 8 stones in a relatively short time period and another who is still trying to lose more weight. We feel these give a nice illustration of the types of issues and the broad spectrum of clients you might encounter.

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1.1.1 Weight patterns

These clients give accounts of different experiences of weight patterns and reflect on the concerns about yo-yoing of weight.

> *"I've always been very very large, my highest was about twenty-four stone… [in] high school I was about seventeen, eighteen stone when I was about seventeen, then I went to university and got around eighteen stone and then went back up to about twenty-three."*

> *"I probably did the normal thing of going from dress size to dress size without realising that I'd got to a size twenty and thinking 'I don't want to be here'… I thought 'I really need to do something about this' so I joined Weight Watchers… I've probably got about another half stone to go and then I'm happy."*

> *"I think it's that fear that you might go, because I've lost weight before and gone back up, and over the last three years I've probably gone down and stayed down and so you just hope that you're not going to bounce back up or fall off the rails again really."*

1.1.2 Self perceptions and body image

Here the clients reflect on changes in self perceptions and body image associated with weight loss.

> *"I guess I've got a lot more confidence, and I don't mind being looked at as much… because it's not that I've never had a lot of confidence, I was always happy to dance and have fun and things, but I think you almost apologise for yourself when you're quite big."*

> *"I wanted to put it back on cos I felt I'd gone too low, I didn't feel comfortable being that thin I didn't feel very strong… I wanted a kind of safe weight, not kind of out-of-control weight but I wanted to find a weight that suited me; I had a two year kind of period of adjustment to finding the weight I want to be."*

> *"…cos the thing is it's great losing loads and loads of weight, but then you get to the end of it and… if you've been larger all your life you've got absolutely no idea what you're meant to look like or what normal is… I got drunk and tried to move out of the way of someone walking towards me and there was a mirror, and actually I didn't associate myself with the person I was seeing."*

> *"…and actually quite a lot of the other girls who are losing weight say the same thing, that they all think in their minds, [they] picture themselves as much much more negative than it is actually."*

> *"It's probably around liking myself, I probably didn't like… the vision that I'd become so it's probably liberated me a little bit in the fact that I feel good about myself, I feel fit and healthy so I feel a lot younger… I would say probably the headline would be I like myself. I think the person I see is the person I feel inside now, whereas probably the two didn't go together before, and probably I've got more confidence."*

> *" …no no, it is … actually kind of allowing myself to, it's alright if I am a size fourteen, it's not the end of the world because actually the only person who's given a hard time…..someone on the street isn't going to say 'You're a size twelve, you're a size fourteen', they're just gonna say 'Look at the person'…it's only me that knows so why am I making myself feel so miserable about that change which is two inches? So it's almost a self-complete, not loathing, but you kind of try to sabotage yourself and make yourself feel awful…"*

1.2 What are the client's strengths and challenges?

The client's strengths and challenges are likely to be highly variable. However, these are individuals who have already successfully lost weight by various means. So they have some insight into what is needed to lose weight. They are likely also to be a relatively motivated group of individuals.

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1.2.1 Maintenance and weight gain

What is often the challenge for people is to know how to maintain weight loss once they have achieved it and the prospect induces fear:

> *"I suppose with weight loss you think 'Right okay, weight loss', but then how do you change isn't it, cos all of a sudden you go from a lifestyle where you're trying to lose weight and then say 'Right okay I've got to my plateau'. I'm hoping I'll reach a normal plateau… I hopefully will just be able to maintain it by the lifestyle that I have at the moment without perhaps, that extra bit of exercise or whatever that's going to help a little bit more weight loss."*

> *"It is scary, maintaining. Losing weight's relatively easy once you're in the swing of it and you know what to do. But it's when you've finished and keeping it off, it's terrifying. Although I'm not terrified now, I kind of got my head around it, but it is very odd."*

> *"It's not about being on a diet, because if you're on a diet then you're going to have to come off it, it's just about changing the way that you think…I think it's about getting as many people involved as you can and make it as normal or make it as integrated into your life as you can, so actually it's not something that's different to what your normality is."*

> *"[The key is] that steady weight-loss and the fact that you've gone to a healthy eating lifestyle rather than some of the silly fad diets I've done before, which were great for losing weight very very quickly but actually as soon as you started eating normally it all went back on again."*

> *"I don't properly see myself ever finishing on… the healthy eating plan but just carrying on, so it's not like it's a diet that I'm stopping cos I'll just be continuing it really."*

It is also the case that many people will have had repeated episodes of weight loss followed by weight gain with limited success maintaining the weight they have lost. This is one of the major challenges for these individuals to find ways to change their lifestyle to help them in their weight maintenance. Often they can manage to lose weight in a relatively short time span but the more permanent lifestyle changes required to maintain weight loss prove elusive and difficult to achieve.

> *"I think I know that I'll still have to go at least two times a week for that maintenance to happen, because I think that it's all about inputs and outputs isn't it, and if you're going to have a nice lifestyle and go out and have the occasional treat then yes, you need to add something; that exercise is the other thing."*

> *"I hate going to the gym, I hate the walk to the gym, I hate getting ready for the gym, I hate the smell of my gym bag but once I'm at the gym it's great and I really enjoy it, and I come home feeling like I've polished my halo and everything's good with the world."*

Other challenges include stress at work, relationships with friends and family which can derail good intentions.

> *"Um… probably, um, stress, workload, so you know when you come in you're really tired and you think 'I can't be bothered to cook anything', so you'd either go and get a takeaway or you do something really quick and not good… [also] outside pressures, other people going 'Oh go on why don't you, it's only today', so those sorts of things."*

> *"I need to get my exercise levels at a level that I'm comfortable with, at the moment I'm going to the gym once or twice a week and I want that to be three times a week but I just talk myself out of going after work sometimes because I'm tired."*

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> *"I suppose that I've actually decided that I want to be nice and healthy and that's the way that I deal with stress now, so it's probably just a different way… because I think before I was stressed I came home thinking 'Oh I'll have a glass of wine' and just sit down and veg out in front of the telly, whereas now I'll go to the gym and then come home and have something nice for tea."*

Clients reflect here on other issues. One interesting observation made was that when the client lost a lot of weight that's when they experienced success and the only way from that point is failure, the notion that you could still be seven and a half stone lighter than you were but that any weight gain was still represented as a failure.

> *"So there's that kind of dread [of putting weight on again], and then if you've got no-one there to support you it's really difficult not to kind of feel that emotion and that kind of worry and not turn to comfort eating because you've got nothing, the only person weighing yourself is you and you kind of go into a bit of denial and you start lying to yourself."*

> *"If you do put weight on you start to panic, and then you get paranoid … it's like when I go home are people going to notice that I've put on weight or there'll be whispers of people going, 'Oh well I knew she couldn't keep it off'. Because there's such a positive thing [when you lose weight], people go, 'Wow you look amazing' and then you kind of go back again and you don't want them to say, 'Oh you've put it back on again'."*

1.3 What do counsellors say about the challenges of working with this client group?

1.3.1 The public and the personal

Weight management is something which is both intensely personal and also very public: it is something we all have our own personal experience of which informs our beliefs, values and behaviours as individuals and practitioners. It is also something that confronts us at our every turn in work environments, shops, doctors surgeries, on TV and in magazines.

1.3.2 Similarities with other areas of practice?

Working with clients around weight loss and management of weight loss combines many of the same experiences of working with addictions or chronic health conditions. There are the inherent tensions of dealing with a behaviour – eating – that for the client is simultaneously a pleasure and also at the heart of their struggles. They are likely to have made numerous attempts to lose weight, often successfully, but what has evaded them so far is the holy grail of keeping it off. There will have been the highs and lows of success and failure and many different approaches taken. So many of the clients will feel very much the expert in their knowledge about weight loss, but they will feel that they have failed to find a way to keep their weight stable. There is also the contrast between the "buzz" of weight loss, when they will be experiencing praise from others and the rewards in health, appearance etc, compared to the long-term much more low-key experience of maintenance.

1.3.3 Particular challenges

- **Abstinence** is not an option; decisions about what and when to eat have to be made over and over again, each presenting a choice point and possible challenge.
- **No hiding place**: Eating is one of the most public behaviours – often our consumption is in the presence of others creating times for support or shame, success or failure for the individual and one which others feel they can comment on. Whilst some of our weight management behaviours may be kept private, the result, in our appearance, is there for all to see and one on which we feel judged and clients will often have a profound sense of shame.
- **Roller-coaster of emotions**: Working with clients around weight management will include emotional and behavioural issues, the roller-coaster ride, their experiences of success and failure past and present, and the emotional ups and downs in response to the ups and downs of their weight. Now that they have lost weight they may well also be experiencing fear of weight regain as they move from losing weight to maintaining.
- **Confidence:** Some of our clients will have had a steady weight gain over time but there will be a significant number who have a long history of weight issues, some dating back to childhood and certainly adolescence in many cases, so it will have a direct relationship with their self-concept and self-esteem. Appearance and confidence around weight will have played a significant part in their relationships with their partner and their social relationships. For many clients the issues around weight will be tied up with their relationships with their parents, as there is a significant link between parental and off-spring overweight.

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1.3.4 The approach in WILMA

WILMA is not a weight loss programme. Getting involved with WILMA will be different for many of the clients because it is focused support that is not wedded to a particular weight management strategy such as Weight Watchers or Slimming World. This will be liberating for some and anxiety provoking for others: some will chose to continue with a particular weight loss programme and will continue to attend those meetings, for others WILMA will hopefully be an enhancement of their own strategies.

Different agendas? Another challenge will be that our goal of weight maintenance may not concur with theirs, i.e. having lost 5% of their body weight they may well want to lose a lot more. So their focus may be on a more active strategy of weight loss, we will be supportive of these aims whilst having our eye on the maintenance of the progress already made.

MI+ For some of us the combination of MI with specific activities such as the diary and goal setting may be new and feel a bit "clunky" until we get used to it. For others used to working fairly long-term with clients, the brief MI might be a challenge.

Expertise: One of the frequent comments from people who have experienced a weight problem over several years and tried various diets is that they "could write the book" on weight loss. The clients will have a handle on it, so we will need to be particularly mindful of this.

> *"The woman who runs my Slimming World class asked me to fill in a food diary two weeks ago and I was really offended."*

1.4 What psychology and research tell us about weight loss maintenance: an overview.

There hasn't been much research looking at weight loss maintenance, it has mainly concentrated on ways to help people lose weight[1,2,3]. A few studies have found that interventions to promote weight loss maintenance have been able to help reduce weight gain at two year follow-up[1,3,4]. However the prevention of weight regain remains a challenge and around a third of the weight lost is regained in the following year[5].

One of the key differences between losing weight and maintaining weight loss is that 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. It is helping clients find these longer term behavior changes that is one of the biggest challenges we face.

Weight loss = Energy out through physical activity and essential bodily functions exceeds energy coming in from food and drink.



Weight maintenance = Energy out through physical activity and essential bodily functions equals energy in.



The psychological processes, skills and strategies which are likely to be effective for weight maintenance may be different from those that are needed to lose weight[6,7]. Research examining 5000 people on the National Weight Control Register (United States) suggests that the only thing those losing weight have in common is that they combined diet and exercise to lose weight[8]. When they looked at the maintenance phase however, a number of common aspects were identified as being important in maintenance. These included:

- low fat diet,
- eating breakfast,
- self monitoring of weight,
- higher levels of physical activity[9].

Other research has supported these findings and also identified a number of other important aspects associated with successful maintenance. These are:

- low calorie and low fat foods,

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- tailoring of advice to the individual,
- self regulation/monitoring of diet, exercise and weight,
- social support,
- internal motivation
- self efficacy[8,10].

These are described in more detail in Part 3.

Part 2: Intervention I: Motivational Interviewing

2.1 MI and Weight Loss Maintenance

The rationale for using motivational interviewing (MI) in weight loss maintenance has been described in the WILMA study protocol. Briefly, it is this: MI is a method for enhancing motivation to change behaviour with sufficient empirical support to justify its new application to weight-loss maintenance. MI will be useful, because it relies on the instincts and motivations of the client to point to changes that make sense to them. The practitioner needs to have an uncluttered mind to listen out for motivations to change this or that, and to slow down, notice and reinforce change talk when it comes.

The aim of this handbook is to describe the content of the method in this setting, to be used as a guide for counsellors and as a platform for providing training that suits their needs and those of the study as a whole.

The rationale for what follows is that as a practitioner, you use the MI style and techniques to promote maintenance of weight loss by talking about any of a number of topics; hence the division of the account below into:

1. Intervention I: Motivational Interviewing
2. Intervention II: Hot Topics

The suggestion is that you discuss weight-related issues (hot topics) using the style and techniques of MI.

2.2 MI: a new conceptual framework

Very recently, Steve Rollnick has worked with Bill Miller on a new simple framework for MI. This will be shared with MI counsellors in the training sessions. Put briefly, we identified four words that capture where we are heading with clarifying what good practice is. These are **ENGAGE**, **GUIDE**, **EVOKE** and **PLAN**. The first two are viewed as the foundation for MI. Which task to focus on will depend on the situation. It's the third and fourth that particularly involve MI skills to elicit change talk. In the WILMA study, these tasks might involve the following:

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ENGAGE

Not too much action talk just yet! Is this client comfortable to talk with you? Are they clear about what your role and approach is? Do they trust you? If your answer to any of these questions is not positive or uncertain, speak with them about their situation and use core MI skills until you feel that engagement is there.

GUIDE

You have a focus on maintenance of weight loss, but what about her? You could talk about this, and she could talk about that? You wonder about giving her information about this, and she seems interested in something else. Are the two of you clear about a useful path for the counselling session? The word guide embraces your efforts to set an agenda that makes sense to both parties, to review things if it feels a little unclear, and point the session in the direction of weight loss maintenance with clarity, honesty and efficiency. Agenda setting is the best, well-worked way of structuring this task, but it can be done less explicitly. However you do it, a session is going well when both you and the client have a focus on weight loss maintenance.

EVOKE

This task comes into its own when the client is happy to talk about weight loss maintenance, and you use the skills and style of MI to evoke change talk. It's a wonderful feeling when a client is doing this, even if there are setbacks in the conversation. Don't jump to action talk too soon. If you are unsure about whether to move into planning - the next process below - ask the client!

PLAN

If the client feels ready for this, be careful of using the righting reflex and suggesting what they could or should do. Have your goal as the eliciting of implementation intentions (very specific change plans) which ideally include self monitoring. However, how you do this in the style of MI is where the skill comes in. The idea is to elicit as many ideas from them as possible, in the spirit of brainstorming, in which you also feel free to add in some suggestions. It's a collaborative process.

You might find yourself moving in and out of the four processes, **ENGAGE**, **GUIDE**, **EVOKE** and **PLAN**, or even having a conversation that covers more than one process at the same time. Yet their qualities are different.

To help you get a feel for the difference between these processes, consider the value of these questions. They are questions you might ask yourself about the helping process and they might be used as a reminder when speaking to clients. Some of them you might even put to the client.

1. ENGAGE
i) How comfortable is this person about talking to me?
ii) How helpful am I being?
iii) Do I understand her concerns?
iv) How am I feeling?
v) Is our service helpful?

2. GUIDE
i) Have we clarified a focus for our conversation?
ii) What kind of change does this person really want?
iii) Are my aspirations for change different from his?
iv) How strongly do I feel about changes she might make?
v) Are we working together with a common purpose?

3. EVOKE
i) What makes this change worthwhile?
ii) Am I steering her too far or too fast in a particular direction?
iii) Am I listening out for change talk?
iv) What's really motivating this person?

4. PLAN
i) What will help him to move forward?
ii) Am I resisting the righting reflex?
iii) Am I providing new ideas while promoting autonomy?
iv) Can we get as far as actually making a concrete plan of action?

2.3 MI Styles and Techniques

This part of these guidelines refers to how you speak with clients. What you talk about is effectively covered in "hot topics".

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2.3.1 Spirit & style

As an MI practitioner, you know that these have been described as not just being client-centred, or worse still as "being nice to people", but as a purposeful and goal-directed activity in which you adhere to three core spirit elements:

> **Collaboration:** Work with clients as a guide. This is not about "being nice and friendly", or "nice and empathic", but about using core skills to engage the client and help them to clarify what changes they might consider.
>
> **Evocation:** You rely on their aspirations and unfolding talk about change as your principle guide. You follow this, using reflection to evoke more change talk, even if the conversation is of a very practical nature (e.g setting goals).
>
> **Autonomy support:** Both your attitude and the words you use reflect respect for their freedom to make up their own mind. You avoid simple, single solution talk and advice-giving, because this merely evokes resistance and a feeling of undermining autonomy. You avoid the "righting reflex". You champion flexibility and you offer options.

These are the three global items on the MITI scale and all elements of technique, like reflective listening, also on the MITI scale, are used in their service. Put simply, *you use a collaborative, guiding style to evoke from clients their own good reasons to change or keep going with weight loss maintenance plans that make sense to them*. You try to keep to a good ratio of reflections to questions.

2.3.2 Goal

As an MI practitioner, you should also know about change talk! This seems to predict subsequent behaviour change, at least in those studies completed to date. Your goal is to use the three spirit elements to quietly listen out for change talk, and to use further reflective listening to explore and reinforce this. This change talk, if you are working collaboratively and listening well, will be aligned with the clients' personal values and aspirations. Unusually perhaps, it might also focus much more on action than in "traditional MI". This difference is an exciting one, but the principle remains the same: your goal is to listen out for change talk and use listening and affirmation to nurture it.

2.3.3 Skills

The OARS skills (open questions, affirmation, reflection & summaries) are the core skills that drive the activity of focusing in on changes, decisions and commitments that make sense to the client.

2.3.4 Useful questions and strategies

A host of these have been developed over the years, many of them for use in brief health care settings [15,16]. As you well know, they are not rigid techniques, vulnerable to technical application that undermines the spirit of MI, but useful questions that you can adapt as you see fit, *though it's not essential to use them.*

One of the strategies that you will find particularly useful in the WILMA study is *Elicit-Provide-Elicit*; that's because the sessions might well be very information-rich, with a host of topics and pieces of evidence that you might want to share with clients. You might be well advised to brush up and practice this skill! Other strategies will be useful in different circumstances. Here is a brief summary, taken mostly from a recently published paper in the British Medical Journal[17]:

1. Typical Day (What's your life like?)

This is superb for enhancing engagement, takes 5-7 minutes, useful early on, and gives you a great feel for the context.

AIM

To have a normal conversation lasting 5-10 minutes, in which rapport is enhanced, clients do most of the talking, and you learn a great deal about their personal and social context (including readiness to change).

PRINCIPLES

- **Convey acceptance:** Do not pass judgement. Consider anything the client says or does as acceptable, or as at least something that does not surprise you.
- **Stay curious:** Don't hesitate to interrupt with a request for help with more detail.
- **Resist the investigative impulse:** Invading the client's account with questions about problems can kill off the atmosphere of acceptance and curiosity. In other words, this is not a conversation about food or eating. The client will probably tell you about this quite naturally.
- **Behaviour and feelings:** Focus on both behaviour ("What happened then?") and feelings ("When you closed the front door, heading for the shops, how were you feeling?).

PRACTICE

1. **Locate a day** "Can you think of a recent day that was fairly typical for you, an average sort of day".
2. **Go through a "typical day"** Be mindful of time and the pacing. Slow it down if the client runs too quickly through the story. Speed it up if it looks like its going to take more than about 10 minutes.
3. **Check if the client wishes to add anything** "Is there anything else about yesterday you want to say more about?"

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4. **Ask any questions of your own**

5. **Practice** You know you are getting better when you interfere less and less with the Typical Day story. The client's degree of comfort in telling the story is your indicator of success.

2. Agenda Setting (What to change?)

This is really useful early on, to help you focus on a change that makes sense to you both. It's the principle task that is an expression of the guiding process. Practice this and you'll find that engagement is enhanced and your conversations will have a much more focused feel to them.

Clients often face more than one option for change. In *agenda-setting*, rather than impose your priority upon clients, you conduct an overview by inviting them to select an issue or behaviour that they are most ready and able to tackle, feeling free also to express your own views. For example, to reach agreement about what to deal with in the consultation you might say: "That's very helpful. Are you more ready to focus on eating or on increased activity? Or is there some other topic that you would prefer to talk about? I'd like to talk about regular weighing at some point, but what makes sense to you right now?

3. Pros and Cons (Why change?)

It is both normal and common for clients to feel ambivalent about both the *status quo* and change. It can be helpful to invite them to say how they see the *pros* and *cons* of a situation. Your next step is to ask them to clarify whether change is a possibility.

Box 1: Exploring the pros and cons
"I want to try to understand exercising better from your perspective, both the benefits for you and the drawbacks. Can I ask you firstly what you like about exercising?" (*Client responds. Use your curiosity to elicit a good understanding.)*

"Now can I ask you what you don't like about your exercising?" (*Client responds. Remember it's their experience that counts, so avoid offering your perspective for the time being.)*

(Then you summarise both sides, as briefly as possible, capturing the words and phrases that the client came up with.) "OK, so let's see if I have this right? You like the fact that exercise helps you unwind and, helps you

manage your stress levels. On the other hand, your main concern about it is that you find it difficult to fit it in with you busy life and family. Is that about right? OK."

(Then you invite the client to consider the next step.) "So where does that leave you now?" *(Client usually describes readiness and any need for advice or information.)*

4. Assess Importance (why) and Confidence (how)

To be efficient you need to spend time where it is most needed. Those who are not convinced of the importance of change are unlikely to benefit from advice about *how* to change. Conversely, a focus on the *why* of change is pointless if the main issue is how to achieve it. This strategy has produced successful outcomes in the smoking field[18], where a recent review also provides support for the efficacy of motivational interviewing[19].

Box 2: Assessing importance and confidence

"Would you mind if we took a moment to see exactly how you feel about weight maintenance?" *(An invitation promotes collaboration and client autonomy.)*

"How important is maintaining your weight for you right now?" *(Elicit a brief review of client's feelings, fears, and aspirations, then ask:)* "How confident do you feel about being able to maintain your weight?" *(Elicit, and then summarise client's view of importance and confidence.)*

(Then tailor your next step accordingly—for example, if importance is low, consider something like:) "Well, do you mind if I just give you some information about some tools that might help you with your weight maintenance, but it will be up to you to decide in the end." *(Emphasising autonomy always helps.)*

5. Exchange information

One of the first successful studies of motivational interviewing placed listening at the centre whilst feeding back test results. This gave rise to the "Elicit-Provide-Elicit" strategy, in which a guiding style is used to encourage clients to clarify the personal implications of information that you provide.

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Box 3: Information exchange
"OK so can I check your understanding of the situation? What do you know about how to maintain your weight loss?" (*Elicit understanding.*) . . . "Well you are right about it being very common that people find it difficult to maintain the weight loss in the longer term. The key is balancing the amount of exercise you do and the amount that you eat. As well as trying to eat healthily, another key factor is monitoring your weight on a weekly basis. This has been shown to be very effective." (*Provide information.*) "OK, now can I ask, how do you think this information applies to you?" (*Elicit client's interpretation*).

6. Make decisions about change (setting goals)

This is the fourth process in the new framework for MI: PLANNING. Goals and targets for change that come only from your side are often met with "Yes, but…" explanations about why they will not work from the client. However, if the client is ready, a guiding style can be used to elicit practical solutions from the client while offering suggestions from your side as well.

Box 4: Making decisions
"It sounds like you really want to try to maintain your weight loss, but you're struggling with imagining how you can do it because it's been difficult in the past." (*Summarising the client's situation.*)

"It will be up to you to decide when and how to do it (*emphasising the client's freedom of choice*) but I am wondering how do you see yourself succeeding with this?" (*Inviting the client to envision change. Client responds, usually identifying main challenges… remember to listen out for change talk!.*)

"So you are hoping you can find a way to try to avoid slipping back into your old eating habits." (*Listening, in response to what client has said.*) "There are lots of things that others have found useful, but what makes sense to you?" (*Inviting client to clarify what will be helpful.*) "OK so you will try and get your husband to join the gym with you and that way you will find it easier to stick with your plan." (*Client clarifies what will be helpful, and the discussion narrows down in favour of a plan that is agreed jointly.)*

The success of the WILMA study will probably depend on your ability to talk quite concretely about this or that change, and to keep to an MI style as you do this. This is breaking new ground in the MI field, talking about goals, self-monitoring diaries, even implementation intentions, all embraced by the spirit of MI! Our team looks forward to hearing about your challenges and successes in this new application of MI, using a new framework.

2.4 Change Talk and Weight Maintenance

This sounds like quite a mouthful – change talk and weight maintenance - but its really quite simple! Change talk occurs when the client uses language in favour of positive change. An MI practitioner listens out for this change talk, and when its heard, she tells herself: "Now I must slow down, free my mind of clutter, and reflect, reflect, reflect"! Why, because it is this expression of change talk that frees the client to consider change, and it actually predicts subsequent change.

You will hear lots of change talk about weight maintenance. Notice that it can vary in strength, and cover things like ability, desire, reasons and need. The closer it is to strong commitment then the closer you and the client are to specific goals and success. Here are some examples of reflection in response to change talk about weight maintenance. Notice how the reflection elicits more change talk – that's the heart of MI!

EXAMPLE 1

Client:	*I need to maybe accept that this is my normal weight and then keep it that way.*
You:	There's a balance that might suit you.
Client:	*It will be a relief to not keep yo-yoing up and down* (more change talk)
You:	(reflect again!)

EXAMPLE 2

Client:	*I want to just get a little more exercise and then it will be more balanced.*
You:	You can see a balanced pattern with just a little more exercise.

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Client: *Yes, I could do that* (more change talk)

You: (reflect again!)

EXAMPLE 3

Client: *I see, so I don't have to diet all the time.*

You: There might be another way for you.

Client: *Well maybe I could do this……* (more change talk)

You: (reflect again!)

Notice how the reflections in the above three examples are not clever or complex. They usually don't need to be. Your task is not to leap too soon to the obvious question about action (e.g. how might you do that?). If you gently reflect change talk, the client will often lead you to action talk.

Patience is very important here. A robust practitioner will accept that the conversation can often go round and round in circles. This does not mean that you are not making progress. Remain curious, and also feel free to be honest about your impression of the conversation. If there is a way forward out of seemingly contradictory conflict, the client will often help you find it.

2.5 What might a session look like?

The section on "hot topics" that follows below goes into some quite specific weight loss maintenance topics. However, before reading this, consider the following when thinking about MI in this setting.

Consider starting a session like this:

1. In an agenda-setting "state of mind", share an overview of topics you could talk about, agree where to begin, and review this agenda at any point.
2. Secondly, use elicit-provide elicit to exchange information about the difference between weight loss and maintenance.
3. Third, use MI skills to focus in on change talk about maintenance.

That's one very simple way of contextualising the process. In time you will develop your own structure that makes sense to you.

2.6 Delivering MI in Two Sessions

This topic will be discussed and developed during the training day and summaries of key suggestions will be sent by the WILMA team and can be added here. However, in brief, this will require the MI to be a little more structured and practitioners should address these key questions to the client:

a) how are you getting on with your efforts to control your weight? (typical day can be useful).

b) weight loss and maintenance: where are you and where would you like to go?

c) getting there – some achievable goals and targets.

2.7 Delivering MI over the Telephone

Again this topic will be discussed and developed during the training day and summaries of key suggestions will be sent by the WILMA team and can be added here.

2.8 Useful Questions

The questions listed below are ones we have found helpful with this client group.

- It would be really helpful for me to speak with you about your journey so far, in terms of weight loss and where you've got to and how it's gone really for you, so can you kind of give me a bit of pen-sketch on that?
- And as you look around you and think about other people and their journey, would you say that you were that different to other people?
- So what do you think you've learnt from those previous times and from this journey now, what have you learnt that's going to be useful information for you?
- What would you say if you're thinking about those kind of overriding goals, what for you represent the overriding goals for the weight-loss or weight-maintenance now? What, you know, what keeps it in mind?

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- So thinking about the next six months or whatever, what do you see as being the kind of things that are going to happen for you and how are you going to approach it?
- And again, looking back when things haven't gone quite how you would've wanted them to, how did habits get undone?
- So thinking about weight maintenance, how do you think, taking for example stress, how do you see that kind of being managed differently?
- And if I were, kind of, to be chatting with your friends and saying what difference, have you seen a difference in her, what would they tell me?
- So of all the differences that it's brought you in your life in terms of, you know, you go to the gym now, your diet is different, you know, you feel different, you look different, which would you say are the things that make weight maintenance the most likely, what are the main things that will keep you on track do you think?

The questions below are some additional questions you may find useful from Steve's book.

- What strategies were useful to you, what helped?
- What changes would you most like to talk about?
- What have you noticed about . . .?
- How important is it for you to change . . .?
- How confident do you feel about changing . . .?
- How do you see the benefits of . . .?
- How do you see the drawback of . . .?
- What will make the most sense to you?
- How might things be different if you . . .?
- In what way . . .?
- Where does this leave you now?

Part 3: Intervention II: Hot Topics

There are a number of aspects which according to the research evidence may be important in weight loss maintenance. These are described in more detail below. In addition to these important topics there are other elements which we feel are important to the success of the intervention, these are boosting intrinsic motivation and feedback and reinforcement. Intrinsic motivation is defined as greater self motivation to carry out the activities needed for weight maintenance. We want to help individuals to identify their own reasons for maintaining weight linked to their own personal values and goals in life.

We also aim to give reinforcing feedback, such as praise and encouragement, to actions that move the individual towards activities that help them maintain their weight. Feedback and encouragement is also important to help client's build confidence in their skills and thereby bolster self efficacy.

Finally, we feel that the key is in the flexibility of approach in discussing these topics. We don't expect that you will necessarily cover all topics although **self monitoring**, **diet** and **exercise** are key.

3.1 Psychological or Behavioural Control Topics

3.1.1 Self Monitoring

What is it?

Self monitoring is perhaps the single most effective method to enhance weight loss maintenance. We want individuals to monitor and record their weekly weight. Participant-held diaries and/or the website will help individuals to monitor their weight weekly. Diet (ate low fat/low sugar/high fibre choices; ate regular meals/breakfast; ate your 5 a day) and exercise behaviours (30/60 minutes per day moderate exercise; less time in sedentary behaviours) can also be recorded in the participant-held diaries (Appendix 5).

Why does it help (the evidence)?

Data from 5000 people on the National Weight Control Register suggests that when trying to maintain weight loss self monitoring is very important[8]. Self monitoring is also recommended in the UK by the National Institute of Clinical Excellence (NICE)[20]. Self monitoring consists of regular self weighing and monitoring of diet and physical activity.

In a systematic review of interventions designed to promote physical activity and healthy eating, self monitoring of behaviour was associated with improved effectiveness

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and combining self monitoring with one of 4 other self regulation techniques (prompt intention formation, prompt specific goal setting, provide feedback on performance and prompt review of behavioural goals) was even more effective. These techniques come from Control Theory[21].

Theories attempting to explain health behaviour change (Self-Determination Theory [22], Self Regulation Theory [23,24], Social Cognitive Theory[11]) suggest that self-monitoring is key to self-regulation, a process by which individuals measure their success in maintaining weight loss by regular self-monitoring of weight. The initial goals and behaviours which led to the weight loss and subsequent maintenance will be reinforced if the outcome of this evaluation is positive, and re-evaluated if not. The process of monitoring will therefore be repeated and become habitual. This can also boost self efficacy.

How can you help?

Encourage participants to monitor their weight weekly, and record this in their diary or submit online (weekly) or by text and inform participants or remind them as appropriate that monitoring diet and exercise behaviours (e.g. in their diary) is likely to facilitate maintenance. Explore with clients which activities are best for them to monitor (apart from weight). See Section 4.5 and Appendix 5 for information on the client diaries.

The clients we interviewed suggested that you need an objective measure of whether you are putting on weight or not. How you look in the mirror is too subjective. Also they felt you can deceive yourself about your weight unless you have objective evidence. They also suggested that self regulation could be used productively to set limits within which weight can fluctuate.

> *"I think it's the weigh-in, I know that some people hate being weighed… but once a week so you can actually see the numbers and you can see the difference, or you can see that you haven't put on weight… it's something that clicks in your head and you can see, [having] something physical that you can see, because actually if you're going on what you look like quite often what you perceive yourself to look like is actually not what you look like."*

> *"… I do think it really helps, writing down everything that you eat, and maybe initially once you've lost weight that's really helpful… it's that extra bit of control, you feel even more in control because you're writing down everything that you eat. I suppose because I know I can correlate me having refined sugars with me having mood swings and feeling really low in energy it's helpful in that way if you can write down not only your food but your moods as well, because you can find a correlation between that."*

> *"I would think with weight maintenance and I do weigh fairly regularly, and I would say that if I notice that a pound or two is creeping on… it is that prompt quickly to say 'Hang on, you've put on a couple of pounds' and bring it back now, whereas I think if I maybe weighed once a week or once every two weeks and then found I'd put on four pounds that could be the bit that made me think 'Hm, how am I ever going to pull that back?'"*

> *"For some people weighing too often can be demotivating and pushes them into a negative spiral, however, I think… for me it's a motivational aid."*

3.1.2 Goal Setting and 'Implementation Intentions'

What are these?

Goal setting is important in helping us to form a plan for change or maintenance of behaviours. Goals can be general or specific, they can be for today, next week or next month. Goals could be e.g. lose weight, eat less fatty food, go to the gym. Goal intentions specify **what** you will do.

Implementation intentions are basically "If-Then" statements, these are important for translating your intention to change your behavior or to do a specific behavior, into action, i.e. actually doing the behavior, like going to the gym.

These 'implementation intentions' have been shown to be very effective in relation to a number of problems that prevent people from changing their behavior. These include;

- 'failure to get started' (failing to act, missing opportunities, initial reluctance to change)
- 'getting derailed' (distractions, temptations, habits, cravings, emotional distress) where unwanted influences get prioritised over pursuit of the ongoing goal.

Implementation intentions specify **when, where and what** one intends to do (e.g. 'every day this week after work I shall run around the lake').

When	Every day this week after work
Where	The park
What	Run round the lake for 30 minutes

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Why does it help (the evidence)?

Goal setting is an important process in behavior change and maintenance as it facilitates planning towards that goal and it facilitates change and allows the client to monitor their behavior in relation to achieving the goal. If the goal is not being achieved it allows the process of problem solving to kick in to facilitate achievement of the goal. Problem solving is a way of dealing with perceived barriers to carrying out weight maintenance behaviours and requires the participants to identify their own solutions to possible barriers, that fit into their individual lifestyles.

A considerable body of research has shown that the link between a person's intention to change their behavior and actually changing it is not strong. Research has shown that formation of implementation intentions doubles the chances of completing the behavior [12,13,14]. Importantly implementation intentions increase the chance of the behavior being automatic or habitual as the situation then triggers the behavior.

They are also important in planning for slip-ups, e.g., "I ate a bit of cake so the diet's out the window, I might as well eat the whole lot". Instead think "If I slip up on my diet then I will not worry too much, but will continue with my healthy eating and exercise plan." Implementation intentions can also be used in ways to reward oneself and reinforce the behavior, e.g., "If I go to the gym this week then I can go out for dinner".

Implementation intentions also help individuals establish new habits, as they help 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, e.g., you see the gym bag in your car and call in at the gym en route home. As behaviours are repeated they become increasingly automatic or habitual and hence more resistant to change.

How can you help?

Encourage clients to:

- Set attainable and reasonable goals.
- Make goals meaningful – how do they fit with a client's overall goals, values etc. For example, if spending time with their family is important and one of their values - then you might want to encourage them to choose exercise which can be done with the family (e.g. swimming) rather than going alone to the gym.
- Listen out for 'implementation' change talk – encourage this.
- Encourage development of implementation intentions "If …. Then….". Note that these can be in relation to smaller or larger goals.

A few observations from our volunteer clients:

> *"Um… it's funny because it's great having a goal but when you reach that goal what's your motivation beyond that? So, while my goal was to get down to normal weight so it was easier to conceive… the fact that it didn't come to that [means] now I don't really have a goal, it's just kind of to maintain and stay healthy almost."*

> *"As long as I've got the right motivations which is things like having my gym bag in the car so I don't go home first and then think 'Ohh perhaps I just can't be bothered, perhaps I'm tired'… I sort of plan my week that I see what I'm doing every day and when it's feasible that I can go to the gym, so I probably go at least once over the weekend and then I would go once in the week."*

3.1.3 Habits

What is it?

Habits are automatic responses to specific cues. They are learned sequences of acts. Habit formation is crucial both to behavior change but also to maintenance. If we are to enable people to maintain weight loss in the longer term making healthy behaviors habitual is critical.

Why does it help (the evidence)?

This is important because often the behaviors required to maintain weight loss are difficult to achieve, e.g. large amounts of daily physical activity, healthy eating in the face of many temptations in our 'obesogenic environment'. Developing habits whereby behaviours are cued by the environment and are more automatic makes behavior change easier and more likely to last as it leads to strong neural connections/pathways and does not require one to think about it too much - as behaviours are automatic.

Habits are functional in obtaining certain goals or end states.

How can you help?

In order to make behaviors habitual there are a few things to encourage clients to try. In the main we need to focus on the 3 key aspects of habit – frequency of occurrence, automaticity of the behavior and functionality. Implementation intentions may help with habit formation as implementation plans regulate the *frequency* of behaviours, the control over the behavior is at least partly transferred from the person to the situation (*automaticity*) where the behavior should take place. Cues and responses should be selected that are *functional*, e.g., running should be scheduled so it doesn't interfere

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with other activities, and the running itself may give rewards like time to think and fresh air. Key points are that:

- Often just repeating the behavior over and over makes it become habitual.
- Implementation intentions can help in the development of new habits
- Cues in the environment also help - so as above 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 (e.g. sight of your gym bag) 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 volunteer clients emphasised the importance of developing good habits and that these got easier as time went on as well as the negative impact of bad habits:

> *"Yeah, and it probably got easier as the journey went on and the fact that you then got used to set foods and menus that you knew you were okay, so… you probably had to think about it more in the beginning."*

> *"I think to be honest I probably won't really introduce it (alcohol), I think I'd got into a habit of a glass of wine in the night, you know, come in, you sort out the kids and you sit down with a glass of wine, and I think it just became a habit."*

3.1.4 Emotional Eating (binge eating), Self Esteem and Coping with Relapse

What are they?

Psychological factors are likely to be key to both weight loss and maintenance, and barriers to maintenance may include eating in response to particular emotions or events. Obesity and previous 'failures' to maintain weight loss may also influence perceptions of self-esteem and self-efficacy and therefore maintenance. Coping behaviours in response to challenges or short-term relapse may also predict long-term maintenance. Emotional eating, self-esteem and coping with relapse will form the content of one of the peer group sessions.

What is the evidence?

There is conflicting evidence about whether particular emotional states (e.g. anxiety, sadness, loneliness, tiredness, anger and happiness) actually increase unhealthy eating behaviours, but there is generally agreement that individuals perceive these emotions to

affect their eating habits, particularly amongst overweight/obese individuals who "binge eat"[25,26]. Those who have difficulty expressing emotions may also have a tendency to binge in response to negative feelings[27].

There is some evidence to suggest that low self-esteem in childhood may be associated with obesity in adulthood[28] and that high self-esteem may be associated with better weight management outcomes in adults[29]. Long-term weight loss maintenance is thought to be associated with problem-focused coping strategies, whereas relapse is associated with more emotion-focused styles and avoidance[10,30]. Encouraging clients to plan how they might cope with lapses in advance may also be effective in preventing relapse[31].

How can you help?

Help clients to identify any emotional triggers for eating and discuss problem rather than emotion-focused approaches to coping with temporary relapse. Instead of responding in an 'emotional' way to relapse, e.g., 'I've eaten too much chocolate because I'm stressed. I'm a failure / I'll never be able to succeed at weight loss maintenance', try and encourage participants to 'problem-solve' instead, e.g., I've eaten too much chocolate because I'm stressed, but it isn't the end of the world. Tomorrow I'm going to make an extra visit to the gym and next time I feel stressed I'll try to do some more exercise instead'.

Encourage clients to discuss how they might manage cravings, and ask them to generate a list of problem-focused/direct coping strategies for 'high risk' situations. Support clients to think of practical ways of avoiding any identified triggers for relapse, e.g. if they know they have a tendency to snack on biscuits when stressed, what would help them overcome this? Maybe they should not buy biscuits or they should try to identify something else that works for them instead, e.g. long bath, going for a walk.

You should also encourage clients to attend the relevant group session, which might be useful for sharing tips on how to overcome emotional triggers and cope with relapse.

The volunteer clients identified that being aware of what the triggers are to over-eating is important as well as the relationship between emotions and eating patterns.

Emotional triggers:

> *"I know what to do and I understand why I eat more than I should do sometimes, if I'm upset and I'm very aware of myself and my body."*

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> *"…so there's that kind of dread, and then if you've got no-one there to support you it's really difficult not to kind of feel that emotion and that kind of worry and not turn to comfort eating."*

> *"… then I'm going to be embarrassed and then I'm going to feel bad about myself, and then I'm just going to want to eat more KitKats."*

> *"I was stressed in work, I came home thinking 'Oh, I'll have a glass of wine' and just sit down and veg out in front of the telly."*

On relapsing:

> *"If it gets to (putting on) the half stone then I start thinking 'Oh! How am I ever going to do this?' because it takes so long to lose that."*

> *"I know when I have put on a couple of pounds more, if my trousers do feel tight I do actually feel quite negative about it and I kind of start [to] panic again."*

3.2 Other Topics

3.2.1 Diet

What is it?

Diet is a key factor in the maintenance of weight loss. It is one of two elements (along with exercise) contributing to 'energy balance'. This concept is crucial to understanding how to maintain weight loss (and indeed lose weight). 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.

Why does it help (the evidence)?

In simple terms the amount eaten in terms of caloric and fat intake must balance out with amount of energy expended through physical activity. Evidence from RCTs and reviews suggest that eating low calorie and low fat foods is important in maintenance. Data from the National Weight Control Registry of 5000 people who have lost weight in the US indicate that low fat and low calorie diet and eating breakfast are associated with weight loss maintenance[8].

How can you help?

The list below indicates some evidence based guidance that can be discussed with clients.

- Decrease fat and sugar intake.
- Look at food labeling for fat and sugar content.
- Increase fruit and vegetable intake, eat at least 5 a day.
- Increase fibre intake (eg eat more such as oats, beans, peas, lentils, grains, seeds, fruit and vegetables, as well as wholegrain bread, and brown rice and pasta).
- Have smaller portions.
- Eat breakfast.
- Drink plenty of water before a meal.
- Eat 3 regular meals.
- Don't starve yourself as it increases the chance of bingeing on unhealthy foods.
- Don't eat in front of the TV or computer - pay attention to what you are eating.
- Don't use food to deal with stress or feeling blue – go and do something else.
- Drink low sugar, low fat drinks .
- Eat low fat dairy foods.
- Reduce alcohol consumption.
- If you slip up don't think "oh well that's it" and then binge, just take it in your stride and then carry on as per your healthy eating plan.
- Remind yourself of where you have come from (photo of old you).
- Have realistic weight goals - get to a healthy weight and maintain it - 10% is usually achievable.

A few more observations from our volunteer clients:

> *"I do need to be quite careful of portion control because I don't seem to get full up, ever, … control is the thing I'm working on at the moment."*

> *"That glass of wine represents quite a few Syns so actually you're better just not doing it or doing it very occasionally."*

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> *"The whole family do it now so it's probably eat lots of vegetables and lots of fruits so if I go round the supermarkets, lots of vegetables and fruits… meat, fish and pasta."*

3.2.2 Social Support

What is it?

Social support from family and friends, and peer support which will be encouraged through the locally provided peer group sessions. MI counsellors will also be a valuable source of professional support for clients.

Why does it help (the evidence)?

Reviews suggest that social support is a key factor in successful weight loss maintenance, and that a lack of support may impede maintenance[30,32]. There is evidence to suggest that social support can increase the proportion of people who complete treatment and maintain all weight lost at 10 month follow-up by around 25%[33] and that continued professional support improves maintenance. Social support may offer benefits like reinforcement, encouragement, motivation, empathy, role modelling, increased self efficacy and confidence. Social support is therefore thought to improve maintenance[10].

How can you help?

In addition to providing professional support to clients, it may be useful to discuss sources of social support that clients can draw on, and explore ways to maximise these (e.g. exercising with a family member or friend). Encouraging clients to attend group sessions and access the peer support they provide is also likely to improve maintenance.

The importance of both peer and professional support was noted by the volunteer clients.

Peer support:

> *"This support group was amazing with Lighter Life and you saw the same women every single week and I did it for two hundred days and I kept in contact with them all…. I just need to have other people who's doing it the same time which was why I joined Slimming World."*

> *"…there being other people there saying exactly the same things as you, saying I had a row with someone and drank a bottle of wine, that kind of thing, so you're not the only one that turns to kind of a physical, comfort eating if you're upset…. Well it, it helps you to feel not necessarily normal but… you can connect with other people… you get their understanding and you can understand them and you can get comfort in that, and it just brings you closer to people and makes you feel a bit more normal, like you're not on your own."*

> *"They had insane [exercise] classes so it was quite good to have someone else who was going to die with you… that was quite fun… now I've got a woman who I work with, we go once a week together, but then the rest of it's my own self-motivation."*

Professional support:

> *"I don't think I could do it without someone there, either reinforcing it and saying You're doing really well you're on the right track, or someone going Okay you didn't do so well but why, what do you think it is?"*

> *"I mean I didn't before any diet I didn't really have any idea what I was meant to be following, you kind of get yourself, well you know how to eat healthily but you don't, so it's almost somebody helping you to structure things…. you can't pinpoint the areas where you're going wrong. So if you're kind of, if there's someone external always ordering things for you then you can almost pinpoint things and you can make little changes instead of looking at it as a whole and thinking 'Oh my God this is too much for me be able to sort out'."*

> *"I'm not sure… I don't know why it clicked in my brain but I didn't want to call it help because then I associate that with failure. It's almost like saying help that you can't do it on my own, but actually I don't think I can do it on my own."*

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The clients also mentioned that there could be negative aspects of social support:

> *"My boyfriend was telling me off… I can go through packets and packets of KitKats and chocolate and initially he wanted me to tell him everything I was eating cos he wanted me to feel bad so I wouldn't do it, and I'm like 'That's not going to work, cos then I'm not going to tell you what I eat and then I'm going to be embarrassed and then I'm going to feel bad about myself, and then I'm just going to want to eat more KitKats.'"*

> *"In my first group I was the only one after four weeks who was stuck on it, and they actually, these full-grown women, very very intelligent started almost picking on me… and I had to move groups in the end."*

3.2.3 Exercise

What is it?

Exercise is a key factor in the maintenance of weight loss. It is one of two elements (along with diet) contributing to 'energy balance'. This balance needs to be sustained by behaviours which can be continued over the longer term.

Why does it help (the evidence)?

Evidence from RCTs and systematic reviews suggest that higher levels of physical activity is very important in maintaining weight loss. Data from the National Weight Control Registry of 5000 people who have lost weight in the US indicate that high levels of physical activity are associated with weight loss maintenance; up to 60-90 minutes of moderate physical activity per day[8,34]. Other work also supports this. Exercise helps by influencing the energy balance and may help by increasing metabolic rate and increasing muscle mass which burns off more calories.

How can you help?

Some evidence based guidance, to discuss with clients, is listed below along with tips to increase physical activity levels:

- Government recommends at least 30 minutes of moderate physical activity (where you get slightly out of breath but can still talk.)
- Research indicates that for maintenance this needs to be 60 minutes a day and possibly up to 90 minutes per day.
- Try to make exercise part of every day.
- Find something you enjoy doing.
- Take the stairs.

- Get off the bus a few stops earlier or park further away.
- Go for a walk in your lunch break.
- Break the 60 mins exercise into smaller chunks.
- If you struggle with fitting in 60 minutes on weekdays, do 30 and then do extra on the weekend.
- Strength training exercise can help as it builds muscle mass and boosts metabolism.
- Spend less time sitting get up for 10 mins every hour.
- If watching TV, get up and jog or walk on the spot during adverts.
- If you miss an exercise session don't think "oh well that's it" and then abandon the plan, just take it in your stride and then carry on as per your exercise plan.

A few more observations from our volunteer clients:

> *"I need to get my exercise levels at a level that I'm comfortable with, at the moment I'm going to the gym once or twice a week and I want that to be three times a week."*

> *"I think having, if either a group there or having more friends that were interested in exercise…. I think it is getting someone to go with me or getting some kind of reinforcement for it, but if you're kind of doing it self-motivation kind of way then it's quite difficult to get any, you have the happy chemicals but you don't have that kind of reinforcement to go, but if you're going with someone else it's much more fun to go with someone else."*

> *"I feel better after it… I probably don't feel as lethargic… I think if I'd had a day in work and then I go home and I haven't been to the gym you don't have that sort of buzz that it gives you, that just makes me feel 'Right, I'm ready for the next part of my day'."*

3.2.4 Barriers to Maintenance

What are they?

Identifying barriers and/or perceived barriers to behaviour change is central to MI and will also form a theme for one of the group sessions. The majority of barriers to maintenance are likely to be related to diet and exercise and may include[35,36]:

- Too tired to exercise.
- Not enough time to exercise (due to e.g. family/job demands).
- Not enough information about how to increase activity.

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- Don't enjoy exercise/physical activity or lack skills.
- No-one to exercise with.
- No social/peer support to exercise (e.g. from partner).
- Cost – not able to find physical activities that are inexpensive.
- Finding it difficult to stick to a routine.
- Meals eaten away from home.
- Craving particular (high fat/sugar) foods.
- Lack of knowledge about portion size.
- Hunger ('healthy foods are not as filling').
- Cost – healthy foods are more expensive.

What is the evidence?

Research suggests maintenance is significantly less likely in individuals who report the following barriers: too tired/not enough time to exercise, no-one to exercise with, hard to stick to a routine, meals often eaten away from home, cost of healthy foods. In a study of weight maintenance in young women aged 18-32 yrs[37] the most common barriers to maintenance related to motivation, time and cost (but did not differ by socio-economic status). Women with children were also particularly likely to report lack of social support as an important barrier to physical activity (from children or partner), and lack of support and time as barriers to healthy eating.

How can you help?

Encourage clients to discuss any barriers to maintenance, and keep a record of reported barriers to monitoring and healthy diet and exercise behaviours. Encourage clients to think creatively about how to overcome these barriers within the constraints of their personal circumstances. Providing information about ways to incorporate physical activity into daily routines, e.g., using the stairs, walking instead of using the bus and providing information about e.g., portion size and exploring ways to increase social support are all likely to facilitate maintenance.

Observations from our volunteer clients related to barriers:

> *"I need to get my exercise levels at a level that I'm comfortable with... but I just talk myself out of going after work sometimes because I'm tired..."*

"My boyfriend is very worried… that I'm going to be stabbed or murdered or whatever if I go running."

"I think it is getting someone to go with me …. it's much more fun to go with someone else."

"I suppose work is a bit that sometimes can impact on [going to the gym] I'm away a lot and then, you know, I'm not able to go as easily."

"You know when you come in, you're really tired and you think 'I can't be bothered to cook anything', so you'd either go and get a takeaway…"

3.2.5 Self Efficacy

A final important element which is key to helping individuals maintain their weight loss is the concept of self efficacy.

What is it?

This refers to the confidence the person has that they have the skills and can carry out the activities required to maintain their weight in specific situations.

Why does it help (the evidence)?

The concept of self efficacy has proved crucial to ideas about health behaviour change and has been integrated into a number of different theories. It was first introduced as the key construct of Social Cognitive Theory[11] which is the main theoretical framework underpinning this intervention. Participants will not only need to know what to do and how to do it but they will need encouragement and feedback that will boost their belief and confidence in their ability to do it.

How can you help?

According to this theory there are three ways a person's self efficacy can be enhanced:

- by their own success at the behavior, e.g. losing weight or maintaining weight;

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- by observing someone similar to themselves being successful at weight loss or maintenance;
- and by verbal persuasion or encouragement from others (e.g. MI counsellors) which encourages the individual to exert more effort.

3.3 CASE STUDIES - You've had the MI style and the topics now "this is how it could look" – 3 cases or clinical challenges

Case 1 – "Poor diet and restricted ability to exercise"

Background

Liz is a 45 year old woman who has been slightly overweight all her life although this has got progressively worse with the birth of her three children. She has been yo-yo dieting over many years but was determined to lose weight recently and managed to lose nearly 3 stone by following her own diet. She wants to maintain this weight loss but feels that she must stay on a diet in order to do so and feels that she just can't keep that up. She says that if she goes off her diet she immediately starts to put on weight, even if she only eats a small amount. Although Liz has managed to lose weight her diet is, in fact, quite poor and not nutritionally sound. She does not exercise as she is self conscious about it as she still feels quite big, but also she has asthma and panics when she becomes short of breath, which happens with the slightest exercise. In addition she broke her ankle a couple of years ago which still gives her pain. Liz does not feel that she could take up and maintain any exercise because of her physical problems and so has a very low self efficacy in relation to physical activity, and is resistant to any exercise plan.

Challenge

The challenge here is to improve this client's self efficacy for exercise as it is extremely low. She is very resistant to exercise, which she might need help with to overcome. A form of appropriate exercise could be explored. There are obvious physical problems that need consideration whilst exploring appropriate physical activity options. She needs a lot of education around healthy lifestyle as her diet also is not ideal.

What could happen next?

Sue Channon reflects:

The primary focus with Liz is going to be engagement: she has worked really hard to achieve the weight loss but has been following her own diet and she may not be certain what having someone alongside her will be able to offer. Early questions can make it clear that she is still in charge: *"What types of things would it be helpful for us to talk about?"* *Her* success in losing the weight particularly in light of the physical health challenges offers great opportunities for affirmations and reflective listening is going to be key in thinking about the best way forward: *"You have worked so hard and succeeded in losing the weight but now it seems difficult to know how to keep it off."*

The first potential trap is going to be jumping into advice and action around her diet and health issues without eliciting her agenda. Once you feel that the two of you have engaged then you can move forward into thinking what it might be possible to put on the agenda without pushing her too far: *"You have said that you really want to try and keep your weight about the same. If we were to make a list of the things you might think are important to help you do that, what would be on that list?"*

Her confidence is low, so thinking about importance and confidence in weight maintenance and the factors associated with confidence could be a useful first step in the journey towards understanding the areas Liz might want to change.

Recognising that lack of knowledge may be an important factor, you could use the elicit-provide-elicit approach:

You: *"One thing some people find useful when they are maintaining weight loss is to understand how to have a reasonably healthy diet. Is this something you think you might find helpful?*

Liz: *"Yes, maybe."*

You: *"So… thinking about what you know already… what would you say makes up a healthy diet?*

Once you have elicited her agenda it will have become clearer how she views her health issues. You can work together to think about how to prioritise and what she feels confident to tackle. If the health issues are not her priority you can put them on the agenda but recognize that she might not be wanting to talk about them yet: *"You mentioned that your asthma gives you some trouble and you know that it is part of the problem with exercise so we might want to come back to that in future sessions, but today you want to think about…"*

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Steve Rollnick comments:

Yes, I like the way Sue describes a process of approaching potentially difficult topics (like health issues, a healthy diet) gently, yet nevertheless she wants us to use agenda-setting and our MI skills to approach them, searching all the time for a balance between the client's aspirations and ours. I like too the way she suggests constructing a list! While MI is such a richly *verbal* skill, we shouldn't get stuck in feeling the need to be "clever" with questions and reflections, if you know what I mean. Lists can be incredibly helpful. Visual aids and tasks like listing, backed by a genuinely curious attitude, can save many words! If you feel stuck, share it with the client, and move on…

Case 2 – "Bereavement and emotional eating"

Background

Jane is in her early thirties and single, and had lost about half a stone by attending a slimming club. She still hasn't achieved her target weight and wants to continue with her diet. But, about 6 months ago her mother became terminally ill and Jane looked after her for a time until she passed away. She tends to have a dysfunctional relationship with food and eats more when she is upset or distressed. Occasionally she binge eats. Because she has been focused on her mother over the past few months and, of course, very upset by events she has not attended her slimming group, not followed a healthy diet, and has not had time to go running which was her preferred form of exercise. Now, Jane is too scared to weigh herself regularly as she feels she is putting on more and more weight, and the confirmation of this would upset her too much, and put her into a spiral of decline. In the meantime, also, her slimming group has disbanded as the facilitator left the area. She can't get back into running as she used to run with her mother prior to her mother's illness. Running reminds Liz too much of these times with her mother, which upsets her and weakens her resolve not to give in to bingeing.

Challenge

This client has had a significant relapse and needs help with motivation to get back on track and stay on track, without being too harsh on herself. She is still in the grieving process, but does not want this to destroy all her previous efforts. She needs help to establish a healthier relationship with food and avoid the all or nothing approach to food that leads to binge eating and yo-yo dieting.

What could happen next?

Steve Rollnick reflects:

- Priority no 1, use your core skills to understand and actively empathise with her predicament. Included here is affirmation, which will comfort her in the experience of bereavement. This sounds like the ENGAGEMENT process Bill and I describe in the new framework for MI. No engagement, no foundation for MI.

  A trap? Falling into just being a good practitioner and losing focus on a return to weight loss and its maintenance. There should be times when you gently steer the discussion towards weight loss, and gauge her readiness to at least talk about this.

- Gently establish whether she is willing to talk about weight loss. She probably will be. Agenda-setting as an explicit process might be useful here, e.g., *"We've been chatting for a while now, and can we take a step back and think about where to go from here. We could talk about adapting to the loss of your mother, about weight loss, or anything else that's important to you? I'd like to get back to weight loss at some point, but it doesn't have to be in this session, we could do that some other time. How do you feel right now? What will be helpful for you?"* This sounds quite a lot like the GUIDE process Bill and I are putting into the new framework. Finding a focus.

- Ask how she feels about her weight loss in the future? The phrasing of this kind of key open question is really important and subtle, and there is no formula you can follow other than to work it out on the spot, keep it general, and make it as simple and as brief as possible. The idea here is to explore her readiness and motivation to change. This is what Bill & I mean by EVOKING in the new framework. You are listening out now for change talk. What could she do? What kind of change could make sense right now? When you hear change talk, you reflect it, because this will encourage her to explore further. If she expresses ambivalence (e.g. *"I'd like to get back to where I was, but I'm so tired all the time and I burst into tears"*), you only need to reflect this back to her with something like, *"there's only so much that you can take on at the moment"*. If she is ready to move, this kind of reflection gives her the space to do it. That's the heart of MI. You clarify, she decides….

- Is there one small thing she could do that would help her to feel better about her weight? You might not get this far in the scenario described above, but if your engagement is good, there's no harm in asking her a question like this, not right at the beginning perhaps, but towards the end. This sounds a lot like the PLANNING process Bill & I describe, and here your goal is not just to elicit a small step from her, but to gently guide her to be as specific as possible about how she might

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make this change. This will elicit commitment language, and ideally but not always possible, an "implementation intention", a very specific plan of action.

Sue Channon comments:

Having someone alongside her who understands the impact of the loss but who is also wanting to support her move towards change could make so much difference to her. Active listening and engagement will help her think through the fact that this doesn't have to be an either / or. She doesn't need to have "finished" grieving before thinking about the future in relation to her weight loss goals. Helping her to think about future plans will enable her to express hope without pressure and hearing herself talk about it may well plant the seed of change that she needs.

Case 3 – "Weight maintainer, busy, stressful life, unsupportive partner"

Background

Kate is in her late 20's and has been trying to lose weight since her teens, often successfully, but she can never seem to maintain the weight loss. She has recently lost 2 stone, and is determined this time to keep it off. She understands that she needs to balance a healthy diet with exercise if she is to do this, but has a stressful job, busy family life and an unsupportive partner, so finds it difficult to maintain the necessary behaviours. Kate's partner has a problem with alcohol, and often drinks in response to stress. His GP has told him his drinking is affecting his health so he is trying to cut down. He has told Kate he can't cope with changing his diet at the same time: she therefore finds it difficult to introduce the family to a healthier diet and often ends up snacking on unhealthy foods. Kate enjoys going to the gym and used to go with her friend after work, but feels she can no longer leave her partner alone in the evenings as she is worried he will find it difficult to cope with their two small children on his own, and that he is more likely to drink if she is not there.

Challenge

To help Kate find ways of overcoming these significant barriers to achieving a healthy diet and exercise plan, e.g., by exercising during her lunch hour and/walking to work or using an exercise video at home. It will be difficult for Kate to change her family's eating

habits given her current circumstances, so encouraging her to identify triggers for eating unhealthy foods/emotional eating might help her resist snacking at home.

What could happen next?

Steve Rollnick reflects:

- This seems like quite a nice concrete weight loss discussion, yet I would nevertheless still start the session broadly to ensure ENGAGEMENT. A good open question might be: "How are things going for you right now?", and conduct a broad review of her circumstances first. Don't forget those affirmations!
- I'd be tempted to use agenda-setting to make sure that we focus on an agreed topic, or I'd make sure by asking her a good GUIDING question like "How do you think I might be of greatest help to you today?", and I'd listen like crazy to the answers!
- This case seems perfect for using the Typical Day review (see page 21). See what you think. It would give you a very good feel for her everyday life, and exactly how she feels day-to-day.
- It seems like she might be ready to make some changes, the problem being what changes could she make in quite difficult circumstances? I'd put this observation and question to her and then work from there. This sound like a PLANNING process.
    - At the heart of this task is eliciting ideas from her, recognising these as change talk when they occur, and using reflective listening when they arise.
    - You can also offer suggestions of your own, or tell her what's worked for others, but make sure that you emphasise her freedom to choose what makes sense to her.
- I'd keep a firm eye open for the use of "self-monitoring" (see page 29). Here I imagine facing a challenge that will be quite a common one. You believe it might be good for a client to use self-monitoring, so how do you encourage uptake of this suggestion? If you just come out with it, the chances are you might meet resistance, because you are limiting the client's autonomy. A nice way of succeeding is to use the Elicit-Provide-Elicit sequence, making sure all the time that you give her choice and promote autonomy. For example:

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You: *"I wonder whether we could talk for a few moments about self-monitoring with a diary and what this actually means?"*

Kate: *"Yes, okay."*

You: *"How do you see the benefits of using a diary?" (ELICIT)*

…….. (PROVIDE any new insights that you feel might be useful) and then ask something like:

You: *"I wonder what you make of this idea of a diary?" (ELICIT and help her decide, emphasizing her freedom of choice).*

Sue Channon comments:

Kate is facing a situation with many competing demands on her resources; in the face of these she has achieved significant success and in addition to affirmation, it will be important to build on these successes using the guiding approach. Eliciting her strategies for success in weight loss and then thinking with her about how these can be adapted for maintenance will emphasise her strengths and also introduce her to ideas for relapse prevention.

Part 4: Study Specific Information

4.1 Study Protocol

Below is a summary of the trial taken from the protocol (see Appendix 2 for the full protocol).

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

To evaluate the impact of a 12 month multi-component intervention or a less intensive version on participants': Body Mass Index (primary outcome); waist circumference; waist to hip ratio; physical activity levels and diet three years from randomisation.

Design

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 three key features; MI, peer support 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 950 obese adults aged 18-70 (current or previous BMI 30+) who have lost at least 5% body weight (independently verified) from community based groups, gyms, commercial weight loss groups, GP surgeries and exercise on prescription schemes. We will also approach people trying to lost weight who will be consented into the study as soon as they have lost 5% of their body weight. Exclusion criteria include; terminal illness, pregnancy, previous bariatric surgery or inability to comply with study protocol.

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Outcome measures

The primary outcome is BMI at 3 years post randomisation and the primary contrast will be between the intensive and control groups. Secondary 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 (one year from randomisation) and at 12 and 24 months after the intervention is complete.

4.2 Description of the Intervention

Intensive Intervention Group:

Participants in this group will have 6 one-to-one MI sessions. These sessions will be delivered fortnightly for three months and will last approximately 60 minutes. For the final nine months of the intervention participants will have monthly MI telephone calls lasting around 20 minutes. 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. They will be encouraged to self regulate by weighing themselves every week and reporting this information to the study team. They will also be encouraged to self monitor diet and physical activity and record this in a diary. MI counsellors will be asked to record participants' goals and implementation intentions at individual sessions and this information will be collected by the study team. Participants also have the option to record goals and implementation intentions in their diary.

Professional-led peer group support sessions will take place monthly, lasting 1.5 hours for four months and will follow on from the face-to-face MI sessions. The purpose of the group sessions is to reinforce the main messages of the intervention as well as allowing people to share their experiences and increase peer support. We will invite participants to 'bring a buddy' (N.B. buddies cannot be other trial participants) to the sessions to

enhance peer support. The group sessions will be led by a facilitator who will revisit evidence based diet and exercise guidance at the initial session. Group sessions will address user or facilitator initiated issues around diet and exercise. These could include: barriers to maintenance, tackling negative thoughts, identifying emotional triggers for eating and coping with relapse. Participants will also have the opportunity to share problems, techniques and tips with their peers.

Less Intensive Intervention Group:

Participants in this group will have two face-to-face tailored MI sessions two weeks apart. They will be encouraged to self regulate by weekly self-weighing (to be reported to the study team) and self-monitoring of diet and activity (which participants can record in their diary if they find this helpful). They will also have the option to record goals set as well as plans for implementation in the diary (goals and implementation intentions will be recorded by MI counsellors at each session). They will also receive two MI based telephone calls at 6 and 12 months lasting around 20 minutes. The group sessions will be the same as the intensive intervention group, i.e. monthly for 4 months following on from the end of the two face-to-face MI sessions.

Control Group:

The control group will be given an information pack detailing lifestyle changes for 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.

4.3 Serious Adverse Event Reporting

Serious Adverse Events (SAEs) are defined as:

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

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- Is a congenital abnormality or birth defect

If at any point during the study you become aware of an SAE in one of your clients, we would ask you to report such an event to the WILMA Trial Manager **within 24 hours of becoming aware of the event**, either by telephone or using the form provided. Detailed instructions for reporting SAEs and the reporting form are provided at the end of the Handbook (See Appendix 3a and 3b).

4.4 Contacting Study Team

4.4.1 Contact details

Address for correspondence and invoicing:
South East Wales Trials Unit (SEWTU)
Dept. of Primary Care & Public Health,
School of Medicine, Cardiff University
7th floor, Neuadd Meirionnydd
Heath Park, Cardiff
CF14 4YS

General fax: (029) 20687611
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Key contacts

Name:	Position:	Email	el:
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Liz Randell	WILMA Trial Manager	RandellE@cardiff.ac.uk	(029) 20687608
Dr Rachel McNamara	WILMA Senior Trial Manager	McNamara@cardiff.ac.uk	(029) 20687146
Dr Sharon Simpson	WILMA Chief Investigator	SimpsonSA@cardiff.ac.uk	(029) 20687181

4.4.2 When to contact the study team

Please send all invoices (see Section 4.8) and requests for materials (e.g. Client Record Forms) and venue hire details to the WILMA Trial Administrator. If you would like information about any aspect of the WILMA study, please contact the Trial Administrator, Trial Manager or Senior Trial Manager.

In addition to the above, we would also like you to contact us in the following circumstances:

1. If you become aware of a Serious Adverse Event in any client, at any point during the study (see Section 4.3 and Appendix 3 (a & b))
2. If you are concerned that a client may have serious mental health problems and/or is at risk of self-harm. More information on the procedure for reporting mental health concerns is provided in Appendix 4 (a & b).

4.5 Participant Diary

An example of the diary given to intervention participants is provided in Appendix 5.

4.6 Client Records

An example of the Case Record Form we would like you to use for recording information at each session is provided in Appendix 6. We will provide you with additional copies for use with clients. If you run out of Client Record Sheets, please contact the WILMA Trial Administrator (details provided above in Section 4.4).

4.7 Booking venues for MI

The WILMA study team can provide you with details of local venues for hire, suitable for conducting the individual MI sessions. We can also book venues for you directly if needs to although we ask that you do this where possible: please contact the WILMA Trial Administrator for more information on venue booking.

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4.8 Claiming Expenses/Payment

At the start of the study, we will provide you with instructions for claiming expenses (for attending supervision sessions and for room hire if applicable). We will also provide detailed instructions on how to submit invoices, which should be sent to the address detailed in Section 4.4.1.

4.9 Lone Worker Policy

When conducting individual sessions, particularly when visiting client's homes, we would ask you to comply with the SEWTU Lone Worker Policy to ensure your personal safety (See Appendix 7).

5.0 Supervision

Supervisors' contact details can be obtained by contacting the WILMA study team on the number above.

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7. Appendices[1]

Appendix 1:	WILMA Study Processes – Flow Chart
Appendix 2:	WILMA protocol V7.0 (15/05/2012)
Appendix 3a:	WILMA Procedural Information Sheet: Serious Adverse Event Reporting (V1.0, 24/02/2010)
Appendix 3b:	WILMA Serious Adverse Event Reporting Form (V1.0, 24/02/2010)
Appendix 4a:	WILMA Procedure for Reporting Harm (V1.0, 03/09/2010)
Appendix 4b:	WILMA Actual or Risk of Harm Reporting Form (V1.0, 18/08/2010)
Appendix 5:	WILMA Intervention Group Diary (V3.0, 09/03/2011)
Appendix 6:	WILMA MI Case Record Form (V1.0, 03/09/2010)
Appendix 7:	SEWTU Lone Worker Policy (V2.0, 28/07/2009)
Appendix 8:	WILMA MI Counsellor Contract (V2.4, 10/05/2012)
Appendix 9:	WILMA MI Counsellor Training Materials
Appendix 10a:	Ethics Permissions Letter (18/03/2010)
Appendix 10b:	Ethics Permissions Letter: amendment 1 (06/09/2010)
Appendix 10c:	Ethics Permissions Letter: amendment 2 (10/05/2011)
Appendix 10d:	Ethics Permissions Letter: amendment 3 (31/08/2011)
Appendix 10e:	Ethics Permissions Letter: amendment 4 (29/11/2011)
Appendix 10f:	Ethics Permissions Letter: amendment 5 (19/04/2012)
Appendix 10g:	Ethics Permissions Letter: amendment 6 (06/06/2012)

[1] All appendices available on request.

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Appendix 2 Group facilitators' handbook









THE WILMA GROUP FACILITATORS HANDBOOK

By

Sharon Simpson, Rachel McNamara, Chris Shaw

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Part 1: 'Setting the scene'

1.1 Summary of the WILMA study

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

To evaluate the impact of a 12 month multi-component intervention or a less intensive version on participants': Body Mass Index (primary outcome); waist circumference; waist to hip ratio; physical activity levels and diet three years from randomisation.

Design

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 three key features; MI, peer support 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 950 obese adults aged 18-70 (current or previous BMI 30+) who have lost at least 5% body weight (independently verified) from community based groups, gyms, commercial weight loss groups, GP surgeries and exercise on prescription schemes. 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: terminal illness, pregnancy, previous bariatric surgery or inability to comply with study protocol.

Outcome measures

The primary outcome is BMI at 3 years post randomisation and the primary contrast will be between the intensive and control groups. Secondary 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

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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 (one year from randomisation) and at 12 and 24 months after the intervention is complete.

For more information please see Appendix 9 for the full protocol.

1.2 Who are the participants?

Participants in the WILMA study will be a mix of people from all sorts of backgrounds. We will be recruiting them from primary care, exercise on prescription schemes, slimming groups and gyms. These individuals will have lost at least 5% of their body weight and have had a previous or current BMI of 30+. We are recruiting men and women aged 18-70, although it is likely we will recruit many more women than men. Men don't tend to volunteer to take part in research as much as women, and although numbers of men and women who are obese are roughly similar, men do not tend to seek help to lose weight.

Some of these people will want to maintain the weight loss they have already achieved, but many will want to continue to lose weight. We wish to support them in both of these aims, but most importantly in maintaining their 5% weight loss. You will likely encounter individuals who have lost weight for many different reasons; cosmetic, family or peer pressure and also for health reasons. Some may have lost weight just to be healthier generally, others because they are awaiting an operation or because they have been diagnosed with a serious health condition, like heart disease or diabetes. Many participants will have what could be called 'normal' weight gain (of for example up to 2 to 3 stones), who have experienced being 'normal' weight but have gained weight perhaps after having children. Others will have a lifetime problem with weight, and weight loss might have resulted in a total change in their perceptions about themselves.

You will encounter individuals who have psychological difficulties associated with their weight, some who have a very high previous or current BMI, as well as those who "just wanted to lose a bit" for example after the birth of a baby. Some of these individuals will have a very dysfunctional relationship with food. The methods for achieving weight loss will also be very variable from calorie counting, just increasing exercise levels, both diet

and exercise changes, prescribed obesity medication, crash diets, slimming plans or groups like 'Lighter Life' or Slimming World. We won't be including anyone who has had bariatric surgery. It is likely given what the research evidence says that many of these individuals will have lost weight and put it back on again in a repeating pattern over the years.

Below are some quotes from volunteers that have been involved in the study, one of whom is trying to maintain weight loss after having lost 8 stones in a relatively short time period and another who is still trying to lose more weight. We feel these give a nice illustration of the types of issues and the broad spectrum of participants you might encounter.

1.2.1 Weight patterns

These participants give accounts of different experiences of weight patterns and reflect on the concerns about yo-yoing of weight.

> *"I've always been very very large, my highest was about twenty-four stone… [in] high school I was about seventeen, eighteen stone when I was about seventeen, then I went to university and got around eighteen stone and then went back up to about twenty-three."*

> *"I probably did the normal thing of going from dress size to dress size without realising that I'd got to a size twenty and thinking 'I don't want to be here'… I thought 'I really need to do something about this' so I joined Weight Watchers… I've probably got about another half stone to go and then I'm happy."*

> *"I think it's that fear that you might go, because I've lost weight before and gone back up, and over the last three years I've probably gone down and stayed down and so you just hope that you're not going to bounce back up or fall off the rails again really."*

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1.2.2 Self perceptions and body image

Here the participants reflect on changes in self perceptions and body image associated with weight loss.

> *"I guess I've got a lot more confidence, and I don't mind being looked at as much… because it's not that I've never had a lot of confidence, I was always happy to dance and have fun and things, but I think you almost apologise for yourself when you're quite big."*

> *"I wanted to put it back on cos I felt I'd gone too low, I didn't feel comfortable being that thin I didn't feel very strong… I wanted a kind of safe weight, not kind of out-of-control weight but I wanted to find a weight that suited me; I had a two year kind of period of adjustment to finding the weight I want to be."*

> *"…cos the thing is it's great losing loads and loads of weight, but then you get to the end of it and… if you've been larger all your life you've got absolutely no idea what you're meant to look like or what normal is… I got drunk and tried to move out of the way of someone walking towards me and there was a mirror, and actually I didn't associate myself with the person I was seeing."*

> *"…and actually quite a lot of the other girls who are losing weight say the same thing, that they all think in their minds, [they] picture themselves as much much more negative than it is actually."*

> *"It's probably around liking myself, I probably didn't like… the vision that I'd become so it's probably liberated me a little bit in the fact that I feel good about myself, I feel fit and healthy so I feel a lot younger… I would say probably the headline would be I like myself. I think the person I see is the person I feel inside now, whereas probably the two didn't go together before, and probably I've got more confidence."*

> *" …no no, it is … actually kind of allowing myself to, it's alright if I am a size fourteen, it's not the end of the world because actually the only person who's given a hard time….someone on the street isn't going to say 'You're a size twelve, you're a size fourteen', they're just gonna say 'Look at the person'…it's only me that knows so why am I making myself feel so miserable about that change which is two inches? So it's almost a self-complete, not loathing, but you kind of try to sabotage yourself and make yourself feel awful…"*

1.2.3 Maintenance and weight gain

What is often the challenge for people is to know how to maintain weight loss once they have achieved it and the prospect induces fear:

> *"I suppose with weight loss you think 'Right okay, weight loss', but then how do you change isn't it, cos all of a sudden you go from a lifestyle where you're trying to lose weight and then say 'Right okay I've got to my plateau'. I'm hoping I'll reach a normal plateau… I hopefully will just be able to maintain it by the lifestyle that I have at the moment without perhaps, that extra bit of exercise or whatever that's going to help a little bit more weight loss."*

> *"It is scary, maintaining. Losing weight's relatively easy once you're in the swing of it and you know what to do. But it's when you've finished and keeping it off, it's terrifying. Although I'm not terrified now, I kind of got my head around it, but it is very odd."*

> *"It's not about being on a diet, because if you're on a diet then you're going to have to come off it, it's just about changing the way that you think…I think it's about getting as many people involved as you can and make it as normal or make it as integrated into your life as you can, so actually it's not something that's different to what your normality is."*

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> *"[The key is] that steady weight-loss and the fact that you've gone to a healthy eating lifestyle rather than some of the silly fad diets I've done before, which were great for losing weight very very quickly but actually as soon as you started eating normally it all went back on again."*

> *"I don't properly see myself ever finishing on… the healthy eating plan but just carrying on, so it's not like it's a diet that I'm stopping cos I'll just be continuing it really."*

It is also the case that many people will have had repeated episodes of weight loss followed by weight gain with limited success maintaining the weight they have lost. This is one of the major challenges for these individuals to find ways to change their lifestyle to help them in their weight maintenance. Often they can manage to lose weight in a relatively short time span but the more permanent lifestyle changes required to maintain weight loss prove elusive and difficult to achieve.

> *"I think I know that I'll still have to go at least two times a week for that maintenance to happen, because I think that it's all about inputs and outputs isn't it, and if you're going to have a nice lifestyle and go out and have the occasional treat then yes, you need to add something; that exercise is the other thing."*

> *"I hate going to the gym, I hate the walk to the gym, I hate getting ready for the gym, I hate the smell of my gym bag but once I'm at the gym it's great and I really enjoy it, and I come home feeling like I've polished my halo and everything's good with the world."*

Other challenges include stress at work and relationships with friends and family, which can derail good intentions.

> *"Um… probably, um, stress, workload, so you know when you come in you're really tired and you think 'I can't be bothered to cook anything', so you'd either go and get a takeaway or you do something really quick and not good… [also] outside pressures, other people going 'Oh go on why don't you, it's only today', so those sorts of things."*

> *"I need to get my exercise levels at a level that I'm comfortable with, at the moment I'm going to the gym once or twice a week and I want that to be three times a week but I just talk myself out of going after work sometimes because I'm tired."*

> *"I suppose that I've actually decided that I want to be nice and healthy and that's the way that I deal with stress now, so it's probably just a different way… because I think before I was stressed I came home thinking 'Oh I'll have a glass of wine' and just sit down and veg out in front of the telly, whereas now I'll go to the gym and then come home and have something nice for tea."*

Participants reflect here on other issues. One interesting observation made was that when the participant lost a lot of weight that's when they experienced success and that the only way from that point is failure; the notion that you could still be seven and a half stone lighter than you were but that any weight gain was still represented as a failure.

> *"So there's that kind of dread [of putting weight on again], and then if you've got no-one there to support you it's really difficult not to kind of feel that emotion and that kind of worry and not turn to comfort eating because you've got nothing, the only person weighing yourself is you and you kind of go into a bit of denial and you start lying to yourself."*

> *"If you do put weight on you start to panic, and then you get paranoid … it's like when I go home are people going to notice that I've put on weight or there'll be whispers of people going, 'Oh well I knew she couldn't keep it off'. Because there's such a positive thing [when you lose weight], people go, 'Wow you look amazing' and then you kind of go back again and you don't want them to say, 'Oh you've put it back on again'."*

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Part 2: What does research tell us about weight loss maintenance?

2.1 Weight maintenance

There hasn't been much research looking at weight loss maintenance, it has mainly concentrated on ways to help people lose weight[1,2,3]. A few studies have found that interventions to promote weight loss maintenance have been able to help reduce weight gain at two year follow-up[1,3,4]. However the prevention of weight regain remains a challenge and around a third of the weight lost is regained in the following year[5].

One of the key differences between losing weight and maintaining weight loss is that 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. It is helping participants find this longer term behaviour change that is one of the biggest challenges we face.

Weight loss occurs when energy expended through physical activity and essential bodily functions (basal metabolic rate) exceeds energy intake from food and drink.



Weight maintenance occurs when energy expenditure through physical activity and essential bodily functions equals energy intake.



It is worth remembering that as people lose weight, basal metabolic rate and the amount of energy expended to complete physical activity (e.g. walking, gardening,

housework) decline. So maintaining an energy deficit or energy balance is difficult and this is one reason that maintaining weight loss is difficult.

The psychological processes, skills and strategies which are likely to be effective for weight maintenance may be different from those that are needed to lose weight[6,7]. Research examining 5000 people on the National Weight Control Register (United States) suggests that the only thing those losing weight have in common is that they combined diet and exercise to lose weight[8]. When they looked at the maintenance phase however, a number of common aspects were identified as being important in maintenance. These included;

- low fat diet,
- eating breakfast,
- self monitoring of weight,
- higher levels of physical activity[9].

Other research has supported these findings and also identified a number of other important aspects associated with successful maintenance. These are;

- low calorie and low fat foods,
- tailoring of advice,
- self regulation/monitoring of diet, exercise and weight
- social support,
- internal motivation
- self efficacy[8,10].

Many of these key factors are incorporated in the WILMA intervention. These are explained in more detail below.

2.2 *Self monitoring*

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Self monitoring involves participants weighing themselves weekly and recording their weight. This is another key aspect of our intervention and we will be asking participants to keep a diary to record their weight (see Appendix 14 for the diary) and also record it online using the study website where they will be able to see a graph of their progress, this information will only be shared with the study team. The diary will also give them the opportunity to record their diet and exercise if they wish. This isn't a necessary part of the intervention but self monitoring has been found to be associated with success in weight maintenance as it is one form of feedback for people to assess the effectiveness of the strategies that they have adopted. So, by weighing themselves regularly they can assess whether they are eating too much, too little, the right amount or whether they need to balance their food and exercise regime differently. If people don't weigh themselves regularly they do not know if they are putting weight back on and can, effectively, 'kid themselves'. It also avoids them putting on an amount of weight that is daunting to deal with. They may put on a pound or two which is easily dealt with, but if they did not weigh themselves for a long time this might turn into 5 pound or half a stone which is a lot more difficult.

Participants will probably not want to monitor diet and exercise by writing it down all the time. They may find that they get into a routine that suits them and only when they have a bit of a disruption to their routine (for example after a holiday or Christmas) that they may want to go back to some more intensive attention to their behaviours. Some people may find it helps them whereas others may not, but it is important to weigh regularly and participants should be encouraged to do this in the group sessions.

But participants must also be reassured that some fluctuation in weight is to be expected depending on circumstances. For women, they may find that their weight changes in relation to their menstrual cycle and may be due to water retention. A good way to use the self monitoring is to set a range of weight within which they aim to maintain. This might be a range of say, 4 – 5 pounds within which they may fluctuate. Similarly, if participants are still aiming to lose weight they need to allow themselves a range which will include a few pounds above what they were last time they weighed themselves in order to allow for normal fluctuations. That way, they should not be too upset if they appear to have 'put on weight' since their last weighing.

Within the group sessions it will be useful to encourage participants to discuss how useful they find the self monitoring and perhaps also hints and tips on how they get into a routine of weighing themselves and maintaining a diet and/or exercise diary. For example, an exercise diary may help people to set goals for themselves by recording steps walked, or distance run or cycled, and by setting incremental steps for increasing this. The diary will give them feedback on their progress and will also allow them to see how changes in exercise impact on their weight.

The participants we interviewed suggested that you need an objective measure of whether you are putting on weight or not. How you look is too subjective a perception. Also you can deceive yourself about your weight unless you have objective evidence. They also suggested that self regulation could be used productively to set limits within which weight can fluctuate.

> *"I think it's the weigh-in, I know that some people hate being weighed… but once a week so you can actually see the numbers and you can see the difference, or you can see that you haven't put on weight… it's something that clicks in your head and you can see, [having] something physical that you can see, because actually if you're going on what you look like quite often what you perceive yourself to look like is actually not what you look like."*

> *"… I do think it really helps, writing down everything that you eat, and maybe initially once you've lost weight that's really helpful… it's that extra bit of control, you feel even more in control because you're writing down everything that you eat. I suppose because I know I can correlate me having refined sugars with me having mood swings and feeling really low in energy it's helpful in that way if you can write down not only your food but your moods as well, because you can find a correlation between that."*

> *"I would think with weight maintenance and I do weigh fairly regularly, and I would say that if I notice that a pound or two is creeping on… it is that prompt quickly to say 'Hang on, you've put on a couple of pounds' and bring it back now, whereas I think if I maybe weighed once a week or once every two weeks and then found I'd put on four pounds that could be the bit that made me think 'Hm, how am I ever going to pull that back?'"*

> *"For some people weighing too often can be demotivating and pushes them into a negative spiral, however, I think… for me it's a motivational aid."*

2.3 Goal setting and action plans or implementation intentions

Goal setting is important in helping us to form a plan for change or maintenance of behaviours. Goals can be general or specific, they can be for today, next week or next

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month. Examples of goals include 'lose weight', 'eat less fatty food', 'go to the gym'. Goal intentions specify **what** you will do.

Implementation intentions are 'If-Then' statements that are important for translating your intention to change your behaviour into a specific action.

Implementation intentions have been shown to be very effective in overcoming a number of problems that prevent people from changing their behaviour. These include

- 'failure to get started' (failing to act, missing opportunities, initial reluctance to change).
- 'getting derailed' (distractions, temptations, habits, cravings, emotional distress) where unwanted influences get prioritized over pursuit of the ongoing goal.

Implementation intentions specify **when, where and what** one intends to do. For example, '**If** it is a weekday, and I have just finished work, **then** I will go to the park and spend 30 minutes running round the lake'.

When	Every day this week after work
Where	The park
What	Run round the lake for 30 minutes

Goal setting is an important process in behaviour change and maintenance as it facilitates planning towards that goal and it facilitates change and allows the participant to monitor their behaviour in relation to achieving the goal. If the goal is not being achieved it allows the process of problem solving to kick in to facilitate achievement of the goal. Problem solving is a way of dealing with perceived barriers to carrying out weight maintenance behaviours and requires the participants to identify their own solutions to possible barriers that fit into their individual lifestyles.

A considerable body of research has shown that the link between a person's intention to change their behaviour and actually changing it is not strong. Research has shown that formation of implementation intentions doubles the chances of completing the behaviour [11,12,13]. Importantly implementation intentions increase the chance of the behaviour being automatic or habitual as the situation then triggers the behaviour. These are also important in planning for slip-ups such as "I ate one cake so the diet's out the window and I might as well eat the whole lot." Instead "If I slip up on my diet then…."

These can also be used in ways to reward oneself and reinforce the behaviour such as "If I go to the gym this week then I can go out for dinner."

Implementation intentions also help individuals establish new habits. Implementation intentions specify a plan of when, where and what 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.

Encourage participants to:

- Set attainable and reasonable goals
- Make goals meaningful – how do they fit with a participant's overall goals and values. For example, if spending time with their family is important then they might want to choose doing exercise with them rather than going alone to the gym.
- Encourage development of implementation intentions "If …. Then….". Note that these can be in relation to smaller or larger goals.

2.4 Habits

The aim of the strategies described above is to make appropriate weight maintenance behaviours automatic, or in other words turn them into good habits. Once something becomes a habit it no longer requires as much effort, as one can do it without thinking about it and it feels strange if one doesn't do it.

Behaviours can become habitual if they are repeated often, or if they are linked to cues in the environment so that the cue triggers the behaviour rather than it requiring an effortful decision. Implementation intentions, discussed above, help by linking environmental cues to the behaviour. This takes away the need for any decision making. For example, the participant may wish to do more exercise so they might form an implementation intention that relates to taking their kit to work so that they can go to the gym on their way home. They can then form a second implementation intention that relates to them going to the gym on their way home from work. This saves them struggling over the decision that evening of whether, once they have got home, to get ready and go out again.

These intentions and plans must be realistic and fit in with lifestyle or they will not be successful. Group work could help identify how such habits may be formed and also

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reassure people that by becoming a habit things become easier to do over time. But it may also be useful to identify bad habits and how these may be broken by replacing them with good habits. For example, a glass of wine in the evening may become a habit as a way of de-stressing after work, but exercise can also be a good de-stressor and once the person has tried it a few times, instead of a sit down and a glass of wine, it may begin to be rewarding of itself as they realise how much better they feel for it and how enjoyable it was.

Many of the strategies described above will help in the formation of habits but it would be a good idea for participants to be explicitly aware of this and to discuss it within the group, so that their self-efficacy for 'good habit formation' can be enhanced.

The participants emphasized the importance of developing good habits and that these got easier as time went on:

> *"Yeah, and it probably got easier as the journey went on and the fact that you then got used to set foods and menus that you knew you were okay, so… you probably had to think about it more in the beginning."*

> *"I think to be honest I probably won't really introduce it, I think I'd got into a habit of a glass of wine in the night, you know, come in, you sort out the kids and you sit down with a glass of wine, and I think it just became a habit."*

2.5 Social support

By social support we mean support from family and friends, and peer support from other people who are trying to follow a weight maintenance or weight loss programme. The Motivational Interviewing (MI) counsellors and Group Facilitators will be a valuable source of support for people but they will also need support on a day to day basis to encourage them and to help them keep to a healthy diet and a good exercise programme.

Helping participants to develop their social support network is a specific aspect of our intervention, and the group work is key to this. There is a lot of research evidence that suggests that more people complete treatment and maintain their weight loss if they have social support, and there are a number of ways in which it helps people. It helps to keep people motivated as they can share experiences and can look to others for role

models. This can give them the confidence to do things that they perhaps thought were not possible for them. That is, it improves their self-efficacy, or their confidence in their own ability to do certain things, such as going to the gym or out running. People can support each other by showing empathy and understanding as they will probably have experienced many of the situations and feelings themselves, and on a practical level, they can exchange hints and tips on how to cope.

We hope to encourage all these things within the group sessions. We need to encourage people to 'buddy up' so that they have particular people that they can go to for help and support, or for company should they want to exercise with someone. As a group facilitator it will be important to monitor these relationships to ensure that they are useful to the individuals concerned and no-one is experiencing any difficulties. For some it may be better to encourage small groups of three or four, but people are likely to gravitate to other like-minded people in the wider group. However, we also need to avoid cliques developing and so it may be best to encourage people to circulate widely in the group when carrying out some of the activities.

Another aspect of the group sessions will be information exchange. As a group facilitator you will encourage people to exchange information about coping mechanisms and will carry out some specific activities which aim to do this.

As well as the support provided by the group we will want to help people get the best support they can from their family and friends. People can sometimes be disruptive when someone is trying to change their behaviour for the positive such as losing weight, or giving up smoking etc and can be unsupportive either knowingly or unknowingly. The group sessions will be an opportunity to explore these issues and exchange experiences, although the facilitator must not allow the discussion to get too embroiled in individual problems as that is what the individual sessions are for. The sessions should be about working with people's strengths. But general strategies of encouraging families to be supportive can be shared along with some personal experience if the participants wish.

The importance of both peer and professional support was noted by the volunteer participants.

Peer:

> *"This support group was amazing with Lighter Life and you saw the same women every single week and I did it for two hundred days and I kept in contact with them all…. I just need to have other people who were doing it the same time which was why I joined Slimming World."*

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> *"I don't think I would be able to do it on my own which is why, although it did feel a bit like, well, not a failure going into a group again but I don't think I could do it without someone there, either reinforcing it and saying 'you're doing really well, you're on the right track, or someone going 'Okay you didn't do so well but why, what do you think it is?"*
>
> *"…there being other people there saying exactly the same things as you, saying I had a row with someone and drank a bottle of wine, ……you can connect with other people… you get their understanding and you can understand them and you can get comfort in that, and it just brings you closer to people and makes you feel a bit more normal, like you're not on your own."*

> *"I think it is getting someone to go with me or getting some kind of reinforcement for it, but if you're kind of doing it self-motivation kind of way then you don't, it's quite difficult to get any, you have the happy chemicals but you don't have that kind of reinforcement to go, but if you're going with someone else it's much more fun to go with someone else."*

Professional:

> *"I don't think I could do it without someone there, either reinforcing it and saying You're doing really well you're on the right track, or someone going Okay you didn't do so well but why, what do you think it is?"*

> *"I'm not sure… I don't know why it clicked in my brain but I didn't want to call it help because then I associate that with failure. It's almost like saying help that you can't do it on my own, but actually I don't think I can do it on my own."*

The participants also mentioned that there could be negative aspects of social support:

> *"My boyfriend was telling me off… I can go through packets and packets of Kit Kats and chocolate and initially he wanted me to tell him everything I was eating cos he wanted me to feel bad so I wouldn't do it, and I'm like 'That's not going to work, cos then I'm not going to tell you what I eat and then I'm going to be embarrassed and then I'm going to feel bad about myself, and then I'm just going to want to eat more Kit Kats.'"*

2.6 *Self efficacy*

This was mentioned previously in relation to social support and refers to the confidence a person has that they have the skills to carry out the activities required for them to maintain their weight.

Much research has shown the importance of self efficacy to many different sorts of health behaviours and is an integral part of theories used to explain behaviour change (particularly social cognitive theory). One of the key aims of Motivational Interviewing is to improve self efficacy and so we wish to further support this in the group sessions.

There are three main processes that tend to bring about improvements in self-efficacy. These are:

1. Experiencing success at the behaviour
2. Observing someone else being successful at the behaviour
3. Encouragement from others.

In relation to the first, participants will have experienced success at weight loss as they must have lost a certain amount to enter the study. However, weight maintenance may require a change in their behaviour and may be very daunting. They may not feel confident that they have the ability to do that. We have discussed self monitoring above, which is one way of allowing people to see their success in weight maintenance, and so by self-monitoring they can give themselves positive feedback. It will be important for the Counsellor and the Group Facilitator to reinforce this positive feedback and sounds of encouragement and reassurance that 'see, you can do it' should help to build their self-efficacy.

It is likely that all will be embarking on some new behaviours during the study, whether it by trying new forms of exercise, increasing exercise, or developing more healthy diets and so they may be contemplating behaviours that they have never tried before. In this case it may give them confidence to see other people being successful. For example, they may feel that they would not be able to go running out in the street or go to a gym as they would feel self conscious. Seeing someone else who is of a similar weight or build as themselves may give them the confidence to do this themselves. This is a 'if they can do it, then so can I' approach. This is one way in which social support can be helpful and is a very important aspect of the group work. It allows people to see what others in their position are doing and open up activities that they previously felt were impossible.

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Verbal encouragement may come from their Counsellor, you as Group Facilitator, or from their family, friends or others in the Group. This will be a combination of positive feedback and reassuring them they have the necessary skills and motivation.

2.7 The WILMA Intervention

The WILMA intervention consists of three main elements Motivational Interviewing, self monitoring and social support. Motivational Interviewing (MI) is the key ingredient of the intervention. MI is a client-centred technique, emphasizing personal autonomy, which enhances motivation for change. MI has been shown to be effective as an adjunct to a behavioural weight control program. It can be useful in maintaining behaviour change as well as initiating change 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 even when delivered by telephone. 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 and even when sessions are as short as 15 minutes.

Motivational interviewing uses 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. MI is not just being "client-centred", or "being nice to people", but is a purposeful and goal-directed activity in which you adhere to three core spirit elements:

Collaboration: Work with clients as a guide. This is not about "being nice and friendly", or "nice and empathic", but about using core skills to engage the client and help them to clarify what changes they might consider.

Evocation: You rely on their aspirations and unfolding talk about change as your principle guide. You follow this, using reflection to evoke more change talk, even if the conversation is of a very practical nature (e.g. setting goals).

Autonomy support: Both your attitude and the words you use reflect respect for their freedom to make up their own mind. You avoid simple, single solution talk and advice-giving, because this merely evokes resistance and a feeling of undermining autonomy. You avoid the "righting reflex". You champion flexibility and you offer options.

For a useful recent paper on MI please see Appendix 18. The MI will be delivered to participants on a one-to-one basis. Participants will receive both face to face sessions and follow-up telephone MI.

Peer and social support is important in weight loss maintenance since the surrounding environment can encourage or impede weight maintenance. Social support can increase the proportion of people who complete treatment and maintain all weight lost at 10 month follow-up by around 25%. Continued professional support has also been shown to improve maintenance and studies have shown that social support is related to better weight maintenance. Social support may offer benefits like reinforcement, encouragement, motivation, empathy, role modelling, increased self efficacy and confidence. The peer group support sessions will facilitate and contribute to participants' social support.

The final element is self monitoring this is useful for weight maintenance and is recommended by NICE. This consists of regular self weighing and monitoring of diet and physical activity. We will be asking participants to weigh themselves weekly.

2.8 The WILMA trial groups

There are three trial groups in the WILMA study; the intensive intervention group, the less intensive intervention group and the control group. Participants will be randomized to one of these three groups.

Intensive Intervention Group

Participants in this group will have 6 one-to-one MI sessions. These sessions will be delivered fortnightly for three months and will last approximately 60 minutes. For the final nine months of the intervention participants will have monthly MI telephone calls lasting around 20 minutes. Diet and physical activity will be discussed in the MI sessions in line with recent NICE 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. They will be encouraged to self regulate by weighing themselves every week and reporting this information to the study team. They will also be encouraged to self monitor diet and physical activity and record this in a diary. MI counsellors will be asked to record participants' goals and implementation intentions at individual sessions and this information will be collected by the study team. Participants also have the option to record goals and implementation intentions in their diary.

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Professional-led peer group support sessions will take place monthly, lasting 1.5 hours for four months and will follow on from the face-to-face MI sessions. The purpose of the group sessions is to reinforce the main messages of the intervention as well as allowing people to share their experiences and increase peer support. We will invite participants to 'bring a buddy' (N.B. **buddies cannot be other trial participants**) to the start of their sessions to enhance peer support. The group sessions will be led by a facilitator. Group sessions will address either user or facilitator initiated issues around diet and physical activity. These will include: barriers to maintenance, social support, tackling negative thoughts, identifying emotional triggers for eating and coping with relapse. Participants will also have the opportunity to share problems, techniques and tips with their peers.

Less Intensive Intervention Group

Participants in this group will have two face-to-face tailored MI sessions two weeks apart. They will be encouraged to self regulate by weekly self-weighing (to be reported to the study team) and self-monitoring of diet and activity (which participants can record in their diary if they find this helpful). They will also have the option to record goals set as well as plans for implementation in the diary (goals and implementation intentions will be recorded by MI counsellors at each session). They will also receive two MI based telephone calls at 6 and 12 months lasting around 20 minutes. The group sessions will be the same as the intensive intervention group, i.e. monthly for 4 months following on from the end of the two face-to-face MI sessions.

Control Group

The control group will be given an information pack detailing lifestyle changes for 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 healthy eating and physical activity.

Part 3: Group sessions

3.1 Group Facilitation Skills

In this manual we provide information on the background to the study, the study itself, the intervention and the content of the individual peer groups but the key to the effectiveness of the WILMA peer support groups is the facilitation skills of the person running the groups. These skills take time to perfect but we offer below a few pointers and suggestions about how to run the groups and improve the experience of the attendees as well as your own experiences within these groups. At its heart group facilitation is about the process of helping people to explore, learn and change.

3.1.1 Key Issues

Role of the group facilitator

Group facilitators have to be to some degree separate from the group, they should not be members of the group as this can cause confusion around the role the facilitator is taking[14]. Facilitators need to be neutral, which can be difficult as they will need to intervene and offer ideas or insights. Facilitating and remaining neutral, 'requires listening to members' views, and remaining curious about how their reasoning differs from others (and your private views), so that you can help the group engage in productive conversation'[14]. A good facilitator is *not the decision-maker*. If the facilitator is seen as able to override decisions made in the group this will affect the way that group members relate to the facilitator[14,15]. Facilitators are *experts on, and encourage the process of the group*.

Try to get everyone involved

One problem with group conversations is that often one or two individuals dominate the group discussion. People often allow others to dominate a conversation even when they find it uncomfortable to do so. In this situation, acknowledge what the speaker is saying and then ask for input from someone else. Be careful also that you are not putting people on the spot particularly those who are shy about talking in front of other people. It might be easier to ask if anyone else has a view or change the topic and ask others for their viewpoint or ideas. One thing to consider when facilitating the group is that you may have to interrupt people. This is hard for many of us as we are taught to listen when others are speaking.

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Handling challenging group members

It is likely that during the course of running the groups that you will encounter 'challenging' individuals. There is the individual who tends to talk over other people and dominate the conversation. You may want to say to the group that you would like everyone to contribute if they are comfortable to do so and you may have to talk to this person after the group, affirming their contribution but suggesting to them that you need their help in getting the other quieter members to contribute and this might involve them making contributions briefer or less often. The opposite end of the spectrum is the person who doesn't contribute. Reminding the group that everyone has something useful to contribute or maybe doing smaller group work with feeding back may help them talk in front of the group. Be sure to affirm what they say when they do contribute. You may also experience people who are insensitive to other group members it is worth reiterating the purpose of the group and the 'safe' environment and then speaking to the person one-to –one, perhaps asking them to help make the group 'safe'.

Being the 'expert'

One of the intimidating things about facilitating a group discussion is feeling like you have to have the 'right' answers. It's easy to worry about being asked difficult questions and not knowing answers. However group facilitation is not about being the expert, you don't have to have all the right answers. The main role of the facilitator is to create and facilitate discussion, to challenge people to consider the topic of discussion and to create a 'safe' place where people feel that they can share their views with others and to help everyone feel valued. If particular questions or issues come up that you need input on from the WILMA team, just tell the group that you will feed back next time on that issue once you have consulted us.

3.1.2 Planning your group session

Below is a list of things to be considered when planning the conduct of your group sessions:

- Make sure the groups are run in the 'spirit of motivational interviewing' e.g. use a guiding rather than a directing style.
- Keep the sessions friendly and 'light'
- Introductions – keep these brief – e.g. one line on why they have come to group - but bear in mind that some group members will be new to the group.
- Set topics and schedules – reiterate the purpose of the group and define the focus of the particular group session.
- Reiterate the 5 golden rules of the group at each session.
- Create a safe environment by reminding everyone of the confidentiality of the group – 'what is said here stays here'.
- Avoid giving unrequested advice in the group.

- End the session by taking stock and looking at any goals the group has set, thanking everyone for their contributions.
- Remind them of the time and topic of the next group session.
- Make sure you keep to time and if anything comes up that requires more discussion maybe schedule that in for next time.
- Summarise anything you have agreed to do.

Other tips on running the groups:

- Paraphrase what an individual has said to make them feel understood – "So what you are saying is….
- Check with the participant that you have understood what they are saying – "Are you saying that …."
- Give positive feedback.
- Elaborate on participants comments.
- Focus on how things could work - not why they don't work (solution focused rather than problem focused).
- Mediate where there are differences between individuals.
- Ask open-ended questions.
- Ask follow-up questions.
- Offer alternative viewpoints to get the discussion going.
- Summarize the main points from the discussion.

3.1.3 Five Golden Rules

These will be shared with participants at the beginning of every group session.

1. Confidentiality.
2. Listen respectfully and agree to disagree.
3. One person to speak at a time.
4. Draw out solutions from the participants rather than give solutions wherever possible.
5. Emphasise the positive – work with people's strengths.

3.2 WILMA groups

Participants in the WILMA study will be expected to attend four group sessions. The groups will be run on a rolling schedule repeating every four weeks. So people will join at different times. Please try and make newcomers as welcome as possible maybe pairing them up with people who have been at the sessions more than once. It is possible that

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some of the sessions will be running with very small numbers, until more participants are recruited. If there are only a few people try and restructure the group based work to cope with these small numbers – you may need to act as a participant in the group work if there are only a few people.

Some people will be very new to the idea of group based support and may find it uncomfortable to talk in front of the whole group or take part in group activities. At the beginning of each session please make it clear that we want everyone to enjoy the session and find it useful and that they don't have to do anything they aren't comfortable with. Try to get volunteers where at all possible to feedback to the main group. Also if people have questions that they don't want to ask in front of everyone please make time to speak to them after the group. If you are asked questions that you don't know the answer to don't worry as you aren't there as the 'expert' but as the facilitator. Tell them that you will consult the team and get back to them at the next session or by email/phone if they have completed their four sessions.

It will be up to you to arrange sessions and a venue, but the WILMA team will help with this if you require us to. We will pay for the cost of the venue which you can claim back from us if you pay for it (see Section 5). If you are ill or need holiday cover please call the WILMA team as soon as possible and we will try and arrange another group facilitator to cover this. If a session has to be cancelled ***it is your responsibility to let the team know in good time so we can try and arrange alternative cover or notify the individuals who would be attending the group***.

3.3 Session structure: Overview

The following section contains information about the content of each of the group sessions, the structure and the content of which will vary between sessions. There are frequently asked questions in part 5 that relate to each of the group topics. We hope these will help you to answer some common questions that participants may have. These groups are to be focused on **'peer support'** and although we have designed them to get across various key bits of information, if members of the group want to discuss anything else with their peers and you, then please make time to do this. If needed you can sacrifice one of the other tasks like the quiz or questionnaire and you can just give them this as a handout at the end.

All participants in both intervention arms will be required to attend 4 group sessions, approximately 1 month apart, following their individual MI sessions. Each group session will be approximately one and a half hours in duration with around 5-20 participants.

At each session we would like you to do a number of things listed below (see Appendix 15 for summary):

- To keep a record of those who attended (Appendix 1), this is very important, so we know who has failed to attend so we can contact them. We would like you to call the team or email to report attendance for each session.
- We would also like you to keep a diary of your observations and what you managed to cover in each session and any problems you came up against (see Appendix 3).
- At the end of each group session we would like you to give participants the summary sheets (appendices 5d, 6d, 7d & 8b) for that session.
- Also at the end of each session we would like you to give participants a brief questionnaire asking how useful they found the session and whether they were already familiar with the information given (Appendix 4).
- All paperwork is to be returned to the WILMA team (your diary of reflections, attendance records and participant questionnaires).

The structure of each session is described below. Please note that there should be flexibility to allow participants to bring their own issues. Each session should therefore begin with a description of what you plan to cover in that session with the opportunity for them to add things into the pot at that point.

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3.4 Group session 1: Barriers, emotional eating & coping with relapse

3.4.1 Session structure

The structure for this session will be as follows:

Component	Timescale	Description
Coffee/introduction	**15 minutes**	Participants can bring a 'buddy' to this section of session only. You will introduce the aims of the session and give participants an opportunity to raise additional issues.
Group task 1	**25 minutes** **15 minutes**	Participants will read the information sheets provided on either barriers to maintaining a healthy lifestyle, or emotional eating and coping with relapse and complete the attached worksheet (see Appendix 5a & 5b). They will then discuss one of these issues in small groups. A member of each group will feedback their 'top tips' for dealing with their assigned topic to the group as a whole. Participants will be given a copy of the worksheet they did not complete at this stage, so that they can add any additional relevant notes. Participants will take away both worksheets as a summary of session content.
Group task 2	**10 minutes** **10 minutes**	Participants will complete a questionnaire looking at emotional aspects of eating (see Appendix 5c). Participants will score their own questionnaire (high/low on each of three factors detailed below) and discuss in their groups.
Summing Up and Q&A	**15 minutes**	Participants will have the opportunity to ask any questions. Then you will sum up the session. The information and worksheets completed earlier in the session can be added to and taken away as a summary of session content (see Appendices 5a & 5b). You will give participants the feedback sheets to complete & return directly to the research team.

3.4.2 Tasks in groups

Group task 1 (total time: 40 minutes)

Each participant will be assigned to a small group, and each group will be given one of a possible two topics from the following to form the basis of the first group task:

- Barriers to maintaining a healthy eating plan (Appendix 5a)
- Emotional eating and coping with relapse (Appendix 5b)

We would like participants to read the topic-specific information sheet provided (i.e. on either barriers, emotional eating or coping with relapse) and complete the attached worksheet. Participants will then discuss their thoughts in small groups, and a member of the group will be asked to feedback to the group as a whole.

Group task 2 (total time: 20 minutes)

Each participant will complete a questionnaire designed to measure emotional aspects of eating (The Three-Factor Eating Questionnaire: Appendix 5c). The questionnaire items cover 3 aspects of eating behaviour 1) restraint 2) disinhibition and 3) hunger. The questionnaire comprises 51 items and 2 parts:

- Part 1 (questions 1-36): 1 point is given to each answer marked 'True'
- Part 2 (questions 37-51): 1 point is given to each answer between 3 and 4 (3-5 for question 50)

The items relating to each factor are shown in the table below:

RESTRAINT (1)	DISINHIBITION (2)	HUNGER (3)
4, 6, 10, 14, 18, 21, 23, 28, 30, 32, 33, 35, 37, 38, 40, 42, 43, 44, 46, 48, 50	1, 2, 7, 9, 11, 13, 15, 16, 20, 22, 25, 27, 31, 36, 45, 49, 51	3, 5, 8, 12, 17, 19, 24, 26, 29, 34, 39, 41, 47

Participants will score their own questionnaires (Appendix 5c: each of the sub-scales will be identified and instructions provided) and then discuss in their small groups.

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3.4.3 Useful Information

Barriers to maintenance

The majority of barriers to maintenance are likely to be related to diet and exercise and may include[16,17]:

- Too tired to exercise
- Not enough time to exercise (due to e.g. family/job demands)
- Not enough information about how to increase activity
- Don't enjoy exercise/physical activity or lack skills
- No-one to exercise with
- No social/peer support to exercise (e.g. from partner)
- Cost – not able to find physical activities that are inexpensive
- Finding it difficult to stick to a routine
- Meals eaten away from home
- Craving particular (high fat/sugar) foods
- Lack of knowledge about portion size
- Hunger ('healthy foods are not as filling')
- Cost – healthy foods are more expensive
- Lack of facilities
- Lack of willpower or self-discipline
- Fear of injury
- Caring for children or others
- Negative perceptions/self-talk – "I can't stick with it"

Research suggests maintenance is significantly less likely in individuals who report the following barriers: too tired/not enough time to exercise, no-one to exercise with, hard to stick to a routine, meals often eaten away from home, cost of healthy foods. In a study of weight maintenance in young women aged 18-32 years[18] the most common barriers to maintenance related to motivation, time and cost (but did not differ by socio-

economic status). Women with children were also particularly likely to report lack of social support as an important barrier to physical activity (from children or partner), and lack of support and time as barriers to healthy eating.

Below are some examples of barriers to healthy eating and exercise plans as experienced by those in the maintenance phase:

> *"I need to get my exercise levels at a level that I'm comfortable with…..but I just talk myself out of going after work sometimes because I'm tired…*

> *"My boyfriend is very worried… that I'm going to be stabbed or murdered or whatever if I go running."*
>
> *"I think it is getting someone to go with me …. it's much more fun to go with someone else."*

> *"I suppose work is a bit that sometimes can impact on [going to the gym] I'm away a lot and then, you know, I'm not able to go as easily."*

> *"You know when you come in, you're really tired and you think 'I can't be bothered to cook anything', so you'd either go and get a takeaway…"*

Emotional Eating (binge eating) & and coping with relapse

Psychological factors are likely to be key to both weight loss and maintenance, and barriers to maintenance may include eating in response to particular emotions or events. Coping behaviours in response to challenges or short-term relapse may also predict long-term maintenance.

There is conflicting evidence about whether particular emotional states (e.g. anxiety, sadness, loneliness, tiredness, anger and happiness) actually increase unhealthy eating behaviours, but there is generally agreement that individuals perceive these emotions to affect their eating habits, particularly amongst overweight/obese individuals who "binge

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eat"[19,20]. Those who have difficulty expressing emotions may also have a tendency to binge in response to negative feelings[21].

Long-term weight loss maintenance is thought to be associated with problem-focused coping strategies, whereas relapse is associated with more emotion-focused styles and avoidance of the issue[10,22]. Encouraging participants to plan how they might cope with lapses and identify solutions in advance may therefore be effective in preventing relapse[23].

It is also worth making a distinction between 1) relapse prevention and strategies for coping identified in advance, and 2) ways of coping with a relapse once it occurs. It might also be helpful to think of relapse not as a 'failure' but as part of a process of changing habits and behaviours that is almost inevitable at some stage[24]. Participants who can identify 'high risk' situations and potential triggers for relapse are more likely to identify adaptive ways of coping, particularly if strategies for coping with cravings can be indentified in advance. High risk situations will vary between individuals but usually fall into several categories (social, emotional/cognitive, environmental, financial) and might include:

- Negative emotional states; feeling anxious, depressed, angry
- Eating/drinking too much after an argument
- Cravings and/or a desire for the positive feelings associated with e.g. eating chocolate
- Social pressure e.g. if out for a meal with family/friends/colleagues
- A lack of confidence e.g. to attend an exercise class (also a potential barrier)

Another important feature of long-term relapse prevention is identifying strategies to limit the damaging effects of a minor or temporary relapse, or in other words to avoid falling into the trap of an all or nothing approach: a minor set-back, or even a series of minor set-backs doesn't mean that a participant will fail to maintain their weight loss in the long-term as long as they resume their healthy lifestyle following a relapse. Other useful tips include:

- List the negative consequences of giving into cravings, as well as the short-term positive ones
- See temporary set-backs as an opportunity for learning e.g. how to avoid a similar situation in future
- Keep calm and review the situation that led to relapse: what could I do differently next time if this happens?
- Giving yourself rewards for maintaining your plan will make slip-ups less likely

Below are some examples of emotional triggers and responses to relapse:

Emotional triggers:

> *"I know what to do and I understand why I eat more than I should do sometimes, if I'm upset and I'm very aware of myself and my body."*

> *"...so there's that kind of dread, and then if you've got no-one there to support you it's really difficult not to kind of feel that emotion and that kind of worry and not turn to comfort eating."*

> *"... then I'm going to be embarrassed and then I'm going to feel bad about myself, and then I'm just going to want to eat more Kit Kats."*

> *"I was stressed in work, I came home thinking 'Oh, I'll have a glass of wine' and just sit down and veg out in front of the telly."*

On relapsing:

> *"If it gets to (putting on) the half stone then I start thinking 'Oh! How am I ever going to do this?' because it takes so long to lose that."*

> *"I know when I have put on a couple of pounds more, if my trousers do feel tight I do actually feel quite negative about it and I kind of start [to] panic again."*

3.5 Group Session 2: Physical activity

3.5.1 Session structure

The structure for this session will be as follows:

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Component	Timescale	Description
Coffee/introduction	**15 minutes**	Participants can bring a 'buddy' to this section of session only. You will introduce the aims of the session and then give participants an opportunity to raise additional issues.
Group task 1	**15 minutes** **5 minutes**	Participants will be asked if they can rearrange the activity cards into light, moderate and strenuous physical activity (see appendix 6a). Answers given.
Group task 2	**10 minutes** **5 minutes**	A short quiz (see Appendix 6b). Answers given.
Group task 3	**15 minutes** **5 minutes**	Thinking about common barriers to physical activity. Participants should try to come up with as many tips as they can to help increase activity levels. Each group will nominate someone to feedback to the group: each spokesperson only needs to briefly summarise the main conclusions on the list.
Group task 4 (if there is time)	**10 minutes**	Participants to complete barriers to physical activity questionnaire (see Appendix 6c). If you run out of time, just give the questionnaire to the participant to take away.
Summing Up and Q&A	**10 minutes**	You will answer any questions and sum up the session. You will provide a summary of the main points in paper form The study team will prepare a summary sheet for each group session (Appendix 6d). The content of these can be added to, based on feedback received from the group participants. You will give participants the feedback sheets to complete & return directly to the research team.

3.5.2 Tasks in small groups

Group task 1 (total time: 15 minutes)

Participants should be split into small groups and given the activity cards (Appendix 6a). They should then be asked to arrange the cards into light, moderate or strenuous physical activity piles, discussion should be encouraged. You should then feedback the correct answers to the group.

Group task 2 (total time: 20 minutes)

The group will be stay in their small groups. Ask them the questions in Appendix 6b and then go through the correct answers (Appendix 6b) and give some of the explanation that is given below each question regarding the correct answers. It is likely these questions will lead to discussion which should be encouraged.

Group task 3 (total time: 20 minutes)

In the same groups encourage the participants to think about common barriers to physical activity. Participants should try to come up with as many tips as they can to help increase activity levels.

Each group will nominate someone to feedback to the group: each spokesperson only needs to briefly summarise the main conclusions of the group.

Group task 4 (total time10 minutes)

Give the participants the barriers to physical activity questionnaire (see Appendix 6c) to complete individually and then discuss in their small groups.

Only complete this final task if there is time, otherwise the questionnaire may be given to participants to take home to complete.

3.5.3 Useful Information

Physical activity is a key factor in the maintenance of weight loss. It is one of the most flexible elements (along with diet) contributing to 'energy balance' and it is the one which people can change most easily. This balance needs to be sustained by behaviours which can be continued over the longer term.

Evidence from RCTs and systematic reviews suggest that a higher level of physical activity is very important in maintaining weight loss. Data from the National Weight Control Registry of 5000 people who have lost weight in the US indicate that high levels of physical activity are associated with weight loss maintenance; up to 60-90 minutes of moderate physical activity per day[8], other work also supports this[9]. Physical activity helps by influencing energy balance and may help by increasing metabolic rate and increasing muscle mass which burns off more calories.

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The benefits of physical activity are far reaching and include:

- Regular moderate physical activity will benefit your health in many ways, both physically and mentally.
- Physical activity can help you sleep better.
- Physical activity reduces your risk of heart disease, stroke, high blood pressure and cancer.
- Physical activity reduces your risk of bone and joint problems.
- Physical activity helps prevent and control diabetes.
- Physical activity helps you feel happier.
- Physical activity can reduce your stress levels.
- Importantly, physical activity helps you manage your weight

While there are many benefits of becoming physically active there are also some potential risks. However, the benefits of exercise for health far outweigh the risks. The potential risks include musculoskeletal injury or a life-threatening cardiovascular event.

- The risk of musculoskeletal injury (torn muscles and sprained joints for example) increases with increasing exercise intensity but the absolute risk of an injury like this in people who are engaging in low-impact, moderate-intensity exercise is low. The risk should also be balanced against the lower risk of a fall-related injury in people who are stronger and have better balance and co-ordination.

- The risk of a cardiovascular event as a consequence of exercise in someone who is apparently healthy is very low and, overwhelmingly, events occur in people with underlying coronary artery disease. The number of cardiac arrests while jogging is something like 1 episode per year for every 18,000 healthy men, but this is lower for people who are frequently active.

To experience the benefits of regular physical activity, you need to encourage participants to aim for at least 30 minutes of moderate activity on five days of the week. Ultimately, as they get fitter, they may wish and be able to do more. If they can do a bit more physical activity than the 30 minutes 5 days a week, then the health benefits will be greater.

What do people need to do?

Some evidence based guidance, to discuss with participants, is listed below along with tips to increase activity levels:

- Government recommends at least 30 minutes of moderate physical activity (where you get slightly out of breath but can still talk).
- Research from the United States[9] indicates that for maintenance this needs to be about 60 minutes at least 5 days a week and possibly up to 90 minutes per day.
- Try to make physical activity part of every day.

- Try to involve your family or friends in some activity as this can help with motivation.
- Find something you enjoy doing, try out different sports or activities like dance.
- Take the stairs.
- Walk to work.
- If it's too far then get off the bus a few stops earlier or park further away.
- Go for a walk in your lunch break.
- Break the 60 mins physical activity into smaller chunks.
- If you struggle with fitting in 60 minutes on weekdays, do 30 and then do extra on the weekend.
- Strength training exercise can help as it can reduce the loss of muscle that most people experience as they get older. This loss of muscle leads to a reduction in strength which can adversely affect quality of life, because performing routine everyday tasks becomes more difficult. Strength training doesn't have to involve weight training, it can include things such as push-ups and knee bends. Exercise professionals are available at all sports centres to provide advice on weight training if you wish to do this – it can be fun!
- Spend less time sitting - get up for 10 mins every hour.
- If watching TV, get up and jog or walk on the spot during adverts. Place the remote control on the other side of the room.
- Buy a pedometer and set yourself an increasing target, with an ultimate target of between 10,000 and 12,000 steps per day. In the first instance use the pedometer to find out just how many steps you take each day – then look to increase it.
- If you miss a physical activity session don't think "oh well that's it" and then abandon your physical activity plan just take it in your stride and then carry on as per your plan.
- Try to go somewhere different and exercise outside such as in a forest, a beach or a park.
- Make sure you vary your activity so you don't get bored.
- Try and locate local clubs and societies so that you meet other people who are interested in exercising – is there a local walking club near you for example.

One thing to note is that it may be difficult to get participants physical activity levels up to 60 minutes 5 days a week. However, they should do at least 30 minutes 5 days a week aiming to do up to 60 minutes 5 days a week, but don't discourage them if they want to do more than this!

Examples of moderate intensity physical activities

We should be encouraging the participants to do 30 minutes of moderate physical activity at least 5 times a week but preferably 60 minutes.

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- Aqua aerobics
- Cycling on the flat at 5-9 mph
- Yoga
- Hiking (not too much uphill)
- Weight training
- Dancing (social)
- Table tennis
- Badminton
- Playing frisbee
- Downhill skiing
- Gardening
- Washing and waxing a car
- Washing windows or floors
- Pushing a pram 1.5 miles in 30 minutes
- Raking leaves
- Walking briskly, e.g. 15-20 min per mile

Participants should be advised that they could possibly make physical activity more manageable for them by doing three 10 minute or two 15 minute sessions of physical activity in order to achieve the minimum 30 minutes per day and this may be no less effective than doing it all together.

They should be advised that one way to sustain a physical activity habit is to incorporate it into their daily routine, e.g. walking to work. Try to encourage them to change the way they think about physical activity, say to them: "Tell yourself it can make you feel better, it will improve your health and it can be fun!"

A few more observations from our volunteer participants:

> *"I need to get my exercise levels at a level that I'm comfortable with, at the moment I'm going to the gym once or twice a week and I want that to be three times a week."*

> *"I think having, if either a group there or having more friends that were interested in exercise…. I think it is getting someone to go with me or getting some kind of reinforcement for it, but if you're kind of doing it self-motivation kind of way then it's quite difficult to get any, you have the happy chemicals but you don't have that kind of reinforcement to go, but if you're going with someone else it's much more fun to go with someone else."*

> *"I feel better after it… I probably don't feel as lethargic… I think if I'd had a day in work and then I go home and I haven't been to the gym you don't have that sort of buzz that it gives you, that just makes me feel 'Right, I'm ready for the next part of my day'."*

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3.6 Group Session 3: Healthy eating

3.6.1 Session structure

The structure for this session will be as follows:

Component	Timescale	Description
Coffee/introduction	**15 minutes**	Participants can bring a 'buddy' to this section of session only. You will introduce the aims of the session and then give participants an opportunity to raise additional issues.
Group task 1	**20 minutes** **10 minutes**	Food labelling task: Participants will be provided with some nutritional information and some questions about food labels (see Appendix 7a). There will also be photographs of a selection of different food products (see Appendix 7b for details of these foods). Participants should use these food products to help them answer the questions (for answers see Appendix 7c). They should be encouraged to discuss their answers with others when completing this task. Answers given
Group task 2	**20 minutes** **10 minutes**	The 5 Topics: Participants should be split into small groups and given one of these topics to discuss: decreasing fat intake, decreasing sugar intake, increasing fibre intake or eating 5 a day to discuss tips on how to achieve these. Feedback
Brief discussion	**10 minutes**	Portion size handout (Appendix 7d).
Summing Up and Q&A	**5 minutes**	You will sum up the session and provide a summary of the main points in paper form (see Appendix 7e). The study team will prepare a summary sheet for each group session. The content of these can be added to, based on feedback received from the group participants. You will give participants the feedback sheets to complete & return directly to the research team.

3.6.2 Group tasks:

Food Labelling (total time: 30 minutes)
We would like participants to complete the worksheet (Appendix 7a) on healthy food labelling. They should be encouraged to discuss their answers with each other whilst doing this. Using the guidance below, you should go through the answers to the questions and expand on relevant points where indicated (Appendix 7c).

5 Topics (total time: 30 minutes)
The participants should be split into small groups or whatever makes sense depending on number of attendees. They should then be given one of these topics:

- decreasing fat intake,
- decreasing sugar intake,
- increasing fibre intake
- eating 5 a day
- decreasing alcohol consumption

You should then ask them to discuss tips on how to achieve these targets and the last ten minutes should be spent feeding back. Each group should nominate a spokesperson to give up to 3 brief tips. You should write these down and participants can also add these ideas to the end of the summary sheets.

Portion Size (total time: 10 minutes)
You should give participants the portion size handout and briefly discuss it with them answering any questions they may have.

3.6.3 Useful Information

What is a healthy diet to maintain weight loss?

Eat breakfast

Research suggests that eating breakfast can actually help people control their weight. It can also provide us with some of the vitamins and minerals we need for good health. Try to go for a healthy breakfast such as wholegrain cereal, low-fat milk and fruit.

Drink less alcohol

Alcohol contains more calories than you might think, a large glass of wine contains 170 calories and a pint of lager around 180 calories. Drinking alcohol tends to increase your appetite and reduce your will power. Cutting down on the amount of alcohol you drink can help with weight maintenance.

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Limit your fat intake

Eating lots of fat can contribute to weight gain as fat is high in calories. Eating a diet that is high in *saturated* fat can also increase your cholesterol levels and increase your chances of developing heart disease. Foods that are high in *unsaturated* fat provide essential fatty acids that the body needs and can actually help lower blood cholesterol. However, unsaturated fats are still high in calories so should be consumed with caution when attempting to maintain weight loss.

Try to limit the amount of fat in your diet. Foods that contain more than 20g of fat per 100g are considered high fat. Foods that contain 3g or less of fat per 100g are considered low fat.

Reducing fat intake – some tips:

- Limit your intake of foods that are high in saturated fats, such as fatty meat and meat products; butter, ghee and lard; cream and ice cream; cheese (particularly hard cheese); pastries; cakes and biscuits; crisps; savoury snacks; coconut oil and palm oil.
- Go easy on foods that are high in unsaturated fats such as avocados; nuts and seeds; sunflower, rapeseed, olive and vegetable oils, and spreads made from these.
- Grill, bake, poach or steam food instead of frying or roasting.
- Trim visible fat and skin off meat before cooking.
- Select lower-fat dairy foods.
- Measure oil for cooking rather than pouring it straight from the container – this will help you use less.
- Try leaving out the butter or spread when making sandwiches – you might not need it if you're using a moist filling.

Eat lots of fruit and vegetables

Fruit and vegetables are good sources of many vitamins and minerals. They tend to be high in fibre and low in fat, so help fill you up without providing too many calories. Research also suggests that individuals who eat plenty of fruit and vegetables are less likely to develop diseases such coronary heart disease and some cancers. You should aim to eat a wide variety of fruit and vegetables and aim for at least five portions a day.

What is a portion?

A portion is approximately 80g, for example, 1 apple, banana or pear, 3 heaped tablespoons of vegetables, 1 handful of grapes or berries.

Beans and pulses can also count toward your 5 a day target but these should be counted a maximum of one portion a day regardless of the amount you eat.

Likewise, a glass of pure fruit juice (150ml) counts as a portion but again only a maximum of once a day.

Although potatoes are vegetables they do not count towards your 5 a day.

Getting your 5 a day – some tips

- Add a handful of dried or fresh fruit to your breakfast cereal
- Drink a glass of pure fruit juice at breakfast
- Eat an apple, banana or some dried fruit as a mid—morning snack
- Include salad or some raw vegetables as part of a packed lunch
- Add vegetables or beans to curries, casseroles or stir fries.
- Include a cooked vegetable as part of your evening meal.
- Have tinned or fresh fruit for pudding.
- Try to avoid adding butter or sauces to vegetables and sugar or syrupy dressings to fruit.
- Tinned fruit should be in natural juice rather than syrup.

Eat plenty of fibre.

Fibre helps to keep the bowel healthy and prevents constipation. Fibre rich foods are also more bulky so they help make us feel full which means we are less likely to eat too much.

Fibre Tips:

- Eat a high fibre breakfast cereal e.g. muesli or all bran.
- Try to include plenty of high fibre foods in your diet. When selecting breads and grains try to go for wholegrain or brown versions.
- Good sources of fibre – some examples

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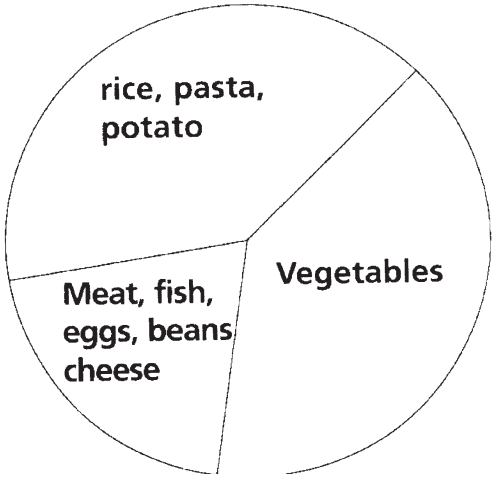
- Fruit and vegetables
- Beans and lentils
- Wholegrain bread
- Brown rice
- Oats
- Seeds

Limit your sugar intake.

Foods and drinks containing lots of added sugars contain calories (and so contribute to weight gain) but often have few other nutrients. You should try to cut down on foods containing added sugars such as fizzy drinks and juice drinks, sweets and biscuits, jam, cakes, pastries and puddings and ice cream.

Reducing sugar intake – some tips:

- Check food labels to help you select low sugar foods. Sugar in a food can be labelled using a range of different terms. These include sucrose, glucose, fructose, maltose, hydrolysed starch and invert sugar, corn syrup and honey.
- Replace sugary snacks with fruit, raw vegetables, or low sugar alternatives.
- Replace sugary drinks with water or unsweetened fruit juice. Try diluting fruit juice with sparkling water.
- Reduce, or cut out, sugar in hot drinks and on cereals.
- Try halving the sugar you use in your recipes. It works for most things except jam, meringues and ice cream.
- Choose tins of fruit in juice rather than syrup.
- Choose wholegrain breakfast cereals rather than those coated with sugar or honey.
- Try to select foods and snacks that are low in sugar (5g or less per 100g)
- Avoid foods that are high in sugar (more than 15g sugar per 100g)



To maintain your weight loss choose to eat foods in the above proportions to get a healthy energy balance

Read food labels

Get into the habit of reading food labels. This will help you select foods that are low in fat and sugar and high in fibre.

Ingredients lists:

The ingredients of a food are always listed in order of weight. So the first item on an ingredients list will be the largest, whilst the last item will be the smallest. Reading the ingredients list can give you a feel for the amount of sugar and fat in a food. For example, if a food lists 'sugar' or 'sucrose' at the start of the ingredients list you know that it is likely to be high in sugar.

Nutrition panel:

Many foods include a panel of nutritional information providing the amounts of energy, protein, carbohydrate and fat per 100g (or 100ml) of the food. Again, this information can give you an idea of whether the food is high in fat or sugar. For example, if a food contains more than 20g of fat per 100g you know it is a high fat food. If it contains less than 3g of fat per 100g you know it is a low fat food. Sometimes sugar will be listed separately under carbohydrates. Less than 5g of sugar per 100g means the product is low in sugar, more than 15g means that it is high in sugar. However, sometimes you will

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only see a total figure for carbohydrates – this figure is made up of both simple carbohydrates (sugars) and complex carbohydrates (starchy foods).

Some products will also list this information 'per serving'. This is useful to give you an indication of the calorie content of the item, but less helpful for figuring out whether it is high or low in sugar or fat. When looking at the calorie content, don't forget to check the number of 'servings' the food item consists of. For example, a small bag of crisps may be just one serving, in which case the calories per serving are the amount of calories you are getting by eating the whole bag. However, other items, such as packaged cakes, biscuits or deserts, may contain two (or more!) servings. So if you ate a packaged cake containing two servings you would need to double the calories per serving to get the amount of calories you had eaten.

Traffic light labelling:

Sometimes you'll also see traffic light colours on food labels that refer to levels of fat, saturates (or 'sat fat'), sugars and salt. These can be a quick and easy way of telling whether a product is high or low in fat and sugar. Green means the food is lower in that nutrient – so the more green on the label, the healthier the product. Amber (or orange) means the food isn't high or low in that nutrient so this is an okay choice most of the time but not quite as good as the green. Red means the food is high in that nutrient so you should try to limit your intake.

A few more observations from our volunteer participants:

> *"I do need to be quite careful of portion control because I don't seem to get full up, ever, and [the slimming group have] got this kind of allotted amount that you can have like chocolate-wise … control is the thing I'm working on at the moment."*

> *"That glass of wine represents quite a few Syns so actually you're better just not doing it or doing it very occasionally."*

> *"The whole family do it now so it's probably lots of vegetables and lots of fruits so if I go round the supermarkets, lots of vegetables and fruits… meat, fish and pasta."*

3.7 *Group Session 4: Intervention tasks and activities*

3.7.1 Session structure

The structure for this session will be as follows:

Component	Timescale	Description
Coffee/introduction	**15-30 minutes**	Participants can bring a 'buddy' to this section of session only. You will introduce the aims of the session and then give participants an opportunity to raise additional issues and to discuss anything brought up at previous sessions where there wasn't time to discuss the topic or you had to find out more information from the WILMA team.
Group Task	**45 mins**	You will split the participants into small group to discuss how useful they found the different tasks and activities (Appendix 8a).
Feedback to group	**15 mins**	Each group will nominate someone to feedback a brief summary of their discussions.
Summing Up and Q&A	**5 mins**	You will sum up the session, answer any questions and provide a summary of the main points in paper form ((Appendix 8b). The study team will prepare a summary sheet for each group session. The content of these can be added to, based on feedback received from the group participants. You will give participants the feedback sheets to complete & return directly to the research team.

3.7.2 Group task

This session is about the various aspects of the study intervention that the MI practitioners will have engaged in with participants. The MI practitioners will have helped participants to set goals and develop implementation intentions, and will have talked about how to boost social support and how to develop good habits. But some participants will only have had two MI sessions, and may not have talked with their MI practitioner about all of these topics. Others may not recognise the terminology, even though their MI practitioner will have addressed these topics. So, we would like you to outline, briefly, what we mean by the topics during the session. There is a suggested outline of what to

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include in the short description of each topic in the following section (3.7.3). But, please, use your own words.

For the task in this session participants will be asked to discuss the topics in small groups, using the questions given in Appendix 8a, and then to feed back to the whole group. If there are quite a few small groups there may be insufficient time for every group to discuss and feedback on every topic, so it may be better if small groups discuss one or two topics each. It will be up to you to organise this to suit the number of participants attending the session. However, everyone will have a chance to contribute to all the topics in the feedback sessions and to learn from all the small group discussions.

The aim is to clarify these concepts for participants and to give them understanding of the benefits of these concepts for weight maintenance. It will allow the group to exchange information, and give useful tips to each other on how to utilise these concepts in practice. We are not asking you to give too much information prior to the discussions because we would like the group to learn from each other. However, during the feedback sessions you may need to fill in any gaps in their understanding based on the information provided on these topics in Section 2.

3.7.3 Useful Information

There are more details on the topics in section 2 of this manual:

- Self Monitoring — see Section 2.2
- Goal setting &developing implementation intentions — see Section 2.3
- Developing good habits — see Section 2.4
- Social support and how to boost it — see Section 2.5

The following are the suggested introductions to each topic discussion but please feel free to use your own words here.

Self Monitoring

"By self-monitoring we mean keeping a check on your progress in maintaining your weight. As part of the study we have asked you to weigh yourself every week so that you can keep an eye on how your weight is doing. By aiming to keep it within certain boundaries (a few pounds) you can allow for normal fluctuation of your weight and can also adjust your diet and physical activity when your weight is either going up or down.

Some people may also like to keep a record of their diet, for example calorie counting, and some people may keep a record of their exercise routine at the gym, or the number of steps they walk a day using a pedometer. But not everyone likes to do that."

Goal setting and implementation intentions

"Goal setting is probably something that you did with the MI practitioner, in that you will have identified what you aim to achieve in terms of a healthy diet or a physical activity routine, or how you would like to behave in certain situations, for example at work or when out for a meal. He/she will have helped you to come up with realistic and achievable goals.

Implementation intentions mean the concrete plans you make to actually do a particular behaviour. For example, a goal may be to do more physical activity but that is not very specific about how you will go about it. Implementation intentions involve deciding what you are going to do, where you are going to do it, and when. So, you may decide to go for a walk for 20 minutes (what) during every work lunch-break at 12.30 (where and when). To do that you take a pair of trainers into work and keep them in your filing cabinet, so come 12.30 you put on your trainers and walk for 20 minutes. It probably also helps if you decide beforehand exactly where you are going to walk to and when to turn round and come back. The more general planning involved at the beginning (e.g. keeping a pair of trainers in work), the easier it is to do on a regular basis. This avoids you having to think about and decide every day how you are going to increase your physical activity for that day."

Social support and how to boost it

"Social support refers to the help and support you get from your family, your friends and the slimming group or exercise class that you go to. Sometimes this might mean having someone to exercise with, or someone who understands your issues and can talk to you about them. It also involves the attitudes that people have about you having lost weight, and continuing to live a healthy lifestyle. You will be asked to think about what sort of social support is most helpful, and what strategies you can use to increase your social support, or turn negative support into positive."

Developing good habits

"It is much easier to maintain a change in your lifestyle if a healthy diet and increased physical activity becomes a habit, rather than something that you have to think about all the time, and make a conscious effort to do. Habits are things that you do automatically, and are difficult to change. We tend to think of habits in more negative terms, that is we think of the bad habits we have rather than the good ones. For instance, you may have a glass of wine every night when you get home, or you may have something sweet to finish your meal. You could consider these to be bad habits. It's very difficult to stop doing those things, so we are aiming to make the good behaviours (such as eating lots of fruit and vegetables) habits as well. In this discussion I want you to think about any good habits you have developed, for example, walking up

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the stairs instead of taking the lift – something like that, - and try to remember what it was like when you first started doing it, and then when it became a habit. What sort of things can you do to turn something into a habit? Think about other habits as well that are perhaps not associated with weight maintenance, and how they became a habit. It may also help to think about how you try and get your children to do things (if you have children), such as cleaning their teeth every night or washing their hands."

Part 4: Study Specific Information

4.1 Contacting the study team

4.1.1 Contact details

Please send all invoices (see Section 4.3) and expenses claims to the WILMA Trial Administrator. If you would like information about any aspect of the WILMA study, please contact the Trial Administrator or Senior Trial Manager.

Address for correspondence and invoicing:

South East Wales Trials Unit (SEWTU)
Dept. of Primary Care & Public Health,
School of Medicine, Cardiff University
7th floor, Neuadd Meirionnydd
Heath Park, Cardiff.
CF14 4YS

General fax: 029 20687611
Confidential fax: 029 20687612
Email address: WILMA@cardiff.ac.uk

Key contacts

Name:	Position:	Email:	Tel:
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Ms Liz Randell	**WILMA Research Associate**	Randelle@cardiff.ac.uk	029 20687608
Dr Rachel McNamara	**WILMA Senior Trial Manager**	mcnamara@cardiff.ac.uk	029 20687146
Dr Sharon Simpson	**WILMA Chief Investigator**	simpsonsa@cardiff.ac.uk	029 20687181

4.2 Booking venues for group sessions

The WILMA study team can provide you with details of local venues for hire, suitable for conducting the group sessions. We can also book venues for you directly if you wish: please contact the WILMA Trial Administrator for more information on venue booking.

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4.3 Claiming expenses/payment

At the start of the study, we will provide you with instructions for claiming expenses. We will also provide detailed instructions on how to submit invoices, which should be sent to the address detailed in Section 4.3.1.

4.4 Lone worker policy

When conducting the group sessions, we would ask you to comply with the WILMA Lone Worker Policy to ensure your personal safety (See Appendix 10).

4.5 Serious Adverse Event Reporting

Serious Adverse Events (SAEs) are defined as:

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

If at any point during the study you become aware of an SAE in one of your participants, we would ask you to report such an event to the WILMA Trial Manager within 24 hours of becoming aware of the event, either by telephone or using the form provided. Detailed instructions for reporting SAEs and the reporting form are provided at the end of the Handbook (See Appendix 11a and 11b). We also like you to tell participants to see their GP if they or you have any concerns about their health.

4.6 Risk of harm reporting

You are required to contact the WILMA trial team if you become aware at any point during the trial that:

A participant has attempted or expresses intent to self-harm, i.e. to cause themselves physical injury or to commit suicide

OR

A participant expresses thoughts and feelings that give you cause to suspect they would be likely to self-harm, i.e. to cause themselves physical injury or to commit suicide

You are required to contact the necessary authorities directly (police or social services as appropriate), should you suspect that a participant has, or is likely to cause significant harm to another individual where the harm relates to physical or emotional harm punishable by law. Should you become concerned about your own safety, or that of other members of the WILMA team at any point during the trial, please contact the WILMA trial team as soon as possible.

The procedure for reporting risk of harm is given in more detail in Appendix 12a and 12b.

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Part 5: Frequently Asked Questions

The following questions are examples of those that participants might raise at the end of the group session. These questions will be added to during the course of the study, based on feedback from group facilitators.

5.1 Barriers, Emotional Eating and Relapse

Q1. What are the most common reasons people give for not being able to maintain a healthy lifestyle?

A1: People often say that a lack of time, feeling tired, the cost of gym membership, and having no-one to exercise with make it difficult for them to stick to an exercise routine. However, there are lots of ways to increase how physically active you are, which is vital for maintaining weight loss, without taking much time out from your busy life and without necessarily investing in gym membership. Lack of knowledge about portion size, cost of healthy foods and cravings are also among the reasons people list for not sticking to their healthy eating plan, but there are many ways to eat healthily at no extra cost, and physical activity and healthy eating will be covered in Group sessions 2 and 3. The group session on 'Barriers and Coping' (Session 1) will provide you with information and tips on how to overcome any barriers to physical activity and healthy eating: we will also discuss how to get back on track if you struggle with maintaining your weight.

Q2. How can I incorporate more physical activity into my life, when I never seem to have any time?

A2: There are lots of ways to increase your general levels of physical activity, even when you don't have much time. You could for example, walk or cycle to work if you live nearby, or get off the bus/train a few stops earlier and walk the rest of the way and use the stairs instead of the lift or escalator where possible. If you are at home, think about walking to the shops instead of taking the car, walking the kids to school etc. Housework and gardening are also great ways to be more physically active. For example, wash the car instead of using the car wash. The group session on 'Barriers and Coping' will focus on sharing tips to overcoming barriers to a healthy lifestyle and encourage you to think creatively about how you can maintain healthy behaviours in the context of your own life and its' demands.

Q3. I tend to eat more/more unhealthily when I'm tired/stressed/unhappy/bored - what strategies can I use to overcome this?

A3: This is a very common issue for people either trying to lose weight, or maintain weight they have already lost. In the 1st group session on 'Barriers and Coping' we will discuss how you can identify any emotional 'triggers' that apply to you, and share strategies for overcoming these. Some evidence suggests that people who exercise regularly control their food intake better than those who are inactive.

Q4. What are the most common reasons for emotional eating or relapse?

A4: The sorts of situations that lead to emotional eating and relapse are very individual but the following are common:

- Negative emotional states; feeling anxious, depressed, angry
- Eating/drinking too much after an argument
- Cravings and/or a desire for the positive feelings associated with e.g. eating chocolate
- Social pressure e.g. if out for a meal with family/friends/colleagues
- A lack of confidence e.g. to attend an exercise class (also a potential barrier)

Q5. I'm too frightened to weigh myself in case I've put weight back on – what can I do to get back on track?

A5: Again, this is a common response for people who have struggled to keep to their healthy eating and exercise plan. The main thing to remember is don't panic- most people 'fall off the wagon' to some extent, but the key to long-term weight loss maintenance is to weigh yourself regularly so that you can keep an eye on any weight gain and employ strategies to get back on track as soon as possible. In the group session on 'Barriers and Coping' we will share tips on possible strategies.

Q6. What is the best way to avoid relapses or slip-ups?

A6: Identifying strategies for coping with high risk situations in advance is a very effective way of preventing or reducing the risk of a relapse. Think about the sorts of situations in which you might be tempted to e.g. eat unhealthily and how you could avoid or reduce the risk of this occurring. Rewarding yourself for 'successes' in these situations e.g. with a good book/long bath etc is also an effective way of minimising the likelihood you will give in to cravings.

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Q7. How can I stop a small weight gain from making me feel guilty and giving up so it becomes a larger gain?

A7: Don't panic! The key is to change the way you view minor slip-ups – try thinking of these as an inevitable part of the process of learning to change your habits rather than as 'failures'. Review the situation that led to the relapse – what could you do differently next time, if faced with a similar situation? If you are able to learn from your slip ups you have a much better chance of maintaining your weight loss in the long-term.

5.2 Physical Activity

Q1. What is moderate intensity physical activity and how do I know I am doing it?

A1: Moderate activities are described in section 3.3.3 and the signs that you're doing moderate intensity activity are:

- an increase in your breathing rate
- an increase in your heart rate to a point where you can feel your pulse
- feeling warm
- working harder at that activity than you would normally without feeling unduly tired or fatigued

However, you should still be able to talk without panting in between your words.

Q2. What are some warning signs I should look out for while exercising?

A2: You should immediately stop exercising if you feel:

- Unusual pain, such as pain in your left or mid-chest area, left neck, shoulder or arm during or just after exercising.
- Sudden light-headedness, cold sweat, pallor or fainting.
- Pain in your joints or muscles that is not just normal tiredness

These might not be the only signs your body will give you. Other signs can include headache, dizziness, nausea and muscular or joint pain. Remember, listen to your body and if you experience any of these consult you GP.

Q3. Do I need to talk to my doctor before I start new physical activity?

A3: You should talk to your doctor before you begin any physical activity program if you:

* Have heart disease, had a stroke, or are at high risk for these diseases (has a close relative had a cardiovascular event before the age of 50 years?)
* Have diabetes or are at high risk for diabetes (has a close family member got diabetes?)
* Have an injury or disability

* Are pregnant
* Have a bleeding or detached retina, eye surgery, or laser treatment on your eye
* Have had recent hip surgery

N.B It is important to emphasise that people should gradually increase their exercise levels and if they have any concerns or experience any of the symptoms described in Q2 they should consult their GP.

Q4. What is the best type of physical activity?

A4: The best type of physical activity is one that people will actually do on a regular basis. It is generally recommended to consider both aerobic exercise and strength training. Aerobic activities help to raise heart rate and increase breathing for an extended period of time. Aerobic exercise improves cardiovascular function and reduces blood pressure. Activities might include fast walking, jogging, bicycling, dancing, swimming, tennis or badminton. Strength training, such as weight lifting, helps make bones stronger, improves balance and increases muscle strength. It also helps you burn more calories as you increase your muscle mass. You should also do stretching both before and after exercise to minimize the chances of injury and to monitor your body as it returns back to the pre-exercise state.

5.3 Healthy Eating

Q1. Can I follow a low-carbohydrate diet (such as the Atkins)?

A1: Cutting out carbohydrates (starchy foods), or indeed any food group, can be bad for your health because you are likely to miss out on important nutrients. Low-carbohydrate diets tend to be high in saturated fats (e.g. in meats and cheeses) which increase your risk of developing coronary heart disease. Such diets also tend to restrict the amount of fruit, vegetables and fibre that you eat, all of which are essential for good health. Rather than trying to avoid carbohydrates they should be making up about a third of your diet. If you are concerned that they don't seem to fill you up as much as protein or fat based foods, try to stick to complex carbohydrates, such as wholemeal bread, brown rice and pasta and fruits and vegetables. These will help keep you feeling fuller for longer compared to more refined carbohydrates such as white bread and sugary foods.

Q2. Can I follow a low GI (glycemic index) diet?

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A2: The glycemic index (or GI) of a food is a measure of the effect of a carbohydrate on blood sugar levels. Carbohydrates that break down quickly release glucose into the blood stream more rapidly. These foods have a high GI and there is evidence to suggest that such foods may give you a short burst of energy but leave you hungry again shortly afterwards. Carbohydrates that break down more slowly release glucose into the blood much more gradually. These foods have a lower GI and will keep you feeling fuller for longer. In general, carbohydrates that are high in fibre and low in added sugar have a low GI (e.g. most fruits and vegetables, wholegrain breads and pasta, beans and pulses), whilst carbohydrates that are high in added sugar have a high GI (e.g. sugar-coated breakfast cereals, white bread, white rice). Thus by selecting low GI carbohydrates you are also likely to be selecting 'healthy' carbohydrates (i.e. ones that are high fibre and low sugar). This should be good for maintaining weight loss. However, you should also bear in mind the fat content of the foods you eat since some low GI foods may be high in fat.

Q3. What are the 'Guideline Daily Amounts' (GDA) labels I see on some packages?

A3: These give an indication of the recommended quantity of nutrients that individuals should be consuming per day. They should be looked at in relation to the serving size, i.e. the amount of the product you are going to eat. So for example, the GDA of fat for women is 70g. So if the item is providing you with 14g of fat it should be making up 20% of your fat intake for the day. However, you should also bear in mind that the GDA figures are guidelines only. They may not necessarily be appropriate for someone who is trying to lose weight, or maintain weight loss, or even for someone who is less physically active than average.

Q4. Where can I find out more?

A4: You can find out more about healthy eating at www.eatwell.gov.uk

Q5. How do food portion sizes affect calorie intake?

A5: Many people trying to maintain weight loss still believe that eating small portions is essential. This is not true. It depends on the food concerned, and how many calories it contains. For example, high-fibre foods can be eaten in larger quantities as a high proportion of their bulk is indigestible. Foods high in dietary fibre also fill up the stomach and take longer to digest, causing us to feel full sooner and for longer. However, calorie-dense foods (high in fat and/or sugar) should be eaten in smaller quantities. Consider these examples.

Calorie-rich foods (e.g. rich ice-cream, cheesecake, butter, sugar) can be very easily digested. Think of how easy it is to say 'Yes' to a slice of cheesecake as a dessert, even after a large main course!

Two pats of butter [90 calories] (which can be eaten in an instant, melted on half a potato or a toasted muffin) contain the same amount of calories as 2 oranges. But try eating 2 oranges quickly! Or see which is easier to eat, 3 oranges or a small croissant (1.5 oz or 40 grams).

One muffin [320 calories] contains the same calories as a whole meal, comprising one 4oz (100g) chicken breast, a cup of mixed frozen vegetables, and a cup of cooked rice. 10 pounds (4.5kg) of apples contains fewer calories than 1 pound (450g) of chocolates. So you can eat a whole pound of apples for the same number of calories as a couple of chocolates. This is because chocolate crams a lot of fat and sugar into a small space.

Q6. How do I cope when I eat out?

A6: It's easy to eat food simply because it's put in front of you. So be aware of what you are eating, and make sure it is you (not someone else) who is choosing how much you should eat. Portion-sizes in many restaurants are over-sized, even super-sized. If you are eating with someone else, try sharing a main course, or order two starters instead of a main course. If you're eating alone, eat half and take the rest home for another meal. Don't feel obliged to "clean your plate". As desserts can be very high in calories, either share a rich dessert several ways or skip it altogether and finish your meal with a piece of fruit or other lower-calorie option.

Don't overdo the beer, wine or other alcoholic drinks when eating out as they contain calories too. Drinking too much can easily lead to over-eating as it stimulates your appetite.

5.4 Intervention Tasks and Activities

Q1.Will it matter if I only weigh myself once a month and not once a week?

A1: Weekly weighing is better because if you only weigh yourself once a month and you have put on quite a bit of weight, say half a stone, it is harder to lose that weight you have put on. However, if you weigh weekly it is easier to keep track of your weight and it should only be a matter of a few pounds which you could easily lose again. Some people like to weigh themselves more often than once a week but we wouldn't encourage this.

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Q2. How can I get the confidence to increase my exercise…..I'm just too embarrassed?

A2: Maybe think of going with a friend to do any exercise. Try and find a type of exercise you enjoy, walking is an excellent form of exercise and doesn't require special equipment and is free. As you get more confident in exercising you may find you want to try different forms of exercise.

Q3. I am quite a shy and private person, do I really need to talk in a group setting?

A3: You don't have to talk during the group sessions if you don't want to. You may learn useful information just by listening to other people's experiences. As you get to know people in the group you might feel happier to talk in the group. However, we do not want you to do anything you may feel uncomfortable with.

Part 6: References

The references below are provided for further information:

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Part 7: Appendices[2]

[2] All appendices available on request.

Appendix 1:	Group session register
Appendix 2:	Weight record form
Appendix 3:	Group facilitator diary
Appendix 4:	Participant feedback sheet
Appendix 5a:	Session 1 information & worksheet: Barriers to maintenance
Appendix 5b:	Session 1 information & worksheet: Emotional eating & relapse
Appendix 5c:	Emotional eating questionnaire
Appendix 6a:	Physical activity cards
Appendix 6b:	Physical activity quiz
Appendix 6c:	Barriers to physical activity questionnaire
Appendix 6d:	Session 2 summary sheet
Appendix 7a:	Food labelling task: interpreting food labels
Appendix 7b:	Details of food for labelling task
Appendix 7c:	Answers to food labelling questions
Appendix 7d:	Portion size handout
Appendix 7e:	Session 3 summary sheet
Appendix 8a:	Group session 4 task: group discussion
Appendix 8b:	Session 4 summary sheet
Appendix 9:	WILMA study protocol (V3.0, 27/04/2011)
Appendix 10:	SEWTU lone worker policy (V2.0, 28/07/2009)
Appendix 11a:	WILMA Procedural Information Sheet: Serious Adverse Event Reporting (V1.0, 24/02/2010)
Appendix 11b:	WILMA Serious Adverse Event Reporting Form (V1.0, 24/02/2010)
Appendix 12a:	WILMA Procedure for Reporting Harm (V1.0, 03/09/2010)

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Appendix 12b: WILMA Actual or Risk of Harm Reporting Form (V1.0, 18/08/2010)

Appendix 13a: Ethics permissions letter (18/03/2010)

Appendix 13b: Ethics permissions letter: amendment 1 (06/09/2010)

Appendix 13c: Ethics permissions letter: amendment 2 (10/05/2011)

Appendix 14: WILMA intervention group diary (V3.0, 09/03/2011)

Appendix 15: WILMA study processes flow chart

Appendix 16: WILMA Group Facilitators contract (V2.3, 24/03/2011)

Appendix 17: WILMA group facilitator training materials

Appendix 18: '10 things MI is not'

Appendix 19: List of Resources

Appendix 3 Safety reporting procedure

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-

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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 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.

Appendix 4 Participant questionnaires and case report forms (example versions)

Appendix 4a: Baseline CRF

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PID	Region ID	Participant Initials	Participant DOB
			d d m m y y y y

South East Wales Trials Unit
Uned Ymchwil De-ddwyrain Cymru

Weight Loss Maintenance in Adults (WILMA)

BASELINE CASE REPORT FORM

Date completed ☐☐ / ☐☐ / ☐☐☐☐ (d d / m m / y y y y)

Name of researcher ☐ (***block capitals***)

Participant ID ☐☐☐☐ **Example:** 0 1 2 3

Region ID ☐☐

Participant initials ☐☐☐ **Example:** R L M **OR** R - M

Participant DOB ☐☐ / ☐☐ / ☐☐☐☐ (d d / m m / y y y y)

TIMEPOINT

BASELINE	☐	1 YEAR PI	☐
POST INTERVENTION (PI) CONTROL	☐	2 YEAR PI	☐
POST INTERVENTION (PI) INTERVENTION	☐		

Instructions for completion of CRF

All information should be completed by the Researcher, with the participant. This form should be completed using **BLACK INK**. Please write clearly using **BLOCK** capitals and keep all responses within the boxes provided.

Options should be selected by putting a cross (X) in the appropriate box. If you need to correct an item draw a single line through it and initial and date as shown: ☒ RM 25/11/10

If for any reason compulsory fields are not completed/you do not have the necessary information, please write 'ND' (Not Done) **NEXT TO** the relevant item as shown: ☐☐☐ ☐ **cm** ND

PLEASE LEAVE ALL NON-APPLICABLE FI ELDS BLANK.

Once completed this form should be sent to:

Dr Rachel McNamara, WILMA Senior Trial Manager
SEWTU, 7th floor Neuadd Meirionnydd, Cardiff University
Heath Park, Cardiff. CF14 4YS.

PID	Region ID	Participant Initials	Participant DOB
			d d m m y y y y

SECTION 1: Participant Contact Details. Please **detach this sheet** from the rest of the CRF booklet and file/return **separately** to the WILMA study team.

Title ☐ **Mr** ☐ **Mrs** ☐ **Miss**
☐ **Ms** ☐ **Dr** ☐ **Other** ***Please specify***

First name/s

Surname

Home address **Address line 1**

Address line 2

Address line 3

Address line 4

Post code

Mobile telephone number

Home telephone number

Alternative telephone number ***(e.g. work)***

Email address

Preferred method of contact ***(e.g. mobile, email)***

Additional contact (name)

Additional contact (number)

Name of GP

GP surgery address **Address line 1**

Address line 2

Address line 3

Address line 4

Post code

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PID	Region ID	Participant Initials	Participant DOB
			d d m m y y y y

SECTION 2: Demographic and occupational information

1. Age ☐☐ **Years**

Example: 3 2

2. Gender ☐ **Male** ☐ **Female**

Example: X **Male** ☐ **Female**

3. Marital/relationship status:

- ☐ **Married**
- ☐ **Civil partnership**
- ☐ **Cohabiting**
- ☐ **Single**
- ☐ **Widowed**
- ☐ **Divorced**
- ☐ **Separated**

Example:

- X **Married**
- ☐ **Civil partnership**
- ☐ **Cohabiting**

4. Ethnicity ('Which of these groups do you regard yourself as belonging to?')

- ☐ **White - British**
- ☐ **White - Irish**
- ☐ **Any other White background**
- ☐ **Mixed - White and Black Caribbean**
- ☐ **Mixed - White and Black African**
- ☐ **Mixed - White and Asian**
- ☐ **Any other mixed background**
- ☐ **Asian/Asian British - Indian**
- ☐ **Asian/Asian British - Pakistani**
- ☐ **Asian/Asian British - Bangladeshi**
- ☐ **Any other Asian background**
- ☐ **Black/Black British - Caribbean**
- ☐ **Black/Black British - African**
- ☐ **Any other Black background**
- ☐ **Chinese**
- ☐ **Other (please specify)**

Example: J A P A N E S E

PID	Region ID	Participant Initials	Participant DOB
			d d m m y y y y

5. Educational status ('Do you have any of the following qualifications?')

- ☐ **A higher degree, like a master's degree, or a PhD**
- ☐ **A first degree, like a BA or BSc**
- ☐ **A certificate or diploma in higher education**
- ☐ **A or AS or S levels**
- ☐ **O levels or GCSE grades A-C**
- ☐ **Other qualifications (please specify)**
- ☐ **None of these qualifications**

Please answer these questions (6-10) about your occupation. If you have never been employed or you are currently unemployed, please complete the questions for the main earner in the household.

6. Employment status ('Do (did) you work as an employee or are (were) you self-employed?')

☐	**Employee**	**Go to question 7**
☐	**Self-employed with employees**	**Go to question 9**
☐	**Self-employed/freelance without employees**	**Go to question 10**

7. **For employees**: How many people work (worked) for your employer at the place where you work (worked)?

Example: 0 0 1 5 5

8. **Supervisory status**: Do (did) you supervise any employees? (A supervisor or foreman is responsible for overseeing the work of other employees on a day to day basis)

☐ **Yes** ☐ **No**

9. **For self-employed**: How many people do (did) you employ?

☐ **1 to 24** ☐ **25 or more**

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PID	Region ID	Participant Initials	Participant DOB
			d d m m y y y y

10. Select **ONE** box that best describes the work that you do / did in your last job:

- ☐ **Modern professional occupations such as: teacher – nurse – physiotherapist – social worker – welfare officer – artist – musician – police officer (sergeant and above) – software designer**
- ☐ **Clerical and intermediate occupations such as: secretary – personal assistant – clerical worker – office clerk – call centre agent – nursing auxilliary – nursery nurse**
- ☐ **Senior manager or administrators (usually responsible for planning, organising and co-ordinating work, and for finance) - finance manager – chief executive**
- ☐ **Technical and craft occupations such as: motor mechanic – fitter – inspector – plumber – printer – tool maker – electrician – gardener – train driver**
- ☐ **Semi-routine manual and service occupations such as: postal worker – machine operative – security guard – caretaker – farm worker – catering assistant – receptionist – sales assistant**
- ☐ **Routine manual and service occupations such as: HGV driver – van driver – cleaner – porter – packer – sewing machinist – messenger – labourer – waiter/waitress – bar staff**
- ☐ **Middle or junior managers such as: office manager – retail manager – bank manager – restaurant manager – warehouse manager – publican**
- ☐ **Traditional professional occupations such as: accountant – solicitor – medical practitioner – scientist – civil/mechanical engineer**

SECTION 3: Method of recruitment and weight loss history

11. Method of recruitment (Please select **one** option):

- ☐ **GP/nurse approached patient in person**
- ☐ **GP/nurse approached patient by letter**
- ☐ **Exercise on prescription counsellor approached patient in person**
- ☐ **Exercise on prescription counsellor approached patient by letter**
- ☐ **Slimming club consultant approached patient in person**
- ☐ **Slimming club consultant approached patient by letter**

Participant responded to advertising in:

- ☐ **Gym**
- ☐ **GP surgery**
- ☐ **Local newspaper/TV**
- ☐ **Community centre**
- ☐ **Other (please specify)**

PID	Region ID	Participant Initials	Participant DOB
			d d m m y y y y

12. a) Have you recently or are you currently involved in any research studies?

☐ **Yes** ☐ **No** ***If NO, go to Q13a.***

b) If so, can you give us some brief details about the research? ***(please write in block capitals)***

13. a) Have you reached your weight loss goal and are trying to maintain the weight you have already lost?

☐ **Yes** ☐ **No**

If YES, go to Q13b: if NO go to Q13c.

b) **If YES,** how long did it take you to reach your weight loss goal? ☐☐ **ns** ***Go to Q14.***

c) **If you haven't yet reached your weight loss goal**, how long have you been trying to lose weight?

☐☐ **Months**

d) **If you haven't yet reached your weight loss goal,** are you still trying to lose weight?

☐ **Yes** ☐ **No** ***If NO, go to Q14.***

e) **If you are still trying to lose weight,** how much more would you like to lose?

☐☐ lbs **OR** ☐☐ kgs

14. How did you lose the weight you lost recently, e.g. weight loss medication, attending Slimming World or Weightwatchers, joining a gym, counting calories etc? ***Tick all that apply***

- ☐ **Weight loss medication**
- ☐ **Slimming club (Weight Watchers, Slimming World etc)**
- ☐ **Gym / increased exercise**
- ☐ **Calorie counting / reduced fat intake**
- ☐ **Other (please specify** ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

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15. a) Are you **currently** attending a weight loss group (e.g. Weight Watchers) or a physical activity group or gym?

☐ **Yes** ☐ **No** ***If NO, go to Q16.***

b) **If YES,** can you give details of the group/gym you are attending? ***(please write in block capitals)***

c) How often do you attend?

- ☐ **More than once a week**
- ☐ **Once a week**
- ☐ **Every other week**
- ☐ **Once a month**
- ☐ **Other (please specify)**

16. How many times have you previously started a slimming group or weight control programme, **including using weight loss medication**, in the last 2 years?

Example: 0 5

17. How many times have you successfully lost at least half a stone in the last 2 years?

18. How often do you weigh yourself?

- ☐ **Daily**
- ☐ **Once a week**
- ☐ **Every other week**
- ☐ **Once a month**
- ☐ **Other (please specify)**

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19. How motivated do you feel to maintain your weight?

Very motivated				Not at all motivated
1	2	3	4	5

20. How confident do you feel that you are able to maintain your weight?

Very confident				Not at all confident
1	2	3	4	5

21. Up to the present time, what is the most you have ever weighed (If FEMALE: do not include any times when you were pregnant)?

. kg OR lbs

SECTION 4: Anthropometry and body composition measurements

22. Height . cm — Example: 0 8 1 . 3

23. Weight . kg

24. Waist circumference . cm

25. Hip circumference . cm

Section 5: Health status

26. a) Have you ever taken weight loss medication? ☐ Yes ☐ No

If NO, go to Q27.

b) **If YES**, please specify any weight loss medications you have ever taken:

Example:

Medication 1 O R L I S T A T

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Medication 1

Medication 2

Medication 3

c) **If YES**, are you still taking weight loss medication? ☐ **Yes** ☐ **No**

If YES, please specify any weight loss medication/s you are still taking:

Medication 1

Medication 2

Medication 3

d) If you answered **NO to Q26c** above, how long did you take weight loss medication for?

Months

27. Have you ever been diagnosed with any of the following health problems (select all that apply)?

- ☐ **Heart disease**
- ☐ **Diabetes**
- ☐ **Depression**
- ☐ **Stroke**
- ☐ **Arthritis**
- ☐ **Hypertension (high blood pressure)**
- ☐ **High cholesterol**
- ☐ **Asthma**
- ☐ **Chronic Obstructive Pulmonary Disease (COPD)**
- ☐ **Back pain**
- ☐ **Other (please specify)**

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Section 6: Resource use

In the last 3 months, have you:

28. a) Seen **any** health professional at your GP surgery? ☐ **Yes** ☐ **No**

If NO, go to Q29a.

b) **If YES**, how many times were you seen by:

Example: 0 2

Your/another GP

Practice nurse

Other health professional

ther please specify:

Example: D I E T I T I A N

29. a) Seen **any** health professional at your home? ☐ **Yes** ☐ **No**

If NO, go to Q30a.

b) **If YES**, how many times were you seen by:

Your/another GP

Practice nurse

Other health professional

If other, please specify

30. a) **In the last 3 months** have you attended an Accident and Emergency (Casualty) department?

☐ **Yes** ☐ **No** ***If NO, go to Q31a.***

b) **If YES**, how many times

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31. a) **In the last 3 months** were you admitted to hospital as an in-patient?

☐ **Yes** ☐ **No** ***If NO, go to Q32a.***

b) **If YES**, how many times ☐☐

c) **If YES,** how many nights did you spend in hospital? ☐☐

32. a) **In the last 3 months** have you received any prescriptions for medicine?

☐ **Yes** ☐ **No** ***If NO, go to Q33a.***

b) **If YES**, which drugs were you prescribed:

Example:

1. Drug name

T	H	Y	R	O	X	I	N	E																	

1. Drug dose

5	0	M	C	G		1	X	D	A	I	L	Y													

1. Drug name

1. Drug dose

2. Drug name

2. Drug dose

3. Drug name

3. Drug dose

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4. Drug name

4. Drug dose

5. Drug name

5. Drug dose

6. Drug name

6. Drug dose

7. Drug name

7. Drug dose

8. Drug name

8. Drug dose

9. Drug name

9. Drug dose

10. Drug name

10. Drug dose

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33. a) And finally, **in the last 3 months** did you **pay** for any services for the specific purpose of helping you with your weight control – for example slimming clubs, health clubs, gyms, swimming pools, exercise classes?

☐ **Yes** ☐ **No**

b) **If YES**, approximately how much did you pay for all of these services **in the last 3 months**?

£ | | | |

Example: 0 3 5

4b: Baseline (and control group 12 month follow-up) questionnaire

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South East Wales Trials Unit

Uned Ymchwil De-ddwyrain Cymru

Weight Loss Maintenance in Adults (WILMA)

Your Questionnaire Booklet

Date completed ☐☐ / ☐☐ / ☐☐☐☐ (d d / m m / y y y y)

Name of researcher ☐

Participant ID ☐☐☐☐

Example: 0 1 9 9

Region ID ☐☐

Participant initials ☐☐☐

Example: R L M OR R - M

Participant DOB ☐☐ / ☐☐ / ☐☐☐☐ (d d / m m / y y y y)

ARM & TIMEPOINT

BASELINE	☐	1 YEAR PI - Intervention	☐
6-MONTH	☐	**1 YEAR PI -Control**	☐
POST INTERVENTION (PI) Intervention	☐	2 YEAR PI - Intervention	☐
PI - Control	☐	**2 YEAR PI - Control**	☐

PID	Region ID	Participant Initials	Participant DOB
			d d m m y y y y

This questionnaire should take around 30-40 minutes to complete but take as much time as you like. Please feel free to ask the researcher any questions if there is anything you don't understand.

For most questions we would like you to put an 'X' in the relevant box. Please use **black** ink and **keep the cross inside the box**:

Example

Bread	None	less than 1 **a day**	1 - 2 **a day**	3 - 4 **a day**	5 or more **a day**
White bread or soft rolls	X				

If you need to correct an item draw a single line through it and write in the correct answer as shown:

Bread	None	less than 1 **a day**	1 - 2 **a day**	3 - 4 **a day**	5 or more **a day**
White bread or soft rolls	~~X~~	X			

For some questions you will need to write your answer. Please use **BLOCK CAPITALS e.g.**

Bread	None	less than 1 **a day**	1 - 2 **a day**	3 - 4 **a day**	5 or more **a day**
Other P I T T A		X			

Or numbers as appropriate e.g.

How many cans of pop or a fizzy drink which isn't sugar free or diet do you drink on a usual day? **(NOTE: A 2 litre bottle = 6 cans)** 0 3

The following two sections ask about your diet and physical activity. Some of the questions in these two sections may seem repetitive but we need to collect all this information so that we can score the questionnaires properly and complete the analyses. We understand that repetitive questions can be off-putting so your cooperation in completing all the questions is **greatly appreciated.**

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Part 1—Your Diet

The questions in this section focus on the food you eat as well as your eating habits and patterns of eating.

The questions below ask about the different foods you eat.

Some of the questions ask you what you eat in a normal *week* but others what you eat in a normal *day*. Please put an 'X' in only one box on each line.

1. About how many pieces or slices of bread do you eat on a **usual day**? **(choose one answer on each line)**

Bread	None	less than 1 **a day**	1 - 2 **a day**	3 - 4 **a day**	5 or more **a day**
White bread or soft rolls	☐	☐	☐	☐	☐
Brown or granary bread, Best of Both, soft grain	☐	☐	☐	☐	☐
Wholemeal bread or rolls or 2 slices crispbread or wholemeal scones	☐	☐	☐	☐	☐
Chapattis, wraps	☐	☐	☐	☐	☐
Other: ☐☐☐☐☐☐☐☐☐☐☐☐	☐	☐	☐	☐	☐

2. About how many **servings per week** do you eat of the following type of breakfast cereal or porridge? **(choose one answer on each line)**

Breakfast Cereal	None	less than 1 **a week**	1 - 2 **a week**	3 - 5 **a week**	6 or more **a week**
Sugar type: Frosties, Coco Pops, Ricicles, Sugar puffs	☐	☐	☐	☐	☐

PID	Region ID	Participant Initials	Participant DOB
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	None	less than 1 **a week**	1 – 2 **a week**	3 - 5 **a week**	6 or more **a week**
Rice/Corn type: Corn flakes, Rice Krispies, Special K	☐	☐	☐	☐	☐
Porridge or Ready Brek	☐	☐	☐	☐	☐
Wheat/oat type: Shredded Wheat, Weetabix, Puffed Wheat, Fruit'n Fibre, NutriGrain, Start, Optivita, Oatibix	☐	☐	☐	☐	☐
Bran type: All-Bran, Bran Flakes, Sultana Bran, Team	☐	☐	☐	☐	☐
Muesli type: Alpen, Jordan's	☐	☐	☐	☐	☐

3. About how many **servings per week** do you eat of the following foods? **(choose one answer on each line)**

	None	less than 1 **a week**	1 – 2 **a week**	3 – 5 **a week**	6 – 7 **a week**	8 - 11 **a week**	12 or more **a week**
Pasta or rice	☐	☐	☐	☐	☐	☐	☐
Potatoes	☐	☐	☐	☐	☐	☐	☐
Peas	☐	☐	☐	☐	☐	☐	☐
Beans (baked, tinned, or dried) or lentils	☐	☐	☐	☐	☐	☐	☐
Other vegetables (any type)	☐	☐	☐	☐	☐	☐	☐

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Fruit (fresh, frozen, canned)	☐	☐	☐	☐	☐	☐	☐

4. About how many **servings per week** do you eat of the following foods? **(choose one answer on each line)**

	None	less than 1 **a week**	1 - 2 **a week**	3 - 5 **a week**	6 or more **a week**
Cheese (any except cottage)	☐	☐	☐	☐	☐
Beefburgers or sausages	☐	☐	☐	☐	☐
Beef, pork, or lamb (for vegetarians: nuts)	☐	☐	☐	☐	☐
Bacon, meat pie, processed meat	☐	☐	☐	☐	☐
Chicken or turkey	☐	☐	☐	☐	☐
Fish (NOT fried fish)	☐	☐	☐	☐	☐
ANY fried food: fried fish, chips, cooked breakfast, samosas	☐	☐	☐	☐	☐
Cakes, pies, puddings, pastries	☐	☐	☐	☐	☐
Biscuits, chocolate, or crisps	☐	☐	☐	☐	☐

5. About how much of the following types of milk do you yourself use **per day**, for example in cereal, tea, or coffee? **(choose one answer on each line)**

Milk	None	less than a quarter pint **a day**	about a quarter pint **a day**	about a half pint **a day**	1 pint or more **a day**
Full cream	☐	☐	☐	☐	☐
Semi-skimmed	☐	☐	☐	☐	☐

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			d d m m y y y y

Skimmed	☐	☐	☐	☐	☐
Other: ☐☐☐☐☐☐☐☐☐☐	☐	☐	☐	☐	☐

6. About how many **rounded teaspoons per day** do you usually use of the following types of spreads, for example on bread, sandwiches, toast, potatoes or vegetables? **(choose one answer on each line)**

Spreads	None	1 **a day**	2 **a day**	3 **a day**	4 **a day**	5 **a day**	6 **a day**	7 or more **a day**
Regular margarine or butter or reduced fat spread such as sunflower or olive spread, Flora, Vitalite, Clover, Olivio, Stork, Utterly Butterly	☐	☐	☐	☐	☐	☐	☐	☐
Low fat spread such as Flora Light, St Ivel Gold, Half-fat butter, Olivite, Flora Pro-activ, Light spread	☐	☐	☐	☐	☐	☐	☐	☐

7. What sort of fat do you usually use for the following purposes? **(choose one answer on each line)**

	Butter, lard or dripping	**Solid cooking fat** (White Flora, Cookeen) **Half-fat butter, Hard margarine** (Stork)	**Soft margarine** (sunflower, soya) **Reduced fat spread** (olive, Flora Buttery, Olivio)	**Vegetable oil, olive oil** or **Low fat spread** (Flora Light, Olivite, St. Ivel Gold)	**No fat used**
On bread and vegetables	☐	☐	☐	☐	☐
For frying	☐	☐	☐	☐	☐
For baking or cooking	☐	☐	☐	☐	☐

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8. How many portions of fruit and vegetable (excluding potatoes) do you eat, of any sort, on a typical day? **(See guidance on portions sizes at end of questionnaire and choose one answer on each line)**

	None	1	2	3	4	5	6	7	8 or more
Fruit	☐	☐	☐	☐	☐	☐	☐	☐	☐
Vegetable	☐	☐	☐	☐	☐	☐	☐	☐	☐

9. How many cans of pop or a fizzy drink **<u>which isn't sugar free or diet</u>** do you drink on a usual day? **(NOTE: A 2 litre bottle = 6 cans)** ☐☐

10. How many rounded teaspoons of sugar do you have on a usual day e.g. in tea or coffee or on cereals? ☐☐ rounded teaspoons

	Never	Monthly or less	2-4 times per month	2-3 times per week	4+ times per week
11. How often do you have a drink containing alcohol?	☐	☐	☐	☐	☐

	1 -2	3 - 4	5 - 6	7 - 9	10+
12. How many units of alcohol do you drink on a typical day when you are drinking?	☐	☐	☐	☐	☐

<u>N.B.One unit of alcohol is about equal to</u> half a pint of ordinary strength beer, lager or cider **or** a small pub measure (25 ml) of spirits **or** a standard pub measure (50 ml) of fortified wine e.g. sherry/port. A small glass (125 ml) of ordinary strength wine (12% alcohol) **or** a standard pub measure of spirits (35 ml) contain 1.5 units of alcohol.

	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
13. How often have you had 6 or more units if female, or 8 or more if male, on a single occasion in the last year?	☐	☐	☐	☐	☐

PID	Region ID	Participant Initials	Participant DOB
			d d m m y y y y

14. Do you smoke? Yes ☐

No ☐ Go to question 17

15. How many cigarettes or roll-ups do you smoke per day? ☐☐

16. How soon after waking up do you smoke your first cigarette or roll-up?

- Within 5 minutes ☐
- 6 to 30 minutes ☐
- 31 to 60 minutes ☐
- 61+ minutes ☐

The questions below ask about how much social support you receive in relation to your eating habits.

Below is a list of things people might do or say to someone who is trying to eat healthily. Please rate each question twice (***family, friends***) by putting an 'X' in the box that applies to you. If the statement does not apply to you please put an 'X' in the box under 'does not apply'.

During the past <u>three months</u>, my family (or members of my household), friends and colleagues have:

17. Discouraged me from eating "unhealthy foods" when I'm tempted to do so	**none**	**rarely**	**a few times**	**often**	**very often**	**does not apply**
Family	☐	☐	☐	☐	☐	☐
Friends and colleagues at work	☐	☐	☐	☐	☐	☐
18. Refused to eat the same foods I eat	**none**	**rarely**	**a few times**	**often**	**very often**	**does not apply**
Family	☐	☐	☐	☐	☐	☐
Friends and colleagues at work	☐	☐	☐	☐	☐	☐

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19. Offered me food I'm trying to avoid	none	rarely	a few times	often	very often	does not apply
Family	☐	☐	☐	☐	☐	☐
Friends and colleagues at work	☐	☐	☐	☐	☐	☐

The questions below ask about why you choose to eat healthily.

Please select the appropriate option. For example, if you feel the statement is very true for you, you should put an 'X' under '7'. If you feel the statement is not true for you, you should put an 'X' under '1'. If the statement is somewhere in between you should put an 'X' in a box between '2' to '6' depending on the truth of the statement to you.

The reason I would eat a healthy diet is because……	Not at all true			Somewhat true			Very true
	1	2	3	4	5	6	7
20. …..I feel that I want to take responsibility for my own health	☐	☐	☐	☐	☐	☐	☐
21. ……I would feel guilty or ashamed of myself if I did not eat a healthy diet	☐	☐	☐	☐	☐	☐	☐
22. ……I personally believe it is the best thing for my health	☐	☐	☐	☐	☐	☐	☐
23. ……others would be upset with me if I did not	☐	☐	☐	☐	☐	☐	☐
24. ….I really don't think about it	☐	☐	☐	☐	☐	☐	☐
25. ……I have thought about it and I believe it is very important for many aspects of my life	☐	☐	☐	☐	☐	☐	☐
26. ……I would feel bad about myself if I did not eat a healthy diet	☐	☐	☐	☐	☐	☐	☐
27. ……it is an important choice I really want to make	☐	☐	☐	☐	☐	☐	☐

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The reason I would eat a healthy diet is because……	Not at all true 1	2	3	Somewhat true 4	5	6	Very true 7
28. ……I feel pressure from others to do so	☐	☐	☐	☐	☐	☐	☐
29. ……it is easier to do what I am told than think about it	☐	☐	☐	☐	☐	☐	☐
30. ……it is consistent with my life goals	☐	☐	☐	☐	☐	☐	☐
31. …..I want others to approve of me	☐	☐	☐	☐	☐	☐	☐
32. …..it is very important for being as healthy as possible	☐	☐	☐	☐	☐	☐	☐
33. ….I want others to see I can do it	☐	☐	☐	☐	☐	☐	☐
34. ….I don't really know why	☐	☐	☐	☐	☐	☐	☐

The questions below ask you about your eating habits.

Please rate the extent to which you agree with the following statement by putting an 'X' under the appropriate number. For example, if you agree with the statement you should put an 'X' under '7'. If you disagree you should put an 'X' under '1'. If the extent to which you agree is somewhere in between you should put an 'X' in a box between '2' to '6'.

Eating healthy food is something……	Disagree 1	2	3	4	5	6	Agree 7
35. ……I do frequently	☐	☐	☐	☐	☐	☐	☐
36. …..I do automatically	☐	☐	☐	☐	☐	☐	☐
37. … I do without having to consciously remember	☐	☐	☐	☐	☐	☐	☐
38. ……that makes me feel weird if I **do not do it**	☐	☐	☐	☐	☐	☐	☐
39. ……I do without thinking	☐	☐	☐	☐	☐	☐	☐

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PID	Region ID	Participant Initials	Participant DOB
			d d m m y y y y

Eating healthy food is something……	Disagree 1	2	3	4	5	6	Agree 7
40. ……that would require effort **not to do**	☐	☐	☐	☐	☐	☐	☐
41. ……that belongs in my (daily, weekly, monthly) routine	☐	☐	☐	☐	☐	☐	☐
42. …….I start doing before I realise I'm doing it	☐	☐	☐	☐	☐	☐	☐
43. …..I would find hard **not to do**	☐	☐	☐	☐	☐	☐	☐
44. …..I have no need to think about doing	☐	☐	☐	☐	☐	☐	☐
45. ….that's typically 'me'	☐	☐	☐	☐	☐	☐	☐
46. ……I have been doing for a long time	☐	☐	☐	☐	☐	☐	☐

These questions ask you about how much confidence you have in controlling your eating.

Please answer the following questions by putting an 'X' under the appropriate number. For example, if you have complete confidence that you can carry out the behaviour specified you should put an 'X' under '10'. If you have no confidence you should put an 'X' under '1'. If your confidence levels are somewhere in between you should put an 'X' in a box between '2' to '9', depending on the level of your confidence.

I can resist eating……	No confidence 1	2	3	4	5	6	7	8	9	Complete confidence 10
47. ……when I am anxious (nervous)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
48. …….even when I have to say 'no' to others	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
49. ……when I feel physically run down or unwell	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

PID	Region ID	Participant Initials	Participant DOB
			d d m m y y y y

I can resist eating	No	Complete
The following questions are concerned with the past four weeks (28 days) only. Please try to answer all the questions.		
	☐☐☐☐☐☐☐☐☐☐	
51. .....when I am depressed (or down)	☐☐☐☐☐☐☐☐☐☐	
52. .....when there are many different kinds of foods available	☐☐☐☐☐☐☐☐☐☐	
53. .....even when I feel it's impolite to refuse a second helping	☐☐☐☐☐☐☐☐☐☐	
54. .....even when I have a headache	☐☐☐☐☐☐☐☐☐☐	
55. .....when I am reading	☐☐☐☐☐☐☐☐☐☐	
56. .....when I am angry (or irritable)	☐☐☐☐☐☐☐☐☐☐	
57. .....even when I am at a party	☐☐☐☐☐☐☐☐☐☐	
58. .....even when others are pressurising me to eat	☐☐☐☐☐☐☐☐☐☐	
59. .....when I am in pain	☐☐☐☐☐☐☐☐☐☐	
60. .....just before going to bed	☐☐☐☐☐☐☐☐☐☐	
61. .....when I have experienced failure	☐☐☐☐☐☐☐☐☐☐	
62. .....even when high calorie foods are available	☐☐☐☐☐☐☐☐☐☐	
63. .....even when I think others will be upset if I don't eat	☐☐☐☐☐☐☐☐☐☐	
64. .....when I feel uncomfortable	☐☐☐☐☐☐☐☐☐☐	
65. .....when I am happy	☐☐☐☐☐☐☐☐☐☐	
66. I can control my eating on the weekends	☐☐☐☐☐☐☐☐☐☐	

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PID	Region ID	Participant Initials	Participant DOB
			d d m m y y y y

Please fill in the appropriate number in the boxes on the right. **Over the past 28 days**……

67. How many times have you eaten what other people would call an unusually large amount of food (given the circumstances)?	
68. On how many of these times did you have a sense of having lost control over your eating (at the time that you were eating)?	
69. Over the past 28 days, on how many days have such episodes of overeating occurred (i.e. you have eaten an unusually large amount of food and have had a sense of loss of control at the same time)?	
70. Over the past 28 days, how many times have you made yourself sick (vomit) as a means of controlling your shape or weight?	
71. Over the past 28 days, how many times have you taken laxatives as a means of controlling your shape or weight?	
72. Over the past 28 days, how many times have you exercised in a "driven" or "compulsive" way as a means of controlling your weight, shape or amount of fat, or to burn off calories	

Please go back and check that you have completed all the questions in this part of the questionnaire

Part 2 — Physical Activity

The questions in this section ask you about the amount of physical activity you do, and when and why you chose to do it.

PID	Region ID	Participant Initials	Participant DOB
			d d m m y y y y

We are interested in finding out about the kind of physical activities that people do as part of their everyday lives.

Questions 1-7 ask you about the time you spent being physically active in the last 7 days

Please answer each question by placing an 'X' in the appropriate box even if you do not consider yourself to be an active person. Please think about the activities you do at work, as part of your housework/gardening, to get from place to place, and in your spare time for recreation, exercise or sport.

Think about all the **vigorous** activities that you did in the **last 7 days**.
Vigorous physical activities refer to activities that take hard physical effort and make you breathe much harder than normal. Think *only* about those physical activities that you did for at least 10 minutes at a time.

1) During the **last 7 days**, on how many days did you do **vigorous** physical activities like heavy lifting, digging, aerobics, or fast bicycling?

☐ **days per week**

☐ No vigorous physical activities
→ **(skip to question 3)**

2) How much time did you usually spend doing **vigorous** physical activities on one of those days?

☐☐ **hours per day**

☐☐ **minutes per day**

☐ Don't know/Not sure

Think about all the **moderate** activities that you did in the **last 7 days**.

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PID	Region ID	Participant Initials	Participant DOB
☐☐☐☐	☐☐	☐☐☐	☐☐☐☐☐☐☐☐ d d m m y y y y

Moderate activities refer to activities that take moderate physical effort and make you breathe somewhat harder than normal. Think only about those physical activities that you did for at least 10 minutes at a time.

3) During the **last 7 days**, on how many days did you do **moderate** physical activities like carrying light loads, bicycling at a regular pace, or doubles tennis? Do not include walking.

☐ **days per week**

☐ No moderate physical activities → **(skip to question 5)**

4) How much time did you usually spend doing **moderate** physical activities on one of those days?

☐☐ **hours per day**

☐☐ **minutes per day**

☐ Don't know/Not sure

Think about the time you spent **walking** in the **last 7 days**. This includes at work and at home, walking to travel from place to place, and any other walking that you might do solely for recreation, sport, exercise, or leisure.

5) During the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time?

☐ **days per week**

☐ No walking → **(skip to question 7)**

6) How much time did you usually spend walking on one of those days?

☐☐ **hours per day**

☐☐ **minutes per day**

☐ Don't know/Not sure

The last question is about the time you spent **sitting** on weekdays during the **last 7 days**. Include time spent at work, at home, while doing course work and during leisure time. This may include time spent sitting at a desk, visiting friends, reading, or sitting or lying down to watch television.

7) During the **last 7 days**, how much time did you spend **sitting** on a **week day**?

☐☐ **hours per day**

☐☐ **minutes per day**

☐ Don't know/Not sure

PID	Region ID	Participant Initials	Participant DOB
			d d m m y y y y

The questions below ask you about your physical activity habits.
Please rate the extent to which you agree with the following statements by putting an 'X' in the appropriate box. For example, if you agree with the statement you should put an 'X' in the box under '7'. If you disagree you should put an 'X' under '1'. If the extent to which you agree is somewhere in between you should put an 'X' in a box between '2' to '6', depending on your level of agreement.

Exercise/physical activity is something……	Disagree 1	2	3	4	5	6	Agree 7
8. ……..I do frequently	☐	☐	☐	☐	☐	☐	☐
9. ……..I do automatically	☐	☐	☐	☐	☐	☐	☐
10. ……I do without having to consciously remember	☐	☐	☐	☐	☐	☐	☐
11. ……that makes me feel weird if I do not do it	☐	☐	☐	☐	☐	☐	☐
12. ……I do without thinking	☐	☐	☐	☐	☐	☐	☐
13. ……that would require effort not to do it	☐	☐	☐	☐	☐	☐	☐
14. ……that belongs in my (daily, weekly, monthly) routine	☐	☐	☐	☐	☐	☐	☐
15. ……I start doing before I realise I'm doing it	☐	☐	☐	☐	☐	☐	☐
16. ……I would find hard not to do	☐	☐	☐	☐	☐	☐	☐
17. ……I have no need to think about doing	☐	☐	☐	☐	☐	☐	☐
18. ……that's typically 'me'	☐	☐	☐	☐	☐	☐	☐
19. ……I have been doing for a long time	☐	☐	☐	☐	☐	☐	☐

The questions below ask about why you choose to engage in exercise.
Please put an 'X' in the appropriate box. For example, if you feel the statement is very true for you, you should put an 'X' under '7'. If you feel the statement is not true for you, you should put an 'X' under '1'. If the statement is somewhere in between you should put an 'X' in a box between '2' to '6' depending truth of the statement to you.

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PID	Region ID	Participant Initials	Participant DOB
			d d m m y y y y

These questions ask you about the social support you receive in relation to physical activity.

Below is a list of things people might do or say to someone who is trying to exercise regularly. Please rate each question twice (family, friends) by putting a ☐ in ☐ box ☐ at ☐ es ☐ ou. ☐ he ☐ statement does not apply to you please put an 'X' in the box under 'does not apply'.

22. .....I personally believe it is the best thing for my health	☐	☐	☐	☐	☐	☐	☐
23. .....others would be upset with me if I did not	☐	☐	☐	☐	☐	☐	☐
24. .....I really don't think about it	☐	☐	☐	☐	☐	☐	☐
25. .....I have thought about it and I believe it is very important for many aspects of my life	☐	☐	☐	☐	☐	☐	☐
26. ..... I would feel bad about myself if I did not exercise regularly	☐	☐	☐	☐	☐	☐	☐
27. .....it is an important choice I really want to make	☐	☐	☐	☐	☐	☐	☐
28. .....I feel pressure from others to do so	☐	☐	☐	☐	☐	☐	☐
29. .....it is easier to do what I am told than think about it	☐	☐	☐	☐	☐	☐	☐
30. .....it is consistent with my life goals	☐	☐	☐	☐	☐	☐	☐
31. .....I want others to approve of me	☐	☐	☐	☐	☐	☐	☐
32. .....it is very important for being as healthy as possible	☐	☐	☐	☐	☐	☐	☐
33. .....I want others to see I can do it	☐	☐	☐	☐	☐	☐	☐
34. .....I really don't know why	☐	☐	☐	☐	☐	☐	☐

PID	Region ID	Participant Initials	Participant DOB
			d d m m y y y y

During the past three months, my family (or members of my household), friends and colleagues have:

35.Exercised with me or offered to exercise with me	**none**	**rarely**	**a few times**	**often**	**very often**	**does not apply**
Family	☐	☐	☐	☐	☐	☐
Friends and colleagues at work	☐	☐	☐	☐	☐	☐
36.Gave me encouragement to stick with my exercise programme	**none**	**rarely**	**a few times**	**often**	**very often**	**does not apply**
Family	☐	☐	☐	☐	☐	☐
Friends and colleagues at work	☐	☐	☐	☐	☐	☐
37.Criticised me or complained about the amount of time I spend exercising	**none**	**rarely**	**a few times**	**often**	**very often**	**does not apply**
Family	☐	☐	☐	☐	☐	☐
Friends and colleagues at work	☐	☐	☐	☐	☐	☐

Questions continue on the following page

The questions below ask you about how much confidence you have in relation to exercise. Please answer the following questions by putting an 'X' in the appropriate box. For example, if you have complete confidence that you can carry out the behaviour specified you should put an 'X' under '10'. If you have no confidence you should put an 'X' under '1'. If your confidence levels are somewhere in between you should put an 'X' in a box between '2' to '9',

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PID	Region ID	Participant Initials	Participant DOB
			d d m m y y y y

How confident are you that you can exercise when you….

	No confidence 1	2	3	4	5	6	7	8	9	Complete confidence 10
38. …are tired?	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
39 …are in a bad mood?	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
40….feel you don't have the time?	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

These next questions are about exercise itself; that is, engaging in the activity of your choice, assuming you were able to get to the place to exercise and that you have all the necessary equipment. How confident are you that you can do the following?

	No confidence 1	2	3	4	5	6	7	8	9	Complete confidence 10
41. Can follow directions from an instructor?	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
42. Pace yourself during the activity to avoid overexertion?	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
43. Perform the required movements?	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
44. Check how hard the activity is making you work?	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

PID	Region ID	Participant Initials	Participant DOB
			d d m m y y y y

The next questions are about scheduling time for exercise. How confident are you that you can do the following?

	No confidence 1	2	3	4	5	6	7	8	9	Complete confidence 10
45. Can arrange your schedule to exercise regularly no matter what.	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
46. Overcome obstacles that prevent you from participating regularly.	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
47. Make up times when you missed your regular exercise session.	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Part 3 — Your General Health

The questions in this section focus on your general physical and psychological health.

We want to know how your health has been in general over that last few weeks. Please read the questions below and each of the four possible answers. Please put an X' in the box that best applies to you. **Have you recently:**

1. Been able to concentrate on whatever you're doing?							
Better than usual	☐	Same as usual	☐	Less than usual	☐	Much less than usual	☐
2. Lost much sleep over worry?							
Not at all	☐	No more than usual	☐	Rather more than usual	☐	Much more than usual	☐
3. Felt you were playing a useful part in things?							
More so than usual	☐	Same as usual	☐	Less useful than usual	☐	Much less useful	☐

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			d d m m y y y y

4. Felt capable of making decisions about things?							
More so than usual	☐	Same as usual	☐	Less so than usual	☐	Much less capable	☐
5. Felt constantly under strain?							
Not at all	☐	No more Than usual	☐	Rather more than usual	☐	Much more than usual	☐
6. Felt you couldn't overcome your difficulties?							
Not at all	☐	No more Than usual	☐	Rather more than usual	☐	Much more than usual	☐
7. Been able to enjoy your normal day-to-day activities?							
More so than usual	☐	Same as usual	☐	Less so than usual	☐	Much less than usual	☐
8. Been able to face up to your problems?							
More so than usual	☐	Same as usual	☐	Less able than usual	☐	Much less able	☐
9. Been feeling unhappy and depressed?							
Not at all	☐	No more than usual	☐	Rather more than usual	☐	Much more than usual	☐
10. Been losing confidence in yourself?							
Not at all	☐	No more than usual	☐	Rather more than usual	☐	Much more than usual	☐
11. Been thinking of yourself as a worthless person?							
Not at all	☐	No more than usual	☐	Rather more than usual	☐	Much more than usual	☐
12. Been feeling reasonably happy, all things considered?							
More so than usual	☐	About same as usual	☐	Less so than usual	☐	Much less than usual	☐

PID	Region ID	Participant Initials	Participant DOB
			d d m m y y y y

By placing a cross in **one box in each group** below, please indicate which statements **best describes your own health state today.**

Mobility
- I have no problems in walking about ☐
- I have some problems in walking about ☐
- I am confined to bed ☐

Self-Care
- I have no problems with self-care ☐
- I have some problems washing or dressing myself ☐
- I am unable to wash or dress myself ☐

Usual Activities (e.g. work, study, housework, family or leisure activities)
- I have no problems with performing my usual activities ☐
- I have some problems with performing my usual activities ☐
- I am unable to perform my usual activities ☐

Pain/Discomfort
- I have no pain or discomfort ☐
- I have moderate pain or discomfort ☐
- I have extreme pain or discomfort ☐

Anxiety/Depression
- I am not anxious or depressed ☐
- I am moderately anxious or depressed ☐
- I am extremely anxious or depressed ☐

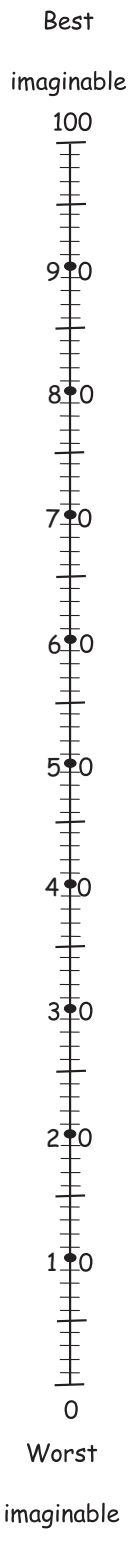
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			d d m m y y y y

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.

Your own health state



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PID	Region ID	Participant Initials	Participant DOB
			d d m m y y y y

Part 4 — Self Regulation

This section focuses on how you manage your weight.

Please answer the following questions by placing a cross in the box that best describes how you are. **Work quickly and don't think too long about your answers.**

If you STRONGLY DISAGREE with a statement, put an 'X' under statement 1. If you DISAGREE put an 'X' under statement 2. If you are UNCERTAIN or UNSURE put an 'X' under statement 3. If you AGREE put an 'X' under statement 4, and if you STRONGLY AGREE put an 'X' under statement 5	Strongly disagree	Disagree	Uncertain/ unsure	Agree	Strongly agree
1. I don't notice the effects of my actions until it's too late	☐	☐	☐	☐	☐
2. I am able to accomplish goals I set for myself	☐	☐	☐	☐	☐
3. I have personal standards and I try to live up to them	☐	☐	☐	☐	☐
4. I tend to keep doing the same thing even when it doesn't work	☐	☐	☐	☐	☐
5. I have a hard time setting goals for myself	☐	☐	☐	☐	☐
6. I have trouble making plans to help me reach my goals	☐	☐	☐	☐	☐
7. I set goals for myself and keep track of my progress	☐	☐	☐	☐	☐
8. I give up quickly	☐	☐	☐	☐	☐

END OF THE QUESTIONNAIRE

Thank you for your time and effort

Researcher/SEWTU staff: please see p

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PID	Region ID	Participant Initials	Participant DOB
			d d m m y y y y



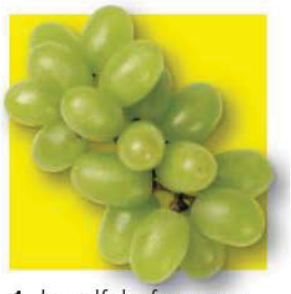
1 medium apple



2 broccoli florets



2 halves of canned peaches



1 handful of grapes



1 medium banana



3 heaped tablespoons of peas



1 medium glass of orange juice



7 strawberries



3 whole dried apricots

5 A DAY

Just Eat More
(fruit & veg)



3 heaped tablespoons of cooked kidney beans



16 okra

NHS

PID	Region ID	Participant Initials	Participant DOB
			d d m m y y y y

SEWTU/RESEARCHER USE ONLY:

Please return to page 23 and ensure the participant has completed the "health state thermometer" question correctly.

Please enter the answer below:

☐☐☐ %

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Appendix 4c: 6 month follow-up postal questionnaire (all arms)

PID	Region ID	Participant Initials	Participant DOB
			d d m m y y y y

Weight Loss Maintenance in Adults (WILMA)

Your Questionnaire Booklet

Date completed ☐☐ / ☐☐ / ☐☐☐☐ (d d / m m / y y y y)

Name of researcher ☐

Participant ID ☐☐☐☐

Example: 0 1 9 9

Region ID ☐☐

Participant initials ☐☐☐

Example: R L M _ R - M

Participant DOB ☐☐ / ☐☐ / ☐☐☐☐ (d d / m m / y y y y)

ARM & TIMEPOINT

BASELINE	☐	1 YEAR PI - Intervention	☐
6-MONTH	☐	1 YEAR PI -Control	☐
POST INTERVENTION (PI) Intervention	☐	2 YEAR PI – Intervention	☐
PI – Control	☐	2 YEAR PI - Control	☐

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			d d m m y y y y

This questionnaire should take around 30-40 minutes to complete but take as much time as you like. Please feel free to ask the researcher any questions if there is anything you don't understand.

For most questions we would like you to put an 'X' in the relevant box. Please use **black** ink and **keep the cross inside the box**:

Example

Bread	None	less than 1 **a day**	1 - 2 **a day**	3 - 4 **a day**	5 or more **a day**
White bread or soft rolls	X				

If you need to correct an item draw a single line through it and write in the correct answer as shown:

Bread	None	less than 1 **a day**	1 - 2 **a day**	3 - 4 **a day**	5 or more **a day**
White bread or soft rolls	~~X~~	X			

For some questions you will need to write your answer. Please use **BLOCK CAPITALS e.g.**

Bread	None	less than 1 **a day**	1 - 2 **a day**	3 - 4 **a day**	5 or more **a day**
Other P I T T A					

Or numbers as appropriate e.g.

How many cans of pop or a fizzy drink which isn't sugar free or diet do you drink on a usual day? **(NOTE: A 2 litre bottle = 6 cans)** 0 3

The following two sections ask about your diet and physical activity. Some of the questions in these two sections may seem repetitive but we need to collect all this information so that we can score the questionnaires properly and complete the analyses. We understand that repetitive questions can be off-putting so your cooperation in completing all the questions is **greatly appreciated.**

PID	Region ID	Participant Initials	Participant DOB
			d d m m y y y y

Part 1—Your Diet

The questions in this section focus on the food you eat as well as your eating habits and patterns of eating.

The questions below ask about the different foods you eat.

Some of the questions ask you what you eat in a normal *week* but others what you eat in a normal *day*. Please put an 'X' in only one box on each line.

1. About how many pieces or slices of bread do you eat on a **usual day**? **(choose one answer on each line)**

Bread	None	less than 1 **a day**	1 - 2 **a day**	3 - 4 **a day**	5 or more **a day**
White bread or soft rolls	☐	☐	☐	☐	☐
Brown or granary bread, Best of Both, soft grain	☐	☐	☐	☐	☐
Wholemeal bread or rolls or 2 slices crispbread or wholemeal scones	☐	☐	☐	☐	☐
Chapattis, wraps	☐	☐	☐	☐	☐
Other:	☐	☐	☐	☐	☐

2. About how many **servings per week** do you eat of the following type of breakfast cereal or porridge? **(choose one answer on each line)**

Breakfast Cereal	None	less than 1 **a week**	1 – 2 **a week**	3 - 5 **a week**	6 or more **a week**
Sugar type: Frosties, Coco Pops, Ricicles, Sugar puffs	☐	☐	☐	☐	☐

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	None	less than 1 **a week**	1 – 2 **a week**	3 - 5 **a week**	6 or more **a week**
Rice/Corn type: Corn flakes, Rice Krispies, Special K	☐	☐	☐	☐	☐
Porridge or Ready Brek	☐	☐	☐	☐	☐
Wheat/oat type: Shredded Wheat, Weetabix, Puffed Wheat, Fruit'n Fibre, NutriGrain, Start, Optivita, Oatibix	☐	☐	☐	☐	☐
Bran type: All-Bran, Bran Flakes, Sultana Bran, Team	☐	☐	☐	☐	☐
Muesli type: Alpen, Jordan's	☐	☐	☐	☐	☐

3. About how many **servings per week** do you eat of the following foods? **(choose one answer on each line)**

	None	less than 1 **a week**	1 – 2 **a week**	3 – 5 **a week**	6 – 7 **a week**	8 - 11 **a week**	12 or more **a week**
Pasta or rice	☐	☐	☐	☐	☐	☐	☐
Potatoes	☐	☐	☐	☐	☐	☐	☐
Peas	☐	☐	☐	☐	☐	☐	☐
Beans (baked, tinned, or dried) or lentils	☐	☐	☐	☐	☐	☐	☐
Other vegetables (any type)	☐	☐	☐	☐	☐	☐	☐

PID	Region ID	Participant Initials	Participant DOB
			d d m m y y y y

Fruit (fresh, frozen, canned)	☐ ☐ ☐ ☐ ☐ ☐ ☐

4. About how many **servings per week** do you eat of the following foods? **(choose one answer on each line)**

	None ☐	less than 1 **a week**	1 - 2 **a week**	3 - 5 **a week**	6 or more **a week**
Cheese (any except cottage)	☐	☐	☐	☐	☐
Beefburgers or sausages	☐	☐	☐	☐	☐
Beef, pork, or lamb (for vegetarians: nuts)	☐	☐	☐	☐	☐
Bacon, meat pie, processed meat	☐	☐	☐	☐	☐
Chicken or turkey	☐	☐	☐	☐	☐
Fish (NOT fried fish)	☐	☐	☐	☐	☐
ANY fried food: fried fish, chips, cooked breakfast, samosas	☐	☐	☐	☐	☐
Cakes, pies, puddings, pastries	☐	☐	☐	☐	☐
Biscuits, chocolate, or crisps	☐	☐	☐	☐	☐

5. About how much of the following types of milk do you yourself use **per day**, for example in cereal, tea, or coffee? **(choose one answer on each line)**

Milk	None	less than a quarter pint **a day**	about a quarter pint **a day**	about a half pint **a day**	1 pint or more **a day**
Full cream	☐	☐	☐	☐	☐
Semi-skimmed	☐	☐	☐	☐	☐
Skimmed	☐	☐	☐	☐	☐

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Other:					
	☐	☐	☐	☐	☐

6. About how many **rounded teaspoons per day** do you usually use of the following types of spreads, for example on bread, sandwiches, toast, potatoes or vegetables? **(choose one answer on each line)**

Spreads	None	1 **a day**	2 **a day**	3 **a day**	4 **a day**	5 **a day**	6 **a day**	7 or more **a day**
Regular margarine or butter or reduced fat spread such as sunflower or olive spread, Flora, Vitalite, Clover, Olivio, Stork, Utterly Butterly	☐	☐	☐	☐	☐	☐	☐	☐
Low fat spread such as Flora Light, St Ivel Gold, Half-fat butter, Olivite, Flora Pro-activ, Light spread	☐	☐	☐	☐	☐	☐	☐	☐

7. What sort of fat do you usually use for the following purposes? **(choose one answer on each line)**

	Butter, lard or dripping	**Solid cooking fat** (White Flora, Cookeen) **Half-fat butter, Hard margarine** (Stork)	**Soft margarine** (sunflower, soya) **Reduced fat spread** (olive, Flora Buttery, Olivio)	**Vegetable oil, olive oil** or **Low fat spread** (Flora Light, Olivite, St. Ivel Gold)	**No fat used**
On bread and vegetables	☐	☐	☐	☐	☐
For frying	☐	☐	☐	☐	☐
For baking or cooking	☐	☐	☐	☐	☐

8. How many portions of fruit and vegetable (excluding potatoes) do you eat, of any

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			d d m m y y y y

sort, on a typical day? **(See guidance on portions sizes at end of questionnaire and choose one answer on each line)**

	None	1	2	3	4	5	6	7	8 or more
Fruit	☐	☐	☐	☐	☐	☐	☐	☐	☐
Vegetable	☐	☐	☐	☐	☐	☐	☐	☐	☐

9. How many cans of pop or a fizzy **drink which isn't sugar free or diet** do you drink on a usual day? **(NOTE: A 2 litre bottle = 6 cans)** ☐☐

10. How many rounded teaspoons of sugar do you have on a usual day e.g. in tea or coffee or on cereals? ☐☐ nded teaspoons

	Never	Monthly or less	2-4 times per month	2-3 times per week	4+ times per week
11. How often do you have a drink containing alcohol?	☐	☐	☐	☐	☐

	1 -2	3 - 4	5 - 6	7 - 9	10+
12. How many units of alcohol do you drink on a typical day when you are drinking?	☐	☐	☐	☐	☐

N.B.One unit of alcohol is about equal to half a pint of ordinary strength beer, lager or cider **or** a small pub measure (25 ml) of spirits **or** a standard pub measure (50 ml) of fortified wine e.g. sherry/port. A small glass (125 ml) of ordinary strength wine (12% alcohol) **or** a standard pub measure of spirits (35 ml) contain 1.5 units of alcohol.

	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
13. How often have you had 6 or more units if female, or 8 or more if male, on a single occasion in the last year?	☐	☐	☐	☐	☐

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			d d m m y y y y

14. Do you smoke? Yes ☐

No ☐ **If No, go to Part 2.**

15. How many cigarettes or roll-ups do you smoke per day? ☐☐

16. How soon after waking up do you smoke your first cigarette or roll-up?

- Within 5 minutes ☐
- 6 to 30 minutes ☐
- 31 to 60 minutes ☐
- 61+ minutes ☐

Part 2 — Physical Activity

The questions in this section ask you about the amount of physical activity you do, and when and why you chose to do it.

We are interested in finding out about the kind of physical activities that people do as part of their everyday lives.

Questions 1-7 ask you about the time you spent being physically active in the last 7 days

Please answer each question by placing an 'X' in the appropriate box even if you do not consider yourself to be an active person. Please think about the activities you do at work, as part of your housework/gardening, to get from place to place, and in your spare time for recreation, exercise or sport.

Think about all the **vigorous** activities that you did in the **last 7 days**.
Vigorous physical activities refer to activities that take hard physical effort and make you breathe much harder than normal. Think *only* about those physical activities that you did for at least 10 minutes at a time.

PID	Region ID	Participant Initials	Participant DOB
			d d m m y y y y

1) During the **last 7 days**, on how many days did you do **vigorous** physical activities like heavy lifting, digging, aerobics, or fast bicycling?

☐ **days per week**

☐ No vigorous physical activities → **(skip to question 3)**

2) How much time did you usually spend doing **vigorous** physical activities on one of those days?

☐☐ **hours per day**

☐☐ **minutes per day**

☐ Don't know/Not sure

Think about all the **moderate** activities that you did in the **last 7 days**. **Moderate** activities refer to activities that take moderate physical effort and make you breathe somewhat harder than normal. Think only about those physical activities that you did for at least 10 minutes at a time.

3) During the **last 7 days**, on how many days did you do **moderate** physical activities like carrying light loads, bicycling at a regular pace, or doubles tennis? Do not include walking.

☐ **days per week**

☐ No moderate physical activities → **(skip to question 5)**

4) How much time did you usually spend doing **moderate** physical activities on one of those days?

☐☐ **hours per day**

☐☐ **minutes per day**

☐ Don't know/Not sure

Think about the time you spent **walking** in the **last 7 days**. This includes at work and at home, walking to travel from place to place, and any other walking that you might do solely for recreation, sport, exercise, or leisure.

5) During the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time?

☐ **days per week**

☐ No walking → **(skip to question 7)**

6) How much time did you usually spend walking on one of those days?

☐☐ **hours per day**

☐☐ **minutes per day**

☐ Don't know/Not sure

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The last question is about the time you spent **sitting** on weekdays during the **last 7 days**. Include time spent at work, at home, while doing course work and during leisure time. This may include time spent sitting at a desk, visiting friends, reading, or sitting or lying down to watch television.

7) During the **last 7 days**, how much time did you spend **sitting** on a **week day**?

☐☐ **hours per day**

☐☐ **minutes per day**

☐ Don't know/Not sure

Questions continue on the following page

PID	Region ID	Participant Initials	Participant DOB
			d d m m y y y y

Part 3 — Your General Health

The questions in this section focus on your general physical and psychological health.

By placing a cross in **one box in each group** below, please indicate which statements **best describes your own health state today**.

Mobility
- I have no problems in walking about ☐
- I have some problems in walking about ☐
- I am confined to bed ☐

Self-Care
- I have no problems with self-care ☐
- I have some problems washing or dressing myself ☐
- I am unable to wash or dress myself ☐

Usual Activities (e.g. work, study, housework, family or leisure activities)
- I have no problems with performing my usual activities ☐
- I have some problems with performing my usual activities ☐
- I am unable to perform my usual activities ☐

Pain/Discomfort
- I have no pain or discomfort ☐
- I have moderate pain or discomfort ☐
- I have extreme pain or discomfort ☐

Anxiety/Depression
- I am not anxious or depressed ☐
- I am moderately anxious or depressed ☐
- I am extremely anxious or depressed ☐

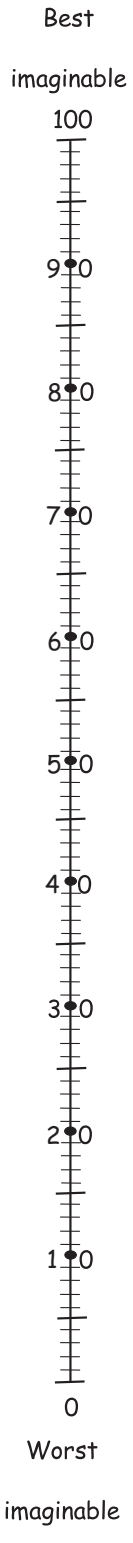
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			d d m m y y y y

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.

Your own health state



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Part 4—Health Status & NHS resource use

The questions in this section focus on your general health, any medication you have been prescribed and any contact you have had with NHS health professionals.

1a) Have you taken weight loss medication **in the last 6 months**? ☐ **Yes** ☐ **No**

b) ***If YES, please specify*** **Example:** | O | R | L | I | S | T | A | T | | | | | | |

If NO, go to question 2.

c) **If YES**, are you still taking it? ☐ **Yes** ☐ **No**

d) If you answered **NO to Q1c** above, how long did you take it for? | | | Months

2. Have you been diagnosed with any of the following health problems **in the last 6 months** (select all that apply)?

- ❑ **Heart disease**
- ❑ **Diabetes**
- ❑ **Depression**
- ❑ **Stroke**
- ❑ **Arthritis**
- ❑ **Hypertension (high blood pressure)**
- ❑ **High cholesterol**
- ❑ **Asthma**
- ❑ **Chronic Obstructive Pulmonary Disease (COPD)**
- ❑ **Back pain**
- ❑ **Other (*please specify*)** | | | | | | | | | | | | | |

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3a) **In the last 3 months** have you seen **any** health professional at your GP surgery?

☐ **Yes** ☐ **No** ***If NO, go to Q4a.***

b) **If YES**, how many times were you seen by:

Your/another GP

Practice nurse

Other health professional

Example: 0 2

If other please specify:

Example: D I E T I T I A N

4a) **In the last 3 months** have you seen any health professional at your home?

☐ **Yes** ☐ **No** ***If NO, go to Q5a.***

b) **If YES**, how many times were you seen by:

Your/another GP

Practice nurse

Other health professional

If other, please specify:

5a) **In the last 3 months** have you attended an Accident and Emergency (Casualty) department?

❑ **Yes** ❑ **No** ***If NO, go to Q6a.***

b) **If YES**, how many times

6a) **In the last 3 months** were you admitted to hospital as an in-patient?

PID	Region ID	Participant Initials	Participant DOB
			d d m m y y y y

❑ Yes ❑ No *If NO, go to Q7a.*

b) **If YES**, how many times ☐☐

c) **If YES**, how many nights did you spend in hospital? ☐☐

7a) **In the last 3 months** have you received any prescriptions for medicine?

❑ Yes ❑ No *If NO, go to Q8a.*

b) If YES, please specify:

Example:

1. Drug name

T H Y R O X T N F

1. Drug dose

5 0 M C G 1 X D A T I Y

1. Drug name

1. Drug dose

2. Drug name

2. Drug dose

3. Drug name

3. Drug dose

4. Drug name

4. Drug dose

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PID	Region ID	Participant Initials	Participant DOB
			d d m m y y y y

5. Drug name

5. Drug dose

6. Drug name

6. Drug dose

7. Drug name

7. Drug dose

8. Drug name

8. Drug dose

9. Drug name

9. Drug dose

10. Drug name

10. Drug dose

PID	Region ID	Participant Initials	Participant DOB
			d d m m y y y y

8a) And finally, **in the last 3 months** did you **pay** for any services for the specific purpose of helping you with your weight control – for example slimming clubs, health clubs, gyms, swimming pools, exercise classes?

☐ **Yes** ☐ **No**

b) **If YES**, approximately how much did you pay for all of these services **in the last 3 months**?

£ ☐☐☐ **Example:** 0 3 5

END OF THE QUESTIONNAIRE

Thank you for your time and effort

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PID	Region ID	Participant Initials	Participant DOB
			d d m m y y y y



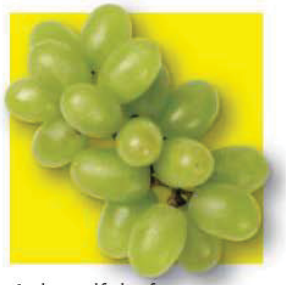
1 medium apple



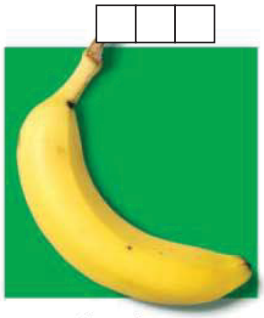
2 broccoli florets



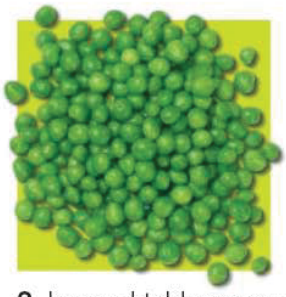
2 halves of canned peaches



1 handful of grapes



1 medium banana



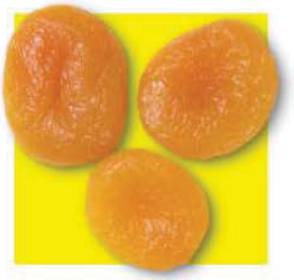
3 heaped tablespoons of peas



1 medium glass of orange juice



7 strawberries



3 whole dried apricots

5 A DAY

Just Eat More
(fruit & veg)



3 heaped tablespoons of cooked kidney beans



16 okra

NHS

Appendix 4d: 12 month follow-up CRF (intervention groups)

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PID	Region ID	Participant Initials	Participant DOB
			d d m m y y y y

Weight Loss Maintenance in Adults (WILMA)

POST INTERVENTION (1 YEAR) CASE REPORT FORM (C)

Date completed ☐☐ / ☐☐ / ☐☐☐☐ (d d m m y y y y)

Name of researcher ☐ (***block capitals***)

Participant ID ☐☐☐☐ **Example:** 0 1 2 3

Region ID ☐☐

Participant initials ☐☐☐ **Example:** R L M **OR** R - M

Participant DOB ☐☐ / ☐☐ / ☐☐☐☐ (d d m m y y y y)

TIMEPOINT

BASELINE	☐	1 YEAR PI	☐
POST INTERVENTION (PI) CONTROL	☐	2 YEAR PI	☐
POST INTERVENTION (PI) INTERVENTION	☐		

Instructions for completion of CRF

All information should be completed by the Researcher, with the participant. This form should be completed using **BLACK INK**. Please write clearly using **BLOCK** capitals and keep all responses within the boxes provided.

Options should be selected by putting a cross (X) in the appropriate box. If you need to correct an item draw a single line through it and initial and date as shown:

☒ RM 25/11/10

If for any reason compulsory fields are not completed/you do not have the necessary information, please write 'ND' (Not Done) **NEXT TO** the relevant item as shown:

☐☐☐.☐ **cm** ND

PLEASE LEAVE ALL NON-APPLICABLE FI ELDS BLANK.

Once completed this form should be sent to:

Dr Rachel McNamara, WILMA Senior Trial Manager
SEWTU, 7th floor Neuadd Meirionnydd, Cardiff University
Heath Park, Cardiff. CF14 4YS.

PID	Region ID	Participant Initials	Participant DOB
			d d m m y y y y

SECTION 1: Weight loss history & maintenance

1. a) Have you reached your weight loss goal and are trying to maintain the weight you have already lost?

☐ **Yes** ☐ **No** ***If YES, go to Q1b: if NO go to Q1c.***

b) **If YES,** how long did it take you to reach your weight loss goal? ☐☐ **ns** ***Go to Q2.***

c) **If you haven't yet reached your weight loss goal**, how long have you been trying to lose weight?

☐☐ **Months**

d) **If you haven't yet reached your weight loss goal,** are you still trying to lose weight?

☐ **Yes** ☐ **No** ***If NO, go to Q2.***

e) **If you are still trying to lose weight,** how much more would you like to lose?

☐☐ lbs **OR** ☐☐ kgs

2. How did you lose the weight you lost recently, e.g. weight loss medication, attending Slimming World or Weightwatchers, joining a gym, counting calories etc? ***Tick all that apply***

- ☐ **Weight loss medication**
- ☐ **Slimming club (Weight Watchers, Slimming World etc)**
- ☐ **Gym / increased exercise**
- ☐ **Calorie counting / reduced fat intake**
- ☐ **Other (please specify)** ☐☐☐☐☐☐☐☐☐☐☐☐☐☐

3. a) Are you **currently** attending a weight loss group (e.g. Weight Watchers) or a physical activity group or gym?

☐ **Yes** ☐ **No** ***If NO, go to Q4.***

b) **If YES,** can you give details of the group/gym you are attending? ***(please write in block capitals)***

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PID	Region ID	Participant Initials	Participant DOB
☐☐☐☐	☐☐	☐☐☐	☐☐☐☐☐☐☐☐ d d m m y y y y

c) How often do you attend?

- ☐ **More than once a week**
- ☐ **Once a week**
- ☐ **Every other week**
- ☐ **Once a month**
- ☐ **Other (please specify)** ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

4. How often do you weigh yourself?

- ☐ **Daily**
- ☐ **Once a week**
- ☐ **Every other week**
- ☐ **Once a month**
- ☐ **Other (please specify)** ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

5. How motivated do you feel to maintain your weight?

Very motivated				Not at all motivated
1	2	3	4	5
☐	☐	☐	☐	☐

6. How confident do you feel that you are able to maintain your weight?

Very confident				Not at all confident
1	2	3	4	5
☐	☐	☐	☐	☐

7. Do you record your weight weekly?

☐ **Yes** ☐ **No**

8. a) Do you know anyone else taking part in the WILMA study?

☐ **Yes** ☐ **No** ***If NO, go to Q9.***

PID	Region ID	Participant Initials	Participant DOB
			d d m m y y y y

b) **If YES,** did they share any information about the study/weight loss maintenance with you?

☐ **Yes** ☐ **No** ***If NO, go to Q9.***

c) **If YES**, which parts of the study or information about weight loss maintenance did they share with you (please give details below)?

d) Did you use the information described above?

☐ **Yes** ☐ **No**

SECTION 2: Anthropometry and body composition measurements

9. Height ☐☐☐.☐ **cm** **Example:** 0 8 1 . 3

10. Weight ☐☐☐.☐ **kg**

11. Waist circumference ☐☐☐.☐ **cm**

12. Hip circumference ☐☐☐.☐ **cm**

Section 3: Health status

13. a) Have you taken weight loss medication **in the last 12 months**? ☐ **Yes** ☐ **No**

If NO, go to Q14.

b) **If YES**, please specify any weight loss medications you have taken in the last 12 months:

Example: O R L I S T A T

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PID	Region ID	Participant Initials	Participant DOB
			d d m m y y y y

Medication 1

Medication 2

Medication 3

c) **If YES**, are you still taking weight loss medication? ☐ **Yes** ☐ **No**

If YES, please specify any weight loss medication/s you are still taking:

Medication 1

Medication 2

Medication 3

d) If you answered **NO to Q13c** above, how long did you take weight loss medication for?

Months

14. Have you been diagnosed with any of the following health problems **in the last 12 months** (select all that apply)?

- ☐ **Heart disease**
- ☐ **Diabetes**
- ☐ **Depression**
- ☐ **Stroke**
- ☐ **Arthritis**
- ☐ **Hypertension (high blood pressure)**
- ☐ **High cholesterol**
- ☐ **Asthma**
- ☐ **Chronic Obstructive Pulmonary Disease (COPD)**
- ☐ **Back pain**
- ☐ **Other (please specify)**

PID	Region ID	Participant Initials	Participant DOB
			d d m m y y y y

Section 4: Resource use

In the last 3 months, have you:

15. a) Seen **any** health professional at your GP surgery? ☐ **Yes** ☐ **No**

If NO, go to Q16a.

b) **If YES**, how many times were you seen by:

Example: 0 2

Your/another GP ☐☐

Practice nurse ☐☐

Other health professional ☐☐ **ther please specify:**

Example: D I E T I T I A N

☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

16. a) Seen **any** health professional at your home? ☐ **Yes** ☐ **No**

If NO, go to Q17a.

b) **If YES**, how many times were you seen by:

Your/another GP ☐☐

Practice nurse ☐☐

Other health professional ☐☐

If other, please specify ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

17. a) **In the last 3 months** have you attended an Accident and Emergency (Casualty) department?

☐ **Yes** ☐ **No** ***If NO, go to Q18a.***

b) **If YES**, how many times ☐☐

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PID	Region ID	Participant Initials	Participant DOB
			d d m m y y y y

18. a) **In the last 3 months** were you admitted to hospital as an in-patient?

☐ **Yes** ☐ **No** ***If NO, go to Q19a.***

b) **If YES**, how many times ☐☐

c) **If YES,** how many nights did you spend in hospital? ☐☐

19. a) **In the last 3 months** have you received any prescriptions for medicine?

☐ **Yes** ☐ **No** ***If NO, go to Q20a.***

b) **If YES**, which drugs were you prescribed:

Example:

1. Drug name

T	H	Y	R	O	X	I	N	E																	

1. Drug dose

5	0	M	C	G		1	X	D	A	I	L	Y													

1. Drug name

1. Drug dose

2. Drug name

2. Drug dose

3. Drug name

3. Drug dose

4. Drug name

4. Drug dose

PID	Region ID	Participant Initials	Participant DOB
			d d m m y y y y

5. Drug name

5. Drug dose

6. Drug name

6. Drug dose

7. Drug name

7. Drug dose

8. Drug name

8. Drug dose

9. Drug name

9. Drug dose

10. Drug name

10. Drug dose

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20. a) And finally, **in the last 3 months** did you **pay** for any services for the specific purpose of helping you with your weight control – for example slimming clubs, health clubs, gyms, swimming pools, exercise classes?

☐ **Yes** ☐ **No**

b) **If YES**, approximately how much did you pay for all of these services **in the last 3 months**?

£☐☐☐ **Example:** 0 3 5

Appendix 5 Qualitative interviews topic guides

Topic guide for intervention group 12 months v3/29.08.2013

Appendix 5a: Qualitative interviews topic guide - intervention

INTERVENTION GROUP: 12 MONTHS

Thank you for agreeing to speak to me today. In this interview I would like to talk to you about how you are getting on now that the intervention has finished.

First of all we talk about where you are at in your weight management goal, how you are coping with your weight and how you feel about it now.

Then I would like to ask you a few questions about your views of the study programme now that you have completed it.

The interview should take about half to three quarters of an hour, but if you want to take a break or stop at any time just tell me and we can stop immediately. You don't have to answer any question you don't want to, so if that is the case please just say so and we can move on to something else.

I'd just like to reassure you, again, of confidentiality. Your name will not be attached to the transcripts of this interview or included in any reports of our findings from these interviews, and we won't disclose anything you say to your counsellor or group leader.

Please feel free to add anything that you think is important but which I may not ask you about.

Do you have any questions?

I'd just like to check if you are happy for me to record the interview?

Shall we begin?

SECTION 1: WEIGHT LOSS/MAINTENANCE HISTORY.

***1.* So, thinking about this last occasion that you lost weight, just before coming into the study, could you tell me a little about that - what motivated you to lose weight and how did you go about it?**

Explore type of diet, what programme did they use, Explore physical activities and exercise, how much they lost, how long it took, how satisfied with weight loss – have they reached their goals or still on weight loss diet? Which weight loss strategy is most affective for them? What did this involve for them?

2. Have you ever discussed weight loss or weight loss maintenance with your GP or nurse?

Did you raise the topic? Was this helpful? What did they offer?

3. The study is about maintenance of your weight loss, do you think that maintaining the weight loss is different in any way to actually losing weight?

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Topic guide for intervention group 12 months v3/29.08.2013

Explore how they manage their weight in different situations and on different occasions

SECTION 2: INTERVENTION AND WEIGHT MAINTENANCE STATUS

I'd like to talk about your experiences of weight loss or weight maintenance during the study in the last year or so.

1. Are you currently attending <slimming world/weight watchers/exercise on prescription/weight management programme>?

IF YES, How helpful is that?

How often attend; why attend ?

IF NO, Why are you no longer continuing with it?

When discontinued; why?

2. If you have used SW/WW/EOR etc before what was it about it that you liked or disliked?

3. Are your family or friends supportive of your weight loss/maintenance and healthy eating and physical activity plans?

Do they join in? Do they get support from anywhere else? Has being part of the study impacted on other family members at all, have they lost weight, changed their diet or done more physical activity?

4. Can you tell me how you have found trying to maintain your weight loss in the last year?

Explore approach to maintenance; barriers and facilitators (explore social and environmental issues); what is hard/easy about maintenance; what is needed to maintain weight loss; what strategies did they use; what did this involve exactly; if they haven't managed to maintain - why not? Explore how these have changed over time

a. Thinking about the study intervention and the counselling sessions specifically, what did you think of them?

Explore how many they attended. If didn't attend – why not, if dropped out, why, what didn't you like; Barriers to attending; What was/was not useful; were there too many/not enough sessions; frequency;

b. Thinking about the telephone sessions now, how did you find them? How did they compare?

Explore how many they attended. If didn't attend – why not, if dropped out, why, what didn't you like; Barriers to attending; What was/was not useful; were there too many/not enough sessions; frequency

c. What sort of things did you discuss with your counsellor?

Topic guide for intervention group 12 months v3/29.08.2013

Explore discussions around dietary strategies, exercise, barriers to WLM, relapse and how they cope, whether WL/WLM were impacted from life events; self-monitoring

Explore further discussion around goal setting and making plans – what sort of goals did they set, how did they achieve these – what plans did they make? Did they receive support for this from family and friends?

d. How did you find the written materials used in the sessions? (summary sheets)

Understandable; useful/not useful; what else would they have liked?

e. Thinking now, about the Group Sessions – did you attend those and if so how useful did you find them?

If didn't attend - why not ; Explore the barriers to attending.

What aspects useful; what aspects not useful; are they meeting other participants outside the sessions; materials used in group sessions; weekly weighing

f. How did you feel about the group sessions ending?

g. We encouraged you to weigh yourself weekly oppose to other times, did you find this useful/helpful?

How often did they weigh?

***h.* Did you use WILMA online or the diaries?**

Was it helpful – if not why not? Do they have suggestions for improvement?

***i.* Could you tell me briefly what you think the best and worse things were about the WILMA programme?**

***j.* Is there anything you could suggest that would make the WILMA programme better?**

SECTION 3: STUDY PROCEDURES (if participant is tiring miss out q's 1-6)

1. How did you hear about the study?

Who introduced it (GP, programme facilitator, or letter); Were they supportive of the study. Was the information provided enough to help you decide whether to take part? Topic guide for intervention group 12 months

2. What made you decide to enter the study and did the fact it was part of a research study affect your decision?

Explore why entered study and expectations of research study. What if had been in control group?

3. How good were the information sheets (given prior to entering the study) for telling you what was involved?

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Topic guide for intervention group 12 months v3/29.08.2013

Was there anything else you would like to have known? Was there anything you didn't understand? Did you understand the randomisation? Were your expectations met/not met?

4. How have you found the questionnaires?

Too long?; Completed all so far?; difficult or easy to complete; number; baseline visit; anything missing?

5. We are interested in finding out what might encourage people to attend the follow-up visits. In WILMA we offered a £20 voucher.

Do you think this was enough – what about £50?

Do you have any other suggestions on how we could improve the attendance of people at the follow-up visits?

6. Have you shared any of the information with anyone else (family, friends, colleagues) or given anyone any hints or tips that you have learnt from the study?

Who – are they in the study; what information

Just a couple of more questions to wind up.

Sum up what they have said about their experiences of losing weight in the past and then ask:

1. Does that sum up your experiences of losing weight in the past?

How successful have you attempts been; what motivated you; what strategies did you use

2. Could you tell me how confident you feel about the future? What is your plan for weight management now?

Explore if they intend to use strategies learned in the study in the future, And if so, which and why.

3. Finally, I'd just like to ask you if there is anything you would like to add?

Appendix 5b: Qualitative interviews topic guide - control

WILMA QUALITATIVE INTERVIEWS TOPIC GUIDE

CONTROL GROUP: 12 MONTHS

Thank you for agreeing to speak to me today. In this interview I would like to discuss your views of weight loss and weight maintenance in general, any weight management programmes you may be using and also your views of our study.

The interview will be roughly in three sections. First of all I'd like to talk to you about your weight loss and maintenance experiences prior to entering the study. Then, I'd like to talk to you about your experiences of weight loss and maintenance since entering the study including things that may have helped or hindered you in your weight management goals. And finally, I would also like to talk to you about the research study itself.

The interview should take about three quarters of an hour to an hour, but if you want to take a break or stop at any time just tell me and we can stop immediately. You don't have to answer any question you don't want to, so if that is the case please just say so and we can move on to something else.

I'd just like to reassure you, again, of confidentiality. Any information you give us will be used anonymously – your name will not be attached to the transcripts of this interview or included in any reports of our findings from these interviews.

Please feel free to add anything that you think is important but which I may not ask you about. It is only by talking to people in this way, can we develop an intervention that is really useful to you and other people who are in a similar situation to you.

Do you have any questions?

I'd just like to check if you are happy for me to record the interview?

Shall we begin?

SECTION 1: WEIGHT LOSS/MAINTENANCE HISTORY.

1. **So, thinking about this last occasion that you lost weight, just before coming into the study, could you tell me a little about that - what motivated you to lose weight and how did you go about it?**

Explore type of diet, what programme did they use, how much they lost, how long it took, how satisfied with weight loss – have they reached their goals or still on weight loss diet?

SECTION 2: EXPERIENCE OF WEIGHT MANAGEMENT DURING THE STUDY.

I'd like to talk about your experiences of weight loss or weight maintenance during the study – the last year or so.

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In this section explore how strategies have changed over time.

1. The study is about maintenance of your weight loss, do you think that maintaining the weight loss is different in any way to actually losing weight?

2. If you were still trying to lose weight can you tell me a little more about the weight loss strategies that you used.

☐ *Focus on weight loss programme; Establish what was involved, how often attended etc;*

☐ *Explore what was useful/not useful, are they still attending? What were the most useful strategies?*

☐ *What were the barriers/facilitators to weight loss?*

☐ *Social and environmental issues.*

3. **If you were trying to maintain your weight loss during the study: What strategies did you use to maintain your weight loss?**

☐ *Explore any formal programmes adopted- what was involved, how often attended.*

☐ *Explore what was useful/not useful, are they still attending? What were the most useful strategies?*

☐ *What are the barriers/facilitators?*

☐ *Social and environmental issues.*

☐ *Explore behaviour change strategies and whether they managed to maintain – if not why not, and if so how?*

4. Are you attending <slimming world/weight watchers/exercise on prescription/weight management programme>?

IF YES, How helpful is that?

How often attend; why attend ?

IF NO, Why are you no longer continuing with it?

When discontinued; why?

5. **If you have used SW/WW/EOR etc before what was it about it that you liked or disliked?**

6. Some people say that if they slip and eat something like a bit of cake or lots of wine on a Saturday then they feel they have failed and then just overeat. Can you tell me how do you tend to react if you slip and don't stick to your eating or exercise plan?

7. Are your family or friends supportive of your weight loss/maintenance and healthy eating and physical activity plans?

Do they join in? Do you get support from anywhere else? Has being part of the study impacted on other family members at all, have they lost weight, changed their diet or done more physical activity?

8. **Have you ever discussed weight loss or weight loss maintenance with your GP or nurse?**

Did you raise the topic? Was this helpful? What did they offer?

SECTION 3: THE RESEARCH PROCEDURES (if participant is tiring miss out q's 1-5)

Now this is the final few questions, and I'd like to talk to you about the research itself. Are you happy to continue, or would you like a break?

1. How did you hear about the study?

Who introduced it (GP, programme facilitator, or letter); Were they supportive of the study. Was the information provided enough to help you decide whether to take part?

2. What made you decide to enter the study and did the fact it was part of a research study affect your decision?

Explore why entered study and expectations of research study. What if had been in control group?

3. How good were the information sheets (given prior to entering the study) for telling you what was involved?

Was there anything else you would like to have known? Was there anything you didn't understand? Did you understand the randomisation? Were your expectations met/not met?

4. How have you found the questionnaires?

Too long?; Completed all so far?; difficult or easy to complete; number; baseline visit; anything missing?

5. We are interested in finding out what might encourage people to attend the follow-up visits. In WILMA we offered a £20 voucher.

Do you think this was enough – what about £50?

Do you have any other suggestions on how we could improve the attendance of people at the follow-up visits?

6. Have you shared any of the information with anyone else (family, friends, colleagues) or given anyone any hints or tips that you have learnt from the study?

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Who – are they in the study; what information;

Just a couple of more questions to wind up.

Sum up what they have said about their experiences of losing weight in the past and then ask:

1. Does that sum up your experiences of losing weight in the past?

How successful have you attempts been; what motivated you; what strategies did you use

2. Could you tell me how confident you feel about the future? What is your plan for weight management now?

Explore if they intend to use strategies learned in the study in the future, And if so, which and why.

3. Finally, I'd just like to ask you if there is anything you would like to add?

Appendix 6 Focus group interview schedule

Introduction

I would like to start off by thanking you all for coming to this discussion group and for all your hard work in the WILMA study. Does everyone know everyone else? (If not can we just quickly go round the group and each person can introduce themselves briefly.

The purpose of today is to find out your views on the WILMA intervention and the study itself. It is important for us to understand exactly how the intervention is delivered in practice and what impact it has had. Also to look at, if it was thought to be beneficial to take this intervention further, what issues would need to be addressed or how could the intervention be improved in order to more efficiently and effectively deliver it. As key facilitators in delivering the WILMA intervention, your opinions in this respect are crucial to our understanding and evaluation of the programme.

To give you a brief outline of the plan for today, we hope to cover topics such as the training provided, the content of the intervention and how this was delivered, and the successes and failures of the intervention in practice. In addition, we would like to explore other issues related to the study procedures and the research process in general. I am keen we stick to some degree to the schedule here and would like to discuss logistical/process issues mainly at the end if possible.

We would encourage an open and honest discussion of views as a group, whether positive or negative, as this is the only way that we can constructively evaluate the WILMA intervention for the future. I'd just like to reassure you, again, of confidentiality. Any information you give us will be used anonymously- your name will not be attached to the transcripts of this interview or included in any reports of our findings from these interviews.

Please provide as much information as you can and feel free to add anything that you think is important but which I may not ask you about.

I am going to have to be a strict chair as we have a lot to get through so apologies if I have to cut short some discussion.

Does anyone have any questions before we begin?

Training/Supervision

1. I would like us to discuss the training that you received in order to deliver the WILMA intervention. I would like to find out your views on:

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a. Firstly the training process and the training materials provided.
b. Was the training sufficient to allow you to confidently deliver the intervention?
c. How did you find the MITI assessment?
d. Do you think there are ways in which the training could be improved, e.g timing, content, booster sessions?
e. Do you feel you needed more support from the team or supervision?
f. How did the peer groups work out if you attended one and how could they be improved?

Intervention Content and Delivery

2. Moving on to the actual content of the intervention, I would like to find out your views about what was involved in the intervention, looking at the each of the different parts of the intervention so starting with MI for WLM
    a. How different was this from your usual delivery of MI in other contexts?
    b. Was there anything about this client group that made them particularly challenging or different? What were the challenges?

3. As part of the WILMA study we included some techniques and 'hot topics' we thought were important with regards to weight management. I would like to ask you a bit about this.
    a. Did you manage to cover any of the WLM techniques in the sessions - self monitoring, social support, habits, emotional eating, coping with relapse, goal setting and implementation intentions?
    b. Did you cover diet and physical activity?
    c. How did you find marrying MI and these hot topics?
    d. Do you think these 'hot topics' were of any help to clients?

4. How well do you think you adhered to the guidance given in the WILMA handbook?
    a. Did you deliver anything in a different way from what was outlined in the handbook (why? were there problems in delivering it in the way proposed?)
    b. Did you provide anything additional in the intervention that was not in the handbook (why? was it something that was missing?)

5. Do you think your sessions would pass the MITI? i.e. how well did you stick to MI?

6. What made for a good MI session?

7. How have the MI phone calls worked out? How were they different from the face to face sessions?

8. How did the brief MI work out?

9.

10. Are there ways in which you think the intervention could be improved?
    a. Staff involved
    b. Components involved

Impact

11. Specifically thinking about participant attendance at the MI sessions:
    a. Did you experience issues with attendance?
    b. What do you think affected attendance (facilitators and barriers) and how can we improve it?

12. What aspects of the intervention do you think facilitated change in clients who were successful in weight maintenance?
    a. Do you think attending the MI sessions made the clients more confident or motivated in dealing with weight management or changing their behaviours?
    b. Do you know if the clients weighed themselves regularly and monitored what they ate, for example, regular self weighing or using the website or food diary?
    c. Did the clients set goals and make plans in terms of their behaviour, for example, to increase the amount of activity they did?

13. What do you think are the barriers for these individuals in trying to change their behaviour?

14. Did participants give you any feedback? Did you get a feel for how happy participants were with MI?

15. If participants withdrew or you never saw them did you get a feel for why that might be the case?

16. On any level do you think it made a difference where they were recruited from, i.e. GP, SW, EOP?

Other Issues

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17. Were there any study specific or process issues you would like to comment on or any barriers or challenges you experienced in delivering the WILMA intervention effectively e.g.
    a. Recruitment issues?
    b. Venue?
    c. Timing?
    d. Audio recording
    e. Paperwork – CRFs, sessions summaries

18. If we were to go for a larger study what key issues would we need to address?
    a. What should stay the same / would require change?

19. Is there anything else you would like to add that hasn't been covered?

Appendix 7 Motivational interviewing case report forms

Appendix 7a: MI face-to-face session CRF

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PID	Region ID	Participant Initials	Participant DOB
			d d m m y y y y



Weight Loss Maintenance in Adults (WILMA)

Face-to-face MI sessions: Case Report Form (CRF)

Notes on completion: A Case Record Form should be completed for all participants at each face-to-face MI session. Once completed, please return to the WILMA study team.

Participant ID number: | | | | |

Session number: |

A. Review (not to be completed in session 1):

Please write briefly below progress made in any of these areas (if covered):

Goal Setting

Implementation Intentions

Self Monitoring

Exercise

PID	Region ID	Participant Initials	Participant DOB
			d d m m y y y y

Diet

Other (please specify)……

B. Plans (to be completed at all sessions):

Please write briefly below any plans agreed in these areas (if discussed)

Goal Setting

Implementation Intentions

Self Monitoring

Exercise

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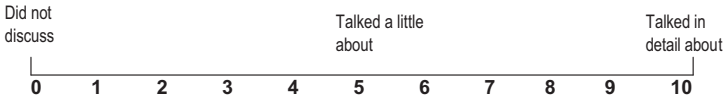
PID	Region ID	Participant Initials	Participant DOB
			d d m m y y y y

Diet

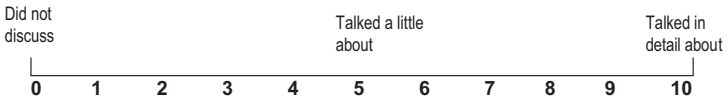
Other (please specify)……

C. Topics covered during the session (to be completed at <u>all</u> sessions)

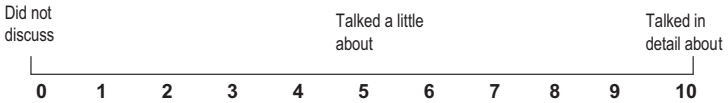
Goal Setting



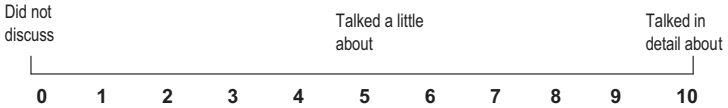
Implementation Intentions



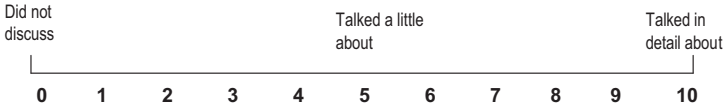
Self Monitoring



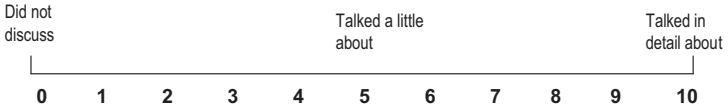
Exercise



Diet



Other



If other, please specify: ……

PID	Region ID	Participant Initials	Participant DOB
			d d m m y y y y

D. Other relevant information (such as barriers to exercise, e.g. injury)

E. Final summary of work done with client (to be completed at last session only)

How successful do you feel the sessions have been?

Challenges and barriers:

What worked well?

F. Closing summary of each session (to be completed at all sessions)

This is to be completed in the last five minutes of the interview. This is a written version of the 'Long Summary'. This is an agreed record of what was discussed: it is a collaborative process and is MI adherent. e.g….."In the last two weeks you have achieved X and Y and these are the new goals you have set yourself today …….. A carbon copy of this should be given to the client.

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PID	Region ID	Participant Initials	Participant DOB
			d d m m y y y y



Closing Summary (to be completed at all sessions)

Session no:

213

Appendix 7b: MI telephone session CRF

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PID	Region ID	Participant Initials	Participant DOB
			d d m m y y y y









South East Wales Trials Unit
Uned Ymchwil De-ddwyrain Cymru

Weight Loss Maintenance in Adults (WILMA)
Telephone MI sessions: Case Report Form (CRF)

Notes on completion: A Case Record Form should be completed for all participants after each telephone MI session. Once completed, please return to the WILMA study team.

Participant ID number: | | | | |

Session number: | |

A. Review (not to be completed following telephone session 1):
Please write briefly below progress made in any of these areas (if covered):

Goal Setting

Implementation Intentions

Self Monitoring

Exercise

PID	Region ID	Participant Initials	Participant DOB
			d d m m y y y y

Diet

Other (please specify)……

B. Plans (to be completed after all telephone sessions):

Please write briefly below any plans agreed in these areas (if discussed)

Goal Setting

Implementation Intentions

Self Monitoring

Exercise

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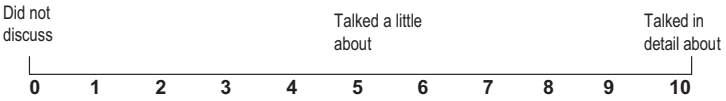
PID	Region ID	Participant Initials	Participant DOB
			d d m m y y y y

Diet

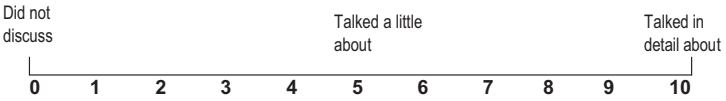
Other (please specify)……

C. Topics covered during the telephone session (to be completed after <u>all</u> calls)

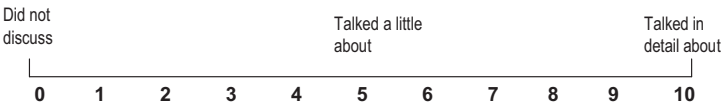
Goal Setting



Implementation Intentions



Self Monitoring



Exercise



Diet



Other



If other, please specify: ……

PID	Region ID	Participant Initials	Participant DOB
			d d m m y y y y

D. Other relevant information (such as barriers to exercise, e.g. injury)

E. Final summary of telephone MI (to be completed after last telephone call only)

How successful do you feel the telephone MI sessions have been?

Challenges and barriers:

What worked well?

F. Closing summary of each session (to be completed at the end of all sessions)

This is to be completed in the last five minutes of the interview. This is a written version of the 'Long Summary'. This is an agreed record of what was discussed: it is a collaborative process and is MI adherent. e.g….."In the last month/6 months (delete as appropriate) you have achieved X and Y and these are the new goals you have set yourself today …….. A copy of this should be returned to the research team who will post to the client.

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PID	Region ID	Participant Initials	Participant DOB
			d d m m y y y y









Closing Summary (to be completed following all telephone sessions)

Session no: ☐

Appendix 8 Unit costs

1. Training (*)

Individual trainers and trainees	Source	Unit cost
Adminstrator	a. (p.244)	14.37
Career Consultant, Careers & Employability	b. Assumed Grade 5	18.53
Community Heart Nurse	a. (p.178)	25.90
Consultant Clinical Psychologist, (top of NHS band 8c)	a. (p.244)	50.16
Counsellor in Private Practice	f. (£25k)	19.84
Counsellor in Private Practice	a. (p.194)	26.85
Counsellor in Private Practice/Senior Lecturer	d. (£45k)	35.71
Counsellor, Drug & Alcohol team	f. (£25k)	19.84
Data Manager (G5),	b. Grade 5	18.53
Deputy Director, Careers & Employability	b. Assumed Grade 5	18.53
Dietitian	a. (p.216)	17.48
Drug & Alcohol Practitioner (p/t; NHS band 6)	a. (p.244)	25.00
Executive Officer	b. Assumed Grade 5	18.53
Family Therapist, Alcohol & Drugs team	f. (£25k)	19.84
Group Worker, Drugs Project	d. (£25K)	19.84
Health Specialist, PCT (Public Health) & freelance MI trainer	a. (p.178)	25.86
Health Visitor	a. (p.177)	25.83
Mental Health Coordinator, Swansea Uni	a. (p.177)	25.83
Mental Health Mentor, & Operations Manager	a. Costed as per NHS therapists (e.g. pp.168-169)	18.02
Outreach Team Manager, NHS	d. Band 7 (£39k)	30.96
PhD student	e. (£14k)	11.11
Practitioner, Drugs Project	f. (£25k)	19.84

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Professor (non-clinical)	f. (£67k)	53.17
Reader	c. Band I	36.21
Research Assistant	b. Grade 5	18.53
Research Assistant	d. (£29k, 0.8 wte)	18.41
Research Associate	b. Grade 6	23.44
Research Fellow	b. Grade 7	26.39
Research Officer & Sessional Counsellor	d. NHS Band 6 (£25k)	19.84
School Councillor & Trainer	a. Costed as per NHS therapists (e.g. pp.168-169)	18.02
Senior Practitioner, Drugs Project	f. (£29K)	23.02
Senior Research Fellow	b. Grade 7/8	32.41
Specialist Cardiac Rehab Health Visitor	a. (p.177)	25.83
Specialist Health Psychologist	a. (p.171)	36.58
Staff/Student Counsellor	a. Costed as per NHS therapists (e.g. pp.168-169)	18.02
Support Worker	a. (p.190)	25.29
Trial Manager	b. Grade 6	23.44
Volunteer Manager, Drugs Project	f. (£14k)	11.11
a. Curtis, L (2012) *Unit Costs of Health & Social Care*, PSSRU, Kent. Hourly rates calculated using Salary and Salary On-costs only.		
b. Cardiff University (2012) Payscales - Single Spine Points 1 - 51 (1% August 2012). Salary On-costs assumed at 25%.		
c. University of South Wales (2013) Pay Scales and Structure (wef 01 08 12), see website: http://hr.southwales.ac.uk/documents/download/154/. Salary Oncosts assumed at 25%.		
d. Salary provided by attendee. Hourly rate is based on 42weeks/year, 37.5 hours/week and Salary On-costs assumed at 25%		
e. Assumed stipend for PhD studentship £14k p.a. Hourly rate is based on 42weeks/year, 37.5hours/week and Salary On-costs assumed at 25%		
f. Assumed salary based on other attendees in same role and/or organisation. Hourly rate is based on		

42weeks/year, 37.5hours/week and Salary On-costs assumed at 25%

(*) Repetition due to level of detail provided on individuals participating in the study.

2. NHS Resource Use

Surgery	Details	Unit Cost £[a]
General Practitioner	11.7mins (inc. direct staff costs and qualifications)	43.00
Practice Nurse	15.5mins @ £53/hour	13.69
Diabetic Nurse	Costed as Clinical Nurse Specialist @ £25 per consultation	25.00
Physiotherapist	Assumed 30min appointment @ £34/hour	17.00
Dietitian	Assumed 30min appointment @ £34/hour	17.00
Mental Health Nurse	Assumed 15.5mins as per Practice Nurse @ £76/hour	19.63
Midwife	Costed as Band 6 Community Nurse - Assumed 30min appointment at surgery @ £58/hour	29.00
Health Visitor	Assumed 15.5mins as per Practice Nurse @ £59/hour	15.24
Counsellor	Costed as per other community therapists (e.g. p168,169) and assumed 30min appointment at surgery @ £33/hour	16.50
Home	**Details**	**Unit Cost £[a]**
General Practitioner	23.4mins (inc. travel, direct staff costs and qualifications)	110.00
Community Specialist Nurse	Assumed same duration as GP Home Visit (23.4mins inc travel@ £49/hour)	19.11
Midwife	Costed as Band 6 Community Nurse - Assumed 30min appointment @ £70/hour (inc travel)	35.00
HOSPITAL	**Details**	**Unit Cost £**
A&E visit	Treatment leading to not admitted	112.00[a]
In-patient stay per bed day	WA21Z (General medicine) National average elective inpatient stay (£564)/Average length of stay 2.58days	218.60[b]

a. Curtis, L (2012) Unit Costs of Health & Social Care, Personal Social Services Research Unit (PSSRU), University of Kent, Canterbury

b. National Schedule of Reference Costs 2012-13 for NHS trusts and NHS foundation trusts.

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Appendix 9 Summary of protocol changes

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).

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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 either telephone, text, email or letter,

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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

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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

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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.

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