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Trials Unit
Uned Ymchwil
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THE WILMA GROUP FACILITATORS HANDBOOK

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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

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."

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."

"[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!'"

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 year⁵.

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 weight⁸. 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 activity⁹.

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

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

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

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."

"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.

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.

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 taking¹⁴. 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.

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

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.

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	<p>Participants can bring a 'buddy' to this section of session only.</p> <p>You will introduce the aims of the session and give participants an opportunity to raise additional issues.</p>
Group task 1	<p>25 minutes</p> <p>15 minutes</p>	<p>Participants will read the information sheets provided on <u>either</u> 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 <u>one</u> of these issues in small groups.</p> <p>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.</p>
Group task 2	<p>10 minutes</p> <p>10 minutes</p>	<p>Participants will complete a questionnaire looking at emotional aspects of eating (see Appendix 5c).</p> <p>Participants will score their own questionnaire (high/low on each of three factors detailed below) and discuss in their groups.</p>
Summing Up and Q&A	15 minutes	<p>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).</p> <p>You will give participants the feedback sheets to complete & return directly to the research team.</p>

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.

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 years¹⁸ 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

eat^{19,20}. Those who have difficulty expressing emotions may also have a tendency to binge in response to negative feelings²¹.

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 relapse²³.

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 stage²⁴. 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 identified 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:

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	Participants will be asked if they can rearrange the activity cards into light, moderate and strenuous physical activity (see appendix 6a).
	5 minutes	Answers given.
Group task 2	10 minutes	A short quiz (see Appendix 6b).
	5 minutes	Answers given.
Group task 3	15 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.
	5 minutes	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 time 10 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 day⁸, other work also supports this⁹. Physical activity helps by influencing energy balance and may help by increasing metabolic rate and increasing muscle mass which burns off more calories.

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 States⁹ 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.

- 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'."

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.

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 as 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

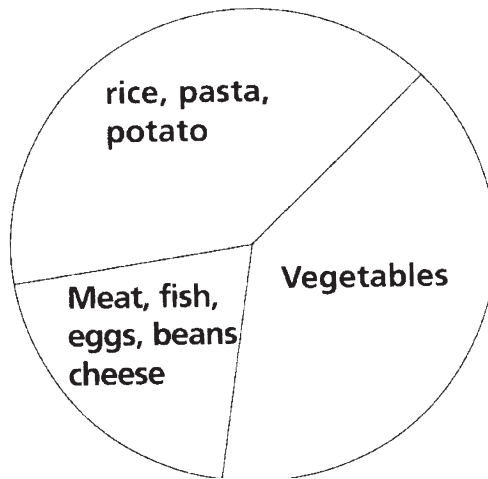
- Fruit and vegetables
- Beans and lentils
- Wholegrain bread
- Brown rice
- Oats
- Seeds

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

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	<p>Participants can bring a 'buddy' to this section of session only.</p> <p>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.</p>
Group Task	45 mins	<p>You will split the participants into small group to discuss how useful they found the different tasks and activities (Appendix 8a).</p>
Feedback to group	15 mins	<p>Each group will nominate someone to feedback a brief summary of their discussions.</p>
Summing Up and Q&A	5 mins	<p>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.</p> <p>You will give participants the feedback sheets to complete & return directly to the research team.</p>

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

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

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:
Ms Naomi Southern	WILMA Trial Administrator	southern@cardiff.ac.uk	029 20687625
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.

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.

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.

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 your 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?

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.

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: Appendices²

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)

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