

## **Is the Small Changes programme clinically effective for adults who are obese?**

SIMPER, Trevor N.

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# Is the Small Changes programme clinically effective for adults who are obese?

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A doctoral project report submitted in partial fulfilment of the requirements  
of Sheffield Hallam University for the degree of Doctor of Professional  
Studies

Trevor Simper  
(October 2014)

## Acknowledgements

Thanks to my supervisor Dr Jeff Breckon, my mother Mrs Diane Simper BSc and the moral support of many friends and colleagues during the five years this project has been ongoing: Jean O'Keeffe and Ray Nolan especially.

## Abstract

*This thesis concerns the treatment of (N=148) male and female clients in a weight management programme: 'Small Changes' the thesis compares treatment as usual with a new approach using motivational interviewing. Firstly a preface sets out the historical context of Small Changes and how it developed and was originally funded before the aims of the thesis and the detail encompassed in each chapter are set out. Following this an introduction chapter presents the key constructs and theories surrounding motivational interviewing. This leads into study 1, a systematic review addressing the question: What should be included in a comprehensive weight management programme? The conclusion to this question is a mixture of input from: nutrition and exercise expertise combined with a clear behavioural approach, measures that encompass important clinical parameters, other than just weight, and sufficient length of follow-up post treatment. This conclusion forms the basis of the study 2 literature review which focusses on the contribution of motivational interviewing for affecting exercise and nutrition behaviours with the aim of improving weight management outcomes. The literature review leads into the methodology for study 2 which outlines the measures used, the follow-up period and the detail of what was done in study 2; sufficiently clearly for others to replicate what was done. From this chapter a separate results chapter reveals the statistical results for the outcome measures included in study 2. The discussion chapter then follows and focusses on the interpretation, critique and analysis of the results and relates these back to the literature presented in the literature review for study 2. Finally conclusions and short-comings of the study 2 investigation are explored and further research considerations made.*

## Key terms

TAU - Treatment as Usual

TF -Treatment Fidelity

MI - Motivational Interviewing

SPAQ - Scottish Physical Activity Questionnaire

SF-36 - Short Form -36

MITI - 3.0 Motivational Interviewing Treatment Integrity coding instrument version 3.

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## Preface

### **Part 1: Background to the study**

Working as a public health specialist in Bradford West Yorkshire (2000-2005) I became aware of the extensive work, locally and nationally, aimed at improving nutrition and increasing the uptake of physical activity. I was also aware that giving clients information, from the broad knowledge base in relation to exercise and dietary advice, was the predominant feature of attempts at supporting people to manage their weight. During the same period I met the co-ordinator of a women's counselling project in Keighley West Yorkshire (Jean O'Keeffe) whilst I was commissioning local health projects on behalf of the NHS. Whilst examining the work she and colleagues were doing around weight management and behaviour change, I was struck by the potential for adopting their behaviour change approach (broadly person-centred counselling) for weight management practice. After a few months training with Jean and her organisation (Versa) I took up a full-time academic post at Sheffield Hallam University in the food and nutrition department. Whilst at the university I identified opportunities for funding around diet and exercise and developed the idea of a weight management project. After obtaining a year's funding (2008) from the All Saint's Educational Trust I invited Jean to Sheffield to help run the project. Initially the project ran twelve-week weight management groups with twelve people per cohort. We gained another year's funding in 2009 from the same body. The following year, the project was again re-funded following a competitive tender (to Barnsley Joint Directorate) in 2010 and the project became 'Small Changes' named by one of our participants. Several preliminary publications developed from this early work via conference proceedings (Simper et al., 2009, 2008a, 2008b) and a peer-reviewed research paper (Paxman et al., 2011).

After three years of running the project it became clear via the scientific literature that many projects were running for periods of time similar to Small Changes (i.e. 10 to 12 weeks) and that empirical evidence was clearly now suggesting that the physical changes from these programmes were equally short-term. Other factors also emerged from the literature, such as: a combination of physical activity and nutritional advice with a behaviour change approach seems to yield better results than using diet or exercise advice (whether in isolation or together). Reading further around behaviour change led me to the concept of 'treatment fidelity' a phrase often used in psychotherapeutic approaches and essentially describing a way of testing to see if a therapy can be corroborated as authentic in its approach (i.e. verified by an independent expert). This in turn led on to meeting Dr Jeff Breckon, a motivational interviewing (MI) trainer and beginning training in MI throughout 2010 and 2011 in the UK, Italy and United States. During this training I designed the present project. The work included in this thesis relates to a one-year treatment as usual group which ran between October 2010 and October 2011 which is compared with a one-year MI group which ran between October 2011 and October 2012.

## **Part 2: Aims and Focus of the Thesis:**

This thesis' first aim is to identify whether the Small Changes motivational interviewing in groups project is a superior approach for achieving significant differences to several weight management parameters when compared to 'treatment as usual' groups. These parameters are sub-divided into three sub-sections; anthropometrical measures, physical and psychological wellbeing measures and 'healthy' behaviours:

Anthropometrical measures:

- Waist to hip ratio
- Body weight
- Body composition
- Body mass Index

Psychological/physical well-being measure:

- Short form-36 - SF36 (wellbeing questionnaire)

Healthy behaviour measures:

- Fruit and vegetable consumption
- Number of minutes of daily physical activity

The thesis also attempts to develop professional practice- which is to be achieved by testing treatment fidelity to MI (via having selected sessions coded and reported on by an independent motivational interviewing coding expert; using the MI treatment integrity tool - MITI 3.0) developed by Moyers and colleagues (2005) which assesses a therapist's clinical effectiveness in performing MI. This aim relates to professional development of the principal investigator and as such is a key focus of a professional doctorate.

## **Chapter 1: Introduction**

The introduction begins with an overview of the range and scope of weight management interventions available and then a concise description of what MI is and the core concepts of this approach and explanation of the terminology used throughout this thesis. It then sets the research in context by establishing the research imperatives for the area of behavioural weight management programmes. This leads into the



sections which introduce MI fully, explaining the core concepts and giving examples of MI in practice.

### **Chapter 2: study 1 systematic review**

Chapter 2 presents the entirety of study 1, a systematic review published in 2013 and focussing on the paper's title: How Successful are Comprehensive Weight Management Programmes? The attempt to answer this question via a review informs the design of the present investigation, and leads into the following literature review for study 2.

### **Chapter 3: Literature Review for study 2.**

This literature review: focusses on the main aim of the thesis: What is the contribution of MI to the existing Small Changes weight management programme? Effectively how might verifiable MI enhance treatment when compared to the existing approach based around education alone. The work reviewed relates to other studies in the field of weight management and MI for both individual and group MI investigations; although there are a limited number of group MI studies and non-specifically for group MI weight management programmes as yet.

### **Chapter 4: Methodology for study 2**

This chapter sets out the quasi-experimental design and all methodology used to address the aim of the present investigation. This is done in sufficient detail for other investigators to replicate the study. The chapter also goes on to describe the methods used in statistical analysis of the data and by doing so leads into the three results chapters which reveal the results of the 7 measures briefly outlined above.

## **Chapter 5: Results**

Chapter 5 presents results, firstly concerning the physical/anthropometrical measures: BMI, bodyweight, body composition and waist to hip ratio. Statistical analysis for each of these parameters is shown. These measures are essentially proxy indicators of successful change and protection to health with, for example, a poor waist to hip ratio signalling greater risk for major threats to public health such as type-two diabetes and cardiovascular disease. This section leads into the next chapter on psychological wellbeing.

This chapter then presents results concerning the physical and psychological wellbeing results, including: the Sf36, a wide ranging measure of psychological wellbeing. The questionnaire covers items which relate to both psychological and physical wellbeing and is perhaps the most widely researched questionnaire of its type with commensurate assurances of its validity. Scores from the Sf-36 indicate the subjects' relative well-being with a higher score equalling greater wellbeing.

The next section concerns the results relating to the healthy behaviour measures: fruit and vegetable consumption and number of minutes of daily physical activity. Vegetable and fruit intake are considered key measures of dietary health and low intake is associated with greater risk for cardiovascular disease certain cancers and type diabetes and increased intake signalling both greater protection from primary disease and reduction of the re-occurrence of secondary disease in patients increasing their intake of these foods.

Finally this chapter presents treatment fidelity results relating to the delivery of MI which links to the second aim of the present investigation. The results are presented from three time points, the beginning, middle and end of the programme. The coding

and subsequent scores are presented here with interpretation and comments from the coder. Further description of MITI coding is included in methods.

## **Chapter 6: Discussion**

The discussion relates the results of the present investigation to the work analysed in the literature review chapters. Comparisons are made and conclusions are drawn in relation to the stated hypothesis.

## **Part 3: Publications arising from the project**

This doctoral investigation has produced a number of academic outputs including conference presentations and peer-reviewed journal papers.

Peer-reviewed journal papers:

SIMPER T (2013) How successful are 'comprehensive' weight management programmes? *Open Research*. 2013 Nov 23 [last modified: 2013 Nov 23] 1

PAXMAN, J. O'KEEFFE, J. HARDEN, C.J. HALL, A. and SIMPER, T.N. (2011). Weight loss is coupled with improvements to affective state in obese participants engaged in behavior change therapy based on incremental, self-selected "Small Changes" *Nutrition Research*. 31 (5), 327-337

Conference presentations:

SIMPER, T.N. and O'Keeffe, J. (2009). Reduced energy intake and maintained loss of weight is observed at 6 months follow up of the 'Small Changes Programme' *European Journal of Obesity* May Vol2,S2 p228.

SIMPER, T.N. HARDEN, C.J. PAXMAN, J.R. and O'KEEFFE, J. (2008a). Energy intake is significantly reduced following the 12-week 'Small Changes' intervention for weight management (POSTER). *Tackling Child and Adult Obesity in Sheffield: Evidence, Policy and Practice*.

SIMPER, T.N. PAXMAN, J. and O'KEEFFE, J. (2008b). Small-group weight management programme using self-selected goals improves General Well Being scores. *International Journal of Obesity*, May S230.

## **Part 4) Contribution to the pool of knowledge**

This investigation shows that motivational interviewing can be superior to the treatment as usual in a group weight management context where treatment fidelity is

assured. In this way the investigation has developed the knowledge base and will hopefully encourage practitioners to utilise motivational interviewing (MI) in order to enhance the effectiveness of group weight management interventions. This thesis makes an original contribution to the understanding of using MI (with treatment fidelity) in groups whilst comparing this to previous 'best practice' and is the individual contribution of the principal investigator.

## **Chapter 1: Introduction**

This chapter begins by briefly introducing a range of potential approaches to weight management before moving on to MI. The key constructs and theories underpinning study 2 and connected terms relating to MI and the components for effective MI consultations are all fully introduced. The divergent approaches to weight management and MI are critically analysed in the following literature review chapter.

### **1.1 Weight management: a brief history**

Weight management has been of interest historically- as corpulence at various periods in time has signified both health and prosperity and alternatively ill-health at other times. Our modern concerns with weight began sometime in the 19<sup>th</sup> century, probably around the 1860's (Yager, 2010) in the United Kingdom and then 20 years or so later in the United States. It was not, however, until around a hundred years later in the 1980's that a rapid escalation in body mass index in Western society was observed, noted by scientists and analysed as a distinct risk for disease and poor health (Von Hippel & Nahhas, 2013). In recent years this escalation in Western populations' bodyweight is reflected by the doubling of obesity rates in England between 1993 and 2008 which in turn is similar to many other European nations (Public Health England, 2011).

### **1.2 The rise of weight management businesses and weight loss interventions**

Weight Watchers was established in 1963, in Brooklyn New York, and currently (2014) the organisation reports a million members taking part in 40,000 groups run by 10,000 leaders, Slimming World founded in Derbyshire in the United Kingdom in 1969 indicate current membership at 0.5 of a million people in the UK alone, these two examples indicate that the weight management 'market' seems to be supported by

a substantial number of people concerned about their weight. The leader in this highly fragmented market: Weight Watchers International had a revenue of 1.8 billion dollars in 2012, representing only 3% of market share (Forbes). The low market share represents a huge industry with other market leaders having less than 1% share and still recording revenues over \$300 million dollars.

These businesses have been joined by the Atkins, South beach and Jenny Craig diets alongside many others. Typically systems inside these services have 'points' for foods with customers being instructed to eat within their own points plan. Certain macronutrients are exaggerated or diminished (e.g. carbohydrates in the Atkins programme) and products relating to the system in question are marketed and sold.

Community Programmes, NHS weight management services and other providers are also often provided via local authority health commissioners and run for free (and not for profit) in communities; especially where levels of obesity and economic deprivation are high. Programmes which follow the National Institute of Clinical Excellence (NICE, 2006) guidance often start with a target of losing 5-10% of starting bodyweight. Programmes also, typically, employ advice and support around physical activity and diet. Small Changes is one such programme. Advice and support are also accompanied by a behavioural approach in some programmes and some data (e.g. Soderlund & Fischer, 2009) suggests that the addition of a behavioural change approach augments the effects of a weight management programme. One such promising approach is MI and although, in a group setting, no data has been published it has been suggested the approach one to one may be more effective than other forms of treatment (Hardcastle et al., 2013, Armstrong et al., 2011, Rubak et al., 2005).

### 1.3 What is MI?

Originally described by Miller (1983), MI is a person-centred directive counselling approach that steers away from persuasion or emphasising the negative consequences of *not* changing. Instead MI steers the client towards their own motivation for positive change. The early work in MI relates to the addictions field. MI has since been adopted by many health care practitioners. These adoptions include those who are interested in diet, physical activity and weight management.

Often health care practitioners have employed advice giving and persuasion to encourage patients to make changes to health-related behaviour (Hardcastle, 2008). Whilst this may represent a reasonable approach where knowledge is lacking, or behaviour is clearly leading to poor health outcomes, it also appears that persuading and ‘educating’ may lead to behaviour change outcome in only a small number of cases. Some researchers have reported values as low as 5-10% success using advice and persuasion. (Britt et al., 2004, Kotte et al., 1988 Bien et al., 1993).

Standard practice in health/medical interaction may assume that this giving of information is paramount (*in certain situations it clearly is, e.g. when the patient has asked for it or an acute medical emergency*), however, this may well be misplaced in interactions where *change* to behaviour (e.g. exercise, diet, smoking cessation, alcohol and treatment adherence) is the intended outcome (Miller & Rollnick, 2013). MI is perhaps in part defined by assuming change is affected by the client’s motivation more than it is by information or convincing arguments from the practitioner. Ergo treatment seeks to identify, through reflective listening, what the client’s motivation is. MI then is not about seeking to motivate people who are, as yet, unmotivated but

rather it is an approach which attempts to uncover and strengthen the client's existing motivation/s.

Miller and Rollnick provide a layperson's definition of motivational interviewing:

*“Motivational interviewing is a collaborative conversation style for strengthening a person's own motivation and commitment to change”*

(Miller & Rollnick, 2013, p.12).

#### **1.4 The spirit/relational aspects of MI**

It is important to note MI is not simply a system broken down into the micro-skills outlined below but also what Carl Rogers called ‘a way of being’ (Rogers, 1980). MI cannot be learnt by simply ‘painting by numbers’ i.e. using these micro-skills as techniques but rather MI has a spirit. Despite this MI is, perhaps, more ‘accessible’ than other forms of psychotherapy. The consensus feeling, for instance, from MI’s originators and the Motivational Interviewing Network of Trainers is that MI practitioners should seek to ‘*give more than they take*’ (MINT forum, 2012). Indeed resources are freely shared and given away to other practitioners and attendees at workshops and training events.

#### **1.5 OARS the technical 'microskills' of MI**

Open questions, affirmations, reflections and summaries (OARS) are the essential micro-skills of MI, the acronym stands for: open questions, affirmations, reflections and summaries, these are introduced in more detail below.

#### **1.6 Open questions**

Open questions allow the client to explore and explain what is going on, essentially how a situation *is* for them. Open questions tend to deter single word answers. Closed questions, alternatively tend to yield information (e.g. age, height, weight)



which may not help with engaging the client or understanding what is going on in relation to problem behaviour. Open questions are used sparingly, for instance to begin a conversation about change: *'Tell me what brings you here today?'* They form an important bedrock for behaviour change as the answers relate to what the client may find useful rather than information the therapist wants to know.

### **1.7 Affirmations**

An affirmation is the selective presentation of a strength or quality in the client noticed by the therapist and is juxtaposed with praise, which might be simply saying *'well done!'* an affirmation rather than just praise is a clear recognition of the client's strengths: *'you are clearly very resilient to keep coming back to different weight management programmes even when it's been tough to make permanent changes'* so an affirmation tells the client what it is that is strong, resilient, intelligent, kind or caring in them and it is specific. The rationale for affirmation over praise is that praise confers a value on the part of the therapist. This intimates that the client changes in order to please the therapist: rather than for the intrinsic recognition of a positive outcome or attribute.

### **1.8 Reflections and reflective listening**

Reflection is a key concept in counselling approaches. In MI reflections tend to be defined as either simple or complex. The simplest reflection is a repeat of the client's words. Deeper reflections, however, seek to explore/understand the *meaning* of what is being said, there are examples given in the methodology chapter. Reflections are key in expressing empathy as in essence they show that the therapist is listening and understanding what the client is saying. In turn expression of empathy is thought to be key in gaining behavioural change outcomes and conversely where therapist empathy is poor outcomes are worse (Miller & Rose, 2013).

Reflective listening is a key component of MI- fundamentally deepening the understanding a therapist has of the client's situation and additionally allowing the client to hear their own voice, thoughts and feelings via the reflective statements of the therapist (Miller & Rollnick, 2013). Reflective listening is akin to hypothesis testing where the listener is attempting to clarify meaning and feeling. Miller suggests that MI would not exist without Rogerian/ person centred counselling (Miller & Rollnick, 2013). Yet MI is not person-centred counselling alone. MI is both person-centred and directive the practitioner has an agenda for examples: weight loss, smoking cessation or reduction in alcohol consumption. The practitioner is operating from a position that suggests that the client is going to be better off if smoking behaviour is reduced or stopped, or it is better to control weight than be overweight/gaining weight and so on. In non-directive or person-centred counselling it would be the client who focusses on direction in therapy; whereas often the practitioner directs in MI. The exploration of change and strengthening of the client's reasons for change are strengthened by skilful questioning and reflecting- even if ultimately it is the client who decides whether change will take place or not.

### **1.9 Summaries**

Summaries are used throughout and towards the end of sessions and seek to clarify meaning and allow the client to accurately hear back their own voice or else disagree: *'that's not quite what I meant'*. Either way the therapist will gain clearer understanding of the client's situation. Summaries collect together several points and can also serve as a platform to move on to a new phase of conversation e.g. to move from focussing to planning. A summary may of course be selective as not everything a client has said will be included; a therapist may choose to summarise certain key points and ignore others. A collecting summary pulls together several

points and invites the client to add more points until the client has finished. A linking summary is similar but links to a previous session:

*'planning what you are going to eat each day helps you stay safe and the time to reflect and ask: what should I do now? really helps you delay or even stop a binge occurring and I remember from last time we spoke you talked about the benefit of stopping to reflect- maybe you could say a little more about that?'*

(Small Changes, session 3, one to one client 26).

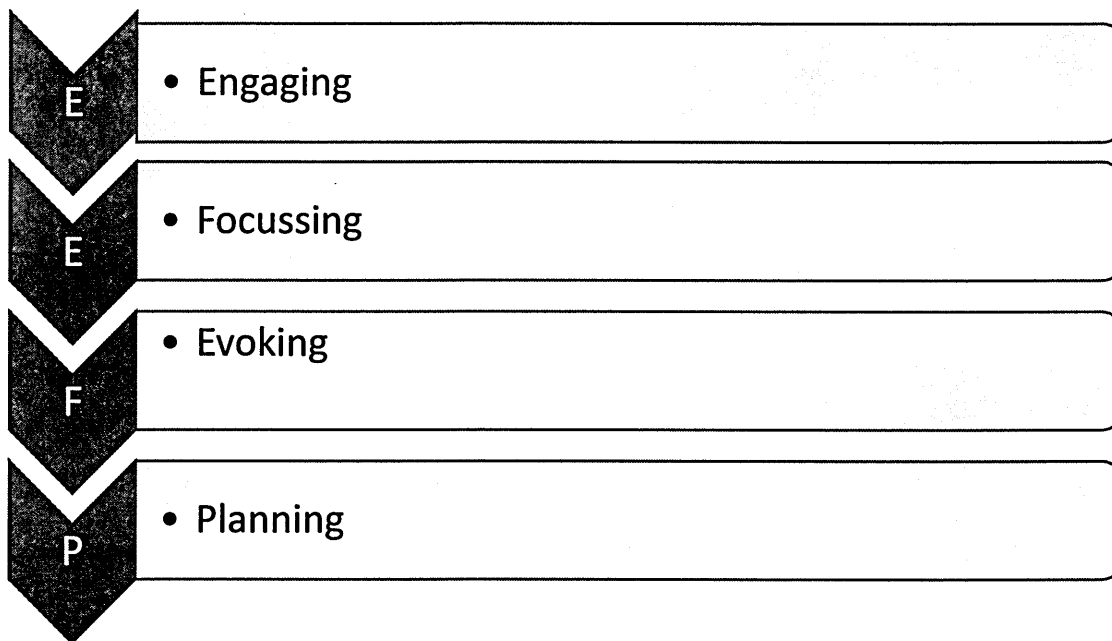
There is a third type of summary which is described (Miller & Rollnick, 2013) as transitional, which could be used to wrap up a session:

*'we spoke a lot about the difficulty with maintaining your healthy choices and relapse and we discussed how you had also been very successful in a number of areas including strategies that are effective for eating healthily and being more active and in fact you decided that even though you are not yet where you want to get to - you are both more active and eating healthier and following today you felt that planning snacks to take to work and preparing your gym kit the night before were what you thought you'd focus on next- is that about right?'*

(Small Changes, session 2, one to one client 11).

## 1.10 The four processes of MI

More recently Miller and Rollnick (2013) have structured their description of MI around the four processes of: engaging, focussing, evoking and planning. These four processes underpin and surround the approach of MI.



**Fig 1. The four processes of MI**

### 1.11 Engaging

In any therapeutic relationship engagement between the client and practitioner is key. Miller and Rollnick (2013) suggest that engagement is more than just smiling and greeting a client (although that is perhaps where it starts) and that using the microskills of OARS may help engender engagement between the two partners (Breckon in Hanrahan and Anderson, 2014) involved in a conversation about change. In relation to engagement Carl Rogers referred to the (idea) relationship between therapist and client as a sort of “*gullible caring, in which clients are accepted as they are, not with a lurking suspicion in the therapists mind that they may in fact be otherwise*” (Rogers and Sanford, 1989). The alternative ‘suspicious’ approach may indeed be pointless.

The client chooses whether they change or not and also how to represent themselves whether the therapist thinks they are telling the truth or not is redundant in this context as accepting that the client is exactly as they present themselves is largely what leads to engagement. And subsequently engagement increases the likelihood of a successful therapeutic alliance.

### **1.12 Focussing**

Often in client presentations there are multiple issues which need attention. For example a client presenting who is concerned about their weight, the way stress is affecting their food choices, the need to eat breakfast, the need to start exercising again and the struggle to plan their meals before shopping. Here the process of focussing may help the client (and the practitioner) to make effective use of what may be a brief conversation. Initially gaining a full picture of what faces the client in terms of difficulty to change is useful before focussing (Breckon in Hanrahan and Anderson, 2014) in conversation terms focussing looks like the following:

*TS: 'there's certainly a lot going on here, you mentioned the school run/difficulty with childcare shopping, smoking and then the need to fit in more physical activity. I wonder with the brief time we have today whether you could choose one of these for us to work on?'*

*C: 'it has to be the physical activity to start with...'*

(Small Changes session 1, one to one, client 14).

Essentially this brief transcript shows the process of focussing within a conversation and leads onto working through one of several important issues. In this case the session was open for the client to focus on whatever was foremost in

their mind, often in the case of services with a specific focus (smoking cessation for example) there may need to be agreement of the focus between client and practitioner.

### **1.13 Evoking**

Evoking in the MI context refers to eliciting and subsequently strengthening a client's own reasons and motivation for change. With the use of open questions for example a client may be encouraged to consider the reasons they *would* change. When presented with such a question clients feel the need to answer and list their reasons for change- these are then reflected back by the practitioner and the client hears what they themselves have said. This process of hearing their own argument for change appears to be much stronger than hearing the health professional's reasons for change (Miller and Rollnick, 2013). The concept of change talk is important in evoking and strengthening the client's commitment to change- in the simplest way, this can be done by asking evocative questions such as '*why would you want to make this change?*' Change talk is explained further below.

### **1.14 Planning**

The planning phase of an MI consultation fits within the approach explained in the preceding sections. In short OARS are used in the process and change talk is listened for in the client's speech. An example taken from one of my own consultations:

C: *'it's been on the agenda for a while... I've known this is what I've got to do it's only now I've got to the point where I'm ready'* (change talk: 'got to do' = reason 'I'm ready'= ability)

TS: *'ready to get started'* (reflection)

C: *'I am as ready now as I'll ever be- I can think about it and go round and round for years without doing anything!'*

TS: *'it may as well be now'* (reflection)

C: *'that's right- seriously I could still be here next year talking to you about doing it and still be sitting here in this state'*

TS: *'you're tired of the status quo and ready to get started- how do you think you'll begin?'* (reflection and then open question seeking elaboration on how the client will make a start)

A key concern with action planning is not prematurely focussing on planning as the resulting outcome may well be momentary discord between client and professional or even worse disengagement. The client's speech will give clues as to readiness to action plan, consider: *'I am going to do this- I have bought the training shoes and I'm ready to get started with this'* versus *'it's all very well all this talk of exercise but I just don't have the time, the job, the kids there's not enough hours in the day'* The former is of course a client ready to action plan the latter needs continued reflective listening and exploration of the issues so that the client can be helped to decide whether change is going to take place or not.

The four processes of MI stop at the point of change that is at the action planning phase, what is perhaps missing then is a maintenance phase- the maintenance of behaviours that have already been enacted (e.g. jogging and eating breakfast every day) maintenance is potentially a further process:

*'I've been slimmer of the year locally and nationally, I've run the London marathon and I've lost the equivalent of my entire bodyweight... but I always put it back on. It*

*always works this way, when I am chasing a goal I am motivated but then once I've got it... I mean what is sexy about staying the same?'* (Small Changes group 4 session 1)

Particularly in the context of public health and weight management it is the long-term behavioural change that commissioners and practitioners are seeking for their clients.

### **1.15 The psycho-linguistics of change**

MI practitioners concentrate on the psycholinguistics of change- Paul Amrhein (Amrhein, 2003) contributed to the understanding of client change talk when he suggested two sub-categories of change talk are often elicited in client speech with one category being stronger than the other in predicting change.

Change talk is either *preparatory* or *mobilising* language with preparatory language signified by clients, for example, saying: *'I should, I want, I could, I ought to,'* these are expressions of Desire, Ability, Reason and Need, essentially alone, such statements are fairly weak predictors of actual change. The stronger mobilising language relates to Commitment, Activation and Taking steps e.g.: *'I am going to'* and *'I will'*. or *'I have started to'* Change talk is often described using the acronym: DARN/CAT.

In sessions with clients I actively seek to identify and strengthen change talk by seeking elaboration, affirming, reflecting and summarising the different forms of change talk. For example, if a client is exhibiting change talk: *'I really feel I ought to do something about this'* I may then ask for elaboration: *'when you say ought to- what do you mean?'* which is likely to lead to more change talk from the client. The rationale for focussing on change talk, (particularly promoting its frequency and



strength via open questions, complex reflections for example) is that this may directly lead to increased likelihood of the desired behaviour change being affected (Gaume et al., 2010; Miller et al., 1993).

### **1.16 Autonomy**

MI is directional as well as client centred. This means that although the focus of change and the decision to change remains with the client, the practitioner, when using MI is steering (often via selected complex reflections) in the direction of change. Indeed it is perhaps non-sensical to have a job title nutritionist for example and expect that going into consultation there is absolutely no agenda on the part of that professional. Autonomy is important as it is not the practitioners to either give or take away (in the present weight management context) but rather is a matter of volition for the client. Autonomy and the expression of this by the practitioner (e.g. *'it is, of course, only you that will decide whether you do make this change or not'*) is key in the demonstration of MI. the expression of autonomy may help the client feel free to choose change without the encumbrance of a professional pressure that they 'must' change.

### **1.17 Ambivalence**

Ambivalence is a core concept in motivational interviewing, the see-saw area of change that people go through when making decisions about whether to change or not. A key idea in MI is 'resolving' ambivalence. Practitioners seek to help clients resolve ambivalence and in some cases have a vested interest in influencing behavioural decisions (an example is where the worker is a smoking cessation specialist and they seek to influence the outcome in the favour of reducing or stopping smoking) It is this 'directionality' which means MI diverges from Rogerian/person centred counselling where, theoretically at least, the counsellor is

not trying to influence outcomes. There are examples in MI where directionality has no place, for example a non-health related ambivalent situation where a client is considering divorce. Here the therapist's responsibility is to 'equipoise' (state of balance) - a non-directionality that sees the client balancing argument for and against but does not seek to influence in one direction or another.

MI focusses on clients who have reasons to change and also reasons to maintain the status quo. A stark example is the client who says:

*'I would like to get fitter, leaner, have more energy... I also like sitting on the sofa eating cheese cake and watching DVDs'*

In relation to medication adherence, smoking, drinking, diet and exercise there is often significant ambivalence over change.

A passage from DiLillo and colleagues' paper on incorporating MI into obesity treatment goes some way towards explaining the relationship between MI and ambivalence:

*“The waxing and waning course of weight loss, the strong potential that overweight clients have a history of prior weight loss failures, and the large number of complex behavioural changes required in weight reduction programs may set the stage for significant ambivalence for some or all of the required changes. MI seeks to move clients into action by identifying discrepancies between their current behavior and desired goals”*

(DiLillo et al., 2003. p.120).

### **1.18 Resistance/discord**

It has been long considered that instructing and information giving can be counter-productive in client/practitioner interactions - often leading to 'resistance' and even dis-engagement between client and practitioner.

MI seeks to avoid argumentation. The phrase: 'rolling with resistance,' was originally used to encapsulate this. Developing discrepancy e.g. between the client's goals and wishes and actual behaviour and promoting autonomy are key features to MI encapsulated by the acronym RULE, (Rollnick et al., 2008):

**R-** Resist the righting reflex

**U-** Understand your client's motivation

**L-** Listen to your client

**E-** Empower your client

More recently MI commentators have begun to talk of 'discord' between the client and therapist as perhaps, resistance implies a value judgment onto the client- and in reality there is discord between two people in a conversation rather than one simply refusing to do what they are told.

### **1.19 Treatment fidelity to MI**

Treatment fidelity seeks to clarify and ensure whether an intervention described specifically (motivational interviewing for example) is commensurate with what experts in that approach to behaviour change say it should be. This is an important professional issue and relates again to the question of what is a professional? Perhaps it is easy to describe an approach or intervention as MI but it is also thought that 'proof' of treatment fidelity is lacking in many studies claiming to use a particular approach (Moyers et al., 2005; Armstrong et al., 2011). What is, therefore, needed is

clearer evidence that the approach was adhered to and understanding of what has actually *been done* in a 'behavioural' intervention (i.e. the therapist's behaviours' and the client's responses and subsequent behaviours). For the present study a 'taxonomy' of behaviours has been produced by analysis of the recorded sessions and is greatly informed by the work of other researchers (Michie et al., 2011; Abrahams & Michie, 2008). The taxonomy included in the method section shows the specific behaviours employed in each of the sessions. Inclusion of MI as a 'technique' in Michie and colleagues' work, is incongruous as MI is an approach typified by both technical skills and underlying 'spirit' in the same way that cognitive behavioural therapy or person centred counselling are identifiable as distinct, yet sometimes converging, therapies. So in this project there is an adapted taxonomy based on Michie and colleagues' work to take this issue into account. The taxonomy is given over to identifying specific behaviours carried out during therapy e.g. OARS (Open questions, Affirmations, Reflections and Summaries).

Whilst a description of MI and understanding what it is, are essentially fairly simple, (indeed MI is often introduced via a two day workshop) effective practice and evidence of competence in MI takes somewhat more time. In counselling approaches clinical supervision and reflection of practice are needed to develop and enhance skills. In MI tools for assessing this 'treatment fidelity' are popular (for example the Motivational interviewing skill code (MISC) and the motivational interviewing treatment integrity scale (MITI) coding tool in its various iterations. Sometimes tools are developed by researchers for their own practice, for example the 'Healthy Lifestyle Pilot study' developed the 1-PASS, which was made up of a rating form,

and this has several MI dimensions described and includes a scale from 1 to 7. A score of 4.0 or more was deemed to indicate adequate MI proficiency.

Despite the fact that counselling/psychotherapeutic approaches need considerable skill, and researchers suggest evaluation and maintenance of treatment fidelity is essential (McHugh & Barlow, 2010) the degree to which this skill is assessed remains limited. In a study on interventions undertaking physical activity counselling only 5 of 26 studies reported treatment fidelity (Breckon, Johnson & Hutchison, 2008). The critical issue here is that although the studies included reported physical activity outcomes the degree to which a given counselling approach was adhered to was unclear. It is therefore reasonable to assume that 'evidence bases' may be falsely representing the relative efficacy of a behavioural approach.

A gold standard for this sort of 'coding' for MI is the Motivational Interviewing Treatment Integrity or MITI tool, currently in its third edition (2012). Treatment Fidelity is considered essential for practitioners to assert that the approach they have used actually is that approach. This is perhaps a necessary safeguard in an approach as accessible as MI. Practitioners can start to train via two day workshops and then build up skills via further training, but without clinical supervision, reflective practice and coding, proficiency will always be in doubt.

The MITI was developed by Moyers and colleagues (2005) and evolved from the MISC (MI skills code) as a means to reduce the complexity of assessing therapists' interactions. It has two components: global ratings and behavioural counts. Madson and Campbell (2006) in a review of fidelity measures in motivational enhancement assess the MITI as 'showing promise' in relation to reliability for observation of

psychotherapy sessions since this time the MITI has gone through two further iterations and is now in its third version MITI 3.0. Intraclass correlation coefficients (ICCs) were assessed by Moyers and colleagues (2005) and were 0.51 for empathy/understanding and .58 for spirit. There was also a range from 0.52 to 0.96 for behavioural counts. Madson and Campbell conclude that these ICCs are 'fair' in relation to clinical significance and yet could be improved (0.40 = poor, 0.40-0.59 = fair, 0.60-0.74 = good, 0.75 = excellent, Cicchetti 1994). Martino and colleagues (2008) also describe the efficiency of MITI and MISC in assessing competency as still 'questionable' yet also suggest that expert-led workshops, followed by clinical supervision are effective means to become proficient in MI.

### **1.20 MI and Social Determination Theory (SDT)**

Motivational Interviewing is not based upon a founding theory; rather it is the result of a psychotherapist's observations in relation to working with client's and the foundation of person centred therapy.

More recently (Vansteenkiste et al., 2012) MI has been thought about with reference to self-determination theory (SDT). SDT essentially posits that intrinsic motivation, the motivation for why people do it for themselves, is stronger than the extrinsic kind whereby somebody is attempting to change for someone or something else. MI could essentially be a vehicle of delivery for SDT. Accordingly SDT would offer MI therapists a potential guide and format to the content of their counselling. Indeed, some SDT-based projects have already delivered interventions using MI strategies (Fortier et al., 2012).

It seems justifiable to suggest that MI practitioners and SDT theorists may need greater understanding of each other's 'basis'. For example, Patrick and Williams (2012) describe MI as a 'set of techniques' which is contrary to Miller and Rollnick's

own understanding of the approach of MI with its contingent elements of spirit and principles. Other elements of MI (OARS for example) do serve as 'techniques' but without an understanding of the underlying approach are redundant. Patrick and Williams (2012) also call for more research to clarify the overlap between MI and SDT.

The next chapter is a systematic review relating to the relative success of well-founded or 'comprehensive' weight management programmes. This then leads into a second literature review critically analysing the work done around MI, behaviour change and weight management.

## **Chapter 2: Study 1, Systematic review- How Successful are 'comprehensive' weight management programmes? Published Dec 2013**

### **2.0 Introduction**

This literature review sets out to identify how successful weight management programmes are when: body-composition, physical activity, nutrition a behavioral change approach and a relatively long period of follow-up are included. These factors are suggested as the constituents of a 'comprehensive' programme. 'Success' is defined by positive changes in the above areas and not solely weight-change. The background to the area and the factors involved in a comprehensive programme are covered before the inclusion criteria for the literature review is explained. The method for carrying out the review and the analysis is then described. A flow chart for identifying and assessing papers from the database is included. A description of the critical appraisal skills programme (CASP) analysis tool, used to initially assess the papers, is also included. A results section then reviews what was found from the papers that were included for this review and highlights the results and findings relative to the above mentioned criteria. A brief discussion and analysis section overviews the main findings from this work, its limitations and suggestions for future reviews.

### **2.1 Background**

Obesity is widespread in the Western world. The number of people in the United Kingdom and the United States, who are either overweight or obese, according to the Body Mass Index, means that it is now 'normal' to be overweight (DOH, 2010). Health problems connected with being overweight are numerous with cardiovascular disease, type II diabetes and certain types of cancer being most prominent. The focus of interventions suggested by Foresight (2007) should be on prevention of excess



weight gain and body-fat deposition in children, changes to food policy, changes to the built environment and weight management with the intention of preventing illness and disease in those already overweight.

Recommendations for physical activity and food differ internationally but are fairly similar to those in the United Kingdom. For those people who are or have been overweight or obese the recommendation is 60 minutes a day of moderate intensity activity on most days of the week (DOH, 2004). However the Health Survey for England in 2008 reports firstly very low levels of physical activity as per previous studies and also uses accelerometry to assess activity levels rather than self-report. These accelerometry results, based on measures from representative samples, suggest that self-reports are probably over-reports and that only 6% of men and 4% of women met the government's guidelines for physical activity (DOH, 2010).

Recommendations also exist for strength training (one set of 10-15 repetitions of between 8 and 10 exercises performed 2-3 days a week). Resistance exercise augments the benefits gained from aerobic training in that it is protective to lean tissue, bone mineral density and results in higher metabolic rates as a result of the additional lean tissue (Surgeon General, 1996). Within the data for physical inactivity there appears no information on how many people engage with exercise that is protective in relation to lean tissue, bone health and balance in the elderly.

Accurate dietary analysis is notoriously difficult to achieve, however, most people in the UK population do not eat the minimum recommended level of at least five portions (400g) of fruit and vegetables recommended by the World Health Organisation (Nishida et al., 2004).

Overweight is ultimately a result of energy intake exceeding energy needs. Genetic differences do occur between individuals but these are seemingly only now expressed

as societal changes to energy use and consumption have meant that genetic predisposition to obesity has been exacerbated in the western world . The identification of the genetic connection to overweight and obesity should provide strong impetus for lifestyle change.

This review contributes to the analysis of what should be included in a weight management intervention for those who are already overweight. It does this by focussing on how 'successful' programmes are that are also considered to be 'comprehensive'. The terms 'success' and 'comprehensive' in this context clearly need defining. This work fills a gap in relation to assessing the effectiveness of studies that use behavioural change techniques, exercise and nutrition and monitoring of body-composition, as well as weight, and measure/treat participants for at least one year. Discussion around what represents a comprehensive weight-management programme could reasonably conclude that the key features are the inclusion of nutrition/food, physical activity and a clear element of behaviour change (Soderlund, 2009; Peri et al., 1984) and a reasonable period of treatment, (Peri et al., 1989) with realistic goal setting as part of the approach (NICE guidelines, 2006).

Soderlund and Fischer (2009) undertook to scrutinise physical activity with/without diet and behaviour modification and found that a combination of exercise, diet and behaviour was favourable. Sharma (2007) reviewed behavioural interventions in treating obesity in adults, recommendations based upon the review include that physical activity and nutrition behaviours must be approached. This review also highlights the need for clear behavioural theory to underpin interventions. The difficulty where the theory is not clear relates to replicating the programme,

identifying what has/has not worked. Based upon the results from this review Sharma also highlights the need for a treatment period of at least 6 months.

## **2.2 Body-composition and quotient of positive change**

Lean tissue loss might/should be considered negative in weight loss programmes just as fat tissue gain is considered negative. This may be especially true where sarcopenia and bone mineral density are key issues (Roubenoff 1997; Fried 2001) e.g. for post-menopausal women and the elderly who are at greater risk of osteoporosis. Physical activity, particularly resistance training has been shown to be protective of lean body tissue in older people whether they lose weight or not whereas weight loss without physical activity results in loss of ‘functional’ lean tissue (Jansen et al., 2002). This functional lean tissue is essential in maintaining limb strength, balance and reducing risk of falls in the elderly.

## **2.3 Physical Activity**

An increase in physical activity has been suggested to affect psychological well-being improvements (Fox, 1999) to the point of concluding that clinical depression can be effectively treated with exercise. Enhanced dietary intake to proffer protection from disease *irrespective* of weight loss and the concept of ‘health at any size’ needs further exploration (Bacon et al, 2005). Seminal work from a large cohort study has shown reduced risk from cardiovascular disease and correlated conditions in persons who for instance are physically active yet overweight (Paffenbarger, 1986).

## **2.4 Treatment Length and Follow-up/ maintenance**

Peri and colleagues (1989) first identified the effects of different treatment lengths in the 1980’s. This issue of how long to treat/run an intervention is vital. However,

given the implications for funding interventions, cost-effectiveness has to be a consideration for commissioners and researchers/practitioners running an intervention.

One-year follow-up of measurements in weight management programmes should perhaps be considered the minimum period for interventions looking for sustained weight management. This is the inclusion criteria for the National Weight Control Registry in the United States. The present review uses a minimum of one year's 'treatment' (which includes carrying out measurements as treatment) as an inclusion criterion.

## **2.5 Nutrition**

Attention to nutrition for weight management is paramount; the relationship between our eating habits and obesity however, is still unclear. Suggestions that the massive rise in people being either overweight or obese is due to gluttony are confounded by the suggestion that our calorie intake over decades has changed little or not at all and has maybe even declined (Prentice & Jebb, 1995). Despite this an energy imbalance is implicated in overweight and obese individuals. Genetic factors may explain individual differences in rates of weight gain amongst people following the same lifestyle i.e. levels of exercise and Kcalorie intake, (Bouchard, 1990) but the principal factors in the aetiology of overweight and obesity are considered to be environmental/behavioural rather than biological (Foresight, 2007).

This leads to the conclusion that just concentrating on one part of the energy balance is non-sensical. Even if health gain and not weight loss is the target, nutrition impacts heavily on our risk of disease irrespective of weight. An example is given by Bazzano and colleagues (2008) who studied a large cohort of people and found that intake of

green leafy vegetables and whole-fruit was inversely associated with type II diabetes development irrespective of BMI.

## **2.6 Behavioural Approach**

Behaviour change in the context of weight management often relates to physical activity and nutritional change. The approach, however, for achieving changes clearly differs. Some programmes have a strict prescriptive protocol and the aim is to use behavioural techniques to help participants achieve that prescription. Others focus on facilitating participants who make the decision over what changes they make. Often Behavioural programmes are not based on a specific theory of behaviour (Sharma, 2007) and indeed only two in this review are.

## **2.7 Weight Loss**

Wing and Hill defined a 10% loss of starting weight as a parameter for measuring success (Wing & Hill, 2001) yet they also conclude that >5% of starting body weight is the point at which significant clinical improvement and reduction of risk for key lifestyle diseases occurs. As long-term weight loss maintenance is notoriously difficult to achieve, focus on what gains people can make by staying the same weight, losing a little weight and improving key lifestyle indices of health is implicated.

## **2.8 What is a Comprehensive programme?**

The criteria for a comprehensive weight management programme therefore arguably should include: a minimum treatment period of 1-year, the inclusion of nutrition, physical activity and behaviour change. Measurements should include: body-composition, weight, dietary-composition, psychological well-being, levels of physical fitness (or amount of participation in physical activity) and dietary change.

Participants in weight management programmes might also be usefully convinced of the efficacy of improvements to diet and physical activity *without* weight loss. Although the other factors are deemed important indicators of health protection weight-loss is arguably the primary outcome measure in interventions seeking to improve health this is despite years of data collection demonstrating the extreme difficulty people have in maintaining large amounts of weight loss.

## **2.9 What is success?**

Success also needs qualification, with some rationale for a ‘clinically significant’ weight loss maintained for a certain period representing a reasonable indication of success (Wing & Hill, 2001). Some programmes consider body-composition and others do not. The present review attempts to evaluate the success using the following criteria: body-composition, as well as weight loss,  $\geq 1$  year of treatment, inclusion of both physical activity and nutrition combined with a behavioural change approach.

Success is defined, for the purpose of this review, by improvements to any of the parameters discussed above. Success may include weight loss or else body-compositional change, fitness gain, improvement to dietary indices or improvement to general well-being; i.e. success should not relate exclusively to weight loss.

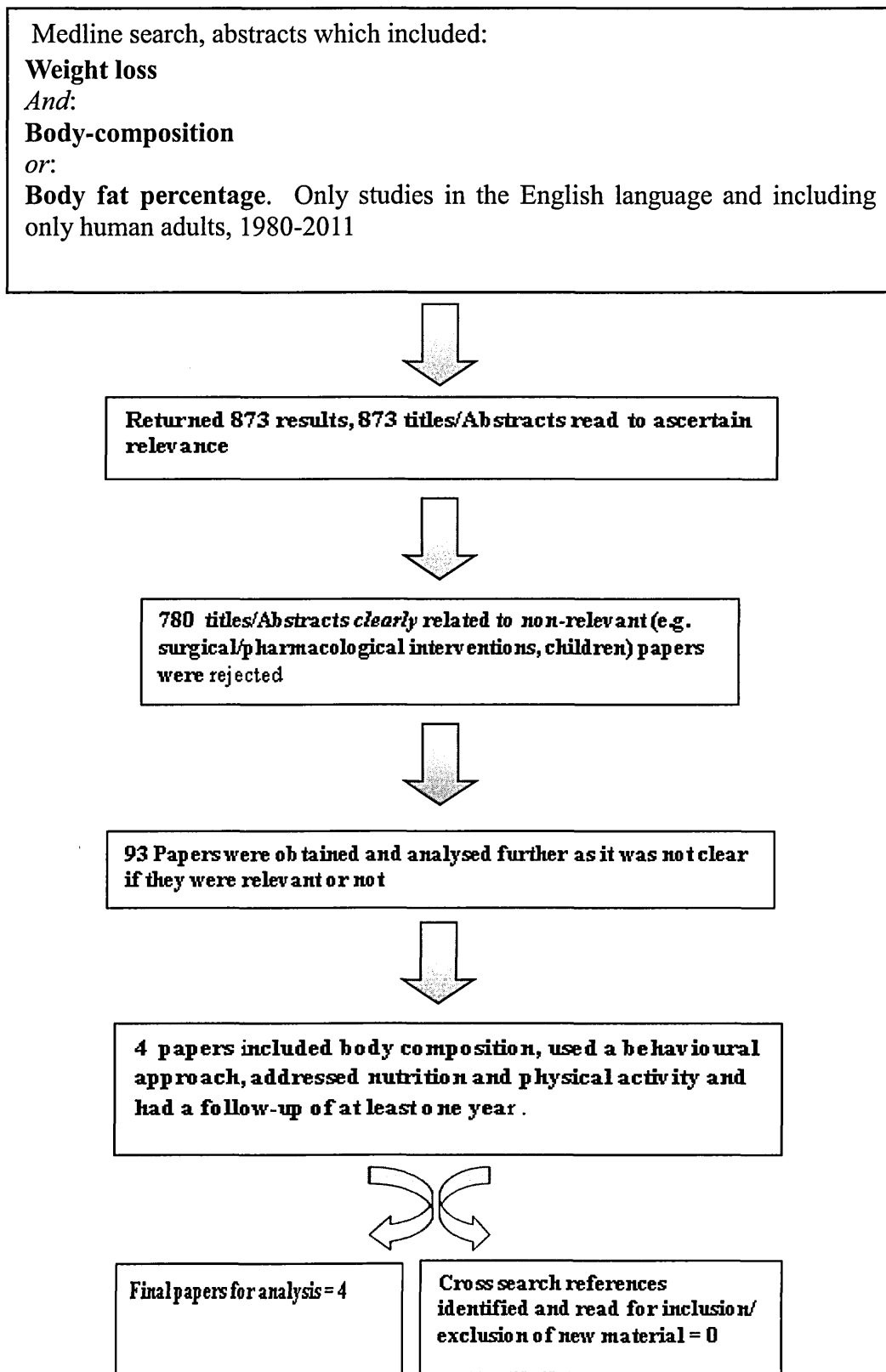
## **2.10 Inclusion Criteria**

Inclusion criteria for this systematic review were as follows: the study had to be a randomised trial. The subjects had to be adults. The publication had to be in the English Language. The date of the study needed to be between 1980 and 2011. The subjects studied needed to be overweight but otherwise healthy. The treatment period needed to be at least one year or else the follow-up post-treatment needed to be at least one year. Studies that looked at physical activity and/or nutrition but had no element of behavioural change were excluded. All studies needed to include body-composition

as well as weight measurement. All the studies needed a subject number of more than 15. Included research papers should also have a control or comparison group element (but not necessarily be randomised control trials).

### **2.11 Method**

Papers were first sought using a Medline search that included the words: weight loss and body-composition or Body fat percentage. From 873 returns titles revealed 92 potential papers that met all the inclusion criteria. Upon examination of these 92 papers 4 were identified as fitting the inclusion criteria. A flow-chart showing the search process is included below, see figure 2. Other databases (CINAHL, COCHRANE and PEDRO) were searched for further results and on preliminary reading no obvious further papers were found. Despite this searching only one database is a limitation of this investigation and other should also be systematically searched.



**Figure 2. Flow chart showing method for identifying the literature included in the review**



## 2.12 CASP Analysis

This study involves analysis of four control trials. To help with this the Critical Appraisal Skills Programme (CASP) tool for analysing randomised trials has been used to inform the review. The programme developed in 1993/1994 and adapted from the work of Guyatt and colleagues (1993, 1994) assists researchers in appraising various study types in public health. The programme has a specific set of tools for each type of approach i.e. randomised control trials, cohort studies, review studies and other studies. The CASP tools include a series of questions (shown below in table 1) reviewers can use to assess the relevancy of the research under scrutiny. CASP suggests that three broad issues need to be considered when reviewing literature:

- **Is the trial valid?**
- **What are the results?**
- **Will the results help locally?**

Table 1. The CASP analysis main questions for analysing randomised control trials

1. Did the study ask a clearly-focused question?
2. Was this randomised controlled trial (RCT) and was it appropriately so?
3. Were participants appropriately allocated to Intervention and control groups?
4. Were participants, staff and study personnel 'blind' to participants' study group?
5. Were all of the participants who entered the trial accounted for at its conclusion?
6. Were the participants in all groups followed up and data collected in the same way?
7. Did the study have enough participants to minimise the play of chance?
8. How are the results presented and what is the main result?
9. How precise are these results?
10. Were all important outcomes considered so the results can be applied?

The four papers that met the inclusion criteria were analysed using the CASP tool and then sorted into five themes (behavioural approach, body-composition, weight loss,

nutrition, and physical activity) which in turn relate to the question: how successful are comprehensive weight management programmes? The results of the review are presented below, beginning with table 2 which shows the authors, subjects, intervention and main findings.

### **2.13 Results**

The four studies included overleaf in table 2- all met the CASP analysis questions and the search criteria of >1 yr follow-up, measures to body composition as well as weight and a clear behavioural approach involving attention to nutritional and physical activity behaviours.

Table 2. A brief description of the articles meeting the inclusion/CASP criteria.

Reference	Subjects	Intervention	Follow up	Results
1.Foster et al, (2010) <i>Ann Int Med</i>	USA, 307 men and women 45 yrs old	Weight and metabolic outcomes after 2 years on a low-carbohydrate versus low-fat diet.	2 years	11% wt loss at 1 year, 7% at two years. Increased (good) HDL cholesterol in the low carb group at all time points
2.Cussler et al, (2008) <i>Obesity</i>	USA 135 women, 40-55 yrs	4 month intensive behavioural programme followed by Internet or self-directed groups for one year.	16 month follow up	Wt loss maintained in both groups at 5% of starting weight. Internet did not surpass results of self-directed group.
3.Silva et al, (2009) <i>J Behav Med</i>	Portugal 239 37 yr old women	1-year weight management intervention based on self-determination theory.	1 year	Weight loss and higher levels of Phys act compared to controls. Behaviour more autonomously (intrinsically) focused at end of intervention.
4. Rapoport et al, (2000) <i>International Journal of Obesity</i>	63, 47.5 years overweight women	1 Year follow-up to people receiving standard or modified CBT which focussed on sustained lifestyle change & not dieting.	1 year	Both forms of CBT gave positive results: weight loss, improved emotional well-being, reduced distress, reduced CVD factors, improved dietary quality and increased fitness and physical activity participation

## **2.14 Behavioural approach across the studies**

The model of behaviour change differed from intervention to intervention (shown in Table 3 below) with one paper simply stating having used a 'behavioural weight loss program' (Cussler et al., 2008) and another describing 'comprehensive behavioural treatment' (Foster et al., 2010) who give examples such as: self-monitoring, stimulus control and relapse management and a clear example of one week's course content for each arm of the low carbohydrate versus low-fat diet. Silva and colleagues (2009) used self-determination theory which focuses on internalising or making intrinsic motivating factors for carrying out an activity that may have been extrinsic or have externally motivating factors, with the rationale that when the motivation for action is internalised it becomes autonomous and results in favourable outcomes for weight management.

Finally Rapoport and colleagues (2000) evaluated the use of cognitive behavioural therapy (CBT) modified especially for weight management (M-CBT) versus a standard CBT (S-CBT). The researchers emphasised a non-dieting approach where instead the focus was on lifestyle change and minimising future weight gain (Rapoport et al., 2000). CBT has an existing evidence base for a range of health problems (Butler, 2006) and takes a variety of approaches including challenging unhelpful thinking and trying out behaviour that may have been previously avoided (Westbrook, 2007).

All studies appeared to follow a semi-prescriptive approach, (to some extent, setting goals determined by the researchers rather than the clients e.g. amount of energy

restriction, amount of physical activity) whilst describing tailoring the intervention to the individual's needs.

Table 3. Behavioural approaches

<b>Paper</b>	<b>Behavioural approach</b>
Rapoport, Clark and Wardle (2000)	Cognitive Behavioural Approach
Cussler et al (2008)	'comprehensive behavioural approach'
Silva et al (2010)	self-determination theory
Foster et al (2010)	'behavioural weight loss approach'

### **2.15 Physical activity**

Physical activity was an element in all the papers reviewed with approaches varying between a prescription of exactly how much exercise should be done, for instance Rapoport and colleagues (2000) and Foster and colleagues (2010) prescribed a specific amount of walking, measuring what the participants did, in terms of physical activity without indicating that this was promoted/suggested by the programme (Cussler et al., 2008; Silva et al 2009). All papers described walking as the main mode of exercise.

All of the papers, except Foster and colleagues (2010), used physical activity questionnaires to assess the duration, (shown below in table 4) type and intensity of physical activity performed and Foster et al used self-report diaries for participants to record their participation. Walking has previously been described as a 'best buy' in public health terms (Hardman and Stensel, 2003) and seems the most readily repeatable, accessible form of exercise for weight management programmes. None of the papers discuss alternative modes of physical activity to walking.

Only one paper (Rapoport et al., 2000) measured ‘fitness’ per se recording lower heart rates at follow-up after repeating a three-minute step test. The other papers recorded increased physical activity participation mostly in the form of increased number of steps. One paper (Cussler et al., 2008) showed a clear relationship between quartile of number of steps and weight loss with those performing least, losing least and those performing most losing most weight and the quartiles in between suggesting a dose response relationship. A comprehensive review suggested that physical activity protects weight regain and may work alone in achieving significant weight loss without diet (Saris et al., 2003).

Table 4. Physical activity measurement

<b>Paper</b>	<b>Physical activity measure</b>
Rapoport et al., 2000	aerobic fitness via step test and questionnaire on leisure time activity
Cussler et al., 2008	7-day physical activity recall interview
Silva et al., 2010	7-day physical activity recall interview
Foster et al., 2010	self-report diary

## 2.16 Nutrition

Only one of the studies reported upon the changes to the quality of subjects' diets (Rapoport et al., 2000). Whereas all attempted to calculate energy intake and changes to calorie intake across the study period. Table 5 highlights the suggested differences between studies. Accurate dietary analysis is notoriously difficult to achieve and subjects are known to under-report intake. Foster and colleagues (2001) focussed specifically on following up participants randomised to either a low-carbohydrate diet or a low-fat diet, saw no body-compositional or weight loss differences between the two groups but more positive blood lipids (and worse side-effects- hair loss, dry

mouth, bad breath, constipation) were found in the group consuming a low-carbohydrate diet.

3-day and 7-day diet diaries were used in two studies and the remaining two describe self-reporting. Rapoport and colleagues (2000) describe detailed nutrient intake, reporting significant reductions in energy consumption, fat intake (both saturated and unsaturated) and sucrose intake. Similarly there were significant increases in protein carbohydrate consumption. This data might be useful across all studies for many reasons e.g. dietary improvement may belie a lack of weight loss.

Table 5. Nutritional assessment

<b>Paper</b>	<b>Nutritional measurement</b>
Rapoport et al.,2000	Epic Food Frequency Questionnaire (estimated measures)
Cussler et al.,2008	3-day diet diaries
Silva et al., 2010	Not measured
Foster et al., 2010	Participants were 'instructed' to eat a set amount (1200-1500 kcals for women, 1500 to 1800 Kcals for men) no mention of how this was monitored

## 2.17 Weight Loss

Table 6 shows the weight loss achieved by each intervention. Across the 4 studies the mean weight loss at one year was around 7% of starting bodyweight. This meets the 5-10% loss of starting weight that can result in substantial reduction of risk from heart disease and type II diabetes (Hill and Wing, 2001). However, the participants' bodyweights at baseline were not the same (neither was BMI) making a mean weight loss across the studies less meaningful. The study with participants achieving the greatest weight loss at one year was also the study with the heaviest subjects.

The baseline bodyweights of participants in all the studies were a mean of 91.8kgs. BMI ranged from 31 to 36 across the studies. Does measuring weight loss as the key indicator send researchers the wrong way? I.e. 2% weight loss or change in body-composition maintained over ten years trumps a 10% loss followed by total regain of weight after two years.

Table 6. Weight loss

Study	Baseline bodyweight	Weight loss
Rapoport et al.,2000	94 Kg	1.9 kg
Cussler et al.,2008	84.6Kg	4.6 kg
Silva et al.,2010	82.1Kg	5.6 kg
Foster et al.,2010	103.5Kg	7kg

## 2.18 Body-composition

There are various methods for measuring body-composition including dual energy air displacement plethsmography absorptiometry, bio-electrical impedance (BIA) and the gold standard measure hydrostatic weighing. Three of the four studies used dual x-ray and BIA for the body-composition analysis. These methods are often used instead of underwater weighing which requires a specialised tank and equipment for analysis and can therefore be prohibitively expensive. Dual energy air displacement plethsmography absorptiometry and Bio-electrical impedance have been shown to correlate highly with the hydrostatic weighing method with both obese women ( $r= 90$ ,  $p=.001$ ) and healthy weight ( $r=96$ ,  $p=.0001$ ) individuals (Erselcan et al., 2000).

Rapoport and colleagues (2000) study used only Waist to Hip Ratio (W:HR) to assess body-composition change and found no change in the subjects WHR even though the subjects had lost two kilograms of weight by the end of the programme. Here we must assume that all the weight loss was lean tissue or that the WHR is not sensitive enough



to detect such small changes to body-composition. The remaining studies all showed loss of lean tissue with around 20-30% of the weight loss coming from lean (NB not all the studies showed statistically significant changes to lean tissue, a meta-analysis of results might help determine). There is acceptance of some weight being lost in weight loss programmes coming from lean; however a question arises here over whether protein intake and physical activity should be emphasised or reinforced in an attempt to minimise loss of lean tissue.

A comprehensive programme might pay close attention to the detail of body-composition and attempt to maximise lean tissue protection. A portable and relatively inexpensive method such as BIA is the most likely method in a community or non-lab based weight management project.

### **2.19 Validity, applicability, reliability**

Power calculations were performed and expressed in all four studies, subject numbers varied from 63 to 307 and all the studies used P-values to express statistical significance for most results. All studies provided a Consort diagram. In human interventions like those presented here, drop-out is a problem and a statistical solution used for 'missing' subjects is baseline observation carried forward (BOCF) where data is input from an earlier time interval to fill in the gaps that occur from participants who drop out or are, for any reason, not measured at the end of the intervention. The BOCF method has been criticised (e.g. Satimazumdar et al., 1999) as the concept ultimately relies upon the assumption of what would of happened to subjects had they not dropped out.

## 2.20 Discussion/Analysis

The included studies all found a 'clinically significant' weight loss at  $\geq 1$  year i.e. between 5 and 10% of initial weight. However, studies did not all include analysis or discussion around the body-compositional data. Two reported differences in body fat percentage from pre to post-intervention but did not examine the ratio of fat to lean loss (Cussler et al., 2008; Rapoport et al., 2000) while the other two show that ratio (Silva et al., 2010, Foster et al., 2008). For example, In Silva's study there was a 5.6 kg loss of fat mass and a 1.1 kg loss of lean body mass. In the Foster study 2kg of the 7kg lost was lean tissue. This information should arguably be included in interventions studying weight management. It is data which adds to our understanding of different interventions and their effects on body-composition/metabolism.

Other work has shown an 80/20 ratio of fat to lean tissue loss, and there may be a protective effect from both physical activity and protein intake on protecting lean tissue during weight loss (Layman et al., 2005). Inclusion of a 'comprehensive' approach to weight management is implicated. Focus should be on preserving lean tissue and losing fat and not just the objective of weight or fat loss alone. The focus on fat loss may in fact obfuscate important metabolic/protective results for people who do not lose weight during an intervention but do make important changes to key indices of health as a result of that intervention (for examples: get fitter increase lean tissue, get better control of blood lipids and blood sugar and increase their score on well-being scales). Body-composition and these other measures could be as important as or more important than weight loss.

There are multiple weight management programmes in the Western world being carried out by researchers, health services and in the community. Clearly when the parameters of conducting a comprehensive programme and achieving clinically

significant weight loss, as outlined by Wing and Hill (2001), are employed, the programmes that have been scrutinised in this review are successful in meeting both criteria.

The problem of overweight is widely considered to relate to nutrition and physical activity and people's behaviour in relation to these. Approaches that include all three of these elements are sufficient in length to gain maximum effect and also consider key measurements of health (not just weight) have been analysed for this review.

However, an outstanding further consideration for debate for public health interventions is cost-effectiveness. There doesn't seem to be inclusion of this in any of the papers reviewed here. The solutions sought by public health providers need this element including so that commissioners are able to assess not only how robust the approach is but also whether it can be paid for. Often interventions run on research grants or money from the public purse. This begs the question: if we do identify and agree upon what success is and how it is achieved, can we afford to pay for it? The United Kingdom, for example, spent £4 billion on obesity-related treatment costs in 2007, projected to rise to £9.7 billion by 2050. In the United States obesity treatment is around \$160 billion.

Body-composition is an important element of weight loss programmes; indeed focus on weight loss alone is negative as it belies the other key parameters that may proffer protection for health as mentioned above. Using an equation, such as the one proposed here, that identifies both negative and positive weight loss and maximising strategies to preserve lean tissue whilst losing fat tissue will be useful. The inclusion of comprehensive content, exercise, nutrition, a behavioural approach and sufficient follow-up are all included in comprehensive interventions.

### **2.21 Future work**

In the field of weight management, the inclusion of a comprehensive programme and clearly agreed measures of success needs augmenting with cost-effectiveness data. What use is the most effective, comprehensive programme if it cannot be paid for? This review sets the scene for further long-term weight management projects which arguably need to include the factors identified herein to qualify as 'comprehensive'.

### **2.22 Limitations**

This review is based upon a search from one database and other databases may provide more material for inclusion. A scoping exercise appears to reveal no obvious new material from COCHRANE, CINAHL AND PEDRO but systematic checking of references is needed before this can be concluded. Alterations to search terms may have also revealed additional results.

This review suggests more than changes to weight need to be accounted for in weight management programmes when assessing efficacy; furthermore an argument for a clear behavioural change approach combined with both food intake and physical activity are implicated by this study. It leads into a literature review which begins by introducing the range and scope of weight management programmes available including some analysis of their relative strengths and weaknesses.

### Chapter 3: Literature review for study 2

This chapter critically evaluates the range and development of weight loss interventions proposed and evaluated in recent decades and secondly critiques the contribution of MI to the area of weight management. This follows on from the systematic review published in 2013 titled: *What should be included in a comprehensive weight management programme?* These two chapters combined focus on the aim of the thesis: to assess the relative efficacy of the Small Changes programme versus treatment as usual and simultaneously explore treatment fidelity in relation to motivational interviewing in the Small Changes programme. The first systematic literature review seeks to answer the question: what equals success in weight management? The usefulness of this is that it then informs significantly what is included in the Small changes programme. The second review contributes to the aims by critically exploring the range of potential interventions to help manage weight and their relative efficacy before focussing in on MI for weight management and the argument for involvement of treatment fidelity.

The first section of this review establishes the imperative for weight management research and then introduces the various approaches to weight management and their development over recent decades.

In the next section the different approaches to weight management are critically assessed beginning with studies which looked at optimal length of treatment and the inclusion of psychotherapeutic approaches for weight management programmes.

Next the pharmacological treatment of weight is assessed with a view to exploring the contribution of popular pharmacological weight loss medications using sibutramine and sibutramine products and Orlistat (xenical) as key examples.

Commercial weight loss interventions and exercise and diet therapy approaches are critiqued in the next section of this review. In combination these sections support the basis for the methodological approach of the current investigation. These sections also give a rationale for dismissing certain approaches (e.g. pharmacotherapy and persuasive-advice giving).

The final section follows on from this by critically reviewing the literature in relation to motivational interviewing as a therapeutic approach in the context of weight management. This last section critically appraises the contribution and efficacy of motivational interviewing groups for weight management. The rationale for this review is to consider the range of possible approaches to weight loss/management and to critically explore these as alternatives to the approach undertaken in the present study.

### **3.1 Essential components of behavioural weight management research**

It is now normal in the United Kingdom, United States and several European Union countries to be overweight. 68% of men and 59% of women in the UK are either overweight or obese and of this one quarter of our adult population are in the obese category signified by having a BMI of greater than 29.9kgm<sup>2</sup>. In the US population these values are significantly higher with, for instance, 35% of the adult population now obese (Health Survey for England, 2012). The fact that so many people fit these higher BMI categories of overweight and above, i.e. obese and morbidly obese, is compounded by increased morbidity and mortality in both overweight and obese people but especially in the obese (Guh et al., 2009). Body mass index has continued to rise over several decades in Westernized populations with a doubling of obesity

prevalence amongst adults in the UK occurring over the last 25 years (Public Health England, 2013). The growing litany of health complaints was first hinted at and then firmly established within the scientific literature base including, cardiovascular disease, stroke, diabetes, many cancers, sleep apnoea, asthma and arthritis. In a systematic review and meta-analysis Guh et al concluded that obesity is clearly associated with: *'the incidence of type II diabetes, all cancers except esophageal and prostate cancer, all cardiovascular diseases, asthma, gallbladder disease, osteoarthritis and chronic back pain. Obesity defined by BMI was also most strongly associated with the incidence of type II diabetes in females'* (Guh et al, 2009) p2458.

### **3.2 Diet cycling**

It is clear that short-term weight loss is achievable for many people, yet concerns about weight cycling suggest that people who continuously lose and then re-gain weight may be at more risk of ill-health and death than those who remain consistently overweight (Wamala 1999, Gregg et al., 2003; Jandacek., et al 2005, Bacon & Aphramoor, 2011). Subsequently research imperatives include focussing on interventions that continue or are followed-up for at least one year. A further issue arising from weight cycling is 'healthful change' to behaviour in someone who remains overweight i.e. this explores the possibility that people can carry out health protecting behaviour without necessarily changing weight (Bacon and Aphramoor, 2011). With this last point in focus weight management projects should include a range of measures besides bodyweight to assess success.

### **3.3 Diverse approaches in the history of weight management**

There is now a wealth of extant research on behavioural weight management programmes; Perri and colleagues carried out seminal work around weight management programmes and behaviour between 1984 and 1993 when this area of

research was in its infancy (Perri et al, 1984, 1987, 1988, 1989, 1993). Although interest in weight and body-shape can be traced through the ages the commercialisation of weight loss and weight loss products and popularised marketed fad diets started in the 19<sup>th</sup> century; 1880 in the United States and around 20 years earlier in the U.K (Yager 2010). Weight Watchers was founded in the United States in Brooklyn New York in 1963 and Slimming World in Derbyshire in the United Kingdom in 1969. It was the 1980's when researchers essentially started to answer the questions: how long should treatment be? And what are the effects of a behavioural intervention on weight management? In one study Perri's group assigned 48 obese patients to either a 20 or 40 week treatment protocol involving stimulus control, self-reinforcement (of healthy behaviours), cognitive modification, problem solving and programmed aerobic exercise. Those on both the 20 and 40 week programme lost the same amount of weight at 20 weeks, however at 72 weeks those on the longer treatment protocol had maintained significantly greater weight loss than those on the 20 week arm of the trial. The lasting contribution from this work was the idea that, to some extent, longer treatment leads to better outcomes (Perri 1989) with treatment seemingly being enhanced by lasting for around a year but with no further outcomes by extending beyond this.

In practical terms, however, weight loss interventions have been typically short-term , for example 15 weeks was the mean programme length for programmes run in the 25 years between 1969 and 1993; this may simply have been/still be a convenient period of time to run a programme (Miller et al 1997). Miller et al's meta-analysis of weight loss papers also yielded the finding that at one year weight loss was around 11kgs at 15 weeks but only 6.6 and 8.6 kg at 1 year- in groups using diet and diet plus exercise respectively (Miller et al., 1997). More recently work began to focus on the idea of



'clinically significant' weight loss i.e. the amount of weight loss needed to effect protection from disease. Wing and Hill (2001) settled on the idea of a 10% loss of starting weight as representing 'success' although the authors acknowledge that protection from disease accrues after weight loss of less than 5%.

### **3.4 Percentage weight loss in clinical weight loss studies**

In a systematic review and meta-analysis which included 80 clinical weight loss studies Franz and colleagues (2007) found a mean weight loss of 5-9% of starting bodyweight (weight loss plateaued at around 6 months). At 48 months the few studies which extended this far showed 3-6% of that weight loss was maintained. Studies in the review included those which assessed; diet alone, exercise alone, diet and exercise together, meal replacements, very low calorie diets (VLCDS) and weight loss medications (Orlistat and Sibutramine). The meta-analysis carried out as part of the review encapsulated 26,455 subjects. The review concluded that diet and exercise combined resulted in modest maintained weight loss. The notion that weight loss alone is the criterion for success, perhaps needs challenging; many authors did not, for example, assess whether weight loss was accompanied by positive changes to body composition. This issue is explored further in section 2.7.

### **3.5 Pharmacotherapy for weight management**

Franz (2007) concludes that the weight loss medications sibutramine and orlistat somewhat augment the effects of diet and exercise. However, more recently the World Health Organisation (2010) published data to suggest a 16% increase in myocardial infarction, stroke, cardiac arrest and CV death amongst sibutramine users resulting in withdrawal of the drug in 2010 (WHO, 2010). In the case of Orlistat (Xenical) concerns over kidney injury (Beyea et al. 2012) are accompanied by some additional (limited) weight loss- the effects and negative side effects (largely

resulting from fatty stools as Orlistat inhibits the absorption of dietary fats and hence increases faecal fat excretion). These factors call in to question its acceptability as a weight management intervention. In terms of empirical work carried out to assess the use of pharmacological interventions for weight-loss/management a number of concerns occur. In a Cochrane review by Norris et al (2005), for instance, of the 22 studies which met the criteria for inclusion 18 were funded by the drug companies who also refused to provide data from numerous unpublished studies. There may be some additional weight loss with medication typically interrupting the absorption of fat. This probably represents a small improvement to the results achieved via lifestyle and may be accompanied by some benign (oily fatty stools and gastric discomfort) and other non-life-threatening side-effects. The national institute for clinical excellence (NHS & HTA 2000) for example lists the following side effects for Orlistat:

- fatty or oily stools
- needing the toilet urgently
- passing stools more frequently
- oily discharge from your rectum (you may have oily spots on your underwear)
- flatulence (wind)
- stomach pain
- headaches
- upper respiratory infections, such as a cold or sore throat

Orlistat is also only subscribed for people who have already successfully lost 5% of starting bodyweight and only used in conjunction with a low fat diet and to be discontinued if patients fail to lose a further 5% of starting bodyweight within three months (NHS & HTA 2000). Drug development continues, for example Lorcaserin (Belviq) developed by Arena Pharmaceuticals was approved by the Federal drug Administration in the United States. It has also filed for marketing the drug in the EU under the name Lorqess although again concerns have been raised over tumours developing in rats and an increase in heart valve disease risk (Colman et al. 2012). Sibutramine, another popular prescription obesity drug, was withdrawn in 2010 (NICE 2010) following evidence of increased risk of heart attack and stroke. Pharmaceuticals may play some role in patients managing their weight when combined with changes to dietary intake and exercise yet not without significant side-effects and potential risk to health.

### **3.6 Commercial weight loss programmes**

In an analysis of commercial weight loss programmes Tsai (2005) found '*suboptimal*' evidence to recommend support for these programmes with the exception of one trial carried out for Weight Watchers (Heshka et al. 2003) which showed a 5% loss of starting weight. However, attrition rates may negate these results, as a study by Volkmar and colleagues concluded that 50% of Weight Watchers participants stopped attending in the first six weeks and 70% within their first 12 weeks (Volkmar et al. 1981). More recently Tsai and colleagues (2012) compared a 'clinic-based' intervention with Weight Watchers for 17 weeks: the subjects randomised to the clinic lost  $4.0 \pm 1.2$  Kgs versus  $0.4 \pm 1.1$  in the weight watchers programme ( $P=.04$  for difference) heavily supporting the clinic-based intervention.

Finley et al (2007) also analysed weight loss and subject retention in a commercial weight loss programme with the authors asserting effectiveness for those who complete the programme. The data encapsulates the effects for these two parameters from 60 164 men and women enrolled in the Jenny Craig Platinum programme. In this work, however, effectiveness needs to be considered in relation to retention; as in the programme under scrutiny the following retention rates were observed: 73% at 4 weeks, 42% at 13 weeks, 22% at 26 weeks, and 6% at 52 weeks. For the 6 people in every 100 customers who make it to one year the results *are* fairly encouraging as 15.6  $\pm$ 7.5% of starting body weight was lost. The issue of retention at 1 year is of fundamental importance as suggested by Peri et al's work suggesting that longer treatment is important in terms of effects and long-term weight management is clearly the aim of both individuals and public health experts (NICE 2006).

### **3.7 Diet and exercise therapy for weight management**

Studies, which compared diet versus diet *and* exercise, favour the latter (by 1.3 kgs greater weight loss) yet this probably does not fully explore the extent to which a combination of diet and exercise work to be more effective. This may be because weight loss alone will not indicate favourable changes to body-composition and other positive metabolic factors-such as the increase in muscle tissue, resulting from exercise, or improved blood pressure and blood sugar control- arguably these are essential elements in assessing how effective a programme has been and not solely the assessment of bodyweight changes (Ross et al 2004).

An example of how the research above might underplay the effects of physical activity on top of dietary control comes from Ross and colleagues (2004) who carried out a study to identify the differences on exercisers staying the same weight, dieters losing weight and those dieting and exercising to lose weight. Although both diet and

diet + exercise groups lost the same amount of weight, the exercise group lost over 2.5% more of their starting body-fat than the diet alone group. Equally the group which exercised but purposefully didn't lose weight (as their diet was manipulated to ensure they stayed the same weight) lost almost exactly the same amount of abdominal fat and achieved similar reductions in fasting insulin production (a key ameliorator of diabetes risk). In many studies including those above in Franz et al's meta-analysis this data is not captured and so exercise alone may be badged a unsuccessful because weight *loss* has not occurred. When comparing these parameters between diet and exercise versus diet alone the indication is clear that metabolically (e.g. insulin sensitivity), as well as in terms of fat loss, the exercise with diet intervention is more efficacious. These and Franz and colleagues' (2007) findings are supported earlier by Miller who in 1997 looked at 25 years of literature comparing diet versus diet and exercise together and although he concludes that interventions were too short he also finds a 2kg greater weight loss sustained in the groups using diet and exercise in combination (Miller et al. 1997).

### **3.8 MI as an approach for weight management**

An exploration of literature available from Medline between 1980 and 2013 revealed 180 results from the search for 'Motivational Interviewing and Weight'. 79 abstracts were obtained after it became clear from the titles that these were relevant to adults and weight loss/maintenance interventions. Following this 31 full papers (including reviews, meta analyses, and control trials) were obtained for further analysis as it was clear only these papers were relevant to a review on the efficacy of MI in adult weight management. Analysis from these 31 papers is included below.

### **3.9 MI for weight loss: the reviews**

MI for weight management has begun to emerge as a preferred treatment in recent years with commentators suggesting it as a recommended approach (Gudzune 2012). The evidence base for delivering MI to individuals and weight loss has grown, with the publication of some robust reviews (Rubak 2005; Armstrong 2011) and randomised control trials (Hardcastle et al., 2013, Channon et al., 2007, Smith-West et al., 2007, Greaves et al., 2008) suggesting the efficacy of MI in improving weight and other clinically important outcomes. Rubak looked at 72 randomised control trials on MI (1991-2004) all of which included weight loss. MI produced significant and clinically important effects in 75% of the studies reviewed. This included equal effects between physiological and psychological parameters. Lowering BMI and reduced cholesterol and lower systolic blood pressure were among the significant results.

More recently Armstrong and colleagues (2011) conducted a review of 12 randomised control trials using MI and concluded that significant weight loss occurred when including MI versus comparator approaches. Hardcastle and colleagues (2013) compared MI to an information only arm and found that important physical parameters (walking and cholesterol levels) changed in the intervention group. Treatment as usual in this study was information only; however, information alone is only expected to have at best a weak effect. Furthermore the authors assert that the changes in skill level of practitioners delivering MI over a six month period would have been only minimal. This seems a debatable point as it would not be difficult to imagine practitioners' skills changing dramatically over a six-month period. A further issue is the lack of clarity over treatment fidelity, there are no scores reported for practitioners carrying out the motivational interviewing. Training was

carried out via two four-hour sessions with the first author of the paper. The authors assert that the dietician and exercise specialist involved in the study were trained to a minimum acceptable standard. It seems important to note that Motivational interviewing is often introduced via a two day workshop but that one of its two developers - Bill Miller - has noted this alone was not enough to gain competency (Miller & Mount, 2001) and that supervision following training is needed (Miller et al., 2004). Hardcastle and colleagues' (2013) paper does allude to monthly meeting with the practitioners for supervision.

MI delivered to groups needs further investigation (Wagner & Ingersoll, 2012) and is in need of particular comparison to the Small Changes programmes- Treatment as Usual. Treatment fidelity in group settings also needs analysing as convincing treatment fidelity in groups has yet to be presented. Treatment fidelity to any psychological intervention should be of primary concern (Bellg et al., 2004) for without this investigators are unable to ascertain whether treatment has actually followed the approach claimed rather than simply naming it. Additionally if treatment fidelity is not observed the literature base defining whether an intervention is effective or not will potentially be falsely influenced. The behaviour change consortium have also suggested that journal reviewers, editors and funding agencies should ensure that treatment fidelity forms part of standard practice in terms of publishing funding and reviewing behavioural change intervention research (Bellg et al., 2005).

### **3.10 - 5% weight loss with MI**

Greaves and colleagues (2008) state that a greater number of MI clients achieve a 5% weight loss target (24% versus 7%) compared with information only subjects MI subjects also achieved the 150 minute physical activity target (38% versus 28%) although this was not statistically significant. The dose of training in this study was again limited at two days although treatment fidelity was checked using the Behaviour change counselling index and the standard achieved was deemed 'satisfactory'. 5% loss of starting bodyweight represent a significant clinical parameter as physiologically protective mechanisms (e.g. enhanced lipid profile and greater insulin sensitivity appear to accrue with this level of weight loss).

### **3.11 MI for weight loss; Meta analyses**

Van Dorsten (2007) also reports (in a meta-analysis) the positive effects for MI on a range of problem behaviours including: diet and uptake of physical activity. Hettema and colleagues (2005) conducted a meta-analysis on 72 clinical trials and Burke and colleagues (2003) also produced a meta-analysis of 30 trials. The findings from these studies showed mild to moderate treatment effects on weight and at least an equal effect when compared to other treatment strategies. When comparing motivational interviewing with other treatment strategies it is perhaps important to note that these 'other' strategies may also be effective and hence there is a search for small improvements to treatment rather than massive change.

### **3.12 Control trials on MI for weight loss**

Carels (2007) investigated a behavioural weight loss programme (BWLP) compared to BWLP plus MI. Though both BWLP and MI groups largely failed to reach treatment goals the BWLP plus MI group lost significantly more weight and increased physical activity compared to the BWLP subjects. Smith (1997) also added



MI to BWLP and concluded that the MI plus group improved blood glucose control, adhered better to the programme they were involved in compared to the BWLP group. Smith-West and colleagues (2007) replicated this study on type II diabetes patients and 5 MI sessions again improved HbA1c (*blood glucose control*) and the MI group lost significantly more weight and had greater adherence to the programme at six months (although not at 18 months).

Smith-West and colleagues (2007) conducted a study on overweight women with type 2 diabetes and found that MI improved weight loss when compared to treatment as usual. HbA1c levels were also significantly lower in the MI group at 6 months (although not at 18 months). In both the MI group and treatment as usual (attention control) group subjects lost weight ( $-4.7 \pm 5.4$  kg for MI v  $3.1 \pm 3.9$  for controls). The MI group began to re-gain weight after 12 months and the controls after 6 months. Despite the initiation of weight regain both groups were lighter at 18 months with the MI group faring better, MI:  $3.5 \pm 6.8$  kgs and the controls:  $1.7 \pm 5.7$  kgs ( $P=0.04$ ). The MI group essentially regained 1.8 kgs between month 12 and 18. Perhaps then, a greater weight loss maintained for longer might be a replicate-able finding for MI and weight loss. The present study has, so far, measured data over one year and so comparison of results with other studies is included in the discussion section.

Pollak and colleagues (2007) found that when practitioners acted in an 'MI consistent' manner patients were more likely to make weight loss attempts. In further work Pollak and colleagues (2010) also suggested that proficiency in MI led to greater weight loss outcomes than acting in an MI inconsistent manner. A problem with this and other papers is clarification over how MI consistency was measured- without the

inclusion of verifiable measures suggesting a minimum proficiency of MI delivery in the practitioners delivering the work, it is difficult to assess proficiency.

### **3.13 MI may not be as effective between white and African American women**

Smith and colleagues (1997) also found significant differences between race/ethnic group with African American women losing less weight than white women regardless of which treatment group they were assigned to. In this study treatment fidelity was checked using coding and reviewed by clinical psychologist supervisors. No mention of a treatment fidelity (e.g. motivational interviewing treatment integrity) score is recorded; however, the authors intimate that the practitioners were reaching a level that was 'competent'. It is, however, difficult to assess this without an understanding of how competence was measured/scored.

Not all studies on MI show positive results, (*although the meta-analyses and review papers so far covered do*). Tappin and colleagues (2005) conducted work which showed a failure of MI to produce an improvement in outcomes for pregnant smokers to either quit or cut down when compared to the control condition which was health promotion information. A key difficulty in assessing the efficacy of MI in different treatment settings relates back to treatment fidelity. If treatment fidelity is not assessed it becomes difficult to assert whether what was done can be confirmed as motivational interviewing.

### **3.14 How much training is needed to become proficient in MI?**

Alongside treatment fidelity the question of how much training is required to reach proficiency in MI needs consideration. Miller and Rollnick (2012) offer some guidance for training based upon empirical evidence and although no answer is definitive, in terms of the exact amount of training/supervision needed, it does seem

clear to them that training sessions to learn about MI combined with supervised practice are needed. In one study by Miller it was found that a training workshop with six half hour follow-up telephone supervision sessions was enough for practitioners to gain proficiency (Miller et al., 2004).

### **3.15 Evidence around MI and weight loss maintenance**

Arguably it is maintenance that represents the ultimate aim of health care practitioners in relation to weight management (Elfhag & Rossner, 2005). Weight cycling is common in those seeking to control weight and the continuous gain and loss of weight may exacerbate the risk associated in an individual is a constant (over) weight. Studies beginning with rats (Brownell et al., 1986) suggested deleterious effects on health and an increase in the speed of regain accompanied by a commensurate slowing in the rate of weight loss in rodents 'dieting' and then regaining weight. Many human studies were subsequently carried out some confirming and others denying this effect in humans (Olson et al., 2000). Seminal work in this area suggests that weight loss maintenance may get significantly easier when individuals maintain weight lost for 2-5 years (Wing & Hill, 2001).

A recent review suggests that MI may be an effective intervention once weight loss has been achieved (Dilillo & West, 2011). Here the suggestion is that exploring and strengthening personal motivations may well help in weight maintenance. Yet this review also acknowledges the need for further examination of the feasibility and reproduce-ability of results in a real world setting and the type and extent of training (a concurrent theme for MI) needs further examination.

Arguably maintenance represents a change, as maintenance is the new behaviour of staying the same which is distinct from constantly changing, for example, a dieter, whose diet then stops etc.

### **3.16 MI in groups**

Burgeoning evidence exists around the use of motivational interviewing in groups (Wagner & Ingersoll, 2013) with some work also showing promise for MI specifically in eating disorders and change to diet (Feld et al., 2001; Minniti et al., 2007; Stahre et al., 2007; West et al., 2010). Wagner and Ingersoll (2013) describe the evidence for MI in groups as '*promising but limited*' (p.70). As yet no group MI weight management intervention data have been published.

A difficulty in assessing the efficacy of MI groups is the paucity of trials available for review. More trials are available for work which combines MI with another approach (e.g. CBT). Wagner and Ingersoll (2013) do, however, include 12 published studies on MI groups, all of which focus on substance use and not weight management.

Some of the promising examples include a study by La Chance and colleagues (2009) who report a single session (3 hrs) of group MI as lowering college drinking when compared with an information group which was time-matched. The nature of the studies available (non-randomised, many single-session studies, comparison with treatment as usual studies) suggests the understanding MI in groups is in its pilot phase. Wagner and Ingersoll conclude that the near-absence of target behaviours outside substance use leave a gap in the literature to see how MI groups might work with other behaviours. Wagner and Ingersoll also state that MI coding should be adapted to groups. Both using MI in weight management groups and MI coding/treatment fidelity are explored by the present study.

### **3.17 Motivation increases in those receiving MI**

Using the self-treatment regulation questionnaire as a measure to identify level and locus of motivation in general practitioners patients Rubak (2009) suggests that motivation increased significantly in an MI group compared to controls even though both control and MI groups received target driven intensive treatment.

### **3.18 MI combined with Social Cognitive Theory (SCT) and Cognitive Behavioural Therapy (CBT)**

Often MI and SCT or CBT are blended. Some studies have examined the effectiveness of an approach that uses both methods. An example from Djuric and colleagues (2011) combined the two therapeutic approaches, as part of an intervention for diet and exercise during chemotherapy, concluding that fruit and veg intake, feelings of well-being, levels of physical activity and body fat levels were all improved. Work has also shown that combining MI and CBT, with obese adolescents, betters the weight loss achieved by the treatment as usual group at least in the short-term (Ball, 2011). Perhaps the exploration needed is MI versus CBT versus MI combined with CBT in a slightly more complex design to identify which combination seems most efficacious with a given group of subjects.

### **3.19 Motivational Interviewing Theory**

Motivational interviewing can be criticised for having no underlying theory. MI was developed from the observations of a psychotherapist (Bill Miller during a sabbatical in Norway) rather than based on a theoretical perspective. In recent years the theory of self-determination has been discussed in combination with MI.

### **3.20 Self-Determination Theory (SDT) and Motivational Interviewing**

SDT has been proposed as a theoretical framework (Markland et al., 2005) to underpin the approach of MI. SDT originally developed from the work of Deci and

Ryan (1980). Essentially the work evolved from attempts to understand the effects of internally and externally supported motivation for change. It is reasonable to suggest that SDT proposes autonomy or self-regulation as more positive and sustainable than 'controlled' or externally motivated change.

The theory (of SDT) and the practice (of MI) appear to be moving closer together, with a recent forum and series of papers (introduced by Teixeira, Palmeira and Vansteenkist 2012) exploring the relationship between SDT and MI in physical activity, health and nutrition behaviours. The title of Miller and Rollnick's (2012) paper from this series: 'Meeting in the middle: motivational interviewing and self-determination theory' suggests that the originators of MI feel that SDT and MI have a certain compatibility. Deci and Ryan (2012) also feel that there is much in common between SDT and MI, particularly the emphasis on autonomy. In their paper, Miller and Rollnick describe MI as a 'bottom-up process,' which essentially, has emerged from the practical experience of treatment in alcohol programmes. They contrast this with the top-down approach of an academic theory and suggest that SDT may help to clarify which factors are effective in MI. This presents a tantalising possibility in the form of theory merging with practice. Vansteenkiste and colleagues (2012) discuss the integration of MI and SDT, highlighting the fact that commentators have suggested SDT can be considered an effective framework for understanding why MI works. Certainly Miller and Rose (2009) seem convinced that MI should now begin to move towards a theory. Miller and Rollnick (2012) have also commented on the likelihood that SDT might be such a theory: '*A marriage may be premature but flirtation is not*'.

Vansteenkiste, and colleagues (2012) discuss three differences between SDT and MI, all of which are around the issue of autonomy. Firstly autonomy and independence

are differentiated in SDT they argue, whereas this is unclear in MI. SDT posits that both counsellor dependent and self-dependent clients can quit smoking for either autonomous *or* controlled reasons. Secondly SDT encompasses an absolute autonomous support, so for instance, when a client makes a clear volitional decision not to adhere to a proposed plan of treatment this would need to be considered a positive outcome, again the authors assert this is unclear in the case of MI. Thirdly the issue of change talk driving the effectiveness of MI (Miller & Rose, 2009) is set against volition as an essential psychological freedom in SDT. Essentially SDT asserts there is a fundamental need for autonomy (Vansteenkiste, *et al* 2012) whereas MI sees autonomy as important to yield effective outcomes, Miller and Rose (2009) supported the notion that change talk is the key ingredient in MI's efficacy. Vansteenkiste, *et al* conclude that autonomy should be defined as volition and represents something as important as a 'basic human need' yet ultimately, with careful handling, MI and SDT can be successfully integrated.

Teixeira and colleagues (2012) discuss the specific issue of SDT and MI in long-term weight management, suggesting that many programmes might fail to succeed, at least partly, because they do not take into account the dimensions of motivation in clients. Programmes describe motivation as either present or lacking, rather than relative to feelings of control or autonomy. Should research begin to focus on subjects' feelings of control/autonomy a greater understanding of motivation might ensue. Two interesting points arise from this i) Teixeira and colleagues show evidence of highly autonomous scoring subjects having better weight loss outcomes and ii) MI tends to explore confidence and importance in clients which gives an example of MI in practice exploring the client's locus of motivation. These two questions: how important is this change? And how confident are you? (Often accompanied by a 1-10

scale) allow the client to explore the reasons for importance/confidence of making change which very often also reveals the reasons/motivation for change.

In the series of publications, mentioned above Resnicow and McMaster (2012) suggest MI with the highly motivated might actually be counterproductive and that 'resistant' or ambivalent clients are where MI is particularly effective. Further to this McMaster and Resnicow also discuss the relative benefit of an MI and SDT merger. The essence of this is that MI offers SDT theorists a clinical adaptation to which they can apply their theory. Accordingly SDT would offer MI therapists a potential guide and format to the content of their counselling. Indeed, some SDT-based projects have already delivered interventions using MI strategies (Fortier et al., 2012).

It seems justifiable to suggest that MI practitioners and SDT theorists may need greater understanding of each other's 'basis'. For example, Patrick and Williams (2012) describe MI as a 'set of techniques' which is contrary to Miller and Rollnick's own understanding of the approach of MI with its contingent elements of spirit and principles. Other elements of MI (OARS for example) do serve as 'techniques' but without an understanding of the underlying approach are redundant. Patrick and Williams (2012) also call for more research to clarify the overlap between MI and SDT.

### **3.21 Hypothesis**

On the basis of the evidence outlined in this chapter, the primary hypothesis of the current investigation is that participants who receive an MI weight management intervention will demonstrate significantly better outcomes than those who receive a treatment-as-usual intervention. The outcomes under investigation are 1) selected



health-related behaviours, 2) psychological enhancement, and 3) selected anthropometrical (physical) measures.

To conclude, this chapter examines a range of weight loss approaches and to some extent establishes that there is a limited effect from commercial programmes with concerns over the poor rates of recidivism, there is also some evidence of pharmacological agent producing small amounts of weight loss when combined with diet and exercise but also concern over life-threatening and non-life-threatening side-effects. The relative contribution of diet and exercise alone and in combination suggests that greater effects are found in those who concentrate on both of these behaviours. Finally the contribution of a psychotherapeutic approach to treatment is considered with some supporting evidence that MI may be an effective approach- the use of MI in groups, however, is still relatively un-chartered with no publications on weight loss with MI groups as yet .

### **3.22 Summary**

Alternative approaches to the one investigated for the present paper have been critiqued in this literature review including those which focus on: Pharmacotherapy, advice giving alone, diet therapy, exercise therapy Finally MI and MI in groups are considered and the imperative for further investigation into these areas established.

Based on the literature the following conclusions can be made:

- Weight management is not a new phenomenon but weight has risen dramatically and markedly in the last three decades
- It is statistically normal to be overweight/obese in the United Kingdom and the United States

- A number of approaches have developed over this time with diet and exercise being the primary behaviours influencing weight
- Pharmacological and commercial interventions are limited in scope and in the case of medication potentially dangerous
- A focus on the behaviours of exercise and diet using a facilitative psychotherapeutic approach is warranted
- Motivational Interviewing in groups is in its infancy with no studies yet published using this approach with groups

### **3.23 Anticipated contribution to the pool of knowledge**

The present study will produce a much-needed contribution to the pool of knowledge concerning the use of motivational interviewing in weight management. The literature review presented in this chapter has demonstrated a number of knowledge gaps in this regard. Further to this the study will present information on testing treatment fidelity in weight management groups.

### **3.24 Lead in to Chapter four; methodology for study 2**

The following methodology chapter describes the methods used for study two in sufficient detail for the study to be replicated.

## **Chapter 4: methodology for study 2**

This chapter considers the methodology used for study 2. It puts the study into context and outlines its development. The chapter then describes the study in detail, describing the outcome measures and the procedure for carrying these out as well as the sessions carried out throughout the programme. Finally the analytical approach adopted and ethical considerations are described.

### **4.1 Study context**

The intervention that formed the basis of the current investigation is known as Small Changes. Small Changes has been in existence since 2008 and was developed from a partnership between a nutritionist (the current author) and a psychotherapist (Jean O'Keeffe). Subsequent to obtaining funding (2008-2010) to run a weight management project, 'Small Changes' developed into a year-long educational programme in 2010. In 2011 a second year of the trial began. This iteration included a supplementary element to the intervention: motivational interviewing. The work was carried out in a large University and conducted amongst participants who were employed by the University at the time the study was conducted. A cohort of people were treated using treatment as usual (the education-only version of Small Changes) and these people are compared to a similar group of people who received the version of Small Changes that included the supplementary motivational interviewing dimension. The current study compares the treatment as usual cohort (2010-2011) to the enhanced MI cohort (2011-2012) on a range of outcome measures.

## **4.2 Participants**

143 participants were recruited in two cohorts (72 and 71 people respectively- one in 2010 and a second 2011). Sampling was carried out via the University internal email system. An email invitation was distributed to all staff members from a single faculty ( $N = 1,066$ ). Participants were invited on a first come first serve basis with the intention of recruiting 70 participants for each arm of the trial (a figure derived by considering the maximum number of participants that time and resources would allow). The email invited participants who were looking for support in managing their weight. In order to be eligible for the study staff needed to have a BMI  $> 29.9 \leq 40.00 \text{ kgm}^2$  this level of BMI is consistent with the World Health Organization's definition of obese.

## **4.3 Outcome measures for study 2**

Quantitative data were gathered via several questionnaires and anthropometrical data recorded in the laboratory at the University Food and Nutrition Department. The following constructs were assessed:

4.3.1 Height and weight

4.3.2 Waist to Hip ratio

4.3.3 Body composition

4.3.4 Physical and psychological well-being- The Short Form-36 (SF-36)

4.3.5 Number of minutes of daily physical activity

4.3.6 Number of portions (1 portion = 80grams) of daily vegetable and fruit intake

### **4.3.1 Height and weight**

Height (in metres and centimetres rounded down to the nearest centimetre) and weight (kilograms and grams rounded down to the nearest 100 grams) were recorded using a SECA 709 mechanical column scale with SECA 220 telescopic measuring rod (SECA Hamburg Germany). The scale consists of a weight balance and stadiometer for measuring height. Participants were asked to void their bladders before physical measurement. Height (without shoes) and weight (indoor clothing) were recorded to the nearest 0.1 cm and 0.1 kg, respectively. For consistency, participants were asked to wear the same clothes at each visit. Height measurements were made at the point of normal breath inspiration with the head orientated in the Frankfort horizontal plane. From these measures, BMI was calculated and rounded to the nearest 0.1.

### **4.3.2 Waist to hip ratio (W:HR)**

Central fat distribution is a key indicator of risk for type II diabetes and coronary heart disease, with W:HR being suggested as more strongly correlated with cardiovascular disease (CVD) risk than waist circumference alone. Every 1cm increase in waist circumference confers a 2% relative risk increase for a CVD event, (De Koning et al., 2007). A waist circumference of greater than 94cm for men and 80cm for women often correlates with a BMI of 25kg/m<sup>2</sup> or overweight (Lean et al. 1995). Greater waist circumference than 102cm for men and 88 cm for women also correlates with a BMI of greater than 30 kg.m<sup>2</sup> (Lean et al., 1995). Waist circumference is measured one inch above the umbilicus using a flexible tape measure; hips are measured at the widest part of the hips. The investigator was trained in taking the measurements and has been encouraged to pay particular attention to applying the same tension and ensuring a constant application of the tape

on each measuring occasion. Participants are encouraged to exhale before the measure is taken.

Furthermore combining waist and hip measurements to form a ratio by dividing the waist measurement by hips measurement is warranted. In men a WH:R of greater than 0.90 suggests a greater morbidity risk and for women a ratio of greater than 0.85 suggests greater risk (WHO, 2008).

#### 4.3.3 Bio-electrical impedance analysis (BIA, spectroscopy)

Bio-electrical impedance was used to detect changes to body-composition. The tests were carried out using a using the hand-held body-stat 1500 unti (Bodystat Ltd Isle of Man). Measurements were made on the subject's right hand side. The following guidelines were also observed before a measurement was taken:

- No eating or drinking 4 to 5 hours prior to the test
- No exercise 12 hours prior to the test
- No alcohol or caffeine consumption 24 hours prior to the test
- Right shoe right sock and all jewellery will be removed and subjects were in the supine position
- Two electrodes were attached at the dorsal surfaces of the hand and two at the dorsal surfaces of the foot
- One electrode was attached at the second metatarsal and the second at the posterior wrist between the styloid processes of the radius and ulna. Another electrode was attached at behind the second metatarsal and the other at the ankle between the tibial and fibular malleoli.

The body stat determined fat mass and fat-free mass. (*Patients with a pacemaker were excluded*) a correlation of 0.83 has been found (Maughan, 1993) between bio-

electrical impedance and the gold-standard hydro-static weighing. Favourable comparison has also been made between BIA and dual-energy X-ray absorptiometry (DEXA) with results showing a high correlation between the two:  $r=.90$ ,  $P<0.05$  (Demura et al., 2004) and a correspondingly high correlation in a DEXA/BIA study comparison in overweight women:  $r=.90$ ,  $P=0.001$ , (Erselcan, 2000). The relevancy of the no alcohol, caffeine and ensuring that the subject is well hydrated is that dehydration returns false results. Hydration is clearly important when using BIA for assessing body-composition as variations will alter results even when body-composition remains constant. Waist circumference, hip circumference and bodyweight measurements were, therefore, also made.

#### **4.3.4 Sf-36**

The Sf-36 (short-form 36) is a general rather than specific tool for assessing both functional health and well-being. The Sf-36 is considered the most extensively validated and used health survey instrument for appraising quality of life (Contopoulos-Ioannidis, 2009). It has been deemed useful for identifying the effects of a number of health interventions (Ware, 1988). The development of the Sf-36 is charted by over twenty years of publications and has been applied in more than 4000 research publications between 1988 and 2000. Subsequent revisions and additions are covered in a series of papers by Ware and colleagues (Ware et al., 1988 to 2001). The Sf-36 has been used in studies that involved weight management and posits that the physical and psychological domains within the questionnaire interlink to present an aggregate score of general wellbeing and health (Ware et al., 2001). This self-report of health status was carried out a baseline and at 12 months in both groups. An aggregate score is formed from the 36 item questionnaire. Higher aggregate scores equal better health. A score of 36 is the lowest feasible score and would represent

very low feelings of physical health and high rating of depression alternatively 161 would be the maximum high score and would represent the opposite.

There are a number of 1-3, 1-5 and 1-6 items in the SF-36, some of which are reversed so some questions have a low value equalling a positive response and others have a low value equalling a negative response i.e. suggestive of poorer well-being. The reverse questions are designed to reduce subject's bias towards the middle of a scale. After the reverse questions are accounted for an aggregate score is produced with a low score equalling poorer well-being and a higher score equalling greater well-being.

An example of a non-reversed item is: Compared to one year ago, how would you rate your health in general now? 1-much better now than one year ago, 2- somewhat better than a year ago, 3- about the same as a year ago, 4- somewhat worse than a year ago and 5- much worse than a year ago. Reversed items include: In general would you say your health is: 1-,excellent, 2- very good, 3-good, 4-fair, 5-poor.

#### **4.3.5 The Scottish Physical Activity Questionnaire (SPAQ)**

The SPAQ is a 7-day recall questionnaire which has been validated against the doubly labelled water technique and according to the National Obesity Observatory (NOO) is acceptable for estimating daily energy expenditure (NOO, 2009). A result of 120 minutes a week moderate exercise and 0 minutes intense exercise were recorded from a one month recall made by a test subject, whose data was corroborated by an accelerometer as insignificantly different ( $P > 0.005$ ). An obvious critique of the SPAQ is the necessity to recall activity, although as suggested



above the SPAQ has been well reviewed and validated against doubly labelled water. Originally validated by Lowther and colleagues (1999) the SPAQ has since been used in subsequent studies (Kirk et al., 2001; Lowther et al 2002; Paxman et al 2011).

#### **4.3.6 Food frequency questionnaire**

Food Frequency questionnaires (FFQ) have been used and validated for collecting data on fruit and vegetable consumption, (EPIC 2012; Johansson, 2010). Cade and colleagues (2002) worked on the development and validation of an FFQ for use in public health nutrition. The relationship between fruit and veg intake and obesity has also been suggested (Godin 2010; Rolls et al., 2004). FFQ's have also been criticised for their accuracy in assessing detailed intake of kcalories and micronutrients (Hackett 2011). Furthermore FFQs have been defended as essentially accurate in the assessment of number of portions of fruit and vegetables consumed (Kristal & Potter, 2006). The choice to include FFQ and specifically the measurement of fruit and vegetables in the intervention relies on the ideas that a) whole fruits and vegetable seem likely to increase satiety and b) fruits and vegetables irrespective of weight change are likely to confer significant nutritional benefit. Although there is also some evidence to suggest increasing fruit and vegetable intake may reduce weight- the evidence is equivocal- a key methodological problem is that often studies do not involve only increasing fruits and vegetables but also reducing fat intake at the same time (Rolls et al., 2004) therefore caution is needed when interpreting increases in consumption as causal of weight loss.

#### **4.3.7 Motivational Interviewing MITI 3.0 'coding' instrument**

Motivational Interviewing was checked for treatment fidelity by coding sessions, these recorded sessions were sent to a MINT (*Motivational Interviewing Network of Trainers*) trainer for independent coding and feedback. MI sessions were also

observed by a MINT trainer the recorded sessions were coded using Motivational Interviewing Treatment Integrity MITI 3.0. Codings were made at baseline, 6 months and 12 months.

#### **4.4 Statistical analysis of the outcome measures**

Data was analysed for homogeneity via histogram and then via repeated measures analysis of variance (ANOVA) for the identification of any differences in the residual data, arising between the treatment and control groups. Repeated measures ANOVA tests were carried out for body-fat, weight, BMI and waist to hip ratio. All of these measures were recorded at 0,3,6,9 and 12 months. Differences between groups for feelings of well-being, fruit and vegetable intake and number of minutes of physical activity between baseline and 12 months were measured using independent samples *t*-test. Matched pairs *t*-test was used to analyse for differences between baseline and 12 months in all measures and descriptive data in the treatment, control and combined groups.

#### **4.5 Study design**

The study involved a quasi-experimental design. A key consideration for this design relates to comparing the Small Changes educational programme to a motivational interviewing protocol. The existing educational programme was a real-world pragmatically driven service rather than a clinical intervention and the driver for this research was to measure the effects from the former educational programme and compare these to the motivational interviewing-led protocol. With that in mind the new MI protocol replicates the recruitment strategy, the measuring time points, length of treatment, number of meetings and measures (with the exception of treatment fidelity- i.e. there is no treatment fidelity measure for an educational programme) used for the educational programme. Participants recruited to the

programme were selected using the same criteria and recruited by the same sampling technique. All participants were also measured and treated in the same facility.

#### **4.6 Intervention-procedure**

The intervention was carried out with two separate cohorts. One group (the educational group) was exposed to the intervention between October 2010 and October 2011 and the second (the motivational interviewing group) between October 2011 and October 2012. After responding to an email advert potential participants were invited to an evening event at the nutrition research facility of the University (at the same day/time and venue that the groups would run) where they were able to gain further detail about the programme before deciding whether to participate.

##### **4.6.1 Recruitment**

Those people who opted to join the programme began the following week and met for two hours each month and had measures taken at baseline, 3, 6, 9 and 12 months. The setting, facilitator and measures were constant between both cohorts. The essential difference between the two cohorts was approach, with one group (educational) receiving core information delivered via advice and education from the facilitator on the subject under discussion at a given month. See Appendix A1 and A2 for the detail of each session in the educational and MI programmes.

The MI cohort received the same time input in the form of two hour groups each month. A key distinction was the approach whereby MI was delivered rather than education and advice (see introduction chapter page 3, sub-sections 1.3-1.19 for a detailed explanation of what was delivered). A second feature of the MI programme relates to the three one to one sessions delivered. A session for each participant was delivered at baseline 6 and 12 months. These were recorded with the client's

permission and then submitted for MITI 'coding' by Stephen Andrew at HetiMaine in Maine New England in the U.S.A the three codings are presented in Appendix E and indicate to what extent the technical and relational aspects of MI have been enacted in the three sessions reviewed. A global score is arrived at for the practitioner and this gives an indication of whether competence in delivery of MI has been reached.

The approach used with the MI cohort is encapsulated in the introduction (sub-sections 1.3-1.19) a taxonomy based on an adaptation of Michie and colleagues (2011) refined taxonomy of behaviour change techniques is also provided in appendix A and appendix G gives a clear example of MI: this is taken from an initial subject interview. All sessions were reviewed for taxonomy items to ensure they matched the item stated in the table and verified.

Data was initially recorded on paper and excel spreadsheets simultaneously in the laboratory and at the time of testing consistently at each measurement point. Data was anonymised and kept on a site file in the principal investigator's office under password protection and lock and key in the case of paper copies and voice recordings. Analysis was carried out after transfer to International Business Machines corporation (IBM) Statistics Package for Social Sciences (version 20. SPSS inc Chicago IL).

#### **4.7 Ethical approval for study 2**

An application for ethical approval was submitted and then approved in October 2010 by the faculty ethics committee, Sheffield Hallam University. The application outlined the objectives, background, research method and study design of the project. The application provided the details of research procedures, including the obtaining of personal information. The application also outlined the proposal for obtaining

informed consent from all participants, and specified the measures taken to ensure anonymity and protect the data relating to all participants.

#### **4.7.1 Respect for subjects taking part**

Signed informed consent was obtained from each participant after they had had time to review the participant information sheet (PIS, which was provided via email before the recruitment meeting) The informed consent and PIS are presented in (Appendix H & I), Data collected in relation to the present investigation was kept on a password protected site file and in the case of raw data under lock and key in the principal investigator's office. Where email communication took place between the principal investigator and the subjects, headings such as 'meeting' were used rather than terms relating to weight management, this example permeated the ethos of the project where conversations were confidential and are only referred to in the present document with all participants anonymised. It was essential that all participants had both written and verbal confirmation of the fact that they could withdraw from the study at anytime without giving prior warning or reason for doing so- this information was provided in the participant information sheet and then verbally expressed at the recruitment interview. Detail in the PIS also includes the possible benefits and side-effects of taking part in the study

#### **4.7.2 Responsibility of the researcher**

Participants de-briefing was explained at the outset in the recruitment meeting. Details of what happened during the trial were presented at the end of the one year programme via a group presentation. All subjects will also have access to an electronic copy of the project following its ratification from the post-graduate research department- which was expressed again at the recruitment meeting and then again at the end of the one-year programme.

#### **4.8 Treatment fidelity in the delivery of motivational interviewing**

Training to deliver the MI component of this intervention initially involved training via three, two-day workshops at beginners, intermediate and advanced levels. Practise was carried out between workshops and some supervision provided from an experienced MI practitioner and member of the Motivational interviewing Network of Trainers (MINT). This training was conducted prior to data gathering for the project. After this initial year a 'test' recording session with a client seeking help with their weight was recorded and submitted to a MITI (motivational interviewing treatment integrity) coder. This training was followed by attendance an international MI conference in Italy and a further training workshop on MI in groups in Scotland. Finally there was delivery of a number of introductory workshops as a co-trainer with an experienced skilled practitioner.

The following year (September 2012) Training with the Motivational Interviewing Network of Trainers (MINT) was completed in the United States. Attending the MINT trainers' forum consolidated the development of MI skills. The 3 original 2-day workshops were helpful in learning about what MI *is*, but it was the supervision (for instance audio recordings submitted for MITI coding) and continuous reflection and feedback from self and others that helps develop skilfulness in the actual *practice* of MI (Miller & Rollnick p.38, 2012).

##### **4.8.1 Treatment fidelity and the MITI coding instrument**

For this project MITI coded sessions were reviewed by three independent trained 'coders' at the beginning, middle and end and of the project. Subsequent scores and feedback are included in the results section. Each assessor (1 for each of the three

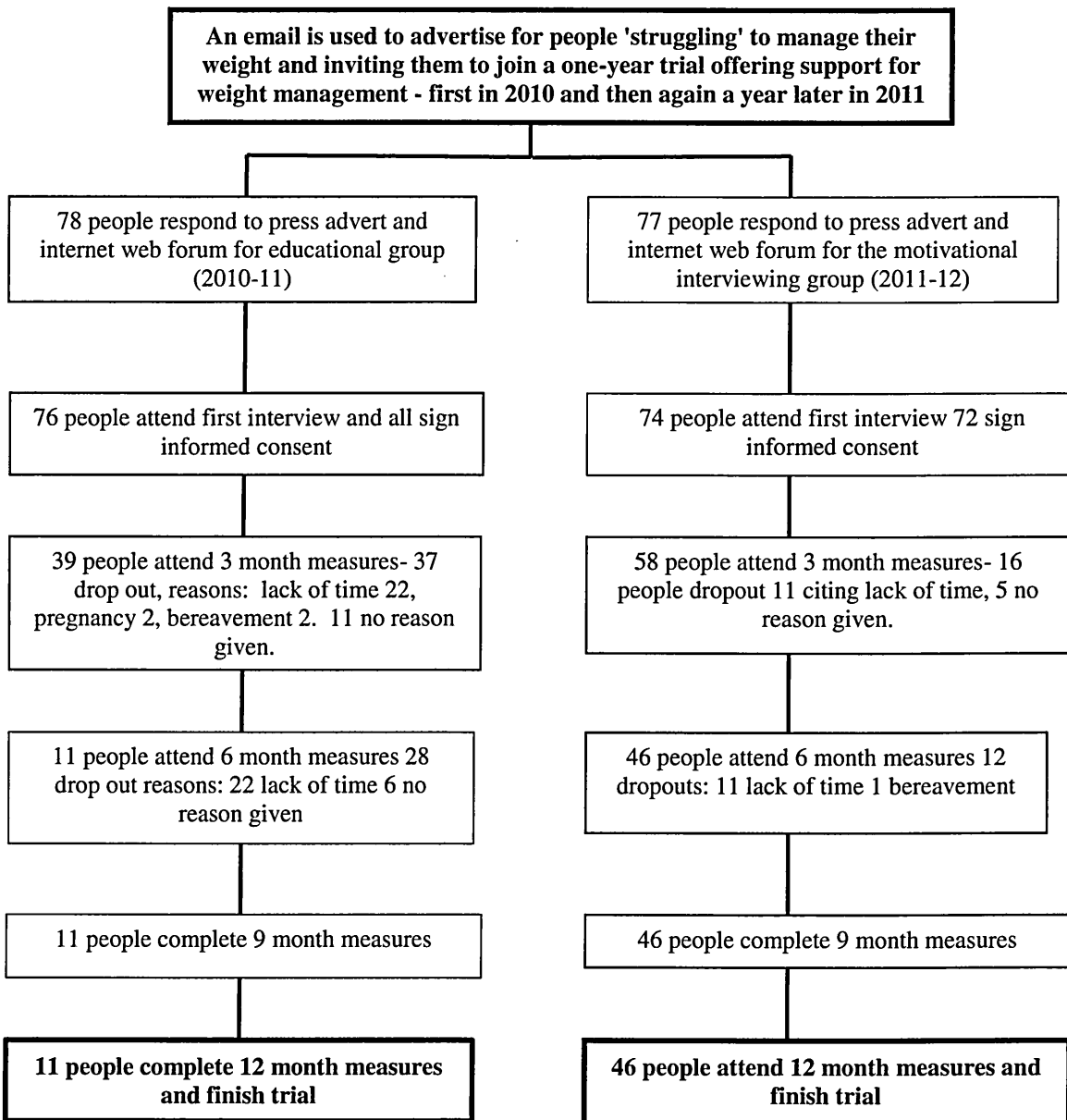
measures) was independent and essentially had no access to the scores or results of the previous sessions' scores in an attempt to ensure validity.

The phrase 'treatment fidelity' is used throughout this work and refers to the notion of checking whether treatment can be confirmed as constituting motivational interviewing. This is achieved by the coding described above by a trained and independent coder and using the motivational interviewing treatment integrity (MITI version 3.0) coding tool. These measures were made at baseline half way and 12 months of the motivational interviewing arm of the programme and carried out by the company HetiMaine under the management of Stephen Andrew New England USA.

#### **4.9 Methodology for study 2: summary**

This chapter presents the method for conducting the present investigation in sufficient detail for replication of the investigation. The procedure and design are explained and each of the outcome measures discussed in detail. This chapter leads in to the first of the results chapters.

Fig 3. Consort diagram for study 2





## Chapter 5: Results

This chapter presents results for the seven outcome measures included in the present investigation. Firstly a description is given of how the data analysis for the measures was conducted and then the results themselves are given. Finally the chapter ends with a description of the outliers from this data set with consideration of whether this may have affected the present results.

### 5.1 Descriptive and inferential statistics

The four physical outcome measures (weight, body-fat percentage, body-mass index, and waist to hip ratio) were recorded at 0, 3, 6, 9 and 12 months. Descriptive statistics were used to summarise all variables for the treatment, control and combined groups presented below in table 7. Matched pairs t-tests were used to analyse differences between baseline and 12 months for each outcome measure. Normality was confirmed for all data using normal probability plots, histograms and Shapiro-Wilk tests.

The four main physiological outcome variables were modelled using repeated measures mixed models to assess differences between treatment groups while accounting for other potential explanatory variables. Residual diagnostics were used to confirm normality.

Differences between groups for changes between baseline and 12 months in the remaining three outcome measures: feelings of well-being, fruit and vegetable intake and number of minutes of physical activity, were analysed using independent samples t-tests.

The characteristics of participants at baseline on each of the seven measures are presented in Table 7.

Table 7 Baseline Participant Characteristics

Variable	Total (n=57) M (SD)	Control (n=11) M (SD)	Treatment (n=46) M (SD)
Weight (KGS)	94.90(15.95)	92.02 (19.8)	95.58 (15.0)
BMI Kg/M2	34.05 (4.42)	33.41 (6.2)	34.20 (3.9)
Body fat %	40.61 (8.11)	41.3(10.5)	40.43 (7.5)
Waist to hip ratio (CM)	0.92 (0.07)	0.90 (0.06)	0.98 (0.08)
Sf36	125.33 (7.9)	125.27 (7.9)	125.34 (8.0)
Mins of physical activity	1498 (1566)	1957(1904)	1360(1465)
Daily Fruit and Vegetable (Portions of 80g)	3.65 (1.5)	3.77(1.9)	3.62(1.5)
Gender %	31.5c? 68.5\$	36.3c? 63.6\$	30.4c? 69.6\$
Age	47.9 (12.3)	41.7 (9.8)	49.3 (12.4)

Table 8, below, shows the baseline to 12 months outcome measures for all variables and indicates the *within group* changes and respective *p* value from paired sample *t*-tests. The table compares within group differences i.e. considering the treatment as usual changes between baseline and 12 months and the same for the MI groups and then both groups combined. After this the residual data is considered, i.e. a comparison is made between the differences from each group or between groups and across all time points Using ANOVA.

In the Treatment As Usual (TAU) group significant changes occurred between baseline and 12 months for waist to hip ratio, feeling of general well-being and number of minutes of physical activity and no significant difference is shown for other

variables. For the MI group there has been a statistically significant change in all variables at the 95% confidence interval.

Table 8 Outcome Measures Baseline to 12 months

Variable		Total (N=57)	Control (n=11)	Treatment (n=46)
Weight (KGS)	Pre	94.90 (15.9)	92.08 (19.8)	95.58 (15.0)
	Post	91.57 (14.6)	90.81 (18.3)	91.80 (13.9)
Difference%		3% ↓↓	1% ↓↓	4% ↓↓
P		<0.001	0.233	<0.001
BMI	Pre	34.05 (4.42)	33.42 (6.29)	34.20 (6.29)
	Post	32.89 (4.28)	32.97 (5.68)	32.87 (3.95)
Difference%		3.5% ↓↓	1.3% ↓↓	3.9% ↓↓
P		<0.001	0.398	<0.001
Bodyfat %	Pre	40.61(8.11)	41.33(10.52)	40.44 (7.56)
	Post	38.94 (7.85)	40.09 (11.14)	38.67 (11.14)
Difference%		4.1% ↓↓	3 % ↓↓	4.4% ↓↓
P		0.002	0.111	0.006
Waist to hip ratio (CM)	Pre	0.92 (0.07)	0.98 (0.06)	0.98 (0.08)
	Post	0.88 (0.06)	0.91 (0.06)	0.87 (0.06)
Difference%		4.3% ↓↓	1% ↓↓	11% ↓↓
P		<0.001	0.022	<0.001
Sf36	Pre	125.3 (7.96)	125.2 (7.9)	125.3 (8.05)
	Post	135.8 (8.4)	135.9 (9.2)	135.9 (8.3)
Difference%		8% ↑↑	8% ↑↑	8% ↑↑
P		<0.001	<0.001	<0.001
Minutes physical activity	Pre	1498 (1566)	1957 (1904)	1360
	Post	1701 (1674)	2441 (2207)	1523 (1496)
Difference%		13% ↑↑	24% ↑↑	12% ↑↑
P		<0.001	0.024	0.002
Fruit & Vegetable portions	Pre	3.65 (1.5)	3.7 (1.9)	3.6 (1.5)
	Post	4.5 (1.9)	4.4 (1.5)	4.6 (2.0)
Difference%		23% ↑↑	18% ↑↑	27% ↑↑
P		0.006	0.452	0.007

P value for paired examples

## 5.2 Measures of well-being

The aggregate score from the SF-36 at baseline and 12 months for both groups are presented below in figure 4. A significant increase in functional and general well-

being between baseline and 12 months occurred in both groups. This was statistically different in the direction of improved well-being in both TAU and MI groups ( $P=0.000$ ). The MI groups reported a baseline aggregate score of 125 rising to 135 which was matched exactly in the TAU group.

### **5.3 Healthy behaviours results**

The number of minutes of physical activity was high in both groups at baseline and rose significantly in both groups. A 24% increase ( $P = 0.024$ ) was observed in the TAU group and a 12% increase ( $P = 0.002$ ) in the MI group. Figure 5 below represents the changes in recorded physical activity for both groups across the one-year programme.

Fruit and vegetable consumption rose significantly in the MI group ( $P = 0.007$ ) and not in the TAU group ( $P 0.452$ ).

#### **5.3.1 Analysis of Repeated Measures**

Observed means are presented for weight, body-fat percentage, BMI, WHR for each treatment group at each time, including baseline.

Differences in these 5 outcomes between treatment groups were assessed using repeated measures mixed models. Subjects were considered to be random effects, this means considered to be uncorrelated with independent variables e.g. age and these are 'nested' within treatment groups which were considered fixed- which means the treatment group either control or experimental does correlate with that group i.e. any differences between the changes relates to the difference in 'treatment' rather than other independent variables, so in effect the same results should be replicated with another group. In each case, a range of covariance pattern models was considered- and

a ‘best-fit’ was chosen covariance relates to how much two random variables change together- so if change between these variables tend to show similar movement then covariance is considered positive (Brown & Prescott, 1999).

Table 9 below shows the mean weights for participants on both the MI and TAU groups at the five different measurement points.

Table 9 Analysis Variable Weight (Kg)

<b>Treatment</b>	<b>Time</b>	<b>N</b>	<b>Mean</b>	<b>SD</b>
MI	Baseline	46	95.58	15.06
	3 Months	46	92.73	15.13
	6 Months	46	91.73	15.09
	9 Months	46	91.56	14.95
	12 Months	46	91.75	13.93
TAU	Baseline	11	92.02	19.84
	3 Months	11	91.45	19.40
	6 Months	11	91.24	18.97
	9 Months	11	89.26	18.71
	12 Months	11	90.82	18.32

The treatment groups did not differ significantly ( $P=0.510$  independent samples t-test) considerably in observed mean weight at baseline. While those in MI group experience a considerable decline in mean weight over the first 3 months, mean weight loss is small in the TAU group until 6-9 months when there is a considerable dip.

Table 10 shows the body-fat percentages of participants from both TAU and mI groups at the 5 different measurement points.

Table 10 Analysis Variable: Body-Fat (%)

<b>Treatment</b>	<b>Time</b>	<b>N</b>	<b>Mean</b>	<b>SD</b>
MI	Baseline	46	40.44	7.56
	3 Months	46	37.38	7.59
	6 Months	46	38.37	7.00
	9 Months	46	37.99	7.58
	12 Months	46	38.67	6.97
TAU	Baseline	11	41.33	10.52
	3 Months	11	40.96	9.81
	6 Months	11	41.11	10.72
	9 Months	11	41.47	10.49
	12 Months	11	40.09	11.14

At baseline, mean observed body fat levels are lower in the MI group and yet a substantial decrease is noted over the first 3 months; there is no corresponding decrease in the TAU group. After 3 months, levels in the MI group tend to rise again.

Table 11 shows the body mass indexes of both the TAU and mI groups at the five different measurement points.

Table 11 Analysis Variable: BMI

<b>Treatment</b>	<b>Time</b>	<b>N</b>	<b>Mean</b>	<b>SD</b>
MI	Baseline	46	34.20	3.92
	3 Months	46	33.17	4.00
	6 Months	46	32.83	4.23
	9 Months	46	32.78	4.29
	12 Months	46	32.87	3.95
TAU	Baseline	11	33.42	6.29
	3 Months	11	33.25	6.35
	6 Months	11	32.63	5.76
	9 Months	11	32.43	6.00
	12 Months	11	32.97	5.68

At baseline, observed mean BMI values are slightly higher in the MI group, but from 3 months onwards they drop to levels comparable with those in the control group.

Table 12 shows the waist to hip ratios for both the TAU and MI groups at the 5 measurement points.

Table 12 Analysis Variable: W:HR

Treatment	Time	N	Mean	SD
MI	Baseline	46	0.90	0.06
	3 Months	46	0.88	0.08
	6 Months	46	0.87	0.06
	9 Months	46	0.86	0.06
	12 Months	46	0.87	0.06
TAU	Baseline	11	0.98	0.08
	3 Months	11	0.93	0.07
	6 Months	11	0.92	0.08
	9 Months	11	0.91	0.07
	12 Months	11	0.91	0.06

In the MI group, observed mean W:HRs are considerably lower than those in the control group. Comparable declining patterns are seen over time in both groups.

Table 13 shows: *p*-values for potential explanatory factors (adjusted only for relevant baselines)

<sup>1</sup> Baseline relevant to outcome – Not adjusted

Explanatory Variable	df	Outcome			
		Weight	Fat	BMI	WHR
Baseline <sup>1</sup>	1	<0.0001	<0.0001	<0.0001	<0.0001
Age	1	0.0001	0.0958	0.0013	0.1058
Sex	1	0.3910	<0.0001	0.9953	0.0001
Time	3	0.0062	0.0294	0.0106	0.0379
Treatment	1	<0.0001	0.1142	<0.0001	0.9693
Height	1	0.6691			

Table 13 indicates that height and sex are unlikely to be significant in a multivariate model for weight once baseline weight has been taken into account. Similarly, sex is unlikely to be significant in determining BMI. It also appears unlikely that treatment has any impact on W:HR, so despite W:HR being statistically different between baseline and 12 months when considering all cases- the difference between the differences of both groups is not significant- once baseline values have been accounted for. This information was used in developing multi-variable models.

### **Multi-variable Models**

For each outcome, an unstructured covariance pattern model was found to be a significant improvement over compound symmetry or autoregressive patterns for fitting multi-variable models.

Potential explanatory factors derived from the initial modelling, as explained above, were fitted in a multi-variable model for each outcome. Non-significant variables were removed by backward elimination until a model containing only treatment effect plus other significant variables remained. I.e. only variable that appear to be significantly correlated with changes remained in the final model.

For weight and BMI, heterogeneity of variance was apparent across different time points. As far as possible, normality and homoscedasticity were assessed using residual diagnostics (separately within time points where variance was shown to be heterogeneous) and were found to be acceptable for all models. These were run and double checked with a statistician.



Table 14 adjusted p-values for potential explanatory factors (adjusted for all other variables in the model).

Explanatory Variable	df	Outcome			
		Weight	Fat	BMI	WHR
Baseline <sup>1</sup>	1	<0.0001	<0.0001	<0.0001	<0.0001
Age	1	0.0021	-	0.0146	0.0440
Sex	1	-	<0.0001	-	<0.0001
Time	3	0.0063	0.0435	0.0108	0.0385
Treatment	1	0.0007	<0.0001	0.0001	0.0867
Treatment*Time	3	-	0.0278	-	-

*Apart from treatment, only variables significant at the 5% level have been retained in the models.*

The section below considers the residual differences between groups i.e. the difference between the differences.

### **Weight**

There was a significant difference ( $P=0.0007$ ) between treatment groups in adjusted mean post-treatment weights of 1.8kg (95% CI: 0.8kg - 2.8kg) in favour of the MI group, even when baseline weight, age and time have been accounted for.

There was a significant difference between time points overall ( $P=0.0063$ ) in adjusted mean post-treatment weights. The only 3 month period to show a significant difference ( $P=0.0066$ ) individually was between 3 months and 6 months with a mean decrease of 0.85kg (95% CI: 0.25kg - 1.46kg). There was no significant treatment by time interaction.

## **Fat**

There was a significant difference ( $P<0.0001$ ) between treatment groups in adjusted post-treatment body fat % of 2.6 percentage points (95% CI: 1.5 - 2.7) in favour of the MI group when baseline body fat, sex and time have been accounted for.

There was a significant difference between time points overall ( $P<0.0001$ ) in adjusted mean post-treatment body fat. The only 3 month period to show a significant difference ( $P=0.0252$ ) individually was between 3 months and 6 months with a mean increase of 0.57 percentage points (95% CI: 0.07-1.06).

There was a significant time by treatment interaction overall ( $p=0.0278$ ).

## **BMI**

There was a significant difference ( $P=0.0001$ ) between treatment groups in adjusted mean post-treatment BMIs of 0.70 (95% CI: 0.36 - 1.04) in favour of the MI group, even when baseline BMI, age and time have been accounted for.

There was a significant difference between time points overall ( $P=0.0108$ ) in adjusted mean post-treatment BMI. The only 3 month period to show a significant difference ( $P=0.0101$ ) individually was between 3 months and 6 months with a mean decrease of 0.40 (95% CI: 0.10 - 0.69).

There was no significant treatment by time interaction.

## W:HR

Once baseline WHR, age, sex and time have been accounted for there was no overall difference between the treatment groups in post-treatment WHR ( $P= 0.0867$ ).

## Treatment Fidelity

Treatment fidelity scores rose between the 1st and 2nd measurement points and then rose again by the 3<sup>rd</sup> measurement point for this parameter. Essentially this indicates that the quality of MI being delivered was a) 'beginning proficiency' moving to 'proficient' in terms of overall fidelity and b) getting 'better' throughout the present study. The full treatment fidelity reports are shown in Appendix E and treatment fidelity changes throughout the study are discussed at 6.3.

Table 15. Showing Global rating scores form the Motivational Interviewing Treatment Integrity tool (MITI version 3.0).

Global rating:	0 months	6 months	12 months
3.5 = beginning competency 4.0 = proficiency			
Score	3.7	4.0	4.6
Indication	Beginning proficiency	Proficient	Proficient

## Outliers

Although residual diagnostics were generally acceptable, analysis indicated noticeable outliers; in particular the bullet pointed results below, these are interpreted in the discussion chapter.

- a female in the control group who initially weighed 110 kg but lost over 15kg between months 6 and 9 alongside a decrease in BMI from 41.8 to 35.7 and a varying W:HR
- a female in the active treatment group who had 41.5% body fat at baseline, but only 32.8% at 3 months, returning to 41.2% at 6 months
- a male in the control group whose W:HR dropped from 1.0 at baseline to 0.86 at 9 months

Two schools of thought appear as prevalent in relation to excluding or including outliers from a data set with exclusion arguing that outliers can be removed as they are not ‘typical’ of response to the treatment variable under investigation: conversely the argument for inclusion suggests that removing outliers falsely represents what occurred in the groups. In this study it is highly likely that these have influenced the model fits and effect estimates; however, it is also possible that in a larger sample these outliers may have been replicated i.e. in a sample twice as large - twice as many of the same outliers may have appeared. Each of these outliers is discussed in turn in the discussion chapter.

## **Chapter 6: Discussion**

This discussion relates to the findings from study 2 and how these connect with the two aims set out in the preface:

- i) This thesis’ first aim was to identify whether the Small Changes motivational interviewing in groups Intervention project is a superior approach for achieving significant differences to several weight management parameters when compared to ‘treatment as usual’ groups.

- ii) The thesis also attempts to develop professional practice- which is to be achieved by testing treatment fidelity to MI (via having selected sessions coded and reported on by an independent motivational interviewing coding expert; using the MI treatment integrity tool - MITI 3.0).

The discussion also critically discusses limitations of the current study and suggestions for further research. Each outcome variable is considered in turn and in relation to both the hypothesis (that the addition of MI to the Small Changes programme will result in improved outcomes) and the corroboration or else conflict with current evidence from the evidence base in the area of MI and weight management.

The key aim of this study was firstly to compare the previous treatment as usual (TAU) approach used for the Small Changes weight management programme with a programme using MI as the approach to support people in making key lifestyle changes. Secondly the focus of the work is on professional practice and specifically for this project my clinical practice/performance as a motivational interviewer/'weight manager'. Therefore besides the empirical outcome measures, there is also the measurement of treatment fidelity to MI and consideration of how this represents significant professional development.

Table 15 below, presents the hypotheses for each variable with subsequent result and *P*-value either supporting or not- that hypothesis. In each case it is the residual data- a comparison between the changes from each group that is considered.

Table 16: showing the hypotheses for all variables and the subsequent support or rejection of each hypothesis.

<b>Variable:</b>	<b>Hypothesis:</b>	<b>Result and <i>P</i> value for between groups diff(95% CI) :</b>
Weight	Will be sig lower at follow up in MI group	Supported ( $P=0.0007$ )
Body-fat	Will be sig lower at follow up in MI group	Supported ( $P=0.0252$ )
BMI	Will be sig lower at follow up in MI group	Supported ( $P=0.0001$ )
W:HR	Will be sig lower at follow up in MI group	Not supported ( $P= 0.0867$ )
Fruit and Veg	Will be sig higher at follow up in MI group	Supported ( $P =0.007$ )
Minutes of PA	Will be sig greater at follow up in MI group	Not supported ( $P = 0.024$ )
SF-36 score	Will be greater at follow up in MI group	Not supported ( $P= <0.001$ )

### 6.1 Summary of Key findings

The MI programme results in modest weight loss of around 4% (of starting body-weight) between baseline and 1 year (in the control group the weight loss of 1% was not statistically significant). Both groups gained an increase in well-being as indicated by Sf-36 scores, both groups' aggregate scores rose by 8%. The control group had a 24% increase in number of minutes of PA between baseline and 12 months which was double the 12% increase in the MI group. There was a 27% increase in fruit and vegetable intake in the MI group versus 18% in the control group. Neither group's waist to hip ratio changed significantly across the programme when baseline values are taken into account in the comparison. Despite this there were significant changes to body-fat, body-weight and BMI in the MI group. Body-fat lowered by 4.4% in the

MI group versus 3% (not significant) in the controls. BMI lowered in both groups: 3.9% in the MI group versus 1.3% in the controls (again not statistically significant in the controls). The key conclusion here is that the addition of MI to the Small Changes MI programme produces an improvement in 5 of the 7 indices (the two exceptions are the number of minutes of physical activity where the control group recorded a higher number of minutes of weekly physical activity than the MI group and waist to hip ratio where neither group changed). The recidivism in the control group was high compared to the MI group (85% versus 31%) and treatment fidelity to MI was observed in the MI group as corroborated by the MITI codings shown in Appendix E and discussed below at 6.1.10 Each of the outcome findings is considered in turn below with reference to previous studies.

### **6.1.2 Weight**

Other studies meeting the criteria of 1 year follow up, body-composition and inclusion of physical activity, nutrition and an agreed behavioural change approach have similar results (Cussler et al., 2008; Silva et al., 2010; Foster et al., 2010: all recording 5-7% weight loss). Weight loss of 5-10% appears to bear clinical significance and from this point of view the one year sustained weight loss recorded from the Small Changes programme signifies an intervention that is not as successful as the interventions referenced above (Wing & Hill, 2001).

In a comparable MI study using weight as an outcome measure results are dissimilar, Armstrong and colleagues recorded a mean baseline weight of 93.64 kgs (for the present study it was 95.58) in people undergoing a 6 month intervention followed-up after one year which indicated weight barely altering at 6 months and rising slightly at 18. These results belie the authors' findings that showed number of steps

increasing and cholesterol levels lowering. Perhaps these results should be interpreted with caution as the cholesterol levels seem to have partly lowered via a reduction in High Density Lipoproteins or 'good' cholesterol (cholesterol which has an affinity for carrying away low density lipoproteins for excretion as bile). The triglycerides in this study have also lowered significantly offering potential clinical benefit to the subjects.

The DOH (2010) and Foresight (2007) not only highlight both the prevalence and the associated health problems that accompany overweight and obesity, but also describe the idea that increases in physical activity and alterations to diet (for example greater intake of vegetables, fruits and plant foods) will result in health protection and health gain irrespective of weight, or in the face of fairly minimal weight loss of around 5% (Bacon, 2005; Blackburn, 1995; Seim & Holtmeir, 1992). In light of these studies the MI Small Changes programme was successful at significantly increasing uptake of physical activity and increases to fruit and vegetable consumption besides favourable changes to body-composition. This leads onto the question of how successful the Small Changes programme in relation to weight loss when compared to other MI studies on weight.

### **6.1.3 Was the programme successful in relation to other MI studies?**

A recent review on MI studies (which all identified weight as an outcome measure) suggests a mean weight difference of 1.47 kgs between controls and MI intervention and in the present investigation this is 1.8 kgs in favour of the intervention group (when baseline bodyweights in both groups are accounted for). Armstrong and colleagues (2011) conclude that MI appears to enhance weight loss in overweight and obese patients. This systematic review and meta-analysis involved 12 studies using



weight as an outcome measure. A limitation of this meta-analysis is the difficulty in accounting for a lack of heterogeneity of 'dose' - as the number of minutes per session and the number of sessions of MI was not uniform and in fact varied widely, for example, the dose of motivational interviewing ranged from 50 to 323 minutes. Indeed, an optimal dose of delivery of MI for successful weight management has not yet been established. The dose of MI received in the MI group, in the present study was 1340 minutes total (mean dose in completers was 864 minutes) there may be a dose response relationship between MI and successful weight management i.e. the present investigation reports greater rates of weight loss than the studies included in Armstrong and colleagues systematic review and meta-analysis although Small Changes also delivered a higher dose of MI. The present investigation was also mostly conducted in a group (with three interspersed one to one sessions) format and again this remains unclear territory in relation to effect sizes across studies- more work should be carried out in this area seeking to identify dose response and optimal format to move forward the knowledge base which at present appears to indicate only that MI may well enhance weight management programmes.

Wing and Hill (2001) acknowledge the favourable physiological outcomes resulting from a 5% weight loss, yet use the criteria of a 10% weight loss as 'successful' citing the finding that with this criteria in mind 20% of all people attempting weight loss are successful. Irrespective of the loss being 5% or 10% it is novel to think of weight loss programmes as successful. Indeed much literature overtly states the opposite. For example Mann and colleagues in their article subtitled: Diets are Not the Answer (Mann et al., 2007) acknowledge the likelihood of a weight loss of 5-10% occurring often within the first six months of a programme but then go on to argue that in most cases this weight is regained with 'interest' and that potentially the negative

cardiovascular effects of losing then regaining weight may outweigh the risks of these individuals staying the same weight and not entering into interventions in the first place. What then should programme providers and researchers do? Avoid intervention as it may do more harm than good? Or relate to the few people who are successful at long-term weight loss- whilst accepting 80% failure? Assuredly successful individuals exist with a population of thousands occupying the Weight Loss Registry in the United States all having lost a minimum of 30lbs and having kept this off for over a year and many for longer than five years. In the present investigation at 1 year 43% of the participants had lost more than 5% of starting bodyweight and maintained that loss, yet only one participant lost and maintained > 10% of starting bodyweight.

All of the weight loss in the present MI programme occurred between 0 and 9 months. This is commensurate with other work (Franz et al., 2007) which suggests that the initial period of an intervention is where all weight is lost and that this weight loss tends to range from 5% to 9%. The remainder of programmes, therefore, relate to the essential component of maintenance. A useful way of thinking about weight loss in percentage terms is that for an individual who is highly overweight and 'wishes/needs' to lose and maintain a loss of 50% of starting weight, their life might need to change irrevocably, e.g. 50% less food, a daily persistent increase in physical activity of 50%. And although there are individuals who undergo epiphanies and change completely their lifestyle (US weight control registry offer some clear examples) this, given the limited success of weight loss interventions, is probably not how the majority of overweight/obese people will choose to live. The Small Changes programme was successful in that a statistically significant weight loss occurred in

the MI but not the control group. This weight loss, however, was modest and did not reach a mean 5% loss of starting weight suggested by other researchers as a minimum metric for success (Wing & Hill, 2001). In the present programme, however, the starting bodyweight and BMI was somewhat lower than some of studies reviewed- and so weight loss in percentage terms may also be expected to be lower- e.g. 90kgs starting weight in the Small Changes programme versus studies with, for example, average starting weights of 100kgs in the studies by Dansinger (2005) discussed below.

A further point of interest when considering weight- is specifically how interventions compare at one year and longer than one year. Studies assessing weight loss at shorter than one year are at risk of representing short-term results of efficacy that are not valid at longer than one year. A key argument around weight loss maintenance is that programmes should be a minimum of a year in length/follow-up (Simper, 2013).

One study, using a minimum of one-year follow-up criterion, compared RCTs of popular dietary interventions; Dansinger and colleagues (2005) analysed Atkins, Ornish, Weight Watchers and Zone diets. They reported weight loss of: 4.8kg's (with 47% dropout) in the Atkins, 3.2 kg loss (35% dropout) in the Zone, 3.0 kg loss (35% dropout) in weight watchers and 3.5kg (50% drop out) with Ornish. The mean average weight for the participants in these studies was 100kg (versus 90 kg in the present study) and so a mean 3.5% weight loss was achieved in these studies at 1 year compared to around 4% in the Small Changes study. The cohort sizes were similar in the Dansinger study; circa 40 participants per arm of study and the dropout rate of 35% which also bears comparison to the Small Changes programme. The MI group

in the present study has a slight improvement in weight loss and recidivism rates with slightly more weight lost with slightly fewer participants lost.

Other well designed RCT's include the use of an internet based programme (Tate Wing & Winnet, 2001). Although the results only cover six months from baseline the 'internet plus behaviour-change' group (who were measured against an internet /education group) lost 4.1 kgs which equalled 5% of starting bodyweight achieved in 45% of the original cohort. A similar result to the one-year findings from the Small Changes investigation.

Mann and colleagues (2007) point out the potent and potential effects of the uptake of physical activity without weight loss. The programmes recording the most success involve physical activity and not diet alone, irrespective of weight loss physical activity appears to ameliorate health risk, (Paffenbarger et al., 1986; Duncan et al., 2003; Ross et al., 2004; Bacon 2005). Evidence then seems to support including physical activity as an independent factor capable of improving health with or without weight loss.

Other work points to the idea of around 5% weight loss as realistic Franz and colleagues (2007) conducted a systematic review and meta-analysis and found that larger studies (48 months) showed 3-6% weight loss, which equated to a modest loss of 3-6 kilos. In many ways Franz and colleagues (2007), Wing and Hill (2001) and Dansinger and colleagues (2005) point in the same direction as this Small Changes study i.e.: modest weight loss in the order of around 5% is achievable and maintainable over the medium term.

#### 6.1.4 Sf-36 (general well-being)

A previous study analysing the effects of MI on Sf-36 scores (including physical and psychological feelings of well-being) in chronic heart failure patients suggested that MI may have a positive effect on general wellbeing (Brodie et al., 2008). Although authors also analysing short and long-term effects of MI on Sf-36 describe MI's impact on quality of life via Sf-36 score as 'limited' (Chair et al., 2013 and Leung et al., 2012) (a difficulty in extrapolating findings from this study is the severe nature of the health-condition the subjects were suffering which may transfer poorly to people not suffering the same life-threatening conditions). Butterworth et al., (2006) conducted a study using the Sf-12 (a sister questionnaire shorter than then the Sf-36) to investigate MI based health coaching on employees (in a University) physical and mental health and found that the MI was successful at improving physical ( $P=.035$ ) both physical and mental ( $P=.0001$ ) well-being compared to controls.

The results in the present investigation from the Sf-36 questionnaire show a significant change upwards in the aggregate scores. The average change is accompanied by very similar standard deviations and is 10 points higher than the baseline score. It is also notable that all of the 46 participants completing the MI programme reported a higher score at 12 months than baseline. Out of a possible 161 points participants in both groups scored 125 at baseline and 135 at 12 months. The change is unlikely to be explained by bias as there is a year's gap between each questionnaire. The participants had no sight of their original questionnaire whilst completing the second and so remembering responses from one year earlier seems unlikely. As participants lost weight and altered other physiological parameters there seems cause at least for hopefulness from these encouraging results. In previous work

we concluded a short term rise in feelings of 'well-being' (Paxman et al., 2011) but this was found using the less well-founded General Well-being Questionnaire (Dupuy, 1972) and did not record participants feelings past 3 months.

Wing and Colleagues (1984) carried out an early review of papers, which analysed mood changes in behavioural weight loss programmes concluding a weight of evidence suggesting a reduction in depression and anxiety indices during the course of a programme. It was suggested that few data interpret this mood effect as a direct result of the behaviour therapy as weight loss in pharmacotherapy and 'social pressure' groups also resulted in elevated mood. This points towards the idea that the weight loss alone, rather than the MI component, could well answer for improvements to well-being. Indeed results from the present investigation need to be interpreted with caution as in terms of Sf-36 scores both groups changed by the same amount; indicating no added benefit from the MI component of study 2.

Specific behaviours have also been associated with reduced anxiety, depression and enhanced affective state. Fox (2007) and colleagues carried out a review of work looking at the effects and the proposed mechanisms by which physical activity may enhance mood state. The broad findings here were that studies assessing mood and increases in physical activity by and large showed a positive effect of exercise on mood. This includes data where participants did not change weight. The mechanisms proposed via which physical activity may exert its positive effects on mood include: endorphin production, confidence enhancement, distraction from negative stimuli, increased hippocampal area and enhanced mood via socialisation (Fox, 2007).

### 6.1.5 Physical Activity

Previous interventions incorporating physical activity assessment and MI found an increase in the mean number of steps when MI is compared with controls (Hardcastle, 2013). As Hardcastle acknowledged, the use of self-report measures might generate doubt over the findings. Indeed, the present investigation also relies on self-report and the results suggest very high levels of moderate activity in a group of people who are obese. This trial presents an interesting comparison with the Small Changes study as a one-year post-intervention follow-up was conducted and some of the outcome measures were the same. Although walking levels and cholesterol levels were improved at one-year, changes to weight, BMI and blood pressure (which were recorded as lower in an earlier publications, Hardcastle et al., 2008) were not maintained 12 months post-intervention. The authors present clearly the staff involved in carrying out the intervention, received, 2 4-hour training sessions and then following the initial training review of audio tapes with the lead investigator/MI trainer. In the Small Changes investigation a more formal treatment fidelity check was carried out and a clear result was that the practitioner's skill level probably increased through the 12 month follow-up. This disagrees with Hardcastle and colleagues' assertion that: *'any improvements in the professionals' skills would have been relatively minor, reflecting a fine tuning rather than wholesale change'* (Hardcastle et al., 2013, p.5) yet in the Small Changes investigation there was an increase of almost 20% in coding scores between baseline and 12 months.

As physical activity levels assessed by the Scottish Physical Activity Questionnaire were so high in both cohorts at baseline for the present investigation it seems reasonable to conclude they were inaccurate. Recommendations for people who are or have been obese are to aim for 1 hour a day of physical activity. In this cohort the

treatment as usual group recorded 4.6 hours moving to over 5 hours of physical activity a day and in the MI group this was 3.2 hours a day rising to 3.6 hours. It seems probable that these rates are over-reported at both baseline and follow-up. Physical activity level self-reports are thought to be consistently over or under-reported (Bauman et al., 2008). Revisiting the raw data only suggests an over-estimation of what is considered 'moderate' intensity exercise and so these results need considerable caution. The second feature of this data, beyond the probable over-reporting, is that the levels in both groups increased. It seems reasonable to assume levels of physical activity have gone up in these cohorts of people where weight loss and body-composition changes have occurred but also reasonable to assume that the number of minutes of physical activity reported are not accurate as absolute scores. Use of accelerometers or other more objective recording devices (for instance accelerometers) may have helped to confirm or deny self-reported physical activity levels.

### **6.1.6 Vegetable and Fruit intake**

In the work around MI and vegetable and fruit intake there has been a clear finding of increased consumption amongst healthy populations and cancer survivors alike receiving MI versus controls. Resnicow and colleagues (2001) conducted a study amongst black churches in the United States and Campbell (2009) and colleagues amongst colorectal cancer survivors and in both cases MI produced statistically significant increases to fruit and vegetable intake which are similar to the present study with each of the two studies above and the present investigation yielding an increase of around one portion (80 grams) of daily vegetable and fruit intake.

Furthermore the recorded increases, from this and other studies, of around one portion a day of vegetables and fruits - may signify another clinical benefit with some



work, for example, suggesting a significant decrease in risk for developing type II diabetes with each extra portion consumed (Bassano et al., 2008). The Small Changes TAU groups' fruit and vegetable consumption did not increase significantly between baseline and 12 months. Previous work has suggested a relationship between total vegetable and fruit intake and bodyweight with a higher number of portions correlating with a lower bodyweight (Bassano et al., 2008). In terms of cause and effect the hypothesis is that vegetables and fruit supplant other more calorie dense foods that would have been consumed instead and/or the high non-starch polysaccharide content of plant foods such as vegetables and fruits pass through the digestive tract largely unaltered and so therefore aid satiety but contribute less in terms of an individual's calorie absorption (Frost., 2014).

The potential cause and effect in relation to fruit and vegetables and weight management, however, remains an empirical question. In this study a statistically significant increase in these foods is also associated with a statistically significant loss of weight and the reverse is true in the control group- perhaps indicating that a relationship does exist between increasing vegetable and fruit intake and more successfully managing weight

### **6.1.7 Waist to Hip ratio**

W:HR is a key indicator of risk for cardiovascular disease and type two diabetes (WHO, 2008) and there is a paucity of evidence around the effects of MI specifically on W:HR with one other MI study also recording no significant alteration in waist to hip ratio (Oldroyd et al., 2001) in subjects completing a stage-matched MI intervention. In the Small Changes programme the waist to hip ratio changed in both groups but this was not significant either in or between groups. No effect was shown

by group or sex, however given the small sample size this may have become parent with a larger cohort.. The seeming lack of change in this measure should be considered in light of significant differences in body-fat, bodyweight and BMI in the MI group, the need for triangulation is clear and a reasonable conclusion is that positive body-compositional alteration occurred in the MI group despite no significant changes to W:HR being detected . There may be experimenter bias or equipment error in any measure, however, this seems less likely when several different parameters are corroborated.

### **6.1.8 Body-fat**

Body-composition changes have been analysed in other work around MI and weight management, for example Resnicow (2012) found no significant decrease in body-fat amongst African American girls attending a church based health programme utilising MI although when high versus low attendance were considered body-fat levels were significantly lowered in the high attenders. Hunter and colleagues (2008) found a significant lowering of body-fat levels at 6 months in subjects taking part in a ‘behavioural internet therapy’ programme which was augmented by 2 MI phone calls and in comparison to a control group.

Body-fat represents an important clinical indicator of risk for disease with higher levels signifying greater risk for key lifestyle related causes of morbidity and mortality, specifically cardiovascular disease, type II diabetes and certain cancers. As body-fat lowers, risk is ameliorated until total percentage body-fat reaches a ‘healthy’ level. Certain levels, around 14% in women- to ensure normal menstrual functioning and around 10% in men- for testosterone production, are needed, essential fatty acids also need to be consumed to help with key cellular processes and, for example, the

transport of fat-soluble vitamins. Levels of body-fat, however, were amongst the treatment as usual and MI groups are around 40% a considerable amount above the amount required for healthy physiological functioning.

Subjects in the MI group lost around 4.4% of their starting body-fat this is an important consideration as body-fat over and above bodyweight may have important implications for human health as suggested in the systematic review (Simper, 2013) key measures of body-composition may capture more than measures of bodyweight alone. For example in the present investigation subjects lost 4% of their starting bodyweight and 4.4% of their starting body-fat, yet practically it is possible to lose 4.4% body-fat and maintain the same bodyweight (Ross et al., 2004).

### **6.1.9 BMI**

BMI is a key population health-measure used to monitor the change in people's height to weight ratio. This works on the scale of a population as changes amongst large numbers are detected and probably represent trends in changes to people's lifestyle habits. The BMI on an individual level needs some caution as the relative muscle mass, physical activity levels obviously affect BMI with athletes, strength athletes particularly, recording high BMI whilst having healthy blood sugar control, levels of body-fat and various commensurate health indices (Prentice and Jebb, 2001).

Rubak and colleagues (2005) report a combined effect estimate of 0.72 for lowering BMI in their review of MI based upon 72 randomised control trials and also reporting a clear clinically positive outcome in 72% of studies looking at physiological outcomes. In the Small Changes investigation there is a difference 0.70 kgm<sup>2</sup> at 12

months in favour of the subjects receiving the MI treatment. In consideration of existing data and the outcomes from the present investigation it seems reasonable to assume that there is a statistically significant effect resulting from MI in relation to BMI.

## **6.2 Outliers from the data set.**

The bullet points below highlight three anomalous results from the data which need some brief interpretation.

- a female in the control group who initially weighed 110 kg but lost over 15kg between months 6 and 9 alongside a decrease in BMI from 41.8 to 35.7 and a varying WHR
- a female in the active treatment group who has 41.5% body-fat at baseline, but only 32.8% at 3 months, returning to 41.2% at 6 months
- a male in the control group whose W:HR drops from 1.0 at baseline to 0.86 at 9 months

This first outlier relates to a subject losing an unusually large amount of weight this appears to be accurate and representative of large changes to lifestyle in that one individual. The second issue relates to a subject losing and then re-gaining body-fat at an unusual rate and at a time when that individual was experiencing steady weight loss. The explanation here is probably a false reading from the bodystat 1500 resulting in a suggestion of extreme body-fat loss between baseline and three months. The third point again is an outlier and represents a subject who has lost a significant amount of weight across the programme alongside an unusually large change to W:HR. It would have been possible to remove the outliers prior to commencing the analysis, however this distorts results which, had the sample size been larger, may have had multiple examples of similar outliers in the data set.

### 6.3 Treatment Fidelity

The treatment fidelity results for study 2 present some interesting issues for consideration in interpreting the findings of this investigation. Whereas all three measures showed at least ‘proficiency’ in relation to MITI scores, there is also a clear development of scores by time. The baseline score of 3.7 for example, represents ‘beginning proficiency’ whereas at 6 months the score of 4.0 equals proficiency and at 12 months a score of 4.6 represents another significant move forward (the highest possible score is 5.0). How might the findings have been affected if the scores were higher at baseline? i.e. one hypothesis is that higher MITI scores might correlate with more weight loss or greater maintenance of outcome measures at one year.

Treatment Fidelity firstly represents a clear representation that the intended approach was adhered to – too often counselling approaches are represented within scientific literature as *fait-accompli* with investigators suggesting an approach was adhered to simply because it is described by name (Bellg et al., 2005; Breckon et al., 2008). In the present investigation the Treatment Fidelity firstly confirms the veracity of the approach as MI; secondly it represents significant professional development for the practitioner.

Treatment Fidelity is not only measured in terms of how the practitioner delivers an intervention but can also be viewed from the point of view of ‘receipt’ by the client- in this project with the practical implications of both time and cost it was only delivery that was considered and in behaviour change interventions this might be considered a minimum requirement.

Professional development is charted throughout this project (study 2) by these three coding sessions recorded using the MITI 3.0 (Moyers et al., 2005) yet these measures are only a snap-shot of the professional journey of the principal investigator. This professional development has involved undertaking training, reflection and supervision- to develop skills around motivational interviewing. This training and development- undertaken mostly between 2010 and 2013 stands alone from the empirical investigations involved in study 1 and study 2 and involved training at numerous workshops, training sessions, and supervision sessions in England, Scotland, Italy and the United States with a variety of trainers including the 'midwives' of MI Bill Miller and Steve Rollnick (Miller and Rollnick, 2013).

A key problem with the current programme relates to assessing MI Treatment Fidelity in the group context. Establishing treatment fidelity for MI groups has so far not been achieved, Miller and Rollnick, 2013. This programme used one to one and group sessions, it was the 1 to 1 sessions which were used to assess treatment fidelity, the groups were observed by a MINT trainer but not 'coded'. A comprehensive coverage of what is currently known about MI in groups (Ingersol & Wagner, 2012) and training around using MI in groups (e.g. Allison, 2-day workshop Feb 2012, Edinburgh) offers hope for the further development of treatment fidelity in group settings.

Other ethical decisions included whether to exclude participants whose BMI was 'not high enough' but were gaining weight rapidly (e.g. a participant whose BMI was 28 but had gained 2 stones in a few months) ethically excluding this person would not of been a reasonable response and so the decision was made to accept a subject who fell

outside the criteria on 'ethical' grounds (subject later dropped out due to an unconnected extremely upsetting/family life-event). Life-events will perhaps always ensure that some people drop-out.

Another interesting issue relates to the university ethics consideration of the research proposal, where reasonable feedback suggested the proposal was making 'onerous demands' on participants by including too many physical measures, why not reduce this and lower burden on them and work for the investigator? In fact participants wanted more not less measures the principle investigator was asked repeatedly to measure blood pressure, cholesterol and metabolic rate by many of the participants so they could identify where they were in relation to 'norms' and as a proxy measure of success to controlling their weight.

#### **6.4 Practice and research implications of this work**

In practice terms it seems reasonable to consider a raft of measures to identify 'success' in an intervention, weight loss alone is a blunt indicator of success and underlying processes such as changes to fruit and vegetable intake and body composition may not be fully represented by mere changes to weight. Similarly the limitation to considering only quantitative data needs consideration; how the client's feel about the programme and how they have been affected by changes made remains unclear.

Perhaps in terms of design, attaining Treatment Fidelity scores at the higher range to ensure consistently stable 'high' scores would improve outcome. A difficulty in interpreting this arises in consideration of the paucity of recordings coded- with only three session out of dozens considered scores may have been higher or lower had

different recordings been submitted for coding. Given the brevity of this investigation and the funding implications it would not have been possible to make further submissions but perhaps is in need of consideration for future work. Each coding is presented in detail in Appendix E, showing the global ratings score and giving counts for clinician behaviour and an overall commentary.

There are implications for me professionally resulting from this work as it is now clear: a verifiable method of behaviour change i.e. being clear about the approach undertaken in treating people is essential to broaden understanding of how weight management works, or does not work. In the case of the present investigation this approach was measured via treatment fidelity measures to MI.

#### **6.4.1 Limitations of the present study and considerations for further research**

The following sections (6.4.2 - 6.4.11) present some of the limitations of the present study and considerations for future MI weight management programmes.

#### **6.4.2 Study Population**

The present investigation is limited in scope in relation to the study population (all participants were recruited from the staff of a University) and in a number of other areas relating to the outcome variables, treatment fidelity and design. The study population can only be generalised to a group of people working for a University largely representing academic staff and so it would be difficult to extrapolate to other groups. A representative sample of the people living in a given area may be more generalizable for example. In the present investigation the resources for recruitment to a wider programme were unavailable and consideration of a representative sample could be considered for future work.



### **6.4.3 Outcome variables**

In any study investigating well-being effects of an intervention there is a wide variety of measures which could be included, for examples: metabolic rate, blood lipid alterations and changes to measures of 'fitness'. In the present investigation some of these measures were removed at the point of ethical consideration as unnecessarily onerous measures for the subjects.

### **6.4.4 Treatment Fidelity limitations**

Treatment fidelity for delivery (i.e. the delivery of MI by the principal investigator) was assessed in the present programme but a number of other possibilities occur including observing/measuring the treatment fidelity for *receipt* of the intervention (by the subjects) could be included. This was out-with the limited time and resources of the present investigation but could be an important consideration for future work in this area (Bellg et al., 2005).

### **6.4.5 Study design limitations**

The present quasi-experimental investigation could also be carried out as an experimental trial using an RCT with crossover. There are numerous cost and time implications for this and a primary aim of the present investigation was to compare what was already being delivered with an MI programme, and in that sense the programme does what it set out to do. In an RCT attention would have to be paid to what was included in the control group. An attractive feature of the present study is that one group of people have been treated with the "earnest intention" of supporting them to manage their weight and this has been compared to a programme with the same earnest intention with the addition of MI. Would an RCT do the same?; often 'treatment as usual' in similar investigations are conducted with the control arm of a trial receiving information leaflets and nothing else. As researchers may be inherently

biased towards positive outcomes it is perhaps important to consider that a programme that intends to measure cutting edge design and theories may also be less likely to compare to a strong control group and so often 'information only' and education only' groups are used for comparison and a question arises over likely bias towards the intervention arm of such an investigation.

#### **6.4.6 Cost**

Although this project did not directly assess cost it seems that the cost of a intervention is an important element in sustaining weight management interventions. With enough evidence around intervention programmes helping clients/patients lose 'clinically significant' amounts of weight is it possible to push policy in the direction of longer term follow-up in weight management programmes? This needs to be analysed and discussed in light of the health economics; If each pound lost 'costs' around £24 (or £50 a kilogram) how does this stack up against the inherent costs of prescription drugs, diabetic clinics, foot-checks, treatment for cardiovascular disease, days off sick, sleep apnoea and the other associated problems related to weight? Is this a viable cost-effective intervention? More investigation into cost/outcomes the Small Changes programme is needed.

As early as 1995, researchers were commentating on the direct and indirect costs of obesity to the United States with \$51.64 Billion dollars of a total \$99.2 billion being attributable to direct medical costs and treatment (Wolf & Colditz, 1997).

More recently in the United Kingdom the total costs of overweight and Obesity have been estimated as: 6.6-7.4 Billion and of this 1100 million relates to direct healthcare costs (McCormick et al., 2007) which equates to 2.3-2.6% of the total NHS

expenditure in 2001/2. This is in terms of the treatment i.e. the consequences of obesity, type II diabetes, cardiovascular disease, stroke angina, and specific related cancers, rather than obesity treatment per se.

#### **6.4.7 Recidivism**

Clearly comparing a group with 85% dropout to a group with 63.8% retention at 12 months has a fundamental problem in that the dropout was so great in the educational group it almost defeats the central idea of comparison which is to see which type of treatment has the greatest 'effect'. Although this was not a randomised control trial- from a professional development point of view it is important for the providers of a weight management service to see where their training and project planning efforts are best placed. This means identifying an optimal time to treat people and also an optimal approach to treating and retaining participants.

In the results and this discussion chapter comparison has taken place between an existing approach and MI with the MI group there was greater positive alteration to weight, BMI and body-fat levels, fruit and vegetable intake. Would this have been detected if there were a similar number of people in both groups at the outcome measures? Both programmes were advertised in the same way entry criteria was the same (BMI 30 plus) and both programmes took place in the same setting- so it is reasonable to conclude it was the MI approach that resulted in greater retention of subjects in the MI arm of this investigation.

Measuring itself may also form a useful part of a programme i.e. the 'Hawthorn' effect and indeed many comments from participants in the programme spoke to the idea of being motivated by being measured. Nevertheless in the face of such great

dropout rates it seems reasonable to hypothesise an effect caused by MI as the TAU group were measured in the same way, at the same facility and using the same measures at the same time-points. One thing were fundamentally different: the use of an MI approach in the delivery.

#### **6.4.8 'Quotient of positive change'**

A further key question for this and future weight loss interventions relates to a quotient of weight 'change' involved in interventions with key concerns being risk reduction for non-insulin dependent diabetes (or else a therapeutic effect for insulin dependent diabetes) cardiovascular disease and certain cancers. The proposal of a 'quotient of positive change' seems warranted- which relates not just to losing fat-weight but more specifically the proportion of lean tissue to body-fat lost/gained. This then should arguably be a corollary to any weight management programme, positive change at the metabolic level and not just the loss of weight as discussed earlier in the study 1 literature review.

#### **6.4.9 Responders v non-responders in this programme versus other work**

Consideration of the people who lost weight (41 out of 46) rather than those who stayed the same or gained weight there shows only a slight difference (around a kilo) nevertheless this makes a 'clinical' difference as in these 'responders' a loss of 5.05% of starting bodyweight has occurred. Rather than 4.0% when you include the non-responders. 41 people lost weight between 0 and 12 months 1 stayed the same 4 gained weight. 63.8% of the cohort completed the study and 36.2% dropped out. The non-responders (those who stayed the same or gained weight) gained 3.1 kilos or 3.45% of starting bodyweight. As there was a 4.85kgs weight loss in the responders - at 1 year - this puts this study in the same range as the studies compared by

Dansinger (2005) -as the rates of weight loss in these papers range from 1.9 to 7 kgs at 1 year.

#### **6.4.10 MI proficiency increased throughout study**

As MI proficiency increased between baseline and 6 months *and* 6-12 months it is also worth entertaining the idea that this could have affected results. Although a level of 'proficient' was observed at baseline (ensuring that what was delivered was essentially motivational interviewing) 'proficiency' this proficiency became competency at 6 months maintained at 12 months. Had competency been the level of MI at 0-6 months would subjects have lost more weight?

#### **6.4.11 Sample Size**

A further limitation to this intervention is the limited sample size and as sample size clearly affects statistical significance the ability to detect affect size is potentially somewhat compromised.

### **6.5 Future research and conclusions**

Weight loss of 5-10% has been shown to be achievable in this and many other studies. Maintenance of that weight loss at 1 year in this study (and longer in some others) is achievable. A recognisable approach (Motivational Interviewing in this case) appears to pay dividends in terms of better rates of recidivism, maintenance etc. than alternatives (e.g. education or Treatment As Usual) both in this study and the others reviewed. Weight loss expectations may be a lot higher than 5-10% of starting weight, but also probably unrealistic for those not undergoing a drastically different lifestyle. That is to say 5-10% weight loss might be thought of as 5-10% change to diet and physical activity behaviours - effectively these would be Small Changes but 40%-50% change to bodyweight might require commensurate percentage changes to

these behaviours. Wing and Hill (2001) go as far as to suggest that with higher levels of weight loss there may be 'extreme' negative psychological consequences including binge eating. This does not appear to be the case with the modest weight losses achieved by participants signed up to the national weight control registry which, like other studies reviewed, shows an improvement in mood and affective state in those people losing modest amounts of weight. It is a valid idea to suggest to people that using a recognisable and verifiable counselling approach- motivational interviewing in this case and other support including: advice around exercise and nutrition- presenting a modest loss of weight, increased uptake of physical activity, improved diet and feelings of psychological well-being as all clearly possible and sustainable at 1 year. This seems to be the key message from the current project- that change is possible and sustainable yet this may not be dramatic weight loss.

The question for prospective Small Changes participants or indeed similar programmes may well be this: Is a programme which is successful in achieving modest weight loss, numerous other health benefits which appear to accrue including reduced waist circumference, improved diet, increased physical activity levels and improved feelings of mood something they feel is worth trying? In an area that is full of commercial enterprises promising to drastically cut weight (and clients with commensurate expectations of dramatic weight loss) and completely change people's lifestyle- the Small Changes type of programme may offer a more realistic and evidence based approach to likely outcomes.

Wing and Hill (2001) refer to the common perception (based upon early research and media representation) that successful long-term weight loss maintenance in not

achievable. Yet the national weight control registry in the United States has over four thousand participants who are (>30lbs weight loss for > 1 yr) successful and notwithstanding the registry they calculate that by applying a 10% of initial weight loss sustained as a criterion for success 20% of all participants in weight loss programmes *are* successful.

In the Small Changes programme the key behavioural differences at one year seem to be an increase in physical activity (which amounts to around 27 minutes extra per day compared to baseline) and slightly more than one portion a day increase of fruit and vegetable intake. In the participants reporting back behaviours from the national weight control registry three main behaviours are clear: a diet high in carbohydrate and low in fat, regular daily physical activity (amounting to an hour or so) and regular self-monitoring of weight (Wing & Hill, 2001).

A longer-term follow-up of participants from the Small Changes is warranted. Two key questions for commissioners of programmes similar to Small Changes are:

Is the programme clinically effective? And what will it cost?

The first of these questions is approached in this thesis the second needs further analysis.

This thesis indicates a potential effect for MI when used in a group format and compares favourably to treatment as usual. Treatment fidelity scores were adequate at baseline and rose throughout the study. Further work should expand upon this involving novel tools for assessing treatment fidelity in groups.

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## Appendix A. Taxonomy items used in small changes MI programme.

Session	Brief detail	Therapist behaviour	Taxonomy Item
1. 1 to 1 interview	Explore importance and confidence to change 1-10 scales use OARS to support	1-10  OARS	1,2,3,4,5,13,12,9
2. Food content (labels)	Clients bring their own food labels and explore these with support materials (e.g. label reading card)	(Use E-P-E) E-to ask what is known re: fat, sugar, salt content and then P- info and detail with permission followed by E- what do you make of your own analysis? OARS	2,3,4,5,6,8,9
3. Making choices	Clients examine fat and salt and sugar content of foods with a rack of test tubes signifying the different amounts found in common products	Again E-P-E clients examine the test tubes after being asked what their thoughts are on fat, sugar and salt content. Then info is provided as asked for or with permission. Finally facilitator asks what are your thoughts about this?	2,3,4,5,6,8,9,13,12,9
4. Adapting recipes/portion sizes	Clients suggest favourite dishes and then prepare these in the kitchen. Clients are also asked to reflect on their own portion sizes this is an issue for some people and not for others- o about you?	E-P-E as client is asked to identify food they wish to cook - recipes ( <i>sometimes healthier versions</i> ) are provided. Clients cook and eat these and then are asked for their thoughts on the acceptability of the meal they have prepared and portion sizes	2,3,4,5,6,8,9
5. Managing supportive relationships	Clients explore who it is that supports them in what they do (generally)		2,3,4,5,8,9,13
6. 1 to 1 interview	focus and agenda decided by client		2,3,4,5,8,9
7. Physical activity	Clients are invited to fill in a 24 hour pie chart showing what it is they do in a day, colouring sections in, as inactive, moderately active and exercising - signified by green, amber and red. At the end of the process clients are asked for their thoughts on their own chart	Awareness raising E-P-E e.g. 'how much do you know about the physical activity guidelines?'  OARS	2,3,4,5,8,9
8. Alcohol	Clients are invited to discuss where alcohol fits in with their weight management- or if it's not an issue discuss what is		2,3,4,5,8,9,13
9. Handling relapse	Previous successes are discussed in relation to managing/losing weight		2,3,4,5,8,9
10. Mood and behaviour	Clients are asked what they make of the idea that mood is linked to how we behave		2,3,4,5,8,9
11.	Progress barriers so far		2,3,4,5,8,9
12. 1 to 1 interview	focus and agenda decided by client		2,3,4,5,8,9

## **Appendix A (continued)**

### **Key to taxonomy of behaviours used throughout the MI programme**

A Taxonomy of behaviour change techniques, adapted from Michie and colleagues' 40 item refined taxonomy of behaviour change techniques (Michie et al. 2011), is presented below - also added are specific behaviours from MI that were not part of the original taxonomy.

1. Use of 1-10 scales to open discussion around importance confidence and promote 'change talk'
2. Open Questions
3. A Affirmations
4. R reflections simple and complex
5. S summaries
6. E-P-E elicit, provide elicit- Provide information (with permission or on request only)
7. Goal Setting (behaviour) e.g. walking this week
8. Goal Setting (general e.g. an overall goal that will be achieved via long term maintenance and numerous 'small changes') not a behaviour as such but the goal of 'reducing my blood pressure'
9. Action Planning detailed planning where, when, how, how much and who with- if relevant
10. Barrier identification/solution planning
11. Review of previous goal/s
12. Self-Monitoring
13. Focus on previous success (look back)
14. Model/demonstrate behaviour
15. Prompts/cues/Triggers
16. Facilitate social comparison
17. Relapse prevention
18. Stimulate anticipation of future rewards (look forward)

Sessions 1-12 all have topics. In the MI group people were invited to decide for themselves the topic of conversation/what to cover e.g.: *7 have various exercises and plans we can use for our session but you may have particular things you want to talk about?* 'When group members choose one of the topics on offer their autonomy is supported (*you are in charge of what we do here-I can make suggestions and tell you about exercises and actions others have found useful if you wish*'. MI group members also had three 1 to 1 sessions throughout the programme and again they are invited to talk about whatever they would like to focus on in relation to changing/maintaining behaviour.

**Appendix B. Food frequency questionnaire fruits and vegetables Please put a (✓) on every line**

Food and amounts	Average consumed during last year (for fruits marked * estimate average consumption when in season)								
	Never or less than once a month	1-3 per month	Once a week	2-4 per week	5-6 per week	Once a day	2-3 per day	4-5 per day	6+ per day
Apples (1 fruit)									
Pears (1 fruit)									
Oranges (1 fruit)									
Grapefruit (half)									
Bananas (1 fruit)									
Grapes (medium serving)									
Melon (1 slice)									
*Peaches, Plums, Apricots									
Strawberries, raspberries, kiwi fruit (medium serving)									
Tinned fruit (medium serving)									
Dried fruit eg. Raisins, prunes (medium serving)									

**Please check that you have a Tick (✓) on every line**

**This food frequency questionnaire is adapted from the original EPIC-Norfolk study. [www.epic-norfolk.org.uk](http://www.epic-norfolk.org.uk) and used with permission**

**Appendix B. Food frequency questionnaire fruits and vegetables Please put a (✓) on every line**

Food and amount	Average consumption during last year								
	Never or less than once a month	1-3 per month	Once a week	2-4 per week	5-6 per week	Once a day	2-3 per day	4-5 per day	6+ per day
Carrots									
Spinach									
Broccoli, spring greens, kale									
Brussels sprouts									
Cabbage									
Peas									
Green Beans, broad beans, runner beans									
Marrow, courgettes									
Cauliflower									
Parsnips, turnips, swedes									
Leeks									
Onions									
Garlic									
Mushrooms									

**Please check that you have a Tick (✓) on every line**

**This food frequency questionnaire is adapted from the original EPIC-Norfolk study. [www.epic-norfolk.org.uk](http://www.epic-norfolk.org.uk) and used with permission**



**Appendix B. Food frequency questionnaire fruits and vegetables Please put a (✓) on every line**

Sweet Peppers									
Beansprouts									

Food and amount	Average consumption during last year								
	Never or less than once a month	1-3 per month	Once a week	2-4 per week	5-6 per week	Once a day	2-3 per day	4-5 per day	6+ per day
<b>Vegetables (cont)</b>									
Green salad, lettuce, cucumber, celery									
Watercress									
Tomatoes									
Sweetcorn									
Beetroot									
Coleslaw									
Avocado									
Baked Beans									
Dried lentils, beans, peas									
Tofu, soya meat, TVP, vegeburgers									

**Please check that you have a Tick (✓) on every line**

**This food frequency questionnaire is adapted from the original EPIC-Norfolk study. [www.epic-norfolk.org.uk](http://www.epic-norfolk.org.uk) and used with permission**

**Appendix B. Food frequency questionnaire fruits and vegetables Please put a (✓) on every line**

**Your diet last year, continued**

**Are there any other fruits or vegetables which you ate more than once a week?**

**Yes:**

**No:**

**Food:**

**Usual serving size:**

**Number of times eaten per week:**

**Please check that you have a Tick (✓) on every line**

**This food frequency questionnaire is adapted from the original EPIC-Norfolk study. [www.epic-norfolk.org.uk](http://www.epic-norfolk.org.uk) and used with permission**



**Appendix C. Scottish Physical Activity Questionnaire**

**PHYSICAL ACTIVITY AT WORK - only complete if you are currently employed and remember do not include light intensity activities**

In the past week, how many minutes did you spend each day:	Mon	Tues	Wed	Thurs	Fri	Sat	Sun	Total
<b>Walking whilst at work?</b> <b>DO</b> include: walking up/down stairs, to and from your desk, "doing the rounds" <b>DO NOT</b> include: standing, sitting at desk etc; i.e. time spent not actually walking								
<b>Manual labour whilst at work?</b> <b>DO</b> include: lifting, stacking shelves, climbing ladders, building work, cleaning <b>DO NOT</b> include: sitting at desk, answering telephone, driving, check-out operation								
<b>Total</b>								

**Was last week typical of the amount of physical activity you usually do?**

<b>YES</b>		
<b>NO - I usually do more</b>	Normally, how much more?	Of which activity?
<b>NO - I usually do less</b>	Normally, how much less?	Of which activity?

Your Health and Well-Being

---

**This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. *Thank you for completing this survey!***

**For each of the following questions, please tick the one box that best describes your answer.**

**1. In general, would you say your health is:**

Excellent	Very good	Good	Fair	Poor
<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

**2. Compared to one year ago, how would you rate your health in general now?**

Much better now than one year ago	Somewhat better now than one year ago	About the same as one year ago	Somewhat worse now than one year ago	Much worse now than one year ago
<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

3. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

Yes, limited a lot	Yes, limited a little	No, not limited at all
--------------------------	-----------------------------	------------------------------

- a Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports .....  1 .....  2 .....  3
- b Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf.....  1 .....  2 .....  3
- c Lifting or carrying groceries .....  1 .....  2 .....  3
- d Climbing several flights of stairs .....  1 .....  2 .....  3
- e Climbing one flight of stairs .....  1 .....  2 .....  3
- f Bending, kneeling, or stooping .....  1 .....  2 .....  3
- g Walking more than a mile.....  1 .....  2 .....  3
- h Walking several hundred yards.....  1 .....  2 .....  3
- i Walking one hundred yards .....  1 .....  2 .....  3
- j Bathing or dressing yourself .....  1 .....  2 .....  3

**4. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?**

All of the time	Most of the time	Some of the time	A little of the time	None of the time
-----------------	------------------	------------------	----------------------	------------------

- All of the time     Most of the time     Some of the time     A little of the time     None of the time
- a Cut down on the amount of time you spent on work or other activities.....  1.....  2.....  3.....  4.....  5
- b Accomplished less than you would like .....  1.....  2.....  3.....  4.....  5
- c Were limited in the kind of work or other activities .....  1.....  2.....  3.....  4.....  5
- d Had difficulty performing the work or other activities (for example, it took extra effort) .....  1.....  2.....  3.....  4.....  5

**5. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?**

All of the time	Most of the time	Some of the time	A little of the time	None of the time
-----------------	------------------	------------------	----------------------	------------------

- All of the time     Most of the time     Some of the time     A little of the time     None of the time
- a Cut down on the amount of time you spent on work or other activities.....  1.....  2.....  3.....  4.....  5
- b Accomplished less than you would like .....  1.....  2.....  3.....  4.....  5
- c Did work or other activities less carefully than usual.....  1.....  2.....  3.....  4.....  5

6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours, or groups?

Not at all	Slightly	Moderately	Quite a bit	Extremely
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

7. How much bodily pain have you had during the past 4 weeks?

None	Very mild	Mild	Moderate	Severe	Very severe
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

Not at all	A little bit	Moderately	Quite a bit	Extremely
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5



9. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks...

All of the time	Most of the time	Some of the time	A little of the time	None of the time
-----------------	------------------	------------------	----------------------	------------------

- |   |                            |                            |                            |                            |                            |
|---|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|
|   | <input type="checkbox"/>   | <input type="checkbox"/>   | <input type="checkbox"/>   | <input type="checkbox"/>   | <input type="checkbox"/>   |
| a Did you feel full of life? .....  | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| b Have you been very nervous? .....   | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| c Have you felt so down in the dumps that nothing could cheer you up? ..... | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| d Have you felt calm and peaceful? .....                                    | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| e Did you have a lot of energy? .....                                       | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| f Have you felt downhearted and low? .....                                  | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| g Did you feel worn out? .....  | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| h Have you been happy? .....  | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| i Did you feel tired? .....   | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |

10. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
-----------------	------------------	------------------	----------------------	------------------

- |                            |                            |                            |                            |                            |
|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|
| <input type="checkbox"/>   | <input type="checkbox"/>   | <input type="checkbox"/>   | <input type="checkbox"/>   | <input type="checkbox"/>   |
| <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |

11. How TRUE or FALSE is each of the following statements for you?

Definitely true	Mostly true	Don't know	Mostly false	Definitely false
-----------------	-------------	------------	--------------	------------------

□                      □                      □                      □                      □

a I seem to get ill more easily than other people .....  1 .....  2 .....  3 .....  4 .....  5

b I am as healthy as anybody I know .....  1 .....  2 .....  3 .....  4 .....  5

c I expect my health to get worse .....  1 .....  2 .....  3 .....  4 .....  5

d My health is excellent .....  1 .....  2 .....  3 .....  4 .....  5

*Thank you for completing these questions!*

## Appendix E. MITI coding at 0, 6 and 12 months

**Fig 21 MI global ratings (based on MITI 3.0)**

3.5 = beginning competency

4.0 = proficiency

### MITI coding 1: at baseline October 2011

#### Showing baseline global scores for Trevor Simper.

<b>Global Ratings score =</b>	<b>average of 3.7</b>
<b>Evocation</b>	<b>1 2 3 X 5</b>
<b>Collaboration</b>	<b>1 2 3 X 5</b>
<b>MI Spirit</b>	<b>1 2 X 4 5</b>
<b>Direction</b>	<b>1 2 3 X 5</b>
<b>Empathy</b>	<b>1 2 3 X 5</b>

#### Showing behaviour counts at baseline for Trevor Simper.

<b>Clinician Behavior Counts</b>	
Giving information	1
MI Adherent (asking permission, affirm, emphasize control, support)	1
MI Non-adherent (advise, confront, direct)	0
Closed questions	6
Open questions	4
Simple Reflections	14
Complex Reflections	12

#### Global MI Spirit Summary measures:

**Showing Baseline scores for spirit/summary measures.**

<b>beginning proficiency=</b>	<b>competency =</b>	<b>My score:</b>
3.5	4.0	<b>3.7</b>
Reflections to question ratio 1:1	>2:1	<b>2.6:1</b>
% complex reflections 40%	50%	<b>46%</b>
% open-ended questions 50%	70%	<b>40%</b>
% MI- adherent 90%	100%	<b>100%</b>

### **Clinician strengths:**

The clinician developed a good collaborative relationship with the client and demonstrated a good understanding of the client's perspective. The clinician kept the interview generally focused on the target behaviour throughout the interview even though there were some periods of wandering off topic.

### **Most important area for improvement**

The Autonomy global rating was rated a 3 because although there were subtle instances of the clinician supporting and encouraging greater client sense of personal choice and control, this could be done more overtly and explicitly. Using more open questions and strategic complex reflections would help evoke more and stronger change talk and commitment language. Being careful not to raise inflection at the end of reflections (which turns them into closed questions) would help in evoking more change talk. Contextual factors: A target behaviour was identified, permitting all aspects of MI to be used. Although the target behaviour was identified as increasing physical activity the interview focused on changing sleep habits, which would then help the client engage in more physical activity.

**MITI coding 2: at 6 months, April 2012:**

**Table 20. Showing global ratings at 6 months.**

<b>Global Ratings=</b>	<b>Average of 4.0</b>
<b>Evocation</b>	<b>1 2 3 X 5</b>
<b>Collaboration</b>	<b>1 2 3 X 5</b>
<b>MI Spirit</b>	<b>1 2 3 X 5</b>
<b>Direction</b>	<b>1 2 3 X 5</b>
<b>Empathy</b>	<b>1 2 3 X 5</b>

**Table 21. Showing clinician behavior counts at 6 months.**

<b>Clinician Behavior Counts</b>	
Giving information	<b>0</b>
MI Adherent (asking permission, affirm, emphasize control, support)	<b>3</b>
MI Non-adherent (advise, confront, direct)	<b>0</b>
Closed questions	<b>3</b>
Open questions	<b>3</b>
Simple Reflections	<b>8</b>
Complex Reflections	<b>22</b>

**Table 22. Showing Global MI Spirit Summary measures.**

<b>beginning proficiency</b>	<b>competency</b>	<b>My scores:</b>
3.5	4.0	<b>4.0</b>

Reflections to question ratio 1:1	>2:1	<b>5:1</b>
% complex reflections 40%	50%	<b>&gt;70%</b>
% open-ended questions 50%	70%	<b>50%</b>
% MI- adherent 90%	100%	<b>100%</b>

**Clinician strengths:**

Trevor, it is apparent from this conversation you have an naturally empathetic and reflective nature, with a proficient ability to extract complex reflections; (“It takes tremendous force of will to do that. “) and (“It connects with the TV demo of not appearing heavy”). Complex reflections formed the majority of responses and brought significant additional value to the discussion. You used a quiet and respectful tone and attitude that opened space for you client to express herself in her own words, and follow her feelings. Your complex reflections worked to identify emotions and processes that were important components of her struggle and bring them out for her to recognize. Your reflections were short for the most part, and easy to understand. You used many simple reflections to confirm the ideas she was expressing. This session had a sustained level of the global scores throughout. You used choice, control and change as responses and topics, directed at opening her awareness to what she meant but did not say. There was a feeling of support of all that she had accomplished and the changes she had made. You came alongside her, and did not ask for more than she could deliver. She was self-directed, addressing issues that were important to her, therefore influencing the session, which allowed him to talk through her circumstances in a supportive environment. Your summaries worked to restate the issues and solutions she had achieved, and identified the remaining issues.

**Most important area for improvement**

Open questions can be used with greater frequency to isolate certain points that need addressing; underlying issues that she is not talking about. They work with complex reflections to move the conversation out of the visible and could address motivation, comparing past, present and future- “what would your life look like without this eating disorder”? or “Do you remember a time in your life this was not present?”. These work to uncover emotions and move the conversation forward. Overall, significant complex reflections, warm tone, supportive. Thanks for your good work on this tape!

**MITI coding 3: at 12 months, October 2012:**

**Table 23. Showing Global ratings at 12 months.**

<b>Global Ratings =</b>	Average of 4.6
<b>Evocation</b>	<b>1 2 3 X 5</b>
<b>Collaboration</b>	<b>1 2 3 4 X</b>
<b>Autonomy support (Autonomy Support)</b>	<b>1 2 3 4 X</b>
<b>Direction</b>	<b>1 2 3 4 X</b>
<b>Empathy</b>	<b>1 2 3 X 5</b>

**Showing clinician behavior counts at 12 months.**

<b>Clinician Behavior Counts</b>	
Giving information	<b>3</b>
MI Adherent (asking permission, affirm, emphasize control, support)	<b>4</b>
MI Non-adherent (advise, confront, direct)	<b>0</b>
Closed questions	<b>0</b>
Open questions	<b>4</b>
Simple Reflections	<b>6</b>
Complex Reflections	<b>17</b>

### 3. Global MI Spirit Summary measures:

#### Showing global MI spirit summary measures at 12 months

<b>beginning proficiency= Average of 3.5</b>	<b>competency = Average of 4</b>	<b>My score:</b>
3.5	4.0	<b>4.6</b>
Reflections to question ratio 1:1	>2:1	<b>5:1</b>
% complex reflections 40%	50%	<b>73%</b>
% open-ended questions 50%	70%	<b>100%</b>
% MI- adherent 90%	100%	<b>100%</b>

#### **Clinician strengths**

Trevor, Thank you for sharing your good work with me. This is a tape with a female client who is discussing her past dieting and trying to lose more weight by bringing more exercise into the picture. The target behavior (sic) is more exercise and how she can get it. I listened to the entire session.

From this session it is apparent that you have the spirit of MI and that your MI skills are highly developed. You convey empathetic sensitivity through your words and tone of voice and your attunement to the client is obvious. Your therapeutic style is one of calm and caring concern and you demonstrated an appreciation for the experiences and opinions of the client with the use of some high level complex reflections. You effectively use primarily reflections most of which were complex to add momentum to the conversation and to direct the conversation toward change talk. . Many of your complex reflections are not just paraphrasing but metaphors e.g. *"You've been chipping away; like holding hands with each other* You avoid advising or directing the client and even state: *"It's what works for you"* resulting in a high global score on autonomy. You appear at ease and natural in using the core MI skills such as open ended questions, reflections, affirmations and summaries. One excellent open ended question you used in the session was: " You've got ideas...what's the most likely candidate". This really brought the conversation toward change talk and action planning.

#### **Most Important area for Improvement**

You effectively use 4 of the five principles of MI: empathy, avoid argumentation, roll with resistance and support self-efficacy. One suggestion I have is to try to incorporate the fifth principle of "Developing Discrepancy" into the conversation. To what extent did you create or heighten the internal conflicts of the speaker relative to increasing exercise



in her life. Could you have used an open question to get the client to present her arguments for and against exercise? (Pro's and Con's; Good Things and Not so Good Things) What might the roadblocks to some of her plans be? How motivated and committed is she on a scale of 1 – 10. Try playing with this principle in the future as it really helps tip ambivalence and affirm action.

I enjoyed listening to your tape. Keep up the good work. I hope my comments were helpful.

Next Steps

Work with developing discrepancy

## **Appendix F Email advert for recruitment**

### **Weight management study**

I am conducting a weight management study at the University designed to help people who are struggling to manage their weight and lead a healthy lifestyle. The project will involve having some measures taken and meeting once a month for two hours on a Thursday evening to talk about weight, diet, exercise and any issues relating to your weight that are important. If you think you might be interested in taking part please contact me at this email address, kind regards Trevor.

Trevor Simper RPHNutr  
Senior Lecturer Food and Nutrition  
Ext: \*\*\*\*  
email \*\*\*\*\*

## Appendix G. Case-study of a first interview.

### The Initial Interview

1. Intro: introduce self, greet client by name ask (e.g.) did you find the place ok? Thanks the client for attending

*'yes I've been up here before I only live over the back here'*

2 . I would like to ask you a few questions about managing your weight if that's ok?

*'yes, well that's what we're here for- how long have you got!' laugh*

3. Please could you start by telling me what has worked for you in the past? (Even for a short time)

*'ohh, well I have lost weight in the past and gained it back, I've lost two and half stone at one time and 2 stone at another. Last year I lost a few pounds but re-gained it' (continues at length)*

How were you initially successful at losing the weight?

*'I just cut back- you know sensible eating less takeaways I did more walking but always regain it when I stop'*

You lose focus and go back to old ways.

*'I hadn't thought of it that way but that's it- I lose focus and then clap it back on- it's as if I stop concentrating and don't notice I've stopped and then I've slipped back and by the time I notice the weight has all come back and sometimes more'*

4. What are the reasons for you to carry on looking after your health? Could we list these and discuss them?

*'I don't want to get ill at my age (54) things start going wrong I want to see my grandchildren grow up and I want to get about without a wheelchair- you know just to be healthy'*

There are lots of reasons for you to look after your health mobility, your health and the grandkids

*'yes absolutely they are all important that's why I'm here to do something about it and really crack it this time'*

5. What (realistically) do you feel would be the best form of support for managing your weight now?

*'I could do with checking in with someone, I want to get ideas and know more about what I should be eating – I'm not daft I know that if I sit on my arse and I eat crap I will be fat- well I am fat let's face it. I've come here because I am hoping you'll tell me how to go on'*

- You feel information from nutritionists would be useful and also support will help spur you on- at the same time you know about the behaviours that affect you weight?

6. On a scale from 1 to 10 how confident do you feel about losing weight, in the near future, with 1 being not confident at all and 10 being very confident?

*'I'm a 7 or 8 now I'm here. I feel like I've made the first step I'm done with dieting I want to get on with something that works- permanently'*

so you're feeling pretty confident- what gives you that confidence?

*'I've lost weight before- I know I can do it I just need to keep it off'*

so we're going to work on sustainable change

*'I don't see the point in it otherwise- it's like a vicious circle losing it and then re-gaining it I mean I may as well lose half a stone and leave it than lose three only to gain it all back again with interest!*

7. On a scale from 1 to 10 how important do you feel managing your weight is with 1 being not important at all and 10 being very important?

*'right now it's priority number one! Ask me another time and it may not be as important but like I said I want to those kids grow up and be there with them when they do and I don't want to get sick, there's life in the old dog yet!'*

Sometimes it is more important than others and your weight goes up and down- when you think like you are now it's really important

*'yes right now it's a 10 I really want to crack this'*

### **What was my intention in asking/responding in this way?**

1. Create rapport show I am a friendly human
2. Seek permission from client to focus on weight management
3. Open question with prompts - no option but to focus on what works even if it was only for a week/day or two

**Reflection** highlight connection between 'loss of concentration' and weight regain

4. Highlights reasons for change and then reflection of 'change talk' to lead the client to talking more about the positive reasons for doing this

5. Confidence scaling opens up client to discuss reasons for being confident if their score is low '2' then researcher could say 'ok so you're not a 1 how come you are confident enough to give yourself a two?' Although in this case the client had a high score and so allowing facilitator to say 'tell me about this high confidence' leave again leading to positive change talk i.e. the reasons he is going to be able to do this.

These questions were set to identify the positive reasons for change from the client. In the practice of motivational interviewing it is thought that focussing on negative issues (tell me what the difficulties have been for you in managing your weight?) will lead to negative responses (*Miller and Rollnick, 2012*). Whereas clients will all of had some experience of success, however fleeting this may have been, and so the initial interview is intended to identify what works for them to manage their weight, to allow us to celebrate success they have had previously/currently had and focus expressly on what works and what is likely to work moving forward with their lifestyle/diet/exercise.

The confidence question is purposefully asked last after the subject has had the opportunity to explore success reasons to maintain/change i.e. maximising the chances of higher confidence. These interviews are conducted at the start of the one year project and were the first meeting between the facilitator and client.

### **case-studies from the programme**

Here is an excerpt from a one to one meeting with a client from the programme, the emboldened words express 'change talk' the client is expressing different levels of change talk in relation to **desire, ability, reason, need, commitment and taking steps**. My role as counsellor/facilitator is to pick up on the change talk and strengthen this via several potential strategies. I have attempted to show this by putting in brackets what my words were intended to achieve.

**Me:** 'Thanks for coming through we've just done a set of measures which were positive I wondered with the brief time we have what would you like to talk about?' (**open question to set the agenda**).

**Client:** '*well just really to talk about what I've been doing and how I'm going to maintain this going forward and about chipping away to **continue to slowly lose more weight***'

**Me:** Maintenance and steady further progress (**Simple Reflection**).

**Client:** '*exactly – I don't want to feel I'm on a diet just to chip away each day. I don't want to be on a diet as I've said before just to be mindful of what I am doing and the then the one area I **need** to work on is exercise. I haven't done all that I can do*'.

**Me:** say a bit more about that then - the exercise (**seeking elaboration**).

**Client:** '*well I'm not a huge fan of the gym so whilst I have been taking the dogs for walks - I have increased my exercise level- and as I have lost a stone I definitely **want** to continue on that journey- I'd like to lose another stone I feel like I've done it kind of easily over this year and exercise I kind of feel **will be** the next thing to push me forward and help me lose that extra stone. I **need** to get into a mind-set where exercise going to help me reach that end goal. So perhaps look at doing maybe a class go to the gym... Just something that/where I enjoy doing it rather than...*

**Me:** 'so you said before the gym thing Is something that doesn't appeal- but then classes you feel differently about' (**double sided reflection- gym not an option classes are**).

**Client:** *'I could go to some classes I would enjoy that erm.. its just pushing yourself at the end of the working day to go out again I mean I walk the dog first thing and again in the evening and that's something I can't get out of I have to do it so it's a good thing I've got a dog but other than that this year I haven't really done a lot of walking out in the countryside I've got to up my exercise I know I've got to do that moving forward.*

**Me:** It's just finding the mode and the way you are going to do it and not that you are disagreeing you need to do it (**Complex Reflection of clients status/thoughts**).

**Client:** *"I'm happy that I need to do it - I am happy the way my food changes of gone just being mindful of what I am eating I'm chipping away at it and that's great because I don't feel I am depriving myself at all I've eaten when I wanted to and then made up for it when the time was right so I think to kind of push that forward I think exercise is the next step.*

**Me:** you have a logical entirely sensible way of approaching this- not doing things that you can't sustain but just being mindful of the food (reflects back an instance mentioned by the client about having one biscuit then stopping) and now it seems you feel it's important to do the same kind of thing with the exercise (**Reflective summary**).

---

**Client:** *'it's an interesting challenge but I know to cement what I've done so far I need to do it and to reach my end goal which is to lose another stone I'll need this and I'm in no rush I can take another year to do this'.*

**Me:** What's your felling about the most likely exercise option? (**seeking action plan**).

**Client:** *'I think classes will be the way Pilates appeals and then there is a sports hall near me where they do classes and maybe I could find something there that I'd enjoy just slowly try things out see what works, what I enjoy...'*

**Me:** Chipping away (**Complex Reflection**).

**Client:** *'Chipping away yeah - I think I've slowly worked on what I'm eating being aware of what I'm doing and slowly improving diet without cutting anything out but just not eating too much it's working and I need to do the same with the exercise'.*

**Me:** So the classes sound like a goer and what else? (**open question seeking more options**).

**Client:** *'In terms of exercise?'*

**Me:** Uh huh.

**Client:** *'Well I've bought a bike! Haven't been on it yet but I am looking forward to it I have a car rack and two grandchildren 5 and 6 years old so this would be a good option. I even thought there's a running club where I live and I know a lady who works here who runs the club and I said to her it would be no good for me I could barely walk fast enough never mind- but she said they have all levels walk/run etc so I am not sure if I'll do it but it's a thought- they have different groups with different paces I could give it a try'*.

**Me:** You might try it and give it a go? This says something about you- you're willing to give stuff a try even when you're not sure you'll take to it...  
**(Affirmation).**

**Client:** *'Yes- it's just working slowly for me- I'm definitely feeling better, feeling more energetic I'm feeling willing to give that extra push to do the exercise side of things now'*.

**Me:** *'Kind of spurred on by the feeling good about your success'*.

**Client:** *'Yes, I've lost nearly a stone'*.

**Me:** *'You made logical choices that suit you, with all the advice in the world it's your choices that made the difference'*.

**Client:** *'They do- I've done diets before I can't maintain them they don't work I couldn't restrict my eating that way- I said at the beginning (of the 1-year programme) I need to find a different way and this has worked'*.

**Table 26. Showing examples of change talk.**

Desire	<b>'I would enjoy'</b>
Ability	<b>'I could'</b>
Reason	<b>'I need to do the same with exercise' (i.e. I've lost half the weight through food now the reason for me doing exercise will be to lose the other half</b>
Need	<b>'I've got to'</b>
Commitment	<b>'Exercise will be the (my) next step'</b>
Taking Steps	<b>'I've bought a bike'</b>

## **Appendix H**

### **Motivational Interviewing/Participant Information Sheet: Recording your Interview**

This form is to help clarify whether you are happy for a recording of your interview to be used for training/supervision purposes or not. You are in no way obliged to have your session/s recorded. Your confidence in me and my respect for your privacy are of the utmost concern to me and I wish this to be very clear. If there are issues or concerns for you re: recording we can still carry on this work, without recording and it will not affect in anyway my commitment to our working together.

If you give consent to be recorded this means that your recording may be played or accessed by people training in Motivational Interviewing with me or else supervising my practice and no one else. Please only give signed permission for this if you are happy to do so. Inside training or supervision sessions no more than your first name will be heard by people listening to the recording i.e. no other identifying information will be included. When people attend training, which might include your recording, they also sign a form that guarantees confidentiality, or else they are Motivational Interviewing Network Trainers who will also not discuss, or use or in any way other than my supervision. In short, no one reviewing this recording will either in part of wholly discuss the material recorded outside the training course or supervision session.

The supervision itself refers to my practice and my behaviours rather than yours i.e. supervisors and trainees want to check what I say and how I respond to you and in that sense all judgement should be on my professional conduct and not on you or your issues. Should you decide you are happy for me to record and use your recording in the way described here please read the questions below (or if you prefer I can read them and this form to you) and then sign where appropriate, kind regards

Trevor Simper



**INFORMED CONSENT FORM**

**TITLE OF PROJECT: Motivational Interviewing recorded session**

**The participant should complete the whole of this sheet himself/herself**

Have you read the Participant Information Sheet above?

YES/NO

Have you had an opportunity to ask questions and discuss this recorded interview?

YES/NO

Have you received satisfactory answers to all of your questions?

YES/NO

Have you received enough information about the recorded interview?

YES/NO

To whom have you spoken?

.....

Do you understand that you are free to withdraw from the interview:

- at any time
- without having to give a reason for withdrawing
- and without affecting your future medical care

YES/NO

Have you had sufficient time to consider the nature of taking part in this recorded interview?

YES/NO

Do you agree to take part in this recorded interview?

YES/NO

Signed ..... Date .....

(NAME IN BLOCK LETTERS).....

Signature of Parent / Guardian in the case of a minor

.....

## Appendix I.

# Small Changes: Participant Information Sheet

**Study Title:** What are the possible health benefits from taking part in a weight management programme at Sheffield Hallam University?

### Invitation

You are being invited to take part in a research study. Before you decide whether or not you would like to take part, it is important for you to understand why the research is being conducted and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Please ask the researcher if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

### What is the purpose of the study?

The purpose of this study is to determine whether taking part in a weight management programme at Sheffield Hallam University can help people to alter their behaviour, and whether this can have benefits for overall health.

### Why have I been given this sheet to read?

You have been given this participation information sheet to read because you have responded to a local advertisement and shown an interest in taking part in this research.

### Do I have to take part?

It is up to you whether or not you would like to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect your rights in any way.

### What will I have to do if I take part?

The study will take place over 12 months. Ten adults will be recruited to take part in the study. You will, initially, be asked to attend monthly weight management sessions. You will also be involved in measurements that will be made at the beginning, middle and end of the programme. You may find that the classes help you to change your behaviour.

The following measurements will be made:

- ❖ Body Measurements;
  - Weight and height
  - Waist circumference, measured using a tape measure
  - Body composition- a very small electrical pulse is passed through the body. This is harmless and you will not feel anything at all. By conducting this test we can estimate how much fat and water is in your body
- ❖ Questionnaires;
  - You will be asked to fill in questionnaires about your eating and exercising habits. A further questionnaire will ask about your general wellness.
- ❖ Other measurements;
  - You will be taking part in sessions each month that use Motivational Interviewing, a technique based upon client centred counselling to help you explore, plan and move towards a healthier lifestyle.
  - These sessions will often be recorded and data shared strictly between the researcher and supervisors of this research you will not be referred to by name in any written documents/subsequent research publications.

***If you agree to take part in this study you will be required to attend all of the measurement sessions and weekly then monthly then bi-monthly weight management classes over the course of one year.***

***In the event of illness or an emergency or if you cannot attend a meeting or a laboratory session we would greatly appreciate it if you could contact us using the details below. If you become unwell, or as a female if you become pregnant, during the 12 weeks, it is important that you please let us know.***

***What are the possible side effects of taking part?***

***There are no known side-effects of the body measurements described.***

***What are the possible benefits of taking part?***

Taking part in the programme will enable you to learn more about research in general and will help you to take an active part in the University's working life. You may well (based on our research so far) benefit from the weight management classes. You might find you want to alter your behaviour in order to live a healthier life. You might also lose some weight; feel fitter/better in general during the programme.

***Will my results be kept confidential?***

All information, which is collected, about you during the course of the research will be kept strictly confidential. Any information about you that is seen by anyone other than the researcher and their supervisor will have your name and address removed so that you cannot be recognised by it.

**Contact for further information**

Trevor Simper RPHNutr  
Senior Lecturer Food and Nutrition  
Sheffield Hallam University  
Sheffield U.K.  
South Yorkshire  
City Campus  
Stoddart Building  
Room 7402a  
S1 1WB  
U.K Tel 0114 2253978  
International Tel 00 44 1142253978  
t.simper@shu.ac.uk