THE WILMA MI PRACTITIONERS HANDBOOK

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Part 1: 'Setting the Scene'

1.1 Who are the clients?

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

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

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

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

1.1.1 Weight patterns

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

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

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

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

1.1.2 Self perceptions and body image

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

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

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

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

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

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

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

1.2 What are the client's strengths and challenges?

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

1.2.1 Maintenance and weight gain

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1.3.1 The public and the personal

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

1.3.2 Similarities with other areas of practice?

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

1.3.3 Particular challenges

- **Abstinence** is not an option; decisions about what and when to eat have to be made over and over again, each presenting a choice point and possible challenge.

- **No hiding place**: Eating is one of the most public behaviours – often our consumption is in the presence of others creating times for support or shame, success or failure for the individual and one which others feel they can comment on. Whilst some of our weight management behaviours may be kept private, the result, in our appearance, is there for all to see and one on which we feel judged and clients will often have a profound sense of shame.

- **Roller-coaster of emotions**: Working with clients around weight management will include emotional and behavioural issues, the roller-coaster ride, their experiences of success and failure past and present, and the emotional ups and downs in response to the ups and downs of their weight. Now that they have lost weight they may well also be experiencing fear of weight regain as they move from losing weight to maintaining.

- **Confidence:** Some of our clients will have had a steady weight gain over time but there will be a significant number who have a long history of weight issues, some dating back to childhood and certainly adolescence in many cases, so it will have a direct relationship with their self-concept and self-esteem. Appearance and confidence around weight will have played a significant part in their relationships with their partner and their social relationships. For many clients the issues around weight will be tied up with their relationships with their parents, as there is a significant link between parental and off-spring overweight.

1.3.4 The approach in WILMA

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

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

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

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

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

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

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

One of the key differences between losing weight and maintaining weight loss is that losing weight requires a negative energy balance, whereas weight maintenance requires continued energy balance. This balance needs to be sustained by behaviours which can be continued over the longer term. It is helping clients find these longer term behavior changes that is one of the biggest challenges we face.

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

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

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

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

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

- low calorie and low fat foods,

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

These are described in more detail in Part 3.

Part 2: Intervention I: Motivational Interviewing

2.1 MI and Weight Loss Maintenance

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

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

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

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

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

2.2 MI: a new conceptual framework

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

ENGAGE

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

GUIDE

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

EVOKE

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

PLAN

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

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

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

1. ENGAGE

i) How comfortable is this person about talking to me?

ii) How helpful am I being?

iii) Do I understand her concerns?

iv) How am I feeling?

v) Is our service helpful?

2. GUIDE

i) Have we clarified a focus for our conversation?

ii) What kind of change does this person really want?

iii) Are my aspirations for change different from his?

iv) How strongly do I feel about changes she might make?

v) Are we working together with a common purpose?

3. EVOKE

i) What makes this change worthwhile?

ii) Am I steering her too far or too fast in a particular direction?

iii) Am I listening out for change talk?

iv) What's really motivating this person?

4. PLAN

i) What will help him to move forward?

ii) Am I resisting the righting reflex?

iii) Am I providing new ideas while promoting autonomy?

iv) Can we get as far as actually making a concrete plan of action?

2.3 MI Styles and Techniques

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

2.3.1 Spirit & style

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

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

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

2.3.2 Goal

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

2.3.3 Skills

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

2.3.4 Useful questions and strategies

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

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

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

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

AIM

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

PRINCIPLES

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

PRACTICE

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

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

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

2. Agenda Setting (What to change?)

This is really useful early on, to help you focus on a change that makes sense to you both. It's the principle task that is an expression of the guiding process. Practice this and you'll find that engagement is enhanced and your conversations will have a much more focused feel to them.

Clients often face more than one option for change. In *agenda-setting*, rather than impose your priority upon clients, you conduct an overview by inviting them to select an issue or behaviour that they are most ready and able to tackle, feeling free also to express your own views. For example, to reach agreement about what to deal with in the consultation you might say: "That's very helpful. Are you more ready to focus on eating or on increased activity? Or is there some other topic that you would prefer to talk about? I'd like to talk about regular weighing at some point, but what makes sense to you right now?

3. Pros and Cons (Why change?)

It is both normal and common for clients to feel ambivalent about both the *status quo* and change. It can be helpful to invite them to say how they see the *pros* and *cons* of a situation. Your next step is to ask them to clarify whether change is a possibility.

Box 1: Exploring the pros and cons

"I want to try to understand exercising better from your perspective, both the benefits for you and the drawbacks. Can I ask you firstly what you like about exercising?" (*Client responds. Use your curiosity to elicit a good understanding.)*

"Now can I ask you what you don't like about your exercising?" (*Client responds. Remember it's their experience that counts, so avoid offering your perspective for the time being.)*

(Then you summarise both sides, as briefly as possible, capturing the words and phrases that the client came up with.) "OK, so let's see if I have this right? You like the fact that exercise helps you unwind and, helps you

manage your stress levels. On the other hand, your main concern about it is that you find it difficult to fit it in with you busy life and family. Is that about right? OK."

(*Then you invite the client to consider the next step.)* "So where does that leave you now?" (*Client usually describes readiness and any need for advice or information.)*

4. Assess Importance (why) and Confidence (how)

To be efficient you need to spend time where it is most needed. Those who are not convinced of the importance of change are unlikely to benefit from advice about *how* to change. Conversely, a focus on the *why* of change is pointless if the main issue is how to achieve it. This strategy has produced successful outcomes in the smoking field[18], where a recent review also provides support for the efficacy of motivational interviewing[19].

Box 2: Assessing importance and confidence

"Would you mind if we took a moment to see exactly how you feel about weight maintenance?" (*An invitation promotes collaboration and client autonomy.)*

"How important is maintaining your weight for you right now?" (*Elicit a brief review of client's feelings, fears, and aspirations, then ask:)* "How confident do you feel about being able to maintain your weight?" (*Elicit, and then summarise client's view of importance and confidence.)*

(Then tailor your next step accordingly—for example, if importance is low, consider something like:) "Well, do you mind if I just give you some information about some tools that might help you with your weight maintenance, but it will be up to you to decide in the end." (*Emphasising autonomy always helps.)*

5. Exchange information

One of the first successful studies of motivational interviewing placed listening at the centre whilst feeding back test results. This gave rise to the "Elicit-Provide-Elicit" strategy, in which a guiding style is used to encourage clients to clarify the personal implications of information that you provide.

Box 3: Information exchange
"OK so can I check your understanding of the situation? What do you know about how to maintain your weight loss?" (*Elicit understanding.*) . . . "Well you are right about it being very common that people find it difficult to maintain the weight loss in the longer term. The key is balancing the amount of exercise you do and the amount that you eat. As well as trying to eat healthily, another key factor is monitoring your weight on a weekly basis. This has been shown to be very effective." (*Provide information.*) "OK, now can I ask, how do you think this information applies to you?" (*Elicit client's interpretation*).

6. Make decisions about change (setting goals)

This is the fourth process in the new framework for MI: PLANNING. Goals and targets for change that come only from your side are often met with "Yes, but…" explanations about why they will not work from the client. However, if the client is ready, a guiding style can be used to elicit practical solutions from the client while offering suggestions from your side as well.

Box 4: Making decisions
"It sounds like you really want to try to maintain your weight loss, but you're struggling with imagining how you can do it because it's been difficult in the past." (*Summarising the client's situation.*)

"It will be up to you to decide when and how to do it (*emphasising the client's freedom of choice*) but I am wondering how do you see yourself succeeding with this?" (*Inviting the client to envision change. Client responds, usually identifying main challenges… remember to listen out for change talk!.*)

"So you are hoping you can find a way to try to avoid slipping back into your old eating habits." (*Listening, in response to what client has said.*) "There are lots of things that others have found useful, but what makes sense to you?" (*Inviting client to clarify what will be helpful.*) "OK so you will try and get your husband to join the gym with you and that way you will find it easier to stick with your plan." (*Client clarifies what will be helpful, and the discussion narrows down in favour of a plan that is agreed jointly.)*

The success of the WILMA study will probably depend on your ability to talk quite concretely about this or that change, and to keep to an MI style as you do this. This is breaking new ground in the MI field, talking about goals, self-monitoring diaries, even implementation intentions, all embraced by the spirit of MI! Our team looks forward to hearing about your challenges and successes in this new application of MI, using a new framework.

2.4 Change Talk and Weight Maintenance

This sounds like quite a mouthful – change talk and weight maintenance - but its really quite simple! Change talk occurs when the client uses language in favour of positive change. An MI practitioner listens out for this change talk, and when its heard, she tells herself: "Now I must slow down, free my mind of clutter, and reflect, reflect, reflect"! Why, because it is this expression of change talk that frees the client to consider change, and it actually predicts subsequent change.

You will hear lots of change talk about weight maintenance. Notice that it can vary in strength, and cover things like ability, desire, reasons and need. The closer it is to strong commitment then the closer you and the client are to specific goals and success. Here are some examples of reflection in response to change talk about weight maintenance. Notice how the reflection elicits more change talk – that's the heart of MI!

EXAMPLE 1

Client:	*I need to maybe accept that this is my normal weight and then keep it that way.*
You:	There's a balance that might suit you.
Client:	*It will be a relief to not keep yo-yoing up and down* (more change talk)
You:	(reflect again!)

EXAMPLE 2

Client:	*I want to just get a little more exercise and then it will be more balanced.*
You:	You can see a balanced pattern with just a little more exercise.

Client: *Yes, I could do that* (more change talk)

You: (reflect again!)

EXAMPLE 3

Client: *I see, so I don't have to diet all the time.*

You: There might be another way for you.

Client: *Well maybe I could do this……* (more change talk)

You: (reflect again!)

Notice how the reflections in the above three examples are not clever or complex. They usually don't need to be. Your task is not to leap too soon to the obvious question about action (e.g. how might you do that?). If you gently reflect change talk, the client will often lead you to action talk.

Patience is very important here. A robust practitioner will accept that the conversation can often go round and round in circles. This does not mean that you are not making progress. Remain curious, and also feel free to be honest about your impression of the conversation. If there is a way forward out of seemingly contradictory conflict, the client will often help you find it.

2.5 What might a session look like?

The section on "hot topics" that follows below goes into some quite specific weight loss maintenance topics. However, before reading this, consider the following when thinking about MI in this setting.

Consider starting a session like this:

1. In an agenda-setting "state of mind", share an overview of topics you could talk about, agree where to begin, and review this agenda at any point.

2. Secondly, use elicit-provide elicit to exchange information about the difference between weight loss and maintenance.

3. Third, use MI skills to focus in on change talk about maintenance.

That's one very simple way of contextualising the process. In time you will develop your own structure that makes sense to you.

2.6 Delivering MI in Two Sessions

This topic will be discussed and developed during the training day and summaries of key suggestions will be sent by the WILMA team and can be added here. However, in brief, this will require the MI to be a little more structured and practitioners should address these key questions to the client:

a) how are you getting on with your efforts to control your weight? (typical day can be useful).

b) weight loss and maintenance: where are you and where would you like to go?

c) getting there – some achievable goals and targets.

2.7 Delivering MI over the Telephone

Again this topic will be discussed and developed during the training day and summaries of key suggestions will be sent by the WILMA team and can be added here.

2.8 Useful Questions

The questions listed below are ones we have found helpful with this client group.

- It would be really helpful for me to speak with you about your journey so far, in terms of weight loss and where you've got to and how it's gone really for you, so can you kind of give me a bit of pen-sketch on that?
- And as you look around you and think about other people and their journey, would you say that you were that different to other people?
- So what do you think you've learnt from those previous times and from this journey now, what have you learnt that's going to be useful information for you?
- What would you say if you're thinking about those kind of overriding goals, what for you represent the overriding goals for the weight-loss or weight-maintenance now? What, you know, what keeps it in mind?

- So thinking about the next six months or whatever, what do you see as being the kind of things that are going to happen for you and how are you going to approach it?
- And again, looking back when things haven't gone quite how you would've wanted them to, how did habits get undone?
- So thinking about weight maintenance, how do you think, taking for example stress, how do you see that kind of being managed differently?
- And if I were, kind of, to be chatting with your friends and saying what difference, have you seen a difference in her, what would they tell me?
- So of all the differences that it's brought you in your life in terms of, you know, you go to the gym now, your diet is different, you know, you feel different, you look different, which would you say are the things that make weight maintenance the most likely, what are the main things that will keep you on track do you think?

The questions below are some additional questions you may find useful from Steve's book.

- What strategies were useful to you, what helped?
- What changes would you most like to talk about?
- What have you noticed about . . .?
- How important is it for you to change . . .?
- How confident do you feel about changing . . .?
- How do you see the benefits of . . .?
- How do you see the drawback of . . .?
- What will make the most sense to you?
- How might things be different if you . . .?
- In what way . . .?
- Where does this leave you now?

Part 3: Intervention II: Hot Topics

There are a number of aspects which according to the research evidence may be important in weight loss maintenance. These are described in more detail below. In addition to these important topics there are other elements which we feel are important to the success of the intervention, these are boosting intrinsic motivation and feedback and reinforcement. Intrinsic motivation is defined as greater self motivation to carry out the activities needed for weight maintenance. We want to help individuals to identify their own reasons for maintaining weight linked to their own personal values and goals in life.

We also aim to give reinforcing feedback, such as praise and encouragement, to actions that move the individual towards activities that help them maintain their weight. Feedback and encouragement is also important to help client's build confidence in their skills and thereby bolster self efficacy.

Finally, we feel that the key is in the flexibility of approach in discussing these topics. We don't expect that you will necessarily cover all topics although **self monitoring**, **diet** and **exercise** are key.

3.1 Psychological or Behavioural Control Topics

3.1.1 Self Monitoring

What is it?

Self monitoring is perhaps the single most effective method to enhance weight loss maintenance. We want individuals to monitor and record their weekly weight. Participant-held diaries and/or the website will help individuals to monitor their weight weekly. Diet (ate low fat/low sugar/high fibre choices; ate regular meals/breakfast; ate your 5 a day) and exercise behaviours (30/60 minutes per day moderate exercise; less time in sedentary behaviours) can also be recorded in the participant-held diaries (Appendix 5).

Why does it help (the evidence)?

Data from 5000 people on the National Weight Control Register suggests that when trying to maintain weight loss self monitoring is very important[8]. Self monitoring is also recommended in the UK by the National Institute of Clinical Excellence (NICE)[20]. Self monitoring consists of regular self weighing and monitoring of diet and physical activity.

In a systematic review of interventions designed to promote physical activity and healthy eating, self monitoring of behaviour was associated with improved effectiveness

and combining self monitoring with one of 4 other self regulation techniques (prompt intention formation, prompt specific goal setting, provide feedback on performance and prompt review of behavioural goals) was even more effective. These techniques come from Control Theory[21].

Theories attempting to explain health behaviour change (Self-Determination Theory [22], Self Regulation Theory [23,24], Social Cognitive Theory[11]) suggest that self-monitoring is key to self-regulation, a process by which individuals measure their success in maintaining weight loss by regular self-monitoring of weight. The initial goals and behaviours which led to the weight loss and subsequent maintenance will be reinforced if the outcome of this evaluation is positive, and re-evaluated if not. The process of monitoring will therefore be repeated and become habitual. This can also boost self efficacy.

How can you help?

Encourage participants to monitor their weight weekly, and record this in their diary or submit online (weekly) or by text and inform participants or remind them as appropriate that monitoring diet and exercise behaviours (e.g. in their diary) is likely to facilitate maintenance. Explore with clients which activities are best for them to monitor (apart from weight). See Section 4.5 and Appendix 5 for information on the client diaries.

The clients we interviewed suggested that you need an objective measure of whether you are putting on weight or not. How you look in the mirror is too subjective. Also they felt you can deceive yourself about your weight unless you have objective evidence. They also suggested that self regulation could be used productively to set limits within which weight can fluctuate.

> *"I think it's the weigh-in, I know that some people hate being weighed… but once a week so you can actually see the numbers and you can see the difference, or you can see that you haven't put on weight… it's something that clicks in your head and you can see, [having] something physical that you can see, because actually if you're going on what you look like quite often what you perceive yourself to look like is actually not what you look like."*

> *"… I do think it really helps, writing down everything that you eat, and maybe initially once you've lost weight that's really helpful… it's that extra bit of control, you feel even more in control because you're writing down everything that you eat. I suppose because I know I can correlate me having refined sugars with me having mood swings and feeling really low in energy it's helpful in that way if you can write down not only your food but your moods as well, because you can find a correlation between that."*

"I would think with weight maintenance and I do weigh fairly regularly, and I would say that if I notice that a pound or two is creeping on… it is that prompt quickly to say 'Hang on, you've put on a couple of pounds' and bring it back now, whereas I think if I maybe weighed once a week or once every two weeks and then found I'd put on four pounds that could be the bit that made me think 'Hm, how am I ever going to pull that back?'"

"For some people weighing too often can be demotivating and pushes them into a negative spiral, however, I think… for me it's a motivational aid."

3.1.2 Goal Setting and 'Implementation Intentions'

What are these?

Goal setting is important in helping us to form a plan for change or maintenance of behaviours. Goals can be general or specific, they can be for today, next week or next month. Goals could be e.g. lose weight, eat less fatty food, go to the gym. Goal intentions specify **what** you will do.

Implementation intentions are basically "If-Then" statements, these are important for translating your intention to change your behavior or to do a specific behavior, into action, i.e. actually doing the behavior, like going to the gym.

These 'implementation intentions' have been shown to be very effective in relation to a number of problems that prevent people from changing their behavior. These include;

- 'failure to get started' (failing to act, missing opportunities, initial reluctance to change)
- 'getting derailed' (distractions, temptations, habits, cravings, emotional distress) where unwanted influences get prioritised over pursuit of the ongoing goal.

Implementation intentions specify **when, where and what** one intends to do (e.g. 'every day this week after work I shall run around the lake').

When	Every day this week after work
Where	The park
What	Run round the lake for 30 minutes

Why does it help (the evidence)?

Goal setting is an important process in behavior change and maintenance as it facilitates planning towards that goal and it facilitates change and allows the client to monitor their behavior in relation to achieving the goal. If the goal is not being achieved it allows the process of problem solving to kick in to facilitate achievement of the goal. Problem solving is a way of dealing with perceived barriers to carrying out weight maintenance behaviours and requires the participants to identify their own solutions to possible barriers, that fit into their individual lifestyles.

A considerable body of research has shown that the link between a person's intention to change their behavior and actually changing it is not strong. Research has shown that formation of implementation intentions doubles the chances of completing the behavior [12,13,14]. Importantly implementation intentions increase the chance of the behavior being automatic or habitual as the situation then triggers the behavior.

They are also important in planning for slip-ups, e.g., "I ate a bit of cake so the diet's out the window, I might as well eat the whole lot". Instead think "If I slip up on my diet then I will not worry too much, but will continue with my healthy eating and exercise plan." Implementation intentions can also be used in ways to reward oneself and reinforce the behavior, e.g., "If I go to the gym this week then I can go out for dinner".

Implementation intentions also help individuals establish new habits, as they help specify a plan of when, where and how a person is going to, for example, start exercising. This results in the behaviour being elicited automatically by the relevant environmental cue rather than by a more effortful decision-making process, e.g., you see the gym bag in your car and call in at the gym en route home. As behaviours are repeated they become increasingly automatic or habitual and hence more resistant to change.

How can you help?

Encourage clients to:

- Set attainable and reasonable goals.
- Make goals meaningful – how do they fit with a client's overall goals, values etc. For example, if spending time with their family is important and one of their values - then you might want to encourage them to choose exercise which can be done with the family (e.g. swimming) rather than going alone to the gym.
- Listen out for 'implementation' change talk – encourage this.
- Encourage development of implementation intentions "If …. Then….". Note that these can be in relation to smaller or larger goals.

A few observations from our volunteer clients:

> *"Um… it's funny because it's great having a goal but when you reach that goal what's your motivation beyond that? So, while my goal was to get down to normal weight so it was easier to conceive… the fact that it didn't come to that [means] now I don't really have a goal, it's just kind of to maintain and stay healthy almost."*

> *"As long as I've got the right motivations which is things like having my gym bag in the car so I don't go home first and then think 'Ohh perhaps I just can't be bothered, perhaps I'm tired'… I sort of plan my week that I see what I'm doing every day and when it's feasible that I can go to the gym, so I probably go at least once over the weekend and then I would go once in the week."*

3.1.3 Habits

What is it?

Habits are automatic responses to specific cues. They are learned sequences of acts. Habit formation is crucial both to behavior change but also to maintenance. If we are to enable people to maintain weight loss in the longer term making healthy behaviors habitual is critical.

Why does it help (the evidence)?

This is important because often the behaviors required to maintain weight loss are difficult to achieve, e.g. large amounts of daily physical activity, healthy eating in the face of many temptations in our 'obesogenic environment'. Developing habits whereby behaviours are cued by the environment and are more automatic makes behavior change easier and more likely to last as it leads to strong neural connections/pathways and does not require one to think about it too much - as behaviours are automatic.

Habits are functional in obtaining certain goals or end states.

How can you help?

In order to make behaviors habitual there are a few things to encourage clients to try. In the main we need to focus on the 3 key aspects of habit – frequency of occurrence, automaticity of the behavior and functionality. Implementation intentions may help with habit formation as implementation plans regulate the *frequency* of behaviours, the control over the behavior is at least partly transferred from the person to the situation (*automaticity*) where the behavior should take place. Cues and responses should be selected that are *functional*, e.g., running should be scheduled so it doesn't interfere

with other activities, and the running itself may give rewards like time to think and fresh air. Key points are that:

- Often just repeating the behavior over and over makes it become habitual.
- Implementation intentions can help in the development of new habits
- Cues in the environment also help - so as above implementation intentions specify a plan of when, where and how a person is going to, for example, start exercising. This results in the behaviour being elicited automatically by the relevant environmental cue (e.g. sight of your gym bag) rather than by a more effortful decision-making process. As behaviours are repeated they become increasingly automatic or habitual and hence more resistant to change.

The volunteer clients emphasised the importance of developing good habits and that these got easier as time went on as well as the negative impact of bad habits:

> *"Yeah, and it probably got easier as the journey went on and the fact that you then got used to set foods and menus that you knew you were okay, so… you probably had to think about it more in the beginning."*

> *"I think to be honest I probably won't really introduce it (alcohol), I think I'd got into a habit of a glass of wine in the night, you know, come in, you sort out the kids and you sit down with a glass of wine, and I think it just became a habit."*

3.1.4 Emotional Eating (binge eating), Self Esteem and Coping with Relapse

What are they?

Psychological factors are likely to be key to both weight loss and maintenance, and barriers to maintenance may include eating in response to particular emotions or events. Obesity and previous 'failures' to maintain weight loss may also influence perceptions of self-esteem and self-efficacy and therefore maintenance. Coping behaviours in response to challenges or short-term relapse may also predict long-term maintenance. Emotional eating, self-esteem and coping with relapse will form the content of one of the peer group sessions.

What is the evidence?

There is conflicting evidence about whether particular emotional states (e.g. anxiety, sadness, loneliness, tiredness, anger and happiness) actually increase unhealthy eating behaviours, but there is generally agreement that individuals perceive these emotions to

affect their eating habits, particularly amongst overweight/obese individuals who "binge eat"[25,26]. Those who have difficulty expressing emotions may also have a tendency to binge in response to negative feelings[27].

There is some evidence to suggest that low self-esteem in childhood may be associated with obesity in adulthood[28] and that high self-esteem may be associated with better weight management outcomes in adults[29]. Long-term weight loss maintenance is thought to be associated with problem-focused coping strategies, whereas relapse is associated with more emotion-focused styles and avoidance[10,30]. Encouraging clients to plan how they might cope with lapses in advance may also be effective in preventing relapse[31].

How can you help?

Help clients to identify any emotional triggers for eating and discuss problem rather than emotion-focused approaches to coping with temporary relapse. Instead of responding in an 'emotional' way to relapse, e.g., 'I've eaten too much chocolate because I'm stressed. I'm a failure / I'll never be able to succeed at weight loss maintenance', try and encourage participants to 'problem-solve' instead, e.g., I've eaten too much chocolate because I'm stressed, but it isn't the end of the world. Tomorrow I'm going to make an extra visit to the gym and next time I feel stressed I'll try to do some more exercise instead'.

Encourage clients to discuss how they might manage cravings, and ask them to generate a list of problem-focused/direct coping strategies for 'high risk' situations. Support clients to think of practical ways of avoiding any identified triggers for relapse, e.g. if they know they have a tendency to snack on biscuits when stressed, what would help them overcome this? Maybe they should not buy biscuits or they should try to identify something else that works for them instead, e.g. long bath, going for a walk.

You should also encourage clients to attend the relevant group session, which might be useful for sharing tips on how to overcome emotional triggers and cope with relapse.

The volunteer clients identified that being aware of what the triggers are to over-eating is important as well as the relationship between emotions and eating patterns.

Emotional triggers:

> *"I know what to do and I understand why I eat more than I should do sometimes, if I'm upset and I'm very aware of myself and my body."*

"…so there's that kind of dread, and then if you've got no-one there to support you it's really difficult not to kind of feel that emotion and that kind of worry and not turn to comfort eating."

"… then I'm going to be embarrassed and then I'm going to feel bad about myself, and then I'm just going to want to eat more KitKats."

"I was stressed in work, I came home thinking 'Oh, I'll have a glass of wine' and just sit down and veg out in front of the telly."

On relapsing:

"If it gets to (putting on) the half stone then I start thinking 'Oh! How am I ever going to do this?' because it takes so long to lose that."

"I know when I have put on a couple of pounds more, if my trousers do feel tight I do actually feel quite negative about it and I kind of start [to] panic again."

3.2 Other Topics

3.2.1 Diet

What is it?

Diet is a key factor in the maintenance of weight loss. It is one of two elements (along with exercise) contributing to 'energy balance'. This concept is crucial to understanding how to maintain weight loss (and indeed lose weight). Losing weight requires a negative energy balance whereas weight maintenance requires continued energy balance. This balance needs to be sustained by behaviours which can be continued over the longer term.

Why does it help (the evidence)?

In simple terms the amount eaten in terms of caloric and fat intake must balance out with amount of energy expended through physical activity. Evidence from RCTs and reviews suggest that eating low calorie and low fat foods is important in maintenance. Data from the National Weight Control Registry of 5000 people who have lost weight in the US indicate that low fat and low calorie diet and eating breakfast are associated with weight loss maintenance[8].

How can you help?

The list below indicates some evidence based guidance that can be discussed with clients.

- Decrease fat and sugar intake.
- Look at food labeling for fat and sugar content.
- Increase fruit and vegetable intake, eat at least 5 a day.
- Increase fibre intake (eg eat more such as oats, beans, peas, lentils, grains, seeds, fruit and vegetables, as well as wholegrain bread, and brown rice and pasta).
- Have smaller portions.
- Eat breakfast.
- Drink plenty of water before a meal.
- Eat 3 regular meals.
- Don't starve yourself as it increases the chance of bingeing on unhealthy foods.
- Don't eat in front of the TV or computer - pay attention to what you are eating.
- Don't use food to deal with stress or feeling blue – go and do something else.
- Drink low sugar, low fat drinks .
- Eat low fat dairy foods.
- Reduce alcohol consumption.
- If you slip up don't think "oh well that's it" and then binge, just take it in your stride and then carry on as per your healthy eating plan.
- Remind yourself of where you have come from (photo of old you).
- Have realistic weight goals - get to a healthy weight and maintain it - 10% is usually achievable.

A few more observations from our volunteer clients:

> *"I do need to be quite careful of portion control because I don't seem to get full up, ever, … control is the thing I'm working on at the moment."*

> *"That glass of wine represents quite a few Syns so actually you're better just not doing it or doing it very occasionally."*

"The whole family do it now so it's probably eat lots of vegetables and lots of fruits so if I go round the supermarkets, lots of vegetables and fruits… meat, fish and pasta."

3.2.2 Social Support

What is it?

Social support from family and friends, and peer support which will be encouraged through the locally provided peer group sessions. MI counsellors will also be a valuable source of professional support for clients.

Why does it help (the evidence)?

Reviews suggest that social support is a key factor in successful weight loss maintenance, and that a lack of support may impede maintenance[30,32]. There is evidence to suggest that social support can increase the proportion of people who complete treatment and maintain all weight lost at 10 month follow-up by around 25%[33] and that continued professional support improves maintenance. Social support may offer benefits like reinforcement, encouragement, motivation, empathy, role modelling, increased self efficacy and confidence. Social support is therefore thought to improve maintenance[10].

How can you help?

In addition to providing professional support to clients, it may be useful to discuss sources of social support that clients can draw on, and explore ways to maximise these (e.g. exercising with a family member or friend). Encouraging clients to attend group sessions and access the peer support they provide is also likely to improve maintenance.

The importance of both peer and professional support was noted by the volunteer clients.

Peer support:

"This support group was amazing with Lighter Life and you saw the same women every single week and I did it for two hundred days and I kept in contact with them all…. I just need to have other people who's doing it the same time which was why I joined Slimming World."

"…there being other people there saying exactly the same things as you, saying I had a row with someone and drank a bottle of wine, that kind of thing, so you're not the only one that turns to kind of a physical, comfort eating if you're upset…. Well it, it helps you to feel not necessarily normal but… you can connect with other people… you get their understanding and you can understand them and you can get comfort in that, and it just brings you closer to people and makes you feel a bit more normal, like you're not on your own."

"They had insane [exercise] classes so it was quite good to have someone else who was going to die with you… that was quite fun… now I've got a woman who I work with, we go once a week together, but then the rest of it's my own self-motivation."

Professional support:

"I don't think I could do it without someone there, either reinforcing it and saying You're doing really well you're on the right track, or someone going Okay you didn't do so well but why, what do you think it is?"

"I mean I didn't before any diet I didn't really have any idea what I was meant to be following, you kind of get yourself, well you know how to eat healthily but you don't, so it's almost somebody helping you to structure things…. you can't pinpoint the areas where you're going wrong. So if you're kind of, if there's someone external always ordering things for you then you can almost pinpoint things and you can make little changes instead of looking at it as a whole and thinking 'Oh my God this is too much for me be able to sort out'."

"I'm not sure… I don't know why it clicked in my brain but I didn't want to call it help because then I associate that with failure. It's almost like saying help that you can't do it on my own, but actually I don't think I can do it on my own."

The clients also mentioned that there could be negative aspects of social support:

> *"My boyfriend was telling me off… I can go through packets and packets of KitKats and chocolate and initially he wanted me to tell him everything I was eating cos he wanted me to feel bad so I wouldn't do it, and I'm like 'That's not going to work, cos then I'm not going to tell you what I eat and then I'm going to be embarrassed and then I'm going to feel bad about myself, and then I'm just going to want to eat more KitKats.'"*

> *"In my first group I was the only one after four weeks who was stuck on it, and they actually, these full-grown women, very very intelligent started almost picking on me… and I had to move groups in the end."*

3.2.3 Exercise

What is it?

Exercise is a key factor in the maintenance of weight loss. It is one of two elements (along with diet) contributing to 'energy balance'. This balance needs to be sustained by behaviours which can be continued over the longer term.

Why does it help (the evidence)?

Evidence from RCTs and systematic reviews suggest that higher levels of physical activity is very important in maintaining weight loss. Data from the National Weight Control Registry of 5000 people who have lost weight in the US indicate that high levels of physical activity are associated with weight loss maintenance; up to 60-90 minutes of moderate physical activity per day[8,34]. Other work also supports this. Exercise helps by influencing the energy balance and may help by increasing metabolic rate and increasing muscle mass which burns off more calories.

How can you help?

Some evidence based guidance, to discuss with clients, is listed below along with tips to increase physical activity levels:

- Government recommends at least 30 minutes of moderate physical activity (where you get slightly out of breath but can still talk.)
- Research indicates that for maintenance this needs to be 60 minutes a day and possibly up to 90 minutes per day.
- Try to make exercise part of every day.
- Find something you enjoy doing.
- Take the stairs.

- Get off the bus a few stops earlier or park further away.
- Go for a walk in your lunch break.
- Break the 60 mins exercise into smaller chunks.
- If you struggle with fitting in 60 minutes on weekdays, do 30 and then do extra on the weekend.
- Strength training exercise can help as it builds muscle mass and boosts metabolism.
- Spend less time sitting get up for 10 mins every hour.
- If watching TV, get up and jog or walk on the spot during adverts.
- If you miss an exercise session don't think "oh well that's it" and then abandon the plan, just take it in your stride and then carry on as per your exercise plan.

A few more observations from our volunteer clients:

> *"I need to get my exercise levels at a level that I'm comfortable with, at the moment I'm going to the gym once or twice a week and I want that to be three times a week."*

> *"I think having, if either a group there or having more friends that were interested in exercise…. I think it is getting someone to go with me or getting some kind of reinforcement for it, but if you're kind of doing it self-motivation kind of way then it's quite difficult to get any, you have the happy chemicals but you don't have that kind of reinforcement to go, but if you're going with someone else it's much more fun to go with someone else."*

> *"I feel better after it… I probably don't feel as lethargic… I think if I'd had a day in work and then I go home and I haven't been to the gym you don't have that sort of buzz that it gives you, that just makes me feel 'Right, I'm ready for the next part of my day'."*

3.2.4 Barriers to Maintenance

What are they?

Identifying barriers and/or perceived barriers to behaviour change is central to MI and will also form a theme for one of the group sessions. The majority of barriers to maintenance are likely to be related to diet and exercise and may include[35,36]:

- Too tired to exercise.
- Not enough time to exercise (due to e.g. family/job demands).
- Not enough information about how to increase activity.

- Don't enjoy exercise/physical activity or lack skills.
- No-one to exercise with.
- No social/peer support to exercise (e.g. from partner).
- Cost – not able to find physical activities that are inexpensive.
- Finding it difficult to stick to a routine.
- Meals eaten away from home.
- Craving particular (high fat/sugar) foods.
- Lack of knowledge about portion size.
- Hunger ('healthy foods are not as filling').
- Cost – healthy foods are more expensive.

What is the evidence?

Research suggests maintenance is significantly less likely in individuals who report the following barriers: too tired/not enough time to exercise, no-one to exercise with, hard to stick to a routine, meals often eaten away from home, cost of healthy foods. In a study of weight maintenance in young women aged 18-32 yrs[37] the most common barriers to maintenance related to motivation, time and cost (but did not differ by socio-economic status). Women with children were also particularly likely to report lack of social support as an important barrier to physical activity (from children or partner), and lack of support and time as barriers to healthy eating.

How can you help?

Encourage clients to discuss any barriers to maintenance, and keep a record of reported barriers to monitoring and healthy diet and exercise behaviours. Encourage clients to think creatively about how to overcome these barriers within the constraints of their personal circumstances. Providing information about ways to incorporate physical activity into daily routines, e.g., using the stairs, walking instead of using the bus and providing information about e.g., portion size and exploring ways to increase social support are all likely to facilitate maintenance.

Observations from our volunteer clients related to barriers:

> *"I need to get my exercise levels at a level that I'm comfortable with… but I just talk myself out of going after work sometimes because I'm tired…"*

"My boyfriend is very worried… that I'm going to be stabbed or murdered or whatever if I go running."

"I think it is getting someone to go with me …. it's much more fun to go with someone else."

"I suppose work is a bit that sometimes can impact on [going to the gym] I'm away a lot and then, you know, I'm not able to go as easily."

"You know when you come in, you're really tired and you think 'I can't be bothered to cook anything', so you'd either go and get a takeaway…"

3.2.5 Self Efficacy

A final important element which is key to helping individuals maintain their weight loss is the concept of self efficacy.

What is it?

This refers to the confidence the person has that they have the skills and can carry out the activities required to maintain their weight in specific situations.

Why does it help (the evidence)?

The concept of self efficacy has proved crucial to ideas about health behaviour change and has been integrated into a number of different theories. It was first introduced as the key construct of Social Cognitive Theory[11] which is the main theoretical framework underpinning this intervention. Participants will not only need to know what to do and how to do it but they will need encouragement and feedback that will boost their belief and confidence in their ability to do it.

How can you help?

According to this theory there are three ways a person's self efficacy can be enhanced:

- by their own success at the behavior, e.g. losing weight or maintaining weight;

- by observing someone similar to themselves being successful at weight loss or maintenance;
- and by verbal persuasion or encouragement from others (e.g. MI counsellors) which encourages the individual to exert more effort.

3.3 CASE STUDIES - You've had the MI style and the topics now "this is how it could look" – 3 cases or clinical challenges

Case 1 – "Poor diet and restricted ability to exercise"

Background

Liz is a 45 year old woman who has been slightly overweight all her life although this has got progressively worse with the birth of her three children. She has been yo-yo dieting over many years but was determined to lose weight recently and managed to lose nearly 3 stone by following her own diet. She wants to maintain this weight loss but feels that she must stay on a diet in order to do so and feels that she just can't keep that up. She says that if she goes off her diet she immediately starts to put on weight, even if she only eats a small amount. Although Liz has managed to lose weight her diet is, in fact, quite poor and not nutritionally sound. She does not exercise as she is self conscious about it as she still feels quite big, but also she has asthma and panics when she becomes short of breath, which happens with the slightest exercise. In addition she broke her ankle a couple of years ago which still gives her pain. Liz does not feel that she could take up and maintain any exercise because of her physical problems and so has a very low self efficacy in relation to physical activity, and is resistant to any exercise plan.

Challenge

The challenge here is to improve this client's self efficacy for exercise as it is extremely low. She is very resistant to exercise, which she might need help with to overcome. A form of appropriate exercise could be explored. There are obvious physical problems that need consideration whilst exploring appropriate physical activity options. She needs a lot of education around healthy lifestyle as her diet also is not ideal.

What could happen next?

Sue Channon reflects:

The primary focus with Liz is going to be engagement: she has worked really hard to achieve the weight loss but has been following her own diet and she may not be certain what having someone alongside her will be able to offer. Early questions can make it clear that she is still in charge: *"What types of things would it be helpful for us to talk about?" Her* success in losing the weight particularly in light of the physical health challenges offers great opportunities for affirmations and reflective listening is going to be key in thinking about the best way forward: *"You have worked so hard and succeeded in losing the weight but now it seems difficult to know how to keep it off."*

The first potential trap is going to be jumping into advice and action around her diet and health issues without eliciting her agenda. Once you feel that the two of you have engaged then you can move forward into thinking what it might be possible to put on the agenda without pushing her too far: *"You have said that you really want to try and keep your weight about the same. If we were to make a list of the things you might think are important to help you do that, what would be on that list?"*

Her confidence is low, so thinking about importance and confidence in weight maintenance and the factors associated with confidence could be a useful first step in the journey towards understanding the areas Liz might want to change.

Recognising that lack of knowledge may be an important factor, you could use the elicit-provide-elicit approach:

You: *"One thing some people find useful when they are maintaining weight loss is to understand how to have a reasonably healthy diet. Is this something you think you might find helpful?*

Liz: *"Yes, maybe."*

You: *"So… thinking about what you know already… what would you say makes up a healthy diet?*

Once you have elicited her agenda it will have become clearer how she views her health issues. You can work together to think about how to prioritise and what she feels confident to tackle. If the health issues are not her priority you can put them on the agenda but recognize that she might not be wanting to talk about them yet: *"You mentioned that your asthma gives you some trouble and you know that it is part of the problem with exercise so we might want to come back to that in future sessions, but today you want to think about…"*

Steve Rollnick comments:

Yes, I like the way Sue describes a process of approaching potentially difficult topics (like health issues, a healthy diet) gently, yet nevertheless she wants us to use agenda-setting and our MI skills to approach them, searching all the time for a balance between the client's aspirations and ours. I like too the way she suggests constructing a list! While MI is such a richly *verbal* skill, we shouldn't get stuck in feeling the need to be "clever" with questions and reflections, if you know what I mean. Lists can be incredibly helpful. Visual aids and tasks like listing, backed by a genuinely curious attitude, can save many words! If you feel stuck, share it with the client, and move on…

Case 2 – "Bereavement and emotional eating"

Background

Jane is in her early thirties and single, and had lost about half a stone by attending a slimming club. She still hasn't achieved her target weight and wants to continue with her diet. But, about 6 months ago her mother became terminally ill and Jane looked after her for a time until she passed away. She tends to have a dysfunctional relationship with food and eats more when she is upset or distressed. Occasionally she binge eats. Because she has been focused on her mother over the past few months and, of course, very upset by events she has not attended her slimming group, not followed a healthy diet, and has not had time to go running which was her preferred form of exercise. Now, Jane is too scared to weigh herself regularly as she feels she is putting on more and more weight, and the confirmation of this would upset her too much, and put her into a spiral of decline. In the meantime, also, her slimming group has disbanded as the facilitator left the area. She can't get back into running as she used to run with her mother prior to her mother's illness. Running reminds Liz too much of these times with her mother, which upsets her and weakens her resolve not to give in to bingeing.

Challenge

This client has had a significant relapse and needs help with motivation to get back on track and stay on track, without being too harsh on herself. She is still in the grieving process, but does not want this to destroy all her previous efforts. She needs help to establish a healthier relationship with food and avoid the all or nothing approach to food that leads to binge eating and yo-yo dieting.

What could happen next?

Steve Rollnick reflects:

- Priority no 1, use your core skills to understand and actively empathise with her predicament. Included here is affirmation, which will comfort her in the experience of bereavement. This sounds like the ENGAGEMENT process Bill and I describe in the new framework for MI. No engagement, no foundation for MI.

  A trap? Falling into just being a good practitioner and losing focus on a return to weight loss and its maintenance. There should be times when you gently steer the discussion towards weight loss, and gauge her readiness to at least talk about this.

- Gently establish whether she is willing to talk about weight loss. She probably will be. Agenda-setting as an explicit process might be useful here, e.g., *"We've been chatting for a while now, and can we take a step back and think about where to go from here. We could talk about adapting to the loss of your mother, about weight loss, or anything else that's important to you? I'd like to get back to weight loss at some point, but it doesn't have to be in this session, we could do that some other time. How do you feel right now? What will be helpful for you?"* This sounds quite a lot like the GUIDE process Bill and I are putting into the new framework. Finding a focus.

- Ask how she feels about her weight loss in the future? The phrasing of this kind of key open question is really important and subtle, and there is no formula you can follow other than to work it out on the spot, keep it general, and make it as simple and as brief as possible. The idea here is to explore her readiness and motivation to change. This is what Bill & I mean by EVOKING in the new framework. You are listening out now for change talk. What could she do? What kind of change could make sense right now? When you hear change talk, you reflect it, because this will encourage her to explore further. If she expresses ambivalence (e.g. *"I'd like to get back to where I was, but I'm so tired all the time and I burst into tears"*), you only need to reflect this back to her with something like, *"there's only so much that you can take on at the moment"*. If she is ready to move, this kind of reflection gives her the space to do it. That's the heart of MI. You clarify, she decides….

- Is there one small thing she could do that would help her to feel better about her weight? You might not get this far in the scenario described above, but if your engagement is good, there's no harm in asking her a question like this, not right at the beginning perhaps, but towards the end. This sounds a lot like the PLANNING process Bill & I describe, and here your goal is not just to elicit a small step from her, but to gently guide her to be as specific as possible about how she might

make this change. This will elicit commitment language, and ideally but not always possible, an "implementation intention", a very specific plan of action.

Sue Channon comments:

Having someone alongside her who understands the impact of the loss but who is also wanting to support her move towards change could make so much difference to her. Active listening and engagement will help her think through the fact that this doesn't have to be an either / or. She doesn't need to have "finished" grieving before thinking about the future in relation to her weight loss goals. Helping her to think about future plans will enable her to express hope without pressure and hearing herself talk about it may well plant the seed of change that she needs.

Case 3 – "Weight maintainer, busy, stressful life, unsupportive partner"

Background

Kate is in her late 20's and has been trying to lose weight since her teens, often successfully, but she can never seem to maintain the weight loss. She has recently lost 2 stone, and is determined this time to keep it off. She understands that she needs to balance a healthy diet with exercise if she is to do this, but has a stressful job, busy family life and an unsupportive partner, so finds it difficult to maintain the necessary behaviours. Kate's partner has a problem with alcohol, and often drinks in response to stress. His GP has told him his drinking is affecting his health so he is trying to cut down. He has told Kate he can't cope with changing his diet at the same time: she therefore finds it difficult to introduce the family to a healthier diet and often ends up snacking on unhealthy foods. Kate enjoys going to the gym and used to go with her friend after work, but feels she can no longer leave her partner alone in the evenings as she is worried he will find it difficult to cope with their two small children on his own, and that he is more likely to drink if she is not there.

Challenge

To help Kate find ways of overcoming these significant barriers to achieving a healthy diet and exercise plan, e.g., by exercising during her lunch hour and/walking to work or using an exercise video at home. It will be difficult for Kate to change her family's eating

habits given her current circumstances, so encouraging her to identify triggers for eating unhealthy foods/emotional eating might help her resist snacking at home.

What could happen next?

Steve Rollnick reflects:

- This seems like quite a nice concrete weight loss discussion, yet I would nevertheless still start the session broadly to ensure ENGAGEMENT. A good open question might be: "How are things going for you right now?", and conduct a broad review of her circumstances first. Don't forget those affirmations!
- I'd be tempted to use agenda-setting to make sure that we focus on an agreed topic, or I'd make sure by asking her a good GUIDING question like "How do you think I might be of greatest help to you today?", and I'd listen like crazy to the answers!
- This case seems perfect for using the Typical Day review (see page 21). See what you think. It would give you a very good feel for her everyday life, and exactly how she feels day-to-day.
- It seems like she might be ready to make some changes, the problem being what changes could she make in quite difficult circumstances? I'd put this observation and question to her and then work from there. This sound like a PLANNING process.
    - At the heart of this task is eliciting ideas from her, recognising these as change talk when they occur, and using reflective listening when they arise.
    - You can also offer suggestions of your own, or tell her what's worked for others, but make sure that you emphasise her freedom to choose what makes sense to her.
- I'd keep a firm eye open for the use of "self-monitoring" (see page 29). Here I imagine facing a challenge that will be quite a common one. You believe it might be good for a client to use self-monitoring, so how do you encourage uptake of this suggestion? If you just come out with it, the chances are you might meet resistance, because you are limiting the client's autonomy. A nice way of succeeding is to use the Elicit-Provide-Elicit sequence, making sure all the time that you give her choice and promote autonomy. For example:

You: *"I wonder whether we could talk for a few moments about self-monitoring with a diary and what this actually means?"*

Kate: *"Yes, okay."*

You: *"How do you see the benefits of using a diary?" (ELICIT)*

…….. (PROVIDE any new insights that you feel might be useful) and then ask something like:

You: *"I wonder what you make of this idea of a diary?" (ELICIT and help her decide, emphasizing her freedom of choice).*

Sue Channon comments:

Kate is facing a situation with many competing demands on her resources; in the face of these she has achieved significant success and in addition to affirmation, it will be important to build on these successes using the guiding approach. Eliciting her strategies for success in weight loss and then thinking with her about how these can be adapted for maintenance will emphasise her strengths and also introduce her to ideas for relapse prevention.

Part 4: Study Specific Information

4.1 Study Protocol

Below is a summary of the trial taken from the protocol (see Appendix 2 for the full protocol).

Background

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

Aim

To evaluate the impact of a 12 month multi-component intervention or a less intensive version on participants': Body Mass Index (primary outcome); waist circumference; waist to hip ratio; physical activity levels and diet three years from randomisation.

Design

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

Population

We will recruit 950 obese adults aged 18-70 (current or previous BMI 30+) who have lost at least 5% body weight (independently verified) from community based groups, gyms, commercial weight loss groups, GP surgeries and exercise on prescription schemes. We will also approach people trying to lost weight who will be consented into the study as soon as they have lost 5% of their body weight. Exclusion criteria include; terminal illness, pregnancy, previous bariatric surgery or inability to comply with study protocol.

Outcome measures

The primary outcome is BMI at 3 years post randomisation and the primary contrast will be between the intensive and control groups. Secondary outcomes include waist circumference; waist to hip ratio; self report physical activity; proportion maintaining weight loss; self report dietary intake; health related quality of life; health service and weight control resource usage; binge eating, psychological well being and duration of participation and drop out from intervention.

Duration and follow-up

The trial will start after participants are recruited and consented, and they have lost at least 5% of their body weight. Participants will be assessed at 6 months during the intervention and followed up at the end of the intervention (one year from randomisation) and at 12 and 24 months after the intervention is complete.

4.2 Description of the Intervention

Intensive Intervention Group:

Participants in this group will have 6 one-to-one MI sessions. These sessions will be delivered fortnightly for three months and will last approximately 60 minutes. For the final nine months of the intervention participants will have monthly MI telephone calls lasting around 20 minutes. Diet and physical activity will be discussed in the MI sessions in line with current government guidance. Participants will be guided to reflect on their values, goals and current behaviour and to develop their own goals and techniques for implementing and maintaining behaviours. They will be encouraged to self regulate by weighing themselves every week and reporting this information to the study team. They will also be encouraged to self monitor diet and physical activity and record this in a diary. MI counsellors will be asked to record participants' goals and implementation intentions at individual sessions and this information will be collected by the study team. Participants also have the option to record goals and implementation intentions in their diary.

Professional-led peer group support sessions will take place monthly, lasting 1.5 hours for four months and will follow on from the face-to-face MI sessions. The purpose of the group sessions is to reinforce the main messages of the intervention as well as allowing people to share their experiences and increase peer support. We will invite participants to 'bring a buddy' (N.B. buddies cannot be other trial participants) to the sessions to

enhance peer support. The group sessions will be led by a facilitator who will revisit evidence based diet and exercise guidance at the initial session. Group sessions will address user or facilitator initiated issues around diet and exercise. These could include: barriers to maintenance, tackling negative thoughts, identifying emotional triggers for eating and coping with relapse. Participants will also have the opportunity to share problems, techniques and tips with their peers.

Less Intensive Intervention Group:

Participants in this group will have two face-to-face tailored MI sessions two weeks apart. They will be encouraged to self regulate by weekly self-weighing (to be reported to the study team) and self-monitoring of diet and activity (which participants can record in their diary if they find this helpful). They will also have the option to record goals set as well as plans for implementation in the diary (goals and implementation intentions will be recorded by MI counsellors at each session). They will also receive two MI based telephone calls at 6 and 12 months lasting around 20 minutes. The group sessions will be the same as the intensive intervention group, i.e. monthly for 4 months following on from the end of the two face-to-face MI sessions.

Control Group:

The control group will be given an information pack detailing lifestyle changes for weight maintenance.

All participants in all groups will still be able to access usual care. They may continue, for example to attend a weight loss group and may still be attempting to lose more weight. Participants in both intervention groups will be given the same information pack as the control group with guidance on diet and physical activity.

4.3 Serious Adverse Event Reporting

Serious Adverse Events (SAEs) are defined as:

Any untoward and unexpected medical occurrence or effect that:

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

- Is a congenital abnormality or birth defect

If at any point during the study you become aware of an SAE in one of your clients, we would ask you to report such an event to the WILMA Trial Manager **within 24 hours of becoming aware of the event**, either by telephone or using the form provided. Detailed instructions for reporting SAEs and the reporting form are provided at the end of the Handbook (See Appendix 3a and 3b).

4.4 Contacting Study Team

4.4.1 Contact details

Address for correspondence and invoicing:
South East Wales Trials Unit (SEWTU)
Dept. of Primary Care & Public Health,
School of Medicine, Cardiff University
7th floor, Neuadd Meirionnydd
Heath Park, Cardiff
CF14 4YS

General fax: (029) 20687611
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Key contacts

Name:	Position:	Email	el:
Rhys Thomas	WILMA Trial Administrator	ThomasR95@cardiff.ac.uk	(029) 20687511
Liz Randell	WILMA Trial Manager	RandellE@cardiff.ac.uk	(029) 20687608
Dr Rachel McNamara	WILMA Senior Trial Manager	McNamara@cardiff.ac.uk	(029) 20687146
Dr Sharon Simpson	WILMA Chief Investigator	SimpsonSA@cardiff.ac.uk	(029) 20687181

4.4.2 When to contact the study team

Please send all invoices (see Section 4.8) and requests for materials (e.g. Client Record Forms) and venue hire details to the WILMA Trial Administrator. If you would like information about any aspect of the WILMA study, please contact the Trial Administrator, Trial Manager or Senior Trial Manager.

In addition to the above, we would also like you to contact us in the following circumstances:

1. If you become aware of a Serious Adverse Event in any client, at any point during the study (see Section 4.3 and Appendix 3 (a & b))
2. If you are concerned that a client may have serious mental health problems and/or is at risk of self-harm. More information on the procedure for reporting mental health concerns is provided in Appendix 4 (a & b).

4.5 Participant Diary

An example of the diary given to intervention participants is provided in Appendix 5.

4.6 Client Records

An example of the Case Record Form we would like you to use for recording information at each session is provided in Appendix 6. We will provide you with additional copies for use with clients. If you run out of Client Record Sheets, please contact the WILMA Trial Administrator (details provided above in Section 4.4).

4.7 Booking venues for MI

The WILMA study team can provide you with details of local venues for hire, suitable for conducting the individual MI sessions. We can also book venues for you directly if needs to although we ask that you do this where possible: please contact the WILMA Trial Administrator for more information on venue booking.

4.8 Claiming Expenses/Payment

At the start of the study, we will provide you with instructions for claiming expenses (for attending supervision sessions and for room hire if applicable). We will also provide detailed instructions on how to submit invoices, which should be sent to the address detailed in Section 4.4.1.

4.9 Lone Worker Policy

When conducting individual sessions, particularly when visiting client's homes, we would ask you to comply with the SEWTU Lone Worker Policy to ensure your personal safety (See Appendix 7).

5.0 Supervision

Supervisors' contact details can be obtained by contacting the WILMA study team on the number above.

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7. Appendices[1]

Appendix 1:	WILMA Study Processes – Flow Chart
Appendix 2:	WILMA protocol V7.0 (15/05/2012)
Appendix 3a:	WILMA Procedural Information Sheet: Serious Adverse Event Reporting (V1.0, 24/02/2010)
Appendix 3b:	WILMA Serious Adverse Event Reporting Form (V1.0, 24/02/2010)
Appendix 4a:	WILMA Procedure for Reporting Harm (V1.0, 03/09/2010)
Appendix 4b:	WILMA Actual or Risk of Harm Reporting Form (V1.0, 18/08/2010)
Appendix 5:	WILMA Intervention Group Diary (V3.0, 09/03/2011)
Appendix 6:	WILMA MI Case Record Form (V1.0, 03/09/2010)
Appendix 7:	SEWTU Lone Worker Policy (V2.0, 28/07/2009)
Appendix 8:	WILMA MI Counsellor Contract (V2.4, 10/05/2012)
Appendix 9:	WILMA MI Counsellor Training Materials
Appendix 10a:	Ethics Permissions Letter (18/03/2010)
Appendix 10b:	Ethics Permissions Letter: amendment 1 (06/09/2010)
Appendix 10c:	Ethics Permissions Letter: amendment 2 (10/05/2011)
Appendix 10d:	Ethics Permissions Letter: amendment 3 (31/08/2011)
Appendix 10e:	Ethics Permissions Letter: amendment 4 (29/11/2011)
Appendix 10f:	Ethics Permissions Letter: amendment 5 (19/04/2012)
Appendix 10g:	Ethics Permissions Letter: amendment 6 (06/06/2012)

[1] All appendices available on request.