Evaluation of an internet based weight loss intervention

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Abstract

Introduction: The increasing obesity epidemic requires investigation of the effectiveness, cost-effectiveness and scalability of alternative delivery methods for weight loss interventions, such as via the internet.

Aims/objectives: To examine characteristics, feedback format, engagement levels, behaviour change techniques used and effectiveness of individualised feedback within internet based weight loss interventions to refine a pre-existing private sector web-based platform 'My dietitian online'. To pilot test this refined platform, to investigate its feasibility and acceptability of this refined platform for delivery in primary care and to inform the design and conduct of a future definitive RCT. To describe website use and explore health professionals' and participants' views and perceptions of the intervention in terms of acceptability, feasibility and usability.

Methods: (i) Systematic review of the components and effectiveness of individualised feedback within internet based weight loss interventions. (ii) A 12-month rehearsal pilot randomised controlled trial (RCT) of an internet based dietary and physical activity intervention in two population groups, with collection of data on anthropometric measures, diet, physical activity, quality of life and predictors of behaviour change. The main focus of the trial was on feasibility, including recruitment and retention rates. (iii) A mixed-methods qualitative process evaluation conducted alongside the pilot RCT comprising analysis of website usage and semi-structured interviews with participants and healthcare professionals to explore their experience of the intervention.

Results The systematic review identified 14 studies. Interventions with individualised feedback led to more weight loss than those with no feedback. Studies examining different modalities of weight loss intervention were very limited. In the pilot trial 61 men with diabetes and 16 post-partum women were recruited. At 12 months retention rates for men were 61% in the intervention arm, 53% in the control arm, and for women were 53% in the intervention arm and 54% in the control arm. Website usage varied greatly between intervention participants, with 49% and 57% of men and women

respectively ever using the website. The semi-structured interviews revealed that participants and health professionals saw an internet based intervention as an appropriate method to implement within the NHS for weight loss, with the suggestions made for integration with current services.

Conclusion High attrition rates along with low adherence to the intervention were identified. Possible refinements to the website were suggested to reduce the burden and time requirements for users.

Candidate statement

I wish to acknowledge the help and contribution I have received throughout my PhD studies.

Firstly the project would not have been possible without the web design and web hosting from PraksisCare or the health professionals involved who delivered the internet based weight loss intervention.

I received help with my systematic review, from James Newham [post-doctoral researcher] acting as a second reviewer, in relation to literature searching, data extraction, collection and analysis.

Two undergraduate placement students assisted with data input for the outcome measures collected during the Pilot RCT.

Statistical advice was received from members of the Institute of Health & Society Statistical team.

Interview transcription was conducted by secretarial staff within the university. Interview coding was second coded by Lorraine McSweeney, research assistant.

My supervisors were involved in planning and organisation throughout the project.

The rest of this PhD work was conducted by myself; because of this I have chosen to write in the first person throughout to enable me to demonstrate my reflections and conclusions from the study and my experiences as a researcher.

Acknowledgements

I would like to dedicate this thesis to the memory of Helen Moore who provided the inspiration to conduct this research.

I wish to show my gratitude to my four supervisors; Ruth Bell, Ashley Adamson, Vera Araujo-Soares and Elaine McColl, who have provided me with excellent guidance throughout and allowed me to develop as a researcher.

I would like to thank everyone in the HNRC office for making it such an enjoyable and supportive environment to work in.

A big thank you goes to my friends and family, the Sherrington clan, for encouraging me as always. I would also like to dedicate this thesis to the loving memory of my dear Granddad. A special thank you goes to my role models, my mum and dad, for making each stage of my education possible and for their complete support. Thank you to Peter, for putting up with me and making me happy.

The project would not have been possible without the funding received from County Durham and Darlington NHS Foundation Trust. Thank you to all the health professionals who were involved in the project. I am also greatly appreciative of my studentship funding through Fuse via ESRC.

Lastly, thank you to all the participants who joined the study and were such an influential part of my PhD.

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Chapter 1 **Background and Introduction**

My thesis begins by outlining the background that led to this research followed by an introduction into the research area, exploring the importance and relevance of conducting an internet weight loss intervention.

The intervention, website, used in this pilot study originated from a Danish study which created a website called ‘Slankedoktor’, translated to Slimming Doctor for English-speaking participants (Brandt, 2011). The original Slimming Doctor study utilised an uncontrolled prospective design. The essence of the intervention was for the dietitians to provide their usual care but via web messages within a website, based on participants’ food and exercise inputs. After the first four month intensive weight loss period participants lost an average of 7kg in weight. The next 16 month maintenance stage showed participants maintaining or increasing their weight loss, with average weight not changing. The results indicated that the internet intervention achieved weight loss similar to that in conventional care and at a lower cost, with the potential for weight maintenance, with participants maintaining weight loss over a sustained time period (Brandt, 2011). Further research with a more robust design for example, randomised controlled trial, was needed to confirm these initial findings.

At the time preceding this study the NHS was seeking evidence-based solutions to the increasing challenge of obesity and in particular weight management in primary care. A PhD student in the Human Nutrition Research Centre had recently completed a study of brief interventions for obesity in primary care; the BiO project (Helen Moore supervised by Adamson; (Moore *et al.*, 2001; Moore and Adamson, 2002; Moore *et al.*, 2003a; Moore *et al.*, 2003b; Nelson *et al.*, 2006)).This study had served to highlight the challenges for primary care for weight management. Major barriers were lack of knowledge and expertise and time pressures in the primary care setting. Moore and Adamson met Brandt (Slankedoktor; (Brandt, 2011) at a European Congress on Obesity meeting (Helsinki 2003). This led to collaboration between Moore and others in UK and Brandt to develop Slankedoktor to be used in the UK; Slimming Doctor. At this time

County Durham and Darlington Foundation Trust approached Adamson with interest in exploring novel solutions for management of obesity in primary care.

A proposal was developed in a partnership between Durham and Darlington Trust, dietitians working in the trust and Newcastle University to pilot the feasibility of the website. The proposal was to test the website as it stood but to allow for some refinement in order to make it appropriate to use within the NHS, i.e. adapting the website so it was possible to provide the same level of service that would be received in a usual NHS dietitian consultation but changing the format in terms of the mode of delivery of the treatment. Funding was secured for the study from the Trust and PhD studentship funding was granted through the UKCRC Centre of Excellence for translational research in public health; Fuse.

The change in mode of communication/delivery of health care professional feedback and advice gave the rationale for my systematic review of examining individualised feedback via internet based weight loss interventions.

The purpose of this PhD study was to evaluate the potential of replacing face to face weight management consultations, usually provided by health care professionals, with internet based consultation delivery. The trust has a large rural community; therefore the concept of harnessing the potential of internet delivered interventions was favoured as a way of attempting to overcome highlighted issues in traditional primary care, such as time and capacity pressures. Internet based delivery has the potential to reduce time required per patient and circumvents the problem of varied geographical spread of patients and health care professionals. This study proposed to examine the viability of replacing face to face consultations with internet based consultations as an alternative mode of health care delivery for weight loss/management in primary care. The website and delivery of the web-based intervention, modified for use in a UK NHS setting, were considered in terms of engagement, acceptability and retention rates. The study involved participants recruited from primary care in the north east of England with the

purpose to identify whether a programme such as this could be implemented in the NHS.

The role I played as researcher began by conducting a systematic review and meta-analyses examining internet based weight loss interventions. I then started with the development of the protocol for the study, to comprise a pilot RCT. I decided on the data collection tools and materials that would be used, and the refinement and finalisation of the intervention to make it appropriate for use in a UK NHS setting. Along with a GP, Dietitian and health psychologist, I trained the health care professionals how to use the internet based intervention and maintained communication with them throughout the intervention. I wrote the application for NHS ethical approval. I was responsible for all recruitment and liaison with GP practices and participants. I conducted all data collection at each of the three time points, along with interviewing of participants and health care professionals. I conducted all quantitative and qualitative data analysis. Throughout, I was advised and guided by my supervisors.

1.1 Aims and objectives

Aim

- To investigate the feasibility and acceptability of an internet based weight loss intervention as delivered in primary care and of undertaking a future definitive randomised controlled trial to evaluate the clinical and cost effectiveness of such an intervention.

Objectives

Chapter 2: Systematic Review

- To describe the characteristics of the study arms within the internet weight loss interventions.
- To assess the compliance and engagement of participants with the weight loss interventions.
- To assess whether internet-based contact is effective when individualised feedback is provided for weight loss in overweight and obese adults.
- To examine the different provisions of feedback within weight loss interventions.
- To identify the behaviour change techniques incorporated within study arms.

Chapter 3: Pilot RCT

- To undertake a pilot randomised controlled trial (RCT) of the internet based weight loss intervention versus usual care in two study populations, in order to assess likely rates of participant eligibility, consent, receipt of intervention and retention for collection of outcome data.

- To examine the comprehensiveness, acceptability and feasibility of the data collection tools and questionnaires proposed for a future definitive trial.

- To estimate the key parameters needed to inform the design and sample size calculations for a future definitive trial.

Chapter 4: Process evaluation

- To describe website use (adherence and engagement with the website) of the participants and health professionals.

- To explore health professionals' and participants' views and perceptions of the intervention in terms of acceptability, feasibility and usability.

The rest of this chapter seeks to set the context of the research presented in this thesis it explores why this research is necessary and potentially a beneficial route to investigate for treatment of obesity and weight management. To begin the wider issue of obesity and public health is discussed then policy and recommended treatments for obesity are examined, outlining what health care systems are currently charged with providing care to patients. The chapter then investigates the issues related to developing complex interventions, such as those needed for weight loss. This is followed by findings from weight loss interventions and specifically NHS based weight loss interventions to identify the advantages and disadvantages emerging from previous research and to highlight gaps in the research. The chapter concludes by presenting the case for why internet based interventions have the potential to be beneficial within the NHS as a new method to deliver weight loss interventions; this focuses on the two population groups involved within this study, post-partum women and men with diabetes presenting a rationale for why these two groups in particular could benefit from an internet based weight loss intervention.

1.2 **Obesity facts**

To assess whether people are overweight or obese validated methods should be used. For adults this involves using Body Mass Index (BMI) (weight kg/ (height m^2)) (NHS Choices, 2014). However, using BMI as a measure of obesity has been met with some criticism. One of its limitations is its inability to take into account muscle density (Foresight, 2007). This causes a problem when measuring people who have a high percentage of muscle, such as sports-men or women. The measurement has potential to misclassify heavily muscled individuals as overweight or obese. However, gold standard alternatives (dual energy x-rays (DEXA) scans or hydrodensitometry) are expensive and not freely available. Despite the limitations of BMI, strong correlations have been identified between BMI and gold standard methods for measuring fatness (Gallagher *et al.*, 1996). BMI is also an easy technique for health care practitioners to use to identify when patients may be at a greater risk of health problems owing to their weight (U.S. Preventive Services Task Force, 2003; Barton, 2010). For these reasons, BMI is generally held to be a suitable anthropometric estimate of fatness for public health purposes. It has been suggested, nonetheless, that other measurements such as waist circumference may be useful in addition to BMI owing to the connection between excess abdominal fat and metabolic syndrome (type 2 diabetes, high blood pressure, obesity) (Manson *et al.*, 1995; National Institute for Health and Clinical Excellence clinical guidelines, 2006 updated 2014; Zhang *et al.*, 2008). This thereby gives an assessment of body composition in addition to fat mass and enables both risk factors to be examined to give an overall assessment.

Table 1-1: International classification of adult BMI

Classification	**BMI (kg/m^2)**
Underweight	<18.50
Normal weight	18.50 -24.99
Overweight	>25.00
Pre obese	25.00-29.99
Obese	>30.00
Obese class I	30.00 -34.99
Obese class II	35.00-39.99
Obese class III	>40.00
(World Health Organisation, 2000)	

Table 1-1 above outlines the different categories of BMI classification for adults (World Health Organisation, 2000), whilst Table 1-2 below outlines waist circumference recommendations (Leans, 1995).

Table 1-2: Risk associated with waist circumference measurement

		Increased Risk	**Substantially increased risk**
	Low	**High**	**Very high**
Men	<94cm	>=94 cm	>=102 cm
Women	<80cm	>=80 cm	>=88 cm
(Leans, 1995)			

Finally Table 1-3 describes the increase in risk as both waist circumference measurement and BMI increases.

Table 1-3: Health risks associated with overweight and obesity in adults based on BMI and waist circumference

BMI classification	**Waist circumference**		
	Low	**High**	**Very high**
Overweight	No increased risk	Increased risk	High risk
Obesity 1	Increased risk	High risk	Very high risk
(National Institute for Health and Clinical Excellence clinical guidelines, 2006 updated 2014)			

Surveys measuring the prevalence of obese adults in England identified 24.7% of men and 25.7% of women with BMI greater than 30. The most recent survey found 66.5% of men and 57.8% of women were overweight (more than 70% of men and women aged 45-65 years) (Health and Social Care Information Centre 2009; Health and Social Care Information Centre, 2014; Public Health England, 2014b) .

Obesity has become a major public health concern with the situation now referred to as an 'obesity epidemic' (Department of Health, 2008; Morgen and Sorenson, 2014; Taylor *et al.*, 2014). Global estimates from 2008 identified approximately half a billion obese adults (more than 10% of the adult population) (World Health Organisation, 2014b), while in England obesity levels have risen by 11% in men and 10% in women in the last ten years (Health and Social Care Information Centre, 2013b).

There is a cause for concern due to the clear link between obesity and a number of comorbidities with serious consequences for quality of life and cost of treatment (Foresight, 2007; World Health Organisation, 2014b). Overweight or obese people are more likely to have high blood pressure and those who are severely obese are likely to die, on average, 8-10 years earlier (Department of Health, 2008; Public Health England, 2014a).10% of all cancer deaths, among non-smokers, and between 75-85% of hypertension

cases are associated with being overweight or obese (Kopelman, 2007; American Heart Association, 2009). The risk of developing type 2 diabetes is increased considerably (8-20 times more likely) for people categorised as obese class III (BMI>40) compared to those who are a healthy weight (Field *et al.*, 2001; Schmidt *et al.*, 2013), with 65-80% of new cases of diabetes being attributed to patients being overweight or obese (World Health Organisation, 2014a). Obesity can also lead to serious psychological conditions such as depression and other mental health problems, which can be caused by social stigmatisation and bullying (Department of Health, 2008; NHS Choices, 2014).

The direct cost of obesity to the NHS is estimated at more than £5 billion per year (Department of Health, 2011b; Department of Health, 2013). In 2004 the estimated impact of the increasing trend in obesity was that by 2023 the incidence of many conditions could be increased: stroke by 5%, angina by 12%, heart attack by 18%, hypertension by 28% and type 2 diabetes by 54% (Department of Health, 2004). These findings were dependent on the trend, increasing weight and BMI, continuing unabated. Although obesity rates appear to be slowing down, i.e. not increasing as previously projected, rates are still increasing and thus the cost to the NHS is still increasing (Wang *et al.*; Department of Health, 2011a). This trend illustrates the impact obesity is having on NHS resources in relation to required hospital admissions, staff time, medication and other interventions.

In addition to the costs for the NHS the rising problem of obesity costs the economy around £16 billion per year, from lost earnings due to premature mortality or obesity/obesity related illnesses resulting in work absences and loss of productivity (Morgan and Dent, 2010; Department of Health, 2011a). This figure is set to rise to £50 billion per year by 2050 if the current obesity epidemic remains unchecked (Foresight, 2007).

In the past body size and image was often an issue associated to women rather than men (Grogan, 2007). However, obesity is now almost as prevalent in men as it is in women. A concern connected to this increase results from survey findings revealing that men are less likely to get their BMI

checked than women (Foresight, 2007). Both men and women can misjudge whether they are overweight or obese but this was most common within men and as a consequence may lead to them not attempting to alter their weight (Chang and Christakis, 2003; Lemon *et al.*, 2009).

Inequality in health is a commonly acknowledged issue which needs in depth consideration. Evidence is available associating obesity with social class, with obesity more common among people with lower social economic status (The Marmot Review, 2010). Findings suggest that those with a lower social economic status and level of education will be less likely to adopt healthy approaches to weight loss or participate in weight loss programmes (Adler *et al.*, 1993; Foresight, 2007). It is important the services or a range of services are available to ensure that everyone has access to weight management services.

Causes of obesity are complex with many factors attributable to the rising trend. There has often been an over simplistic view that the solution to obesity is easy and an individual should merely eat less and exercise more. It has now started to be recognised that this individualistic view needs to be moved away from to adopt a more socio-ecological perspective (Kirk and Penney, 2013). There is now clear evidence of how individual choices are influenced by modern society (Department of Health, 2008).

The increased use of technology has led to people using devices that require minimum physical activity, such as automated transport, escalators and internet shopping (European Food Information Council, 2003; World Health Organisation, 2004). This development has also impacted on the types of common occupation. Manual labour jobs, requiring moderate intensity physical activity, have decreased gradually over the last five decades resulting in a decrease in occupation related energy expenditure, which is seen to account for a portion of the increase in mean body weight amongst the population (Church *et al.*, 2011). The physical environment also plays an important part in food choices. The number of restaurants, fast food and takeaway outlets has increased making foods high in hydrogenated fats and salt content readily available. Research has shown that exposure to

takeaway food outlets was associated with greater body mass index and greater odds of obesity (Thomas *et al.*, 2014). These food sources, which tend to be nutritionally poor with plenty of calories and low levels of vitamins, are often the cheaper, and therefore more desirable, options for the public (Foresight, 2007). Physical surroundings also impact on the amount of physical activity people perform. Many areas of housing now support the use of cars rather than making it safer for people to walk or cycle. Issues such as availability, cost, individual preference and local knowledge are influential factors to determine whether people will increase their physical activity (Seefeldt *et al.*, 2002; Mansfield *et al.*, 2012).

Some of the causes of obesity included above illustrate how the obesity epidemic is not just attributable to individual behaviour but also to changes in the environment. These findings demonstrate that in order to challenge 'obesogenic environments' society's involvement is essential. Obesity has been shown to reduce individual life expectancy but this impact could be even greater in the future, leading to national reductions in life expectancy, unless reversal strategies to halt the rising trend are implemented (Department of Health, 2004; Lean *et al.*, 2006). Obesity is acknowledged as a major health problem, with the need for intervention essential. Therefore the variety of approaches implemented to tackle this issue will now be discussed.

1.3 **Policy**

Government reports state that a whole population (life course) approach to obesity is needed which incorporates the wider environment in order to improve people's health (Department of Health, 2011a). Dedicated resources need to be set aside to enable the promotion of healthy eating, assisting people to make healthy food choices (e.g. healthy food options in canteens) and to encourage people to become more physically active (i.e. providing facilities such as walking or cycle routes) (Department of Health, 2011a; Department of Health, 2013).

National Institute for Health and Clinical Excellence (NICE) recommends advice and treatment in relation to weight management should take into

consideration patients' needs and preferences. Therefore tailoring (personalisation) of information and recommendations is essential. Tailoring advice is important to ensure that potential barriers, such as lack of facilities, time or knowledge, can be addressed and facilitators, such as support, resources and education, can be enhanced (Mühlbacher and Bethge, 2013; National Institute for Health and Clinical Excellence public health guidelines, 2014).

National Institute for Health and Clinical Excellence clinical guidelines (2006 updated 2014) describe the clinical care pathways which should be available for those who are obese or overweight:

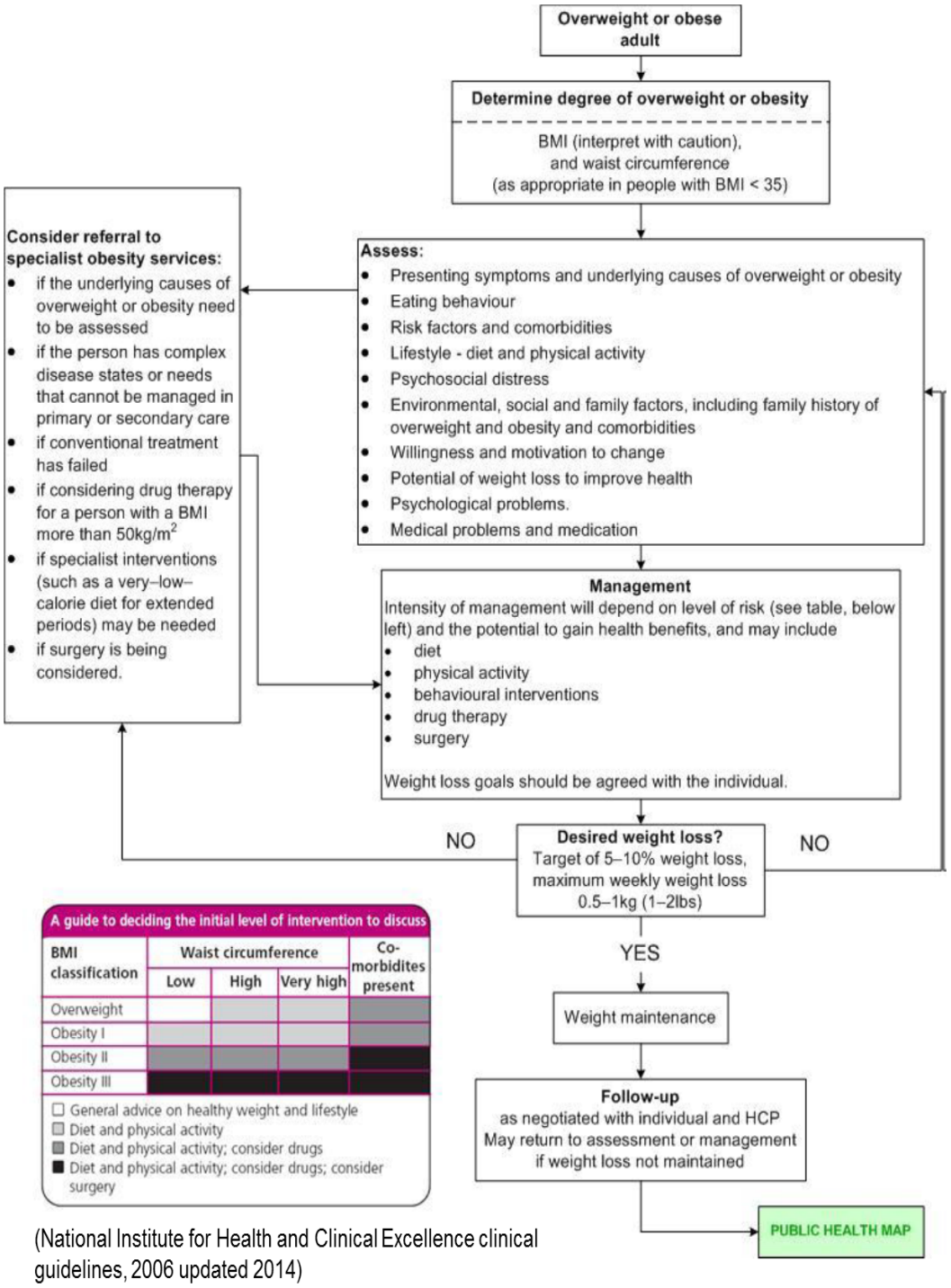
- The first treatment recommended to patients should be lifestyle modification (healthier eating behaviour, increasing physical activity). It is stated that weight management programmes should include behaviour change strategies when approaching lifestyle modification. Examples of effective strategies outlined are self-monitoring, goal setting, social support, relapse prevention, cognitive restructuring (and several more).

- If this is unsuccessful drug treatments may be considered if deemed to have potential benefits for the patient.

- When patients reach the classification of Obesity III (BMI >40 kg/m^2) then bariatric surgery may be recommended. This may be suggested for those patients who are classification Obesity II (BMI 35-40 kg/m^2) and have another serious disease (i.e. type 2 diabetes or high blood pressure). Clinicians have also been advised to consider surgery assessment for patients with diabetes who are within the Obesity I classification group (BMI 30-35 kg/m^2).

- Bariatric surgery would be the first option of treatment for those with BMI >50 kg/m^2.

Figure 1-1: Clinical care pathway for adults



(National Institute for Health and Clinical Excellence clinical guidelines, 2006 updated 2014)

Figure 1-1 (National Institute for Health and Clinical Excellence clinical guidelines, 2006 updated 2014) above illustrates how management of obesity is undertaken in primary or secondary care. It also indicates why

patients may be referred to specialist obesity services. The pathway outlines how patients move from weight loss to weight maintenance phases. The public health map mentioned at the bottom of the flow chart can be seen below in Figure 1-2.

Figure 1-2: Public health map: recommendations on delivery

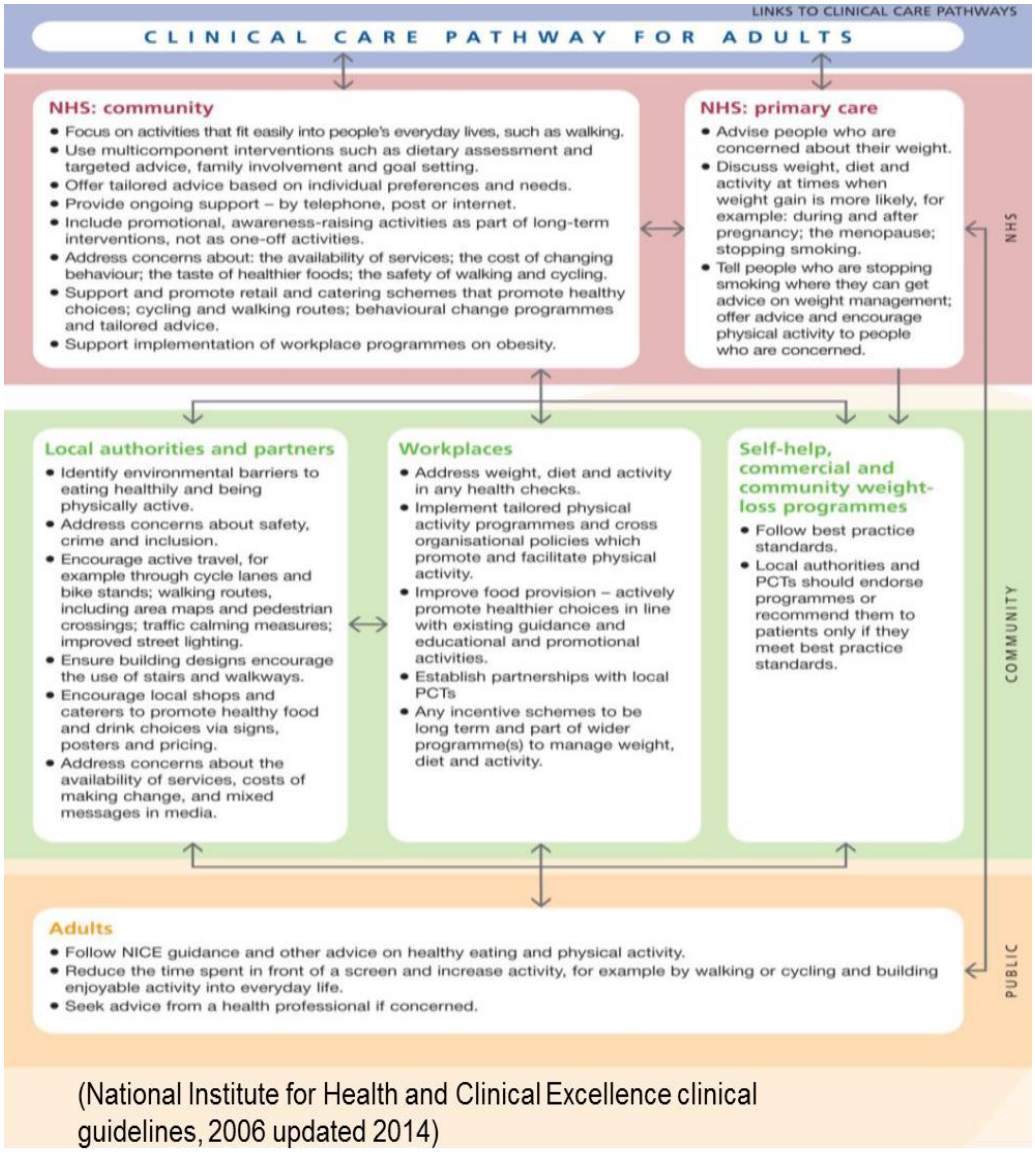


Figure 1-2 (National Institute for Health and Clinical Excellence clinical guidelines, 2006 updated 2014) above illustrates the different systems and people involved in obesity management. Due to the health risks associated with being obese or overweight, prevention and management is a priority for all. Therefore local authorities, workplaces, NHS, schools and individuals all need to be involved to support behaviour change. Health professionals who

advise on diet, weight and activity need training, experience and enthusiasm to motivate people to change (Story *et al.*, 2002; Jackson *et al.*, 2013; National Institute for Health and Clinical Excellence public health guidelines, 2014).

To maintain a healthy weight 'energy balance' is required, energy intake should not exceed energy expenditure (Hall *et al.*, 2012; National Heart, 2013; Hill *et al.*, 2012). Dietary advice to enable 'energy balance' are eating five portions of fruit and vegetables per day, watching meal portion sizes, eating as little as possible fried foods or food/drinks high in sugar or fat and eating fibre-rich or starchy foods. For energy expenditure it is recommended that people minimise sedentary activities and try to take part in enjoyable activities that can be incorporated into everyday life (for example walking or cycling) (NHS Choices, 2011; National Heart, 2013).

Weight loss programmes should only be recommended to patients if they are based on a balanced healthy diet, encourage regular physical activity and expect people to lose no more than 0.5-1kg (1-2lbs) a week (The Diabetes Prevention Program Research, 2002; NHS Choices, 2012). NICE states that if programmes do not meet these criteria then they are unlikely to help a person maintain a healthy weight in the long term (National Institute for Health and Clinical Excellence clinical guidelines, 2006 updated 2014).

Some government initiatives include devoting approximately £14 million to Change 4 Life (public health campaign) in 2011/12 for health promotion (Mayor, 2009; Department of Health, 2011a). Another approach is the Public Health Responsibility Deal, https://responsibilitydeal.dh.gov.uk/ (Department of Health, 2012b). Organisations voluntarily sign up to the Responsibility Deal and pledge to take action to improve public health, through their duties as employers, their commercial actions and their community involvement. One aim is to cut five billion calories from the nation's daily diet with supermarkets, food manufacturers, caterers and food outlets all joining the campaign. Around 70% of companies contacted to provide reports on their progress have done so, with more expected to be received (Department of Health, 2012b).

Research funding is also available, with a previous competition of £4 million for technological innovative solutions to tackle health problems, with £100 million being provided for ground-breaking clinical NHS research to test new treatments (Department of Health, 2011a). More evidence is necessary to assess the impact that specific interventions can have on weight loss/management in primary care (National Institute for Health and Clinical Excellence clinical guidelines, 2006 updated 2014; Department of Health, 2011a).

1.4 **Methodology**

1.4.1 ***Philosophical underpinnings of qualitative vs quantitative research***

The distinctions often made between quantitative and qualitative are based on the philosophical underpinnings of each perspective to investigate particular areas of interest. Quantitative research tends to be explained using terms such as numbers, positivist paradigm, artificial settings, behaviour, realism, hypotheses, causality or deductive (Bryman, 1984; Hammersley, 1992; Cohen *et al.*, 2007). In contrast qualitative research is often described as phenomenological, interpretation, meaning, description, idealism, words, natural setting, constructivism, inductive or collectivism (Bryman, 1984; Bryman, 1992; Hammersley, 1992; Baum, 1995). This distinction can be extended to state that quantitative methods are based on the assumption that behaviour can be explained by objective facts and independently of the researcher (Scotland, 2012). Quantitative methods examine relationships between variables and help to establish cause and effect to enable the possibility of replication and comparison of groups though hypothesis testing (Creswell, 2011). In contrast qualitative methods follow the notion that multiple realities exist; they are subjective and differ from person to person (Guba and Lincoln, 1994). Immersing the researcher in the setting enables enough information to be revealed to try and ‘make sense’ of the situation (Firestone, 1987). Owing to this qualitative methods are usually exploratory and can often lead to new avenues for further research (Bryman, 1984) and hypothesis generation. Qualitative methods focus on context and the

meaning of human lives and experiences, facilitating the collection of data when measures do not exist and providing the depth of understanding concepts (Creswell, 2011). This is illustrated in the alternative data collection methods implemented in research. Quantitative research includes experiments, structured observations or surveys in comparison to qualitative research which tends to conduct focus groups, participatory or non-participatory observation and unstructured or semi-structured interviews (Bryman, 1992).

1.4.2 *Mixed method research*

A mixed method design consists of two separate components of data collection and analysis within a single study, with at least one quantitative method and at least one qualitative method (Bryman, 1992). Mixed method research has developed over the last 25 years and is recognised as the third major paradigm (Teddlie and Tashakkori, 2009). Controversies still remain with regards to whether such different methods, with contrasting philosophical underpinnings, should be used together (Creswell, 2011). However, advocates of mixed method research support the use of 'whatever tools are required to answer the question' (Teddlie and Tashakkori, 2009). The need for greater clarity over the language used to describe using both quantitative and qualitative methods has been acknowledged, with descriptions such as 'multi-method', 'mixed method' or 'multiple methods' all used within the literature (Stecher and Borko, 2002). However, the term 'mixed method' for the combination of qualitative and quantitative methods within a single study has been suggested as the most appropriate phrase to adopt and to help standardise terminology within this paradigm (Teddlie and Tashakkori, 2003).

A document produced by the UK Medical Research Council (MRC) providing guidance on the development and evaluation of RCTs for complex health interventions highlights the importance of incorporating qualitative methods (MRC (Medical Research Council), 2000). Using qualitative methods within a RCT can improve the intervention, facilitate interpretation of pilot trial findings and could potentially save money by identifying interventions more likely to

be effective in future trials (Bradley *et al.*, 1999; O'Cathain *et al.*, 2013). Qualitative methods can also be utilised to identify why a service or treatment does or does not work and how these results can be used in the real world (O'Cathain *et al.*, 2014).

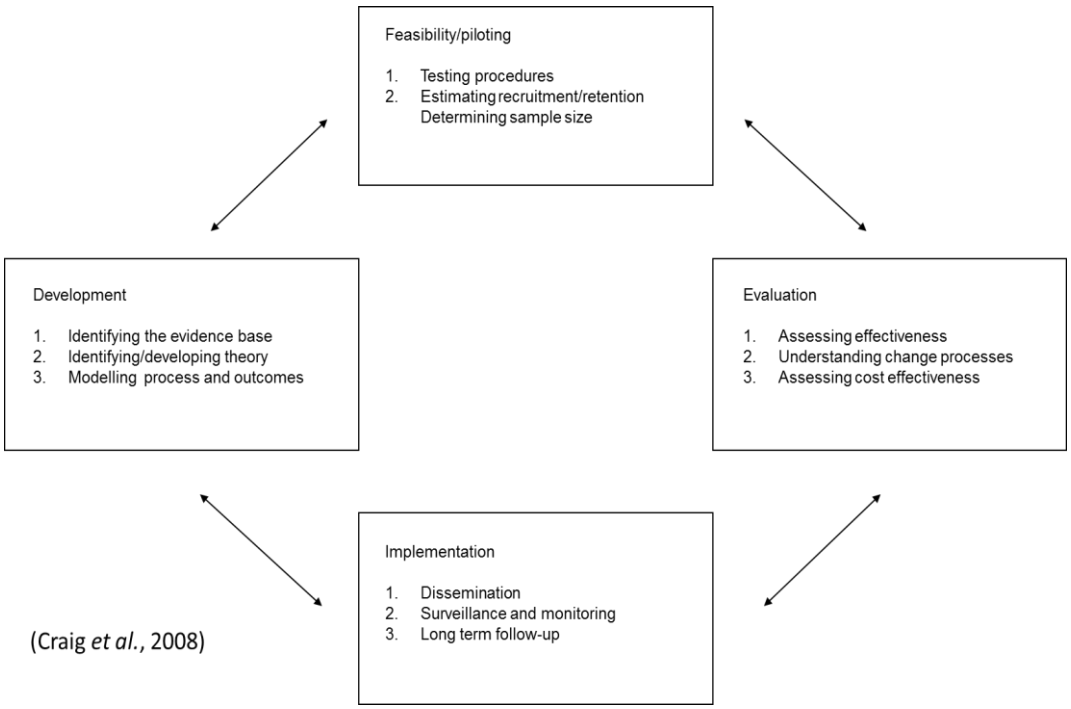
It is important to understand the impact of health service delivery and requires focus on processes as well as outcomes (Fulop *et al.*, 2001). Social or health phenomena are so complex that the use of different methodological and philosophical approaches is needed to best understand and reveal these complexities (Byrne and Humble, 2007). Mixed method research can increase confidence in findings and enables society to be heard (O'Cathain and Thomas, 2006; O'Cathain *et al.*, 2007).

A mixed method design was incorporated within this study. Quantitative analysis of pilot RCT results along with website usage data was used to measure the retention and adherence of both the health professionals and the participants to the intervention, whilst the qualitative method, semi-structured interviews, allowed the intervention user and provider experience to be investigated. Although the two approaches are very different in their philosophical underpinnings, it is the strengths and weaknesses of both approaches which makes use of both beneficial (Firestone, 1987; Bryman, 1992), capitalising upon the strengths of different techniques whilst neutralizing or eliminating some disadvantages of each of the methods (Bryman, 1984; Creswell, 2011). This type of triangulation protocol, using different methods to study a problem from a range of perspectives, can lead to a more thorough understanding of research questions and a more complete picture or answers being gained (O'Cathain *et al.*, 2013; Creswell, 2014), thus valuing both subjective and objective knowledge of the research area (Morgan, 2007). Using multiple perspectives can enhance and enrich the meaning of a singular perspective and enables processes or experiences to be examined as well as outcomes (Plano Clark, 2010). This is important for a pilot or feasibility study, such as my PhD project, as this allows all aspects related to acceptability to be investigated to enable an informed decision in relation to the suitability of a future definitive trial.

1.5 **Intervention development**

To ensure best practice an intervention requires intervention mapping to create theory-based objectives, design, methods, implementation and evaluation to enhance health interventions (Bartholomew *et al.*, 1998; Bartholomew *et al.*, 2006). This development should be based on available evidence, followed by various piloting work depending on the key uncertainties within the study and finally evaluation before a large RCT study can be performed (Craig *et al.*, 2008).

Figure 1-3: MRC Framework key elements of the development and evaluation process



This is outlined in Figure 1-3 above, which describes the various stages of intervention development to produce a thorough intervention to be incorporated within a definitive RCT. The process of intervention development requires several stages and may not necessarily follow a linear order depending on the particular design and study in question (Craig *et al.*, 2008).

The CONSORT (CONsolidated Standards of Reporting Trials) 2010 Statement was produced with the aim of improving the reporting of parallel-

group randomised controlled trials (RCT) (Schulz *et al.*, 2010). CONSORT 2010 was developed through collaboration between clinical trial methodologists, guideline developers, knowledge translation specialists, and journal editors. When authors refer to CONSORT statement guidelines and the corresponding checklist this enables viewers to understand a trial's design, conduct, analysis and interpretation, and results. The quality in reporting of randomised controlled trials in the area of weight loss appears to have improved since the revised CONSORT statement publication (Moher *et al.*, 2001) outlining checklists of adequate reporting, with the most up-to-date version created in 2010 (Schulz *et al.*, 2010) . However, a previous systematic review, post publication of the original CONSORT statement, examined the quality of reporting for weight loss interventions and identified inadequate reporting of primary outcomes and the method of allocation concealment showing there are still areas requiring improvement (Thabane *et al.*, 2007). Few weight loss or other behaviour change intervention evaluations are reported in enough detail to allow replication to occur (Michie *et al.*, 2009b).

CONSORT guidelines highlighted the need for more precise reporting for complex behaviour change interventions (Schulz *et al.*, 2010), with the addition of the Template for Intervention Description and Replication (TIDieR) checklist and guide outlining the minimum to report for complex interventions (Hoffmann *et al.*, 2014).

CONSORT guidelines have been extended to address the increase in eHealth/mobile interventions/RCTs and as a result the CONSORT EHEALTH checklist has been created. One of the essential recommendations within this checklist is adequate intervention description, including the description of any behaviour change techniques, in order to improve and standardise reporting (Eysenbach, 2011).

1.5.1 *The role of theory and behaviour change techniques*

The first step in the development of complex interventions, when using the MRC framework (Craig *et al.*, 2008), entails the identification/development of the evidence base as well as the theory. Identifying the theory base allows

understanding of the mechanisms of change within the intervention. The use of evidence based theory is important as it offers a common language to explain the process of behaviour change. Existing evidence and theory can guide the choice of which predictors and mediators of change to measure and on how to target these with specific active ingredients or behaviour change techniques (BCTs) (Michie *et al.*, 2008).

Sniehotta *et al* (2005a) (2005b) refers to specific building blocks associated with behaviour change. From these papers five blocks can be extracted: 1. Environment and social influences, 2. Knowledge and skills, 3. Motivation, 4. Planning, 5. Self-regulation. Figure 1-4 below illustrates the higher up the blocks a person reaches the greater the likelihood of behaviour change.

Figure 1-4: The Building Blocks of Behaviour Change

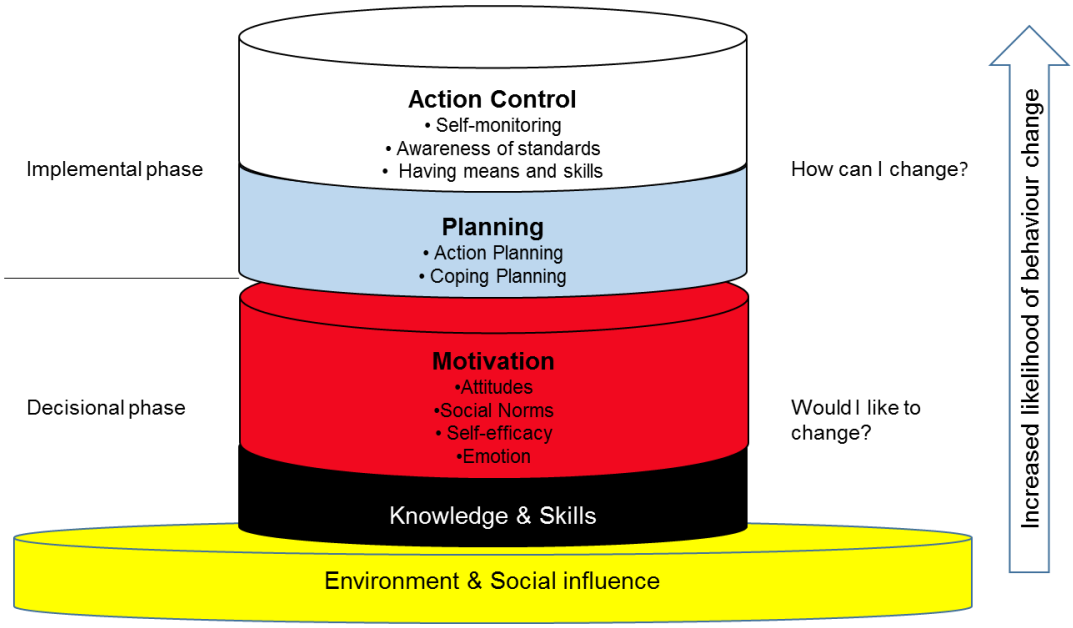


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Figure 1-4 outlines how a person's behaviour (or change) are initially influenced by environmental and social factors, such as social support, green spaces or food outlets. The second block focuses on a person's knowledge or skills, i.e. their education and how this could potentially impact on their motivation to acknowledge the need to change behaviour.

Motivation, as shown within the third block in Figure 1-4 above, relates to several variables which could enable intention formation. This relates to Social Cognitive Models.

An example of a Social Cognitive Model is the Social Cognitive Theory (SCT) (Bandura, 1977; Bandura, 1988), which explains psychosocial functioning in terms of triadic reciprocal interaction. The reproduction of a behaviour is influenced by the interaction of three determinants: 1) Personal, whether a person has low or high self-efficacy towards a behaviour, 2) Behavioural, the response a person receives after performing a behaviour, 3) Environment, aspects of the environment or setting that influence the individual's ability to successfully complete a behaviour (Bandura, 2002). However, Bandura states how behaviour can be conditioned and that personal factors can be altered to improve the organisational functioning of a person (Bandura, 1988). Outcome expectancies can impact on a person learning a behaviour as there is a need to understand what the potential outcomes will be when a behaviour is repeated or performed. Identification is another factor as people are more likely to follow behaviours modelled by someone with whom they can identify with (Bandura, 1988). A key construct within the SCT is self-efficacy, the judgment of how well a person can accomplish actions required to deal with potential situations (Bandura, 1977). It is acknowledged that by increasing self-efficacy a person is more likely to believe they can perform a behaviour and therefore they will be more motivated to perform the behaviour. To improve self-efficacy peoples' beliefs in their capabilities need to be strengthened. Ways to strengthen self-efficacy follows are: 1) Success experiences, so a person has experience of succeeding and overcoming difficulties, 2) Modelling, observational learning of how to break down complex skills into subskills as well as receiving guided practice within different situations and learning how to apply these new skills, 3) Social persuasion, providing encouragement that a person can perform a behaviour, 4) Physiological state, reducing stress.

Another Social Cognitive Model is the Theory of Planned Behaviour (TPB) (Ajzen, 1985; Ajzen, 1991) or the more recent and updated Reasoned Action Approach (RAA) (Fishbein and Ajzen, 2010), which identified theoretical

constructs of attitude towards the behaviour, perceived behavioural control and subjective norms as influential in explaining intention and subsequently behaviour. The first construct attitude towards the behaviour relates to the beliefs, knowledge and expectations a person has about a behaviour. It is the degree to which a person has a favourable or unfavourable evaluation or appraisal of the behaviour in question (Ajzen, 1991). Secondly, the construct subjective norms relates to perceived social pressure to perform or not to perform a behaviour. Lastly, perceived behavioural control is a construct that was not in the original theory, the Theory of Reasoned Actioned (Fishbein, 1975). It was added to create the TPB and relates to people's perception of the ease or difficulty of performing a behaviour. Behaviour is strongly influenced by a person's confidence in their ability to perform a behaviour (Ajzen, 1991). Much of Ajzen's knowledge about the role of perceived behavioural control emerged from the research conducted by Bandura on self-efficacy. As a general rule, the more favourable the attitude and subjective norm with respect to a behaviour, and the greater the perceived behavioural control, the stronger an individual's intention should be to perform the behaviour in question (Ajzen, 1991).

Similarities are present between the SCT and TPB in terms of the theoretical constructs that shape their theories, however they differ in terms of identifying how to use the theory to change behaviour. The TPB does not entail a planning stage. The SCT states how the value of theory is judged not only by its explanatory and predictive power but also on the power to improve human functioning (Bandura, 1988). This is a criticism of the Theory of Planned Behaviour, where suggestions on how to develop factors to improve intention and the likelihood of behaviour are lacking, with few studies using the model to actually develop a behaviour change intervention (Hardeman *et al.*, 2002). In contrast the Social Cognitive Theory uses explicit guidelines to enhance wellbeing and to enable psychological change. To increase motivational levels the Social Cognitive Theory states that changes aimed at increasing self-efficacy are paramount (e.g. modelling) to strengthen people's beliefs in their capabilities. This can be achieved through techniques such as goal setting or social persuasion (Bandura, 1988).

The importance of these variables in influencing intention/goal formation has been acknowledged as a necessary but not sufficient step for behaviour change. There still appeared to be a missing connection in understanding health behaviour, a 'gap' between intentions and actions (behaviour) (Orbell and Sheeran, 1998). After a goal is set it is crucial to enact on intentions in order to translate intentions into actions and overcome the intention behaviour gap (Orbell and Sheeran, 1998). The intention behaviour gap is an area of importance as intentions do not necessarily guarantee that they will result in a particular behaviour being performed. Intentions to change one's habitual lifestyle are rarely effective (Sutton, 1994). Therefore, the notion of behavioural intentions alone is inadequate to understand lifestyle changes. New psychological processes have been investigated that increase our knowledge on the volitional/post-intentional stages, such as action planning (implementation intention), coping planning and action control.

Moving from the motivational phase to the implementation phase, illustrated in block four within Figure 1-4, new research points to the crucial role of volitional constructs, such as action planning and coping planning, from the Health Action Process Approach (Schwarzer, 2001; Sniehotta *et al.*, 2005a; Sniehotta *et al.*, 2005b), a theory that aims at actively incorporating post intentional volitional processes. The Health Action Process Approach believes there are two phases that occur during the behaviour change process. Phase one is the motivational phase where intentions are formulated, as outlined previously by the Social Cognitive models above. The second phase incorporates volitional constructs such as action planning, implementation intentions and specifying goal intentions to enable the initiation and maintenance of intentions (Schwarzer, 2001). Implementation intentions by Gollwitzer (1999) address "how can I change?" and involve the creation of specific plans of when, where and how a behaviour will be performed to lead to goal attainment. Goal intentions are chosen with set end points or outcomes. When this action plan is initiated it is then that the action has to be maintained. Coping planning can help a person overcome any barriers or difficulties by anticipating personal risk situations and then planning coping strategies in detail (Sniehotta *et al.*, 2005b). Action planning

can be influential if incorporated early in a process where as coping planning can be more influential later in an intervention (Sniehotta *et al.*, 2005b). Planning can be used to bridge the gap between intention and health behaviour (Sniehotta *et al.*, 2005a). The Health Action Process Approach (Schwarzer, 2001) enables the connection between intentions into action/behaviour to be examined. In previous research the theory has been used not only as the basis of questionnaire creation but also for the development of interventions (Scholz *et al.*, 2009; Strobl *et al.*, 2013; Szczepanska *et al.*, 2013).

The fifth and final building block is action control involving self-monitoring, awareness of standards and having the means and skills to achieve behaviour. Action control relates to self-regulation theories, such as Control Theory (Carver, 1982), which has a basic construct known as the discrepancy-reducing feedback loop. The task of changing health related behaviour starts with monitoring of the behaviour (e.g. eating) or of an outcome of interest (e.g. weight). This is then gauged against a 'comparator' usually associated with an initially set goal i.e. portion size reduction. At this stage if any discrepancy becomes apparent, e.g. high portion size, it can lead to a behaviour change ('output function'). This process is looked at as key to self-regulation. Self-regulation processes can be used to reduce the intention behaviour gap and facilitate the understanding of the progression from intention to action. Control Theory has received some criticism, with claims it underestimates both the role of emotion in self-regulation (Caprara and Cervone, 2000) and people's ability to contribute creatively to their personal development (Bandura, 1997). However, self-regulation based interventions have been identified as twice as effective as interventions without self-regulation strategies (Michie *et al.*, 2009a).

The selection of theories, and theoretical constructs, can be used as a basis for designing interventions. However, choosing which theory to include can be a difficult task as there tends to be a lack of consensus, with interventions designed to change the same behaviour differing dramatically in their content (Abraham and Michie, 2008). Abraham and Michie (2008) created a taxonomy of BCTs, an extensive list of behaviour change techniques (with

definitions) and linking techniques to theoretical constructs, to better support intervention description. As part of this process these authors identified how different BCT's related to distinct theories. This clarified the link between the inclusion of techniques and theory-specified change processes, facilitating theory testing and aiding the development of theory-based interventions (Abraham and Michie, 2008). An issue when examining previously tested interventions is the lack of reporting on intervention description. Analysis identified very limited reporting on which techniques were present within interventions or how techniques linked to theoretical constructs, with theory not extensively used in the development of interventions (Prestwich *et al.*, 2014). This may be owing to journal size pressures but limited intervention description impacts on replication fidelity. The need for accurate description of theoretical basis, BCTs and mode of delivery within published interventions is still a challenge that remains to enable effective interventions to be better understood and replicated (Abraham and Michie, 2008; Webb *et al.*, 2010b; Prestwich *et al.*, 2014).

Active ingredients within an intervention are behaviour change techniques (BCTs) that are incorporated into an intervention's design in order to change behaviour and improve health (National Institute for Health and Clinical Excellence public health guidelines, 2014). The role, inclusion and identification of BCTs within interventions, specifically weight loss interventions will be explored to illustrate how they can impact on the intervention itself or the outcome of a study. Within this PhD thesis the identification of BCTs incorporated into the internet based intervention will be examined in Chapter 3. The creation of the intervention, where the inclusion of specific BCTs would usually take place, occurred prior to this study (Brandt, 2011), as mentioned earlier in this chapter.

As mentioned earlier BCT taxonomies have been developed to outline existing BCTs and provide definitions with regards to what constitutes each BCT based on theory, the newest version (v1) containing 93 clustered BCTs (Michie *et al.*, 2013). Using these taxonomies allows researchers to use the definitions to code when BCTs are present within an intervention, therefore outlining what aspects could potentially have impacted on the outcome.

When analysing or describing a complex behaviour change intervention coding of BCTs help outline key ingredients of an intervention. However, when coding for the presence of BCTs within an intervention no assumptions can be made. The standardised vocabulary within the BCT taxonomy must be adhered to in order to state the presence of any BCT thus promoting consistent reporting and coding between researchers (Abraham and Michie, 2008) and allowing for an accumulation of scientific evidence that can then be used on evidence based care.

A previous systematic review (Dombrowski *et al.*, 2011) examined which theories and BCTs (Michie *et al.*, 2008) were effective in increasing weight loss in interventions with participants with co-morbidities. Results identified the most commonly incorporated BCTs for diet and physical activity behaviour change interventions were related to Social Cognitive Theory, Control Theory, theories of social comparison and social support theories. Findings also revealed the number of Control Theory related BCTs integrated within an intervention had a positive association with weight loss. No other theory congruent BCT combinations demonstrated trends in weight outcomes (Dombrowski *et al.*, 2011). Control Theory (Carver, 1982) aims to reduce the discrepancy between current behaviours and/or outcomes and desired behaviour/outcome goals. Control Theory BCTs consist of 'prompt specific goal setting', 'prompt review of behavioural goals', 'prompt self-monitoring of behaviour' and 'provide feedback on performance'.

The creation of theory based questionnaires are a useful tool to examine theory constructs in greater depth (Ajzen, 2002b; Francis *et al.*, 2004). A theory based questionnaire was used within this pilot study to investigate relevant constructs from several different theories. Findings can then be used to inform a definitive trial or help aid further development and refinement of the intervention. The results could be used to inform intervention design in relation to BCTs that could help improve identified participant weaknesses i.e. relapse prevention strategies could be inbuilt into the intervention if coping plan scores were lower than the majority of the

other constructs. Previous research allows evidence based development to occur in order to create an appropriate intervention for the study in question.

1.6 **Weight loss interventions**

A systematic review by Douketis *et al* (2005) compared the various techniques for weight loss and concluded that dietary/lifestyle therapy led to <5kg weight loss after 2-4 years (a modest weight loss). Pharmacologic therapy resulted in 5-10kg weight loss after 1-2 years and surgical therapy resulted in 25-75kg weight loss after 2-4 years. The review identified a number of limitations in the studies reviewed, in particular inadequate study duration, large subject attrition to follow up and lack of usual care comparator groups (Douketis *et al.*, 2005). Research examining long term effects after bariatric surgery is still in its infancy but results are showing positive signs in connection to improvements or resolutions of co-morbid conditions, such as hypertension or diabetes (Buchwald *et al.*, 2004; Christou *et al.*, 2006; Adams *et al.*, 2007). However, as found in other areas of weight loss treatment, bariatric surgery also appears to face the common problem of weight regain, suggesting more research investigating long term effects is needed (Shah *et al.*, 2006).

A systematic review assessing trials using exercise alone as a method for weight loss discovered that exercise resulted in small weight loss but when exercise intensity was increased the magnitude of weight loss also increased (Shaw *et al.*, 2006). A more recent systematic review by Dombrowski *et al* identified a greater magnitude of change in weight loss interventions that focused on one behaviour (exercise or diet) in comparison to those that incorporated both behaviours at the same time (Dombrowski *et al.*, 2010). However, greater long term weight loss was found for those interventions combining diet and exercise advice. In connection to this an earlier review identified both a 20% greater initial weight loss and a 20% greater sustained weight loss after one year for the combined intervention, the use of diet and exercise together, than the diet only intervention (Curioni and Lourenco, 2005). However, in both the combined and the diet alone interventions almost half of initial weight loss was regained after one year. The results

illustrated how diet with exercise can produce clinically meaningful initial weight loss but this is only partially maintained after one year (Curioni and Lourenco, 2005).

Adding to these findings are two reviews which investigated the use of behaviour therapy. Behavioural treatments aim to enhance dietary restraint by providing adaptive dietary strategies, discouraging maladaptive dietary practices and increasing motivation to be more physically active. The objective is to provide a person with coping skills such as goal setting, self-monitoring or stimulus control. The results showed that combining behaviour therapy along with a diet and exercise approach produced greater weight reduction than diet or exercise alone (Shaw *et al.*, 2005; Gallagher *et al.*, 2013).

A previous systematic review of reviews examined intervention components and concluded that effectiveness was increased by social support, targeting both diet and physical activity, greater frequency of contact and incorporating clusters of self-regulatory behaviour change techniques, such as goal setting or self-monitoring (Greaves *et al.*, 2011).

A difficulty with making comparisons of weight loss interventions is the heterogeneity of interventions and the comparator groups that are examined (Norris *et al.*, 2005; Shaw *et al.*, 2005). Interventions are often varied with regards to what the participants are required to follow and what behaviour change techniques are incorporated. There is also great variability in the comparison groups that are used, which are often not usual care groups (Douketis *et al.*, 2005), making it hard to evaluate interventions in comparison to real world everyday practices.

1.7 **NHS weight loss interventions**

Previous research has revealed that three commercial weight loss programmes, Weight Watchers, Slimming World and Rosemary Conley, were more effective in relation to participants' weight loss than primary care treatments (Jolly *et al.*, 2011). In Jolly et al's study primary care treatments were a group weight loss programme (Size Down), a nurse-led one-to-one

support in general practice and one-to-one support by a pharmacist, with another arm free to choose the treatment they preferred and a comparator group given a free 12 week pass to a fitness centre. Group based treatments appeared to be most effective, with the suggestion that one-to-one NHS services may have suffered due to difficulty arranging convenient appointment times in comparison to commercial groups that meet at a regular time each week. Within the free choice arm women appeared to prefer commercial options whereas men more often opted for the NHS services. However, free choice of treatment did not appear to increase weight loss in comparison to being allocated to an arm. Another point to note is the provision of data from commercial groups, which was unable to be independently verified and therefore could not be checked for errors.

Evidence suggests that traditional primary care treatments (one-to-one consultations with dietitians or practice nurses) can be costly, ineffective and subject to high attrition rates (Jebb *et al.*, 2011; Jolly *et al.*, 2011). Jebb *et al.* (2011) compared standard care with a commercial group and identified that the specifics of standard care varied between and within different countries, identifying the complexity of investigating and comparing the effectiveness of primary care practice. However, other studies have shown that primary care treatments have achieved and maintained clinically valuable weight loss (Ross *et al.*, 2008; Korhonen *et al.*, 2014). With Korhonen *et al*'s study finding at a three-year follow-up visit, 18% of subjects had lost ≥ 5% of their initial weight and 70% had stabilized their weight. Although 12% gained weight this still illustrates how, for the majority of overweight and obese patients, a primary care lifestyle screening programme can support sustained weight management (Korhonen *et al.*, 2014). Ross *et al* investigated the counterweight programme, an intervention tailored to patient's stage of change, in line with transtheoretical model. The intervention included balanced diet information, an eating plan, physical activity recommendations, behaviour management and weight maintenance and prevention of regain. Patients were asked to commit to nine appointments in 12 months after initial screening. This included six individual appointments (10–30 minutes each) or six group sessions (1 hour each) over a 3-month period, and then follow-up

at 6, 9, 12, 24 months. Results identified greater mean weight loss within higher appointment attenders, suggesting more focus on enhancing attendance and retention would be beneficial in future research (Ross *et al.*, 2008).

A previous study, the BiO project, introduced training sessions (3 x 90 minutes) for health professionals in primary care, to promote and improve obesity management in primary care (Moore *et al.*, 2003a; Moore *et al.*, 2003b; Nelson *et al.*, 2006). The training session was delivered by four dietitians (one working in each of four areas) and was based on best evidence in relation to the benefits of weight loss, effective treatment options, reducing dietary intake, increasing physical activity and pharmaceutical interventions. The training was found to improve practitioner's knowledge of obesity management but did not affect the weight outcome of at risk patients (Moore *et al.*, 2003b). However, after training the recording of weight and targets (weight and dietary) did occur more frequently in the intervention arm but implementation was still low. Qualitative work was conducted to investigate why and revealed that obesity management trials within primary care resulted in miscommunications, with practice nurses unclear whose responsibility it was to execute the programme, assuming researchers would conduct the task (Nelson *et al.*, 2006). The primary care staff felt negatively about approaching the issue of weight management as they were not trained to do so and felt there was a lack of options to advice/suggest to patients (Nelson *et al.*, 2006). The suggestion for interprofessional education and training to create a multidisciplinary health care team is recommended (Kirk and Penney, 2013). In another study health professional advice appeared to increase motivation in an at-risk population but only a minority of overweight or obese adults received any advice (Jackson *et al.*, 2013). More intensive weight counselling training may be necessary and beneficial to increase provision of advice and support but appears to be a complex task to implement within primary care.

These findings suggest that a change in current primary care approaches may be required. Therefore research is needed to investigate alternative

methods in relation to weight/ obesity management; one alternative approach could be the provision of weight management via the internet. This would enable the sensitive issue of obesity to be discussed in a less intensive situation than the traditional face to face consultations.

1.8 **Internet-based interventions**

Human computer interaction (HCI) is a rapidly developing field with the rise of technology and the increasing incorporation of it within health care. HCI relates to the study, design and use of interfaces between people and computers and how computer technology can influence a human's work or activities (Stuart *et al.*, 1980; Dix, 2009). HCI is cross cutting amongst several fields such as computer science, behavioural sciences, design and several others areas (Lew *et al.*, 2007). An important aspect of HCI is user satisfaction. The goal of HCI is to improve user and computer interactions by making computers more appropriate for users' needs (Lew *et al.*, 2007; Hewett *et al.*, 2014). The emphasis is to try and bridge the gap between the computer and the human. An important aspect of designing and evaluating user interfaces is good knowledge of the potential end users (Beaudouin-Lafon, 1993). Although information systems are designed with humans in mind, many are still far from user-friendly (Lew *et al.*, 2007). The challenge for information systems and designers is to improve the interaction between computers and humans so computers are responsive to humans needs, therefore shifting from purely designing technology to user-centred design (Beaudouin-Lafon, 1993; Lew *et al.*, 2007). Computer based features to enable this interaction include self-monitoring tools so users can be involved in improving their health and changing behaviour (Evers, 2006), along with providing tailored feedback so the advice is relevant to each user. Tailored feedback has been shown to increase the effectiveness of an intervention, in terms of increased behaviour and self-reporting (Khaylis *et al.*, 2010; Compernolle *et al.*, 2015) and again illustrates the need for individualised interaction.

In 2013 83% of households had access to the internet, the vast majority through broadband connections, with over half of users able to connect to

the internet via their mobile phones (Office for National Statistics, 2013). The largest proportion of internet users was the youngest age group (16-24 years old) at 99%. However, the amount of non-users in all age groups decreased from 2011 to 2014, with 43% of internet users actively searching online for information relating to health problems (Office for National Statistics, 2014). These statistics illustrate the potential audience available in relation to changing behaviour (weight management) via the internet.

Reasons for attrition and non-attendance within face-to-face consultations include personal reasons, cost of travel, limited availability and lack of parking at venues (Dombrowski *et al.*, 2012). In comparison internet-based weight loss interventions could minimise these problems by reducing stigma, increasing the convenience and control for the user and reducing the cost of an intervention (Griffiths *et al.*, 2006; Ramadas *et al.*, 2011). However, potential disadvantages of internet interventions are unfamiliarity and (lack of) availability/access to technology (Fotheringham *et al.*, 2000; Leslie *et al.*, 2005; McTigue *et al.*, 2011; Meischke *et al.*, 2011; Mouttapa *et al.*, 2011). Internet based interventions have often been associated with a lack of medical importance or relatedness by patients possibly due to not being in the physical presence of a medically trained health professional as patients are usually accustomed to when provided with health care (McTigue *et al.*, 2011; Mouttapa *et al.*, 2011). Quality assurance for this study was highlighted to emphasise the credibly of the intervention through the incorporation and explanation of NHS health care professional involvement.

Internet weight loss interventions have the potential to offer long term programmes at a low cost, in comparison to traditional face-to-face approaches (Griffiths *et al.*, 2006; Manzoni *et al.*, 2011), which are advantages that would be beneficial to the NHS. Weight loss internet interventions can enable personalised messages to be sent automatically to the participants. In contrast, other approaches involve the time and expertise of a health professional where specific feedback is tailored towards the participant's progression (Nelson *et al.*, 2006; Hunter *et al.*, 2008; Ramadas *et al.*, 2011). Internet interventions are able to incorporate advantages seen

in face to face one-to-one or group consultations. The online member interaction combines social support, such as that which could be received from a group consultation, with one-to-one advice from a healthcare professional (Ramadas *et al.*, 2011), whilst maintaining the patients' privacy and anonymity (Bennett and Glasgow, 2009).

The nature of internet based weight loss interventions means that participant involvement in the form of data monitoring needs to occur so a participant can be provided with feedback on their behaviour. Therefore the participant is required to input self-monitoring data about their behaviour onto the website, in the form of daily food intake and exercise input. Research to identify effective behaviour change techniques to maintain engagement and usage of internet weight management interventions are necessary (Neve *et al.*, 2010; Arem and Irwin, 2011b), with studies often failing to report on adherence within interventions (Coons *et al.*, 2012b).

Previous reviews have demonstrated that internet weight loss interventions can be more effective than control or usual care arms in terms of weight loss and engagement with physical activity and diet (Norman *et al.*, 2007; Neville *et al.*, 2009b; Neve *et al.*, 2010; Arem and Irwin, 2011b). Although in previous research it has become apparent that internet interventions can also have high attrition rates (Neve *et al.*, 2010; Arem and Irwin, 2011b; Coons *et al.*, 2012b). Several reviews have shown that studies in this area have produced inconclusive results, with several reporting no consistent benefits of internet-based weight loss interventions in comparison to control arms (Norman *et al.*, 2007; Neville *et al.*, 2009a; Enwald and Huotari, 2010; Neve *et al.*, 2010; Reed *et al.*, 2012). Heterogeneity between studies, varying in terms of control groups, intervention components and/or study length was apparent, making it difficult to generalise findings (Neville *et al.*, 2009b; Neve *et al.*, 2010; Arem and Irwin, 2011b). As a result, it is difficult to group similar studies for comparison and thus draw definite conclusions on effectiveness and acceptability across all internet-based interventions (Neville *et al.*, 2009a; Neve *et al.*, 2010). This identifies the need to conduct further

research within the area of internet weight loss interventions as many uncertainties are still existent.

Internet weight loss interventions have the potential for wide reach to the general public in terms of being implemented as a public health intervention. Internet based weight loss interventions could be applicable to a varied range of people owing to the individualised information, guidance and feedback that could be provided in relation to their behaviour. Previous research demonstrates the value of examining internet weight management interventions, especially in relation to specific target groups that are notoriously hard to recruit and retain for traditional consultations. Two such groups were chosen as the target populations for this study; post-partum women and men with type 2 diabetes. The rationale for this choice is given in 1.8.1 and 1.8.2 sections below.

1.8.1 *Post-partum women*

One of the population target groups who were included in the study due to the possible advantages was post-partum women. The pregnancy statistics showed that there were 729,674 live births in England and Wales in 2012, increasing slightly (by 0.8%) from 723,913 in 2011 (Office for national statistics, 2012). However, being obese increases the health risks to a mother during the antenatal, intrapartum, and postnatal periods. The Confidential Enquiry into Maternal and Child Health report (2003-2005) (Lewis, 2007) summarises the risks related to obesity during pregnancy for the mother as maternal death or severe morbidity, cardiac disease, spontaneous first trimester and recurrent miscarriage, pre-eclampsia, gestational diabetes, thromboembolism, post-caesarean wound infection, postpartum haemorrhage or low breastfeeding rates.

The psychological impact of obesity during pregnancy is relatively unexplored. Issues raised in qualitative research include a sense of greater social acceptance of increased body size during pregnancy, difficulties adjusting to post-pregnancy body shape, anxieties of both women and healthcare professionals about raising the topic of obesity during pregnancy and a lack of awareness of the risks associated with obesity during

pregnancy amongst some women (Harris, 1979; Wiles, 1994; Zahorick, 2000; Morin, 2002; Heslehurst, 2007; Nyman *et al.*, 2010).

Obesity during pregnancy and continued levels of obesity post-partum (especially if wanting to child bear again in the near future) are problematic as it can lead to the need for additional healthcare due to complications associated with the pregnancy. The resource implications relating to maternal obesity include increases in caesarean deliveries and length of hospital stay, requirements for neonatal intensive care and a need for appropriate equipment to manage safely the care of obese mothers (Galtier-Dereure, 1995; Galtier-Dereure, 2000; Ramsay, 2006; Chu, 2007; Heslehurst, 2007; Chu *et al.*, 2008; Heslehurst, 2008).Therefore it is important to look at the expected levels of obesity within pregnancy. In the United States, the prevalence of obesity amongst pregnant women has been identified as ranging from 18.5% to 38.3% (Garbaciak *et al.*, 1985; Abrams and Laros, 1986; Naeye, 1990; Taffel *et al.*, 1993; Siega-Riz *et al.*, 1994; Cogswell ME, 1995). Being very overweight (obese), BMI of more than 30, is increasingly common, with around 15-20% of pregnant women now within this category in the UK (NHS Choices, 2013). Prevalence of obesity in women in early pregnancy has doubled over the last two decades (Heslehurst *et al.*, 2010; Smith *et al.*, 2011). One year after childbirth half of women retained ten or more pounds with 36% moving up one or more BMI category (Gould Rothberg *et al.*, 2011). Weight gain in pregnancy does not just affect the pregnancy itself but may contribute to the development of obesity in the future (Rooney and Schauberger, 2002; Siega-Riz *et al.*, 2004; Linne and Neovious, 2006; Gunderson, 2009; Olander *et al.*, 2011). Weight loss after pregnancy is a sensitive issue to approach but is an important subject to tackle, especially for women who were obese prior to pregnancy (National Institute for Health and Clinical Excellence, 2010).

Traditional weight management consultations in pregnant and post-partum women frequently have poor retention rates. New mothers have new demands on time and energy and set appointments can often be overwhelming or inconvenient (Klohe-Lehman *et al.*, 2006; Kuhlmann *et al.*,

2008; Montgomery *et al.*, 2012). Interventions outside the home are unlikely to affect postpartum weight loss (costs tend to outweigh potential benefits). Individualised programmes in the home (via telephone or internet) may be more feasible and successful (Østbye *et al.*, 2009; Wilkinson *et al.*, 2013), especially owing to the substantial number of women now using the internet for health information throughout pregnancy (Huberty *et al.*, 2013).

All of the risks associated to obesity before, during and after pregnancy show why weight loss interventions are necessary within this population group. Previous studies show how face to face consultations are not necessarily the most appropriate intervention that post-partum women will be able to follow over a long term period. Therefore a home based intervention, such as this internet intervention, may be a more feasible weight loss method for post-partum to adopt within their every changing daily lives.

1.8.2 *Men with type 2 diabetes*

Another population group that could potentially benefit from an internet weight loss intervention and therefore were included in the study is men with type 2 diabetes. Overall in 2012 there was found to be a 6% prevalence of diabetes in England (UK average 6%) equating to 2,703,044 people (3.2 million in the UK) who have been diagnosed with diabetes (Health and Social Care Information Centre, 2013a; Diabetes UK, 2014). Around 90% of those diagnosed with diabetes were found to have type 2 diabetes, the dominant type within the general public (Department of Health, 2007; Diabetes UK, 2010; Health and Social Care Information Centre, 2011/12). Of those diagnosed with type 2 diabetes 55% were men, with 45% women (Diabetes UK, 2010; Health and Social Care Information Centre, 2011/12). International Diabetes Federation (IDF) has stated that worldwide 80 per cent of people with type 2 diabetes are overweight or obese at the time of diagnosis (Diabetes UK, 2009). Examining the number of men who are obese and have type 2 diabetes equates to approximately 24 per 1000 in the UK.

Prevalence levels for diabetes per age group in England can be seen in Table 1-4 below (Diabetes UK, 2010).

Table 1-4: Diabetes prevalence per age group

Age group (years)	Males (%)	Females (%)
16-34	1.8	2.1
35-54	9.4	6.6
55-74	26.3	20.2
75+	15.9	12.2
Average overall	6.3	5.3

An estimated 850,000 people are still thought to be undiagnosed and approximately seven million at high risk of developing type 2 diabetes, a worrying figure owing to the importance of early diagnosis (Diabetes UK, 2012).

Diabetes has been associated to escalating global rates of obesity. Of all serious diseases, type 2 diabetes has the strongest association with obesity (Williams, 2004; Hauner, 2010). 'Diabesity' is threatening to engulf health care systems globally (Hossain *et al.*, 2007; Lau, 2010; International Diabetes Federation, 2011). It is currently estimated that 10% of the NHS budget is spent on diabetes equating to nearly £10 billion per annum (NHS Confederation, 2007a; Kerr, 2011; Hex *et al.*, 2012).

Modest weight loss of 5-10% is associated with significant reduction in blood sugar, lipid and blood pressure levels (Chan *et al.*, 1994; Colditz *et al.*, 1995; World Health Organization, 2006; Lau, 2010) which would lower the risk of a person with diabetes developing a diabetes related disease and could improve their current condition.

Recruiting men to weight loss programmes is notoriously difficult with men less likely to attend NHS or commercially run weight loss services (Wolfe and Smith, 2002; Bye *et al.*, 2005; Wilkins *et al.*, 2007; Ross *et al.*, 2008; Morgan *et al.*, 2011c). A previously used individualised online service was shown to be successful in decreasing HbA1C and 2HPPT in obese type 2 diabetes patients (Kim and Kim, 2008). It has been identified that men were attracted

to programmes that did not require extensive face-to-face time commitments (Morgan *et al.*, 2011c) outlining the potential for men to favour or at least be accepting of internet-based interventions. Weight loss interventions have been shown to have positive effects on both the closely related obesity and diabetes conditions. With men particularly challenging to recruit to face to face services, more private and convenient healthcare, such as this internet based intervention, may be an appropriate alternative that allows men to access weight loss services without the negative stigma men may associate to traditional treatments.

This background and introduction has identified the issues associated with the area of obesity and current treatment practices and how an internet based weight loss intervention could offer a valuable tool for use in weight management. For the purpose of this pilot study two population groups whose health could be improved by weight loss have been selected.

As outlined in the aims and objectives, section 1.1, the following succeeding chapters will present my systematic review, the pilot RCT and then the process evaluation of the pilot RCT. Each of the chapters are presented in the same format following a traditional report style: Introduction, Method, Results and Discussion, therefore each chapter focuses on just one part of my PhD study. Finally the thesis concludes with my fifth chapter, a discussion chapter, focusing on the overall findings and key implications for future research, policy and practice based on the results from my PhD studies.

Chapter 2 **Systematic Review of internet-based interventions providing individualised feedback for weight loss in overweight and obese adults.**

2.1 **Introduction**

This chapter discusses my systematic review and meta-analysis of internet weight loss interventions. The main areas of focus are outlined in the aims and objectives, see 2.2. Systematic reviews seek to collate all evidence that fits pre-specified eligibility criteria in order to address a specific research question. For this review the research question aimed to examine how effective individualised feedback is for weight loss when provided via the internet. Systematic reviews aim to minimise bias by using explicit, systematic methods (Higgins and Green, 2011a).

Previous reviews examining internet based weight loss interventions have been discussed in Chapter 1. In order to add to current literature this review focuses on the effect of incorporating individualised feedback within internet weight loss interventions. Feedback has been identified as one of the key components of technology based weight loss interventions (Khaylis *et al.*, 2010; Tang *et al.*, 2014). Frequency of contact has been significantly associated with weight loss (Dombrowski *et al.*, 2011). It is important to investigate how communication is incorporated via an internet based weight loss intervention. It has also been acknowledged that different modes of delivery, via technology, are able to enhance weight loss effectiveness, such as the integration of individualised feedback and email counselling (Tang *et al.*, 2014). Therefore it appears important to investigate the different types of delivery mode to identify the various types of feedback, and communication, which can be delivered via the internet and the subsequent effectiveness of these variations.

The number of studies incorporating internet interventions has increased over recent years in relation to weight loss research (Broekhuizen *et al.*,

2012). More research is required to explore the effectiveness, feasibility and acceptability of internet interventions as an alternative mode of delivery for weight loss treatment to identify whether these could be potentially beneficial over current usual care practices.

2.2 **Aims & Objectives**

- To describe the characteristics of the study arms within the internet weight loss interventions.
- To assess the compliance and engagement of participants with the weight loss interventions.
- To assess whether internet-based contact is effective when individualised feedback is provided for weight loss in overweight and obese adults.
- To examine the different provisions of feedback within weight loss interventions.
- To identify the behaviour change techniques incorporated within study arms.

2.3 **Method**

The Cochrane handbook for systematic reviews for interventions was used to follow specified guidelines recommended when conducting a systematic review (Higgins and Green, 2011a).

The proposal for this systematic review (see appendix A) was accepted onto Prospero (International prospective register for systematic reviews) on 17/05/2012, registration number: CRD42012002115.

The systematic review is reported in accordance with the PRISMA statement checklist (Moher D, 2009).

2.3.1 ***Types of studies***

Randomised controlled trials. There were no restrictions by year of publication or language.

2.3.2 *Types of participants*

Men and women with a body mass index (BMI) categorised as overweight or obese (>25kg/m^2) were included. Participants ≥18 years old were included.

2.3.3 *Types of interventions*

Studies in which the active intervention was an internet-mediated behaviour change interventions targeting diet, physical activity or both, for weight loss were included. Only interventions that incorporated some form of individualised feedback/contact delivered via the internet were included (for example, email or web-based messaging).

The following definition for feedback from Michie *et al*'s 2011 'Taxonomy of behaviour change techniques to help people change their physical activity and healthy eating behaviours: The CALO-RE taxonomy' (Michie *et al.*, 2011) was used to decide whether individualised feedback was incorporated in each study.

Michie *et al*, 2011, pg. 9:

"Provide feedback on performance - This involves providing the participant with data about their own recorded behaviour or commenting on a person's behavioural performance (e.g. identifying a discrepancy between behavioural performance and a set goal or a discrepancy between one's own performance in relation to others)."

Feedback was only classified as individualised if the information received by the participant was personal to their own weight loss experience. Studies with interventions including only generic feedback, non-specific to the individual, were excluded. Individualised feedback could include both automatic (computer processed) feedback and feedback provided by a health care professional or other individual. These two different methods of feedback were addressed separately in the data analysis stage to enable comparisons between the type of feedback provided and the effectiveness.

Studies that incorporated both internet and personal contact (enhanced arms) were included but at least some individualised feedback must have been delivered via the internet. Studies combining internet and personal contact were addressed separately to interventions delivered solely via the internet.

There were no restrictions in terms of length of intervention or follow up but studies were grouped according to data collection points and total study length (including intervention and follow up phases).

2.3.4 *Comparison arms*

Studies in which the comparator condition was routine, non-surgical or non-pharmacological, standard care for overweight or obese individuals or comprised alternative interventions delivered via the internet but which did not include individualised feedback were included.

2.3.5 *Types of outcome measures*

For a study to be eligible, the primary outcome measure needed to be change(s) from baseline to post-intervention in one or more of: body weight, body fat percentage (assessed by callipers or electronically), waist circumference and/or BMI.

If presented data was also abstracted for any of the following secondary outcomes: measures of effectiveness, acceptability, engagement and attrition/retention rates.

Behavioural change techniques (Michie *et al.*, 2011) and theoretical frameworks used to develop the interventions (Michie and Prestwich, 2010) have also been examined.

2.4 **Search methods for identification of studies**

2.4.1 *Electronic databases*

Databases searched were Scopus (1977-present), Web of Science (1970-present), EMBASE (1988-present), MEDLINE (1996-present), PsycINFO (1987-present), ASSIA (1987-present), IBSS (1951-present), the Sociological

Abstracts (1052-present) and CINAHL (1982-present) and Clinical Trial registers between 9-16/02/12 and were updated on 26/03/14.

2.4.2 *Search strategy*

The above databases were searched with combinations of the key words “internet”, “web”, “computer”, “online”, “eHealth”, “nutrition”, “diet*”, “physical activity”, “exercise”, “weight”, “weight loss”, “overweight”, “obes*”, “randomi*ed controlled trial”, “randomi*ed”, “randomi*ed trial”, “randomi*ed clinical”, “controlled clinical trial” and “clinical trial”.

Criteria for considering studies for this review are outlined in Table 2-1

Table 2-1: Inclusion criteria for studies to the systematic review

Inclusion criteria	
Population	Adult participants with BMI>25kg/m^2
Interventions	Targeting diet and/or physical activity for weight loss Delivered at least in part via the internet Incorporating some form of individualised feedback to the participants
Comparator	Alternative interventions receiving no individualised feedback via the internet
Outcome	Body weight, body fat, waist circumference or BMI
Study Design	Randomised controlled trials (including pilot studies)

2.4.3 *Hand searching*

Conference publications and key, relevant journals related to the review research topic (Obesity Journal, International Journal of Obesity, Journal of Medical Internet Research, Journal of Nutrition and Dietetics) were also searched additionally to database searches to allow thorough exploration.

2.4.4 *Reference checking*

Reference lists of identified studies and citation indexes of papers citing the identified studies were searched.

2.4.5 *Personal communication*

Experts in the field were contacted and asked if they are aware of any other studies, which not have been published, relevant to the review.

2.4.6 *Supplementary information*

To increase the available information and better describe the intervention and the behaviour change techniques used, authors were requested to send any intervention materials and to allow the authors of the current systematic review to log into their intervention website if possible. The majority of

studies replied to the request for further intervention description but only seven studies had documents which provided extra intervention information. Three of these returned manuals outlining either counsellor session notes (Hunter *et al.*, 2008; Harvey-Berino *et al.*, 2010) or a participant user guide (Kraschnewski *et al.*, 2011). Two studies had additional papers outlining the intervention protocol in greater detail (Van Wier *et al.*, 2009; Morgan *et al.*, 2011b), with another study having supplementary material available online (Appel *et al.*, 2011). Lastly one study sent a summary report created at the end of the study (Hersey *et al.*, 2012).

2.5 **Data collection**

2.5.1 ***Selection of studies***

All studies generated from the previously defined search strategies were evaluated against the pre-defined inclusion criteria by my colleague, James Newham (post-doctoral research associate with experience in meta-analyses) and me. Any disparities were addressed by involving a third reviewer, Vera Araujo-Soares and reaching an agreement. A record of included and excluded studies was kept.

2.5.2 ***Data extraction***

Data was extracted from the studies in relation to the following information by James Newham and myself together and entered into Review Manager or the corresponding table.

- Study author, publication year and country where research took place.
- Method of selection/recruitment of participants
- Participants recruited (age, gender).
- Methodological quality of the evidence.
- Intervention characteristics and comparison groups.
- Reporting of intervention components - based on Template for Intervention Description and Replication (TIDieR) checklist and guide (Hoffmann *et al.*, 2014) and guidelines of minimal intervention detail to be

described in research reports (content/elements, provider, format, setting, recipient, intensity, duration and fidelity) (Davidson *et al.*, 2003).

- Commercial/non-commercial websites - A commercial website is a company limited website that usually would already be in the public domain and the majority of which charge the participants to access the website. A non-commercial website would usually have been created for research purposes, be free of charge to the user and typically cease operation at the end of the research project.
- Behaviour change techniques used - Coding of the behaviour change techniques (BCTs) was conducted for each of the studies by myself, with 20% independently checked by James Newham and Vera Araujo-Soares, who was also consulted to resolve discrepancies. These were coded based on Michie *et al.* (2011) CALO-RE taxonomy of behaviour change techniques to help people change their eating and physical activity behaviours.
- Theoretical framework – Theories used to develop interventions were recorded if mentioned by the authors. I am aware that a mixture of theories may be used in one study and authors were contacted if any uncertainties arose (Michie and Prestwich, 2010).
- Weight loss ([non] significance), body fat percentage, waist circumference and BMI results. Any other outcome measures were also extracted.
- Engagement levels, recruitment, retention and attrition rates.

2.5.3 *Quality assessment*

The studies that qualified for inclusion into the review were assessed independently by James Newham and me with regards to their methodological quality. Methodological quality was assessed for each of the studies by me and independently checked by the other reviewer, James Newham (Kappa = 0.89).

Quality assessments criteria focused on how studies reported randomisation, allocation concealment, blinding, incomplete outcome data, selective outcome reporting and other sources of bias (see appendix B). Studies were

assigned a quality rating of low, high or unclear for each criterion based on the criteria set out in the Cochrane Collaboration Handbook (Higgins and Green, 2011a). James and I were able to agree on all quality assessment rating. A third reviewer (Vera Araujo-Soares) was arranged if disagreement occurred but this was not necessary.

All authors were contacted to ask for further information for intervention description or materials.

2.6 **Data synthesis and analysis**

The data extracted from the included studies was analysed in the following way:

2.6.1 ***Primary outcome analysis***

The change in score from baseline to each data collection point endpoint was analysed for:

- Weight loss
- Body fat percentage
- BMI
- Waist circumference
- Effectiveness – Number of participants showing a 5-10% decrease in their original body weight (guideline recommendations to improve a person's health (National Institute for Health and Clinical Excellence clinical guidelines, 2006 updated 2014)).

Statistical analysis of the data was carried out through meta-analysis using the software Review Manager 5. Data was analysed using mean (SD) change for each of the intervention and control arms and compared whether significant differences were present between the different arms. Meta-analysis was conducted, with intention–to-treat data used if possible.

Any enhanced arms, internet interventions with additional components such as telephone calls or in person appointments, within a study were not included in the meta-analysis for feedback versus no feedback but are

examined in the ‘internet feedback versus internet plus additional components’ narrative descriptions later in the chapter, see 2.9.3.

Some trials had three arms, two active and one control. This trial design can be an issue in meta-analyses, as entering two intervention arms separately means the control participants would then be counted twice. To overcome this problem, recommendations from Cochrane guidelines (Higgins and Green, 2011b) were followed; this approach involves combining all relevant experimental intervention arms of the study into a single group providing a single sample size, mean and standard deviation for the intervention arm.

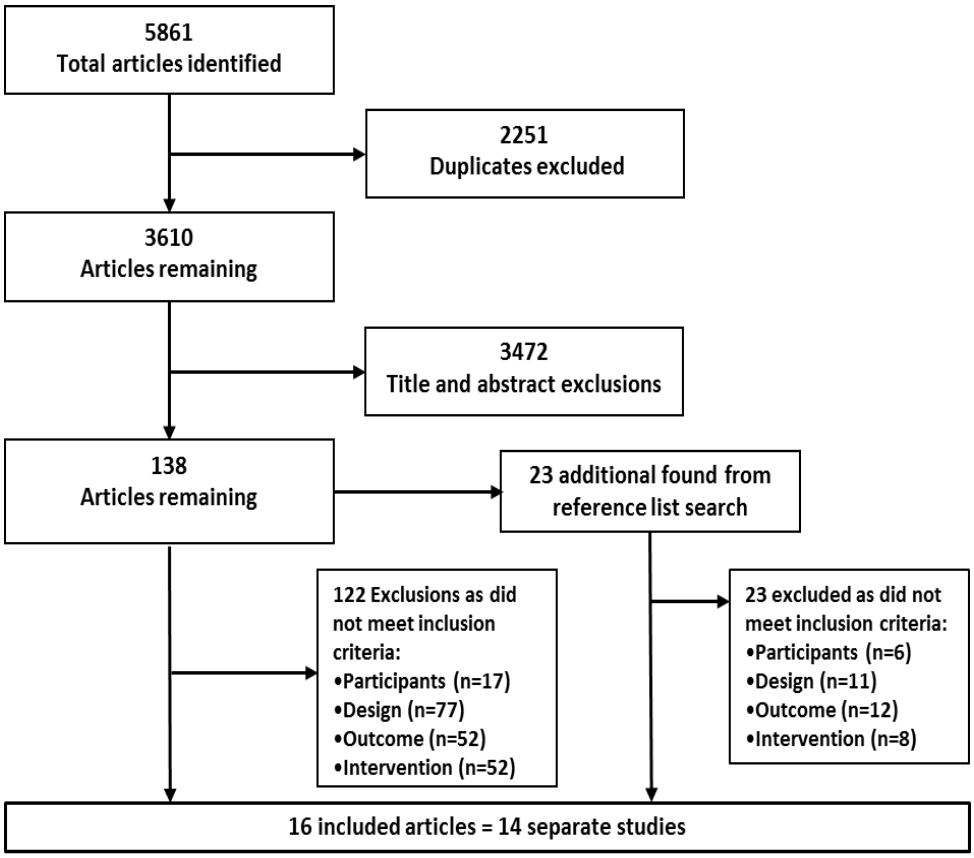
Unfortunately one study was unable to provide data in the format required and therefore is not included in the meta-analyses (Hersey *et al.*, 2012). The majority of studies reported standard deviation (SD) and mean values. However, a small number of studies (three) were only able to provide standard error of the mean (SEM). Analysis was performed initially combining the SD and SEM values to enable all study results to be examined. However, sensitivity analysis was then performed to repeat results but excluding SEM studies due to the range of error being lower when SEM is reported. Therefore analysis was repeated without the included SEM studies to examine if any impact on the effectiveness of outcomes was identified, e.g. weight loss for intervention arms becoming significantly different to the control arms.

2.6.2 ***Secondary outcome analysis***

- Level of engagement - average number of log-ins, how often features of the intervention were accessed, time spent on the website/each feature.
- Retention rates – number of participants remaining and adhering to randomised arm and also number of participants remaining in study for data collection (comparison to rates in the control group).
- Attrition rates – number of participants withdrawing from allocated arm and number of participants with loss of follow up data collection (comparison to levels in the control group).

2.7 **Results**

Figure 2-1: Screening for eligible studies



16 articles and 14 separate studies were included in the review as shown in Figure 2-1 above, which illustrates the reasons excluded studies were not eligible.

2.7.1 ***Description of included studies***

The characteristics of the included studies are summarised in table 2.2 below.

Table 2-2: Study characteristics of included studies

Study	Setting	*N*	Percentage of females	Retention Of Participants	Length of intervention	Follow-up
Appel 2011	USA	415	264/415 (63.6%)	394/415 (94.9%)	24 months	None
Chambliss 2011	USA	120	99/120 (83%)	95/120 (79.2%)	3 months	None
Collins 2012	Australia	309	180/309 (58%)	260/309 (84.1%)	3 months	None
Harvey Berino 2010	USA	481	447/481 (93%)	462/481 (96%)	6 month	None
Hersey 2012	USA	1755	1292/1755 (74%)	492/1755 (28%)	12 months	15-18 months (post-randomisation)
Hunter 2008	USA	446	224/446 (50%)	399/446 (89.5%)	6 months	None
Kraschnewski 2011	USA	100	69/100 (69%)	88/100 (88%)	3 months	None
McConnon 2007	UK	221	170/221 (77%)	131/221 (59.3%)	12 months	None
Morgan 2011	Australia	110	All male (0%)	90/110 (81.8%)	3 months	14 weeks
Morgan 2011	Australia	65	All male (0%)	46/65 (70.8%)	12 months	None
Tate 2001	USA	91	81/99 (89%)	71/91 (78%)	6 months	None
Tate 2003	USA	92	83/92 (90%)	77/92 (83.7%)	12 months	None
Tate 2006	USA	192	162/192 (84.3%)	155/192 (80.7%)	6 months	None
Van Weir 2011	Netherlands	1386	457/1386 (33%)	792/1386 (57.1%)	6 months	12 and 24 months (post-randomisation)

All studies took place between 2001 and 2012. The majority (nine) were conducted in the USA, three in Australia, one in the Netherlands and one in the UK.

In total the number of participants was 5783 with 3535 females (61.1%). Two studies included male participants only (Morgan *et al.*, 2011a; Morgan *et al.*, 2011b). All fourteen studies included both physical activity and diet information and feedback to the participants. The length of the active interventions ranged from three to 24 months. Data collection tended to be at more than one time point, with three studies conducting follow ups post-intervention. All of the characteristics can be seen in more detail in Table 2-2 above.

Ten of the fourteen studies included health problems as part of the exclusion criteria (Tate *et al.*, 2001; Tate *et al.*, 2006; Hunter *et al.*, 2008; Van Wier *et al.*, 2009; Harvey-Berino *et al.*, 2010; Chambliss *et al.*, 2011a; Kraschnewski *et al.*, 2011; Morgan *et al.*, 2011a; Morgan *et al.*, 2011b; Collins *et al.*, 2012). Hersey *et al* (2012) allowed participants with health problems providing they had provider approval. Two studies exclusively included participants with health problems. Appel ***et al's*** study (2011) focused on participants with one or more cardiovascular risk factor and Tate ***et al's*** (2003) inclusion criteria stating participants had to have one or more risk factor for type 2 diabetes (other than obesity). One study (McConnon *et al.*, 2007) did not mention any inclusion/exclusion criteria in relation to health problems.

2.7.2 ***Study categorisation***

Studies varied in the nature of the intervention and comparison groups. In order to facilitate analysis, the studies were categorised into groups with similar comparisons as follows:

1. Internet feedback versus no feedback (12 studies included) – studies had to include one arm providing feedback via the internet and one arm that provided participants with no form of feedback, see 2.8.1.
2. Human internet feedback versus no feedback (eight studies included) – studies had to include one arm providing human delivered internet based feedback against one arm that was provided with no feedback, see 2.8.2.
3. Automatic internet feedback versus no feedback (six studies included) – studies had to include one arm that providing internet based

feedback through an automated system against one arm that was provided with no feedback, see 2.8.3.

4. Automatic feedback versus human feedback (one study included) – studies had to include one arm providing internet based feedback through an automated system against one arm that received human feedback, see 2.9.1
5. Feedback mode of delivery and impact on outcome (two studies included) – studies had to have two intervention arms both providing feedback to the participants but differed with regards to the mode of delivery by which the feedback was given, see 2.9.2.
6. Internet feedback versus internet feedback with additional components (four studies included) – studies had to include one arm providing feedback via the internet in comparison to one arm that provided feedback via the internet but had extra communication with participants (i.e. telephone or face to face feedback contact in addition), see 2.9.3.

The studies are described in detail (see 2.8) within the categories that each of the studies were assigned to (studies can appear in more than one category). All studies are examined in further depth in relation to intervention description in Table 2-3, type of feedback provided in Table 2-4, weight loss outcomes in Table 2-5 and engagement with the interventions in Table 2-6.

2.7.3 *Intervention description*

The Template for Intervention Description and Replication (TIDieR) checklist and guide created by Hoffmann *et al.* (2014) and the minimal intervention description table outlined by Davidson *et al* (2003) were incorporated to describe key aspects and details of the included studies interventions. These aspects are outlined in relation to the included studies within Table 2-3.

Table 2-3: Intervention description

Study	Content/Elements	BCTs*	Provider	Format	Setting	Recipient	Intensity	Fidelity
Appel A	Control - Provided with publication "Aim for A Healthy Weight" and material via a static study web site with links to other sites offering healthy eating and weight loss recommendations.	Information on consequences in general; Goal setting behaviour and outcome	Primary care providers (PCP) provided usual medical care.	Self-help	Web Clinic visits medical centre	Obese patients with at least one cardiovascular risk factor	Usual schedule from PCP, met at baseline and 24 month follow up for study	N/A
Appel B	In person - same as Remote Support but had in person contact in addition and more frequent contact. Personalised advice based on inputted data, received online and in person.	Information on consequences in general; Goal setting behaviour and outcome; Barrier identification; Prompt review of behavioural goals; Self-monitoring of behaviour and behavioural outcome; Provide feedback on performance; Use of follow up prompts; Social support; Relapse prevention; Stress management; Motivational interviewing; Time management	Weight loss counsellors and PCP.	Telephone, automated emails, in person one to one or group sessions	Web Phone Medical centre	Obese patients with at least one cardiovascular risk factor	1-3mths weekly, 4-6 thrice monthly, 7-24 twice a month, automated feedback monthly and usual visits to PCP.	The Intervention director, with the support of investigators, will implement quality control procedures 1) direct observation and audio taping of contacts to ensure adherence to study protocol and 2) case management to discuss clinical issues related to participants 3) regular quality control reports provided by Health ways computer-based system to assess completion of contacts as per protocol.

Appel C	Remote Support - a lifestyle intervention: 1) telephone counsellor contacts 2) a lifestyle counselling curriculum via the web and 3) online tools for behavioural self-monitoring. 9 introductory modules and 21 additional modules. The curriculum focuses on self-monitoring, stimulus control, social support, problem solving, and cognitive restructuring. Personalised advice based on inputted data, received online.	Information on consequences in general; Goal setting behaviour and outcome; Barrier identification; Prompt review of behavioural goals; Self-monitoring of behaviour and behavioural outcome; Provide feedback on performance; Use of follow up prompts; Social support; Relapse prevention; Stress management; Motivational interviewing; Time management	Weight loss counsellors	Telephone, automated feedback emails	Web Phone	Obese patients with at least one cardiovascular risk factor	1-3mths weekly, 4-6 monthly, 7-24 every other month, automated feedback of self-monitoring monthly.	As above for group B
Chambliss A	Waiting list, told not to change any eating or PA habits and offered opportunity for basic programme	None	None	None	None	Overweight men and women , no major health problems	None	N/A
Chambliss B	Basic - Met with trained health educator, received individualised tailored calorie plan and instructions on use of the weight management software system. 1hr group seminar on weight management strategies. Personalised advice based on inputted data, received online.	Information on consequences in general; Goal setting behaviour; Self-monitoring of behaviour; Provide feedback on performance	Health educator	In person visits, emails through software system and from health educator.	Web based and in person clinic visits	Overweight men and women , no major health problems	Weekly feedback emails, monthly clinic visits	Use of structured protocols and predetermined scripts assisted health educators in providing information and support.

Chambliss C	Enhanced - Same as above but 2hr seminar which also included behavioural weight management strategies as well as B (weight loss, self-monitoring, nutrition and PA. Step counters, monthly email newsletters and brief telephone consultations. Personalised advice based on inputted data, received online and in person.	Information on consequences in general; Goal setting behaviour; Barrier identification; Prompt review of behavioural goals; Self-monitoring of behaviour; Provide feedback on performance; Environmental restructuring; Social support; Relapse prevention; Stress management; Time management	Health educator	In person visits, emails through software system and from health educator.	Web based and in person clinic visits	Overweight men and women , no major health problems	Same as above but in addition monthly telephone calls and behavioural tracking forms assessed by health educator.	Use of structured protocols and predetermined scripts assisted health educators in providing information and support.
Collins A	Waiting list, told not to change any eating or physical activity habits	None	None	None	None	Overweight men and women , no major health problems	None	Not mentioned
Collins B	Basic - web based basic program including calorie targets, food and exercise diaries, educational tips, online forums, newsletters with new content on website, self-monitoring of progress, goal setting and graphs.	Information on consequences in general; Goal setting behaviour and outcome; Prompt review of outcome goals; Self-monitoring of behaviour and behavioural outcome ;Provide instruction on how to perform behaviour; Social support	Website	Web based system	Web based	Overweight men and women , no major health problems	Weekly newsletters, educational tips, PA plans, menu plans, calorie targets.	Not mentioned
Collins C	Enhanced - Same as above but automated personalised feedback on their diet and PA, weight loss and website use. Reminders to use certain features (with email, text and phone call if continued lack of response on website). Personalised advice based on inputted data, received online.	Information on consequences in general; Goal setting behaviour and outcome; Prompt review of outcome goals; Self-monitoring of behaviour and behavioural outcome ;Provide feedback on performance; Provide instruction on how to perform behaviour; Social support	Website	Web based system	Web based	Overweight men and women, no major health problems	Same as above but weekly automated feedback, reminders	Not mentioned

Harvey Berino A	In person - treatment components were the same as the 2 other groups but not online, in person group sessions were attended. Paper journals instead of electronic. Personalised advice based on inputted data in person.	Information on consequences in general; Normative information about others' behaviour; Goal setting behaviour and outcome; Barrier identification; Set graded tasks; Prompt review of behavioural goals; Rewards contingent on successful behaviour; Self-monitoring of behaviour and behavioural outcome ;Provide feedback on performance; Provide instruction on how to perform behaviour; Social support; Relapse prevention	Counsellor	In person group sessions	In person group session	Overweight adults at two clinical centres	Weekly in person session	Programs received identical behavioural lessons and individualised feedback on progress. Group counsellors used a written protocol that outlined standard lessons with counsellor guides to ensure comparability of intervention methods.
Harvey Berino B	Internet - Weight loss treatment focused on the modification of eating and exercise habits using behavioural strategies and self-management skills. Homework assignments, dietary intake, PA and weight journals. Weekly group online chat rooms. All done on the web site. Personalised advice based on inputted data, received online.	Information on consequences in general; Normative information about others' behaviour; Goal setting behaviour and outcome; Barrier identification; Set graded tasks; Prompt review of behavioural goals; Rewards contingent on successful behaviour; Self-monitoring of behaviour and behavioural outcome ;Provide feedback on performance; Provide instruction on how to perform behaviour; Social support; Relapse prevention	Counsellor	Web, email communication and group chats	Internet	Overweight adults at two clinical centres	Weekly chat room sessions on homework, progress and self-monitoring journals	As above for group A

Harvey Berino C	Hybrid - Same as above but once a month an online chat was substituted with an in person group meeting. Web site included tips and recipes, BMI calculator, PA local events, bulletin boards for members and educational resources. Personalised advice based on inputted data, received online and in person.	Information on consequences in general; Normative information about others' behaviour; Goal setting behaviour and outcome; Barrier identification; Set graded tasks; Prompt review of behavioural goals; Rewards contingent on successful behaviour; Self-monitoring of behaviour and behavioural outcome ;Provide feedback on performance; Provide instruction on how to perform behaviour; Social support; Relapse prevention	Counsellor	Web group communication and in person group sessions	Web and in person sessions	Overweight adults at two clinical centres	Same as above but replaced one weekly session with an in person session	As above for group A
Hersey A	RCT 1 - book HEALTH manual and eHealth tools (basic internet component) - weight management demonstration using cognitive behavioural methods to increase PA and improve diet (goal setting, problem solving, self	Information on consequences in general; Goal setting outcome; Barrier identification; Rewards contingent on effort or progress towards goal; Self-monitoring of behaviour and behavioural outcome; Social support; Relapse prevention; Time management	Lifestyle coaches	Website	Web	Non active duty TRICARE beneficiaries	Weekly self-assessment reporting weight, food intake and PA	Not mentioned
Hersey B	RCT 2 - same as RCT 1 but added an interactive version of eHealth - tailored computerised feedback based on weekly assessments. Personalised advice based on inputted data, received online.	Information on consequences in general; Goal setting outcome; Barrier identification; Rewards contingent on effort or progress towards goal; Self-monitoring of behaviour and behavioural outcome; Provide feedback on performance; Social support; Relapse prevention; Time management	Lifestyle coaches	Web and email communication	Web	Non active duty TRICARE beneficiaries	Weekly assessments, feedback on each assessment.	Not mentioned

Hersey C	RCT 3 - same but added telephonic coaching support provided by trained health lifestyle coaches (telephone calls and personal emails). Personalised advice based on inputted data, received online and via the telephone.	Information on consequences in general; Goal setting outcome; Barrier identification; Rewards contingent on effort or progress towards goal and on successful behaviour; Self-monitoring of behaviour and behavioural outcome; Provide feedback on performance; Social support; Relapse prevention; Motivational interviewing; Time management	Lifestyle coaches	Web and email communication and telephone calls	Web and phone	Non active duty TRICARE beneficiaries	Weekly assessments, feedback on each assessment either email or phone call.	Not mentioned
Hunter A	Usual care - see PCP for a preventive health visit, assessment of diet and weight. Each base included a fitness centre, weight loss and healthy cooking classes, nutrition consultants, opportunities for individual assessments and recommendations.	Information on consequences in general; Provide instruction on how to perform behaviour	PCP and nutritionist	In person individual sessions	In person	Overweight US Air Force officers	Annual assessment, US AF members are expected to work out minimum 3 times a week and tested annually for fitness	Not mentioned

Hunter B	Behavioural Internet Therapy (BIT) plus usual care - generally asked to restrict calories and increase PA, self-monitoring diet and PA journals received personalised feedback. Lessons and quizzes on common strategies. LEARN program for weight management, behavioural modification approach to weight management with assigned reading. Personalised advice based on inputted data, received online.	Information on consequences in general and for the individual; Goal setting behaviour and outcome; Action planning; Barrier identification; Prompt review of behavioural and outcome goals; Self-monitoring of behaviour and behavioural outcome; Rewards contingent on effort or progress towards goal; Provide feedback on performance; Provide instruction on how to perform behaviour; Use of follow up prompts; Social support; Relapse prevention; Stress management; Motivational interviewing; General communication skills training	Counsellor	Web and email communication	Initial in person meeting then web based	Overweight US Air Force officers	Weekly journals at least 5 times a week with weekly feedback. Weekly lessons 20-30 mins. 10-15 mins spent giving Pp feedback. 2 brief motivational interviews, 15 mins.	Not mentioned
Kraschnewski A	Waiting list control - notified they would access to website after 12 weeks	None	None	None	None	Overweight and obese adults	None	Not mentioned

Kraschnewski B	Achieve Together website implementing 36 weight control behaviours, algorithms matched Pps to 3 role models close to them on gender, age and target body weight. Prompted to build diet plan by selecting preferred practices and goals. Pps received tailored feedback to help them choose practices, automatic email reminders were sent if no logins in a week. Personalised advice based on inputted data, received online.	Information on consequences in general; Normative information about others' behaviour; Goal setting behaviour and outcome; Prompt review of behavioural and outcome goals; Prompt generalisation of target behaviour; Self-monitoring of behaviour; Provide feedback on performance; Provide instruction on how to perform behaviour; Facilitate social comparison; Social support	Web based, algorithms	Web and email	Web	Overweight and obese adults	Told to access website at least once a week, at every log in prompted to log diet, PA and weight for last 7 days. Automated email reminder if not logged in during the week.	Not mentioned
McConnon A	Advised to continue with their usual approach to weight loss and given a small amount of printed information at B reflecting the type of information available within primary care.	Information on consequences in general	None	Written material	In person primary care	Obese patients from GP practices	None	Not mentioned

McConnon B	Intervention website offering a combination of dietary advice, PA advice and behaviour therapy. Provided advice, tools and information to support behaviour change. Designed for patients to manage own care. Personalised advice, motivational statements based on self-reports of progress. Automatic generic emails were generated if Pps did not visit the website. Personalised advice based on inputted data, received online.	Information on consequences in general; Goal setting behaviour; Self-monitoring of behaviour and behavioural outcome; Provide feedback on performance; Provide instruction on how to perform behaviour; Social support	Web based, algorithms	Web and email communication	Web	Obese patients from GP practices	Frequency of use was designed to be varied based on the participants own needs, seen by researcher at B, 6 and 12 months. However emails were sent if they did not log in regularly to encourage them to visit more followed by mail and telephone if no response.	Not mentioned
Morgan (a) A	Wait list control group	None	None	None	None	Male overweight or obese shift workers	None	Not mentioned
Morgan (a) B	Workplace POWER program: information session, handbook, study website (daily diet and exercise information), 7 individualised dietary feedback sheets, and group based financial incentive pedometers. Personalised advice based on inputted data, received online .	Information on consequences in general and for the individual; Goal setting outcome; Barrier identification; Rewards contingent on successful behaviour; Self-monitoring of behaviour; Provide feedback on performance; Social support	Researcher (health/PE or nutrition and dietetics)	In person initial tutorial then web and email communication	Web	Male overweight or obese shift workers	Asked to enter weight once a week, daily eating and exercise for first 4 weeks, 2 weeks in second month and 1 week in third month. Self-reported variables regarding PA, diet were also assessed.	Not mentioned
Morgan (b) A	One face to face information session, weight loss booklet but no website access.	Information on consequences in general	None	Written material	In person tutorial	Overweight or obese male university staff or students	None	Not mentioned

Morgan (b) B	SHED-IT Internet group, one face to face information session, weight loss booklet, use of free website plus 3 months support. Self-monitoring of weight, dietary intake and exercise, set goals and social support. Individualised feedback including anecdotes and weight loss strategies. Ask questions to a notice board which researchers would answer weekly. Personalised advice based on inputted data, received online.	Information on consequences in general; Normative information about others' behaviour; Goal setting outcome; Self-monitoring of behaviour and behavioural outcome; Provide feedback on performance; Social support	Researcher	In person initial tutorial then web and email communication	Web and one in person meeting	Overweight or obese male university staff or students	Asked to enter weight once a week, daily eating and exercise for first 4 weeks, 2 weeks in second month and 1 week in third month.	Not mentioned
Tate 2001 A	Initial introductory group weight loss session, 1hr lesson on behavioural weight control - calorie restriction, increase PA gradually, importance of self-monitoring but did not submit journals only IBT group did, web resources to track diet and exercise daily. Web site access resources about diet, exercise, behavioural topics such as social support, stimulus support and managing stress.	Information on consequences in general; Social support; Stress management	Therapist (doctoral clinical psychologist)	Website and in person tutorial	Website and in person	Healthy overweight adults employed by a large network of hospitals	Encouraged to enter weekly reports but did not actually submit these to the therapist. Follow up at 3 and 6 months.	Not mentioned

Tate 2001 B	Same as internet education group but internet behaviour therapy had electronic diaries, weekly self-monitoring information, ask questions. Email messages were sent weekly including a behavioural weight loss lesson and personalised feedback (structured guidance), included individualised feedback sent personally from therapist, recommendations and reinforcement based on progress via the website. Bulletin board with other users. Email enquiry if not logged in for a while.	Information on consequences in general; Self-monitoring of behaviour and behavioural outcome; Provide feedback on performance; Provide instruction on how to perform behaviour; Social support; Stress management	Therapist (doctoral clinical psychologist)	Web and email communication	Web and in person	Healthy overweight adults employed by a large network of hospitals	Instructed to submit reports and diaries weekly. Weekly emails were returned to participants. Follow up at 3 and 6 month appointments	Not mentioned
Tate 2003 A	Web site provided a tutorial on weight loss, a new tip and link each week and a directory of selected internet weight loss resources	Information on consequences in general; Self-monitoring of behaviour; Social support	Website	Website and email reminder	Web	Overweight or obese and 1 or more other risk factor for type 2 diabetes	Each week participants received an email reminder to submit their weight and received weight loss information.	Not mentioned

Tate 2003 B	Same as basic internet group but had communication with weight loss counsellor. Instructed to report calorie, fat intake, exercise expenditure and comments or questions for the therapist via a web based diary. Personalised advice based on inputted data, received online.	Information on consequences in general; Self-monitoring of behaviour; Provide feedback on performance; Use of follow up prompts; Social support	Counsellor masters or doctoral degree in education, nutrition or psychology	Web and email communication	Web	Overweight or obese and 1 or more other risk factor for type 2 diabetes	Participants were instructed to submit daily diaries for the first month and were given the option of submitting daily or weekly thereafter. First month the therapist emailed participants 5 times a week and then weekly emails for the remaining 11 months. Personal follow up emails were sent if a Pp did not report.	Not mentioned
Tate 2006 A	Face to Face group session instructed to follow a calorie restricted diet and meal replacements and to increase PA. Shown how to use Slim Fast web site including weekly reports, weight loss tips, recipes and e-buddy network system.	Information on consequences in general; Self-monitoring of behaviour and behavioural outcome; Provide instruction on how to perform behaviour; Social support	None	Website	Web	Overweight or obese adults willing to take meal replacements as part of their dietary regime	For all groups weekly email prompts were sent reminding Participants to report weight.	Not mentioned

Tate 2006 B	Automatic feedback - same as NC but also had access to separate website that offered additional features including electronic diary, message board. Second weekly email to submit online diary and a behavioural lesson on topics similar to diabetes prevention program. Pre-programmed computer feedback returning tailored feedback when diary is submitted.	Information on consequences in general; Goal setting behaviour; Barrier identification; Prompt review of behavioural goals; Self-monitoring of behaviour and behavioural outcome; Provide feedback on performance; Provide instruction on how to perform behaviour; Social support	Feedback algorithms	Web and email communication	Web	Overweight or obese adults willing to take meal replacements as part of their dietary regime	Reminded to enter weekly reports/diaries. Sent weekly online lessons/topics.	Not mentioned
Tate 2006 C	Human feedback - same as above but feedback from not automatic but was via an email from a human weight loss counsellor whom they never met in person. Personalised advice based on inputted data, received online.	Information on consequences in general; Goal setting behaviour; Barrier identification; Prompt review of behavioural goals; Self-monitoring of behaviour and behavioural outcome; Provide feedback on performance; Provide instruction on how to perform behaviour; Social support	Human weight loss counsellor	Web and email communication	Web	Overweight or obese adults willing to take meal replacements as part of their dietary regime	Reminded to enter weekly reports/diaries. Sent weekly online lessons/topics.	Not mentioned
Van Weir A	All groups received self-help brochures about overweight, healthy diet and PA.	Information on consequences in general	None	Self-help after initial information	Own surroundings	Employees from 7 Dutch service sector companies, overweight and able to read and write Dutch	Measurements were conducted for all groups at B, 6 and 12 months.	N/A

Van Weir B	Phone - in addition had access to a lifestyle intervention program based on behaviour modification (10 modules) in the form of a workbook. After finishing each module the Pp was contacted by their counsellor by phone to receive personalised feedback.	Information on consequences in general; Goal setting behaviour; Self-monitoring of behaviour; Provide feedback on performance	Personal counsellor (2 dietitians and 2 physical activity scientists)	Written information and telephone calls	Own surroundings	Employees from 7 Dutch service sector companies, overweight and able to read and write Dutch	10 modules to complete with feedback after each module completed.	Standardised protocol for each counsellor to follow
Van Weir C	Internet - as above but internet group accessed program through an interactive web site composed of personalised web pages. Encouraged to set behavioural goals for diet and PA. Contacted by their counsellor receiving personalised feedback via email.	Information on consequences in general; Goal setting behaviour; Self-monitoring of behaviour; Provide feedback on performance	Personal counsellor (2 dietitians and 2 physical activity scientists)	Web and email communication	Web	Employees from 7 Dutch service sector companies, overweight and able to read and write Dutch	10 modules to complete with feedback after each module completed.	Standardised protocol for each counsellor to follow
***BCTs = Behaviour change techniques incorporated into each intervention arm**								

No studies reported on the modification of the interventions within their research papers. Studies did not vary greatly regarding the number of study arms included. Seven studies included two arms and seven studies included three arms. However, the studies did vary in terms of the nature of control/comparison arms, the range of which is shown in Table 2-3.

Six of the fourteen websites used were commercial (owned by a profit organisation) (Tate *et al.*, 2006; Harvey-Berino *et al.*, 2010; Chambliss *et al.*, 2011a; Morgan *et al.*, 2011a; Morgan *et al.*, 2011b; Collins *et al.*, 2012). Seven were non-commercial sites (Tate *et al.*, 2001; Tate *et al.*, 2003; McConnon *et al.*, 2007; Hunter *et al.*, 2008; Appel *et al.*, 2011; Kraschnewski *et al.*, 2011; Hersey *et al.*, 2012) and for one study it remained unclear (Van Wier *et al.*, 2009).

Provision of Feedback

Studies varied with regards to the type, access and frequency of feedback, outlined in Table 2-4.

Table 2-4: Provision of feedback

Study	Feedback type	Access to feedback	Frequency	Additional contact
Appel 2011	Automatic	Received email	Weekly (3 months) Monthly (remaining 21 months)	Reminder log in emails
Chambliss 2011	Human	Received email	Weekly	
Collins 2012	Automatic	Log into website	Weekly	Reminder log in emails followed by SMS messages then finally phone calls
Harvey Berino 2010	Human	Log into website	Weekly	
Hersey 2012	Automatic	Log into website	Module completion	
Hunter 2008	Human	Unclear	Weekly	
Kraschnewski 2011	Automatic	Log into website	At log in	Reminder log in emails
McConnon 2007	Automatic	Log into website	At log in	Reminder log in emails
Morgan 2011a	Human	Received email	Seven messages	
Morgan 2011b	Human	Unclear	Seven messages	
Tate 2001	Human	Received email	Weekly	Reminder log in emails
Tate 2003	Human	Received email	Weekly	
Tate 2006	Human Automatic	Received email Log into website	Weekly	Reminder diary completion emails
Van Weir 2011	Human	Received email	Module completion	

* Automatic feedback = algorithms created to send feedback based on inputs
* Human feedback = health professionals providing feedback
* Access to feedback relates to how participants received the feedback they were being provided
* Blank boxes equate to additional contact not being mentioned in the paper

The type of feedback that participants received varied between incorporating human delivered internet feedback via a researcher or health professional and providing automatic internet feedback (using algorithms which sent pre-programmed responses based on participant input or choices), see Table 2-4. One study was three-armed and included no feedback (control group), human internet feedback and automatic internet feedback specifically to compare different types of feedback (Tate *et al.*, 2006).

Methods for participant access to internet feedback varied between needing to log into the website and receiving a web based message/email containing the feedback, see Table 2-4. Tate *et al.* (2006) incorporated both of the above two formats: automatic internet feedback arm having to log into the website to receive feedback, whereas the human internet feedback arm were sent an email with the feedback.

Frequency of feedback also varied, with the majority of studies providing it on a weekly basis. One study changed to monthly feedback after three months and two studies decided on a pre-arranged number of feedback occasions for the course of the intervention, see Table 2-4. In contrast to a set amount, feedback was also provided based on user engagement. Two studies incorporated automatic internet based messages, such as motivational statements and positive reinforcement, when participants logged into the website (McConnon *et al.*, 2007; Kraschnewski *et al.*, 2011). Two other studies provided feedback based on a progression basis, responding to participants whenever they completed a lesson module or assessment (Van Wier *et al.*, 2009; Hersey *et al.*, 2012). These methods of contacting participants appeared to be ways of providing reinforcement to the participants for engaging with the intervention.

Additional contact to the participants included studies using reminder emails prompting participants to log in or complete diaries on the website, see Table 2-4. Collins *et al* (2012) incorporated the greatest amount of additional contact sending SMS messages if the participant still did not log in after the

reminder email, and then a phone call if the SMS did not have any effect. The rationale for this strategy was to try to re-engage/maintain participants with the intervention.

Only four studies included description about the theoretical background underpinning the behaviour change intervention, with all referring to Social Cognitive Theory.

2.7.4 *Effectiveness of web-based interventions aiming to achieve weight loss*

Eleven studies identified weight loss in internet feedback arms statistically significantly differed from the control at the end of the active intervention. However, three of the studies found no statistically significant difference between the arms, see Table 2-5 below. Reporting on the effectiveness of interventions, in terms of participants losing ≥5% weight loss, was unreported for six of the studies and remained unclear as to whether clinically meaningful results had been achieved. Only three of the studies reported how intervention arms had been effective at losing ≥5% mean weight loss of initial body weight per arm, see Table 2-5.

Table 2-5: Weight loss outcomes for internet-based interventions

Study	Results (by arms, internet feedback intervention arm in bold)	Significant difference between groups at post-test	Effective* (Group ≥5% loss)
Appel 2011	A) n = 138, 6 months: -1.5 (0.4) 12 months: -1.1 (0.5) 24 months:-0.8 (0.7) B) n = 138, 6 months: -5.8 (0.6) 12 months: -5.4 (0.7) 24 months: -5.1 (0.8) **C) n = 139, 6 months: -6.0 (0.5) 12 months: -5.7 (0.7) 24 months: -4.5 (0.7)**	No between B and C Greater weight loss for B and C compared to group A	Yes – Group B and C at 6 and 12 months, Group B at 24 months. Larger percentage of participants for group B and C than group A. Group C highest percentage of weight loss.
Chambliss 2011	A) n = 30, 0.3 (2.2) **B) n = 45, -2.7 (3.3)** C) n = 45, -2.5 (3.1)	Yes: significant weight loss for groups B and C compared to group A ($p<0.001$).	No Sig percentage of participants for group B and group C than group A. Group B highest percentage.
Collins 2012	A) n = 104, 0.36 (2.33) **B) n = 99, -2.14 (3.31)** **C) n = 106, -2.98 (4.05)**	Yes: significant weight for groups B and C compared to group A	No Higher percentage of participants for Group B and C than A.
Harvey Berino 2010	A) n = 161, -8.0 (6.1) **B) n = 162, -5.5 (5.6)** C) n = 158, - 6.0 (5.5)	Yes: mean weight loss for group A was significantly greater than achieved by group B or C ($p<0.01$).	Unclear Did not differ sig between groups ($p=0.12$)
Hersey 2012	A) n = 598 **B) n = 579** C) n = 578 No data		
Hunter 2008	A) n = 222, 0.6 (3.4) **B) n = 224, -1.3 (4.1)**	Yes: significant difference in weight loss for group B compared to group A ($p<0.001$)	Unclear – no mean % for groups. Sig larger percentage of participants for group B than group A.
Kraschnewski 2011	A) n = 50, 0.6 (2.4) **B) n = 50, -1.2 (2.95)**	Yes: Sig greater weight loss for group B ($p<0.01$)	Unclear
McConnon 2007	A) *n* = 110, 6 months: -0.45 (0.37) 12 months: -0.9 (0.36) **B) *n* = 111, 6 months: 0 (0.37) 12 months: -0.63 (0.36)**	No	Unclear Larger percentage of participants for group B than group A.

Morgan 2011a	A) n = 45, 0.3 (3.67) **B) n = 65, -4 (5.51)**	Yes: significant mean difference for weight change (p<0.001)	No Sig larger percentage of participants for group B than group A (p<0.001)
Morgan 2011b	A) n = 31, -3.1 (6.5) **B) n = 34, -5.3 (6.6)**	No	Yes: group B Non sig difference but group B had higher percentage of 5% participants than group A.
Tate 2006	A) n = 67, 3 months: -2.3 (3.4) 6 months: -2.3 (5.4) **B) n = 61, 3 months: -4.1 (4.3) 6 months: -3.5 (5.4)** **C) n = 64, 3 months: -5.3 (4.2) 6 months: -5.9 (6.2)**	Yes: greater loss in group B (*P* = 0.005) and C (*P* = 0.001) compared with group A at 3 months. Greater loss in group C compared with group A at 6 months (*P* < 0.001)	Yes: groups B & C Sig larger percentage of participants for group B & C than group A(p<0.05) .
Tate 2003	A) n = 46, -2.0 (5.7) **B) n = 46, -4.4 (6.2)**	Yes: greater loss in group B at 12 months (*P* = 0.04)	No Sig larger percentage of participants for group B than group A (p<0.05)
Tate 2001	A) n = 45, 3 months: -1.0 (2.4), 6 months: -1.3 (3.0) **B) n = 46, 3 months: -3.2 (2.9), 6 months: -2.9 (4.4)**	Yes: greater loss in group B at 3 (*P* < 0.001)and 6 months (*P* = 0.04)	Unclear Larger percentage of participants for group B than group A (p=0.05)
Van Weir 2011	A) n = 448, 6 months: -1.14 (0.17), 24 months: -1.05 (0.33) B) n = 453, 6 months: -2.8 (0.25), 24 months: -1.46 (0.29) **C) n = 450, 6 months: -1.81 (0.22), 24 months: -1.92 (0.27)**	Yes: greater loss in group B and C at 6 months No: no significant differences between groups at 24 months	Unclear Likelihood of a 5% weight loss sig higher for group B than group A (p<0.05) but not for group C (p =0.053)
* Weight loss (kg) for each study arm at each of the time points. Intervention groups in bold * Effectiveness equals ≥5% mean weight loss of initial body weight per arm			

2.7.5 *Engagement/uptake of internet interventions*

Reporting of compliance with intervention components is important to assess participant's engagement and to illustrate how the intervention was utilised (see overview of study engagement in Table 2-6). The study arms described in Table 2-6 (e.g. Appel B) are the same categorisations given to each arm described in detail in Table 2-3. All studies were examined for reported results in relation to intervention engagement.

Table 2-6: Engagement with the internet based weight loss interventions

Data collected	Study	Type of data	Results 3 months	6 months	12 months*	Significant difference between groups	Correlation with weight change	Correlation with attrition
Log-ins	Appel *et al* 2011	Median no. of weeks with log-ins	-	B) n = 138: 20.5 C) n = 139: 23	B) 32 *22-26 months C) 35 *22-26 months	NR	NR	NR
	Hersey *et al* 2012	Use of website (outside of assessments)	-	-	A) n = 598, 35% B) n = 579, 38% C) n = 578, 46%	Yes: Group C compared to A & B (no p values)	Yes: 38.3% losing 7% for those using website compared to 18% among those who didn't (no p values)	NR
	Hunter *et al* 2008	Mean number of log-ins	-	B) n = 224, 49.1	-	N/A	Yes: p<0.001	NR
	Kraschnewski *et al* 2011	Mean number of log-ins	B) n = 50, 7.7 (5.1)	-	-	N/A	No: p=0.4	NR
	McConnon *et al* 2007	Mean number of log-ins	-	-	B) *n* = 111, 15.8 (15.2)	N/A	No: p=0.16	NR
	Tate *et al* 2006	Median number of log-ins	-	A) n = 67: 34. B) n = 61: 20 C) n = 64: 32.5	-	Yes: Groups A & C greater than B: *p* = 0.03 (over 6 months)	Yes: p = 0.04	NR

	Tate *et al* 2003	Mean number of log-ins	Reported in graph form not in actual statistics.			Yes: p< 0.05	Yes: Group A, p < 0.001 Group B, p = 0.003	Yes: p<0.01
	Tate *et al* 2001	Mean number of log-ins	A) n = 45: 8.5 (10.4) B) *n* = 46: 19 (10.9):	A) 1.0 (3.0) B) 6.8 (6.2)	-	Yes: Group B: p < 0.001 (3 and 6 months)	Yes: Group A p = .03 Group B: *p* = 0.003 (between 0 and 6 months)	NR
Self-monitoring (Inputting of data)	Chambliss *et al* 2011	Logging data at least 5 days a week	B) n = 45, 85% C) n = 45, 70%	-	-	NR	NR	NR
	Harvey Berino *et al* 2011	Percentage of weeks journals were submitted	A) n = 161, 73% B) n = 162, 63% C) n = 158, 71%	-	-	No: p = 0.13	NR	NR
	Morgan *et al* 2011 POWER	Mean number of diet entries Mean number of exercise entries Number of weekly weight check-ins recorded	B) n = 65, 42 (34) B) n = 65, 24 (25) B) n = 65, 6 (of 14)			N/A	Yes: diet entries (p<0.04) No: exercise entries (p=0.24) Yes: weekly weight entries (p=0.01)	NR

	Morgan *et al* 2011 SHED-IT	Adherence: Diet intake Physical activity Weighed myself regularly (1-5 scale strongly disagree to strongly agree)	-	-	B) n = 28, 2.6 B) n = 28, 2.5 B) n = 28, 4.1	N/A	Yes: diet entries (p<0.001) exercise entries (p=0.004) weekly weight entries (weight p=0.004)	NR
	Tate *et al* 2006	Mean number of weeks diary submitted	-	B) 11.4 (9.2) C) 17.2 (8.7)	-	Yes: p=0.000 (Greater for Group C)	Yes: groups B and C (p<0.001)	NR
	Appel *et al* 2011	No.of modules completed	-	B) n = 138: 12 C) n = 139: 12	B) 8 *22-26 months C) 16 *22-26 months	NR	NR	NR
	Hersey *et al* 2012	Completion of weekly assessments	-	-	A) n = 598, 44% B) n = 579, 45% C) n = 578, 49%	Yes: Group C compared to Group A or B (no p values)	Yes: 41.5% participants lost 7% weight among completers of 3 or more weekly assessments compared to 17.1% of those who did not (no p values)	NR
Social support	Harvey Berino *et al* 2011	Attendance – number of online chats/in person meetings attended	-	A) n = 161, 71% B) n = 162, 76% C) n = 158, 72%	-	No: p = 0.25	NR	NR

	Van Weir *et al* 2011	Median number of counselling sessions	-	-	B) n = 453, 2 (incomplete cases), 10 (completers) C) n = 450, 1(incomplete cases), 5 (completers)	N/A	NR	NR
	Harvey-Berino *et al* 2011	Perceived social support	-	A) n = 161: 7.9 (3.0) B) n = 162: 6.4 (3.1) C) n = 158: 6.8 (3.0)	-	Yes: p<0.02 (Group A compared to group B). Not between group C and either group A or B.		

* unless otherwise stated N/A – Not applicable NR – Not recorded

* Data collected relates to the website usage data collected in relation to how participants adhered to the intervention – data has been split into different website features
* Last two columns examine whether the data collection results for the website features were correlated to either weight loss or attrition.

As is shown in Table 2-6 when examining the same intervention component variance occurred with regards to how it was monitored. For example eight studies investigated how participants logged into the intervention websites using median log-ins (number of weeks and number of log-ins), mean log-ins and percentage of users. Therefore this makes comparisons between studies difficult to conduct. However, the four studies which reported on significant difference between the arms all identified that the internet interventions with feedback logged into the website on a more frequent basis than those not receiving feedback (Tate *et al.*, 2001; Tate *et al.*, 2003; Tate *et al.*, 2006; Hersey *et al.*, 2012). Five studies found a correlation between greater number of log-ins and weight change, however two studies did not find this correlation (see Table 2-6). Tate *et al* (2003) identified that non-attenders at the 12 month follow up were found to have significantly fewer logins in the first 3 months than attenders.

Another monitored component of the websites was the self-monitoring data, for diet, exercise or weight, inputted by participants. Seven of the studies reported on this aspect of the website, see Table 2-6. Again variance was present in how the data was measured. Several studies identified a significant correlation between weight change and the number of days entered for diet and weekly weight inputs (Tate *et al.*, 2001; Tate *et al.*, 2006; Hunter *et al.*, 2008; Morgan *et al.*, 2011a; Morgan *et al.*, 2011b) However, no correlation was found for weight and exercise entries in two of the studies (Morgan *et al.*, 2011a; Morgan *et al.*, 2011b) suggesting a better predictor of weight change may be the level of self-monitoring for diet or weight rather than exercise. Morgan *et al.* (2011b) identified that participants, after three months, tended to monitor their weight but not their diet or exercise.

Social support as a component of the website, such as online chat rooms or bulletin boards, was only monitored within two of the included studies, see Table 2-6. Features were more frequently optional functions of the website to facilitate social support and therefore were not required as part of the intervention.

Participants in Kraschnewski *et al* ’s (2011) study rated the website as average (3.0 on a 1-5 likert scale). Participants in Chambliss ***et al’s*** (2011a) study were satisfied with the programme overall. The majority of Morgan ***et al’s*** (2011b) male participants stated that the website was helpful. Those who used the website more frequently scored significantly higher on items relating to the understanding of the website, enjoyment, quality and quantity of support received and preference of internet support over face to face (Morgan *et al.*, 2011b).

2.7.6 *Retention rates*

Table 2-7: Retention rates

Categorisation group	Intervention	Control	Difference between arms
Internet feedback	1298/2119 (61.3%)	1193/1934 (61.7%)	0.94 (0.89, 1.00)*
Human internet feedback	739/1035 (71.4%)	689/934 (73.8%)	0.94 (0.89, 1.00)
Automatic internet feedback	559/1084 (51.6%)	504/1000 (50.4%)	0.93 (0.83, 1.04)
Automatic internet feedback versus human internet	**Automatic** 44/61 (72%) **Human** 52/64 (81%)	59/67 (88%)	0.89 (0.73, 1.08)
Feedback mode of delivery	422/612 (69%)	414/614 (67.4%)	1.04 (0.99, 1.09)
	Intervention	**Intervention plus**	
Internet feedback with additional components	488/919 (53.1%)	490/925 (53.0%)	0.99 (0.96, 1.02)

Retention rates are based on the number of participants remaining at the end of the intervention from all included studies in comparison to the number of participants recruited to the study
* Significant difference in retention rates between the arms

Retention rates for individual studies ranged from 53% up to 88% illustrating the variance in attrition rates in internet weight loss studies. Retention rates in Table 2-7 are based on the overall totals from all included studies within each categorisation group, with numbers relating to participants who provided follow up data at the last time point. All studies included participant flow charts enabling retention rates to be examined, with four studies also reporting retention percentage rates (McConnon *et al.*, 2007; Appel *et al.*, 2011; Collins *et al.*, 2012; Hersey *et al.*, 2012). The internet feedback versus no feedback retention results identified borderline statistical significance ($p<0.05$). Statistical significance may be a function of large sample size. Retention rates were not significantly different ($p>0.05$) between the control arms and the intervention arms for any other study categorisation group, see Table 2-7 above. When comparing the automatic internet feedback arms

retention rates to the human internet feedback arms, retention rates were nearly 20% lower for the automatic internet feedback arms (51.6%) in comparison to the human internet feedback arms (71.4%).

2.7.7 *Quality assessments*

Table 2-8: Assessment of methodological quality/risk of bias

Study	Randomisation	Allocation concealment	Blinding	Incomplete outcome data	Selective outcome reporting
Appel	L	U	L	L	L
Chambliss	L	L	U	L	U
Collins	L	L	L	L	H
Harvey Berino	L	U	U	U	L
Hersey	L	U	L	L	L
Hunter	L	U	L	L	H
Kraschnewski	L	L	U	L	U
McConnon	L	L	L	L	L
Morgan a	L	L	U	L	L
Morgan b	L	L	L	L	L
Tate 2003	L	U	U	L	H
Tate 2006	L	U	U	U	U
Tate 2001	L	U	U	L	U
Van Weir	L	L	L	U	H

Table 2-8 above outlines how studies scored in relation to the methodological quality criterion. The reporting of blinding could be lacking and allocation concealment often unclear within several studies. Reporting was also often lacking for secondary outcomes that had previously been stated in study protocols (see selective outcome reporting column).

Other sources of bias

The studies in this review were relatively free of risk of other biases but some factors were present. The majority of studies had a high percentage of white, female participants, which can often arise in weight loss interventions, but could impact on the generalisability of the findings. Three studies provided monetary incentives for the completion of assessments, which may have biased the findings in terms of retention rates and thus outcome results (Tate *et al.*, 2001; Tate *et al.*, 2003; Tate *et al.*, 2006).

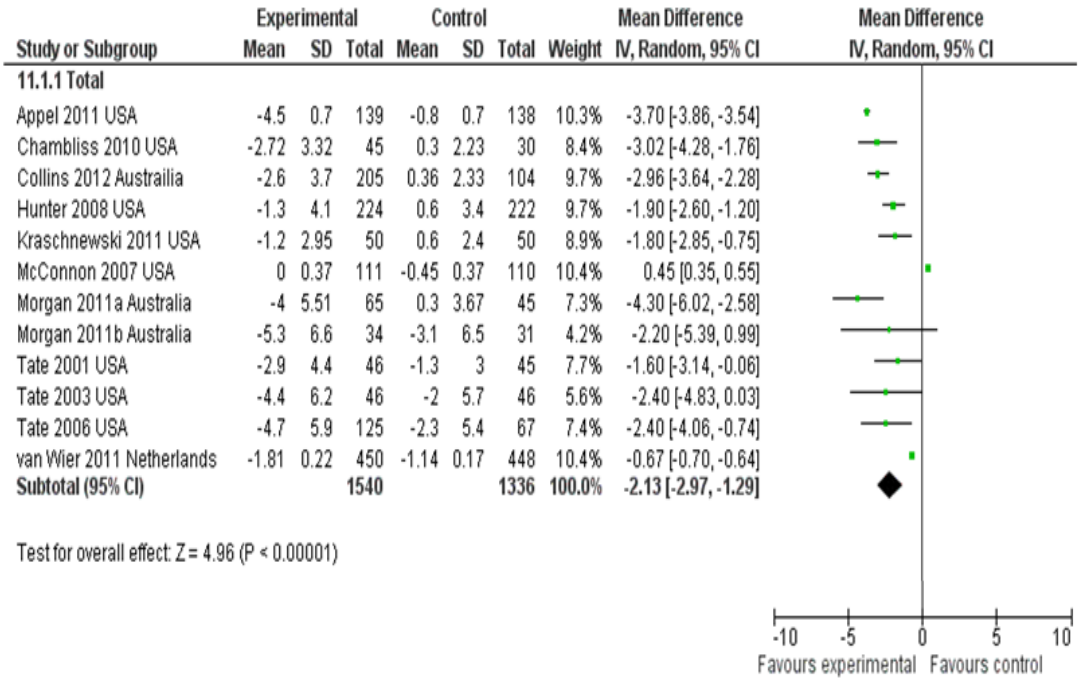
2.8 **Meta-analysis/synthesis of results**

This results section discusses the results identified for the first three study categorisation groups outlined in 2.7.2.

2.8.1 ***Internet feedback versus no feedback.***

12 studies were included in this meta-analysis. Outcomes of weight loss, 5% weight loss, BMI change and waist circumference change were analysed for the last follow-up within each study ("Total") as well as at three, six and twelve (or more) month data collection points. Results are presented for weight loss outcomes in Figure 2-2 below.

Figure 2-2: Internet feedback versus no feedback weight loss forest plot



As shown in Figure 2-2 above the arms receiving internet feedback lost significantly greater weight than those participants in the no feedback control arms. All outcomes were found to be statistically and clinically (≥ 5% body weight loss) significant at study end points, see appendix C for full meta-analysis results. This was also true for studies where data collection was conducted at three and six months. At 12 months, only BMI and waist circumference outcomes significantly greater losses for the internet feedback intervention arms compared to control arms. A higher proportion of

intervention participants reached ≥5% weight loss but this difference was not significant between the arms at 12 months (1.53 [0.82, 2.84]; p=0.18).

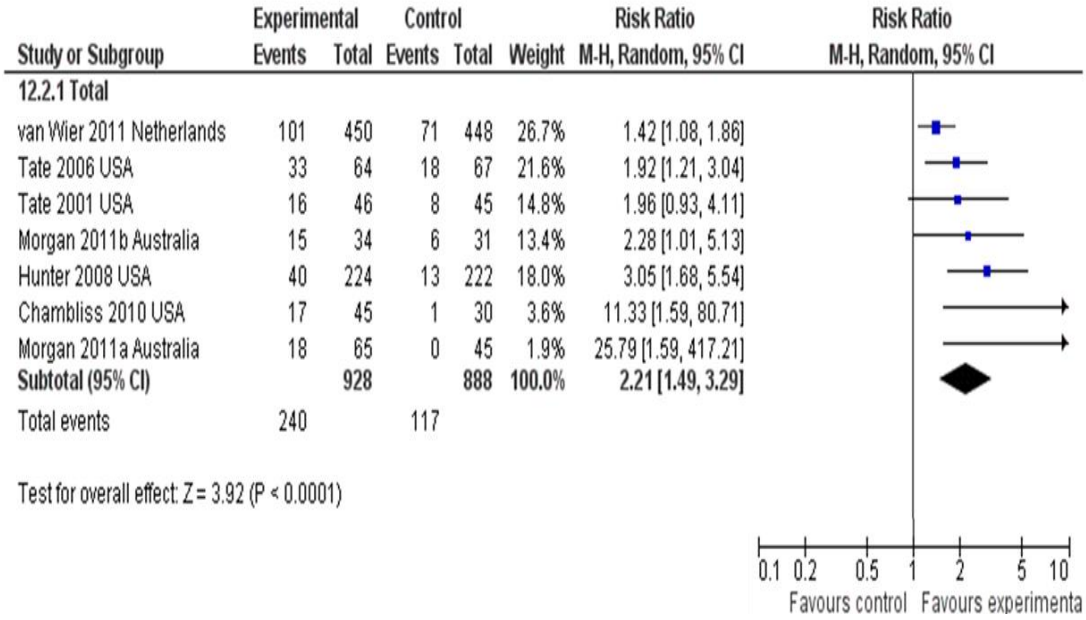
As outlined in the methods section 2.6.1 sensitivity analysis was conducted to repeat analysis with the exclusion of the three studies using SEM (Appel *et al* (2011), McConnon *et al* (2007) and van Weir *et al* (2009)). Tables of results are shown in appendix C. Removing the three SEM studies reduced heterogeneity, I^2 levels becoming non-significant. Weight loss and 5% weight loss at six months showed even greater significant difference between intervention and control arms (p<.00001). At 12 months the difference in weight loss between arms became significant (p<.05) favouring the intervention arms.

2.8.2 *Human internet feedback versus no feedback*

Eight studies (Tate *et al.*, 2001; Tate *et al.*, 2003; Tate *et al.*, 2006; Hunter *et al.*, 2008; Van Wier *et al.*, 2009; Chambliss *et al.*, 2011a; Morgan *et al.*, 2011a; Morgan *et al.*, 2011b) were included in this analysis.

Results for the outcome measure of mean weight loss are shown in Figure 2-3 below and illustrate that those arms with human feedback lost significantly more weight than those in the no feedback arms. Six interventions achieved statistically significant differences between the arms favouring the experimental arms for the main outcome measure, weight loss (Tate *et al.*, 2001; Tate *et al.*, 2003; Tate *et al.*, 2006; Hunter *et al.*, 2008; Chambliss *et al.*, 2011a; Morgan *et al.*, 2011a).

Figure 2-3: Human feedback versus no feedback weight loss forest plot



All outcomes, weight loss, change in waist circumference, 5% weight loss and BMI change, demonstrated statistically and clinically significant losses for the human feedback intervention arms in comparison to the control arms at endpoint (total), three, six and 12 months (except for 5% weight loss at 12 months), see appendix D for full human feedback meta-analysis results.

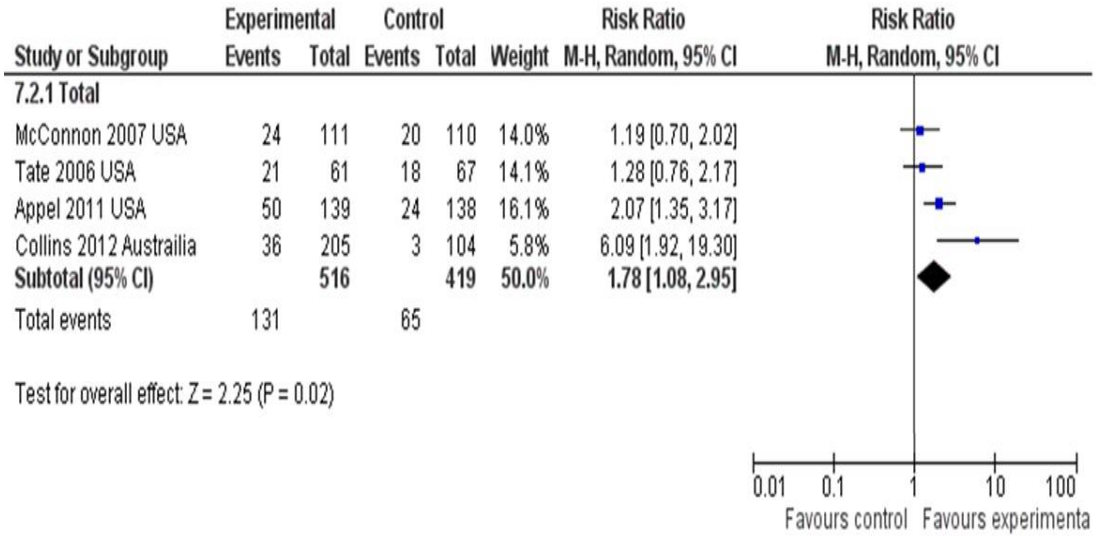
Sensitivity analysis to exclude SEM studies within the human feedback versus no feedback section required the exclusion of van Weir ***et al's*** study (2009). Tables of results are shown in appendix D. Therefore only weight loss and 5% weight loss outcomes were repeated. Excluding van Weir *et al* (2009) impacted on the six month analysis for weight loss and 5% weight loss by increasing the significance level (p<.00001). Removing the one SEM study within the human feedback section reduced heterogeneity, I^2 levels becoming non-significant.

2.8.3 ***Automatic internet feedback versus no feedback***

Six studies compared automatic feedback versus no feedback (Tate *et al.*, 2006; McConnon *et al.*, 2007; Appel *et al.*, 2011; Kraschnewski *et al.*, 2011; Collins *et al.*, 2012; Hersey *et al.*, 2012).

Full results for the outcome measures of mean weight loss, change in waist circumference, 5% weight loss and BMI change are shown in appendix E. Four studies (Tate *et al.*, 2006; Collins *et al.*, 2010; Appel *et al.*, 2011; Kraschnewski *et al.*, 2011) reported significant differences between the intervention and the control arms for the main outcome measure, weight loss, favouring internet feedback intervention arms.

Figure 2-4: Automatic feedback versus no feedback weight loss (kg) forest plot



As Figure 2-4 shows above those participants receiving automatic feedback had significantly greater weight loss to those receiving no feedback. Several outcomes and time points were not possible to include within the meta-analysis owing to low numbers of studies, see appendix E. Significantly greater weight loss was identified for the intervention arms in comparison to the control arms, at three months but not at six or twelve months. The endpoint (total) result for 5% weight loss was clinically and statistically significant, with those in the intervention arms being more likely to lose 5% weight loss than control arm members. However, the 12 month result showed no significant difference between the likelihood of the intervention and the control arm losing ≥5% initial body weight. BMI change had significant results for both endpoint (total) timeframe and three month data (Appel *et al.*, 2011; Collins *et al.*, 2012). Waist circumference measurements at the end of active interventions did not identify a significant result.

Sensitivity analysis to exclude SEM studies within the automatic feedback versus no feedback section required the exclusion of McConnon *et al* (2007) and Appel *et al* (2011). Tables of results are shown in appendix E. Weight loss could not be analysed for six or 12 month time points due to lack of relevant studies. The end point (total) weight loss result did alter from a non-significant result to p<.0001 by excluding the two studies. No meta-analysis could be performed for waist circumference or BMI change.

2.8.4 *Summary*

Meta-analysis shows arms incorporating internet feedback were more effective for weight loss than arms with no feedback provided to participants. The type of internet feedback was rather evenly mixed with eight studies looking at human feedback and six looking at automatic feedback versus controls. However, meta-analysis was not possible for many of the outcome measures (e.g. BMI, waist circumference) within the automatic feedback analysis owing to low numbers of studies. Both the automatic and the human feedback results were found to have greater weight loss than the control arms. There were significant differences for weight loss at all time points for the human feedback studies but this was only true of the automatic feedback studies at three months.

2.9 **Comparisons between different modes of feedback**

Some groups had enough studies in order to perform meta-analysis where as some did not and therefore are narratively described.

2.9.1 *Automatic feedback versus human feedback*

The only study to compare the alternative modes of providing feedback via the internet was Tate *et al* (2006). The six month study examined three website arms, with no feedback arm, human internet feedback or automatic internet feedback.

Tate *et al* (2006) found that participants in the human arm logged on to the website more frequently and submitted a greater number of self-monitoring

diaries than those allocated to the automatic arm, with diary submission significantly associated with weight loss, see Table 2-6.

Both the automatic and the human intervention arms lost significantly more weight than the control arm with no differences between the two interventions arm at three months. By six months the human intervention arm differed from the control arm but the automatic arm did not differ from the control or human arms, see Table 2-5. These findings suggest that human feedback may be effective over a longer time period than automatic.

2.9.2 *Feedback mode of delivery and impact on outcome*

Only two studies included two different feedback modalities as intervention arms. One of the studies, Van Weir *et al* (2009), provided feedback in the form of individual telephone calls, whilst the other study by Harvey-Berino *et al* (2010) provided in-person treatment (face to face occasions), see Table 2-3 for detailed intervention description. For both studies the other modality intervention arm was the internet feedback arm. As the non-internet intervention arms were different, e.g. telephone and in person, it was deemed inappropriate to compare them through meta-analysis.

Results showed weight loss and percentage of initial body weight lost were significantly greater for the in-person arm than for the internet arm in Harvey-Berino *et al's* study (2010), see Table 2-5.

In Van Weir *et al*'s study (2009) those allocated to the phone arm and internet arm experienced significant weight loss at six months and the two year follow up, see Table 2-5. However, there was no significant difference between the intervention arms, neither the phone nor the internet arm were more effective at achieving weight loss, after two years, than the arm using self-directed materials (control).

Findings from van Weir *et al* (2009) showed the phone arm completed a greater number of counselling sessions compared to the internet arm, see Table 2-6. Harvey-Berino *et al* (2010) found no significant difference in session attendance or the number of self-monitoring journals submitted

across the arms, see Table 2-6. However, the in person participants perceived members to be more supportive than those in the internet arm, see Table 2-6.

The results illustrate that the other modalities did not tend to be significantly different to the internet arms. However, with only two studies to compare, using different comparison modalities, it is difficult to draw any conclusions but highlights the need for more research in this specific area.

2.9.3 *Internet feedback versus internet feedback plus additional components*

Four studies were identified as incorporating additional components within arms that were providing internet feedback (Harvey-Berino *et al.*, 2010; Appel *et al.*, 2011; Chambliss *et al.*, 2011a; Hersey *et al.*, 2012).

The additional components incorporated alongside internet interventions consisted of behaviour management seminars (Chambliss *et al.*, 2011a), in person group sessions (hybrid) (Harvey-Berino *et al.*, 2010; Appel *et al.*, 2011) and telephone and email coaching support (Hersey *et al.*, 2012).

However, although these arms contained additional components the results identified no significant difference in weight loss between the enhanced arms and the internet feedback only arms (Harvey-Berino *et al.*, 2010; Appel *et al.*, 2011; Chambliss *et al.*, 2011a; Hersey *et al.*, 2012) see Table 2-5.

Usage data showed mixed results in terms of comparisons between the internet feedback only arms and the additional component arms, see Table 2-6. Appel *et al.* (2011) identified similar website usage for both the internet only arm and the additional component arms. However, Hersey *et al.* (2012) found greater use of the website and completion rates for online module assessments within the additional components arm, which was in contrast to Chambliss *et al* (2011a) who reported a higher percentage of the basic arm logged into the website five days a week compared to the enhanced arm. Participants in all arms rated their alliance with their counsellor similarly but

hybrid participants rated their in-person counsellor significantly poorer than their online counsellor (Harvey-Berino *et al.*, 2010), see Table 2-6.

Therefore it appeared that the additional components did not increase weight loss or perceived social support and was inconsistent in increasing website usage, suggesting that additional components may not improve outcome results.

2.10 Behaviour change techniques

An older taxonomy version, containing 40 BCTs, has been applied to code the included studies within this review as this is specifically related to physical activity and healthy eating behaviours (Michie *et al.*, 2011).

Table 2-9: Number of included Behaviour change techniques

	Number of behaviour change techniques			
Arms	Median	LQ-UQ	Range	Min-Max
Control	2	0-3.5	14	0-14
Internet feedback	9	6.5-12.5	15	4-19
Internet feedback plus	13	11.3-14	3	11-14

More BCTs were present within the internet feedback intervention arms in comparison to the control arms within the included studies, see Table 2-9. Examining the intervention arms that also contained additional components, such as in person contact or telephone calls mentioned in 2.9.3, the median number of BCTs was greater than the internet feedback only. However, this can be attributed to the lower range identified within these arms in comparison to the internet feedback only.

Table 2-10: Behaviour change techniques present within included studies

BCTS	Control	Internet feedback	Internet feedback plus
	14 study arms	14 study arms	4 study arms
1. Provide information on consequences in general	10	14	4
16. Prompt self-monitoring of behaviour	4	14	4
19. Provide feedback on performance	1	14	3
29. Plan social support/social change	5	12	3
17. Prompt self-monitoring of behavioural outcome	3	9	2
5. Goal setting (behaviour)	2	9	3
6. Goal setting (outcome)	3	8	3
21. Provide instruction on how to perform the behaviour	3	7	1
8. Barrier identification/problem solving	2	6	4
10. Prompt review of behavioural goals	1	5	3
35. Relapse prevention/coping planning	2	4	3
4. Provide normative information about others' behaviour	1	3	1
36. Stress management/emotional control training	1	3	1
11. Prompt review of outcome goals	0	3	0
27. Use of follow up prompts	0	3	0
12. Prompt rewards contingent on effort or progress towards goals	1	2	1
13. Provide rewards contingent on successful behaviour	1	2	1
38. Time management	1	2	2
2. Provide information on consequences for individual	0	2	0
37. Motivational interviewing	0	2	1
9. Set graded tasks	1	1	1
7. Action planning	0	1	0
15. Prompting generalisation of target behaviour	0	1	0
28. Facilitate social comparison	0	1	0
39. General communication skills training	0	1	0
3. Provide information about others' approval	0	0	0
14. Shaping	0	0	0
18. Prompting focus on past success	0	0	0
20. Provide information on when and where to perform the behaviour	0	0	0
22. Model/demonstrate the behaviour	0	0	0
23. Teach to use prompts/cues	0	0	0
24. Environmental restructuring	0	0	1
25. Agree behavioural contract	0	0	0

BCTS	Control	Internet feedback	Internet feedback plus
26. Prompt practice	0	0	0
30. Prompt identification as role model/position advocate	0	0	0
31. Prompt anticipated regret	0	0	0
32. Fear arousal	0	0	0
33. Prompt self-talk	0	0	0
34. Prompt use of imagery	0	0	0
40. Stimulate anticipation of future rewards	0	0	0
*BCTs were deemed as present within an intervention if they corresponded to the definition provided within the taxonomy of BCT created by Michie et al (2011)			

All included BCTs across the different arms can be seen in Table 2-10. Comparing the different study arms identified the same BCTs most commonly used across the three study arm categories, see Table 2-10. The internet feedback arms incorporated the most BCTs (25) within the included interventions, with the control arms including the least (17). 14/40 BCTs were not included in any of the study arms. The most prevalent within all arms was 'providing information on consequences in general'. This was the only BCT that was present in the majority of the control arms. Common techniques within both the internet feedback arms and the internet plus arms were 'provide feedback on performance', 'planning social support/social change', 'prompting self-monitoring of behaviour/behavioural outcome' and 'goal setting (behaviour and outcome)'. These most commonly used BCTs tended to be clustered within the studies, with all study interventions using all the above techniques with the exception of two which did not include social support and two which did not include including goal setting. As mentioned in Table 2-9 the amount of BCTs included in interventions differed greatly, this was also the case when examining the number incorporated in relation to weight loss results. The most effective studies (Tate *et al.*, 2006; Harvey-Berino *et al.*, 2010; Appel *et al.*, 2011; Morgan *et al.*, 2011b) in terms of weight loss (kg) still differed greatly, ranging from seven to 14 BCTs, and did not appear to be consistent in relation to included BCTs. As mentioned all included the above commonly clustered BCTs but differed in the inclusion of 'motivational interviewing', 'normative information about others' or the 'use of

rewards'. The majority of these most effective studies also included 'barrier identification' and 'prompt review of behavioural goals' but these BCTs also appeared in less successful interventions. When examining the least effective interventions (McConnon *et al.*, 2007; Hunter *et al.*, 2008; Van Wier *et al.*, 2009; Kraschnewski *et al.*, 2011) in terms of weight loss (kg) achieved, these also had large differences with one intervention containing four BCTs and another containing 12, suggesting that number of included BCTs was not positively correlated with greater weight loss. Nonetheless and not surprisingly the least effective control groups were the wait list arms that did not include any BCTs. The variance in terms of the included BCTs and weight loss achieved made it difficult to identify why particular studies may have been more effective. In terms of the BCTs that differed between the intervention arms there was not a constant BCT that was used in the internet feedback plus additional components arms and not in the internet feedback arms or vice versa. This could explain why the additional component arms did not appear to improve weight loss in comparison to internet feedback only.

2.11 **Discussion**

2.11.1 ***Summary of key findings***

Findings from this review suggest that incorporating individualised feedback may be an important behaviour change technique for effective interventions delivered via the internet. Internet feedback arms appeared to be more effective for weight loss than arms where participants received no feedback. Participants receiving internet feedback were identified as twice more likely to achieve 5% weight loss than those in the no feedback arms. The outcome ≥5% was still more likely for the internet interventions than the control arms but was lower for automatic internet feedback (1.78) than for human internet feedback (2.21) and the overall internet feedback group (2.13).

The different feedback provided via the internet was rather equally mixed with eight studies providing human feedback and six studies incorporating automatic feedback versus controls. Both appeared as more effective for

weight loss than controls. Human internet feedback achieved better participant retention rates than the automatic internet feedback studies. Adding additional components did not appear to increase weight loss and therefore a solely internet based intervention may be as effective. Examining engagement in terms of using the website it emerged that both the number of log-ins and the number of entered self-monitoring data were significantly correlated with weight change. Interventions appeared to contain more BCTs than the control arms. The results from the BCT coding of study arms illustrates the variance in intervention designs, not only between control and intervention arms but also within the intervention arms included in these internet weight loss studies. Clusters of BCTs, notably goal setting, self-monitoring, feedback, information and social support, tended to be incorporated but great variance was present in the other additional BCTs included within intervention arms, meaning it was not possible to identify whether certain BCTs resulted in greater weight loss. Even within the most effective studies (in terms of weight loss) BCTs were incorporated differently, with goal setting and self-monitoring varying between behavioural and outcome related. The type of BCTs incorporated did not appear to be the only influential factor within the interventions as great differences were present within the studies with the greatest weight loss. Studies also differed in how the BCTs were delivered, either automatically and human provided, and the intensities of the intervention, which identifies the need for better intervention description and also greater reporting on intervention fidelity as this could be influential to the effectiveness for weight loss.

Only 2/14 achieved low risk of bias for all criterions. Improvement is needed in the reporting of allocation concealment and blinding so it is clear whether these were conducted. Selective reporting was the only criterion to receive high risk of bias scores. Therefore studies need to ensure that all outcomes mentioned within method sections or previous protocols are then present within the final results.

2.11.2 *Comparison to previous literature*

As in previous reviews internet based weight loss interventions appeared to be more effective than comparison arms (Neville *et al.*, 2009a; Arem and Irwin, 2011a). However, in terms of significant differences between arms or clinical effectiveness of internet interventions, results were mixed (Norman *et al.*, 2007; Enwald and Huotari, 2010; Neve *et al.*, 2010; Reed *et al.*, 2012). Heterogeneity between included studies was evident and is a finding discovered in earlier reviews (Norris *et al.*, 2005; Shaw *et al.*, 2005; Manzoni *et al.*, 2011). Retention rates are frequently of interest within weight loss interventions with studies often having high attrition rates, with previous reviews ranging from 20-43% for participant dropouts (Melville *et al.*, 2010; Neve *et al.*, 2010; Arem and Irwin, 2011a; Coons *et al.*, 2012a). Attrition rates discovered in this review were similar to previous research ranging from 12-47%.

Enhanced interventions incorporating additional components, such as in person meetings or telephone coaching, were not found to add to the effectiveness of the internet weight loss interventions, supporting recent findings by Dickinson *et al.* (2013). In contrast another study identified participants who received telephone coaching were more likely to use the website. However, weight loss was greater but not significantly difference to the basic arm, with a large number of participants refusing the extra phone calls (Dennison *et al.*, 2014).

Engagement and adherence to interventions could play an important part to reveal how a participant experiences an intervention (Kroeze *et al.*, 2006; Neve *et al.*, 2010; Arem and Irwin, 2011a; Donkin *et al.*, 2011). Engagement with the website is of importance as it could help to identify which website features participants may have greater preference for and whether aspects are related to weight loss. The intensity of an intervention can also have an influence on the outcome (Davidson *et al.*, 2003), however it is unknown what constitutes the optimum intensity due to many other factors being involved in complex interventions. This area would benefit from future

research (Neville *et al.*, 2009a; Neve *et al.*, 2010), with many studies failing to report on adherence to the intervention (Coons *et al.*, 2012a).

The review identified a number of studies not reporting on several quality assessment criterions, with only two studies perceived as having low risk of bias for all criterions. Previous reviews also found mixed standards for reporting of criterion (Norman *et al.*, 2007). Improvement has been emphasised for selective reporting and the reporting of allocation concealment (Thabane *et al.*, 2007) as found within this review but with the addition of blinding.

2.11.3 *Strengths and limitations of review*

Type of review

Alternative approaches to reviewing the evidence could have been undertaken such as a critical review, narrative literature review, overview, meta-synthesis, scoping review, mapping or realist review. All of these review types will be outlined and discussed. However, it is worth highlighting that a systematic review was chosen owing to the implementation of systematic methods, which minimise researcher bias in the evidence gathering and evaluation process (Higgins and Green, 2011b).

A critical review involves extensively researching the literature and critically evaluating its quality. Literature reviews, also commonly referred to as narrative reviews, or overviews can be used to identify and survey the existing or current literature to gain a broad perspective within a certain research area (National Center for Biotechnology Information, 2005). However, these types of reviews tend to lack the systematicity of structured approaches used in systematic reviews as protocols, criteria and search strategies do not tend to be produced or followed (Cook *et al.*, 1997). Therefore researcher bias could influence the search techniques implemented, data extracted and subsequent emerging hypotheses (Oxman *et al.*, 1994; National Center for Biotechnology Information, 2005; Grant and Booth, 2009). Meta –synthesis is the bringing together of qualitative data to allow new interpretation of a research field (Schreiber *et al.*, 1997). However,

this form of evidence synthesis was not appropriate to use as the research question of interest was in relation to how effective interventions, providing feedback via the internet, were and thus required quantitative outcome measures to be analysed. Alternatively scoping reviews and mapping reviews share several characteristics of the systematic review; however these are usually performed to inform whether a full systematic review is needed owing to limitations in their rigour (Grant and Booth, 2009). These reviews do not tend to include formal quality assessment. Formal quality assessment of the studies is included within a systematic review and meta-analysis enables the findings of several studies to be summarised quantitatively (Subject Centre for Information and Computer Sciences, 2007). Finally another alternative method of literature searching would be a realist review. These reviews evaluate and understand the mechanisms of how complex programmes work (or why they fail) in certain contexts or settings (Pawson *et al.*, 2005; Gough, 2013). However, realist reviews cannot use formulaic approaches and are non-standardizable and non-reproducible, unlike systematic reviews. Key features of a realist review rely on reviewer's judgement, with quality assurance often dependent on the reflexivity of the reviewer (Pawson *et al.*, 2005).

As my research question aimed to examine the effectiveness of internet based weight loss interventions it was important to use a protocol and criterion-driven, search strategy to identify relevant papers and to use standardized data analysis to ensure reproducible results that were not impacted by researcher bias. However, the systematic review identified how complex internet based weight loss interventions are which suggests future research adopting a realist review may be useful to examine how different mechanisms could have potentially impacted on the intervention outcomes. This may also be useful in terms of investigating the different contexts used for weight loss interventions. This systematic review identified limited research examining the comparison of different modes of delivery, i.e. face-to-face versus internet or telephone, therefore this would be dependent on the available evidence.

Lack of evidence

Limited evidence for several of the categorisation groups examined within this review made it difficult to draw any definite conclusions

Feedback mode of delivery categorisation group also had the complication of the two studies included examining two different types of modalities for feedback (in person and via the telephone).

Time points in each study were investigated and how this impacted on the outcome measures. This was difficult for some time points and outcomes owing to the lack of studies that could be included. Time point collections varied throughout the studies, with fewer studies reporting on longer-term outcomes.

Heterogeneity

The studies included in the review varied considerably in terms of study length, comparison groups and intervention components. Heterogeneity in studies is common within internet based weight loss interventions (Neville *et al.*, 2009a; Neve *et al.*, 2010; Webb *et al.*, 2010a; Arem and Irwin, 2011a). However, the key aspect was investigating whether individualised feedback was effective in comparison to arms that received no feedback at all; which was consistent throughout all the studies included in the meta-analysis.

It was apparent that interventions varied in relation to included features and that this may impact on end findings. An example of this is how a participant retrieved feedback. Logging on to receive feedback may lead to the participant remaining on the website and using other features whilst they were logged on. However, for some people, emails are regularly checked for work or leisure purposes and therefore email feedback may mean the participant is more likely to access the feedback and on a more regular basis. The use of either method may have had an effect on the results or the engagement data produced by the study. To try and overcome these differences studies were categorised according to the main types of feedback. This then enabled studies with the same main features to be

compared. However, a limitation is the inability to control for all feature differences which were present between studies owing to the wide range of features and delivery opinions available.

BCT coding

Internet-based weight loss interventions tend to be multi-component interventions and are therefore very difficult to investigate. Owing to small sample sizes within the included studies analysing the relationship between effectiveness and BCTs could not be conducted in this review. This area would be useful to examine in future research and could possibly be performed if the inclusion criteria were broadened by removing the necessity of providing individualised feedback to give a wider scope of internet based weight loss interventions and subsequently a greater number of studies and sample size.

Intervention description

An aspect that added to the difficulty of analysis related to studies having arms categorised as enhanced arms. Chambliss ***et al's*** study (2011a) included an enhanced behavioural arm that also received seminar sessions on behaviour management strategies, step counters and newsletters and Hersey ***et al's*** (2012) enhanced group also received telephone coaching support. This was solved by excluding the enhanced groups from the internet feedback versus no feedback analysis but including them in the internet feedback versus internet feedback with additional components analysis.

However, in Collin ***et al's*** study (2012) the 'enhanced' arm did not provide any additional components in comparison to other studies therefore all three study arms were used in the internet feedback versus no feedback meta-analysis. To solve the problem of having three relevant arms within a study Cochrane guidelines for combining two intervention groups were used. This technique was also used for the two experimental intervention groups from Tate *et al* (2006) study, where the human internet based feedback arm and

automated internet based feedback arm were combined to provide one single intervention arm.

To be included in this review intervention arms had to receive individualised feedback via the internet. Different names were often used for this type of weight loss intervention, including basic feedback (Chambliss *et al.*, 2011a), interactive web (Hersey *et al.*, 2012), internet therapy (Tate *et al.*, 2001; Hunter *et al.*, 2008), internet/web support (Tate *et al.*, 2006; McConnon *et al.*, 2007; Kraschnewski *et al.*, 2011; Morgan *et al.*, 2011a; Morgan *et al.*, 2011b; Collins *et al.*, 2012), remote support (Appel *et al.*, 2011) or behavioural e-counselling (Tate *et al.*, 2003). This was also a problem within the control arms from the studies, for example the use of the term usual care varied from Hunter ***et al's*** study (2008), which consisted of a once a year health check, access to a fitness centre and weight loss classes in comparison to McConnon ***et al's*** (2007) study where usual care equated to continuing the participant's usual approach to weight loss and receiving printed information, similar to what they would receive in primary care. The lack of a set definition/description may be one of the problems within this area of research as it could easily lead to confusion. This is one of the reasons why broad definitions for both the comparison groups and the intervention groups were used in this review protocol/search strategy.

This relates to the issue of intervention description and how it can vary greatly, making classification of intervention components very complicated. To make it as fair as possible any intervention manuals, reports or previous protocols were requested from all authors. Receiving manuals tended to result in more BCTs being coded as more intervention detail was accessible. This is not ideal as only a small number existed or were received from authors. Instead recommending that study manuals, or any additional intervention description, be made publicly available may try to target this issue. However, this may present problems in relation to IP or commercial sensitivity issues. Following frameworks, such as TIDieR (Hoffmann *et al.*, 2014), may help to maintain a minimum standard when reporting interventions descriptions.

2.11.4 *Implications for policy, practice and further research*

Further research into internet-based feedback in comparison to other modalities would be useful to assess how healthcare professionals' roles could be adapted and to identify the most effective ways of providing feedback. This was highlighted by only two studies examining internet health care provision in comparison to other modes, such as in person or telephone calls. Further research would allow greater comparison between the modes of delivery and weight loss. This review highlighted that the control arms tends to be wait list, usual care, or a website but with no interaction with a health professional/advice. Usual care allows real world practices to be examined in relation to internet interventions but these were often what could be classified as minimal interventions. Investigating alternative modes of delivery would enable the delivery type to be examined in addition to the intervention itself. More investigation may require search criteria to be expanded or adapted from the criteria used in this study.

Research was also found to be limited in the investigation of human feedback versus automatic feedback and how the different types of feedback compare against each other. One study within this review explored these feedback variations but further research could be used to reveal the advantages and disadvantages both options provide.

A low number of studies were found to have conducted long term research and exposed the need for longer interventions to be investigated (NICE guidelines 2006, Weinstein 2006, Neve 2010). Van Wier *et al.* (2009) illustrated why longer follow ups can be important as significant differences in weight loss between arms at six months were no longer significant by 24 months. Identifying low number of studies proved useful in showing where research was lacking and where research may be important to focus on in the future.

This review enabled the use of individualised feedback to be investigated in depth and identified significantly greater weight loss in the arms receiving feedback compared to when feedback was not provided to participants. Focusing on feedback enabled the variety of provision, in terms of who

creates the feedback and how participants receive it, to be explored. Feedback appears to be an important component to internet weight loss interventions. However, through BCT coding it was apparent that feedback is not the sole component that was commonly incorporated within the internet weight loss interventions. It appeared that instead interventions tended to use similar clusters of BCTs, which would probably have impacted on the effectiveness of the interventions. Therefore it is not possible to determine whether feedback is a more important BCT than other BCTs that were present within the interventions. Further investigation into the BCTs used in each intervention and the relationship to effectiveness would be an important path to explore. Study sample sizes were too small to be able to draw conclusive results with regards to effectiveness and BCTs included, therefore this analysis was not conducted. In the future extending the search to all internet weight loss studies could aim to increase the studies meeting inclusion criteria and hopefully enable investigation to identify which included BCTs, or clusters of, are related to improved outcomes.

This review has illustrated how complex internet weight loss interventions are in terms of their variability and the numerous components incorporated, illustrating why it is important to have a consistent way of describing interventions to compare intervention content and active ingredients. This would advance the literature in terms of identifying the key BCTs that appear to improve weight loss effectiveness, an aspect currently still unknown within internet weight loss interventions.

This information has implications for healthcare practice as it illustrates how internet-based weight loss interventions may be an alternative technique to provide weight management to patients within the NHS. However, although research in relation to internet weight loss interventions is increasing, studies comparing internet based interventions to alternative methods of delivery are still lacking. Further research is needed to compare against current practice in order to establish whether internet based interventions provide additional benefit than in person services. Identifying effective BCTs could be used to

develop the most effective intervention possible to then enable fair comparison between the different modes of delivery.

Chapter 3 **Rehearsal Pilot Randomised Controlled Trial**

‘Randomised controlled trials (RCTs), when appropriately designed, conducted and reported represent the gold standard in evaluating healthcare interventions’ CONSORT statement update guidelines for reporting parallel group RCTs (Schulz *et al.*, 2010). RCTs enable participants to be randomly allocated to intervention groups, aiming to reduce bias and imbalance between groups (Stolberg *et al.*, 2004). RCTs allow analysis to be performed irrespective of whether the participant received the allocated intervention (intention to treat analysis). RCTs are the most rigorous way of examining whether a treatment and an outcome have a relationship (Sibbald and Roland, 1998).

Therefore it is important to conduct definitive RCTs when comparing two interventions in health research. However, RCTs are not possible in every situation and may not be appropriate or feasible to implement. In areas of significant uncertainty, feasibility and pilot work is desirable before proceeding to a full trial.

‘Pilot studies are a smaller version of the main study used to test whether the components of the main study can all work together. It is focused on the processes of the main study, for example to ensure that recruitment, randomisation, treatment, and follow-up assessments all run smoothly’ (National Institute for Health Research, 2014).

‘Feasibility studies are pieces of research done before a main study in order to answer the question “Can this study be done?”. They are used to estimate important parameters, for example willingness to be recruited, randomised or complete outcome measures, that are needed to design the main study’ (National Institute for Health Research, 2014).

These terms are sometimes used interchangeably and there is not always consensus on the use of the terms.

Pilot studies allow the estimation of important parameters, such as recruitment and retention, the determination of sample size and the testing of

procedures (Lancaster *et al.*, 2004; Craig *et al.*, 2008) as well as the identification of the resources and staffing needed to conduct an intervention (Thabane *et al.*, 2010). Feasibility studies are useful to determine the acceptability of the intervention to the intended patients and those delivering the intervention (Lancaster *et al.*, 2004; Thabane *et al.*, 2010). This enables additional development if necessary before long term implementation (main trial) and evaluation are conducted (Craig *et al.*, 2008).

The analysis of any type of pilot study should be mainly descriptive. It is not appropriate to place significance on results when a power calculation has not been conducted (Lancaster *et al.*, 2004). If pilot or feasibility trials are not conducted prior to a full trial it is at significant risk of not being able to recruit to time and target and/or deliver the intervention and trial processes as intended. Conducting a feasibility/pilot study before a main trial can increase the likelihood of a successful main study (Thabane *et al.*, 2010).

This chapter assesses the outcome measures implemented within the study, whereas actual use (engagement and adherence) to the intervention (website) is discussed in Chapter 4.

3.1 **Aims & Objectives**

- To undertake a pilot randomised controlled trial (RCT) of the internet based weight loss intervention versus usual care in two study populations, in order to assess likely rates of participant eligibility, consent, receipt of intervention and retention for collection of outcome data.

- To examine the comprehensiveness, acceptability and feasibility of the data collection tools and questionnaires proposed for a future definitive trial.

- To estimate the key parameters needed to inform the design and sample size calculations for a future definitive trial.

3.2 Features of the internet based weight loss intervention

Table 3-1 below outlines the features included on the website along with the research team's judgement with regards to the associated behaviour change techniques therefore incorporated into the website.

Table 3-1: Website feature descriptions and associated behaviour change techniques

Features of the website	Aspects of the feature	Behaviour change technique (Michie *et al.*, 2011)*
Daily food intake input	Food consumed during the day is inputted here. Type and amount of food and time consumed are entered. This information is then converted into calories consumed and represented in a pie chart showing percentages for food types consumed (fats, carbohydrates, proteins, fibre).	Self-monitoring of behaviour
Physical activity input	Type, time and intensity of any completed physical activity is inputted. This is translated into calories burnt.	Self-monitoring of behaviour
Body measurements	Participants enter waist, weight recordings and amount of steps taken. These are then presented in a graph to display the participant's progress.	Self-monitoring of behavioural outcomes
Diet Budget	For each day participants have an outline of the calories they have consumed, calories burnt and the allowance they have remaining.	Self-monitoring of behaviour
My community	Users can interact through forums, diaries and chat rooms. 'My community' acts as their 'support system'. Attention is drawn to other users' experiences and behaviour. Recipes and relevant articles are provided for the users.	Plan social support/social change Facilitate social comparison Provide instruction on how to perform the behaviour

Features of the website	Aspects of the feature	Behaviour change technique (Michie *et al.*, 2011)*
Consultant feedback	The user receives a notification that feedback is available for them to read. Consultations allow the user to be provided with information in relation to weight loss and the benefits and how it will affect them personally. Feedback is provided weekly (for the first three months) by the dietitian for each user through web based messages. After three months frequency of consultations is based on what the dietitian deems necessary. Participants will also receive monthly web based consultations from an exercise expert during the study. Example daily or weekly food diaries from the consultant can provide users with instruction on how to perform the behaviour.	Provide information on consequences of behaviour in general Provide information on consequences of behaviour to the individual Provide feedback on performance Monitoring of behaviour Monitoring of behavioural outcomes Provide instruction on how to perform the behaviour.
*The BCTs identified as included within the website are categorised through the research teams judgement, rather than the developers of Slimming Doctor explicitly including these features to incorporate these BCTs.		

The internet intervention (website) contains various features that the participants can use for reference, to input data or to interact with their dietitian, exercise expert or other participant users.

3.2.1 *Development of the website*

For the current study the website from the Danish study (Brandt, 2011) has been adapted by the research team, changes are outlined in Table 3-2.

Table 3-2: Refinement of the intervention

Feature	Original Slimming Doctor website	PhD Project website
Logo User	The Nordiska DNA Diet.	NHS Branding.
Logo Consultants	Praxis Medicare	NHS Branding.
Contact details	My Genomics address at bottom of the page.	NHS address.
Feedback button	This button allows users to provide the website team with feedback on the functioning of any of the website features i.e. register a technical problem. This button was on the left hand side on the website.	No change.
Instruction	Instructions on how to use the web. Contains all instructions together of how to use each page.	Instructions included in each section and made relevant to the particular page.
Personal status bar	Next consultation Date, Daily calorie Intake, Weight chart, Weight Input, Menu Plan. Remains at the top of the screen throughout however participants can choose to hide it.	No change.
Home	Notifications of consultant feedback. My personal information: My profile questions, DNA Information. Lists showing recent (last 5): Consultations, Forum posts, Diary entries, Exercise, Food, and Calorie totals (colour coded, green and red).	Kept notification here. No DNA information needed. The previous website conducted DNA testing to provide participants with specific diet plans. This study did not wish to follow this method and therefore all DNA information was removed from the website.
My Graphs	Entry boxes for: Weight, hip, waist measurements and steps. Graphs to represent data.	No change.

Feature	Original Slimming Doctor website	PhD Project website
My Food	Entry boxes for: Breakfast, mid am snack, lunch, mid pm snack, evening meal and evening snack. Also blank entry box at bottom of page to enter food and choose a drop down option for what meal/snack it should go into. When food is entered suggestions for varieties of the food or drink appear. Measurements have to be added for each item. Entered food is represented in a pie chart at side of page (percentages for food types: carbohydrates, fat, protein, fibre or alcohol). Favourite food can be added and appear at side of page.	Entry boxes kept the same except food database option moved to top of the page and free text boxes appear after. The food database was moved to the top of the page to make participants more aware that a pre-programmed list of food entries was available to use, this was also a suggestion made by the dietitians. Favourite food changed to English spelling.
My Exercise	Add exercise box (2 places to enter this, 1 has suggestions). Can either write up exact time and speed of exercise or just simply add in free text box. Can also make notes to consultants in free text box. Favourites/previous inputs can be seen on the side of the page.	No change. Spelling of favourites to be changed to English version.
My Diary	Browse entries, My entries or write new entry. New entry: Title, tags, category, status, space to write, privacy (me and consultant only is now set as default).	Drop down option of to whom the diary entry goes has default set to consultant only. Option to make this public if the participant wishes. This change was made so that participants were given privacy in terms of the information they were entering but had the option to share with others if they wished.
e-Consultations	List of previous e-consultation feedbacks.	No change.
Community	What's new, My profile, Messages, Groups, Albums, Diaries, Members, Forum, Chat, Privacy Settings/ Notification settings.	No change.

Feature	Original Slimming Doctor website	PhD Project website
Recipes	Search box (by title or ingredient). Recipes (drop down option to look at certain meals).	Change4Life recipes [1] were integrated into the website. Original recipes were not culturally appropriate for UK participants and therefore Change4Life recipes were deemed more relevant and useful for participants.
Articles	Website specific. Tips: Food, diet, lifestyle.	Articles were used from NHS choices website[2]. More articles were added that the health professionals believed to be useful to aid the participant's weight loss. Some specific articles were only available to the health professionals who were able to send them to participants they thought would find them relevant.
My Data	Notifications for consultation feedback. DNA Profile. Invoices. Membership Personal Information – Date of birth, gender, address, height, weight. Profile Questions – Weight history, work, motivation, household, food habits, and physical activity.	Deleted DNA Profile, invoices or membership.
Consulting	Review Menu plan, Exercise, Diet, No of days from delivery plan, No of consultations still needed. Work list. Pencil sign next to name links to feedback page.	Way of providing consultations kept the same. Dietitians added menu plans for different calories i.e. 1500 calories that can be adapted easily for food preferences. Menu plans were added that the dietitians used in usual practice. These materials would save the dietitians time when providing participant consultations.
Clients	Assigned consultant type, Recently associated users. Recent consultations, Delivered consultations.	Recently associated users – not necessary. Participant sent reminder to their email that a consultation has been sent to them.

Feature	Original Slimming Doctor website	PhD Project website
Consultation/ Feedback	Top of page – personal information Left hand side – previous dietary, exercise and diary input. Middle – writing space, profile (DNA, Calorie allowance) and profile questions. Right hand side – Measurements and previous consultations.	No change except DNA information option deleted. Health professionals created templates to use for consultations throughout project. Common advice or topics could be made into templates that the health professionals could save, adapt and re-send, thus saving time when providing consultations.
Logout	Option at top of the page.	No change.

1. http://www.nhs.uk/change4life/Pages/meal-planner-recipe-finder.aspx
2. http://www.nhs.uk/Livewell/Pages/Livewellhub.aspx

* Table illustrates each feature within the website, describing how it was incorporated in the original website and any changes that have taken place to adapt and refine it for the My Dietitian website in this study.

Table 3-2 above outlines how refinement and finalisation of the intervention occurred for each feature of the website.

Health professionals, two senior dietitians and two exercise experts (health improvement specialists), joined the project. Initially the intervention was solely going to provide dietitian advice but it was decided that exercise advice was also an important aspect of weight loss and therefore exercise experts were invited to take part in delivering the intervention. The health professionals were introduced to the internet based intervention, by me, and asked to provide their views on the website as it currently stood, in terms of what they liked, disliked, believed needed adding or was not essential for themselves or the participants. All comments were noted and combined to give an overall view from all the health professionals. Their involvement in the refinement and finalisation of the intervention was deemed important as it was them who would be using the website to provide healthcare to the participants. An example of a suggestion was the inclusion of relevant articles, from NHS Choices or their personal materials, that would be helpful for both the participants to read and for the health professionals to send/suggest to the participants via their web based consultations. Feedback and questions were acknowledged and alterations, identified as appropriate and feasible, took place on the basis of this feedback. However, time and resources were quite limited in terms of making changes to the website before the study's ethics application and the start of the intervention. The health professionals were made aware that feedback was required on the content/resources within the website rather than the structure or design of the website.

3.2.2 *Training*

The two dietitians and two exercise experts delivering the web-based consultations were trained in how the website works, the services available and how to provide feedback to participants. The training was carried out by a GP and dietitian who were involved in the Danish study and a psychologist from Newcastle University, who is part of my supervisory team. Training took place in the dietitian's workplace, an office based within a local community

hospital, which allowed the four health professionals computer access. The training consisted of eight hours split between two half day sessions. The health professionals were presented to, see appendix U, in relation to behaviour change techniques (BCTs) previously connected to more successful weight loss interventions (goal setting, self-monitoring, action planning, coping planning/relapse prevention, barrier identification and review of behavioural goals) (Dombrowski *et al.*, 2011). Examples were then given of how these BCTs could be integrated into the intervention and the online consultations provided by the health professionals. Training focused on how to navigate around the website, how to access participant information about their food and exercise input and how to provide a web based feedback message. Several messages (templates) were already embedded in the website as examples for the health professionals. Practice consultations were conducted, with the health professionals being trained in how to create their own templates, adapt and send them to participants.

3.3 **Method of the pilot RCT**

3.3.1 ***Design***

Two multi centred patient randomised parallel group two arm rehearsal pilot randomised controlled trials (identical trials in each of two patient populations).

CONSORT flow diagrams of the stages (see Figure 3-2 and Figure 3-3) for the parallel pilot randomised controlled trial of the two groups were created to allow tracking of recruitment, retention and attrition levels (Moher *et al.*, 2001).

3.3.2 ***Participants***

Target population

Participants were obese adult (18 years and over) patients registered with general practices within the catchment area of County Durham and Darlington NHS Foundation Trust. General practices were identified by the primary care research network (Northern and Yorkshire) and approached for

expressions of interest to participate in the study by a clinical trial coordinator. After initial interest was expressed I contacted practices and provided them with more information. Agreement to take part and organising what was required from each practice was then arranged between the practice and I. Two distinct patient populations were considered: post-partum women and men with diabetes, as described in Chapter 1.

Inclusion criteria

1. Women who have had a baby (from three months up to two years after childbirth) and who have a BMI ≥30 and <40 kg/m^2 at baseline measurement. NICE guidelines state the postnatal check 6-8 weeks after childbirth is an appropriate opportunity to discuss weight loss and the options available (National Institute for Health and Clinical Excellence, 2010), therefore a minimum of three months post-partum was chosen to allow discussion of weight loss to have taken place. Women who were breastfeeding were eligible for inclusion as evidence shows weight loss advice is not harmful during this period (Dusdieker *et al.*, 1994; McCrory *et al.*, 1999). Women had to be aged 18 or over.

2. Men who had been diagnosed with type 2 diabetes and had a BMI ≥30 and <40 kg/m^2 at baseline measurement. Men had to be aged 18 or over, with no upper age restrictions.

3. Participants were required to have access to the internet (home, workplace, public location) on any device (desktop computer, laptop or mobile phone).

Exclusion criteria

The majority of the exclusion criteria applied to both study populations.

1. Patients with BMI > 40 kg/m^2. When a patient reaches a BMI 40kg/m^2 lifestyle modification may no longer be appropriate and bariatric

surgery may be recommended (National Institute for Health and Clinical Excellence, 2006).

2. Patients unable to access the internet.

3. Patients unable to give written informed consent in English. Such patients were excluded as they would be unable to engage with the internet intervention which is currently only available in English. Within the constraints of a PhD study, the resources were not available to use a translator or produce the web-based resources in other languages.

4. Patients identified by their GP as having a contraindication to the weight loss intervention (such as previous eating disorders or other mental health problems).

5. In the post-partum women population, patients who were currently pregnant were excluded from the study.

Sample size

The suggested sample size for pilot trials is 30 participants per arm (Lancaster *et al.*, 2004; Thabane *et al.*, 2010), thus to enable estimation of parameters for a future trial. A 1:1 allocation ratio to the intervention and control groups was planned. Therefore the aim was to recruit 60 patients per population, post-partum women and men with diabetes; 120 in total. Recruitment took place over seven months (November 2012- May 2013) to ensure the project timeline was adhered to and achieved.

3.3.3 *Screening, Recruitment and Consent*

Health professionals

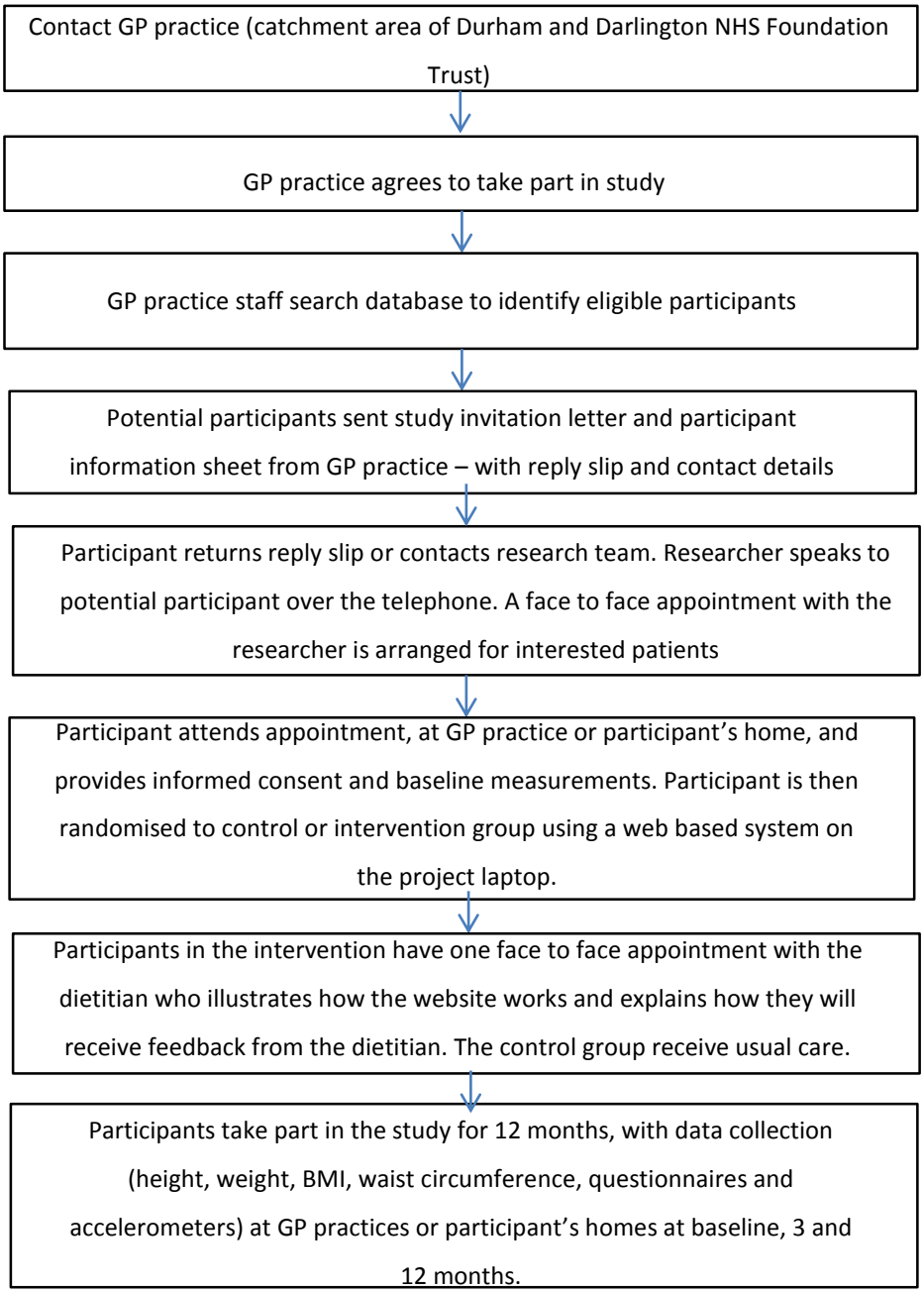
My supervisory team (consisting of two professors and two senior lecturers from Newcastle University) and I collaborated with a team of three health professionals (Head of Dietetics and Nutrition, Head of Service (Health and wellbeing) and a senior dietitian) within County Durham and Darlington NHS Foundation Trust. After consultation with NHS collaborators two dietitians

and two exercise experts were recruited to work within the study intervention. They were given the health professional information sheet (see Appendix F) and signed consent forms (see Appendix G) to state they were willing to work on the project and to take part in an interview towards the end of the study.

Participants

Participants were recruited from GP practices as follows:

Figure 3-1: Recruitment Flow chart



As the study was accepted on the NIHR clinical research network portfolio (ISRCTN: 48086713), the local Primary Care Research Network (PCRN), Northern and Yorkshire, were able to support and provide funding to aid recruitment for both GP practices and participants. During this time the PCRN were going through several changes which led to three different clinical trial co-ordinators assisting with the study through the recruitment stages. The PCRN co-ordinators emailed study information to GP practices identified as being located in the catchment area of County Durham and Darlington Foundation Trust (within County Durham Primary Care Trust and Darlington Primary Care Trust). A letter was sent to suitable practices inviting them to take part in the study (see Appendix H). The practices were informed of the nature of the study and asked if they wished to participate. Any expressions of interest from practices to take part in the study could be provided by contacting the PCRN co-ordinators. Once interest had been expressed the PCRN co-ordinators then forwarded any information about the GP practice to me, from which I then took over any further communication. Once a GP practice had agreed to take part, the practice performed a database search to identify patients who met the study inclusion criteria, see Figure 3-1. The 11 practices were paid a fee of £273 for providing this service, which was PCRN standard procedure. A GP from each practice then assessed each list of patients to check for contraindications, i.e. patients who met the exclusion criteria or were not appropriate for the intervention and study. An opt-in design for recruitment was adopted. Patients who met the inclusion criteria were identified and contacted through the post, by the GP practice, with an initial letter of invitation (see Appendix I) and the participant information letter (see Appendix J). The letter included contact details for the research team. Interested patients had to return the expression of interest slip (enclosing their telephone number or email address) or contact me directly by telephone or email.

An anonymous screening log of those who were eligible for invitation to participate in the study from each GP practice was constructed. The log of participants, which I completed, contained information regarding the number of letters sent out to patients in each study population. Each invitation letter

included a reply slip with the option for patients to state a reason for not taking part in the study, which they could send back to me. Any reasons provided for declining participation were recorded, although the right to refuse participation without giving reasons was respected.

On receipt of an expression of interest form or call, I then explained the study to the patient in more detail over the telephone and if the patient continued to express interest an appointment was made to meet with them to seek written informed consent.

The baseline appointment entailed the participant providing informed consent (see Appendix K), which was taken in person by myself, either in the GP practice or the participant's home depending on their preference. This took place once the person had read the participant information sheet again. Each participant signed three consent forms, one for the participant to keep, one for their medical records and one that I retained which, was stored in the study file. The copies of consent forms were stored in a secure filling cabinet within university premises.

Baseline measurements (described in greater detail in 3.3.6) then took place. After this, I randomised each participant to one of the two arms using the Sealed Envelope™ web based system on the project laptop (see 3.3.4 for details). The randomisation took place after I had left the participant. The participant was then sent confirmation through the post of which arm they were assigned to and what action to take next.

A recruitment log was maintained outlining how many participants agreed to take part in the study from each involved practice. The log recorded how many participants attended the recruitment appointment and how many participants consented to the study.

3.3.4 *Randomisation*

Participants from both target groups were randomised to either usual care (control arm) or the internet website intervention arm. Randomisation involved 1:1 allocation to the intervention and the control arms. The Sealed

Envelope TM web based randomisation system, an online software application for randomising patients into clinical trials, was used on the project laptop, thereby ensuring concealment of allocation. The two study populations, men with type 2 diabetes and post-partum women were randomised separately. Each participant was allocated a patient ID number when randomised. To successfully conduct a randomisation, questions relating to inclusion criteria (needing a yes answer) and exclusion criteria (needing a no answer) needed to be answered within the web based system. For both groups the exclusion criteria questions were the same, i.e. whether the participants had a BMI<30 or>40 kg/m^2, had no access to the internet, could not provide informed consent in English and/or were identified by their GP as having a contraindication making the weight loss intervention inappropriate. In addition the randomisation system for post-partum women had a question asking whether they were currently pregnant. The inclusion criteria questions were the same for questions BMI>30 and<40kg/m^2 and access to the internet but differed with the men with diabetes population questions asking whether they were male and diagnosed with type 2 diabetes whereas the post-partum women questions asked whether they were female and had a baby from three months up to two years ago.

The allocation schedules were set up independently by a member of the supervisory team not involved in participant recruitment. Stratification was used to ensure that potential confounding variables that may affect outcome were balanced between the intervention and control arms. The purpose of this was to replicate conditions/processes that would be used in a future main trial. Men with diabetes were stratified based on the medication they were taking for their diabetes; the three options were diet only, oral hypoglycaemic agents or insulin. If a participant was on insulin and tablets they were assigned to the insulin category. The post-partum women were stratified on the basis of how many children they had, one versus two or more. Only after a participant has provided their informed consent and had their baseline measurements recorded were they randomised into the study. Participants were informed of their allocated arm following randomisation. Blinding was not possible at any stage of the study.

1. Control arm

The control arm experienced usual care for weight loss (including referral to dietitian/practice nurse, attending set appointments as usual, or no specific treatment if deemed appropriate) as per the normal practice in their general practice. Taking part in the study did not influence what usual care was offered to the patient, with no specific arrangements to review or refer participants.

2. Intervention arm

Intervention participants received a letter through the post with the website address (http://mydietitian.org.uk) and log in details. Participants were encouraged to log onto the website before their initial face to face consultation with their assigned dietitian, which lasted approximately one hour and involved reviewing the participant's current food intake. Participant details were passed on to the dietitians by me. Initial consultations were then arranged by the dietitian directly with the participant via telephone (or email if a telephone call was not possible). The participants received advice or guidance by messages from the dietitian sent via the website, once a week for the first three months and then monthly for a further period of nine months. Each participant also had monthly scheduled on-line consultations, for the first three months, with an exercise expert to advise them on physical activity, which dropped down to every three months for the last nine months of the intervention, but no face to face consultation was offered. Some variations of feedback timings were made if the dietitian or exercise expert thought it necessary, such as if a participant needed additional help an extra consultation could be added. Consultations were not structured but included information that the health professional judged to be most important to the participant achieving weight loss. However, all consultations could be saved as templates within the website if a health professional believed it could be useful and may be a common problem/area for advice within the participants. Participants could ask questions of the consultant through their food and exercise daily inputs but these messages were only answered through their next scheduled message from the dietitian/exercise expert.

3.3.5 *Ethics*

Ethical issues

NHS ethical favourable opinion was gained from NRES Committee East of England - Cambridge Central Proportionate Review Sub-committee on 9th August 2012 (REC reference: 12/EE/0361), see appendix L. NHS County Durham and Darlington R&D approval was sought and obtained on 24th October 2012. I also sought and gained a research passport and letter of access (RE-1316). A study substantial amendment, requesting the use of health visitors to provide study information to patients, received a favourable opinion from Cambridge Central Proportionate Review Sub-committee on 5th April 2013.

It was essential to inform patients that participation was voluntary, entirely their choice and that if they did not take part it would not affect the care they received at present. There was a potential risk that participants may have felt disadvantaged if randomised to the control arm. However, it was explained to every participant that randomisation to the control or intervention arm was by chance allocation and out of my control. It was made clear that the control arm would receive usual care and therefore any treatment they received was recommended by the NHS. GPs were informed of all patients involved in the study. Another ethical issue, which exists for any pilot study, is the study not being powered to provide definitive evidence of effectiveness.

Withdrawal of participants

Participants were informed that they were free to withdraw at any time throughout the study. If a participant withdrew they were asked if they would be willing to stay in the study for the purposes of data collection, even if withdrawing from the intervention. However, if they were not willing to stay in the study they were asked if they wished to state a reason and for it to be recorded, though the right to withdraw without giving a reason was observed. Consent was sought to retain data collected up to the point of withdrawal.

Confidentially

All data remained strictly confidential. I was responsible for ensuring confidentiality and data protection. Data were handled in accordance with the Caldicott Principles and the Data Protection Act, 1998. All study files, data and transcripts were kept in a secure locked filing cabinet with restricted access or a password protected computer. Participants were identified using numerical IDs for any electronic datasets, with a key linking to named patients held separately.

Quality Control and Assurance

Quality control was maintained through adherence to study protocol, clinical trial regulations, research governance and principles of Good Clinical Practice guidelines (ICH, 1996). I completed Good Clinical Practice training and passed the online course in 2011.

Dissemination and Outcome

Individuals remained anonymous in all study reports. Participants and health professionals received a summary of results at the end of the study. Health professionals within the participating trust were informed of the research and its findings through a debrief meeting with the dietitians and exercise experts involved in the study. Relevant training, conferences and courses allowed findings to be showcased in the form of oral presentations, posters or seminars. Peer reviewed publications are planned for the systematic review, pilot RCT and process evaluation.

3.3.6 *Data collection*

The data collected comprised the variables and measures being considered as potential primary and secondary outcomes, or explanatory variables, for a potential definitive trial.

Table 3-3: Data collection time points

Outcome Measures	Baseline	3 months	12 months
Demographic variables	✓	✓	✓
Rates of recruitment, adherence, retention, attrition and completion of outcome measures.	✓	✓	✓
Anthropometric measures	✓	✓	✓
Physical activity – Accelerometers	✓	✓	✓
24 hour food diary – diet assessment	✓	✓	✓
Obesity and Weight Loss Quality of life (OWLQOL) and Weight Related Symptoms measures (WRSM)	✓	✓	✓
Predictors of behaviour change	✓	✓	✓

The baseline collection, conducted by me, of the outcome measures mentioned in Table 3-3 above took place when the participant was recruited to the study. This required participants to have their height, weight and waist circumference measured. They were asked to complete two questionnaires whilst in the appointment and then provided with a food diary and accelerometer to complete at home and return to me once they were completed. Appointments lasted approximately 20-60 minutes depending on outcome measure completion time. The same outcomes measures were then collected again by me at three and 12 months (approximately) after the participant had joined the study. The 12 month collection point was the last data collection point; therefore participants were required to meet with me three times if they stayed in the study for the whole time period of 12 months (unless they also took part in an interview which meant they met with me four times). Three and 12 months were monitored to assess initial weight loss

during the intensive intervention period (three months) but also allowed longer term weight loss/maintenance (12 months) to be examined, when treatment intensity had been reduced, which is often lacking in weight loss research (Neve *et al.*, 2010).

Primary outcomes for the pilot trial

- Recruitment and retention into trial, as measured by: Rates of participant screen eligibility, response to invitation, full eligibility, consent and retention at three and 12 months.

Secondary outcomes for the pilot trial

- Comprehensiveness, acceptability and feasibility of the measures proposed as primary or secondary outcomes or explanatory variables in the future definitive RCT, namely:-
  - Anthropometric measures (Body weight, Height, Body Mass Index, waist circumference).
  - Diet and physical activity data.
  - Predictors of behaviour change.
  - Quality of life.
- Parameter estimates (in particular variability) of the proposed primary and secondary outcomes measures for the future definitive RCT to inform sample size calculations.

Eligibility, recruitment and retention were assessed by logging participants' response and progress in the study. These figures were complemented by recording the number of outcome measures recorded at each data collection time point.

Comprehensibility, acceptability and feasibility of the proposed outcome measure and predictors were assessed through rates of completion, missing data and implausible values, and distribution of scores.

Demographic variables

Age, ethnicity, postcode, date of birth, current and past weight loss attempts, work status (occupation), household information and gender were recorded by me at the initial meeting with the participant. The men were also asked for information about their diabetes, including medication use and date of diagnosis. Post-partum women were asked about the number of children they had had, their ages and the type of childbirth deliveries they had experienced. All these variables were recorded on their data collection record sheet (see Appendix M).

Anthropometric measures

I recorded the anthropometric measurements with each participant having these measurements recorded on an individual data collection sheet (see Appendix M).

Height was recorded using a Leicester height stadiometer and participants were asked to stand as straight as possible with their shoes off.

Body weight was measured using Shekel personal floor scales (H151-7, Class III), allowing capacity weight up to 250kg. Each participant was required to produce two body weight readings to check for consistency. If these were not consistent then a third reading was required and an average of the three readings used as the final body weight recording. Participants remained clothed but were asked to remove coats and shoes.

The Shekel scales also allowed a participant's height to be entered along with body weight to calculate a BMI recording.

Waist circumference was measured, midway between the lowest rib and the iliac crest, underneath clothing using a tape measure. Waist circumference has been suggested as a measure of interest in relation to weight management due to the important link to health owing to the connection with abdominal fat (Leans, 1995). It is also a measurement that the public may be more familiar with, whilst BMI may not be fully understood.

In this pilot trial anthropometric measures where monitored in terms of completion rates.

When investigating weight loss/management both diet and physical activity should be monitored in order to assess the individual behaviour changes that may be occurring (National Institute for Health and Clinical Excellence clinical guidelines, 2006 updated 2014; Roberts *et al.*, 2009). Therefore within this study outcome measures were collected to examine the participant's food intake and physical activity levels.

Diet

Participants completed a 24 hour food diary (see Appendix N) at baseline, three months and at the end of the study following their data collection appointments. Participants received the food diary, along with an explanation from me on how to complete it, at the data collection appointment and were asked to return the food diary via the pre-post envelope provided when completed. The 24 hour food diary prompts the participant to describe all food and drink consumed within the last 24 hour period. The time, quantity, place of consumption and description of the type of food and drink was recorded and the participant stated which day and date this occurred and whether this was a typical day for them.

In this pilot trial, the primary focus was on how many diaries were returned, completed and the quality of the data collected. From the participants perspective the focus was on how comprehensible the instructions had been for the participants to follow and what the experience of completing the diary had been like.

Physical activity

Accelerometers were worn by participants during the study to assess levels of physical activity. Participants were asked to wear the Actigraph GT1M accelerometers (Actigraph, Pensacola, FL) for seven days after each data collection point. The accelerometers were given to the participants at each data collection appointment by me and asked to be returned via post using a

pre-paid envelope provided. The Actigraph is a small, unobtrusive, and lightweight monitor worn on the right hip on an elastic waistband. Actigraph monitors have been used previously and found to be a valuable tool to examine activity patterns (Cooper *et al.*, 2000; Matthews *et al.*, 2002).

The participants were also given an activity belt diary (Appendix O) which they filled in whenever they wore the belt. This included the day and date worn, time it was put on and taken off, any times it had been removed and additionally if they had travelled and if so for how long during the day. This allowed the researcher to assess the level of physical activity for a participant based on the actual wear time of the belt. Data could only be analysed if an accelerometer was returned with a completed activity belt diary.

As with the food diaries, a key focus in the pilot trial was on rates of wearing and returning the accelerometer, diary completion and how comprehensible the instructions had been for the participants to follow.

Questionnaires

Table 3-4: Questionnaire descriptions

Questionnaire	Scale/sub scale	Question Scoring	Overall score	Notes
Obesity and Weight-Loss Quality Of Life (OWLQOL) (Patrick *et al.*, 2004)	17 questions regarding feeling about your weight	All questions 0-6 scale (not at all - a very great deal)	0-100	Higher score equalling better quality of life
Weight Related Symptom Measure (WRSM) (Patrick *et al.*, 2004)	20 questions regarding symptoms and how much they are a burden to you	Firstly Yes or No as to whether they have experienced the symptom. Followed by 0-6 scale (not at all - a very great deal)	0-120	Higher score equalling worse symptom burden
Predictors of behaviour change (Sniehotta *et al.*, 2011)	74 questions split over four sections			

Questionnaire	Scale/sub scale	Question Scoring	Overall score	Notes
1.Current weight views	21 questions about views about your weight problem	1-7 scale (strongly disagree-strongly agree)		Higher score equals more positive view on their current weight problem
2.Current diet views	24 questions on personal views about your diet:	All 7 point likert scales		Split into 7 different predictors(see diet predictors below)
2a. Diet Attitude	6 questions for attitude towards sticking to a healthy weight loss diet	1-7 scale (e.g. dull-interesting/ boring-stimulating)		Higher score equals more positive attitude to a healthy weight loss diet
2b. Diet Control	3 questions of persons control (confidence/ability) to stick to a healthy weight loss diet	1-7 scale (not confident - confident/ incapable-capable)		Higher score equals higher belief of control to stick to a healthy weight loss diet
2c. Diet Intention	1 question for intention to stick to a healthy weight loss diet	1-7 scale (disagree-agree)		Higher score equals greater intention to stick to a healthy weight loss diet
2d. Diet Subjective norms	1 question regarding what people close to them thinking they should stick to a healthy weight loss diet	1-7 scale (disagree-agree)		Higher score equals they think people close to them believe they should be sticking to a healthy weight loss diet
2e. Diet Action Planning	4 questions about the use of a detailed action plan regarding sticking to a healthy weight loss diet	1-7 scale (disagree-agree)		Higher score equals a detailed action plan to stick to a healthy weight loss diet
2f. Diet Coping Planning	3 questions about the use of a detailed coping plan regarding sticking to a healthy weight loss diet	1-7 scale (disagree-agree)		Higher score equals a detailed coping plan to stick to a healthy weight loss diet

Questionnaire	Scale/sub scale	Question Scoring	Overall score	Notes
2g. Diet Action Control	6 questions asking what they had done in the last week to stick to a healthy weight loss diet	1-7 scale (disagree-agree)		Higher score equally higher use of action control to stick to a healthy weight loss diet
3. Current physical activity (PA) views	23 questions on personal views about your physical activity:	All 7 point likert scales		Split into 7 different predictors(see PA predictors below)
3a. PA Attitude	6 questions for attitude towards participating in regular PA	1-7 scale (e.g. dull-interesting/ boring-stimulating)		Higher score equals more positive attitude to participate in regular PA
3b. PA Control	3 questions of persons control (confidence/ability) to participate in regular PA	1-7 scale (not confident-confident/ incapable-capable)		Higher score equals higher belief of control to participate in regular PA
3c. PA Intention	1 question for intention to participate in regular PA	1-7 scale (disagree - agree)		Higher score equals greater intention to participate in regular PA
3d. PA Subjective norms	1 question regarding what people close to them thinking they should participate in regular PA	1-7 scale (disagree - agree)		Higher score equals they think people close to them believe they should be participating in regular PA
3e. PA Action Planning	3 questions about the use of a detailed action plan regarding participating in regular PA	1-7 scale (disagree - agree)		Higher score equals a detailed action plan to participate in regular PA

Questionnaire	Scale/sub scale	Question Scoring	Overall score	Notes
3f. PA Coping Planning	3 questions about the use of a detailed coping plan regarding participating in regular PA	1-7 scale (disagree-agree)		Higher score equals a detailed coping plan to participate in regular PA
3g. PA Action Control	6 questions asking what they had done in the last week in relation to participating in regular PA	1-7 scale (disagree-agree)		Higher score equally higher use of action control to participate in regular PA
4.Social support	6 questions regarding views about social support	1-7 scale (none of the time-all the time)		Higher score equals the person believing they have greater social support

Quality of life questionnaires

Participants had their quality of life measured (see Appendix P) at baseline, 3 months and at the end of the study. Quality of life was a relevant outcome for this study due to the importance of understanding the impact of a healthcare intervention on a patient's life (Addington-Hall and Kalra, 2001). This allows the respondent to assess their own quality of life and subsequently their perspective of disease and perceived need for treatment (Carr and Higginson, 2001). An obesity-specific quality of life questionnaire enables both obesity related impairments and weight loss benefits to be examined in relation to the patient's quality of life (Kolotkin *et al.*, 2001b).The Obesity and Weight-Loss Quality-of-Life (OWLQOL) Instrument and the Weight Related Symptoms Measure (WRSM) (Patrick *et al.*, 2004) were used to assess quality of life for each participant during the duration of the study. The OWLQOL, as shown in Table 3-4 consists of 17 items, including questions on feelings and emotions in relation to the person's weight or shape. It is a disease specific instrument for use with those who have BMI greater than 27 and to measure the impact of obesity and weight loss. In line with the

developers' instructions, each question's score was reversed before being added together, and then taking away the lowest possible score from the total score. This was then divided by the possible raw score range and finally timed by 100 to give a single OWLQOL score. Scores can range from 0 to 100, with 0 showing the biggest impact and 100 showing the least impact and therefore greater quality of life.

The WRSM includes 20 items of medical symptoms related to weight, for example pain in the joints and increased sweating. The participant needed to answer yes or no to having each of the twenty different symptoms included in the WRSM. The level of bothersomeness was then rated on a seven point Likert scales, which was used for both the OWLQOL and the WRSM, ranging from not at all (0) to a very great deal (6). A total score was calculated by adding all of the bothersomeness scores from each symptom. Total scores can range from 0 to 120, with higher scores signifying worse symptom burden.

Both the OWLQOL and the WRSM have previously been shown to have good internal consistency (Guttman-Cronbachs α = OWLQOL, 0.90 and WRSM, 0.87) and test-retest reliability (Guttman-Cronbachs α = OWLQOL, 0.95 and WRSM, 0.83) (Patrick *et al.*, 2004).

In this pilot trial the OWLQOL and WRSM were investigated in terms of completion of materials and how comprehensible the instructions had been for the participants to follow, as a whole and for individual questions.

Predictors of behaviour change questionnaire

Predictors of behaviour change questionnaire (see Appendix Q) (Sniehotta *et al.*, 2011) consists of 74 questions, split into four main sections, each examines different factors in relation to behaviour change, as shown in Table 3-4.

The first section was in relation to 'Your views on your current weight' a shortened version of the Illness Perception Questionnaire–R (IPQ-R) (Moss-Morris *et al.*, 2002; Sniehotta *et al.*, 2009). The IPQ-R has previously been

found to have good internal reliability and good stability when test-retest reliability was examined at three weeks and at the longer period of six months (Moss-Morris *et al.*, 2002). To reduce participant burden a psychometrically shortened IPQ-R, the IPQ-PS, was used which incorporates the three highest factoring items for each subscale identified in a previous study (Moss-Morris *et al.*, 2002). The IPQ-PS is a reliable and valid alternative, which allows for psychometric analyses (Sniehotta *et al.*, 2009).

These 21 questions had response categories on a five point Likert scale ranging from strongly disagree to strongly agree. To score this section of the questionnaire question number 1, 7, 8 and 21 have the scores reversed and then all the scores are added together.

The next two sections 'your views on physical activity' and 'your personal views on your diet' both asked participants to rate, on a seven point Likert scale. Included in each of the two sections were questions relating to the Reasoned Action Approach (RAA)(Fishbein and Ajzen, 2010) based on the theories of planned behaviour and reasoned action, with six relating to attitude towards the behaviour, three for perceived behavioural control, one for perceived norms and one for intention. Participants were asked to answer questions in relation to the RAA owing to the influence the components of the RAA have shown to have on actual behaviour and the likelihood of it occurring, continuing or changing (Fishbein, 2008; Fishbein and Ajzen, 2010).

The questionnaire also included three questions (four questions in the case of dietary behaviours) related to Action Planning and three questions on Coping Planning. Planning constructs have been suggested as important when examining how intention translates into behaviour (change). Therefore action and coping planning are key components to investigate, as predictors of behaviour change, due to a previous study's findings that both types of planning may be influential as they operate differently and at different timeframes in the behaviour change process (Sniehotta *et al.*, 2005b).

Finally six questions were used to assess Action Control (Sniehotta *et al.*, 2005a) for physical activity and a healthy weight loss diet. Action control questions focus on self-monitoring, awareness of standards and effort. Action control has previously been found to mediate between intention and behaviour with regards to exercise (Sniehotta *et al.*, 2005a).

To measure social support the ENRICHd Social Support Instrument (ESSI) (Vaglio *et al.*, 2004) was used. This questionnaire measures social support with six questions answered in a likert scale (five point scale from none of the time to all the time). One question, number seven, was not included in this study as marital status was already asked in the personal background section. Besides, in previous studies this question was also consistently the one that correlated most poorly to all the other questions. The scores were added together to give a total score, with higher scores meaning greater social support. Findings on the psychometric characteristics of this scale reveal good levels of validity and reliability (Cronbach's $\alpha = 0.88$) as a measure of social support (Vaglio *et al.*, 2004).

In this pilot trial the Predictors of behaviour change questionnaire were investigated in terms of completion of materials and how comprehensible the instructions had been for the participants to follow, as a whole and for individual questions and sections.

3.3.7 ***Data handling***

Quantitative data were inputted into SPSS Statistics 21.0 software. Data collection points can be seen above in Table 3-3. A screening log was recorded, consisting of the number of participants eligible for participation, not eligible, declined, consented and randomised. Reporting of the rehearsal pilot RCT follows CONSORT statement guidelines (Schulz *et al.*, 2010).

Food diaries were analysed as a method of assessing adherence to the intervention outcome measures in terms of completing and returning food diaries. In addition all food diary data was entered into an Access database by a Food and Nutrition undergraduate placement student and double checked by me. All food items were coded using McCance and Widdowson

food composition codes (Food Standards Agency, 2002) within a purpose designed Access database used in the Human Nutrition Research Centre, Newcastle University. For food weight not recorded by participants average weights were used from published food portions (Ministry of Agriculture Fisheries and Food, 1993). The query function then allowed nutrient outputs to be created from the data (energy, fat, protein, carbohydrate, total sugars and alcohol intake). Data were then exported to SPSS to be analysed.

Levels of adherence with regards to wearing and reporting wear time for the accelerometers were examined. Participants were asked and encouraged to wear accelerometers for seven days, for at least eight hours a day but were informed that at least three days would be needed in order for their data to provide sufficient valid data. Accelerometer data were imported into ActiLife 5 Software. Participant wear time was entered into the software, by me, before any data were downloaded. Downloaded data included step counts, calorie expenditure, levels of sedentary and moderate to vigorous activity. Daily data calculations were then exported to an excel database to enable overall activity totals to be calculated by an undergraduate student, which were then checked by me. The physical activity data were then transferred to SPSS for analysis by me.

3.3.8 *Data analysis*

Eligibility, recruitment and retention rates

Participant recruitment, rejection, retention and attrition rates were calculated to assess how patients responded to being approached to join a study and also how well they were retained within the study; CONSORT flow diagrams have been used to present the data, see Figure 3-2 and Figure 3-3 (Moher *et al.*, 2001). The CONSORT statement suggests the use of flow diagrams to depict participation throughout a study to try and improve the reporting of an RCT, allowing the trial procedure to be clearer and enabling the reader to assess the validity of its results (Moher *et al.*, 2001).

Recruitment was calculated as the number of participants providing informed consent divided by the number of eligible participants contacted. Retention

was calculated as the number of participants remaining at each data collection point (three and 12 months) divided by the number of participants recruited at the start of the study. Attrition rates were the inverse percentages gained from the retention rate calculations. These figures will be used to inform how many participants would need to be recruited in a definitive RCT in order to be likely to retain sufficient participants.

Descriptive statistics

Descriptive statistics were used to examine rates of completion of each measure, rates of implausible values and five figure summaries (minimum, maximum, median, lower and upper quartiles). Means and standard deviations were also calculated to inform sample size calculations for a potential definitive trial.

Measurements for weight, BMI, waist circumference, physical activity, diet and questionnaire results were analysed using descriptive statistics for all participants in both the intervention and the control arms. Changes from baseline to three months and from baseline to the end of the study for all measures were analysed. Completion of measures and questionnaires was recorded to assess adherence and feasibility for using these data collection methods with participants.

3.4 Results from the rehearsal pilot randomised controlled trial

3.4.1 *Practice involvement*

As the study was adopted onto the NIHR Portfolio the study was assisted by the Primary Care Research Network. The Network staff contacted practices to enquire whether they would be interested in taking part in the study. Eight GP practices agreed to take part and to perform database searches to identify potential participants for both the men with type 2 diabetes and post-partum women populations. However, only seven practices conducted the searches with one practice unable to do so owing to time pressures. Four more practices agreed to conduct post-partum women only searches as recruitment levels for this group had not been met, with all four completing

the search. GP practice size ranged from 1663 to 19976 patients and varied in terms of location with some practices based in town centres (n=4), some within housing estates (n=4) and others situated in rural villages (n=3).

Table 3-5: Average practice identification rates for eligible participants

Practice identification rates	Men with diabetes	Post-partum women
Mean (SD)	138.3 (146.6)	15.3 (11.9)
Median (LQ-UQ)	81 (38-233)	11 (4-28)
Range (Min-Max)	418 (10-428)	30 (4-34)
* Average number of potentially eligible participants identified from each GP practice database search		

As shown in Table 3-5 above on average the search identified a much greater number of potentially eligible men than women. The range of number of men identified also illustrates the variance between the practices, with one practice finding 428, a large majority of the overall number of the 968 potentially eligible men identified, see Table 3-10.

Statistics were examined from County Durham and Darlington, the area that participants were recruited. Investigating diabetes rates from Chapter 1 revealed of those diagnosed approximately 55% were men and 80% were estimated to be overweight or obese (Diabetes UK, 2010). This enabled estimates per every 1000 people to be calculated and used in comparison against the number of potentially eligible participants identified from each GP practice database search, see Table 3-6.

Table 3-6: Number of overweight or obese men with Type 2 diabetes within County Durham and Darlington

	No. within County Durham and Darlington	No. per every 1000
Population	600,000	
Diagnosed with T2D*	39,230	65
Men with T2D*	21,969	37
Overweight or Obese men with T2D*	17,575	29
*T2D = Type 2 diabetes		

The GP practice patient number records enabled the number of men at each practice to be retrieved (Department of Health, 2012a). The size of the practice in terms of how many men aged over 16 years old was taken into consideration and used to calculate how many men, approximately, would be expected to be obese men with diabetes in each practice, see Table 3-7.

Table 3-7: Number of identified men with type 2 diabetes compared to expected numbers

Practice identification rates	No. of practices for Men with diabetes
Greater number identified	5
As expected	0
Fewer number identified	2

The majority of the practices found more potentially eligible men with type 2 diabetes than expected. Prevalence rates appeared as slightly higher (29/1000), see Table 3-6, than the UK average estimate (24/1000) as County Durham and Darlington prevalence rates of diabetes is approximately 6.5 in every 100 people where the UK average is around 6 in every 100. It was expected that higher than national levels would be identified as higher levels of obesity and diabetes are estimated in the north east (National Heart Forum, 2008). Therefore this is a conservative estimate as the statistic used,

80%, for levels of overweight and obesity in people with type 2 diabetes is a national percentage rather than regional level. GP practice database search appear to identify appropriate numbers of eligible participants enabling the recruitment target to be met and therefore appears as a suitable method of identification for men with diabetes.

To examine the number of potentially eligible post-partum women identified, County Durham and Darlington prevalence levels of pregnancies were examined. General Fertility Rate (GFR) relates to the number of live births per 1000 women aged 15-44 years (Office for national statistics, 2012). Using statistics from NHS Choices (NHS Choices, 2013) stating 15-20% of pregnancies are in obese women, enabled estimation of how many women per 1000 were likely to be obese and pregnant, see Table 3-8.

Table 3-8: Number of obese pregnancies within County Durham and Darlington

	No. within County Durham	**No. within Darlington**
Pregnancy rate per 1000	59.2	68.6
Obese pregnancies per 1000	8.9-11.8	10.3-13.7

These estimates of expected obese pregnant women per 1000 women could then be compared to the potentially eligible women identified from the GP practice database searches within this study. The size of the practice in terms of how many women registered aged 15-44 years old was taken into consideration and used to calculate how many women, approximately, each practice should find through their database search (Department of Health, 2012a), see Table 3-9.

Table 3-9: Number of identified women compared to expected numbers

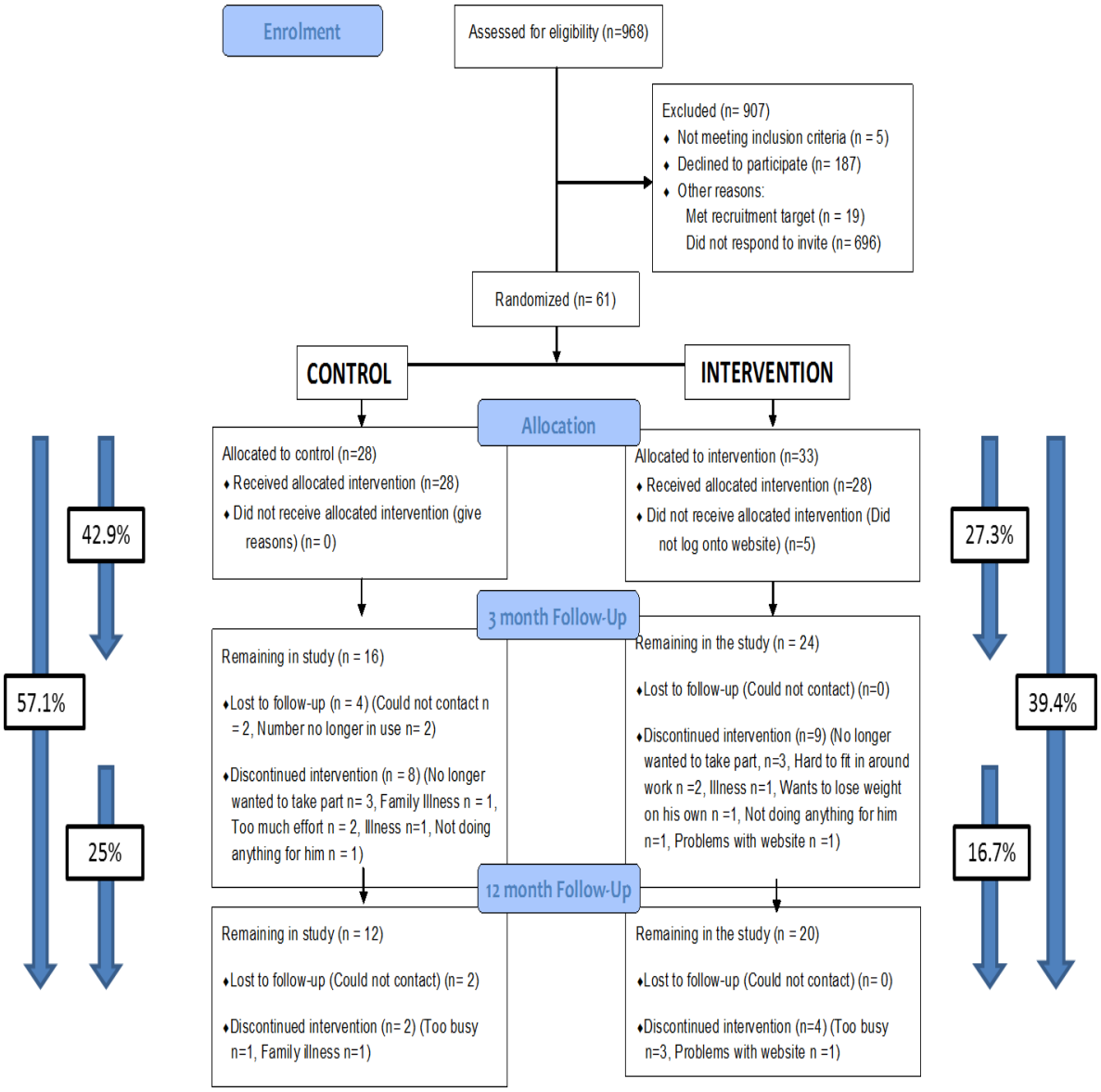
Practice identification	**No of practices for Post-partum women**
Greater number identified	5
As expected	2
Fewer number identified	4

Comparing estimated expected numbers of obese pregnant women to the actual identified number in each practice showed a variable picture. As with the estimates for men with diabetes the numbers may be slightly conservative due to using the average of 15-20% of pregnant women being in the obese category. However, in the north east obese levels tend to be higher than other parts of the country (National Heart Forum, 2008), which in turn would mean that the estimated expected numbers would actually be slightly higher than identified above. This explains why some practices were able to identify higher numbers of eligible participants but this does not explain why other practices found lower numbers. However, it should be acknowledged that not all practices will have average fertility rates and there will be some difference between practices, which would contribute to the number of eligible women identified. Feedback from practice managers and GPs did inform me that the post-partum database searches were more difficult to complete owing to the sensitive issue of checking pregnancy outcomes to ensure the patient was eligible and due to less frequent recording of BMI for this population group.

3.4.2 *Eligibility, Recruitment, Retention and Attrition levels*

Men with diabetes

Figure 3-2: CONSORT recruitment flow diagram: Men with type 2 diabetes participants



Post-partum women

Figure 3-3: CONSORT recruitment flow diagram: Post-partum women participants

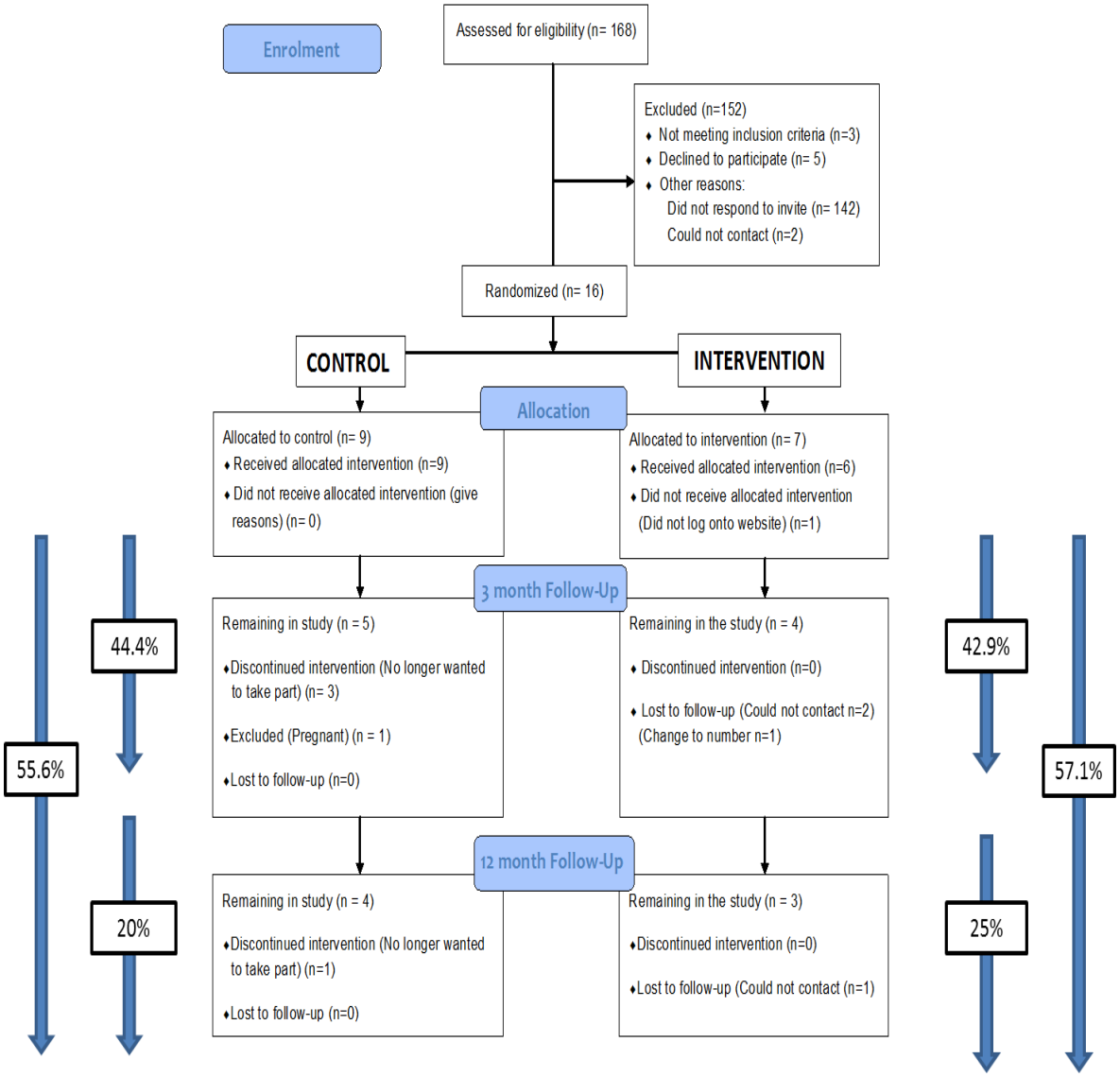


Figure 3-2 and Figure 3-3 above show participant flow throughout the study period for each of the population groups.

Response rates

Table 3-10: Response to study invitation letter

	Men with diabetes No. of participants (%) [CI]	**Post-partum women** No. of participants (%) [CI]
Practice searches	7	11
Eligible participants identified	968	168
Expressed interest	85 (8.8) [0.071; 0.108]	21 (12.5) [0.081; 0.187]
Ineligible	5 (0.5) [0.002; 0.013]	3 (1.8) [0.005; 0.056]
Recruited	61 (6.3) [0.049; 0.081]	16 (9.5) [0.057; 0.153]
Declined	187 (19.3) [0.169; 0.220]	5 (3) [0.01; 0.072]
Non-responders	696 (71.9) [0.689; 0.747]	142 (84.5) [0.780; 0.895]

For both target groups the response rate, that is those who expressed interest, was rather low, see Table 3-10, but a higher proportion of the post-partum women expressed interest in joining the study in comparison to the men with diabetes. Four practices conducted post-partum women searches only as recruitment numbers had not been met in the first seven practices.

Five men were found to be ineligible as three had BMI<30 and two had BMI>40. Of the 80 eligible participants 61 were recruited, within five months of the recruitment period, the remaining 19 were contacted to thank for their response but were informed that the study had reached its recruitment target. Three women were found to be ineligible with all three having BMI>40 and I was unable to contact two of the women who expressed interest. Therefore recruited responses equated to 16/168 over a seven month period, substantially lower than the recruitment target of 60.

Table 3-11 below outlines where the data collection appointment took place for both the men with diabetes and the post-partum women at each of the time points.

Table 3-11: Data collection appointment location

	Men with diabetes		Post-partum women	
Time point	**GP practice**	**Participant's home**	**GP practice**	**Participant's home**
Baseline	61 (100)	0	12 (75)	4 (25)
3 months	36 (90)	4 (10)	2 (22)	7 (78)
12 months	23 (72)	9 (28)	0	7 (100)
Number of participants (%)				

The proportion of visits at home gradually increased with length of study. This could be for a number of reasons, such as familiarity with me, me becoming familiar with the participants or room availability within the practice. The women tended to prefer home visits rather than GP practice appointments, which could be due to them having young children and this being the more practical option. In contrast the men with type 2 diabetes often had appointments at the practice so visiting may not have been an inconvenience for them.

Attrition rates

At three months, there was a greater loss of participants from the control arm than the intervention arm, in men (Figure 3-2) whereas attrition rates were similar in both arms for women (Figure 3-3). A similar pattern was seen at 12 months, by which time over half of women (intervention and control) and control men had dropped out, and around 40% of men in the intervention arm.

As shown in Figure 3-3 the main reason for attrition in the women's intervention arm was loss to follow up, with me being unable to get in contact

with the participant. For the control arm however the main reason was participants opting out of the study as they did not want to continue or found the study not of use to them. A main reason given to leave the study for men, by 12 months, was being too busy to take part, especially in the intervention arm.

Responses were also received from people who did not want to take part in the study and completed their invitation slip to inform the research team.

Table 3-12: Reasons for declining participation in the study

Reason not to take part	Men No. of responses	Women No. of responses
No reason given	115	
No internet access	29	
Poor health	12	
Time/Work commitments	10	
Age (believe themselves too old)	8	
Lost weight already	3	
Moved home	3	1
Happy with lifestyle	3	
Involved in another research project	2	
Mental health issues	1	
Don't want to be involved in research	1	
Wanted to lose weight on their own		3
Pregnant	-	1
Total	**187**	**5**

Table 3-12 shows the various reasons provided by decliners. The majority of potentially eligible men (696 = 71.9%) and women (142 = 84.5%) did not respond to the invitation letters.

3.4.3 *Baseline characteristics*

Demographic variables were assessed to characterise the participants at baseline.

Table 3-13: Baseline characteristics for men and women groups

	Post-partum women		Men with diabetes	
	Control (n=9)	**Intervention (n=7)**	**Control (n=28)**	**Intervention (n=33)**
Demographic variables	**Median (LQ-UQ)**	**Median (LQ-UQ)**	**Median (LQ-UQ)**	**Median (LQ-UQ)**
Age (years)	33 (30-37.5)	28 (23-31)	61 (54.5-66.8)	58 (50-67.5)
Education (years)	17 (12.5-17.8)	16 (14-18)	12 (11-12)	12 (10-14)
Ethnicity: White (Number (%))	9 (100)	7 (100)	28 (100)	33 (100)
Marital Status N (%)**:**				
Married/relationship	8 (88.9)	6 (85.7)	25 (89.3)	24 (72.9)
Single	1 (11.1)	1 (14.3)	1 (3.6)	4 (12.1)
Divorced/separated	0 (0)	0 (0)	2 (7.1)	3 (9.1)
Widowed	0 (0)	0 (0)	0 (0)	2 (6.1)
Type of childbirth N (%)**:**				
Natural	3 (33.3)	4 (57.1)	-	-
Caesarean	6 (66.7)	3 (42.9)		
Age of index child* (mths)	12 (7.5-12.5)	12 (12-17)	-	-
Number of children	2 (1-2.5)	2 (1-2)	-	-
Type of Medication N (%)**:**				
Diet only			7 (25.0)	7 (21.2)
Tablets	-	-	16 (57.1)	18 (54.6)
Insulin			0 (0)	1 (3.0)
Both			5 (17.9)	7 (21.2)
Year of diagnosis[#]	-	-	2009 (2003-2010)	2008 (2003-2010)

*Average age of child in months allowing inclusion in the study (inclusion criteria >3 months and <24 months).
[#] Year of type 2 diabetes diagnosis

For both the men and women baseline characteristics were similar in both the control groups and the intervention groups, Table 3-13. All participants were white, with the majority married or in a relationship. The main treatment method for the men with type 2 diabetes was oral hypoglycaemic agents, typically metformin tablets.

Index of multiple deprivation (IMD) scores were calculated, using individual's postcodes, for this study's sample, see Table 3-14 below.

Table 3-14: Mean IMD scores

Population	Mean IMD score	Range
Study sample*	26.5	5.8 - 67.3
County Durham[#]	26.4	-
Darlington[#]	25.4	-
* (Geoconvert UK Data Service, 2007) # (Department of Communities and Local Government, 2010)		

This illustrates a wide range of IMD score within the participants in this study. The participants' mean average IMD score is also similar to the average IMD scores for County Durham and Darlington, suggesting the sample in this study are representative of IMD levels within the two areas participants were recruited from.

Baseline characteristics, for outcome measures, were also examined in relation to responders and non-responders to the study at three months and 12 month data collection points. Responders were participants that completed data collection at the set time points, non-responders were those that did not attend or actively withdrew from the study.

Table 3-15: Men with type 2 diabetes demographic variables for responders versus non-responders at 3 and 12 months

	Men with Diabetes 3 months		Men with Diabetes 12 months	
	Responders (n=40)	**Non-responders (n=21)**	**Responders (n=32)**	**Non responders (n=29)**
Demographic variables	**Median (LQ-UQ)**	**Median (LQ-UQ)**	**Median (LQ-UQ)**	**Median (LQ-UQ)**
Age (years)	63 (54.5-68)	56 (47.5-61.5)	64 (56.2-67.8)	56 (47.5-64)
Education (years)	12 (10.8-13)	11.5 (10-12)	12 (10-12)	12 (10-13)
Ethnicity: White N (%)	40 (100)	21 (100)	32 (100)	29 (100)
Marital Status N (%)**:**				
Married/relationship	35 (87.5)	12 (57.1)	28 (87.5)	19 (65.5)
Single	2 (5)	5 (23.8)	2 (6.3)	5 (17.2)
Divorced/separated	2 (5)	3 (14.3)	1 (3.1)	4 (13.8)
Widowed	1 (2.5)	1 (4.8)	1 (3.1)	1 (3.5)
Type of Medication N (%)**:**				
Diet only	10 (25)	4 (19)	6 (18.8)	8 (27.6)
Tablets	22 (55)	12 (57.1)	18 (56.2)	16 (55.2)
Insulin	1 (2.5)	0	1 (3.1)	0
Both	7 (17.5)	5 (23.8)	7 (21.9)	5 (17.2)
Year of diagnosis	2008 (2002-2010)	2009 (2003-2011)	2008 (2002-2010)	2009 (2003-2011)
Height (cm)	177 (174-180.9)	176 (171.5-181.8)	177.3 (173.6-181.5)	176 (173-179.5)
Weight (kg)	106.3 (99.2-115.4)	113.9 (97.5-121.7)	106.3 (99.2-115.2)	112.7 (97.5-119(
BMI	33.3 (31.6-36.5)	35.1 (32-37.8)	33.2 (31.6-35.5)	36 (31.3-37)
Waist circumference (cm)	119.5 (112.5-124.9)	117.8 (113-125.5)	118.5 (112.5-124.9)	119 (113-125)
OWLQOL	70.6 (54.9-87.3)	51 (28.4-73.5)	70.6 (54.9-87.3)	56.9 (35.3-80.4)
WRSM	30 (8-49)	24 (14-38.5)	26.5 (14-38.5)	30 (12.5-47.5)

* Responders were participants that completed data collection at the set time points.
* Non-responders were those that did not attend or actively withdrew from the study

Examining the men's baseline characteristics identified that responders and non-responders were similar for most variables at three and 12 months, with age slightly higher for responders. Examining responders and non-responders of the study with regards to their baseline anthropometric measures showed the responders tended to have lower body weight but differences were small and significance testing not appropriate for the small number of participants. Responders were found to have higher baseline quality of life than the non-responders, however there was very little difference for the symptom burdensome scores (see Table 3-15 above).

Table 3-16: Post-partum women demographic variables for responders versus non responders at 3 and 12 months

	Post-partum women 3 months		Post-partum women 12 months	
	Responders (n=9)	**Non-responders (n=7)**	**Responders (n=7)**	**Non-responders (n=9)**
Demographic variables	**Median (LQ-UQ)**	**Median (LQ-UQ)**	**Median (LQ-UQ)**	**Median (LQ-UQ)**
Age (years)	31 (29.5-34)	30 (23-37)	31 (29-35)	32 (24.5-35)
Education (years)	16.5 (13-18)	15 (14-17)	17 (12-18)	15.5 (14-17)
Ethnicity: White N (%)	9 (100)	7 (100)	7 (100)	9 (100)
Marital Status N (%)**:**				
Married/relationship	8 (88.9)	6 (85.7)	6 (85.7)	8 (88.9)
Single	1 (11.1)	1 (14.3)	1 (14.3)	1 (11.1)
Divorced/separated	0	0	0	0
Widowed	0	0	0	0
Type of childbirth N (%)**:**				
Natural	5 (55.6)	3 (42.9)	4 (57.1)	3 (33.3)
Caesarean	4 (44.4)	4 (57.1)	3 (42.9)	6 (66.7)
Age of index child* (mths)	12 (12-16)	8 (6-13)	12 (10-12)	12 (9.5-16.8)
Number of children	2 (2-3)	2 (1-2)	2 (2-3)	2 (1-2)
Height (cm)	163 (159.5-174.3)	159 (157-169.5)	168.5 (159.5-174.5)	159.5 (157.5-167)
Weight (kg)	94 (80.7-108.2)	94.3 (85.6-103.5)	100.8 (82.4-110.1)	92 (84.4-99.7)
BMI	33.5 (31-36.6)	35.6 (33.4-38.7)	34.4 (31.6-37)	33.8 (33.4-38)
Waist circumference (cm)	114 (99-118.5)	114 (110-126)	115 (104-119)	112 (103-122.5)
OWLQOL	36.3 (23-51.5)	38.2 (12.7-51)	36.3 (25.5-52.9)	38.2 (16.7-50.5)
WRSM	26 (7-31)	18 (4-37)	23 (0-30)	30 (5-39.5)

*Average age of child in months allowing inclusion in the study (inclusion criteria >3 months and <24 months).
* Responders were participants that completed data collection at the set time points.
* Non-responders were those that did not attend or actively withdrew from the study

Table 3-16 showed responders and non-responders baseline characteristics were very similar, with both having a mixture of natural and caesarean childbirths. Responders at three months had, on average, an older child (12 months) in comparison to the non-responders (8 months) but by 12 months the median age was the same for both groups. Anthropometric measures showed by 12 months responders had greater weight and waist circumference averages but again significance testing was not appropriate. Responders tended to have higher baseline quality of life scores but also higher symptom burden than non-responders at the three month collection point, although 12 month responders had lower baseline symptom burden than the non-responders.

3.4.4 *Response rates*

Table 3-17: Outcome measure response rates (number of participants completed (%)) across assessment times by group (control vs experimental)

	Men with diabetes									**Post-partum women**								
	Control (n=28)			Intervention (n=33)			Total (n=61)			Control (n=9)			Intervention (n=7)			Total (n=16)		
Outcome measures	**B**	**3**	**12**	**B**	**3**	**12**	**B**	**3**	**12**	**B**	**3**	**12**	**B**	**3**	**12**	**B**	**3**	**12**
Anthropometric measures	28 (100)	16 (57)	12 (43)	33 (100)	24 (73)	20 (61)	61 (100)	40 (66)	32 (52)	9 (100)	5 (56)	4 (44)	7 (100)	4 (57)	3 (43)	16 (100)	9 (56)	7 (44)
OWLQOL /WRSM*	26 (93)	16 (57)	12 (43)	33 (100)	24 (73)	20 (61)	59 (97)	40 (66)	32 (52)	9 (100)	5 (56)	4 (44)	7 (100)	4 (57)	3 (43)	16 (100)	9 (56)	7 (44)
Predictors of Behaviour change	24 (86)	16 (57)	12 (43)	33 (100)	24 (73)	20 (61)	57 (93)	40 (66)	32 (52)	9 (100)	5 (56)	4 (44)	7 (100)	4 (57)	3 (43)	16 (100)	9 (56)	7 (44)
Accelerometers	18 (64)	11 (39)	8 (29)	23 (70)	15 (45)	15 (45)	41 (67)	26 (43)	23 (38)	5 (56)	1 (11)	2 (22)	2 (29)	3 (33)	1 (11)	7 (44)	4 (25)	3 (19)
Food diaries	17 (61)	14 (50)	7 (25)	24 (73)	18 (55)	15 (45)	41 (67)	32 (52)	22 (36)	5 (56)	2 (22)	3 (33)	3 (33)	3 (33)	2 (22)	8 (50)	5 (31)	5 (31)

Number of participants completing outcome measure (%) ***B = Baseline, 3 = 3 months, 12 = 12 months***
*OWLQOL/WRSM = Obesity and Weight Loss Quality of Life/Weight Related Symptom Measures

As expected completion rates decreased for all groups over the study time period (baseline to three months to 12 months), see Table 3-17. Total rates, for both the men and women, showed that anthropometric measures and both questionnaires (OWLQOL/WRSM and predictors of behaviour change) were completed by more participants than accelerometers and food diaries. However, the completion rate for food diaries by the women was higher than for the accelerometers, whereas for the men these two outcome measures had similar completion rates. Higher completion rates, for all of the outcome measures at all three data collection points, were revealed for the men with type 2 diabetes intervention group in comparison to the control group. For the women anthropometric measures and questionnaire completion rates were similar for the intervention and control groups. Accelerometers and food diary responses rates varied throughout the study for both intervention and control, with each arm having higher response percentages at different time points. However, one reason for this is related to the low number of participants in each arm, therefore meaning one participant could impact greatly on the percentage of completion.

Table 3-18: Reasons participants were not included in accelerometer data analysis

	Men with diabetes		**Post-partum women**	
Exclusion reasons	Control	Intervention	Control	Intervention
Refusal	5	3	1	1
Blank diary	5	6	3	0
No diary	9	6	3	1
Insufficient data	3	5	3	3

* Refusal = participant refused to wear accelerometer
* Blank diary = participants did not complete diary of wear time
* No diary = No diary was returned with accelerometer
* Insufficient data = participant did not wear accelerometer for required length of time

Table 3-18 above outlines the reasons as to why several returned accelerometers could not be included in the analysis. When no diaries were returned it was unknown as to whether the accelerometer had been worn or whether the participant was just returning the accelerometer without wearing it. One woman in the intervention group returned the accelerometer and diary but the dates completed on the diary were not recorded by the accelerometer suggesting the battery may have run out before the participant started wearing it.

3.4.5 *Anthropometric measures*

Anthropometric measurements, collected by me using calibrated instruments, were obtained for study participants at baseline, three and 12 months.

Table 3-19: Anthropometric measures for men with diabetes across assessment times by group (control vs experimental)

	Baseline						3 months						12 months					
	Control (n=28)			Intervention (n=33)			Control (n=16)			Intervention (n=24)			Control (n=12)			Intervention (n=20)		
Outcome measure	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)
Height (cm)	176.9 (6.9)	177.0 (172.5-179.4)	29 (164-193)	177.7 (7.3)	176.0 (173.8-181.5)	39.5 (158.5-198)	177.0 (6.7)	177.3 (171.4-179)	28 (169-193)	177.7 (7.7)	176.3 (174.1-181.5)	39.5 (158.5-198)	176.0 (5.7)	177.3 (170.9-179)	20 (165-185)	178.2 (8.4)	177 (173.8-182.6)	39.5 (158.5-198)
Weight (kg)	108.5 (13.4)	109.3 (96.9-119.0)	45.2 (87.2-132.3)	107.2 (10.9)	106.5 (100.1-115.4)	43.2 (86.6-129.8)	104.4 (12.2)	105.7 (92.3-114.9)	38.6 (85.5-124.1)	103.6 (10.2)	102.2 (97.4-110.3)	44.3 (84.4-128.7)	103.8 (14.3)	100.7 (91.9-118.1)	40.3 (86.1-126.4)	100.7 (12.3)	99.2 (90.7-106.8)	46.8 (81.2-128)
Weight change (kg)	-	-	-	-	-	-	-2.6 (2.7)	-2.2 (-3.7--0.9)	9.7 (-8.6-1.1)	-2.6 (2.7)	-2.35 (-4.5--0.9)	10.3 (-8.4-1.9)	-2.8 (4.4)	-2.5 (-5.0-0.2)	16.1 (-12.6-3.5)	-5.4 (5.9)	-4.3 (-7.8--1.0)	21.4 (-18.5-2.9)
5% weight loss (No. (%))	-	-	-	-	-	-	3 (18.8)	-	-	3 (12.5)	-	-	4 (33.3)	-	-	8 (40)	-	-
BMI	34.6 (3.0)	34.4 (31.6-37.0)	9.1 (30.3-39.4)	33.9 (2.6)	33.3 (31.6-36.4)	8.2 (30.4-38.6)	33.3 (2.8)	33.3 (30.8-36.1)	8.7 (28.7-37.4)	32.8 (2.4)	32.2 (31.1-34.5)	9.9 (28.4-38.3)	33.4 (3.3)	33.3 (29.9-36.8)	8.9 (29.3-38.2)	31.6 (2.6)	31.3 (29.8-33.2)	9.9 (27.5-37.4)
BMI change	-	-	-	-	-	-	-0.9 (0.9)	-0.7 (-1.1--0.2)	3.2 (-3.0-0.2)	-0.8 (0.9)	-0.9 (- 1.4--0.2)	3.4 (-2.8-0.6)	-0.9 (1.4)	-0.8 (-1.6-0.8)	5 (-3.9-1.1)	-1.3 (2.0)	-1.7 (-2.7--0.3)	7.8 (-6.5-1.3)
Waist circumference (cm)	119.7 (8.9)	119.5 (114-126.8)	32 (103-135)	117.7 (7.6)	118.0 (112-124)	33 (100-133)	117.7 (7.9)	118.5 (109.8-124.8)	22 (106-128)	115.4 (7.6)	112.5 (108.5-122.8)	26 (102-128)	118.2 (9.3)	117 (112.3-126.8)	31 (103-134)	113.1 (7.1)	112 (107-121)	21 (103-124)
Waist change (cm)	-	-	-	-	-	-	-3.2 (2.7)	-3.0 (-1.25--5.0)	11 (-9-2)	-2.5 (3.1)	-2.0 (-1.0--3.0)	14 (-11-3)	-2.6 (3.5)	-2.0 (-3.8--1.0)	12.5 (-10.5-2.0)	-4.5 (4.9)	-3.5 (-7--1.3)	19 (-17-2)

Table 3-20: Anthropometric measures for women across assessment times by group (control vs experimental)

	Baseline						3 months						12 months					
	Control (n=9)			Intervention (n=7)			Control (n=5)			Intervention (n=4)			Control (n=4)			Intervention (n=3)		
Outcome measure	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)
Height (cm)	164.1 (6.5)	161.5 (158.8-170)	18 (156-174)	165.3 (9.1)	163.0 (158.0-174.5)	24 (157-181)	164.6 (6.4)	161.5 (159.5-171.3)	14.5 (159.5-174)	168.6 (10.9)	167.8 (158.8-179.4)	10.9 (158.8-179.4)	165.9 (6.7)	165.0 (160-172.6)	14.5 (159.5-174)	171.2 (11.9)	174.5 (158-174.5)	23 (158-181)
Weight (kg)	93.9 (8.7)	94.3 (84.4-102.2)	23.8 (82.4-106.2)	94.8 (15.6)	92.0 (79-110.1)	37.2 (75.6-112.8)	93.6 (9.5)	93.0 (84.6-103.0)	23.1 (82.4-105.5)	93.2 (22.0)	91.4 (73.4-114.8)	45.9 (72-117.9)	95.0 (12.0)	94.4 (84.2-106.4)	29.2 (81-110.2)	97.0 (14.7)	102.5 (80.3-102.5)	27.9 (80.3-108.2)
Weight change (kg)	-	-	-	-	-	-	-0.1 (0.9)	-0.4 (-0.85-0.7)	2.4 (-1-1.4)	-1.2 (4.4)	-2.6 (-4.5-3.4)	9.9 (-4.8-5.1)	-0.9 (4.0)	-0.9 (-4.6-2.9)	9.7 (-5.7-4.0)	-2.5 (6.4)	-4.6 (-7.6--4.6)	12.3 (-7.6-4.7)
5% weight loss (No. (%))	-	-	-	-	-	-	0 (0)	-	-	0 (0)	-	-	1 (25)	-	-	1 (33.3)	-	-
BMI	34.9 (2.4)	33.5 (33.4-37.2)	7.1 (31.6-38.7)	34.6 (3.6)	34.4 (30.3-37.3)	10 (30-40)	34.5 (2.3)	34.1 (32.4-36.9)	5.6 (31.6-37.2)	32.4 (3.5)	32.2 (29.2-35.7)	7 (29-36)	34.5 (3.9)	34.1 (31.2-38.3)	7.7 (31.3-38.8)	33.0 (0.8)	33.1 (32.2-33.1)	1.5 (32.2-33.7)
BMI change	-	-	-	-	-	-	-0.04 (0.4)	-0.2 (-0.3-0.3)	1 (-0.4-0.6)	-0.4 (1.4)	-0.8 (-1.5-1.2)	3.1 (-1.5-1.6)	-0.3 (1.4)	-0.4 (-1.6-1.0)	3.4 (-2.0-1.4)	-0.6 (2.2)	-1.3 (-2.4--1.3)	4.3 (-2.4--1.3)
Waist circumference (cm)	114.6 (7.9)	114.0 (107-122)	22 (104-126)	108.1 (15.5)	112 (94-119)	44 (84-128)	112.0 (7.9)	111.0 (106-118.5)	21 (104-125)	103.1 (17.6)	102.5 (87.5-119.4)	33.5 (87-120.5)	112.3 (12.3)	108.0 (103.5-125.3)	27 (103-130)	105.3 (9.0)	110 (95-110)	16 (95-111)
Waist change (cm)	-	-	-	-	-	-	-0.4 (2.9)	0 (-3.0-2.0)	7 (-3-4)	-0.6 (5.4)	-0.3 (-6-4.4)	12 (-7-5)	-2.3 (5.9)	-2.5 (-7.8-3.5)	14 (-9-5)	-5.0 (5.3)	-7.0 (-9.0--7.0)	10 (-9-1)

Change variables relate to change in measurements from baseline to three months and baseline to 12 months. All changes, for men and women groups, were decreases (i.e. positive changes) at both three and 12 months. The number of men who achieved 5% weight loss of their initial body weight at three months was low, see Table 3-19, with only three (18.8%) participants from the control group and three (12.5%) from the intervention group reaching this target recommended by NICE guidelines to improve health (National Institute for Health and Clinical Excellence clinical guidelines, 2006 updated 2014). This increased at 12 months with four (33.3%) of the control arm and eight (40%) of the intervention arm losing 5% of their initial body weight. None of the participants had lost as much as 10% of their initial body weight at three months. However, at 12 months one of the control arm (8.3%) and three of the intervention arm (15%) had lost 10% of their initial body weight. As shown in Table 3-20 none of the female participants achieved 5% weight loss at three months, with only one from the intervention arm (33%) and one from the control (25%) losing 5% of their initial body weight by 12 months.

3.4.6 ***Website usage***

In relation to adherence to the intervention the website was examined in terms of users versus non users amongst those allocated to the intervention arm. ‘Users’ relates to participants who entered information onto the website. ‘Non-users’ were those participants who did not log onto to the website or only logged onto the website once and did not enter any inputs after creating their website account. The health professionals continued to send consultations irrespective of participant website use. Non-users feedback therefore was more generic and supportive, rather than specific targeted advice, due to the lack of participant information available. Participants did receive an email informing them that a consultation had been sent to them but it did require them to log on to view the web-based message. Unfortunately, it was not possible to monitor whether consultations were viewed or not by participants. However, it emerged from interview findings that non-users of the website did not log on in order to read health professional feedback.

Table 3-21: Website usage by intervention participants (number of participants (%))

	Men with type 2 diabetes			Post-partum women		
	Baseline (n=33)	3 months (n=24)	12 months (n=20)	Baseline (n=7)	3 months (n=4)	12 months (n=3)
User	16 (48)	16 (67)	12 (60)	4 (57)	4 (100)	2 (67)
Non-user	17 (52)	8 (33)	8 (40)	3 (43)	0 (0)	1 (33)

* Users relates to participants who entered information onto the website
* Non-users were those participants who did not log onto to the website or only logged onto the website once and did not enter any inputs after creating their website account

Of those at baseline who were non-users and never entered any data on the website, five (15% of all those randomised to the intervention, 29% of the non-users) never logged on to create a website account, as shown in Figure 3-2. Of the five who did not create accounts and never visited the website three failed to attend the initial face to face meeting with the dietitian. At three months the findings revealed that the nine intervention men who dropped out of the study by three months were all non-users of the website, see Figure 3-2. By the end of the study, 12/20 (60%) of the remaining men were still using the website. In contrast 6/20 (30%) ceased using the website between three and 12 months, with 2/20 (10%) never logging on but still attending the study data collection appointments. The four intervention participants who withdrew from the study before the 12 month data collection point were all non-users of the website.

Amongst the seven women allocated to the intervention group at baseline four (57%) were users of the website, with three (43%) non-users, see Table 3-21. The four intervention participants who attended their three month data collection were all users of the website, therefore none of the non-users attended their three month appointment. By 12 months, of the three intervention women remaining, two were still using the website (67%).

3.4.7 *Questionnaire findings*

Table 3-22: Questionnaire results for men across assessment times by group (experimental vs. control)

	Baseline						3 months						12 months					
	Control (n=24)*			Intervention (n=33)			Control (n=16)			Intervention (n=24)			Control (n=12)			Intervention (20)		
Outcome measure	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)
OWLQOL	30.3 (20.6)	30.0 (14-47.3)	77 (2-79)	31.2 (22.1)	29.0 (15-40.5)	88 (0-88)	25.6 (20.1)	18.5 (8.5-22.8)	63 (1-64)	28.0 (18.1)	24.5 (16.8-35.3)	81 (2-83)	75.4 (14.9)	73.5 (61.3-89.8)	46 (54-100)	76.3 (22.8)	80.5 (64.8-93.8)	79 (23-102)
WRSM	60.6 (24.4)	62.3 (39.0-80.0)	85.3 (13.7-99)	63.6 (23.9)	61.8 (49-82.4)	98 (0-98)	69.4 (19.7)	70.1 (60.1-87.3)	64.7 (29.4-94.1)	67.7 (22.7)	70.6 (51.2-86.1)	83.3 (14.7-98)	27.3 (14.6)	26.5 (15.8-39.8)	47 (5-52)	19.5 (17.1)	13.0 (6.8-31.8)	65 (0-65)
Views on weight	63.4 (15.3)	66.5 (62-71.5)	80 (0-80)	60.0 (17.4)	63 (56.5-69)	84 (0-84)	64.6 (6.4)	65.5 (61-69)	25 (52-77)	64.3 (8.9)	64.5 (58.3-92.8)	34 (44-78)	63.4 (4.3)	64.5 (62.3-66.0)	13 (55-68)	62.6 (8.4)	62.0 (57.5-65.8)	42 (41-83)
Views on personal diet	43.1 (28.3)	46.5 (23.3-67.5)	101 (0-101)	53.9 (32.3)	50 (32.5-83.5)	114 (0-114)	55.3 (23.5)	50.5 (33.3-82)	63 (26-89)	66.3 (31.4)	67 (36.5-92.8)	99 (15-114)	86.0 (23.4)	86.5 (74.5-104)	78 (43-121)	88.6 (19.3)	92.5 (71.5-104.5)	71 (53-124)
Views on physical activity	56.8 (32.3)	61.5 (30.5-81.8)	104 (0-104)	67.6 (27.3)	70 (50-83.5)	114 (0-114)	81.4 (18.0)	82.5 (67.3-95)	61 (53-114)	85.6 (26.1)	89 (71.3-108)	98 (26-124)	51.4 (31.2)	42.0 (27.5-69.5)	107 (6-113)	59.6 (36.9)	67.0 (20-98.5)	114 (3-117)
Social support	22.0 (8.8)	24 (18.8-28.8)	30 (0-30)	23.0 (7.6)	26 (19.5-29)	30 (0-30)	22.8 (7.0)	25.5 (18.3-28)	23 (7-30)	26.6 (4.1)	28.5 (24.3-29.8)	15 (15-30)	25.3 (5.3)	28.0 (21.3-28.8)	18 (12-30)	25.7 (5.6)	29.0 (21-30)	17 (13-30)

* OWLQOL = Obesity and Weight Loss Quality of Life/ WRSM = Weight Related Symptom Measures = completed by 26 participants at baseline
* Views on weight, personal diet, physical activity and social support all sections from Predictors of behaviour change questionnaire
* Higher score = more positive result in all but WRSM scores, with higher score = more burdensome symptoms

Table 3-23: Questionnaire results for women across assessment times by group (experimental vs. control)

	Baseline						3 months						12 months					
	Control (n=9)			Intervention (n=7)			Control (n=5)			Intervention (n=4)			Control (n=4)			Intervention (n=3)		
Outcome measure	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)
OWLQOL	24.8 (16.7)	26 (10-39.5)	50 (0-50)	17.9 (14.6)	23 (2-32)	32 (0-32)	26.2 (21.2)	25 (7.5-45.5)	55 (3-58)	14.3 (6.3)	13 (9-20.8)	15 (8-23)	45.5 (21.8)	43.5 (26.5-66.5)	43 (26-69)	56.3 (15.0)	64.0 (39-64)	27 (39-66)
WRSM	29.1 (16.9)	25.5 (16.7-41.7)	49 (10.8-59.8)	46.4 (6.8)	48 (38.2-51)	18.6 (36.3-54.9)	37.4 (17.5)	35.3 (21.6-54.4)	42.1 (20.6-62.7)	46.3 (9.3)	45.1 (38.3-55.6)	22.5 (36.3-58.8)	18.5 (6.0)	18.5 (12.8-24.3)	13 (12-25)	11.3 (7.8)	9.0 (5-9)	15 (5-20)
Views on weight	71.9 (3.3)	72 (69.5-74)	11 (67-78)	67.7 (5.9)	70 (60-72)	15 (59-74)	71.2 (5.0)	71 (67.5-75)	14 (64-78)	68.5 (4.1)	68 (65-72.5)	10 (64-74)	70.8 (4.4)	71.0 (66.5-74.8)	9 (66-75)	68.3 (11.7)	73.0 (55-73)	22 (55-77)
Views on personal diet	28.4 (19.5)	31 (6-43)	52 (1-53)	59.7 (25.0)	58 (43-87)	72 (23-95)	43.4 (28.9)	47 (14.5-70.5)	69 (10-79)	62.5 (41.2)	62.5 (22.8-102.3)	93 (16-109)	63.8 (40.0)	65.5 (24.5-101.2)	88 (18-106)	92.0 (29.1)	103.0 (59-103)	55 (59-114)
Views on physical activity	61.2 (17.0)	62 (43-75)	47 (41-88)	78.7 (22.4)	71 (65-102)	65 (50-115)	70.4 (30.7)	81 (39.5-96)	76 (26-102)	66.8 (47.5)	60.5 (25-114.8)	102 (22-124)	57.3 (31.3)	52.0 (30.8-89)	65 (30-95)	96.3 (11.7)	101.0 (83-101)	22 (83-105)
Social support	26.4 (5.2)	28 (24.5-30)	16 (14-30)	25.0 (3.2)	25 (23-27)	10 (20-30)	24.2 (7.2)	26 (18-29.5)	18 (12-30)	19.3 (13.3)	24 (5.3-28.5)	29 (0-29)	21.0 (8.5)	20.0 (13-20)	17 (13-30)	21.3 (11.7)	26.0 (8-26)	22 (8-30)

* OWLQOL = Obesity and Weight Loss Quality of Life/ WRSM = Weight Related Symptom Measures
* Views on weight, personal diet, physical activity and social support all sections from Predictors of behaviour change questionnaire
* Higher score = more positive result in all but WRSM scores, with higher score = negative and more burdensome symptoms

The various questionnaires given to participants and how they were scored are shown in Table 3-4. Table 3-22 above examines the questionnaire results for men with diabetes. Table 3-23 above illustrates the post-partum women questionnaire findings and shows how those remaining in the study completed the questionnaires provided, with no participant refusing to complete either the OWLQOL/WRSM or the 'Predictors of behaviour change' questionnaires. Full response rates were shown earlier in Table 3-17.

Table 3-24: Men with type 2 diabetes Questionnaire score changes from baseline to 3 and 12 months

	3 months		12 months	
	Control (n=16)	**Intervention (n=24)**	**Control (n=12)**	**Intervention (n=20)**
Outcome measure	Median (LQ;UQ)	Median (LQ;UQ)	Median (LQ;UQ)	Median (LQ;UQ)
OWLQOL change	2.0 (-4.7;9.3)	-2.0 (-7.8;9.8)	0.5 (-3.3;13.6)	3.2 (-0.2;13.5)
WRSM change	-2.5 (-8;3.8)	-3 (-12.8;7.8)	0.5 (-9;3.8)	-10 (-20.0;-1.3)
Views on weight change	1.5 (-5.3;4.8)	1.0 (-5.0;5.0)	-2 (-6.0;2.0)	-2 (-8.3;4.0)
Views on personal diet change	17 (2.5;60)	22.6 (4.3;39.8)	28.5 (-24.5;79)	14.5 (-7.3;37.5)
Views on physical activity change	20 (1.0;36.8)	15.5 (-12;54)	23 (-39.8;46.0)	17 (-33.0;72.0)
Social support change	0 (0;2.8)	0 (0;2.0)	1 (0;7.0)	1 (0;3.0)

* Change scores increasing show positive improvements for each of the sections, except WRSM change where scores would need to decrease to show improvement for participant symptoms

Table 3-25: Post-partum women Questionnaire score changes from baseline to 3 and 12 months

	3 months		12 months	
	Control (n=5)	**Intervention (n=4)**	**Control (n=4)**	**Intervention (n=3)**
Outcome measure	Median (LQ;UQ)	Median (LQ;UQ)	Median (LQ;UQ)	Median (LQ;UQ)
OWLQOL change	9.8 (-2.9;17.6)	-2 (-9.1;9.6)	5.4 (-0.4-5.4)	9.1 (-7.1-9.1)
WRSM change	3 (-1.5;5.5)	-8 (-20.3;7.3)	11 (-4;11)	18.3 (-27;-3)
Views on weight change	-3 (-5.0;3.0)	-2 (-6.3;0)	0 (-2;0)	2 (-13;2)
Views on personal diet change	-2 (-25.0;44.5)	-14 (-79;57.8)	4 (-18;4)	32 (-19;32)
Views on physical activity change	9 (-19.5;48.5)	4 (-36.8;21.5)	23 (-13;23)	42 (25;42)
Social support change	-1 (-3;2.5)	-2 (-24;5.0)	-1 (-3;-1)	1 (-19;1)
* Change scores increasing show positive improvements for each of the sections, except WRSM change where scores would need to decrease to show improvement for participant symptoms				

OWLQOL scores increased for men and women, control and intervention arms, when examining change from baseline to 12 months, suggesting increased quality of life. Symptom burden (WRSM scores) had lowered by 12 months for both men and women intervention arms, implying less bothersome weight related symptoms. In contrast, symptom burden increased for both control arms (men and women), suggesting that by 12 months participants in the control arms were experiencing more burden/problems from the symptoms associated with their weight , i.e. their sleep or breathing problems had deteriorated. Social support increased for both the groups of men but decreased for both women groups by 12 months suggesting decreased perceived levels of social support within the women. Participants scores for the 'views on weight' section decreased for both arms, men and women, contrary to increased scores for 'views on physical activity' and 'views on diet, scores (except men's 'views on physical activity' decreasing from three to 12 months). This implies participants tended to have

more positive views on physical activity and diet by the end of the study but more negative views on their weight.

There were no missing questions in either the OWLQOL or WRSM where as missing data within the Predictors of Behaviour Change questionnaire did occur.

Table 3-26: Missing data from Predictors of behaviour change questionnaire (number of participants not answering set questions)

Men with diabetes	**Views on diet section**						**Views on physical activity section**						**Views on weight section**
	Q1	**Q2**	**Q3**	**Q4**	**Q5**	**Q6**	**Q1**	**Q2**	**Q3**	**Q4**	**Q5**	**Q6**	**Q8**
Baseline	3	3	3	1	1	3	1	0	1	2	2	2	0
3 months	0	0	0	0	0	0	0	0	0	0	0	0	0
12 months	0	0	0	1	0	0	0	1	1	0	2	0	1
Post-partum women	**Views on diet section**						**Views on physical activity section**						
	Q10-24						**Q12-23**						
Baseline	1						1						
3 months	1						0						
12 months	1						0						

Missing data

Missing data at baseline was identified with the full section on ‘views on weight’ uncompleted by one man. At three months two women participants missed the full section of ‘social support’. No full sections were missing for 12 month completed questionnaires.

Missing individual questions were identified at baseline, three months (women only) and 12 months, shown in Table 3-26. Questions 10 to 24 from the ‘views on diet’ section and questions 12 to 23 from ‘views on physical activity’ each made up two pages of the questionnaire and therefore it is likely the participants turned over two pages within the questionnaire bypassing these questions. It appeared that men were more likely to miss individual questions with women more likely to miss full sections. However, it was not the same participant that missed the full ‘views on diet’ section at each time point. All other question numbers not included within Table 3-26 were completed by all remaining participants. Although this illustrates that missing data did occur, this was low most participants completing all questions.

Table 3-27: Predictors of behaviour change for men across assessment times by group (experimental vs. control)

	Baseline						3 months						12 months					
	Control (n=24)			Intervention (n=33)			Control (n=16)			Intervention (n=24)			Control (n=12)			Intervention (n=20)		
Questionnaire Measures	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)
Physical activity:																		
Attitude	4.4 (2.6)	5.6 (2.4-6.3)	6 (1-7)	4.8 (2.2)	5.5 (3.7-5.8)	6 (1-7)	5.6 (1.0)	5.8 (5.2-6.4)	4 (3-7)	5.4 (1.5)	6.0 (4.7-6.6)	6 (1-7)	5.6 (1.0)	6.0 (4.7-6.4)	3 (4-7)	5.5 (1.2)	5.9 (4.5-6.3)	4 (3-7)
Control	4.4 (2.5)	5.3 (3.4-6.3)	6 (1-7)	4.6 (2.3)	5.0 (2.5-6.8)	6 (1-7)	5.6 (0.8)	5.7 (5.3-6.0)	3 (4-7)	5.3 (1.8)	5.8 (4.8-6.6)	6 (1-7)	5.2 (2.0)	6.0 (4.2-6.6)	6 (1-7)	5.2 (2.0)	6.0 (4.2-6.6)	6 (1-7)
Intention	4.6 (2.6)	6.0 (4-6.8)	5 (2-7)	4.9 (2.3)	6.0 (4-7)	5 (2-7)	5.8 (0.9)	6.0 (5-6.8)	3 (4-7)	5.7 (2.0)	6.0 (5.3-7)	6 (1-7)	5.7 (1.4)	6.0 (5-7)	5 (2-7)	5.3 (1.9)	6.0 (4-7)	6 (1-7)
Subjective norms	4.6 (2.8)	6.0 (1.8-7)	6 (1-7)	4.9 (2.5)	6.0 (3-7)	5 (2-7)	5.5 (1.6)	6.0 (4.3-7)	6 (1-7)	5.1 (2.1)	6.0 (4-7)	6 (1-7)	5.6 (1.4)	6.0 (4.3-7)	4 (3-7)	5.1 (1.8)	6.0 (4-6.8)	6 (1-7)
Action planning	2.2 (2.0)	1.7 (0.3-4)	5 (1-6)	3.5 (2.3)	3.0 (1-5.8)	6 (1-7)	3.2 (1.8)	2.5 (1.8-5)	5 (1-6)	4.4 (2.2)	5.0 (2.3-6)	6 (1-7)	3.0 (2.2)	2.2 (1.2-4.3)	6 (1-7)	3.8 (2.4)	4.8 (1-6)	6 (1-7)
Coping planning	1.7 (1.5)	1.5 (0.3-2.9)	5 (1-6)	3.2 (2.1)	2.3 (1-5.2)	6 (1-7)	3.1 (1.4)	3.3 (1.8-4)	4 (1-5)	3.7 (1.9)	4.0 (1.8-5.3)	6 (1-7)	2.5 (1.9)	1.7 (1-3.6)	6 (1-7)	3.6 (2.2)	3.8 (1-5.3)	6 (1-7)
Action Control	2.1 (1.9)	1.6 (0.3-2.8)	6 (1-7)	3.0 (1.9)	2.5 (1.3-4.6)	6 (1-7)	3.2 (1.7)	3.6 (1.4-4.5)	5 (1-6)	4.1 (2.0)	4.0 (2.5-5.9)	6 (1-7)	2.9 (1.9)	2.1 (1.4-3.8)	6 (1-7)	3.7 (2.3)	3.8 (1-5.8)	6 (1-7)

	Baseline						3 months						12 months					
	Control (n=24)			Intervention (n=33)			Control (n=16)			Intervention (n=24)			Control (n=12)			Intervention (n=20)		
Questionnaire Measures	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)
Personal diet:																		
Attitude	4.5 (2.7)	6.0 (0.8-6.5)	6 (1-7)	5.2 (1.9)	5.5 (4.7-6.7)	6 (1-7)	3.4 (2.9)	5.0 (1-6)	6 (1-7)	4.3 (2.8)	5.7 (1-6.6)	6 (1-7)	5.8 (0.9)	5.7 (5.2-6.8)	3 (4-7)	5.6 (1.1)	5.8 (5.4-6.5)	5 (2-7)
Control	4.8 (2.7)	6.0 (3.7-6.7)	6 (1-7)	5.6 (1.6)	6.0 (4.8-6.8)	5 (2-7)	3.6 (3.1)	5.3 (1-6)	6 (1-7)	4.4 (2.9)	6.0 (1-6)	6 (1-7)	6.1 (0.9)	6.0 (5.3-7)	3 (4-7)	6.1 (0.9)	6.0 (5.8-6.9)	3 (4-7)
Intention	5.0 (2.7)	6.0 (5-7)	4 (2-6)	5.6 (1.6)	6.0 (5-7)	4 (2-6)	3.6 (3.1)	5.0 (1-6)	6 (1-7)	4.4 (2.9)	6.0 (1-6.5)	6 (1-7)	2.1 (3.0)	1.0 (1-5.5)	6 (1-7)	3.8 (3.2)	5.5 (1-7)	6 (1-7)
Subjective norms	4.7 (3.0)	6.5 (0.3-7)	6 (1-7)	6.0 (1.8)	7.0 (6-7)	5 (2-7)	3.7 (3.2)	4.0 (1-7)	6 (1-7)	4.4 (3.0)	6.0 (1-7)	6 (1-7)	6.3 (1.1)	7.0 (6-7)	3 (4-7)	6.3 (1.2)	7.0 (6-7)	4 (3-7)
Action planning	2.9 (2.0)	3.5 (1-4.5)	5 (1-6)	4.2 (1.9)	4.0 (2.9-6)	6 (1-7)	2.7 (2.6)	3.0 (1-5)	6 (1-7)	3.8 (2.7)	5.0 (1-6)	6 (1-7)	4.8 (1.7)	4.8 (4-6.4)	6 (1-7)	5.5 (1.5)	5.9 (5-6.5)	6 (1-7)
Coping planning	2.5 (1.9)	3.0 (1-4)	6 (1-7)	3.5 (1.8)	3.3 (2-5)	6 (1-7)	2.5 (2.3)	2.7 (1-4.7)	5 (1-6)	3.2 (2.5)	4.0 (1-5.3)	6 (1-7)	3.6 (2.0)	4.0 (1.3-5.5)	6 (1-7)	4.8 (1.9)	5.2 (3.8-6)	6 (1-7)
Action Control	2.8 (2.1)	2.8 (1-4.9)	6 (1-7)	3.6 (1.8)	3.2 (2.2-5.4)	6 (1-7)	2.9 (2.7)	3.7 (1-5.3)	6 (1-7)	3.6 (2.6)	4.0 (1-5.9)	6 (1-7)	4.7 (2.0)	5.6 (2.7-6)	6 (1-7)	5.0 (1.3)	5.1 (3.8-6)	4 (3-7)

* All questionnaire measures (theoretical constructs) were based on seven point Likert scales, with 1 = the lowest, most negative score and 7 = the highest, most positive score

Table 3-28: Predictors of behaviour change for women across assessment times by group (experimental vs. control)

	Baseline						3 months						12 months					
	Control (n=9)			Intervention (n=7)			Control (n=5)			Intervention (n=4)			Control (n=4)			Intervention (n=3)		
Questionnaire Measures	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)
Physical activity:																		
Attitude	5.7 (1.2)	6.0 (4.4-6.9)	3 (4-7)	5.8 (0.9)	6.2 (5.5-6.5)	3 (4-7)	5.6 (1.3)	5.2 (4.5-7)	3 (4-7)	5.3 (1.0)	5.4 (4.3-6.3)	3 (4-7)	6.0 (0.7)	5.9 (5.5-6.8)	2 (5-7)	6.6 (0.4)	6.7 (6.2-6.7)	1 (6-7)
Control	5.4 (0.9)	5.7 (4.7-6)	3 (4-7)	6.2 (0.5)	6.3 (6-6.7)	2 (5-7)	4.8 (1.4)	4.0 (3.7-6.3)	3 (4-7)	5.9 (0.3)	5.8 (5.7-6.3)	1 (6-7)	5.2 (1.3)	5.5 (3.8-6.3)	3 (3-6)	6.8 (0.4)	7.0 (6.3-7.0)	1 (6-7)
Intention	5.0 (1.3)	5.0 (4.5-6)	4 (2-6)	6.3 (0.8)	6.0 (6-7)	2 (5-7)	5.4 (1.1)	5.0 (4.5-6)	3 (4-7)	6.5 (0.6)	6.5 (6-7)	1 (6-7)	5.3 (1.5)	5.0 (4-6.8)	3 (4-7)	7.0 (0)	7.0 (7-7)	0 (7-7)
Subjective norms	5.0 (1.9)	5.0 (4-7)	6 (1-7)	4.7 (2.8)	6.0 (1-7)	6 (1-7)	4.8 (1.3)	4.0 (4-6)	3 (4-7)	5.0 (2.7)	6.0 (2.3-6.8)	6 (1-7)	5.5 (1.3)	5.5 (4.3-6.8)	3 (4-7)	4.3 (3.1)	5.0 (1-5)	6 (1-7)
Action planning	2.4 (1.5)	2.3 (1-3.3)	4 (1-5)	3.5 (2.4)	4.0 (1-5)	6 (1-7)	2.4 (1.9)	1.0 (1-4.5)	4 (1-5)	2.9 (1.9)	2.7 (1.3-4.8)	4 (1-5)	3.2 (2.6)	2.8 (1-5.7)	5 (1-6)	6.7 (0.6)	7.0 (6-7)	1 (6-7)
Coping planning	2.4 (1.6)	2.3 (1-4.2)	4 (1-5)	2.6 (1.6)	3.0 (1-4)	4 (1-5)	1.8 (1.3)	1.0 (1-3)	3 (1-4)	2.5 (1.3)	2.5 (1.3-3.8)	3 (1-4)	3.0 (2.5)	2.5 (1-5.5)	5 (1-6)	5.1 (1.3)	5.7 (3.7-5.7)	2 (4-6)
Action Control	2.3 (1.0)	2.3 (1.6-2.8)	3 (1.4)	2.7 (1.7)	3.3 (1-4.2)	4 (1-5)	2.7 (1.6)	3.5 (1-4.1)	4 (1-5)	3.2 (2.0)	3.3 (1.3-4.9)	4 (1-5)	3.4 (1.1)	3.3 (2.4-4.5)	3 (2-5	5.6 (1.6)	6.0 (3.8-6)	3 (4-7)

	Baseline						3 months						12 months					
	Control (n=9)			Intervention (n=7)			Control (n=5)			Intervention (n=4)			Control (n=4)			Intervention (n=3)		
Questionnaire Measures	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)
Personal diet:																		
Attitude	5.9 (1.0)	6.2 (5.2-6.8)	3 (4-7)	6.2 (0.6)	6.0 (5.8-6.8)	2 (5-7)	3.5 (3.3)	5.0 (1-7)	6 (1-7)	4.4 (3.4)	6.2 (1-7)	6 (1-7)	5.8 (0.6)	5.8 (5.3-6.5)	2 (5-7)	5.1 (0.3)	5.0 (4.8-5)	1 (5-6)
Control	6.2 (0.5)	6.3 (5.8-6.7)	2 (5-7)	5.3 (1.9)	6.0 (4-7)	5 (2-7)	3.1 (3.0)	5.0 (1-5.8)	5 (1-6)	3.8 (3.0)	5.0 (1-6)	6 (1-7)	4.8 (2.0)	5.3 (2.8-6.4)	5 (2-7)	5.2 (2.3)	6.0 (2.7-6)	4 (3-7)
Intention	6.6 (0.5)	7.0 (6-7)	1 (6-7)	5.6 (2.5)	6.0 (6-7)	6 (1-7)	3.2 (3.2)	4.0 (1-6)	6 (1-7)	3.2 (3.5)	2.5 (1-7)	6 (1-7)	2.0 (2.1)	2.5 (2-5.5)	6 (1-7)	4.3 (3.8)	6.0 (1-6)	6 (1-7)
Subjective norms	6.1 (0.8)	6.0 (5.5-7)	2 (5-7)	4.9 (2.5)	6.0 (2-7)	6 (1-7)	3.3 (3.3)	4.0 (1-7)	6 (1-7)	3.3 (3.4)	3.0 (1-7)	6 (1-7)	5.5 (1.3)	5.5 (4.3-6.8)	3 (4-7)	4.3 (3.1)	5.0 (1-5)	6 (1-7)
Action planning	4.3 (1.9)	4.5 (2.9-5.9)	6 (1-7)	3.5 (2.3)	4.0 (1-5.5)	6 (1-7)	2.0 (2.5)	1.0 (1-5)	5 (1-6)	2.2 (3.1)	0.5 (1-5.5)	6 (1-7)	3.0 (2.9)	3.0 (0.3-5.8)	5 (1-6)	6.7 (0.6)	7.0 (6-7)	1 (6-7)
Coping planning	4.0 (2.0)	4.0 (2.3-5.5)	6 (1-7)	2.5 (1.5)	3.0 (1-4)	4 (1-5)	1.9 (2.4)	1.0 (1-4.3)	5 (1-6)	1.9 (2.9)	0.5 (1-4.5)	6 (1-7)	2.9 (2.9)	2.7 (0.3-5.8)	6 (1-7)	5.0 (2.6)	6.0 (2-6)	5 (2-7)
Action Control	4.0 (1.4)	4.2 (3.2-4.8)	5 (2-7)	2.7 (2.0)	2.5 (0.5-5)	5 (1-6)	2.2 (2.4)	1.5 (1-4.9)	5 (1-6)	2.2 (3.1)	0.5 (1-5.6)	6 (1-7)	3.8 (2.9)	4.0 (1.0=6.3)	6 (1-7)	5.2 (2.7)	6.7 (2-6.7)	5 (2-7)

* All questionnaire measures (theoretical constructs) were based on seven point Likert scales, with 1 = the lowest, most negative score and 7 = the highest, most positive score

Overall scores from the Predictors of Behaviour Change questionnaire are presented in Table 3-22 described earlier. However, two sections ‘views on personal diet’ and ‘views on physical activity’ within the questionnaire comprise of several different predictors, see Table 3-4 for full descriptions. Results in Table 3-27 above outline the scores or the individual predictors within these two sections for the men in the study. Similar scores for intervention and control group participants were observed for the attitude, control, intention and subjective norm constructs, within the physical activity section. The intervention group had slightly higher scores at baseline but slightly lower than the control group by three and 12 months. The other constructs action planning, coping planning and action control achieved lower scores, with coping planning the lowest. The intervention group had higher scores at all time points compared to the control group. Both the intervention group and control group scores increased from baseline to 12 months. These findings were very similar for the personal diet section except intention was higher than attitude, subjective norms and control by 12 months in both groups.

Table 3-28 outlines the results identified for the women in the study and their predictor construct scores. The scores identified were very similar for the men and women in the physical activity scores except attitude scores in the women were higher than intention, control and subjective norms throughout. Subjective norm scores were lowest at each time point. As with the men, the women’s action planning, coping planning and action control scores were lower than attitude, intention, control and subjective norms scores. The intervention group scored higher than the control group throughout but both groups increased their scores from baseline to 12 months. Diet scores followed a similar pattern to the physical activity scores, as they did within the men, except attitude, intention, control and subjective norms scores decreased form baseline to three and 12 months. Action planning, coping planning and action control scores were lower again, except for the control subjective norm scores being lower and the intervention action planning scores being higher at 12 months. Action planning, coping planning and action control scores were higher in the control group at baseline but

decreased from baseline to 12 months while intervention scores increased making their scores higher than the control's group by 12 months.

A minimum size of 300-400 participants has been suggested as appropriate to conduct reliability testing (Kline, 1986; Charter, 1999; Charter, 2003; Yurdugul, 2008) as low sample sizes mean alpha coefficients can be unstable. When small sample sizes are used to test internal consistency they cannot produce sufficiently precise reliability coefficients (Charter, 2003). However, the literature is variable and other findings state sample size calculations should be based on the number of items/questions relating to each construct within a questionnaire, as well as power and error values in contrast to rules of thumb (Novick and Lewis, 1967; Cortina, 1993). To assess whether measuring of internal consistency for each of the constructs, using Cronbach's alpha (Cronbach, 1951) was possible in relation to the study's sample size a computer programme (https://www.statstodo.com/SSiz1Alpha_Pgm.php) was utilised to identify appropriate sample size needed. Computed sample sizes showed the study's sample size was adequate to conduct reliability testing. All constructs were calculated, see Table 3-29 below, except intention and subjective norms for both diet and physical activity as these only consisted of one question each and therefore internal consistency could not be assessed.

Table 3-29: Cronbach alpha for each theoretical construct within the Predictor of Behaviour Change questionnaire

Theoretical Construct	Gender	
	Men	**Women**
Physical activity		
Attitude	0.91	0.86
Perceived Behavioural Control	0.92	0.67
Action Planning	0.96	0.98
Coping Planning	0.97	0.97
Action Control	0.95	0.91
Diet		
Attitude	0.85	0.70
Perceived Behavioural Control	0.90	0.82
Action Planning	0.91	0.96
Coping Planning	0.93	0.98
Action Control	0.93	0.89
* Cronbach alpha is recommended to be ≥ 0.7 to show internal consistency (Nunnally, 1967)		

The Cronbach alpha scores identified, see Table 3-29 above, show strong internal consistency with all but one construct achieving ≥ 0.7 as recommended for non-clinical studies (Nunnally, 1967; Bland and Altman, 1997). The one construct which was slightly < 0.7, 0.67, was perceived behavioural control for physical activity within women participants. The alpha scores identified also compare closely to those found in a previous study which used the Predictor of Behaviour Change questionnaire (Sniehotta *et*

al., 2011) and further confirms the questionnaire items as a reliable method to measure the included theoretical constructs.

Table 3-30: Predictor of behaviour change score changes from baseline to 3 and 12 months in men

	3 months		12 months	
	Control (n=16)	**Intervention (n=24)**	**Control (n=12)**	**Intervention (n=20)**
Questionnaire Measures	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
Personal diet: Attitude change	-1.0 (3.8)	-0.9 (2.8)	0.8 (2.2)	-0.1 (1.4)
Control change	-1.1 (4.0)	-1.3 (2.7)	0.8 (2.8)	0.3 (1.5)
Intention change	-1.3 (4.0)	-1.4 (2.7)	-3.3 (3.2)	-2.2 (3.3)
Subjective norms change	-1.0 (3.9)	-1.6 (3.2)	1.0 (1.7)	0.1 (1.7)
Action planning change	-0.3 (2.7)	-0.3 (3.0)	1.5 (2.7)	1.0 (1.9)
Coping planning change	-0.1 (2.8)	-0.3(2.6)	0.9 (2.5)	1.3 (2.5)
Action Control	0 (2.7)	0 (2.4)	1.4 (3.5)	1.1 (1.9)
Physical activity: Attitude change	1.1 (2.2)	0.5 (2.6)	1.0 (2.6)	0.5 (2.1)
Control change	1.2 (1.8)	0.6 (2.4)	0.6 (1.9)	0.7 (1.8)
Intention change	1.1 (2.5)	0.8 (2.5)	0.8 (3.0)	0.6 (2.5)
Subjective norms change	0.8 (2.0)	0.3 (3.2)	0.6 (2.9)	0.3 (2.8)
Action planning change	1.3 (1.7)	0.6 (1.9)	1.0 (2.1)	0.1 (2.5)
Coping planning change	1.4 (1.8)	0.5 (1.8)	0.7 (1.6)	0.6 (2.2)
Action Control change	1.1 (1.9)	0.8 (1.8)	0.7 (1.9)	0.5 (2.3)

*For all predictors a positive score = participant has increased/improved with regards to that particular predictor.

Table 3-31: Predictors of behaviour change score changes from baseline to 3 and 12 months in women

	3 months		12 months	
	Control (n=5)	**Intervention (n=4)**	**Control (n=3)**	**Intervention (n=3)**
Questionnaire Measures	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
Personal diet: Attitude change	-2.4 (2.7)	-1.8 (3.7)	-1.0 (0.5)	-1.0 (0.8)
Control change	-3.1 (3.1)	-1.4 (2.9)	-1.5 (2.1)	-0.6 (0.7)
Intention change	-3.3 (3.4)	-2.3 (3.4)	-4.6 (3.1)	-2.3 (4.2)
Subjective norms change	-2.8 (3.9)	-1.7 (4.7)	-0.3 (1.0)	1.0 (2.6)
Action planning change	-2.3 (2.9)	-1.0 (2.5)	-1.1 (2.3)	3.4 (3.1)
Coping planning change	-2.1 (3.1)	-0.4 (3.2)	-0.6 (1.8)	3.2 (3.2)
Action Control	-1.8 (2.1)	-0.5 (2.1)	-1.2 (1.6)	1.8 (4.9)
Physical activity: Attitude change	-0.5 (0.7)	-0.7 (1.5)	-0.5 (0.6)	0.4 (0.9)
Control change	-0.3 (1.4)	-0.6 (0.7)	-0.3 (1.8)	0.2 (0.2)
Intention change	1.0 (2.2)	0.5 (1.3)	0.8 (2.9)	0.7 (0.6)
Subjective norms change	-0.4 (1.8)	1.0 (2.7)	0 (1.4)	1.3 (2.3)
Action planning change	0.2 (1.3)	-0.9 (1.4)	0.7 (1.8)	2.9 (4.0)
Coping planning change	-0.2 (0.4)	0.1 (0.8)	0.8 (2.2)	3.2 (2.3)
Action Control change	0.6 (1.3)	0 (1.5)	1.0 (1.2)	2.8 (3.8)

*For all predictors a positive score = participant has increased/improved with regards to that particular predictor.

Scores changes, from baseline to three months and baseline to 12 months, for the various predictors of change within the diet and physical activity sections were calculated and can be seen above in Table 3-30 for the men with diabetes. The diet section from baseline to three showed slight decreases in all scores except for action control in both groups, meaning scores had worsened for the majority of the predictor of behaviour change constructs for diet. Baseline to 12 months identified slight increases for all except intention for both groups and attitude for the intervention group. The

physical activity section showed increases for all constructs at three and 12 months, illustrating slight improvements in the predictor of behaviour change constructs relating to physical activity. The missing data in relation to the Predictor of Behaviour Change questionnaire was presented in Table 3-26. Questions that were unanswered/missing from the questionnaires completed by the men were questions relating to attitude for both diet and physical activity. This was most probably owing to the presentation of the attitude questions, with all six questions grouped directly underneath each other with no gaps between. This may have led the men to view them as one question rather than the men purposively missing these questions.

For the women in the study all construct scores decreased from baseline to three months, with a greater decrease in the control group, see Table 3-31. Similar occurred in the control group by 12 months but the intervention group had mixed changes with all increasing except attitude, control and intention. For the physical activity section again mixed results were identified, with all very minor scores changes. By 12 months the majority of scores had increased slightly except for attitude and control in the control group. The questions that were missed by the female participants were in relation to action planning, coping planning, action control and social support but this may have been due to complete pages being missed out owing to questionnaire length and presentation rather than purposively not answering the questions.

3.4.8 *Table 3-31* ***Physical activity data***

Table 3-32: Physical activity data for men across assessment times by group (experimental vs. control)

	Baseline						3 months						12 months					
	Control (n=18)			Intervention (n=23)			Control (n=11)			Intervention (n=15)			Control (n=8)			Intervention (n=15)		
Physical activity Measures	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)
Days Reported	7.0 (0)	7 (7-7)	0 (7-7)	6.8 (0.7)	7 (7-7)	3 (4-7)	7.0 (0)	7 (7-7)	0 (7-7)	6.8 (0.6)	7 (7-7)	2 (5-7)	6.9 (0.4)	7 (7-7)	1 (6-7)	6.7 (0.6)	7 (7-7)	2 (5-7)
Days worn	6.0 (1.7)	7 (4.8-7)	5 (3-7)	6.4 (0.8)	7 (6-7)	3 (4-7)	6.6 (0.9)	7 (7-7)	3 (4-7)	6.4 (1.1)	7 (6-7)	4 (3-7)	6.1 (1.1)	6.5 (5.3-7)	3 (4-7)	6.3 (1.2)	7 (6-7)	4 (3-7)
Weekly minutes	4128 (1296)	4606 (3045-5255)	4196 (1355-5551)	4101 (1425)	4041 (3617-5170)	4209 (2145-6354)	5001 (1026)	5257 (4746-5610)	3574 (2551-6125)	4402 (1220)	4498 (4082-5347)	4587 (1540-6127)	3637 (967)	3499 (3236-4575)	2870 (1816-4686)	3911 (1212)	4333 (2532-4617)	4073 (2010-6083)
Mean cpm*	186.6 (114)	192.4 (148.3-221.4)	543.7 (3.4-547.1)	179.6 (87.1)	180.3 (117.5-242.9)	268.5 (89.5-357.9)	271.4 (147.9)	243.3 (153.5-387)	500 (110.5-611)	210.0 (116.3)	180.8 (98.8-259.7)	410 (76.4-486.5)	234.7 (147)	170 (133.2-408.9)	375.1 (74.5-449.6)	252.7 (144.9)	232.9 (165.8-327.7)	577.2 (72.4-649.6)
Weekly hours	68.8 (21.6)	76.8 (50.8-87.6)	69.9 (22.6-92.5)	64.6 (27.1)	67.3 (60.3-79.4)	104.5 (1.4-105.9)	83.4 (17.1)	87.6 (79.1-93.5)	59.6 (42.5-102.1)	73.4 (20.4)	75 (68-89.1)	76.5 (25.7-102.1)	60.6 (16.1)	58.3 (53.9-76.3)	47.8 (30.3-78.1)	65.2 (20.2)	72.2 (42.2-77)	67.9 (33.5-101.4)
Total Sedentary minutes	3008.4 (992)	3204 (2345-3947)	3408 (1007-4415)	2835.7 (1222)	2856 (2421-3543)	4732 (301-5024)	3070.5 (1309)	3217 (2196-4326)	4457 (217-4674)	3155.8 (916)	3135 (2727-3686)	3717 (1138-4855)	2711.2 (858)	2642.3 (2364-3337)	2886.3 (1036-3922)	2896 (822)	3136.8 (1892-3254)	2585.8 (1641-4227)
Sedentary percent	72.9 (7.3)	72.8 (68-75.9)	30.5 (59.9-90.4)	69.0 (15.8)	71.4 (64.2-79.3)	74.3 (7.7-82)	67.7 (8.7)	68.5 (65.1-72.5)	31.7 (45.9-77.6)	74.0 (6.6)	73.4 (70.7-76.8)	25.6 (61.4-87)	73.5 (9.9)	77.4 (63.6-81.4)	26.7 (57-83.7)	75.1 (7.0)	75.1 (68.2-81.6)	22 (63.8-85.8)
Total MVPA minutes	66.1 (56.2)	49 (11.5-114)	179 (1-180)	64.3 (51.7)	55 (15.5-116)	181 (7-188)	166.6 (181.2)	81 (31-248)	519 (6-525)	101.4 (104.4)	62 (27-145)	362 (2-364.8)	113.2 (124)	59.5 (35.1-211.6)	345.8 (12.3-358)	145.7 (125.4)	127 (51-214.8)	502.5 (4.3-506.8)

	Baseline						3 months						12 months					
	Control (n=18)			Intervention (n=23)			Control (n=11)			Intervention (n=15)			Control (n=8)			Intervention (n=15)		
Physical activity Measures	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)
MVPA minutes per day	11.6 (9.9)	8.7 (2.7-17.9)	35.2 (0.3-35.5)	10.7 (8.6)	8.2 (2.9-17.7)	30.8 (1-31.8)	24.9 (25.6)	13.5 (4.4-35.4)	74.1 (0.9-75)	14.3 (15.7)	8.9 (0.8-18.4)	52.1 (0-52)	19.0 (20.0)	11.7 (5.3-41.3)	49.4 (1.8-51.1)	21.5 (17.3)	18.1 (8.5-30.7)	71.7 (0.7-72.4)
MVPA percent	1.7 (1.7)	1.3 (0.4-2.2)	6.7 (0.04-6.7)	1.6 (1.3)	1.4 (0.3-2.4)	6.7 (0-6.7)	3.4 (3.6)	1.7 (0.5-4.6)	10.9 (0.1-11)	2.3 (2.3)	2.1 (0.5-3.3)	8.4 (0.1-8.5)	3.0 (2.8)	1.9 (1.1-5.9)	7.5 (0.3-7.8)	3.4 (2.2)	3.3 (1.5-5.1)	8.1 (0.2-8.3)
Weekly steps	23250 (10864)	26754 (15810-30431)	37007 (3248-40255)	23588 (13209)	23833 (15388-34111)	46570 (5117-51687)	38510 (21136)	26668 (24222-54692)	63929 (17884-81813)	26770.6 (17233.0)	22144 (12775-40725)	57825 (3059-60884)	24004 (14890)	18876 (13682-34915)	42497 (11385-53882)	29494 (19022)	26555 (14064-41345)	75569 (3561-79130)
Average steps per day	3762 (1397)	3876 (2712-5009)	4669 (1081-5751)	3926 (1878)	3405 (2198-5059)	6653 (731-7384)	5743 (2862)	4471 (3560-7813)	8698 (2989-11688)	4202 (2571)	3790 (2129-5818)	9710 (437-10147)	4018 (2438)	3153.7 (2271.7-6739.5)	6293 (1626-7919)	4602 (2760)	3794 (2853-5906)	10711 (594-11304)
Weekly Calorie expenditure	1846 (1006)	1989 (1023-2510)	3378 (231-3609)	1794 (1042)	1939 (1054-2181)	3637 (457-4094)	3217 (2046)	2511 (1412-5280)	5631 (1087-6718)	2067 (1267)	1743 (903-3650)	3755 (442-4197)	1666 (1388)	888 (736-2733)	3738 (719-4457)	1946 (1163)	1775 (859-2901)	3934 (332-4266)

*cpm = counts per minute

* For each physical activity measure the higher the score the better as this equates to the participants being more active, apart from sedentary minutes and percent where lower results equate to more positive findings as this means the participants are sedentary for lower amounts of time

Table 3-33: Physical activity data for women across assessment times by group (experimental vs. control)

	Baseline						3 months						12 months					
	Control (n=5)			Intervention (n=2)			Control (n=1)			Intervention (n=3)			Control (n=2)			Intervention (n=1)		
Physical activity Measures	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)
Days Reported	7.0 (0)	7 (7-7)	0 (7-7)	7.0 (0)	7 (7-7)	0 (7-7)	7.0	7	0	6.0 (1.0)	6 (5-6)	2 (5-7)	6.0 (1.4)	6 (5-6)	2 (5-7)	7.0	7	0
Days worn	6.8 (0.5)	7 (6.5-7)	1 (6-7)	5.0 (2.8)	5 (3-5)	4 (3-7)	7.0	7	0	4.7 (2.5)	5 (2-5)	5 (2-7)	6.0 (1.4)	6 (5-6)	2 (5-7)	2.0	2	0
Weekly minutes	4692 (903)	5011 (4007-5219)	2303 (3117-5420)	3425 (1379)	3425 (2450-3425)	1950 (2450-4400)	4395.0	4395	0	3379 (1720)	3520 (1592-3520)	3432 (1592-5024)	3886 (1006)	3887 (3175-3887)	1423 (3175-4598)	1727	1727	0
Mean cpm	284.0 (73.9)	271.6 (216-358)	180.4 (199-380)	264.9 (101)	264.9 (193-265)	143.4 (193-337)	340.2	340.2	0	387.5 (77.3)	382.5 (313-383)	154.3 (313-467)	251.7 (62.9)	251.7 (207-252)	89 (207-296)	403.7	403.7	0
Weekly hours	78.2 (15.0)	83.5 (66.8-87.0)	38.4 (52-90.3)	57.1 (23.0)	57.1 (40.8-57.1)	32.5 (40.8-73.3)	73.3	73.3	0	56.3 (28.7)	58.7 (26.5-58.7)	57.2 (26.5-83.7)	64.8 (16.8)	64.8 (52.9-64.8)	23.7 (52.9-76.6)	28.8	28.8	0
Total Sedentary minutes	2342 (193)	2613 (1208-3340)	2933 (486-3419)	2248 (802)	2248 (1681-2248)	1134 (1681-2815)	2258.0	2258	0	1984 (1011)	1891 (1024-1891)	2015 (1024-3039)	2774.4 (804)	2774 (2206-2774)	1136 (2206-3342)	1127.8	1127.8	0
Sedentary percent	50.7 (23.5)	61.9 (53.3-64.8)	14.5 (52.1-66.6)	66.3 (3.3)	66.3 (64.0-66.3)	4.6 (64-68.6)	51.4	51.4	0	59.5 (5.4)	60.5 (53.7-60.5)	10.6 (53.7-64.3)	71.1 (2.3)	71.1 (69.5-71.1)	3.2 (69.5-72.7)	65.3	65.3	0

	Baseline						3 months						12 months					
	Control (n=5)			Intervention (n=2)			Control (n=1)			Intervention (n=3)			Control (n=2)			Intervention (n=1)		
Physical activity Measures	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)
Total MVPA minutes	80.4 (34.4)	62 (55-115)	84 (49-133)	108.5 (113.8)	108.5 (28-108.5)	161 (28-189)	111.0	111	0	186.7 (135)	180 (55-180)	270 (55-325)	108.3 (24)	108.3 (91.3-108.3)	34 (91.3-125.3)	116.8	116.8	0
MVPA minutes per day	11.9 (5.3)	8.9 (7.9-17.6)	12 (7-19)	18.2 (12.5)	18.2 (9.3-18.2)	17.7 (9.3-27.0)	15.9	15.9	0	36.6 (9.5)	36 (27.5-36)	18.9 (27.5-46.4)	19.0 (8.5)	19 (13-19)	12 (13-25)	58.4	58.4	0
MVPA percent	1.7 (0.6)	1.6 (1.2-2.3)	1.5 (1.1-2.7)	2.7 (2.2)	2.7 (1.1-2.7)	3.2 (1.1-4.3)	2.5	2.5	0	5.0 (1.5)	5.1 (3.5-5.1)	3 (3.5-6.5)	3.0 (1.4)	3.0 (2.0-3.0)	2.0 (2.0-4.0)	6.8	6.8	0
Weekly steps	34881 (12657)	35506 (22448-47001)	30660 (19605-50265)	24595 (15805)	24595 (13419-24595)	22352 (13419-35771)	34216	34216	0	39356 (21216)	41624 (17097-41624)	42250 (17097-59347)	26207 (2625)	26207 (24351-26207)	3712 (24351-26207	18561	18561	0
Average steps per day	5222 (2207)	5072 (3207-7313)	5577 (2801-8378)	4792 (451)	4792 (4473-4792)	637 (4473-5110)	4888	4888	0	8451 (114)	8478 (8325-8478)	224 (8325-8549)	4439.6 (609)	4440(4009-4440)	861 (4009-4870)	9280	9280	0
Weekly Calorie expenditure	2635 (823)	2462 (1902-3455)	2057 (1675-3732)	2244 (2142)	2244 (730-3759)	3029 (730-3759)	3257	3257	0	3107 (2873)	2257 (755-2256)	5555 (755-6309)	1591 (193)	1591 (1455-1591)	274 (1455-1728)	1065.2	1065.2	0

*cpm = counts per minute

* For each physical activity measure the higher the score the better as this equates to the participants being more active, apart from sedentary minutes and percent where lower results equate to more positive findings as this means the participants are sedentary for lower amounts of time

Table 3-32 illustrates the physical activity results for the men with diabetes and highlights that the accelerometers were not worn by all participants. Table 3-33 above demonstrates the physical activity findings for the post-partum women, where again it is evident that not all participants wore accelerometers as asked to at each data collection point. For full response rate information see Table 3-17. Adherence to wearing an accelerometer, to examine the outcome measure physical activity within the participants, was lower in comparison to anthropometric and questionnaire response rates.

Table 3-34: Men with type 2 diabetes physical activity change from baseline to 3 and 12 months

	3 months		12 months	
	Control (n=10)	**Intervention (n=12)**	**Control (n=8)**	**Intervention (n=13)**
Physical activity Measures	Median (LQ;UQ)	Median (LQ;UQ)	Median (LQ;UQ)	Median (LQ;UQ)
Weekly minutes change	672 (388.5;2665.8)	-258.6 (-1121.5;655.8)	-785.4 (-1772.8;1148.7)	200.5 (-1124.6;1924.6)
Total counts change	285414 (83256;1323531)	78838 (-2242;396038)	-51770 (-600607;270942)	219961 (-59748;692962)
Mean cpm change	68.5 (4.2;138.3)	37.5 (-8.0;79.3)	-13.9 (-88.8;131.4)	76.0 (44.5;142.5)
Weekly hours change	11.2 (6.5;44.4)	-1.2 (-18.7;24.5)	-13.1 (-29.5;19.1)	-0.8 (-25.8;45.7)
Total Sedentary minutes change	515.5 (-152.5;1296.8)	-124 (-948.6;265)	-593.4 (-1307.3;673.3)	232.3 (-872.6;1592.4)
Sedentary percent change	-4.6 (-13;1.2)	-0.2 (-2.2;2.8)	2.9 (-3.6;7.8)	2.3 (-0.2;38.1)
Total MVPA minutes change	41 (-8.8;206.8)	23 (-6.5;100.3)	25.3 (-39.8;94.1)	95.5 (21.6;204.3)
MVPA percent change	0.7 (-0.1;3.0)	0.9 (-0.2;2.2)	0.5 (-0.2;1.7)	2.3 (0.7;4.5)
Weekly steps change	10142 (4081;33516)	1934 (378;12495)	2008 (-8992;15716)	3561 (1665;23606)
Average steps per day change	1449 (585;4788)	386 (190;2066)	-2123 (-4971;-105)	-1757 (-3736;673)
Weekly Calorie expenditure change	958 (180;3130)	123 (-176;593)	-125 (-763;388)	333 (-302;767)

* For each physical activity measure an increasing score equates to the participants being more active, while decreasing scores mean they are less physically active apart from sedentary minutes and percent where decreasing results equate to more positive findings as this means the participants are sedentary for lower amounts of time

Table 3-35: Post-partum women physical activity change from baseline to 3 and 12 months

	3 months		12 months	
	Control (n=1)	Intervention (n=1)	Control (n=2)	Intervention (n=1)
Physical activity Measures	Median (LQ;UQ)	Median (LQ;UQ)	Median (LQ;UQ)	Median (LQ;UQ)
Weekly minutes change	-616	-858	-1127.4 (-1841.8;-1127.4)	-723
Total counts change	-192521	24539	-849109 (-963204;-849109)	223756
Mean cpm change	3.4	119.5	-106.4 (-129.6;-106.4)	210.5
Weekly hours change	-10.3	-14.3	-18.8 (-30.7;-18.8)	-12.1
Total Sedentary minutes change	1772	-657	1224.9 (-406.8;1224.9)	-553.3
Sedentary percent change	-3.2	-4.3	17.8 (17.4;17.8)	-3.3
Total MVPA minutes change	-22	27	-6.8 (-41.8;-6.8)	88.8
MVPA percent change	-0.1	2.3	0.7 (-0.7;0.7)	5.6
Weekly steps change	-1290	3678	-16679 (-25914;-16679)	5142
Average steps per day change	-184	582	-2285	4808
Weekly Calorie expenditure change	-475	25	-1864 (-2004;-1864)	335
* For each physical activity measure an increasing score equates to the participants being more active, while decreasing scores mean they are less physically active, apart from sedentary minutes and percent where decreasing results equate to more positive findings as this means the participants are sedentary for lower amounts of time				

Of the control participants, one man did not complete baseline data but did return their accelerometer and activity diary for analysis at three months. This was also the case for three men and two women in the intervention arms who did not complete baseline data collection but did return their accelerometers and activity diaries at three months.

By 12 months the men with type 2 diabetes control arm appeared to lower sedentary wear time and increase MVPA, see Table 3-34. However, this was the opposite for the women's control arm, see Table 3-35. MVPA increased

for both the men and women intervention arm from baseline to 12 months although so did sedentary wear time for the men's intervention arm. All the men and women control participants who returned accelerometers at 12 months completed the diary sheet and returned the accelerometer at baseline to enable change to be examined. A further two intervention arm men returned their accelerometers at 12 months had no baseline measure against which to measure change.

3.4.9 *Food diaries*

Table 3-36: Food diary analysis results for men

	Baseline						3 months						12 months					
	Control (n=17)			Intervention (n=24)			Control (n=14)			Intervention (n=18)			Control (n=7)			Intervention (n=15)		
Energy & Nutrients	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)
Energy (KJ)	5967 (2600)	5512 (3487-7891)	8165 (1861-10026)	6658 (2581)	6302 (4659-8493)	9373 (2583-11956	6488 (2217)	6821 (4293-7797)	7648 (3597-11245)	5927 (1925)	6144 (4025-7693)	6027 (2547-8574)	6915 (2238)	6318 (5737-8806)	6871 (3385-10256)	6946 (2631)	6534 (5115-8158)	10505 (3780-14285)
Energy (Kcal)	1415 (617)	1306 (828-1873)	1935 (442-1873)	1581 (614)	1497 (1103-2024)	2235 (614-2848)	1542 (528)	1619 (1020-1854)	1825 (861-2685)	1406 (456)	1464 (957-1824)	1435 (599-2034)	1640 (538)	1492 (1365-2090)	1658 (787-2445)	1643 (624)	1525 (1224-1914)	2501 (890-3391)
Fat (g)	47.5 (29.5)	45.6 (23.8-64.3)	114.11 (14.9-129.0)	56.0 (31.5)	55.0 (27.6-70.5)	124.9 (16.0-140.9)	52.6 (28)	51.9 (33.2-66.1)	107.7 (15.0-122.6)	44.8 (19)	49.8 (29.8-59.1)	66.2 (9.2-75.4)	60.5 (34.9)	62.0 (30.6-77.6)	109.2 (6.3-115.5)	58.3 (31)	48.8 (36.0-69.5)	121.7 (22.5-144.3)
Fat (%)	29.4 (8.5)	30.4 (23.8-33.3)	35.4 (16.5-51.8)	30.6 (8.3)	29.9 (24.7-38.3)	29.5 (15.4-44.9)	30.5 (12)	30.9 (18.1-39.5)	38.3 (13.3-51.6)	28.6 (7.7)	30.4 (24.7-35.5)	26.6 (10.7-37.2)	30.7 (13.1)	35.8 (18.4-40.9)	35.3 (7.2-42.5)	31.3 (8.8)	28.1 (24.2-34.2)	33.6 (22.8-56.4)
Protein (g)	63.6 (31.0)	62.5 (39.7-85.8)	102.0 (20.8-122.8)	80.0 (44.7)	69.4 (51.6-98.3)	194.0 (31.6-225.6)	76.4 (31)	76.5 (44.0-98.4)	103.9 (34.9-138.8)	69.3 (34)	63.6 (44.7-92.2)	125.9 (15.7-141.7)	71.4 (27.1)	75.6 (66.0-80.1)	91.7 (21.4-113.1)	78.6 (33)	79.0 (141.9-275.3)	111.4 (29.3-140.6)
Protein (%)	18.6 (7.5)	16.6 (13.7-21.7)	31.8 (10.3-42.1)	20.5 (7.0)	20.1 (15.2-25.3)	30.2 (6.8-37)	20.2 (6.7)	18.9 (15.7-23.3)	24.1 (11.9-35.9)	19.4 (6.6)	17.4 (15.6-25.8)	21.9 (9.2-31)	17.2 (4.1)	17.9 (12.4-20.9)	10.8 (-14.6 - 3.6)	19.6 (7.5)	17.4 (15.7-24.3)	32.4 (8.9-41.3)
CHO* (g)	194.5 (88.4)	194.3 (121.5-239.2)	336.8 (32.7-369.4)	200.0 (72.7)	198.1 (137.3-246.5)	251.2 (75.2-326.4)	190.6 (81)	189.7 (126.6 - 228.6)	289.6 (73.4-363.0)	190.2 (73)	187.7 (122.1 - 223.7)	305.5 (93.6-399.1)	215.9 (56.1)	215.8 (170.8-261.7)	152.2 (141.7-293.9)	212.0 (92.0)	195.6 (141.9-275.3)	328.4 (109.3-437.7)

	Baseline						3 months						12 months					
	Control (n=17)			Intervention (n=24)			Control (n=14)			Intervention (n=18)			Control (n=7)			Intervention (n=15)		
Energy & Nutrients	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)
CHO* (%)	55 (10.6)	56.9 (51.1-62.1)	39.1 (29.6-68.7)	51.7 (8.2)	50.2 (46.8-56.5)	31.2 (34.4-65.6)	49.6 (13.7)	47 (39.6-62.2)	46.7 (29.3-76)	54.7 (11.2)	52.2 (47.4-58.1)	42.2 (42.8-85)	55.7 (16.7)	48.1 (46.5-67.9)	47 (41.5-88.5)	51.6 (10.5)	51.6 (46.4-61.7)	33.3 (30.9-64.2)
Total Sugars (g)	84.3 (58.1)	66.2 (43.2-115.0)	237.0 (4.0-241.0)	64.8 (42.2)	56.3 (32.4-83.4)	161.3 (8.1-169.3)	65.7 (43)	57.1 (38.6-79.8)	170.0 (17.9-187.9)	83.2 (67)	78.0 (33.1-108.1)	297.8 (11.0-308.8)	62.6 (27.7)	61.6 (41.2-91.3)	80.2 (18.5-98.8)	97.6 (68)	77.6 (47.7-130.1)	252.5 (27.7-280.2)
Alcohol (g)	0.6 (2.5)	0 (0-0)	10.2 (0-10.2)	3.3 (14.2)	0 (0-0)	69.0 (0-69)	5.8 (15)	0 (0-0)	50 (0-50)	1.4 (5.8)	0 (0-0)	24 (0-24)	0 (0)	0 (0-0)	0 (0-0)	2.5 (6.7)	0 (0-0)	22 (0-22)

*CHO = carbohydrates
* Higher averages = higher consumption of energy or nutrients on average from participants within the arm.

Table 3-37: Food diary analysis results for women

	Baseline						3 months						12 months					
	Control (n=5)			Intervention (n=3)			Control (n=2)			Intervention (n=3)			Control (n=3)			Intervention (n=2)		
Energy & Nutrients	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)
Energy (KJ)	7979 (4018)	8563 (4160-11505)	10042 (3667-13709)	10663 (3695)	8587 (8474-8587)	6455 (8473-14928)	2524 (1864)	2524 (1206-2524)	2636 (1206-3842)	7298 (761)	7640 (6426-7640)	1403 (6426-7829)	5871 (2829)	7052 (2643-7052)	5276 (2643-7918)	7936 (4885)	7936 (4482-7936)	6908 (4482-11390)
Energy (Kcal)	1898 (961)	2042 (985-2739)	2403 (869-3273)	2534 (874)	2040 (2018-2040)	1525 (2018-3543)	605 (447)	605 (289-605)	633 (289-922)	1726 (338)	1801 (1520 - 1801)	339 (1519-1859)	1402 (670)	1677 (639-1676)	1252 (639-1677)	1876 (1149)	1877 (1064-1877)	1626 (1064-2689)
Fat (g)	69.5 (52.8)	57.42 (24.5-120.6)	127.9 (22.1-150.0)	107.6 (47.1)	96.2 (67.2-96.2)	92.1 (67.2-159.3)	36.8 (27)	36.8 (17.5-36.8)	38.7 (17.5-56.2)	51.6 (17)	46.1 (38.2-46.1)	32.3 (38.2-70.5)	57.1 (20)	63.9 (34.2-63.9)	39.0 (34.3-73.3)	69.9 (41)	69.9 (40.8-69.9)	58.2 (40.8-99.0)
Fat (%)	30.1 (10.2)	27.7 (20.8-40.7)	23.2 (18.1-41.3)	37.7 (7.1)	40.5 (29.6-40.5)	13.3 (29.6-42.9)	54.7 (0.3)	54.7 (54.4-54.7)	0.5 (54.4-54.9)	26.6 (6.5)	23 (22.6-23)	11.1 (22.6-34.2)	39.2 (7.9)	34.9 (34.3-34.9)	14 (34.3-48.3)	33.8 (1.4)	33.8 (33.1-33.8)	1.4 (33.1-34.5)
Protein (g)	102.5 (53.1)	83.3 (66.6-148.1)	138.2 (53.9-192.1)	74.5 (18.6)	82.1 (53.2-82.1)	34.8 (53.2-88.0)	22.8 (11)	22.8 (14.7-22.8)	16.2 (14.7-22.8)	55.9 (3.8)	54.5 (52.9-54.5)	7.3 (52.9-60.2)	69.7 (38)	82.3 (27.4-82.3)	72.2 (27.4-99.6)	71.8 (3)	71.8 (69.6-71.8)	4.4 (69.9-73.9)
Protein (%)	24 (11)	19.6 (14.5-35.7)	23.8 (12.7-36.5)	12.2 (3.5)	10.4 (9.9-10.4)	6.3 (9.9-16.3)	16.9 (4.9)	16.9 (13.4-16.9)	6.9 (13.4-20.3)	13 (1.5)	13.4 (11.4-13.4)	2.9 (11.4-14.4)	19.3 (2.0)	19.6 (17.1-19.6)	3.9 (17.1-21)	18.6 (10.7)	18.6 (11-18.6)	15.2 (11-26.2)
CHO* (g)	227.0 (113)	234.1 (132.9-317.5)	311.6 (83.0-394.7)	325.4 (128)	288.8 (219.6 - 288.8)	248.3 (219.6-467.9)	47.4 (40)	47.4 (18.9-47.4)	57.0 (18.9-75.9)	276.0 (27)	267.9 (254.3-267.9)	51.5 (254-306)	161.3 (89)	205.8 (59.2-205.8)	159.8 (59.2-219.0)	257.8 (207)	257.8 (111.8-257.8)	292.1 (111.8-403.9)

	Baseline						3 months						12 months					
	Control (n=5)			Intervention (n=3)			Control (n=2)			Intervention (n=3)			Control (n=3)			Intervention (n=2)		
Energy & Nutrients	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)	Mean (SD)	Median (LQ-UQ)	Range (Min-Max)
CHO* (%)	48.5 (10.7)	45.9 (40.9-57.3)	28.1 (38.2-66.4)	51 (6.7)	52.8 (43.5-52.8)	13.1 (43.5-56.6)	29.5 (4.8)	29.5 (26.1-29.5)	6.8 (26.2-32.9)	64.2 (5.7)	66.9 (57.7-66.9)	10.3 (57.7-67.9)	44.2 (6.3)	46.3 (37.1-46.3)	12 (37-49)	51 (12.8)	51 (42-51)	18 (42-60)
Total Sugars (g)	109.8 (61.8)	92.9 (67.1-160.9)	166.7 (44.8-211.4)	115. 1 (56.7)	98.8 (68.3-98.8)	109.8 (68.3)	22.0 (14)	22.0 (12.2-22.0)	19.7 (12.2-31.9)	143.5 (58)	122.9 (98.4-122.9)	110.9 (98.4-209.3)	70.3 (49)	88.9 (14.7-88.9)	92.5 (14.7-107.2)	164.4 (206)	164.4 (18.6-164.4)	291.7 (18.6-310.3)
Alcohol (g)	0 (0)	0 (0-0)	0 (0-0)	6.4 (11.1)	0 (0-0)	19.2 (0-19)	0 (0)	0 (0-0)	0 (0-0)	0 (0)	0 (0-0)	0 (0-0)	0 (0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)

*CHO = carbohydrates
* Higher averages = higher consumption of energy or nutrients on average from participants within the arm.
Note: Due to small sample sizes LQ and median are reported in the table at 3 and 12 months as UQ could not be computed.

Table 3-36 above illustrates food intake energy and nutrient results for men with diabetes. Table 3-37 shows food intake findings for the post-partum women in the study. Completion rates for the food diaries were very similar to the rates identified for the accelerometers for both the men and women and were again lower than anthropometric and questionnaire response rates.

Table 3-38: Men with type 2 diabetes food intake change from baseline to 3 and 12 months

	3 months		12 months	
	Control (n=14)	**Intervention (n=18)**	**Control (n=7)**	**Intervention (n=15)**
Energy & Nutrients	Median (LQ;UQ)	Median (LQ;UQ)	Median (LQ;UQ)	Median (LQ;UQ)
Energy (KJ)	-125 (-169;2278)	-852 (-3431;2446)	1317 (-2096;2577)	766 (-1397;4583)
Energy (Kcal)	-24 (-400;542)	-204 (-825;584)	312 (-495;623)	178 (-336;1089)
Fat (g)	5.4 (-20.3;25.1)	-0.02 (-40.5;15.6)	11.3 (-12;34.9)	14.9 (-34.5;39.7)
Fat (%)	4.9 (-6.3;13.9)	-1.6 (-9;10.3)	5.1 (-2.3;11.6)	5.6 (-11.7;23)
Protein (g)	24.8 (-25.1;35)	-0.8 (-22.6;21.3)	0.6 (-11.4;17.6)	33.2 (-4.4;55.1)
Protein (%)	4.6 (-3.6;12.7)	1.1 (-1.9;8.9)	-1.9 (-2.5;3.6)	5.1 (-3.9;20.1)
CHO* (g)	2.3 (-81.7;43.8)	-14.6 (-67.9;65.7)	67.9 (-94.0;97.7)	22.5 (-52.6;154.6)
CHO* (%)	-5.7 (-17.2;13.6)	6.9 (-2.7;20.8)	-3.8 (-12.4;11)	12.2 (-4.2;19.6)
Total Sugars (g)	-21.1 (-48.9;3.8)	17.3 (-28.1;42.5)	-7.7 (-55.4;17.4)	34.8 (2.1;63.7)
Alcohol (g)	0 (0;0)	0 (0;0)	0 (0;0)	0 (0;0)

* CHO = carbohydrates
* Increasing change scores = increased consumption on average from participants in either arm, whilst decreasing change scores = decreased consumption from baseline to 3 or 12 months

Table 3-39: Post-partum women food intake change from baseline to 3 and 12 months

	3 months		12 months	
	Control (n=2)	**Intervention (n=3)**	**Control (n=3)**	**Intervention (n=2)**
Energy & Nutrients	Median (LQ;UQ)	Median (LQ;UQ)	Median (LQ;UQ)	Median (LQ;UQ)
Energy (KJ)	-4453 (-5459;- 4453)	-2160 (-7099;-2160)	-5790 (-6659;-5790)	-594 (-399;-594)
Energy (Kcal)	-1048 (-1283;-1048)	-521 (-168;-521)	-1381 (-1566;-1381)	-153 (-955;-153)
Fat (g)	-2.9 (-4.7;-2.9)	-50.1 (-88.8;-50.1)	-23.1 (-76.8;-23.1)	-11.8 (-55.4;-11.8)
Fat (%)	33.9 (31.5;33.9)	-11.1 (-19.9;-7)	16.2 (-6.4;16.2)	-2.5 (-8.4;-2.5)
Protein (g)	-100.2 (-161.2;-100.2)	-21.9 (-35.1;-21.9)	-4.5 (-164.7;-4.5)	4.1 (-12.6;4.1)
Protein (%)	-10.4 (-21.5;-10.4)	1.5 (-2.9;1.5)	19.6 (17.1;19.6)	18.6 (11;18.6)
CHO* (g)	-164.2 (-164.5;-164.2)	-34.5 (-200;-34.5)	-175.7 (-181.2;-175.7)	3.6 (-107.8;3.6)
CHO* (%)	-25.4 (-40.2;-25.4)	10.3 (4.8;10.3)	-8.6 (-17.3;-6.6)	1.0 (-1.5;1.0)
Total Sugars (g)	-69.2 (-80.7;-69.2)	-0.4 (-55.2;-0.4)	-74.8 (-122.6;-74.8)	41.2 (-49.7;41.2)
Alcohol (g)	0 (0;0)	0 (-19.2;0)	0 (0;0)	-9.6 (-19.2;-9.6)

*CHO = carbohydrates
* Increasing change scores = increased consumption on average from participants in either arm, whilst decreasing change scores = decreased consumption from baseline to 3 or 12 months
Note: Due to small sample sizes LQ and median are reported in the table as UQ could not be computed.

At three months change in median nutrient intakes in the control men varied, for example median energy intake decreased in comparison to median fat, protein and carbohydrate intakes (g) increased. In the intervention men median energy intake decreased as well as median fat, protein and carbohydrate intakes, see Table 3-38. At 12 months median intakes of the majority of nutrients reported, in both the control and intervention group, increased, with the exception of percent energy from protein, carbohydrate and total sugars (g) in the control group, see Table 3-38.

At three months, the women in both the control and intervention group had a decrease in median energy and median intake of the majority of nutrients.

The exception to this was percent energy from fat increased in the control group, and in the intervention group, percent energy from protein and CHO increased, see Table 3-39. At 12 months female control groups showed a decrease in median energy and median intake of the majority of nutrients reported, except for percent energy from fat and protein. For women in the intervention group median energy intake, fat (percent energy and g) and alcohol intake decreased; in contrast protein (percent energy and g), carbohydrate (percent energy and g) and total sugars (g) increased. The number of women participating was low and therefore these results should be treated with caution due to the small sample size and the impact this could have on over/under reporting. This is illustrated by the large decrease in median energy intakes at three months and 12 months, especially in the control group, see Table 3-39, which can be explained by the mean and range in Table 3-37.

Participants also recorded the weight or estimated weight of the food item consumed in their food diaries. Table 3-40 below outlines participant completion of the requested food weights. If participants did not include the food weight an average weight was used based on predetermined measurements (Ministry of Agriculture Fisheries and Food, 1993).

Table 3-40: Completion rates for food intake item weights (number of participants completing outcome measure (%))

	Men with diabetes									Post-partum women								
	Control			Intervention			Overall			Control			Intervention			Overall		
Food weights reported	**B (17)**	**3 (14)**	**12 (7)**	**B (24)**	**3 (18)**	**12 (15)**	**B (41)**	**3 (32)**	**12 (22)**	**B (5)**	**3 (2)**	**12 (3)**	**B (3)**	**3 (3)**	**12 (2)**	**B (8)**	**3 (5)**	**12 (5)**
Participant provided food weight	6 (35)	4 (29)	2 (29)	8 (33)	5 (28)	2 (13)	14 (34)	9 (28)	4 (18)	1 (20)	2 (100)	3 (100)	1 (33)	1 (33)	1 (50)	2 (25)	3 (60)	4 (80)
Average weights used	11 (65)	10 (71)	5 (71)	16 (66)	13 (72)	13 (87)	27 (66)	23 (72)	18 (82)	4 (80)	0 (0)	0 (0)	2 (66)	2 (66)	1 (50)	6 (75)	2 (40)	1 (20)

Number of participants completing outcome measure (%) ***B= Baseline, 3 = 3months, 12 = 12 months (number of participants in each group)**

* Food diaries required weight/measurements of each food or drink included in the diary to be recorded. If participants completed this information they were classified as participant providing food weight in the table. If this information was missing, no weights were included in the food diaries, participants were classified in the average weights used row

As shown in Table 3-40 above the majority of men who returned the food diaries did not provide food weights. Therefore in both the control and intervention arms a large number of food diaries were analysed using average weights. Although a small number of women completed food diaries those who did were more likely to provide food weights than men. Reporting of food weights also increased in the control arm for the women from baseline to 12 months.

Quality of responses

As with other data collection tools it was important to assess both the completion rate and also quality of the completed food diaries. Quality of recordings was assessed by a comparison of reported energy intake with estimated energy requirement. This was calculated by extracting the reported energy intake in MJ ((KJ)/1000) as a ratio of a participant's Basal Metabolic Rate (BMR). BMR is energy requirement at rest. BMR was calculated within the Access database and based on participant's gender, age and body weight, as shown by the equations in Table 3-41 (Schofield, 1985).

Table 3-41: Individual Basal Metabolic Rate (BMR)

Age	Equation (kJ/day)	Standard Error of Estimation
Men:		
< 3	249 × W - 127	292
3–10	95 × W + 2110	280
10–18	74 × W + 2754	441
18–30	63 × W + 2896	641
30–60	48 × W + 3653	700
> 60	49 × W + 2459	686

Age	Equation (kJ/day)	Standard Error of Estimation
Women:		
< 3	244 × W - 130	246
3–10	85 × W + 2033	292
10–18	56 × W + 2898	466
18–30	62 × W + 2036	497
30–60	34 × W + 3538	465
> 60	38 × W + 2755	451
(Schofield, 1985) W = body weight (kg)		

This then produced a ratio. In general a ratio of Energy Intake:BMR (EI:BMR) of >1.3 would reflect a sedentary lifestyle and weight maintenance but this would increase if performing higher levels of exercise (Goldberg *et al.*, 1991). Therefore it is not unlikely that participants within this study would have an EI:BMR ratio of less than 1.3 as they were intending to actively attempt weight loss and therefore subsequently would be expected to report lower energy intakes. Although participants within the control groups did not receive a weight loss intervention, participating in a study relating to weight loss may have impacted on their motivation to lose weight.

Table 3-42: Ratio of reported Energy Intake to Estimated Basal Metabolic Rate

Ratio	Number of participants		
	Baseline (n=49)	**3 months** (n=37)	**12 months** (n=27)
<1	33	28	18
1-1.3	10	7	7
>1.3 -1.7	4	2	0
>1.7	2	0	2

Table 3-42 shows the majority of participants (70%) had an EI:BMR ratio of <1 suggesting a high percentage of underreporting of food intake in this sample therefore compromising quality and dietary data. A number of participants (21%) had a ratio of 1-1.3, which is not unexpected owing to these participants actively trying to lose weight but this may be due to underreporting.

3.5 **Discussion**

3.5.1 ***Summary of key findings***

Rates of eligibility, consent, adherence and retention to the intervention

The recruitment target of 60 participants was achieved for the men with diabetes population group. This was not the case for the post-partum women group, with only 16 (27% of the target 60) recruited. Rather than a lack of interest in joining the study this could be attributed to the low numbers of potentially eligible women identified in the GP practice database searches in contrast to the high number identified for men with diabetes. This is illustrated by 12.5% of the identified post-partum women expressing interest in the study in comparison to 8.8% from the invited men with diabetes.

Of those randomised to the intervention arm five participants (12.5%) did not receive the intervention as they did not log onto the website at any time during the intervention period. Two of these participants however did met with the dietitian but both stated they were unable to gain computer access at the three month data collection point. However, the remaining three failed to attend the face to face consultation with the dietitian or to use the website. These participants were not contactable despite numerous attempts by myself or the dietitian so it is possible they may have changed their mind about taking part in the study.

66% of the men with diabetes participants completed three-month follow-up measurements in comparison to 56% of the post-partum women. By 12

months retention rates in both population groups had decreased with 52% of the men with diabetes remaining and 44% of the post-partum women.

Completion rates for each outcome measure showed the anthropometric measures, closely followed by both questionnaires (OWLQOL/WRSM and the Predictors of behaviour change) as the highest throughout the study, which is not surprising as these measures were completed in the face to face data collection appointment.

Acceptability and feasibility

Examination of the questionnaire results showed that response rates for the men with diabetes participants were higher for the intervention arm than the control arm at baseline for both the quality of life questionnaire (100 % versus 92.9%) and the predictor of behaviour change questionnaire (100% versus 85.7%). At three months and 12 months all participants remaining completed both questionnaires. Questionnaire response rates for post-partum women revealed that all participants at baseline and all participants remaining in the study at three months and 12 months completed the quality of life and the predictor of behaviour change questionnaires.

Rates of provision of physical activity data for men with diabetes were similar at each time point. The post-partum women, both arms, achieved rather variable adherence levels for outcome assessment at each of the time points, owing to the small numbers in each arm. Accelerometers were completed by a lower percentage of the participants than anthropometric measures or questionnaires but those who returned accelerometers tended to complete the accompanying diary sheet to a high standard.

Food diaries response rates increased for the men and the women in the intervention arm by three months. Twelve months response rates for men with diabetes were similar to other time points, while for women the response rate increased for the control arm but decreased in the intervention participants. However, this is probably a chance observation given the small number of women remaining in the study at 12 months. As the majority of food diaries reported very low energy intakes it would be expected that

participants lost weight. On average weight losses were identified, however, these would appear rather conservative in comparison to the food diary intakes reported. Therefore results suggest the food diaries were not completed to a high standard, with the majority (70%) appearing to underreport their food intake, which could be linked to another problem arising from the food diaries of participants not recording food item weights and average weights needing to be used in order to analyse the data.

Key parameters for a future trial

It was possible to produce descriptive statistics of mean (SD), median (LQ-UQ) and range (minimum-maximum) for each outcome measure. Although significance testing was not possible owing to small population numbers it was not the aim of the study to identify differences between groups or time points. The aim was to test feasibility and identify statistics which can now be used to inform sample size calculations for a future definitive trial.

3.5.2 *Comparison with other literature*

Recruitment

Previous research has shown great variability in respect of trial recruitment levels, 9-83%, and in terms of the recruitment techniques implemented.

Table 3-43: Recruitment percentages for different recruitment methods

Recruitment method	Percent recruited (%)
Workplace emails	9-53
Advertisements	11-83
(radio, posters, flyers, newspapers)	
Recruitment website	49-53
GP practice mail out	30
GP referral	39
Community outreach and mail out	45

As shown in Table 3-43 above, methods for recruitment ranged from a wider audience approach such as different advertisement techniques (McConnon *et al.*, 2007; Chambliss *et al.*, 2011a; Kraschnewski *et al.*, 2011; Collins *et al.*, 2012) to a targeted approach through GP practice mail outs or referrals (Tate *et al.*, 2003; Appel *et al.*, 2011) with varied success. This study incorporated a targeted approach but achieved lower percentages than identified in previous studies. One difficultly when comparing against previous research is the reporting of recruitment numbers. Published work often reports the number from those assessed for eligibility not the actual numbers who viewed the invitation. This is an issue with using wider audience approaches as specific numbers who have viewed the study invitation are often not possible to identify and therefore may make recruitment percentages appear higher in comparison to mail outs where exact numbers are known. Many of the studies used several methods to recruitment rather than one single approach (Hunter *et al.*, 2008; Chambliss *et al.*, 2011b; Morgan *et al.*, 2011b; Collins *et al.*, 2012). This may be a possible way to increase recruitment but could be incorporated as a stepped method rather than all at once to establish whether different methods were more successful.

Retention

Previous studies investigating internet weight loss intervention recorded attrition levels ranging from 14 to 26.7% for the intervention arms and ranging from 6.7 to 22.2% for the control arms at three months (Tate *et al.*, 2001; Chambliss *et al.*, 2011a; Kraschnewski *et al.*, 2011; Morgan *et al.*, 2011a; Collins *et al.*, 2012). This demonstrates that the attrition rates (see Figure 3-2 and Figure 3-3) from this study at three months are on the high side of previous reports for the men with diabetes intervention arm (27.3%). The men with diabetes control arm (42.9%) and both the control arm (44.4%) and the intervention arm (42.9%) for the post-partum women attrition rates are all substantially greater than previous studies at three months. The 12 month attrition rates for the intervention arm for men with diabetes (37.4%)

were within the boundaries seen in previous research, however again the men's control arm (57.1%) had higher dropout than previously recorded and for the post-partum women in both the intervention arm (57.1%) and the control arm (55.6%).

As might be expected it was apparent that those who were not active on the website that did not attend follow up data collection. Although the interview findings from this study have suggested some reasons why participants may have been inactive on the website, see Chapter 4, reasons why they left the study may need further investigation to increase our understanding of why high attrition rates were identified. However, when contacted for further follow up reasons tended to be focused around lack of time or other priorities, Figure 3-2.

Twelve month attrition levels from previous studies range from 17.4 to 51.4% for internet based intervention arms and 15.2 to 35.5% for control arms (Tate *et al.*, 2003; McConnon *et al.*, 2007; Morgan *et al.*, 2011b). This study identified higher rates of attrition than previous studies for all arms except the men's intervention arm. Retention rates for internet based interventions were higher when compared to wait list control or usual care arms but achieved similar retention rates when comparator arms involved participants accessing a website but receiving no feedback or contact. Retention rates were also similar when examining studies comparing internet based intervention with telephone calls or face to face interventions, however this is difficult to compare owing to only two studies comparing these different modes of intervention delivery.

Completion of outcome measures

Questionnaire completion was high by the study participants. This corresponds to previous findings that showed the vast majority of participants completed the questionnaires provided (Sniehotta *et al.*, 2011; Karlsen *et al.*, 2013).

Accelerometer completion percentages were higher than achieved in a previous study (Cooper *et al.*, 2000), which examined normal, overweight

and obese adult activity levels. However, completion rates in this study were lower than a study which incorporated telephone call reminders and incentives for completion (Sharpe *et al.*, 2011) but this involved women who were from economically disadvantaged backgrounds where incentive may be even more influential. These suggestions may still be techniques that could be implemented in the future to try to increase adherence to accelerometer use and completion of accelerometer diaries, and could possibly be considered as a way of increasing actual engagement with the intervention website and its intervention tools and resources.

Food diaries are noted for low compliance, as seen in this study, with self-reported diaries often a disadvantage owing to the high burden they can place on the participant (Medical Research Council, 2014). This burden of food diaries was acknowledged and recording requested only for a 24 hour period at each time point, however it still appeared to be off-putting to many participants. Lack of a diet recall interview is most probably a main reason why food diaries were completed to a low quality. The inclusion of this in a future main trial may help to improve both completion rate and quality.

During the study several strengths and limitations to the methodology became apparent.

3.5.3 *Strengths and limitations*

Recruitment

In hindsight and considering loss to follow up it may have been helpful to recruit the 19 men who were excluded as the recruitment target was already achieved. A future trial would need to recruit enough participants considering the loss to follow up across time. However, it was not deemed necessary to do so within this study as an objective of the trial was to identify retention rates and therefore recruitment targets were not based on detecting significance but on feasibility at each stage.

Another limitation was the use of an opt-in technique for recruitment. This has been shown to produce lower response and recruitment than opt out

methods of recruitment (Angus *et al.*, 2003; Treweek *et al.*, 2010) but at present appears to be favoured by ethics committees, owing to controversy over contacting participants before they have given their permission.

Many of the men with diabetes declined participation in the study. Unfortunately the majority of responders did not offer reasons as the study was advised by ethics to make this a voluntary option. The most common responses for declining study participation were no internet access, work commitments, poor health and age. The prevalence of type 2 diabetes increases with age (Diabetes UK, 2014) therefore it was not surprising that old age and poor health were issues that arose. However, the study did recruit participants with a large age range of 37-79 years.

Internet access

Ofcom statistics showed in 2013 that 17% of households did still not have access to the internet, which is an issue when investigating the use of technology in health care (Office for National Statistics, 2013). This study tried to extend the ability for people to take part by allowing the internet access to be in any situation i.e. participants could use a public computer in a library. Only one participant mentioned this was where they accessed the website/internet however they did not attend their 12 month data collection appointment although this was attributed to family illness rather than any mention of access problems. However, needing to use public facilities to access the internet does create extra burden on a participant as it means attending a public place and working around their opening hours to enable adherence to the intervention. Therefore removing or reducing the potential advantages of flexibility and instant access assigned to using a computer in comparison to usual face to face meetings.

As internet access is not available to everyone, a way to approach this could be to convert the website into a mobile or tablet application (61% of the UK are now smartphone users and 44% reported to own a tablet, with both increasing rapidly over the past year (Ofcom, 2014)) as well so access is more readily available across different devices, takes advantage of the

ubiquitous nature of the smartphone and is assigned to a device associated to leisure time rather than work. This was also suggested by some participants and will be discussed in Chapter 4 in relation to the interview findings. However, the large majority of households (83%) do now have access to the internet (via PCs, tablets or smartphones), with the percentage of non-users declining in all age groups since 2011 (Office for National Statistics, 2014).

It has been identified that internet health interventions may best benefit those already privileged, well-educated with access to resources (Gilmour, 2006).. Within this study participant IMD scores ranged from 5.8-67.3 and the IMD mean average was 26.5, which is very similar to average IMD scores within the two areas of recruitment (County Durham 26.4 and Darlington 25.4). This implies that participants came from areas representative of the deprivation levels of County Durham and Darlington. However, people may still have been excluded from the study as they could not gain access to a computer or due to poor literacy. Statistics show that of the 17% of households without access to the internet, 20% stated this was due to lack of computer skills and 13% connecting it to the costs related to equipment and access (Office for National Statistics, 2013). However, 7% stated that it was due to internet access being available elsewhere (Office for National Statistics, 2013), which supports the inclusion used within this study of enabling participants to access the internet in public venues. This concurs with suggested ways to improve equality within health interventions, such as providing free services and improving readability and cultural acceptability of the health information (Gilmour, 2006).

BMI recording

Another issue that arose was in relation to the GP practice database searches. It became apparent that BMI records were not always up to date within the GP records. This did impact on recruitment to some extent with eight (three women and five men) identified as ineligible owing to five (three women, two men) having BMI>40 and three (all men) having BMI<30. A Quality of Outcomes Framework (QOF) indicator used to assess practice

achievement in relation to obesity is that practices should have a list of patients whose BMI is >30 in the preceding 15 months (Health and Social Care Information Centre, 2013a). Another indicator relates to diabetes care and states that patients should have recorded in their notes BMI within the preceding 15 months (Health and Social Care Information Centre, 2013a). As the QOF indicators are part of an incentive scheme this would suggest that BMI would be an important aspect that would be monitored for both obese and patients with diabetes. However, no indicators appeared to relate specifically to pregnancy or post-partum. An issue with these indicators is the potential for a patient's BMI to change over the period of 15 months. As this study aimed to recruit a rather small number, 120 and reached 77, the number of ineligible patients equated to less than 10%. However in a future trial, recruiting a larger number of participants, this could potentially be a greater issue due to an increased number of ineligible patients and subsequently the time taken to screen during recruitment. NICE guidelines are proposing annual diabetes checks to be incorporated into the QOF indicators, therefore suggesting that all indicators, including BMI measurement, are conducted at least every 12 months (National Institute for Health and Clinical Excellence, 2014). This outlines how monitoring is acknowledged as an essential part of a patient's healthcare, however it does appear that BMI may be monitored better for those with other co-morbidities. This is an issue for practice and policy within the area of obesity in addition to the impact inaccurate recording can have on research. A previous study suggested how protocols should be created to encourage health professionals to routinely measure BMI and provide action for those with a BMI outside the normal range in a bid to make health care professionals more aware about obesity (Kirk *et al.*, 2009).

Outcome measures

Participants were asked to complete several different outcome measures during the duration of the study.

Diet

Food diaries were an outcome measure that showed rather poor completion in terms of reporting quality. However, underreporting of energy intake is common in previous research (Briefel *et al.*, 1997; Braam *et al.*, 1998; Black, 2000), especially in overweight participants (Livingstone and Black, 2003), which can be caused due to poor memory or embarrassment (Lee and Nieman, 2003). The majority of the food diaries had no weights recorded for the individual food items, with participants commenting that weighing food was time consuming or they did not own scales. As well as poor completion of weights there were also poor descriptions of foods, with meals being recorded instead of individual foods making up a meal. This could potentially have impacted on the energy intake calculated and therefore the quality of the response identified, as individual aspects of the meal may not have been reported resulting in underreporting occurring. Although the food diaries were explained in a face to face meeting, there was no follow up interview to assess food diaries and check for completeness with the participants. This is standard protocol in most dietary surveys (Whitton *et al.*, 2011) however, it must be considered that while interviews would add to the quality of food diaries it also adds to cost for data collection. In a future trial to assure better quality and higher response rate the food diaries should be completed in with a follow up interview with a researcher or rather use a retrospective diet recall method. Unfortunately the time and resources to do this was not available within this pilot study. 24 hour recalls can be expensive and put higher burden on the participant (Schatzkin *et al.*, 2003; Richardson *et al.*, 2011). A 24 hour food diary was used to enable low participant burden and due to self-reporting, remain a low cost measure (Dugdill and Stratton, 2007; Roberts *et al.*, 2009; Medical Research Council, 2014). Alternative food intake measures are food frequency questionnaires (FFQ) or seven day food diaries. Seven day food diaries have been shown to be the better estimate for average intake (Day *et al.*, 2000; Schatzkin *et al.*, 2003), however, four day diaries are now more commonly used in national surveys (Whitton *et al.*, 2011), with seven day being too burdensome for participants and previously shown to increase reporting bias (Ministry of Agriculture Fisheries and Food,

1993). New methods for technology supported methods for both prospective and retrospective methods may offer a low cost, low burden solution which could be explored in further studies.

Physical activity

Using accelerometers allowed objective physical activity data to be collected, which allows frequency, intensity and duration of activity levels to be examined (Richardson *et al.*, 2011). Although accelerometers are expensive to purchase and need specialist software to analyse data (Dugdill and Stratton, 2007; Roberts *et al.*, 2009; Medical Research Council, 2014), this study had access to both accelerometers and ActiLife 5 software, meaning two limitations were overcome relatively easily. Lower rates identified for physical activity completion data may have been owing to the burdensome task of wearing an accelerometer and completing a diary for a week. However, with many participants, when contacted about the return of the accelerometer, it seemed they had simply forgot to start wearing them, with some often unsure if it was still working. The accelerometers have no visual sign that they are working, in fact the only time a red light flashes is when the accelerometers are not recording. This is the opposite of a pedometer, which participants may have been more familiar with, which displays a screen when it is switched on. Also sending accelerometers back in the post, rather than in person, may have also led to participants forgetting to complete the task. An alternative method of physical activity data collection is the International Physical Activity Questionnaire (IPAQ), a validated questionnaire usually taking around 15 minutes to complete (Craig *et al.*, 2003; Ekelund *et al.*, 2006; Maddison *et al.*, 2007). Although the IPAQ can be a low cost questionnaire to implement it does rely on the self-reporting of participants rather than the objective measure achieved with the use of accelerometers.

OWLQOL/WRSM

Findings demonstrated no missing data within the OWLQOL or WRSM questionnaires, suggesting that these instruments were highly acceptable to these populations. The OWLQOL and WRSM are valid and reliable

questionnaires, which are quick to complete meaning low burden and time resources required of participants and researchers (Niero *et al.*, 2002). The OWLQOL and WRSM placed importance on incorporating the perception of obese participants by basing the questionnaire on findings emerged from interviews and focus groups (Patrick *et al.*, 2004). In contrast to the Obesity-specific quality of life questionnaire (OSQOL) which has not been tested on obese participants (Kolotkin *et al.*, 2001a). As with all existing quality of life questionnaires the OWLQOL and WRSM are self-report questionnaire (Duval *et al.*, 2006), which although may usually be a limitation, enables the aim of gaining patients perspectives to be achieved. The Impact of weight on quality of life questionnaire (IWQOL) has also been identified as a validated and reliable obesity-specific questionnaire able to identify short term weight change (Kolotkin *et al.*, 1995; Kolotkin *et al.*, 1997). However, as this study was over a 12 month period the OWLQOL and WRSM were favoured owing to the responsiveness to both short and long term reductions in weight (Patrick *et al.*, 2004).

Predictors of behaviour change questionnaire

Missing data were identified within the Predictors of Behaviour change questionnaire, albeit in low numbers. This suggests the majority of the questions were suitable for use. However, several may need some adjustment to be used in a larger scale trial. For example the ‘views on diet’ and the ‘views on physical activity’ sections had questions 1-6 that appeared to cause some confusion. This may be owing to the questions not having spaces in between each question (see Appendix Q) and therefore participants could not tell which separate questions were. Making it as clear as possible could lead to less missing data. One woman missed several questions in a row suggesting full pages may have been missed, possibly turning two pages over at once, which could be attributed to the length of the questionnaire. Several participants appeared to find the Predictors of Behaviour change questionnaire time consuming and an onerous task to complete, which suggests that a shortened version may be more suitable for participants. However, shortened versions of questionnaire sections (ESSI

and IPQ-RS) were used where possible, which are validated and reliable questionnaires (Moss-Morris *et al.*, 2002; Vaglio *et al.*, 2004; Sniehotta *et al.*, 2009). A strength of the questionnaire is the creation being based on key components for weight loss identified in previous research (Fishbein and Ajzen, 2010; Dombrowski *et al.*, 2011).

All outcome measures were useful to examine the complex process of weight loss. Anthropometric measures and quality of life can be used to identify the health benefits that arise from the intervention, whilst monitoring diet and physical activity enable the individual behaviour changes to be investigated and enable explanation of weight loss. Finally investigating predictors of behaviour change can allow further examination into the experience of losing weight and the components that can influence the end behaviour/result. Data collection at baseline, three and 12 months enabled all these outcome measures to be monitored in terms of short and long term change. A six month collection point was suggested but unfortunately time and resource restraints meant this was not feasible. Collecting at this time frame may have been useful for both data purposes and for the participants with regards to motivation, particularly the control participants, as nine months elapsed before assessment occurred again.

RCT methodology for technological interventions

As described in the introduction of this chapter RCTs are the gold standard method when evaluating health care interventions (Sibbald and Roland, 1998; Stolberg *et al.*, 2004; Schulz *et al.*, 2010). However, it is important to acknowledge the conflict that can occur in terms of the need to conduct a rigorous RCT that can last over several years and the need to keep up with the fast progression of technologies. Research faces the reality of falling behind commercial companies, weight loss examples such as Slimming World, Weight Watchers and Rosemary Conley, in terms of their ability to regularly update their websites or mobile phone applications. I believe for my PhD a pilot RCT was the correct method to use as a way of piloting randomisation methods in anticipation that the definitive study would be an RCT. In addition to examining the use of a website within the NHS, it also

allowed the investigation of what constituted usual care within two at risk populations. As suggested in HCI research it is essential to understand the end users (Beaudouin-Lafon, 1993) and further trialling/piloting looking at participatory action research would enable user and provider involvement to inform the development and refinement of the intervention. RCTs may have weaknesses such as evaluating a moving target, i.e. updating an intervention website during the study. Although this can be problematic it is not a limitation confined to technological innovations. Interventions may often need modifications for practical reasons for either the provider or the recipient. This can be essential to intervention delivery and it is suggested for transparency and replication purposes that modifications are logged and acknowledged within the evaluation process (Wells *et al.*, 2012). Within my systematic review only 2/14 studies compared the effectiveness of different modalities therefore I believe that a RCT examining a weight loss intervention with alternative modes of delivery within the NHS would be important for this research area. RCT methodology remain the most robust way of determining the effectiveness of an intervention (Schulz *et al.*, 2010).

Time and team management

I have learnt a great amount during my time managing the study team. It was a complex trial involving a variety of professions. The success of the trial was largely due to the support of the NHS and other collaborators. My skills in co-ordinating and liaising with all involved have been developed through both challenges and successes. The study was also supported greatly through the oversight of my supervisory team and the skills they brought to the process.

3.5.4 *Implications for policy, practice and further research*

Post-partum women

For a future study it appears that database searches reveal low numbers of eligible post-partum women and therefore a much greater number of practices would have been needed to reach the aim of recruiting 60 women. This study aimed to look at routes that could normally be used in primary care. Patients referred to a dietitian or an exercise referral system would

usually have to be referred by their GP based on their judgement, which is why GP practices were investigated as the method of identification (National Institute for Health and Clinical Excellence clinical guidelines, 2006 updated 2014). However, it did appear that alternative recruitment strategies may be more appropriate for a post-partum group. Midwifery departments and commonly offered services (i.e. Sure Start) may be possible pathways to investigate in order to try and reach a larger number of post-partum women. Other weight management studies trying to recruit postpartum women have reported difficulties with either recruitment or retention or both (Leermakers *et al.*, 1998; McCrory *et al.*, 1999; Lovelady *et al.*, 2000; O'Toole *et al.*, 2003).

Research in this area is limited in terms of weight management for post-partum groups. Previously research has focused on the effect of weight loss on lactation (Dewey *et al.*, 1994; McCrory *et al.*, 1999; Lovelady *et al.*, 2000). Research is lacking examining the effect of reducing post-partum weight retention (Kinnunen *et al.*, 2007) and there is a need for further research to identify the best approaches to recruitment.

The lack of weight management services available for pregnant or post-partum women has been identified even though midwives believe it is an appropriate and feasible service to provide (Kinnunen *et al.*, 2007). This suggests the potential for the involvement of midwifery services for recruitment, which already have contact with post-partum women.

As the women's recruitment target was not met an IRAS ethics study amendment was submitted for ethical approval to try to increase recruitment. This amendment was approved by the ethics committee five months into the seven month recruitment period. The amendment planned to provide health visitors with participant information sheets to give out to potentially eligible patients. Unfortunately the study and this approach were met with resistance from the Head of Children and Family Services who was the line manager for health visitors. There was concern about the health visitors having the time or skills to introduce the study to their patients and subsequently no health visitors were approached to take part in the study. Many changes occurring within their organisation may have been a contributor to the concern felt by

the health visitor manager. Therefore this method of recruitment was not implemented and did not add to the recruitment level. However, in future work this may be a way of approaching potentially eligible post-partum women about research studies and would be an interesting recruitment route to investigate in future research. In hindsight it may have been more productive to contact the line manager of the health visitors in advance of the ethics amendment to discuss our proposals, allow them to be involved in the process and get advice on this approach. Instead I believe being contacted after ethics approval was off-putting and instantly created a practice and research barrier. This study has allowed me to learn how certain people can be key players in facilitating or obstructing the success of the study. This outlines the importance of establishing good communication in advance to enable co-operation between researchers and health professionals to work effectively. This study was well supported in terms of how the researchers and NHS collaborators integrated into one study team.

A second ethics amendment was submitted via IRAS with the aim to interview women who had not responded to the original study invitation letter. These interviews hoped to examine reasons why women did not join the study. This amendment was not approved so this avenue could not be followed. This unfortunately meant that reasons women did not join the study could not be examined, therefore this may be a possibility for future research.

In terms of interest from post-partum women it is also worth noting that as the study was accepted on the UK Clinical Research Network Portfolio database the study details were available to the public. Since the study has been included on the UKCRN portfolio, 12 women have been in contact with the research team to enquire about the study. Unfortunately the study was only able to recruit women within County Durham and Darlington NHS Foundation Trust, making these women ineligible for inclusion in the study. No men contacted the research team after viewing the study on the portfolio database. Post-partum women actively seeking study information is an

interesting finding and this could potentially be another avenue to explore for recruitment.

Future research

Participants were sent an email to inform them when a consultation had been sent, which required them to log in to the website to receive, thus encouraging them to return to the website. However, no specific features of the web based intervention were incorporated that engaged with the participant to keep them motivated to continue. The reason for this was to enable the health professional's feedback to be examined to see if that solely could maintain commitment from the participants, which was not the case for many of the participants. However, features such as inbuilt messages to remind them to enter food or exercise inputs or motivational statements to reinforce when participants were active within the website may be possible suggestions for a future trial. The idea of sending text message reminders to people who had not logged on or entered information was discussed but deemed not suitable and in addition time restraints meant this was not appropriate to incorporate. However, this option may be another possibility for future research.

Usual care

The provision of usual care was monitored at each data collection point and found to be for the majority of participants no service provision for weight loss. A couple of men had been referred to a one-off dietitian appointment, two participant (one man and on woman) were offered exercise on referral and one woman was offered a 12 week Slimming World trial, of the 37 that were randomised to the usual care groups. This shows how at risk populations may not receiving the care they need and that is recommended by NICE guidelines (National Institute for Health and Clinical Excellence clinical guidelines, 2006 updated 2014). Future research could examine further what constitutes usual care but would also benefit from including traditional weight loss services, such as individual face to face consultations, which were not able to be captured within this research. This would enable

traditional services to be compared with alternative services such as an internet based weight loss intervention.

Outcome measures

In a future trial outcome measures would be examined to identify differences between the intervention and control groups and at each data collection time point:

- Anthropometric measurements could be used as the primary outcome to assess body measurements, with anthropometric measures commonly being the primary outcome in previous trials, as shown by my systematic review in Chapter 2.
- Diet intake could be a secondary outcome, with diaries examined to identify how food/drink portions, consumption and energy intake vary.
- Physical activity could be a secondary outcome to investigate the change in levels of physical activity.
- Quality of life could be a secondary outcome examined in comparison of the study arms and the different time frames.
- Predictors of behaviour change questionnaire could be used as an explanatory/mediating variable as social factors can be one of the explanatory variables that can influence behaviour and behaviour change. The development of the intervention takes this into account in some of the active features provided within the web based tool (e.g. chat room, discussion forum) so assessing this could inform us if the proposed mechanisms of change are being influenced during the intervention (in comparison to the control group) and having, in turn, an impact on behaviour across time (relative influence).

Although response and retention rates were at the lower end of those observed in previous trials, adherence to outcome measures, such as anthropometric measures and questionnaires was high in study completers.

Whilst the results are only descriptive statistics they show positive indications in terms of increased weight loss (kg and %) and reduced waist

circumference and BMI for the intervention arm from three months to 12 months in comparison to results identified from baseline to three months. This was not found for the control arm, whose measures remained relatively unchanged for the men from three to 12 months. Control women achieved increased weight loss, reduced waist circumference and BMI but not to the extent of the intervention arm. This shows the potential in relation to longer term weight loss based on initial findings from this 12 month internet based intervention, highlighting the need for more research in this area to investigate long term effects within weight loss.

Chapter 4 **Process Evaluation**

Qualitative or multiple method process evaluations allow a study to be examined in greater depth than do the quantitative outcome results gained from RCT findings alone (Oakley *et al.*, 2006). They enable the implementation, receipt, adherence and completion of intervention components to be investigated, and reveal the experiences and views of the end-users of the intervention and/or the health professionals implementing the intervention (Oakley *et al.*, 2006; Craig *et al.*, 2008). Process evaluations are important to allow the actual processes and components of the intervention to be explored (Ritchie *et al.*, 2003; Saunders *et al.*, 2005; Oakley *et al.*, 2006) which can be essential for complex interventions such as the one used within this study.

This chapter will examine the process of delivery and uptake of an internet based weight loss intervention. This will be described by using both the website usage data and interviews conducted with the participants and the health professionals involved in the study.

4.1 **Aims & Objectives**

The overall aim of the process evaluation is to identify the experience of using the internet based intervention. It aims to identify how the intervention was implemented and how the intervention was viewed and accepted by the participants and the health professionals.

- To describe website use (adherence and engagement with the website) of the participants and health professionals.
- To explore health professionals' and participants' views and perceptions of the intervention in terms of acceptability, feasibility and usability.

4.2 Method for website usage

4.2.1 *Design*

Website usage was tracked and monitored for the participants randomised to the internet intervention group. This was examined for the number of received and sent consultations (web based messages) and of food or exercise diary inputs.

4.2.2 *Participants*

Inclusion criteria

Any participant randomised to the intervention arm who created a log in account was included in the website usage data collection and analysis.

Exclusion criteria

The study protocol and participant information leaflet indicated that if participants expressed that they did not wish their data to be analysed then their website statistics would be excluded from the process evaluation. In practice, no participants made such a request.

Sample size

The sample size aimed for with intervention participants was 60, with 30 of these being men with type 2 diabetes and 30 being post-partum women.

4.2.3 *Data Collection*

Logging of website data was conducted throughout the study. Participation rates for recruitment, retention and attrition (reported in Chapter 3) were logged from the initial invitation letters through intervention allocation (baseline) to follow-up (three and 12 months), enabling an audit trail to be maintained (Moher *et al.*, 2001).

4.2.4 *Data analysis*

The recorded website data was examined to identify:

- Average number of log ins for participants

- Number of self-monitoring diaries completed (dietary intake and exercise inputs)
- Number of consultations sent by the health professionals to the participants in comparison to scheduled consultations
- Number of diaries/messages sent to the consultants by participants

4.3 Method for Interviews

4.3.1 *Design*

Semi structured interviews, lasting between 15-60 minutes, were recorded, transcribed and analysed. During the interview process the purpose was to get an overall view of the internet based weight loss intervention (My Dietitian website).

4.3.2 *Participants*

Inclusion criteria

Any participants already included in the pilot RCT, described in Chapter 3, were in principle eligible to take part in the interview process.

Exclusion criteria

The study protocol and participant information leaflet indicated that if participants expressed that they did not wish to complete an interview then they would be excluded from this aspect of the process evaluation. In practice, no participants made such a request.

Sample size

For the interview study, participants from the intervention arm were purposively sampled for interview based on their level of engagement with the intervention. Levels of engagement were split into three categories; non active, moderate and active users. Non active users were participants who created an account on the website but never visited the website again or logged any information onto the website. Moderate users were participants who logged information into the website but on average this tended to be

once a week or less and activity levels varied throughout the study. Active users were participants who used the website on a regular and frequent basis. These criteria were applied in selecting for interview men with diabetes who were randomised to the intervention arm of the trial. Owing to the low numbers of post-partum women within the intervention arm inclusion was more restricted and therefore interviews were conducted on an opportunistic basis. All four intervention group women remaining in the study were telephoned by me but unfortunately two were not able to be contacted and therefore only two interviews took place.

Control arm participants were also interviewed to ascertain their views on usual care provision but only a small number, three or four, were aimed for from each population (men with diabetes; post-partum women). This was to allow the usual care experience to be acknowledged but to ensure the focus stayed on one of the main aims of the process evaluation, to examine the experience of using the intervention.

All the health professionals (two dietitians and two exercise experts) involved in the study were asked to take part in an interview.

The exact number of interviews conducted depended on the variety of participants included in the study and on the point at which data saturation was believed to have occurred, “the point of diminishing return where increasing the sample size no longer contributes to new evidence” (Ritchie *et al.*, 2003).

4.3.3 ***Data collection***

Each participant completed written informed consent forms at the beginning of the study which stated whether they were willing to take part in an interview during the course of the study (see Appendix K - participant consent form). Participants were then telephoned by myself between six and nine months into the study and asked again if they would be willing to take part in an interview. Interviews dates and times were then scheduled to best suit the participant.

Interviews took place in the participants' homes or the GP practice, depending on the participant's preference. An interview topic guide was followed (see Appendix R for topic guide for intervention participants) and all interviews were conducted by me. The topic guide for those in the intervention arm covered how participants used the website and factors helping and hindering engagement. For the control arm participants, the topic guide included their reactions to being assigned to the control arm, their weight loss experiences, how they felt about their weight and their experience of what 'usual care' consisted of (see Appendix S for topic guide for control participants).

Health professional interviews were conducted by me with the two dietitians and two exercise experts involved in the project. Interviews took place nine months after the study began in the health professionals workplaces in private rooms. The focus of these interviews included how the health professionals had found using an internet based intervention to provide health care treatment to patients, how this differed from usual practice and whether the intervention was an acceptable method of treatment within the NHS (see Appendix T for topic guide for health professionals).

4.3.4 *Data analysis*

Interviews were recorded using an Olympus digital voice recorder. Participants were informed that all conversations would be recorded unless requested otherwise at any time during an interview. All recorded interviews were then transcribed, by a secretary within Newcastle University, to provide interview transcripts which could then be analysed. All transcripts were anonymised. Transcripts were fully read through by me to check for any missing information, usually caused due to difficulty hearing the participant. Audio recordings were then listened to in order to try and decipher any missing data. The transcripts were imported into QSR NVivo 10 Software and analysed, enabling an audit trail to be maintained and therefore allowing the qualitative research to be dependable and increase rigour (Bowen, 2009). Framework analysis, following five steps, was used to analyse the interview transcripts. Printed transcripts were used for the first three steps of

analysis, with NVivo used to aid the analysis process during the final two steps. The five steps I followed were (Ritchie and Spencer, 1994; Srivastava and Thomson, 2009):

1. Familiarization: reading through interview transcripts and listening to audio recordings allowed me to immerse myself in the data and provided an overview of the diverse material gathered during the interview collection process. Prominent and key ideas were noted during this stage.
2. Identifying a thematic framework: Using the initial key ideas and notes, along with the aims of the study, themes were identified by me. A thematic framework was created and applied to an initial few transcripts, with refinement to the framework occurring as additional and more representative recurrent themes emerged.
3. Indexing: Themes within the thematic framework were then indexed to provide a number for each theme. The framework was then applied to each participant's transcript. This allowed me to identify the contexts within which themes were occurring and if any associations were present between themes.
4. Charting: In this stage NVivo was used to allow both thematic and case analysis to be examined. Participant characteristics were entered for variables such as age, gender, study arm, population group and website use. Headings and subheadings were created for emergent themes within the framework. This allowed quotes and sections of text to be moved into the associated headings/subheadings for which they had been indexed to in the interview transcripts. Using the framework matrix function within NVivo data could be summarised based on each heading/subheading and by interviewee, which provided an overall view of each theme but also enabled individual responses to be examined in relation to particular participant characteristics.
5. Mapping (interpretation): The final stage involved the process of interpreting and explaining the data using the emerging summaries to search for associations, to compare and contrast views and to identify a structure to represent how the intervention had been experienced.

Framework analysis allows key issues and characteristics to be identified and patterns and associations within and between participants to emerge from the interview data (Ritchie and Spencer, 1994). The emerging themes were used to evaluate how the intervention has been implemented and the experience of following the intervention. This analysis can provide information for further development of the website intervention and also what would be necessary for a future trial.

4.4 **Results**

4.5 **Website data**

4.5.1 ***Participants***

The number of participants randomised to the intervention arm was 40, 33 of which were from the men with diabetes population group and seven from the post-partum women group. Of these 40, six did not log on (five men and one woman) and create an account and therefore were not included in the website data collection and analysis. Therefore website usage was collected from 34 participants, 28 men with diabetes and six post-partum women.

4.5.2 ***Analysis/results***

The average number of web based messages sent and received by the participants during the study (three and 12 months) are shown in Table 4-1. The website usage has been divided so it is possible to see the participant's activity in relation to their food intake as well as their exercise levels and also how they interacted with their allocated dietitian and exercise expert.

Table 4-1: Website usage data averages per intervention participant

Website usage	3 month website usage				12 month website usage			
	Men with diabetes (n=28)		Post-partum women (n=6)		Men with diabetes (n=18)		Post-partum women (n=6)	
	Median (LQ-UQ)	Range (Min-Max)	Median (LQ-UQ)	Range (Min-Max)	Median (LQ-UQ)	Range (Min-Max)	Median (LQ-UQ)	Range (Min-Max)
Health professional sent consultations	13 (12-15)	11 (5-16)	13 (11-13)	3 (11-14)	22 (20-25)	15 (14-29)	22 (19-23)	7 (17-24)
Dietitian sent consultations	12 (10-12)	10 (4-14)	11 (10-12)	3 (10-13)	20 (18-22)	10 (13-23)	20 (18-22)	6 (16-22)
Exercise expert sent consultations	2 (1-2)	4 (0-4)	1 (1-2)	1 (1-2)	2 (1-3)	6 (0-6)	1 (1-3)	2 (1-3)
Participant sent messages	1 (0-8)	34 (0-34)	17 (2-49)	101 (0-101)	9 (0-32)	75 (0-75)	19 (2-59)	141 (0-141)
Food related messages	1 (0-7)	33 (0-33)	17 (2-43)	77 (0-77)	7 (0-29)	68 (0-68)	19 (2-52)	110 (0-110)
Exercise related messages	0 (0-1)	7 (0-7)	0 (0-6)	24 (0-24)	1 (0-2)	7 (0-7)	0 (0-8)	31 (0-31)
Food intake entries	8 (1-59)	82 (0-82)	2 (1-34)	40 (1-41)	99 (3-246)	330 (0-330)	2 (1-37)	40 (1-41)
Exercise entries	3 (0-26)	69 (0-69)	1 (0-26)	27 (0-27)	22 (2-124)	262 (0-262)	1 (0-28)	35 (0-35)
Log ins	-	-	-	-	43 (12-167)	490 (1-491)	29 (2-71)	90 (1-91)

The expected number of health professional sent consultations over the first three months was 15, with 12 of these coming from the dietitians and three consultations coming from the exercise experts. By 12 months the expected number of sent consultations from the health professionals was 27, 21 from the dietitians and six from the exercise experts. Table 4-1 above shows the average (median) number of health professional sent consultations was lower at both data collection points (13 at three months, 22 at 12 months for both the men with diabetes and the post-partum women), identifying that the participants received fewer consultations than scheduled. This can be explained by the individual results for number of consultations provided by each health professional (dietitian or exercise expert). The number of dietitian sent consultations provided was approximately the number scheduled to occur. However, the exercise experts appeared to provide fewer than the scheduled number of consultations, averaging lower numbers for the men and women at both three and 12 months.

Food messages sent from the participants to the health professionals occurred more often than the sending of exercise messages. Usage of the self-monitoring features was less frequent for the women but this may be connected to the lower numbers involved in the study. The food intake entries were used more frequently than the exercise entries, with both demonstrating high levels of variance between participants in the number of times these features were used (see range values in Table 4-1). The usage data is represented in Table 4-2 for the men with diabetes and Table 4-3 for the post-partum women to illustrate the large variance identified of how participants used features within the website.

Table 4-2: Use of interactive website features for men with diabetes

Feature used	Website usage for men with diabetes			
	3 months (n=28)		12 months (n=18)	
	Frequency	No. of participants	Frequency	No. of participants
Dietitian sent consultation	0-3	0	13-16	1
	4-7	2	17-20	9
	8-11	11	21*	2
	12*	9	22	4
	13-14	6	23	2
Exercise sent consultation	0	3	0-1	6
	1-2	19	2-3	8
	3*	5	4-5	3
	4	1	6*	1
Participant food message	0	14	0-4	8
	1-7	8	5-10	4
	8-14	2	11-28	0
	15-21	0	29-38	5
	22-33	4	68	1
Participant exercise message	0	18	0	8
	1-2	8	1-3	7
	3-7	2	4-7	3
Food entries	0	9	0-11	6
	1-10	5	12-51	3
	11-30	4	52-141	0
	31-60	4	142-201	4
	61-82	6	201-301	3
			302-330	2
Exercise entries	0	10	0-11	8
	1-10	6	12-51	3
	11-30	6	52-101	2
	31-60	4	102-201	2
	61-69	2	202-301	3
*= proposed number of consultations agreed in study protocol				

Table 4-2 above demonstrates the number of men who received the proposed number of consultations from both the dietitian and the exercise expert. For the three month dietitian scheduled consultations 9/28 (32%) received the 12 messages as proposed, six participants (21%) received more and 13/28 (47%) receiving fewer consultations than the weekly feedback proposed. For the three month exercise expert scheduled consultations 5/28 (18%) received the three consultations as expected. Only one participant (4%) received more consultations than scheduled with 22/28 (78%) receiving fewer than the proposed number of three consultations.

Twelve participants (43%) received fewer than expected of both types of consultation. After 12 months only two participants (11%) received the scheduled 21 consultations from the dietitians, with 10/18 (56%) receiving fewer and 6/18 (33%) receiving more than scheduled. In relation to exercise expert consultation only one participant (6%) received the scheduled six messages, whereas the remaining 17/18 (94%) received less than proposed. Overall 10/18 (56%) received less of both types of consultation.

The number of men who sent food messages to the dietitians by three months was 14/28 (50%) and by 12 months was 12/18 (75%). At both time points a larger number of participants sent dietitian based messages than exercise related messages, 10/28 (36%) at three months and 10/18 (56%). After cross tabulating the sent food messages data and the sent exercise related messages it did not appear that sending more food messages equated to more exercise messages being sent e.g. participant 21 sent 28 food messages to the dietitians but only two messages to the exercise experts, however, in contrast participant 24 only sent 11 messages to the dietitian but sent more messages (four) to the exercise expert.

Entering food intake on the website was implemented by 68% (19/28) of the men over three months, with 64% (18/28) of the participants using the website to input exercise entries. At 12 months the same number of participants, 14/18 (78%), completed food and exercise entries within the website, with the same four people who didn't use the food intake diaries also not using the exercise diaries. Those that entered more food intake entries also tended to enter a higher number of exercise entries. However, one participant did not follow this pattern, entering a high number of food entries but a very low number of exercise entries. Two participants were found to enter more exercise entries than food and one participant entered equal entries for both, with the rest of the participants entering more food entries.

Table 4-3: Use of interactive website features for post-partum women

Feature used	Website usage for post-partum women			
	3 months (n=6)		12 months (n=6)	
	Frequency	No. of participants	Frequency	No. of participants
Dietitian sent consultation	0-9 10-11 12* 13	0 4 1 1	16 19 20 21* 22	1 2 1 0 2
Exercise sent consultation	0 1 2 3*	0 4 2 0	1 2-3 4-5 6*	4 2 0 0
Participant food message	0 2 17 32 77	1 1 2 1 1	0-2 17 20 32 110	2 1 1 1 1
Participant exercise message	0 24	5 1	0 31	5 1
Food entries	0 1 2 31 41	0 3 1 1 1	0 1 2 35 41	0 3 1 1 1
Exercise entries	0 1 25 27	2 2 1 1	0 1 25 35	2 2 1 1
*= proposed number of consultations agreed in study protocol				

Table 4-3 above demonstrates the number of post-partum intervention participants who received the proposed number of consultations from both the dietitian and the exercise expert. For the three month dietitian scheduled consultations 1/6 received (17%) the 12 messages as proposed, one participant received one more message than scheduled (17%) and 4/6 (67%) received 1-2 fewer consultations than the weekly feedback proposed. For the three month exercise expert scheduled consultations no participants received the three consultations as expected. Two participants (33%)

received one fewer consultation than scheduled with 4/6 (67%) receiving two fewer than the proposed number of three consultations. Four participants (67%) received fewer than expected of both types of consultation. By 12 months none of the women received the scheduled number of 21 dietitian consultations, with 4/6 (67%) receiving fewer whereas 2/6 (33%) received more than planned. In contrast all of the participants received at least three fewer consultations from the exercise expert than the six scheduled by 12 months.

The percent of women who sent a food related message to the health professionals was 83% (5/6) whereas only 17% (1/6) of the women sent an exercise related message at both three and 12 months. As only one participant sent an exercise related message it is not possible to see if those who sent food messages were also more likely to send exercise messages. However, the one woman who sent the exercise related message did also send the most food messages. More participants made food intake entries (6/6, 100%) than exercise entries (4/6, 67%) at three and 12 months and it appeared that those entering more food intake entries also entered more exercise entries.

4.6 **Interview results**

4.6.1 ***Participants***

The number of participants and health professionals approached and interviewed are outlined in Table 4-4 below.

The number of women remaining in the intervention group was rather low, n=4 by three month data collection point, with only two women in the intervention group able to contact to take part in the interviews. Three women in the control group were also able to be contacted and agreed to be interviewed. Ten men in the intervention group were interviewed, three of whom were classified as non-active/non users of the website. Three of the men interviewed were classified as active users of the website while four men were classified as moderate users. Three men in the control group were also interviewed. All the health professionals, two dietitians and two exercise

experts, involved in the study took part in an interview. Three of which were women, with one man who was an exercise expert.

Men with type 2 diabetes intervention group interviews ceased when emerging data from the interview transcript and initial analysis began to repeat in content, therefore data saturation was apparent. However, this was not possible for the women's intervention group interviews, which had to be conducted on an opportunistic basis. This was also the case for the women's control group interviewees, owing to low number of recruited post-partum women. The men's control group interviewees' data did not reach saturation but as study aims focused on intervention experiences and owing to pressing time restrictions it was decided that it was pragmatic to end interview data collection. No sampling criteria was followed for this group but a range of experiences in terms of medication, years since diagnosis and age were still aimed for within those interviewed (see Table 4-4 below), enabling the control arm experience to be examined.

Table 4-4: Interview sampling table

	Number approached	Number interviewed	Age	Type of childbirth	Age of child (months)	Medication	Years since diagnosis
Women Control	4	3	29-38	1 Caesarean 2 Natural	8-12	-	-
Women Intervention	4	2	31	1 Caesarean 1 Natural	5-17	-	-
Men Control	4	3	61-77	-	-	1 Diet only 2 Tablets	2-17
Men Intervention	10	10	41-78	-	-	2 Diet only 6 Tablets 2 Insulin	2-14
Health professionals	4	4	27-53	-	-	-	-

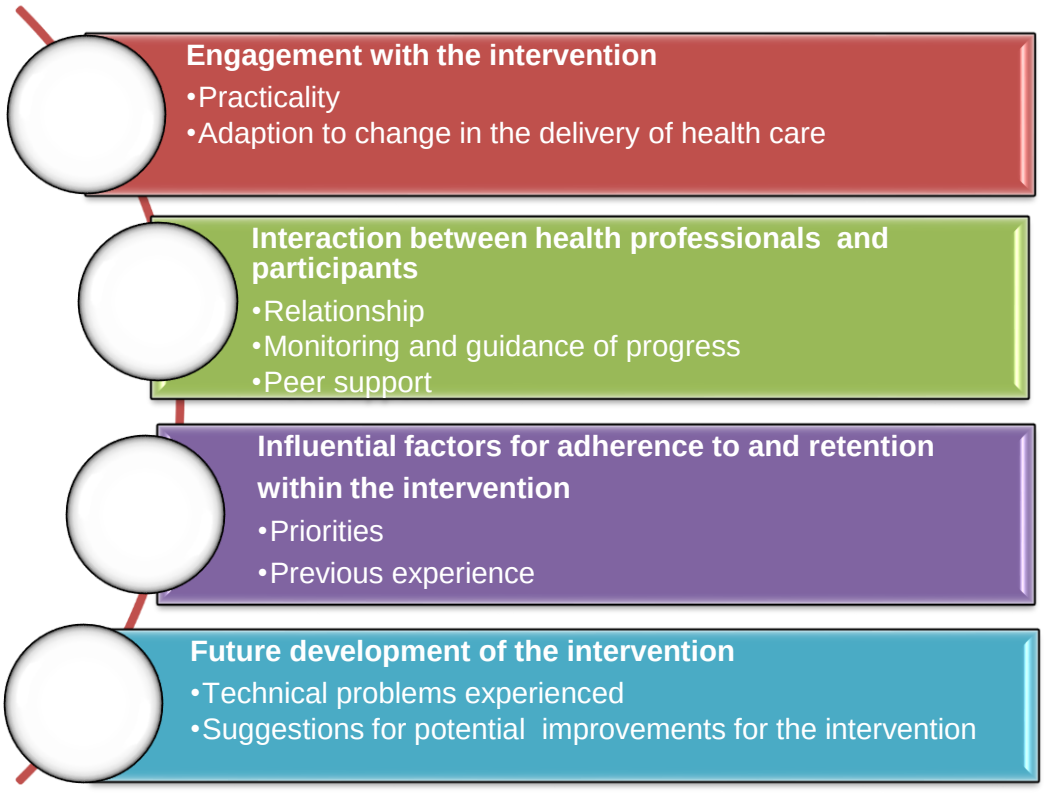
4.6.2 *Analysis/results*

A research assistant was also involved in the analysis stage to identify emerging themes from the interview transcripts. The research assistant and I then discussed our respective emerging themes and used this opportunity to detect and validate which were the most prominent thematic codes. The use of a second coder aided the analysis stage as discussions allowed the initial large number of emerging thematic codes to be reviewed, strengthened and validated. This enabled codes to be grouped into main headings, with subsequent sub headings.

4.6.3 *Health professional and intervention participants interview results*

From the interviews four main themes (nine sub-themes) were identified, following the Framework analysis of the health professionals' and intervention participants' interview transcripts, see Figure 4-1 below for full outline of theme headings and sub headings.

Figure 4-1: Interview themes for intervention participants and health professionals



The health professionals' and intervention participants' emerging themes are discussed below to contrast and compare the experience of using the website from both perspectives. The findings from control group interviews are discussed separately (see Figure 4-2 for theme headings).

1. **Engagement with the internet based intervention**

The first theme to be examined is the health professionals' and participants' engagement with and use of the website. This theme has two subheadings that emerged from the interviews.

1a. Practicality

Whilst examining levels of engagement with the intervention the aspect of practicality emerged; in essence this relates to how both participants and health professionals viewed the website in terms of its usability.

The interview findings revealed how a given feature of the website could often be viewed both positively and negatively within each of the stakeholder groups interviewed.

'it's there right in front of you. Also that you can see the other kind of consultations that they've had with the dietitians and stuff and that's good to see the feedback what they're giving them' (Exercise expert 1, age 35).

'It's squeezed up on one side and it was a bit fiddly having to keep moving it up for each little bit' (Dietitian 2, age 53).

The website was generally praised for the capability to display a review of the participant's activity within the one page where health professionals could create a consultation. This enabled all relevant information, to aid the creation of feedback, to be available at the same time. However, this layout meant the information was often hard to read as participant activity inputs were shown on a day to day basis. All the provided information was essential to view but appeared to impact on the viewing quality experience for the health professionals. The need for a compromise emerged in order to balance the

provision of information alongside the necessity for the website to be straightforward to ensure it was not off-putting to use.

'No bother at all…it was pretty easy to, once you got used to it you could just go straight in' (Participant 34, Male, age 67, moderate user).

'Okay when I got used to it but I think it could be made much simpler.' (Participant 24, Male, age 66, active user).

New experiences appeared to take time to become accustomed to. Even though the website aimed to be intuitive and easy to use it became apparent that more information and demonstration features could often be desired to make using the website manageable from each participant's initial use.

'It's just that guidance would have been useful, or a little – I don't know whether - a 'demo'' (Participant 20, Male, age 58, moderate user).

Use of the intervention was viewed positively owing to the flexibility that was available in terms of how the website could be utilised. There was the freedom to access the website whenever best suited the participants and the health professionals with regards to how it could fit in their working day.

'when you've got half an hour/an hour you can get on and have a chat with them' (Exercise expert 1, age 35).

'Because sometimes, these clubs hold these meetings in the evening time as well, which I don't like going out of an evening anyway.' (Participant 21, Male, age 54, moderate user).

'Again it's flexible they haven't got to be restricted to clinic type hours…they can do it when they want…and you haven't got issues of them not turning up or cancelling' (Dietitian 2, age 53).

The website was viewed as more accessible than usual treatment, such as face to face meetings, overcoming the difficulty of fitting restricted clinic hours and appointment times into everyday life. Using the website appeared to be more convenient than attending in person appointments.

‘*rather than have appointments and have to trail wherever it is, I think they’re quicker and they’re more expedient at getting the message across.’ (Participant 20, Male, age 58, moderate user).*

‘I think for some people it would be the convenience of it. They’re not having to leave the house and that would probably be the benefit that I would say if that’s how people want to interact and if that works for them then yeah, it’s probably the way that the worlds going to go isn’t it?’ (Exercise expert 2, age 27).

‘I suppose it’s less time or onerous and you can do it all from your desk’ (Exercise expert 2, age 27).

The website consultations were mentioned as less time-consuming for both the health professionals and the participants. The health professionals found that delivering consultations was quick, although checking records to ensure accurate thorough feedback was attributed to be a longer process.

‘It could be, you could do it in five minutes or so, it depends how much they’d put in in terms of they’d done every day of a food diary…in terms of the patients time they can get a lot more feedback.’ (Dietitian 1, age 50).

‘with the best will in the world, if we’re going to clinics, we can only have a certain number of clinics in a certain number of places for people and coming out to an appointment is not an easy thing for people to necessarily do but if you want to keep in touch with them frequently then this is a very good way for them to do it’ (Dietitian 1, age 50).

The online consultations appeared to provide a more efficient way for both the health professionals to deliver feedback and for the participants to receive guidance in comparison to traditional face to face appointments. Health professionals were aware that web-based messages had the potential to improve their efficiency. One way it appeared that could increase efficiency for the participants was to incorporate the website into a mobile phone application.

‘if you can get it on your phone I would use it more because I really liked the outcome on my phone from Slimming World.’ (Participant 51, Female, age 31, active user).

'Yes, it you could set it up with an app so you could do it on the phone and you could do it on the move. So instead of having to at the end of the day' (Participant 62, Female, age 31, active user).

'I don't dislike it I just didn't go back on because that's it, if I could just put it on Google I would have probably gone on a bit more or if it was on my phone – I'm more on my phone than I am on the real computer' (Participant 51, Female, age 31, active user).

The quotes illustrate how a mobile phone application could be used to increase the level of access to the intervention. These suggestions were made prominently by the post-partum women that were interviewed. With several companies now using the internet to provide customer service peoples' views tended to acknowledge that the delivery of previous face to face interactions were evolving.

1b. Adjustment to the change in the delivery of health care treatment

An internet based intervention, such as the website implemented in this study, is a mode of delivery not usually applied in traditional NHS weight loss treatment. Therefore, using findings from the conducted interviews it was possible to examine how the health professionals and intervention participants coped with this change in format.

'And I've got a bit quicker as I've got a bit more used to the website because it was definitely slower to start with' (Dietitian 2, age 53).

'the knowledge that if you can stick with it you get to know it and you just get used to it.' (Participant 24, Male, age 66, active user).

Familiarising themselves with the concept of using an internet based intervention appeared to take time but became easier as users' experience of the website increased. Several of the participants who used the website on a regular basis were cautious at the start of the intervention. One aspect met with uncertainty was entering personal information onto the website.

'I was a bit hesitant about the use of sending stuff initially, but now I've got used to it I'm fine with that.' (Participant 20, Male, age 58, moderate user).

This appeared to be resolved by the participant gaining trust with using the website and acknowledging that information shared would remain confidential between the participant and the health professionals assigned to them. However, some participants found the process of adjusting to using a web based intervention more difficult, following a gradual change in routine by using a more traditional method of monitoring before then inputting information into the website.

'sometimes I wasn't going on the laptop and then set it up I mean I know it's only minutes, but but I thought right, it gives me something to do as well so I kept the, I kept my own diary hand written diary and then just transfer it' (Participant 29, Male, age 65, active user).

Although this is positive step owing to the participant actively using the website, it identifies that there are likely to be complexities in adjusting to the internet weight loss intervention. In this instance it appeared to make the monitoring of behaviour a longer process for this participant, even though this did not appear to be discouraging for him.

In contrast some participants seemed unable or unwilling to adapt to the change in how the healthcare was being delivered. This negativity or disbelief in using the internet for weight loss treatment generally related to the participants that were not active on the website.

'but I would have thought it might have been easier just to have had a blank piece of paper and then written down what you had eaten and where you had done the exercise, and then just posted that to you once a week or once a month' (Participant 48, Male, age 49, non-user).

'I would think more face to face would be better...because I would tend to think whatever she was putting on the website and say you should be doing this, you should be doing that, you could be sat the other end going yeah whatever and you just, you just waffle away anyway type of thing' (Participant 54, Male, age 65, non-user).

It appeared that these non-active intervention participants preferred a face to face situation and had the belief that it could be easier to ignore the information or advice provided by the healthcare professionals when delivered remotely. It

also emerged that these participants did not enjoy entering information on the website and found writing an easier and quicker option for recording food and exercise activity. These opinions appeared to be mainly from pre-judgement as the participants had initially logged on to create an account but never revisited the website again. This suggests that beliefs and attitudes towards an internet based weight loss intervention may have resulted in the inability to change. Another consideration could be that lack of familiarity or experience using a computer could have been a contributor to the lack of adherence or willingness to try. Both non-users, participants 48 and 54, quoted above did not use computers for other aspects of their life e.g. work or personal use. However, the other non-active user, participant 13, used computers daily for work use. Extensive use of a computer also appeared to be a possible hindrance for adherence to the website, with the participant not wanting to spend his personal time on a computer that he may have spent all day already on.

One aspect related to the change in delivery mode was the inability to observe or hear the participant's information in real time, with entered text unable to convey the context of the information.

'Sometimes when they're telling you what you want to hear face to face you know that it's not true from their body language and you lose that' (Dietitian 2, age 53).

'completely different because even on the phone you're not face to face but they're giving you an immediate response and you can kind of gauge if someone's not interested' (Exercise expert 2, age 27).

The health professionals were expected to give feedback based purely on participant data input, such as food intake or exercise activity; with this mode of operation and information receipt very different for cues which may be recognised in a face to face meeting.

'It might be, it might just be because they're not used to communicating in that way, therefore they don't see the point in putting something where you're not going to get an immediate response.' (Dietitian 1, age 50).

The quote above may illustrate a limitation to this format of behaviour change intervention delivery by comparison with the two way conversation with non-

verbal cues that one would expect in a face to face appointment. The issue of delayed response emerged as a new challenge to participants in terms of the type of healthcare they had received in the past. The participants would normally be used to a response from a health professional straight away whereas the website provided feedback on a weekly or monthly basis. A positive of providing responses via the website appeared to be the ability for the health professionals to take time with the response they provided to the participant. The response not being immediate made the feedback process easier in relation to providing considered and thorough responses.

'I think it's a very good way to do it especially when you get some patients that are maybe more challenging than others, you would get a little bit of distance to look at what they've done before you then have to reply to them. So to be perfectly honest that's quite nice sometimes!' (Dietitian 1, age 50).

Both health professionals and participants believed it was necessary to make the sending of consultations (web based messages) less disjointed, as within the intervention website the receiving and sending of messages did not occur in the same place. Alternatively embedding messages into one section, similar to receiving emails, would allow people to be familiar with the process owing to emails being a popular form of two way (albeit asynchronous) communication.

In addition to the different delivery of health care it became apparent from the interviews that participants also had to adjust to receiving weight loss treatment and advice. Participants were familiar with diabetes treatment or information about pregnancy but weight loss was a service with which many had little previous involvement through the NHS; this lack of past experience of weight loss management input from health professionals will also be discussed later in respect of the findings from control group participants. Owing to this, expectations for the intervention were varied with regards to what the exercise experts and dietitians would require and provide.

'Within it, again, it is: "What do I want out of the website and what do you want out of it?"' (Participant 50, Male, age 78, active user).

‘but I thought they would have given us, say look it, you should do this, so that I would say ooops I’m like getting wrong’ (Participant 29, Male, age 65, active user).

This resulted in some participants having unmet expectations of what the website would entail. Some participants revealed how they expected very detailed structured plans for their food intake, with participants often tending to want more guidance about their daily intake. However, the opposite emerged in relation to the exercise experts, with participants tending to pre-judge that they were either incapable or already doing sufficient.

‘He has contacted me, but I couldn’t show… I try to walk 10,000 paces every day or a couple of miles to three miles. I don’t want to get into pumping iron, so I do exercise as far as I want to go.’ (Participant 50, Male, age 78, active user).

‘He was saying you’ve got to increase to over, up it in steps of 1,000, over 10,000 steps and I thought, “That’s not for me”’ (Participant 24, Male, age 66, active user).

Several participants had the idea that the exercise expert would simply want them to go the gym or lift weights. It appeared that this was off putting for the participants, with many believing ‘at their age’ they would not be capable of that level of physical activity.

‘I mean you can only do so much at my age anyway’ (Participant 29, Male, age 65, active user).

‘it would have actually been nice to sit down and speak to him face to face and say, “This is what I am doing. Where am I going wrong? Where I am going right?”’ (Participant 48, Male, age 49, non-user).

Many participants believed that having the opportunity to talk through these expectations may have avoided the misconceptions that appeared to take place during the study. This also relates to the following theme of interaction, especially the initial face to face meeting of the participants with their designated dietitian.

2. Interaction between the health professionals and the participants

2a. Relationship

The two dietitians arranged a one off face to face meeting with each of their assigned participants at the start of the study, as soon as possible after randomisation to the intervention, before any communications were delivered via the website. The dietitians and participants described how the initial meeting was helpful to introduce the dietitian to the participants with whom they would be communicating with via the website during the intervention. However, the exercise experts did not meet with their participants in person at any point throughout the study. This face to face appointment between the dietitians and the participants appeared to have a positive impact, allowing a 'relationship' to be established. The relationship between the health professionals and their participants was very varied in terms of the connection between the dietitians and their participants in comparison to the exercise experts and their participants.

Participants appeared impressed with the dietitian's commitment and convenience with regards to the initial meeting.

'Excellent, very helpful, it came at a convenient time for me. In fact I think it was in the evening time, didn't rush. I mean, I know how busy people are and it wasn't a case of like, "Looking at my watch, I need to be away somewhere else", they spent a lot of time, went through all of the things, very courteous, very respectful, and very good, excellent. I was pleased with that.' (Participant 20, Male, age 58, moderate user).

'I was a bit like I say apprehensive because every dietician I ever but meeting her was really really good, it kind of put a face to her and made it easier to converse with her via the chat, because you kind of had a mental imagine who this was and you have a little bit more personal relationship with her you know' (Participant 16, Male, age 38, moderate user).

The quotes seem to suggest that even if the participant only meets with the health professional once it still then allows the feedback to become more

personal than when it is received from someone one who has never met you, therefore impacting on further communications.

'this is who I'm talking to and you're not just I don't know a nameless blob out there somewhere they know you're a real person' (Dietitian 2, age 53).

'you can put a face to the person who's putting those comments in' (Participant 21, Male, age 54, moderate user).

'Yes, I've still got a picture of her in my mind's eye.' (Participant 24, Male, age 66, active user).

Communication via the website appeared to be easier and more accepted following the face to face meeting, enabling visualisation of the person receiving or sending the message. This appeared to add context to the web based communications, an aspect which seemed to be absent from the exercise expert's communications.

'just for that client to meet the person who they're going to be talking over the internet and just to build just a little bit of a better rapport' (Exercise expert 1, age 35).

'Even to that sort of level through language, definitely I wouldn't have liked to have done it without having met them because you really wouldn't have had a clue.' (Dietitian 1, age 50).

Both of the exercise experts stated how meeting with their participants may have enabled the consultations to be more personal and allow a rapport to develop. A face to face meeting seemed to provide additional knowledge about participants and the type of conversation that was appropriate. It was evident that the initial meeting allowed the personality of the participants to be embedded into the dietitian's communications, in contrast to the exercise experts who seemed to realise their ability to have a greater connection with the participants was lacking.

'It's just putting a bit of personal side to it isn't it and that's always the way that we've worked before on a physical activity side anyway, you see someone for their initial consultation, you might send them off to other exercise sessions but then they still know who you are' (Exercise expert 2, age 53).

‘That would've helped me because it would have felt more like I knew who was watching. It felt a lot more distant with the exercise person. So it felt like it could've been that that message has gone across the board.’ (Participant 62, Female, age 31, active user).

Without meeting the exercise expert initially the consultations provided by them were not received as positively as when sent by the dietitians, even to the extent that they felt they could be automatic messages rather than from a real person. The lack of personal interaction appeared to create distance between the participants and the exercise experts, with feedback sometimes perceived as generic rather than individualised. Meeting with the dietitian, before communicating via the website, allowed the participants to acknowledge that a real person was monitoring them and added professionalism and familiarisation to the intervention rather than messages ‘emerging’ automatically through the computer.

‘Because really, if we hadn't have met, and then you suddenly see these comments, "You must do this, you must do that," and you think who's she or he to tell me what to do? Now I found that he didn't know what problems I have. Now, if I'd met him face to face, I could have explained a lot more.’ (Participant 21, Male, age 54, moderate user).

The participants revealed that meeting with the exercise expert may have been useful with regards to establishing participants’ capabilities and personality to aid future communication via the website.

‘he might have more insight if he sees you whether or not you are capable of doing certain things, just to kind of give him an idea of your body type you know’ (Participant 16, Male, age 38, moderate user).

It was apparent that participants felt that certain issues would have been helpful to discuss in person so the participant and health professional were in sync with the guidance that was needed. Meeting face to face, even just the once, was clearly something that was important to the participants and the health professionals. This suggests that even when using an internet based intervention an initial face to face meeting would strongly be recommended to enable a rapport to be developed.

2b. Monitoring and guidance of progress

The concept of being monitored and gaining advice appeared to be a strong motivator for participants to respond to the study invitation.

'I thought that it may motivate us more than just doing it on me own.' (Participant 29, Male, age 65, active user).

'because it gives you that motivation…if you feel no-one's watching you, then you could go and have that extra hamburger or cream cake.' (Participant 21, Male, age 54, moderate user).

The opportunity to join the study appeared as a chance to take action against their weight problem. The influence of having other people to support the participants appeared to be a big enticement. It also emerged that monitoring and guidance were the key aspects that participants wanted to engage with in the intervention.

'I was using it purely for the main function of the monitoring, my food intake and my exercise.' (Participant 24, Male, age 66, active user).

'Mainly went on to try and write in what I'd had and see what the dietician had said back.' (Participant 51, Female, age 31, active user).

Monitoring allowed participants to view their own behaviour, which for some participants was enlightening.

'*It's good because it makes you realise how much you're eating' (Participant 34, Male, age 67, moderate user).*

'Yes, definitely. When I was - I found that really helpful. Which is why I felt the need to do it properly and actually weigh things and put the amounts in. Instead of just quickly written down what I'd eaten so that I could see the actual reading and the actual how many calories I'd eaten. I did find that very helpful.' (Participant 62, Female, age 31, active user).

The participants were able to monitor both their food intake and their physical activity. However, it became apparent that the participants' main focus tended to be in relation to food. The exercise experts were aware of the importance of

food to the participant and this was also evident in the participant's levels of physical activity self-monitoring in comparison to monitoring of food consumption.

'when I did like the first initial consultation we had like some questions for the guys to answer and I didn't get many responses back from them, eh, there was only a couple who answered them' (Exercise expert 1, age 35).

Response appeared to be low when set questions were created by the exercise experts to find out more about the participants. Another issue that emerged was the accuracy of participant's inputted information.

'If the participants weren't putting in the weights properly then it is better that they fill in the free text. If they were doing the weights accurately it possibly added to it a little bit' (Dietitian 2, age 53).

The quote above illustrates that although the participants could choose to enter food weights to get a calorie reading they often would use the default weight from the website and therefore would not get an accurate calorie intake and provide false information to the dietitian.

'Garbage in and garbage out. If you are putting rubbish into a system, you can only get rubbish out of a system. You try to be accurate.' (Participant 50, Male, age 78, active user).

Participants were divided in the way they monitored their food and exercise, with some enjoying free text and some finding the calorie or energy expenditure readings the important part of the monitoring process. Providing the participants with calorie intake and expenditure appeared to allow them to gain some control over their behaviours and provided guidance on what they needed to do for the remainder of the day. Those participants who tended to want calorie outputs also seemed to enjoy using the pie chart displaying percentages for the different food types consumed.

The monitoring and entering of information appeared to be a useful practice follow, with participants finding it encouraging to view information about their own behaviour. However, when time was limited, the task of entering

information felt time-consuming and a slow process to ensure accurate accounts were entered.

'I think the menus require some pretty solid attention. Obviously, they are trying to be helpful, but it is the way they are presented. It is labour-intensive.' (Participant 50, Male, age 78, active user).

'Which was quite motivating that it took time but it's when you run out of time. Then that's it, there's no - there didn't seem like there was a quick was of just doing it in a minute or two and it's done' (Participant 62, Female, age 31, active user).

'I've been trying to fill in the missed days as well. That's what I've been trying to do. But of course, you can't always remember everything you've had.' (Participant 21, Male, age 54, moderate user).

Often when participants were absent from the website they felt they had to be retrospective with their data input, even if this was off putting to their use, rather than simply starting afresh from the present day. This may be one of the reasons that some of the participants had periods away from the website or stopped using the website altogether.

'it's gets where I don't want to have to tell you what I've had today or eaten all week or explain everything I've eaten and what I've done and I know I obviously want to lose weight but it would be nice to not explain myself all the time.' (Participant 51, Female, age 31, active user).

It was also evident that there was a limit on the amount of monitoring that some participants wanted to have to complete. There is a difficult balance to strike between ensuring that health professionals are provided with enough information to deliver useful feedback while avoiding placing too much burden on the participant. As a result of this the health professionals commented on how it was essential to make the feedback individualised and informed by the participant's data entry.

'it hasn't been a waste of time for them to put all that detail in because you have actually picked up on it' (Dietitian 1, age 50).

Consultations on a whole were rather quick to create and send to participants. Acknowledgement of the participants' self-monitoring appeared to be an essential aspect in the provision of guidance to ensure they knew it was a human and personal response rather than simply an automated message.

'if I've got a problem I contact her and she normally comes back to me.' (Participant 24, Male, age 66, active user).

'But it obviously is getting monitored and that gives me the confidence to carry on using it. It's a trust thing as much as anything else, and I'm more than trustful of it.' (Participant 20, Male, age 58, moderate user).

Feedback consultations seemed to provide participants with the reassurance that they could be helped with any issues, comforted by the knowledge that professional guidance was available if needed. This did equate to a more time-consuming process to ensure thorough and appropriate responses were provided but this was still believed to be a quicker process in comparison to a face to face appointment. However, some participants still appeared to expect more from the dietitian.

'I think a structured plan from a dietitian saying this is what you should be doing; this is how many calories you should be consuming".' (Participant 13, Male, age 41, non-user).

Participants who stated that more structure was needed tended to be those who only logged onto the website once and did not actually follow the intervention for long enough to receive their first feedback from the health professionals.

In line with the findings the participants voiced that the guidance they required most was from the dietitians rather than the exercise experts. This was also what was intended in the proposed consultation schedule and what actually occurred.

'I think I'm monitored more with the dietitian than you are with the exercise' (Participant 29, Male, age 65, active user).

This is not surprising as dietitians did provide more regular feedback than the exercise experts throughout the study. However, participants also stated that the dietitians delivered more appropriate advice in relation to individual

preference, ability or health.

'the exercise is the only thing I'm a little bit disappointed in…it was like cut and dry and twice I replied saying look it I don't want this' (Participant 29, Male, age 65, active user).

'Yes, the dietician. Yes, it wasn't just a quick five minutes; it felt thorough and it felt helpful' (Participant 62, Female, age 31, active user).

This suggests that the exercise experts consultations may have needed to be more often and thorough in their content. This notion was supported when the dietitian's frequency of contact decreased after three months and they themselves tended to not find the reduced contact sufficient.

'I am aware now that I send them a monthly email and then they reply to me maybe the next day and I'm not looking again for another month and by the time I'm replying to that question it's sort of irrelevant' (Dietitian 2, age 53).

'I lost motivation, at times, during the three months when it was weekly…but it felt like I got back on the wagon quicker when I knew someone was there going, "Why are you not logging anything?" Whereas on a monthly basis, it doesn't have the same impact. Yes, I've just not been very good at all' (Participant 62, Female, age 31, active user).

'I don't think he came onto the website until about six or seven weeks after I'd started. Of course, I think he should have been there right from the start as well' (Participant 21, Male, age 54, moderate user).

On the whole, weekly contact with dietitians seemed appropriate but preferred frequency of contact did vary between participants. For the exercise experts it appeared that scheduled monthly contact from the start was not enough for the participants even though several stated they did not really want or need advice from the exercise expert. The exercise experts expressed their belief that the site could possibly have been staffed solely by the dietitians.

In addition to the guidance provided by the health professionals the participants appeared to be encouraged by the visual feedback aspects built into the website, such as pie charts of food intake or graphs of measurement progress.

'But yes, so the pie chart worked nicely that way. I could see, oh no and spur me into trying' (Participant 62, Female, age 31, active user).

'I like the graph…reminding myself that I haven't lost anything you know and just say oh this needs to go down…and it was when it started dropping it and hasn't gone back up at all, I quite like that as well, was a nice it kind of showed you, you know where you are going' (Participant 16, Male, age 38).

These features were helpful as a provision of information for the health professional and for the participant to view their own progress and enable participants to have a level of responsibility towards their behaviour and actions.

2c. Peer support

Website usage demonstrated that social interactive features of the website, such as discussion forums and chat rooms, tended not to be utilised by the participants. Reasons for inactivity between participants were examined.

'it looked really good but there wasn't any chat going on, like it was like, because the participants aren't friends in kind of real life they weren't chatting to each other' (Exercise expert 1, age 35).

'But yes, where their close-knit circle of friends can support them with the whole trial and weight loss and things. I think that adds more value than strangers, because it's a personal, intimate thing' (Participant 13, Male, age 41, non-user).

'well that's the thing, with Slimming World or Weight Watchers or anything like that, they have recipes everyone can use them, you're all on the same thing…not everyone's doing the same diet on here, so you haven't got common' (Participant 51, Female, age 31, active user).

Although people may enjoy talking to others going through similar situations it appeared that this was a difficult concept when the other people were unknown to them and there was a lack of common ground. It appeared that support from close friends or family was the desired interaction and strangers were not the correct audience with whom to discuss personal matters.

'I walked eight miles a day in bright sunshine – well who's interested in that? I'm not. I just want to do my own thing and have this one to one with my dietitian and myself. Really who cares?' (Participant 24, Male, age 66, active user).

Several participants did not appear to be interested in other people experience and therefore did not think others would be interested in theirs. Although this did not seem to be an important feature of the website for the majority of the participants they recognised how it could be a useful feature for certain populations.

'I'll accept that it could be ok for somebody that on his own, or she's on her own and got nobody else' (Participant 29, Male, age 65, active user).

'I don't wanna have dealing with the general public in general, but I imagine, with social media being so prevalent these days, I think a lot of people especially younger people will find that very very enriching' (Participant 16, Male, age 38, moderate user).

Social interaction was deemed suitable for younger people, who could be using social media on a regular basis already. However, as interviewees who related social support features to younger people were 38 or older, this seemed to be based on preconceived ideas of what younger people would want rather than actual facts. Another group that were mentioned were those on their own, who did not have friends and family to turn to for support or advice. The social interaction aspect of the website was compared to internet dating several times with regards to people experiencing similar situations, looking for similar outcomes and needing an encouraging environment to support them. Some of the participants revealed how they contemplated using the interactive features of the website.

'I did go into that My Community, to see if anyone else was opening up their posts so that everyone could see it. But nobody had, so I didn't open up mine. Whether it's a fear of not knowing the other people' (Participant 21, Male, age 54, moderate user).

'If someone else had been, I might have started. I think it depends what sort of comments were on there when I looked. Whether they felt representative of the

sorts of conversations I might want to have. But it might be motivational' (Participant 62, Female, age 31, active user).

However, the participants tended to be discouraged by the lack of interaction and did not feel they wanted to be the first one to start a conversation.

All the health professionals believed it was an appropriate way for participants to share stories and discuss issues with people who were going through similar experiences. Interactive aspects of websites were acknowledged as growing in popularity.

'I should, I would think it would be short sighted not to have it in because it is only going to become a more popular way to communicate with people who do the same thing as you' (Dietitian 1, age 50).

An alternative that could be considered for future web-based interventions could be for the health professionals to begin a discussion on a topic to see if this would facilitate subsequent interaction between participants. However, human resource costs and time availability would need to be assessed in terms of cost effectiveness. A future study could inform the facilitator, a health care professional used to supervise the interactions, when participants were using the discussion forums to avoid them having to actively monitor activity whilst conducting a cost-benefit analysis.

3. Influential factors for adherence to and retention within the intervention

From the interviews it emerged how other aspects in participants' lives could influence how (and how often) they were able to use the intervention.

3a. Priorities

Several aspects of the participants' lives that often resulted in a deviation away from the intervention also tended to be the reasons that healthy behaviour was not followed through with and therefore affected their ability to try to lose weight. The main commitments that emerged were family life, work, lack of time and holidays.

Having the responsibility of looking after children and attending to the needs of dependents before their own often left little free time, which then didn't necessarily want to be used on something that felt like a chore.

'because I haven't had the time or I have been, couldn't, to be honest couldn't be bothered, by the time I'm getting home, say I'm not sitting on the computer tonight' (Participant 29, Male, age 65, active user).

'it's finding the time to logon 3 times a day and write down what I'm eating and also usually the tea time one it's like really hectic from the time the kids come in from school, do their homework, making tea, sort of tidying up after it, you're getting ready for bed and things like that so I just and then by the time I get some time on my own I don't really want to work' (Participant 51, Female, age 31, active user).

The participants were not instructed how often to enter information or visit the website but participants still appeared to set their own targets as shown in the quote above. Family responsibilities and caring for others also emerged in relation to the opposite end of the lifespan.

'my mum's being diagnosed with cancer…so we're having to travel daily organising carers, this and that, it's knocked this on the head a little bit' (Participant 29, Male, age 65, active user).

A health issue within the family could result in day to day life changing drastically, resulting in the intervention not being an essential priority at that particular time. Engagement with the invention was also affected by inaccessibility to the internet or a computer.

'Recently, with my health, I haven't been going on my computer much at all, because I've not been able to look at it. So of course, I've missed quite a few days out.' (Participant 20, Male, age 58, moderate user).

'Also, when I've been away on holiday, so I've missed five or six days there. Then I was back a week, then we had another couple of weeks away, so there was no computer use then' (Participant 21, Male, age 54, moderate user).

Ill health and retirement had large impacts on many of the participants' lives. These were unavoidable stages in the participants' lives but a crucial aspect

was whether the participant would then return after a period of time away from the website, with the ability to do so varying greatly within the intervention participants.

'Your body wants to do this and your brain tells you that you should do that. There is an inner conflict.' (Participant 50, Male, age 78, active user).

This illustrates how participants' conflicting wishes and intentions would determine what their priorities were at any given time, therefore impacting on subsequent decisions and actions. However, non-active participants on the website, such as participant 54 below, were not ready to make changes to their current lifestyle.

'she says I think you should only be drinking half of it, just went through my mind you can think what you want like, you know I'm still gonna drink the six pints' (Participant 54, Male, age 65, non-user).

Certain stages in the participants' lives did, however, appear to make changes in behaviour easier. Many of the participants had begun retirement, which some believed was a positive change to their lifestyle that enabled them the time to not only join the study but actively use the internet intervention.

'I think if I had still been working the way I used to I just simply wouldn't have time to do what I'm doing. But I have now, so that's a huge difference' (Participant 21, Male, age 54, moderate user).

'it wasn't until I retired and obviously when I was diagnosed I thought bloody hell I'm gonna have to do something' (Participant 29, Male, age 65, active user).

Health was viewed as important to participants, especially owing to the age of some of the participants. Being diagnosed with diabetes appeared to have an impact on the participant's motivation to lose weight.

'Well, obviously diabetes was a new thing to me so I was keen on getting as much information and learning all about it as best I can' (Participant 20, Male, age 58, moderate user).

Although ill health (e.g. receiving a diagnosis of diabetes) could be a hindrance to losing weight and using the internet weight loss intervention, it appeared for

some to also be a source of encouragement and motivation to ultimately improve their health. Therefore retirement appeared as a potentially good time to approach adopting healthier behaviours.

3b. Previous experience

Most of the internet intervention participants interviewed had experienced weight loss cycles previously, losing weight but unable to maintain the loss.

'I have tried most of these diets. To begin with, they do work, and then they seem to stop working and you end up piling all the weight on… You tend to lose heart.' (Participant 48, Male, age 49).

This experience appeared to still be demotivating in the sense of reminders of how they had failed previously. Negative memories also seemed present for past health care experiences.

'Not really, I didn't really interact at all. But yes, like I say, I'm sort of disillusioned with dietitians a bit' (Participant 13, Male, age 41, non-user).

For some participants it was apparent that previous meetings affected how they viewed dietitians and the job that they did in general, creating difficulty in communicating with the dietitian within the study. Previous face to face weight loss attempts were referred to in comparison to the internet based intervention.

'Yes, I mean, I found the – I've done Weight Watchers and to be honest with you it's very good. But it is the structure they give you and you've got a goal to go every week to go and get weighed. You can actually see things working and you can see – so I think that works. It works well for millions of people and I think it's a formula that works, and maybe could be adopted by the NHS.' (Participant 13, Male, age 41, non-user).

'I've been to Weight Watchers and that and you just go in there and there's a load of women in there…I'm the only bloke in there quite often' (Participant 24, Male, age 66, active user).

'you would never see me in a slimming club' (Participant 20, Male, age 58, moderate user).

It is apparent from the quotes above that both delivery modes have advantages and disadvantages. Face to face meetings were favoured by some for providing structure and the goal of getting weighed weekly in front of others. However, slimming classes are also very dominantly female populated, which can alienate men from wanting to attend and a reason why an internet based intervention may be preferable for others.

The participants found the balance between living life and losing weight a hard task, both were desired but 'life' often overlooked weight loss.

'I have always had a problem with weight. It has been the bane of my life, to try and match life with weight.' (Participant 50, Male, age 78, active user).

'Subtle small, little changes over a long period of time; there's no quick result. People don't get overweight overnight, and you don't lose the weight overnight' (Participant 13, Male, 41, non-user).

Participants were vocal that they did not want their weight problem to become their life. Previous weight loss attempts had seen them cross paths with others that took dieting very seriously and had become 'obsessed' with the process, which the participants were aware they didn't want to. This links to the notion of sustainability and enabling food and exercise changes to become part of their daily lifestyle.

4. Future development of the intervention

An aspect that emerged from the interviews with the health professionals and the participants was the need for further refinement of the intervention.

4a. Technical problems experienced

This appeared to be owing to technical problems that had arisen throughout the study. Technical problems, however small, seemed to be off putting in terms of encouraging participants to continue engagement and adherence with the intervention. Other improvements which health professionals and participants believed would enable the intervention to be improved upon were also voiced. An outline of common technical problems and improvements that were voiced in the interviews are shown in Table 4-5.

Table 4-5: Emerging problems and suggested improvements for the intervention

Health professionals	**Technical problems**	**Improvements**
1.	Incorrectly states that consultations had not been sent.	Not using the intervention on its own but using telephone calls or face to face meetings in addition if deemed necessary.
2.	Difficult to find appropriate articles to embed in consultation.	Being able to view a full week's food or exercise input rather than just daily.
3.	Discrepancies between Dates on graphs and dates of participant data input.	
4.	Consultation scheduling table not straight forward to use.	
Intervention participants	**Technical problems**	**Improvements**
1.	Website did not seem smooth or simple to use.	Not using the intervention on its own but using telephone calls or face to face meetings in addition if deemed necessary.
2.	Two stage log in to ensure website only used by participants caused confusion about usernames and passwords.	Incorporating intervention into a mobile phone application.
3.	Food database not finding suitable options for consumed food.	Food database options appearing in alphabetical order.
4.	Calorie readings not correct for food consumed.	Entering own calorie information.
5.	Diary section would often not enter text.	Making website more colourful and appealing.
6.	Graphs did not show full time period, only last three months.	Including healthy eating or exercise recommendations to compare against their own progress.
7.	Participants wanted more guidance on how to use the website.	Stated that training or demonstrations may be helpful.

The website appeared to have several technical problems throughout the study and was referred to as ‘clumsy or clunky’ by several of the participants with regards to its programming and functioning.

‘if you don’t sweat the small stuff and the little things, the end user they may not know why it doesn’t feel right, they mightn’t even noticed that there are things they are wrong, but they will notice that something is wrong and feel that clumsiness and you know do shy away from it, it’s all about the polish that comes with software and website’ (Participant 16, Male, age 38, moderate user).

Aspects such as the food database not finding the correct food item meant incorrect and inaccurate recordings may have been selected to find an alternative. This did not instil the participant’s confidence with regards to the database’s ability to compute their information.

Problems with the functioning of the website were also evident when interviewing the health professionals. For example, a frequent difficulty was that the website would incorrectly state that a consultation had not been sent when in fact it had. This added to the time required when sending consultations as it had to be checked to see if messages had actually been sent.

Both the health professionals and the participants stated that minor problems had begun to add up making the thought of using the website off putting at times. Therefore it is extremely important to make sure that any technical issues are resolved to allow the functioning and general use of the website to be as efficient as possible in order to encourage regular use of the website so participants want to return and use the website again.

4b. Suggestions for potential improvements of the intervention

Participants also suggested that including healthy eating or exercise recommendations would allow them to compare their own performance against these set recommendations. Other comments emerged during the interviews with regards to the website needing more colour to be more appealing.

'Another observation I would make is that on the website, there is an awful lot of text. There are not many cheerful graphics.' (Participant 50, Male, age 78, active user).

This suggests that, as well as functionality and professionalism, the website also needs to be visually attractive to make it interesting to users.

Improvements were raised as to ways in which the intervention could aid productivity and ease of use for both health professionals and participants, with the overall objective being to create a website that could be less time-consuming and straightforward for users to operate whilst providing adequate support.

However, it was also the view from all the health professionals and the majority of the participants that the website was not the best option as a stand-alone system.

'possibly a bit more interaction either by phone or a bit more face to face occasionally you know if necessary' (Dietitian 2, age 53).

The health professionals stated how, at some points during the study, it would have been beneficial to have had the option of calling a participant or arranging a face to face meeting as an additional way of gaining information from the participant. For example, less active participants may have been encouraged to engage by a personal interaction.

'There were times when you would look at it and you would think I really – before I can say very much – I need to get some answers from you and you would want to be able to pick up the phone and say can I just say or ask you this, this and this…so there were times when it would have been nice to have the option to, right we'll have our check-ups and reviews weekly on the internet but can I give you a call if it's something that I really need a response to straightaway?' (Dietitian 1, age 50).

Face to face contact was a technique that was familiar to the health professionals and seemed desirable as a method of contact alongside the internet based intervention, possibly due to them being accustomed to using this communication method in their normal practice. The combination of sending

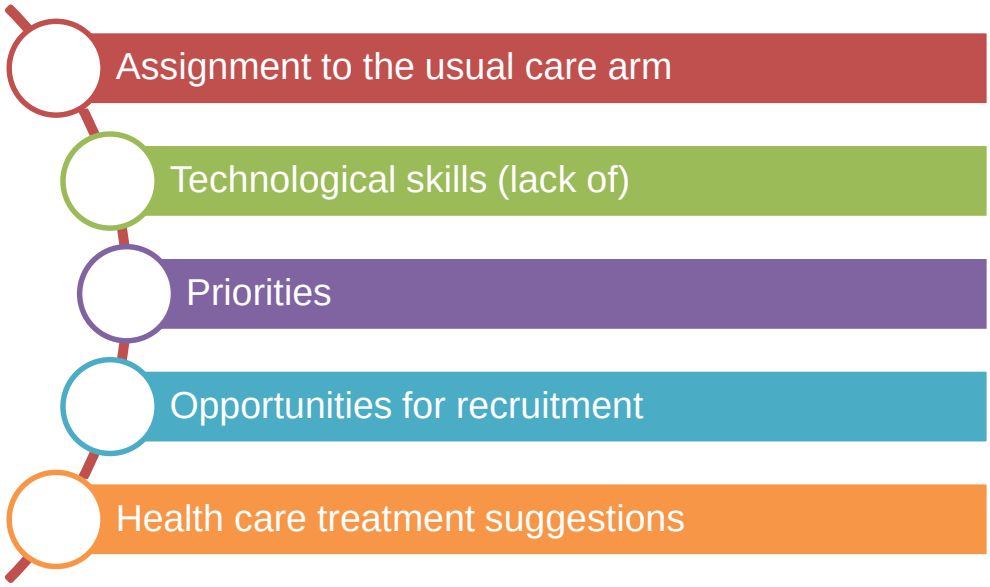
messages via the website but also being able to communicate directly with one another appeared to add value and comfort for both the participants and the health professionals. This could be linked to the need for and familiarity of immediate responses and the lack of this within the internet intervention, mentioned previously in relation to the sub-theme of adjustment to the change in delivery of health care treatment.

This again highlights the difficulty in changing habit and what people are familiar with. However, using a combination of delivery modes rather than relying on one method could have the ability to adapt to individual preference and needs. It emerged that all the health professionals and the majority of the intervention participants believed an internet based intervention could be incorporated within the NHS as a way of delivering weight loss behaviour change support. More investigation into how this could be most effectively implemented into health care practice is needed.

4.6.4 *Control group (usual care) participants*

Participants were interviewed and revealed their experience of being randomised to the usual care arm. Five themes emerged from the interview findings, see Figure 4-2 below.

Figure 4-2: Interview themes for control arm participants



1. **Assignment to the usual care arm**

What constituted usual care varied between the participants. Only two of the control group participants were referred to dietitians with both of these being referred on a one off basis. The men with diabetes attended diabetic checks with practice nurses, with the regularity of these dependent on the participant's condition but appearing to vary from monthly up to twice a year. The majority of the men mentioned how they had attended or were referred to Diabetes Education and Self-Management for Ongoing and Newly Diagnosed (DESMOND) training when first diagnosed. Several participants mentioned how they had previously joined a slimming club but none were currently members, although some stated they still tried to follow the eating guidelines. The majority of control group participants received no weight loss treatment through the NHS.

'I did go to the doctor and asked, see if there was anything on offer but they said because I wasn't overly overweight erm I wasn't actually physically having

any problems, there wasn't really anything available for me because I was still young and this that and the other erm so there wasn't anything on offer really (Participant 47, Female, age 29).

The quote above demonstrates the predicament that obese patients can often face. They are classified as obese and need to lose weight but do not meet the criteria, i.e. BMI not high enough, to be referred by a doctor to services available or services may be unknown and therefore not recommended.

The control group participants mentioned how receiving the information gave them the impetus to try and lose weight.

'I'm quite pleased it came. Otherwise, I would probably still be sitting on the couch, eating a pie.' (Participant 23, Male, age 61).

The participant above stated how he believed that changes in his behaviours could be attributed to joining the study. The participant received no treatment through the NHS but had returned to a gym he was previously a member of. It appeared that joining the study may have possibly provided enough incentive to increase healthy behaviours, even though no treatment was actually provided. This could possibly be attributed to the knowledge that follow up data collection would be occurring. Participants were asked how they had felt when they had been informed of their randomisation to the usual care group.

'well I think it's more personal the usual care group, you know you speak face to face than you are on the internet I think it's erm I'm alright, I'm a one fingered wizard on the computer but it would take me a long time to reply to anything and get I myself flustered, so yes the care group is better for me' (Participant 32, Male, age 62).

'Well it's this website you see, I would say for me it's not suitable' (Participant 18, Male, age 77).

Some men in the control group seemed to be pleased to be allocated to the usual care arm, suggesting this was their personal preference. This appeared to be due to a lack of confidence in using a computer and even though they were only seen (by me) at data collection points this still was viewed as preferable to

the internet intervention. However, this was not the case for the women in the control group.

'I actually totally forgot I was even on it' (Participant 47, Female, age 29).

'I was gutted because I'd really signed up so that I could get the extra help and I thought oh that's typical, I'm in the wrong group' (Participant 78, Female, age 38).

The three women in the control group who were interviewed showed disappointment in being assigned to the usual care. One participant had even forgotten she was still in the study until the next data collection point had arrived and she was contacted by me. This illustrates the lack of any substantial help or service for the post-partum women and explains why they hoped to be randomised to the internet based intervention. The internet based intervention was perceived as delivering more support than they were receiving in the usual care group.

'Basically, more information on it; I think I would have received more information, more support and, perhaps, seen the dietitian again. Because I'm a person that does take a little bit of - I need a cattle prod' (Participant 23, Male, age 61).

'it's something concrete isn't it, something you can look at and something you can fill in, something you can do and I think if you've got that concrete then it's easier, it helps more' (Participant 77, Female, age 30).

Support was described in the context of receiving information about food and healthy eating but also when describing the help that could be received from dietitians. Control group participants identified support as communicating with people going through similar situations, either via a forum or in a group face to face setting. This was mentioned as a way of sharing stories and gaining new information. It was mentioned that more support would be appreciated and that support was severely lacking with regards to receiving any usual care treatment to help them lose weight.

2. Technological skills (lack of)

Computer ability or experience using the internet emerged as factors that appeared to be lacking for some of the men in the control group.

'No maybe not because for a start I cannot use it, I would have had to rely on the wife all the time' (Participant 18, Male, age 77).

'doesn't fit everybody no it's not everybody's cup of tea, do you know what I mean, some people don't know how to switch it on, how can they gan on, I can switch it on, I can, I cannot talk to people that's it, I have to say see me grand-daughter she can ask all the questions' (Participant 32, Male, age 62).

There appeared to be a reliance on others in terms of what the men in the control group would be capable of doing via the internet. However, a lack of skills in using computers did not stop them joining the study. This could possibly be owing to the participants knowing they had others they could rely on to help them or may be related to the strong desire to lose weight and the need for assistance in any format offered to them, again illustrating the lack of help available for obese participants in usual care.

'Yes, but throughout their lives, it's got to be a good thing; anything that anybody can do to help someone who wants to lose weight. It must be a good thing, no matter what it is.' (Participant 23, Male, age 61).

'it's all computers now the days are gone where you can just sit down and talk to somebody over the desk it's gone, it's all gone, if you want anything now you get on the computer, it's as simple as that' (Participant 32, Male, age 62).

The evolution of computers as a communication method was acknowledged and may have been an influencer for participants joining the study, with the view that they would have to conform to this new mode of delivery in order to keep up with societal changes. However, it was apparent that not all were ready for this change.

'because I cannot switch the computer on never mind use a website but I think if you get something in black and white, sent or you know if I want to know anything I'll read about it' (Participant 18, Male, age 77).

Preference for familiar methods, such as printed paper based informational materials, emerged from the interviews. Lack of skills was not an aspect that materialized from the men's intervention group interviews, even those who were low users of the website. This suggests that the preconception of an internet based intervention may be more daunting and provoking of self-doubt than is experienced when actually utilizing the website. However, lack of skills may have emerged owing to the particular selection of control group participants interviewed. Adapting to an internet based intervention was however met more positively from the women's control group.

'yeah that would be fine, but you still get in contact, you still are speaking to somebody erm so I think for me that would have been, I think I would have managed all right with that, because I'm naturally, even though you are not talking face to face you actually still have a conversation with them kind of in an email version erm so I think I would have been ok' (Participant 47, Female, age 29).

It appeared that the new mode of delivery would be viewed as appropriate so long as feedback on their behaviours was still available. Some uncertainty was associated to the idea of a new experience, relating to the concept of adjustment that emerged in the intervention participant interviews. It did appear that the women within the control arm were more flexible to the possibly of a change in healthcare than the men. However, this could possibly be due to the men being older and not necessarily having the technology skill set that the women possessed, therefore creating greater demand on the men in terms of adjusting to using a website for healthcare.

3. Priorities

Personal experience and priorities of the individual emerged as aspects that could potentially influence the adherence to a weight loss intervention. It emerged that most of the control group participants, as with the intervention group participants, had gone through the process of trying to lose weight several times.

'I did really well but I've put weight back on' (Participant 77, Female, age 30).

'I've been doing then erm Celebrity Slim I've been using that erm and then a little bit of exercise, but I lost track again, I'm getting slim and stop, I lose a little bit and so I kind of like went off track again (laughter) I'm trying to get back into it but haven't, I keep going oh I'll start again on Monday, but then I haven't' (Participant 47, Female, age 29).

This demonstrated how weight loss attempts could be successful but maintaining this loss was very difficult for the participants. Weight loss was commonly reversed with the person needing to begin the process again. Beliefs were voiced with regards to the complexity of weight loss attempts.

'I don't know, someone to look at the psychology of it, anybody like that just to help you through that sort of thing…peoples can feel unwell, they feel desperately depressed if they get too hungry. So I think a lot of people need help that way.' (Participant 23, Male, age 61).

The quote above demonstrates how much impact trying to lose weight can have on a person. This relates back to why people seemed to need the idea of someone else being there to watch and support them in order to bolster their attempt. Losing weight is a multifaceted, long term process that many people struggle with. Therefore it was not surprising that the control participants appeared to have previous experience in trying to lose weight.

As with the intervention participants, there were clear barriers that emerged as disruptive in the process of trying to lose weight. These arose in the form of family and health.

'but because I've got the children and no child care I couldn't go to the gym' (Participant 77, Female, age 30).

'I had pleurisy and I was bad for five month erm and they put me on steroids' (Participant 32, Male, age 62).

'I do think the weight has a lot to do with it but I cannot go for walks, it's out the question, me legs' (Participant 18, Male, age 77).

The first quote describes a mother who was recommended for an exercise referral programme by their doctor but could not attend as she had no childcare. This represents how some treatments are impractical and individual

circumstances should be discussed; otherwise services may be wasted and are unbeneficial to the patient in question. Health concerns also need to be taken into consideration. Losing weight is beneficial but it may not be the most pressing issue in a person's life at certain times, especially when major health problems are present. This is an important factor to consider when discussing help and services to eligible patients.

Another factor that emerged was time availability and unsurprisingly spare time was not something people had much of.

'people don't have time to make appointments and stuff. I mean the only reason I'm able to do this now is because I'm not back at Uni until next week but if you're at work or you're at Uni you know you're busy' (Participant 77, Female, age 30).

Participants having less available leisure time can be problematic as it reduces the capacity for people to attend face to face appointments. Interviews were able to address how using an internet based intervention would work in relation to their daily commitments.

'with having the kids and working I thought oh suits me, I can do it when I'm on the go, that'll be brilliant. I think only if it wasn't too onerous it needs to be something simple and it needs to be quick.' (Participant 78, Female, age 38).

One of the women in the control group described how the internet based intervention was appealing as she believed it could be a better solution to fit around her priorities, such as work and children. However, crucial to this being advantageous was the need for the intervention to be easy to use and straight forward in order to lower time requirements.

4. Opportunities for recruitment

From the recruitment rates of the intervention it is apparent that women participant numbers were low for both the identification of eligible post-partum women and the number recruited to the study. During the women's control group interviews ways to try and improve recruitment or identification of eligible women were discussed.

'like the centre you go to [Sure Start] yeah you take, it's normally the first month or so, I was there quite often' (Participant 47, Female, age 29).

'or you know they give you these bounty packs don't they? When you are pregnant and when you have, you get one I think before the baby comes and they have all sort of leaflets and stuff and it's NHS…I don't know maybe a leaflet in there to say and this is who you can contact if you are interested after, I suppose you got to be careful because people are all like you don't want to be losing weight if you are breast feeding and don't you put pressure on these women but women will put the pressure on themselves and it's doing in the right way I think' (Participant 78, Female, age 38).

The women's control group were consistent in their belief that women could be informed of weight loss services relatively quickly after childbirth so they were aware of options available to them. This was even mentioned as possible towards the end of the pregnancy itself. Suggestions for contacting potentially eligible women was to combine with services that the women would already be visiting/receiving, such as free baby packs, Sure Start or the midwives. Participants stated timeframes they considered it would be suitable to join a study like this.

'I would, would say, I would say by the time say four months, by the time you've done that you got yourself into a routine so kind of routine, you kind of like back in some kind of normality type of thing erm so I would say yeah any earlier I would sort of it probably would, for me would be too much to think about' (Participant 47, Female, age 29).

For post-partum women it appeared that setting the study inclusion criteria for three months after childbirth, or over, was a reasonably appropriate time point. With regards to when a weight loss intervention may be appropriate for the other population group, men with type 2 diabetes, it appeared that as soon as possible after diagnosis was the consistent view.

'I think the first time you're diagnosed with diabetes you need the help there and then. Because diabetes is a very debilitating disease if you don't get it under control.' (Participant 23, Male, age 61).

Diagnosis appeared to be an unnerving time, with lots of uncertainty, new information and a time when any support to try and improve their condition would be welcomed. However, it appeared that assistance in losing weight was something that would be appreciated at any time after diagnosis also, which is supported by the average year of diagnosis from the men with diabetes in this study being 2005, eight years previous to recruitment.

It was apparent that different time points would be preferred by different people but both population groups felt the inclusion criteria was appropriate in terms of when to contact and recruit participants (post-partum women: three months-two years after childbirth, and men with diabetes: any time after diagnosis). Knowledge about research and available services was deemed to be helpful information to learn about as early as possible, after childbirth or after diagnosis of diabetes. It was suggested that providing information about a study though health services that patients would already be accessing would enable more eligible patients to be targeted and may make the information appear more trustworthy.

5. Health care treatment suggestions

Owing to many of the control group participants not receiving any form of treatment for weight loss it emerged from the interviews what they would prefer in relation to the type of health care they could receive and what would be appropriate. Information and recommendations for the participants to follow appeared as helpful ways of guiding the participants in their efforts to lose weight.

The belief from the control group participants appeared to be that, had they been allocated to the internet based intervention, they would have received more guidance and information than they had received in the usual care group, which seemed to be very minimal or non-existent in most cases.

'if you were assigned to somebody to talk to, I think if I had somebody there that was like pushing me…I don't know like ring you up or send you an email, how you doing' (Participant 47, Female, age 29).

'for me I think it is important if you can have sort of a relationship with somebody so if it was through your computer, if it was the same person talking to you' (Participant 78, Female, age 38).

'Yeah so an example of what you could have for breakfast, what you could have for dinner and that would be your calorie intake for that day. If you've got something easy to follow it helps because you could just do that and you don't have to think right what can I do, you don't have to put as much thought into it because it's already done for you if you like.' (Participant 77, Female, age 30).

The desired guidance tended to be in relation to a dietitian and feedback on the food they consumed. The view appeared to be that they would not do as well on their own compared to how they would fare if they had a dietitian guiding them. It seemed that it was the knowledge that someone was monitoring them that was the necessity, with some participants clearly wanting some of the responsibility taken away from them personally and placed on the health professional instead. Having a designated health professional to talk to appeared to be a desired aspect of treatment.

'I'd rather see an NHS dietitian, to be fair.' (Participant 23, Male, age 61).

'I went to see the doctor I go to which is only half a mile up the road and the chemist is round the corner, the all know me in there erm all the receptionists I know the fathers really and the doctors I get on with really well so I just, it's good up there like' (Participant 32, Male, age 62).

This also emerged in the context of trust and how professionalism and familiarity were important to the participants. Contact with the same person emerged as important to allow a relationship to develop and to be available when support was needed.

Accessibility was another factor that emerged as crucial to the success and acceptability of an intervention.

'now you've got access to the internet everywhere, it's on your phone, it's in your house, it's at work and I think it's just, it is appropriate because everyone uses it don't they?' (Participant 77, Female, age 30).

'nowadays with the modern technology on the phones it's immediately accessible and erm it's sort of you don't have, it's not hassle if that makes sense it fits in with your lifestyle' (Participant 78, Female, age 38).

The women in the control group identified how an internet intervention would fit into daily life easily owing to the high convenience of the internet. This was also mentioned in relation to mobile phones, highlighting the practicality of accessing the internet on the phone but also suggesting a mobile phone application as a possible method of intervention delivery, as emerged from the intervention participants' interviews.

It appeared to be the belief that health care did not need to mean permanent treatment but initial assistance to aid and sustain behaviour change was necessary.

'I definitely don't think a permanent thing but I think, I don't know, maybes, maybes up to a year and then once the person is confident and they know what they're doing and they feel that they don't need that help anymore and they're OK to go on their own, I don't maybes a year is too long (Participant 77, Female, age 30).

Importance was more strongly associated with the right knowledge in order to provide them with the confidence that they are able to control their behaviour changes when they were left to their own devices.

'I suppose I was going to say, that's the change for life' (Participant 78, Female, age 38).

It was evident that participants needed support to learn about changing their behaviours and how to maintain them but it was also acknowledged that the process of losing weight was a lifelong process that was ultimately their own responsibility and lifestyle change.

4.7 **Discussion**

4.7.1 ***Summary of key findings***

Participants' utilisation of the web based messages to health professionals tended to be directed to the dietitians rather than the exercise experts. However, it is important to acknowledge this may be owing to having more frequent communication from them and having had the initial face to face meeting. The pre-determined protocol for the intervention incorporated more dietitian consultations, than exercise expert, with the participants. This relates to the interview findings where participants felt a greater level of guidance and monitoring from the dietitians rather than the exercise experts. However, it was also evident that the dietitians were more adherent with achieving their scheduled number of consultations than the exercise experts.

Both the interview findings and the website usage data illustrated variance between how the participants interacted with their dietitian in comparison to their exercise expert. It was apparent that the initial face to face meeting impacted on the rapport the participants had with the dietitians. The exercise experts did not encounter the participants in person. This seemed to be influential on the relationship formed and the subsequent format and frequency of the guidance and monitoring of behaviour.

Participants and exercise experts both discussed how participants placed more importance on diet advice in comparison to exercise guidance. Although, it is important to acknowledge how the intervention itself gave more prominence to diet advice providing a face to face meeting and more frequent consultations in comparison to the exercise expert interaction with participants. Therefore this is likely to have impacted on the frequency that participants self-monitored for the two behaviours, food intake and physical activity, and how often queries were sent to their consultants.

High variance was identified in respect to website usage for most of the features analysed but in particular for the food and exercise entries. This is not surprising owing to some participants not inputting any food or exercise entries in contrast to other participants who made entries on a daily basis. A greater number of participant food entries were completed in comparison to exercise entries. Men

with diabetes entered self-monitoring data, for both food intake and exercise, more frequently than the post-partum women. This could be attributed to the women having more responsibilities at home and caring for a young baby, which relates to one of the themes from the interviews which suggested that engagement with the intervention could be effected by priorities in people's lives.

Participants described how some previous weight loss attempts were successful but that they faced difficulty with maintenance of weight loss. In the current intervention, health professional feedback was provided for 12 months to provide some support with longer term weight loss maintenance. However, it is worth considering the reality that weight management is a lifelong endeavour for most people who have lost weight and a set duration or number of appointments may not always be appropriate. This was supported by the interview findings, with several participants revealing they would like more support, whereas others preferred less contact, showing the need for an individual approach.

An inactive section of the website was the social support 'my community' features, with potential users probably being those with more spare time and less or no dependents to care for. From the interview findings participants revealed how social support is indeed important but that participants will value this more from their close knit community and not from a group of strangers, explaining the lack of engagement within the 'my community' section of the website. Due to each diet being tailored to the individual the participants recognised that the scope for sharing in this kind of programme was lower. Either the interactive section of the website becomes redundant or a new way of managing this is proposed that renders it more usable/useful. A suggestion to increase engagement could be the use of health professionals to facilitate the group. However, this would add to time and monetary resources and, from the emerging interview findings, it seemed a more beneficial aspect may be to support people in using and strengthening the social networks they already have and populate their context of living.

Several intervention participants did not go on to use the website after the initial log in to create their account. Non-users appeared uncertain about the potential

of the website for weight loss. This highlights an issue when approaching a new method of treatment.

The majority of the health professionals and intervention participants appeared to agree that the intervention could be appropriate to use within the NHS. However, they deemed it may be more suitable with additional components such as face to face meetings or telephone calls in addition to the internet based communication. Post-partum women and health professionals suggested that a mobile phone application may be a preferable and alternative way to deliver the intervention.

The results illustrate how the interviews and website usage reinforced each other's findings. The inclusion of both process evaluation techniques has allowed intervention adherence levels to be investigated whilst delving deeper into how the intervention was experienced and examined some of the possible reasons for why the website was used in the way it was.

4.7.2 *Comparison to previous literature*

Findings from the website usage data from this study is in agreement with previous studies. A greater number of participant food entries were completed in comparison to exercise entries, results also identified in previous research (Morgan *et al.*, 2011a). The social support features, were also the least used feature in a previous internet weight loss study (McConnon *et al.*, 2009).

Interviews revealed health professionals and participant believed additional components such as face to face meetings or telephone calls were needed in addition to the internet based communication. This reflects recent research by Dennison *et al.* (2014) which identified that those receiving additional telephone coaching were more likely to complete online information and persist with the intervention for longer. In Dennison *et al*'s study, participants in the telephone coaching arm also lost more weight (though the difference was not significant) than those in the web only arm, although 58% could not be contacted or refused the scheduled telephone calls (Dennison et al, 2014). However, Collins *et al.* (2013) found no difference in their study between the basic and the enhanced arms, where additional reminders and phone calls were incorporated,

suggesting extra features may not be an essential aspect to incorporate within an intervention, as identified in my systematic review.

The suggestion of using a mobile phone application instead of a website was voiced by participants. Waring *et al.* (2014) examined pregnant women's views for a website or mobile application for guidance on gaining healthy weight during pregnancy, 86% believed either would be appropriate delivery methods, of those interested 89% stating preference for a mobile version. This may be owing to the finding that the 89% claimed to use the internet daily, with 75% stating they did so via a smartphone or tablet, illustrating how access to the internet have progressed. This is supported by Hearn *et al.* (2014) who identified that perinatal women required quick and trustworthy information that could be readily available via their mobile device.

Participants also seemed to have preference for at least one face to face meeting. The meeting appeared to allow a relationship to develop and enabled trust and familiarity to continue during communications via the website. Previous research illustrated how the familiarity of GPs appeared to increase patients' trust in their health care experience in contrast to often negative views on pharmacists to whom the patients had limited exposure (Gidman *et al.*, 2012). A study by Morgan *et al.* (2012) identified mixed findings with some participants happy to have had just the one initial face to face meeting with the health care professionals. However, several participants in Morgan's study believed this type of encounter should have been on a more frequent basis, agreeing with some of the participants within this study who believed that more frequent face to face meetings may have been beneficial in addition to the internet based intervention.

Weight loss maintenance emerged as a difficult and daunting prospect for participants in the interviews. Maintaining weight loss has been shown in a previous review to be difficult, with almost half of weight loss regained after a year (Curioni and Lourenco, 2005). Therefore weight maintenance is an important and challenging aspect of the weight loss experience and interventions need to be designed to incorporate longer term support and strategies for maintenance (Dombrowski *et al.*, 2014), currently being

investigated by the NUlevel study, ongoing research within Newcastle University.

4.7.3 *Strengths and limitations*

Mixed method approach

Using mixed methods enabled different data collection and analysis techniques to be implemented concurrently (Gorad and Taylor, 2004). A potential disadvantage of collecting data in this manner is the chance for findings to contradict each other (Creswell and Plano Clark, 2011), raising challenges of interpretation. However, within this study the findings from the qualitative and quantitative methods were congruent, with the insights gained from the interviews illuminating likely reasons for variability in website usage between participants and by health professional group.

Logging website usage allowed greater insight into how (and how often) the participants and health professionals used the website. This allowed process evaluation of the internet intervention and was a method of data collection used in several previously conducted studies of similar interventions (Tate *et al.*, 2001; Tate *et al.*, 2003; Tate *et al.*, 2006; Hunter *et al.*, 2008; Morgan *et al.*, 2010; Morgan *et al.*, 2011a). The website was able to identify how the participants self-monitored their own behaviours of food intake and physical activity. In addition to this, it enabled communications between the participants and the health professionals to be monitored in order to view how the operation of health care provision had occurred.

In addition interviews revealed how website users found the experience and whether they believed the internet intervention was an appropriate means of delivering weight loss guidance. It was also important to examine how the health professionals found the experience in terms of relating to patients, how long it took to provide consultations in comparison to face to face appointments and how comfortable they felt using the website. However, one limitation of using interviews is the tendency for the interviewees to be people who are willing to take part and therefore may have a more motivated perspective. In terms of the health professional perspective all four involved were able to take part in the interview process but opportunistic interviewing samples were

necessary for certain participant groups. A positive finding was no participants or health professionals refusing participation in an interview.

Interviews of those who had discontinued in the study may have brought to light additional reasons as to why the website was not appropriate/accepted by the participants. A reason this was not conducted was participants had previously informed me that they no longer wished to take part in the study so this wish was respected.

Semi structured interviews were used to allow me to direct the conversation but enabled the interview to embrace the information divulged by the participants. This allowed the interview to incorporate the participants' or health professionals' personal perceptions and beliefs to be unveiled in the process and give a greater unearthing of the experience (Sofaer, 1998).

Analysis

In terms of analysing the interviews, Framework analysis was used owing to the systematic and comprehensive nature of the analysis process (Gale *et al.*, 2013). A framework is decided upon based on primary observations from transcripts. However, Framework analysis allows amendment throughout to adapt to the findings, enabling change to occur as the process progresses (Ritchie and Spencer, 1994; Gale *et al.*, 2013). Using Framework analysis allows within-case and between-case analysis enabling comparisons between, and associations within, cases to be made (Ritchie and Spencer, 1994; Srivastava and Thomson, 2009). This was made easier through the use of NVivo and the function to produce Framework matrixes, which allowed the examination of findings across themes and between different participants groups i.e. gender, age or website use.

Mode of delivery

A limitation with delivering an intervention via the internet is the lack of context available when provided with information i.e. body language or tone of voice. In comparison to a face to face consultation where these aspects can be observed and used to aid communication and advice to a patient, these tools are lost as information is received through text rather than the sender itself. Unfortunately

this limitation associated with this mode of delivery is unavoidable. However, allowing a one off face to face meeting for the dietitians and the participants enabled personalities to be revealed and allowed some initial face to face communication to occur before using the website, an aspect the dietitians, within the interviews, noted as useful in terms of creating consultations.

4.7.4 *Implications for practice and further research*

For participants, especially unskilled computer users, experiences of technical difficulties appeared as potentially detrimental to website appeal and use. Common issues arose; see Table 4-5 the addressing of which was suggested as essential to improve productivity and adherence to the website.

The fact this intervention is delivered via a computer that many of us associate to work suggests that the use of a more ubiquitous platform that people tend to associate more with leisure time activities, such as their mobile phones, may be a more acceptable and feasible format to deliver an intervention. This is supported by findings from the interviews revealing participants, particularly the post-partum women, would have found this an easier way of incorporating the intervention into their lifestyle.

An issue to consider is the development of technology and the tendency of people to use electronic communications very instantly and in real time (Anton *et al.*, 2012). A previous study identified that participants wanted information to be accessible, quick and portable (Hearn *et al.*, 2014). This is supported by the increase in smartphone owners (51%) almost doubling over the past two years and the rise of tablet owners from 11% to 24% in the past year, both devices that enable immediate access to the internet (Ofcom, 2013).

Receiving feedback on a weekly or monthly basis, as provided within this study, may not be a format that people are accustomed to when communicating via the internet using a computer or a mobile phone. Therefore communication flow is an area that would need more consideration for future research. Automatic responses would enable instant communication to be more achievable; however the interviews demonstrated the importance placed on developing a relationship with the health professional. Health professionals could possibly provide feedback based on participant input or queries, however this would

have to be considered carefully in relation to workload and costings for an intervention.

Tailoring the mode of delivery to the clients' preferences needs to be taken into account when creating an intervention. An internet intervention did not seem to appeal to all participants within this study and should be noted for future interventions. This also links to the emergence that both health professionals and participants believed that the intervention may have been improved with the additional of occasional phone calls or face to face meetings at certain stages throughout the internet intervention.

Many participants had previously experienced weight cycles, with initial weight loss not sustained. This relates to the relevance of weight maintenance interventions. Memories of success followed by failure were ever present in the participants' minds and appeared to impact on their motivation or belief. Weight loss was hard for many participants but for the majority weight maintenance was a bigger struggle. Weight loss was viewed as a constant battle in order to maintain their progress. Obesity is cause by many different factors and addressing the individual factors influential to weight gain is necessary (Kirk *et al.*, 2012). This study lasted for 12 months, which is longer than many previous internet weight loss interventions. However, more research examining weight maintenance for longer time frames is necessary.

For a future trial it is recommended that exercise experts meet with the participants, in addition to the dietitians, to enable a relationship to develop with their participants. However, it appeared that participants often did not believe they could or needed to increase their exercise. More time may be necessary to discuss what the participant feels is possible and how the participant could make small manageable changes, with participants seeming to believe initial capabilities would be suitable to discuss in person at the beginning so that realistic expectations were outlined. The importance of increasing levels of physical activity should be emphasised in addition to adapting diet. Multi-component interventions (focusing on diet and physical activity change) are recommended owing to their increased likelihood for effective weight loss in comparison to single component interventions (National Institute for Health and Clinical Excellence clinical guidelines, 2006 updated 2014; Cavill and Ells,

2010; Sweet and Fortier, 2010). Therefore feedback frequency should be equal in terms of the consultations provided by the dietitians and exercise experts.

Overall the participants and health professionals appeared to believe that an internet based weight loss intervention could be an appropriate treatment within the NHS.

'All I hope is that the NHS do take something like this on board.' (Participant 21, Male).

However, it was evident that improvements to the website were necessary in order to maximise retention and usage. Interviews findings have revealed how an internet based intervention is a mode of delivering weight loss advice that could be more accessible and convenient than traditional face to face meetings that follow set time and location structures.

Chapter 5 **Discussion**

5.1 **Key findings**

Systematic review

The meta-analysis identified that intervention arms incorporating individualised internet feedback were more effective than those without. However, when examining the individualised internet feedback arms many BCTs were present, meaning it is not possible to identify which BCT or combination resulted in the intervention arms being more effective. More research is necessary to identify which individual, or groupings of, BCTs are more effective for weight loss in internet interventions.

Pilot RCT

A key aspect identified during the pilot RCT was the difficulty in identifying post-partum women using GP practice searches, this led to not meeting the recruitment target. The GP database searches identified a small number of eligible patients, although once identified, the proportion of approached women who agreed to take part was higher than that for the men. This suggests an alternative recruitment technique may be necessary to recruit this group rather than that post-partum women did not consent to take part. The recruitment target of 60 was achieved for the men with diabetes. Each of the outcome measures tested were seen to be feasible to implement within a RCT. The food diaries and accelerometers had lower adherence in contrast to the questionnaires and anthropometric measures, although this may have been owing to the inability to complete these within the data collection appointment thus relying on self-completion.

Process evaluation

In terms of acceptability of the intervention both participants and health professionals suggested improvements that they believed essential in order for them to consider the internet based intervention as appropriate to use in practise in the long term. Several of these suggestions related to technical problems and ease of use of the system from both the participants and the health professionals' perspective. Aside of this both groups believed that an

internet based weight loss intervention would be an appropriate service to implement as a weight loss treatment within the NHS, with the suggestion being to integrate it with traditional health care methods such as face to face or telephone appointments.

5.2 **Consistency of findings**

Findings from the pilot RCT and process evaluation in terms of how the intervention was received by participants and health professionals were largely consistent with one another. It was clear that there was variability between end-users in how, and how often, the website was utilised with regards to the distinct features accessed and intensity of engagement. However, the receipt of weekly feedback from health professionals seemed to be the feature that the majority of participants favoured.

Recent research has indicated there is benefit to daily weighing (Steinberg *et al.*, 2014) and cites the ability to gain instant feedback and how it can be beneficial. New advances in technologies which people have become accustomed to, such as smart phones and the internet, allow instantaneous communication and illustrate the need for future research to consider the level of contact that people require or expect. Although receiving weekly feedback seemed to be the feature that the majority of participants favoured, there was variation in the preferred level of contact, with several participants believing that the level of contact should be determined on an individual basis.

In addition to frequency of contact the interview findings also revealed how mode of contact was important. Interview findings identified that the exercise experts' advice was not as well accepted as dietitians' advice since the former had never met the participants, resulting in communication feeling automated rather than delivered by a human. Participants described feeling more comfortable exchanging information with the dietitians. This was supported by the website usage data showing more communication from participants to the dietitians. This is consistent with findings of my systematic review which revealed that web based interventions (or study arms) with human feedback retained more participants than those with automated feedback. One study within the systematic review (Tate *et al.*, 2006) showed the 'human feedback' arm logged in more and completed more self-monitoring diaries than those in

the ‘automated feedback’ arm. However, it should be noted that dietitians in this study had more contact with the participants on the website than the exercise experts and this may have, at least in part, influenced participant engagement and satisfaction with the health professionals.

The findings from primary data collection within this current study did not always coincide with systematic review findings. As mentioned within my systematic review, Chapter 2, the included studies varied in terms of how the interventions were delivered. However, website features tended to be similar with regards to the inclusion of self-monitoring tools, feedback provision, social support features and provision of information.

This pilot RCT incorporated human delivered feedback, as did eight of the studies included in the systematic review but differed from six of the interventions, within the systematic review, which provided automated feedback. This study was conducted over 12 months as were other studies (Tate *et al.*, 2003; McConnon *et al.*, 2007; Hersey *et al.*, 2012) rather than a shorter term period found in some studies, such as 3 months (Morgan *et al.*, 2010; Chambliss *et al.*, 2011a; Kraschnewski *et al.*, 2011; Collins *et al.*, 2012). Within this current study contact, after the initial one off face to face appointment, was only available via the internet. A desire for additional components, more inter-personal interaction to the intervention, such as follow up telephone calls or face to face meetings, emerged from the interview findings. Despite this, the systematic review findings, which identified four studies (Harvey-Berino *et al.*, 2010; Appel *et al.*, 2011; Chambliss *et al.*, 2011a; Hersey *et al.*, 2012) providing additional components, such as face to face sessions or telephone follow ups, showed that they did not increase effectiveness of interventions in terms of weight loss. However, previous research has shown telephone calls to participants did increase the use of a weight loss website (Dennison *et al.*, 2014) suggesting that they may not increase outcome measures, such as weight loss, but rather could be useful for satisfaction, engagement or adherence to an intervention. This relates to views emerging from this study interview findings which concerned additional components to facilitating participants to feel engaged and connected, although depending on cost incorporating these extra resources within an intervention may not be considered cost effective if not leading to increased weight loss.

More studies are needed to examine the use of additional components when all other web features are the same, in order to measure the added value in terms of engagement or compliance and outcome.

It has been suggested that internet based weight loss interventions could benefit from greater integration with primary care, allowing the internet to complement the existing system rather than replace it, by incorporating advantages from different modes of health care delivery (Dickinson *et al.*, 2013). This links to findings from the interviews conducted in this study. Both participants and health professionals believed an internet based intervention could be used within the NHS but felt, at times, they needed to follow more traditional routes to best meet the needs of the patient and so the health professionals could provide the best care possible. This view is supported by previous study findings by Reed *et al.* (2012). The addition of computer-based technology (education or support provided via a website) to non-computer-based interventions (in person sessions) increased weight loss but the substitution of a computer-based intervention resulted in less weight loss (Reed *et al.*, 2012). This raises the question of the effectiveness of an internet provided intervention (delivering information or counselling via web based messages/emails) as a standalone mode of delivery in comparison to other modes.

Griffiths *et al.* (2006) explored interventions to identify why health care interventions had incorporated the use of the internet. This revealed several reasons including low cost, convenience, stigma reduction and increased user and supplier control. However, positive aspects such as increased accessibility for people with mobility problems could also incur opposite negative effects such as isolation through lack of face to face contact. Griffiths *et al.* (2006) highlighted the need for further research to evaluate what added advantages or disadvantages are present from the use of the internet as a mode of delivery of interventions and how they compare to usual treatments. This would allow the most appropriate intervention and mode of delivery, or combination of modes, to be developed and incorporated in order to best suit the population being targeted.

As identified within the systematic review, existing research is limited with regards to direct comparisons of conventional face to face weight loss interventions, as typically offered in the NHS (one to one consultations or group sessions), with internet delivered weight loss interventions. The pilot RCT conducted here intended to compare standard weight loss approaches (control) with the study internet intervention but unfortunately usual care for the two population groups included in this study was minimal or non-existent. Although this allowed comparison against what was experienced as 'usual care', it also meant actual NHS weight loss services were not examined. However, even if controls had been receiving NHS weight loss services this pilot RCT was not powered to investigate efficacy.

5.3 **Strengths and limitations**

Strengths and limitations of my research have been examined in previous chapters but a summary of the main issues is provided below.

Mixed method design

A key strength of this study was the use of multiple methods. When one method, quantitative or qualitative, is used the research is vulnerable owing to both having limitations and weaknesses (Johnson and Turner, 2003; Kelle, 2006; Creswell and Plano Clark, 2011). Therefore in the present study a multiple method design was used to produce a more robust, coherent and complete picture than either method could provide if used alone (Yauch and Steudel, 2003; Gorad and Taylor, 2004; Ostlund *et al.*, 2011).

By conducting a process evaluation alongside the trial, it was possible to explore reasons why usage and engagement with the intervention differed amongst participants and also to derive suggestions for future refinement of the intervention.

Timeframe

The pilot RCT was conducted over a 12 month period. Long term interventions are not as common as short term interventions in internet weight loss research, though interventions of longer duration are increasing, as shown within my systematic review (6/14, 43% collecting 12 month follow up data). Within the

pilot RCT, changes in anthropometric measures showed that improvements continued from three to 12 months in intervention participants. It therefore may have been beneficial to research for a longer period, such as 24 months, after the period when the intervention had finished, to examine what further changes would occur after the end of active support and whether ongoing support would be needed for weight loss maintenance. The need for longer term research to be conducted for internet based weight loss interventions has been identified in previous systematic reviews (Weinstein, 2006; Neve *et al.*, 2010).

Retention

High attrition was identified for all the study groups, with only the men's intervention arm showing rates of attrition similar to those reported previously. However, the rate of attrition was lower between three months to 12 months than in the first three months. This shows potential for retaining those participants that remained past the initial few months for longer periods. This suggests that for some participants more encouragement may be needed at the beginning of the intervention to improve retention within the study, such as Schneider ***et al'***s study which reported that email prompts significantly increased revisits to the programme (Schneider *et al.*, 2012). For other participants the initial period is the time where participants can decide whether it is the right time and right intervention for them and for some it may not have seemed appropriate to continue.

Evidence based practice

A main limitation of the study is the lack of an explicit evidence or theory base for the intervention. An important aspect for interventions is for the treatment to be theory-and evidence-based in order for it to be effective. The use of theory ensures that the relevant behavioural determinants are targeted by applying the appropriate techniques and allows understanding of the determinants involved (Michie *et al.*, 2008). The intervention was adapted from a previously described Danish study (Brandt, 2011), which describes no evidence based development. However, retrospective mapping of elements within the intervention to the BCT taxonomy was conducted.

Further evaluation of the intervention could monitor in greater depth the features used within the intervention, how often they were used, how long for and by whom, monitoring which was not possible to examine for the participants' website usage within this study. Tracking more intensely the participants' website usage could then be used to map website features onto the BCTs incorporated into the intervention to identify how BCTs were utilised by the participants. BCT taxonomies can be used to improve the reporting of behaviour change and intervention development, resulting in improved replication and evidence synthesis (Michie *et al.*, 2011), with the newest taxonomy (v1) examining 16 clusters of 93 individual BCTs (Michie *et al.*, 2013). However, in this current study BCT identification was based on the research teams' retrospective judgement rather than any explicit description from the intervention (website) developers of the intervention development process. Future improvements to build on evidence generated from previous research would be crucial to allow evidence based practice, enabling effective theory and BCTs to be embedded in the intervention from the initial development stage.

Interview findings revealed that within this study monitoring and feedback, typical BCTs within weight loss interventions, were important features, with participants mentioning how these features motivated them to engage with the website. This concurs with findings from a recent systematic review (Dombrowski *et al.*, 2011) examining which theories and behaviour change techniques (BCTs) (Michie *et al.*, 2008) were effective in increasing weight loss in intervention studies. The findings from Dombrowski *et al*'s systematic review suggested that increasing the number of Control Theory related BCTs (prompt specific goal setting, prompt review of behavioural goals, prompt self-monitoring of behaviour, provide feedback on performance) used within an intervention was associated with an increase in weight loss (Dombrowski *et al.*, 2011). The results of that review also revealed that three specific dietary BCTs (provision of instructions (dietary), prompt self-monitoring of behaviour, relapse prevention) showed a significant association with more successful interventions in terms of difference in mean weight loss between intervention and control groups. Previous research findings such as these could be used to refine and strengthen the current intervention.

Support on how to set goals for behaviour change, coupled with how to circumvent barriers and engage potential facilitators for nutritional and physical activity guidance is essential for continuation and progression in weight loss (Silva *et al.*, 2008; Hwang *et al.*, 2010; Dombrowski *et al.*, 2012). Therefore, not only do effective BCTs need to be integrated into the intervention but they also need to be feasible for participants to accomplish and adhere to. This links to the issue of goal conflict (barriers) and goal facilitation and how people tend to have multiple goals which can conflict or facilitate each other (Riediger, 2007). This was reflected in the findings from the interviews in the current study where participants described the various priorities they had to balance in daily life. A way to approach multiple goals could be to use personal project analysis to rate the projects (goals) in a person's life in terms of importance, effort, stress etc. Personal project analysis may be used for reducing goal conflict and enhancing goal facilitation, which may lead to possible explanations and predicting of behaviour (Presseau *et al.*, 2008).

Social support features, such as chat rooms or forum boards, previously identified as an important aspect of weight loss (Hwang *et al.*, 2010; Khaylis *et al.*, 2010), were available within the intervention but were not utilised by the participants. Interview findings identified participants gained social support through those close to them within everyday life. This highlights how BCTs may not be utilised in the same way if they are implemented using different modes of delivery, i.e. social support via the internet in comparison to face to face. Therefore how certain BCTs are incorporated within the intervention, such as social support, may need adaptation to ensure they are suitable and accepted by participants, to increase the impact or utilisation of them.

Study team

Working within a multi-disciplinary team allowed expertise from clinical trial design, trial implementation, statistical advice, nutritional and physical activity advice (academic and clinical) and health psychology to be incorporated and enabled the study design and execution to be strengthened. Advice was provided for my systematic review, pilot RCT and process evaluation allowing knowledge and guidance to be provided based on previous experience and research.

5.4 Implications for policy, practice and research

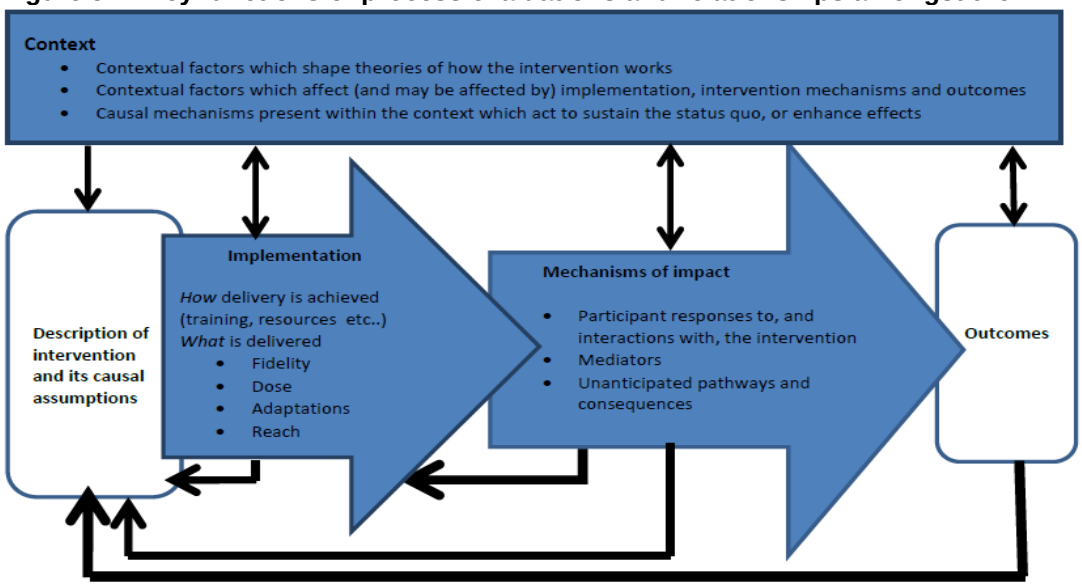
Recruitment

A finding from the pilot RCT was the low rate of identification of post-partum women via GP practice searches with the consequence of not meeting the recruitment target, suggesting that other approaches may be needed to identify post-partum women for this type of weight loss intervention. As mentioned within the interviews, the use free bounty packs provided by midwifery services after childbirth may be a possible alternative method of identification of eligible women as may Sure Start children's centres. More research is needed to investigate these different identification routes, illustrating how important the identification stage is in terms of providing contact to the desired populations.

Process Evaluation

A new MRC framework on process evaluations authored by Moore *et al.* (2014) has followed Craig ***et al's*** earlier document to focus in depth on the role and nature of process evaluations within the broader framework for the design and evaluation of complex interventions. Although this document was not used to guide my process evaluation, as it was published after I had conducted my process evaluation, it is worth addressing how my process evaluation compares to the new framework. The key functions of process evaluations are outlined within the document and illustrated in Figure 5-1 below (Moore *et al.*, 2014).

Figure 5-1: Key functions of process evaluations and relationships amongst them



The guidance indicates that process evaluations may be conducted within feasibility phases/studies. Within this study's process evaluation it was possible to examine key implementation functions, as outlined in Figure 5-1. Intervention resources are outlined in section 3.2 and training materials are shown in appendix U. Fidelity and dose in relation to intervention delivery are examined within section 4.5.2 and describes how health care professional intervention delivery compared to the predetermined protocol. A mechanism of impact that I was able to investigate was participant's response to the intervention, through interviews and retention rates, and their interactions with the intervention, through website usage data. However, this pilot study was not designed or powered to identify the mediators impacting on outcomes or the unanticipated pathways and consequences. As a result the context functions, including casual mechanisms, were not able to be investigated within this pilot study. However, interviews did enable further exploration into how factors could impact on implementation and outcomes. The use of purposive sampling is suggested and is a method I used within my interview data collection. The document states that process evaluations can differ greatly depending on the area of research but hopes the document is useful as guidance to aid key decision making when developing a process evaluation.

Intervention improvement

Improvements to the website are also indicated as necessary in order to develop an evidence based intervention that incorporates BCTs identified as being effective in promoting weight loss. Common reasons participants gave for disengaging with the website were issues such as being too busy, being hard to fit the intervention around work, and/or other priorities. However, the web based intervention is an intervention that aims to be completely under the participant's control in terms of time. For this to be perceived as so hard to fit into participants' lives, suggests that perhaps the quality of the experience with the website was not to a standard that some participants expected and/or enjoyed. Therefore it is apparent that the website needs further development, with user engagement, in terms of making the website as efficient, practical and user friendly as possible.

A suggestion to increase the practicality and accessibility of the intervention was to incorporate the website into a mobile phone application, with previous research and a synthesis review identifying that participants tended to view this mode of delivery as appropriate and convenient for weight loss (Turner-McGrievy and Tate, 2011; Kirk *et al.*, 2012; Aguilar-Martinez *et al.*, 2014; Hearn *et al.*, 2014; Waring *et al.*, 2014). This identifies a possible development for future research.

It has been noted in previous research that multicomponent weight loss interventions can be more effective in comparison to single component i.e. diet or physical activity alone (Sweet and Fortier, 2010; National Institute for Health and Clinical Excellence public health guidelines, 2014). Therefore adaption of the current intervention to enable dietitian and exercise expert input to be equal may help to overcome negative responses received from the interviews with regards to the level of guidance and support received from the exercise experts.

Outcome measures

Turning to trial procedures, all outcome measures appeared to be appropriate within this study. An issue that needed consideration was how to incorporate all outcome measures without putting too much burden on the participants. However, it is worth noting that participants were only required to meet with me on three occasions over the period of a year. The option of house visits was also offered to increase convenience for the participants. In addition appointments took a maximum of an hour, with some participants completing all measures within twenty minutes. Appointment length of time was mainly dependent on the participant's progression through the two questionnaires. I believe all outcome measures should be retained in a future trial although some modifications, which will now be discussed, could be made with regards to the instruments used.

Levels of adherence and compliance with food diaries and the wearing of accelerometers (along with the completion of the diaries on the use of the accelerometers) were lower than the other outcome measures' completion rates. Outcome measures to collect food and exercise data could be used from the self-monitoring features within the website rather than additional methods of

collection that add extra burden. Therefore, one method of data collection could be implemented and utilised simultaneously as an intervention tool for participants to provide feedback on how they are doing, i.e. self-monitoring, but also for assessment purposes within a study to provide measures of the impact of the intervention, as a secondary measure of effectiveness. Self-monitoring is linked to greater weight loss (Burke *et al.*, 2011; Hwang *et al.*, 2013) and therefore more development is needed to make this aspect as easy and quick as possible for participants to engage with within the intervention. However, using self-monitoring methods within the website would mean the control group would need to be permitted access to a limited set of the web based tools.

The paper based food diaries collected within our study, as an assessment tool, were generally not completed to a good standard. By using the data entered into the website it would allow a greater amount of data to be accessed about the participant's food intake. In addition if completion was poor this could form part of the dietitian's feedback in order to improve completion of the self-monitoring tool. However, there is a narrow balance that needs to be acknowledged between providing enough information for health professionals without placing too much burden on participants in terms of self-monitoring.

Accelerometers are precise instruments that provide a variety of information but as the majority of participants were sedentary individuals it appeared, that in terms of improving physical activity levels, measures of steps taken and distance travelled (which could be assessed by pedometers) may be more relevant than MVPA measured via an accelerometer. Accelerometers may be necessary for assessment purposes but are not appropriate as use as intervention tools to increase physical activity, such as previously identified (Bravata *et al.*, 2007; Kang *et al.*, 2009). To enable objective physical activity data to be collected across the intervention and to capitalise on the impact of daily feedback, pedometers could be provided to participants to provide immediate feedback and data then entered into the website. These data could be used by the exercise experts to provide tailored intervention. The provision of pedometers in obese women identified greater weight loss compared to a group provided with physical activity information only (Cayir *et al.*, 2014). Pedometers are cheap which would make them feasible to use within a larger scale trial. Pedometers as a physical activity self-monitoring instrument could be

realistically suggested for participants to buy for themselves with potential to retain after study period, prolonging the possibility of long term self-monitoring and feedback. Rapid changes and developments in how monitoring and feedback can be provided, such as the 'my fitness pal' application, enable active monitoring through mobile phones which have the potential for data collection (automated remote collection) whilst allowing self-monitoring to occur. New technologies provide potential for future intervention development and research but evaluation of such packages or applications is required.

The anthropometric measures (weight loss, BMI and waist circumference) were successful in terms of acceptance from participants and completion rates. Both questionnaires, OWLQOL/WRSM and the Predictors of behaviour change, were also well completed by participants, with only slight alterations to the presentation of some questions within the Predictors of behaviour change questionnaire needed to improve the efficiency of completion.

Reflection on my work

Overall looking back over the study as a whole I believe the trial process and procedures worked well, as shown in Table 5-1.

Table 5-1: Summary of findings against 14 methodological issues for feasibility research

Methodological issues	Findings	Evidence
1. Did the feasibility/pilot study allow a sample size calculation for the main trial?	Measure of variability and retention rates identified. Sample size calculation for main trial was conducted.	Target of 60 achieved for men. 16/60 achieved for women. Number of practices required: 71 Number of participants needing to be identified/contacted: 9913 Number needing to be randomised: 637 Number needed at 12 months to detect target difference: 274 (137 per arm).

Methodological issues	Findings	Evidence
2. What factors influenced eligibility and what proportion of those approached were eligible?	High numbers of eligible men (968) were identified from GP practice database searches. However, low numbers were identified for women (168). Ineligibility was due to BMI being too low or high.	3 out of 19 approached were ineligible for women. 5 out of 66 approached were ineligible for men.
3. Was recruitment successful?	Recruitment was successful for the men but recruitment was more difficult and limited for women as a low number of eligible women were identified and contacted.	Response to study invitation was low, 9% of identified men and 13% of women expressing interest in the study.
4. Did eligible participants consent?	High conversion to consent.	Of the 61 eligible men and 16 eligible women all were recruited.
5. Were participants successfully randomized and did randomization yield equality in groups?	Worked well.	Allocation concealment was achieved. Fairly equal sized groups. Well balanced on stratification variables.
6. Were blinding procedures adequate?	Blinding was not possible and was not planned.	Blinding not implemented.
7. Did participants adhere to the intervention?	Low adherence to intervention website.	Only 20 out of 40 (50%) allocated intervention participants actively used the intervention website.
8. Was the intervention acceptable to the participants?	The intervention appeared to be acceptable to participants.	All eligible participants consented once full study information was explained. The majority of participants interviewed believed the intervention to be feasible to implement within the NHS.
9. Was it possible to calculate intervention costs and duration?	Not assessed within this pilot trial.	No costs calculated.
10. Were outcome assessments completed?	Diet and physical activity measures had lower completion rates than other outcome measures.	See summary of outcome measure response rates in table 3-16.

Methodological issues	Findings	Evidence
11. Were outcomes measured those that were the most appropriate outcomes?	Outcome measures used did assess main areas of interest.	Anthropometric measures allowed health outcomes to be measured whilst diet and physical activity measures enabled the behaviours to be examined. Quality of life assessed how obesity impacted on participants' lives whilst predictors of behaviour change assessed the individual components involved.
12. Was retention to the study good?	Substantial attrition was identified.	Remaining Men: 3 months: 73% I, 57% C 12 months: 61% I, 45% C Remaining Women: 3 months: 57% I, 56% C 12 months: 43% I, 44% C
13. Were the logistics of running a multicentre trial assessed?	Number of participants recruited from each GP practice varied amongst the 11 involved in the study. This was largely influenced by the number of eligible participants identified in the GP database search.	63 (82%) of the 77 recruited were from the 3 practices where the greatest number of eligible participants were identified.
14. Did all components of the protocol work together?	Components had strong synergy.	There were no difficulties identified in my ability to implement any of the study processes. Participants were recruited, randomised and progressed into the appropriate trial arm smoothly.
Methodological issues based on Shanyinde *et al.* (2011). C = Control, I = Intervention.		

A study by Bugge *et al.* (2013) identified the difficulty faced in deciding what changes are necessary as a result of a pilot RCT and acknowledged the need to outline study problems and the possible solutions. Problems appeared to be addressed by solutions relating to study context, trial design, the intervention or all three and whether these could be effective or feasible within trial or real world settings (Bugge *et al.*, 2013). The main issues that arose within this study was the low initial response rates to express interest in joining the study and retention rates. Possible solutions to these problems could be the use of an opt-

out recruitment approach, rather than opt-in, which could be incorporated into a real world setting as well as trial context. However, this may impact on retention levels, unlike the use of incentives which could aid both uptake and retention. Incentives would have to be carefully assessed in terms of costings and cost effectiveness, which would probably not be possible for a real world context but could be appropriate for a trial context. Another solution could be the improvement of the intervention, with suggestions such as creating a mobile phone application in addition to a website to make it accessible to more people therefore hopefully increasing uptake, retention and possibly adherence. Another potential improvement to the intervention would be the integration of services to allow consultations to take the form of different modes of delivery (face to face, telephone or internet), which again could improve interest in the study, retention and adherence.

Sample size calculations, as reported in Table 5-1 above, were calculated using the Power and Size package to identify the sample size needed for a main trial, while other calculations were based on response and retention rates from the current study. Sample size was identified based on the main trial being a superiority trial and achieving a 10%, 15% or 20% absolute target difference (90% power, 5% significance level, 1:1 allocation and analysis with Fisher's exact test) between the control and the intervention arms in terms of percentage of participants losing ≥ 5% weight loss at 12 months. The 20% absolute target difference calculations are reported in Table 5-1 as this identified the most feasible sample sizes for a main trial.

Using GP practice rooms as bases in which to conduct data collection appointments was very useful to allow more time for appointments rather than conducting all house visits. However, having a lone worker (Guardian 24) log in allowed me to be more flexible and conduct home visits when needed. Only one of the practices charged a fee for using a room within their GP practice, which could have greatly impacted on costs if all practices requested payment. However, practices were generally very helpful and accommodating.

I have learnt that creating a relationship with health professionals you wish to work with in practice is essential and allows you to outline what you wish to do, whilst allowing them to discuss what will be possible. The health professionals

involved within this study were very open and honest about how they wanted to be involved but were unfamiliar and new to being involved with research and clear that the time they were able to commit was limited. In response I tried to keep them as informed as possible and from the start outlined that this project was investigating a different mode of delivery but that feedback/advice to the participants via the website was completely in their control.

Managing and working as part of a multi-disciplinary team was often a challenging experience owing to time and resource pressures. However, the experience is one that I enjoyed and believe I have benefited from and developed as a researcher. The project has allowed me to work with health professionals and researchers and to experience both the academic and practical sides of an intervention and a trial. Working with patients has also been an interesting and rewarding aspect of the project. I enjoyed meeting with participants, seeing how they progressed over the year and realising the difference research and practice can have on individuals. I have developed as a researcher with regards to time and team management, patient skills and individual skills which I have experienced during the course of this study. All of which have increased my passion and interest in health and specifically the area of obesity.

I have to acknowledge how my role in the research may have impacted on the study or my interpretation of the study. Having an academic/research background may have affected the way I analysed and interpreted findings. My background is in health psychology, which may have impacted on certain focuses within the study, for example incorporating a predictor of behaviour change questionnaire to explore theoretical constructs. This background may also have impacted on how I interacted with the health care professionals as I was aware that I was not from the work environment that they were accustomed to. To address this I made a conscious effect to work around their workloads and acknowledged the necessity to create and maintain a relationship with the health care professionals involved in the study. However, maintaining communication throughout may have impacted on their commitment and adherence to the intervention. My communication tended to be more based around practical, protocol driven, or research issues. In contrast a clinician, such as dietitian, may have focused more on clinical issues such as

consultation information, follow ups or participant outcomes. I was involved in the training of the health care professionals and therefore it is inevitable that this influenced how the intervention was delivered. However, they were instructed to deliver consultations as they would in usual practice circumstances and I believe the health care professionals treated their participants with the same professionalism as they would use on a daily basis in their occupations as dietitians or exercise experts. My role as researcher may have also impacted on the recruitment, retention and adherence of participants as it was me that introduced them to the study, recruited them and met with at each of the data collection time point. I was also available to contact if participants had any queries or issues with the study. This has to be acknowledged but is unavoidable in terms of a person's personality, of me as the researcher or patients as the participants, either strengthening or weakening the commitment or enjoyment of the study. However, I followed the same format and procedure for each of the participants at each of the time points. This also highlights why the inclusion of a control group was useful as both groups met with me at the data collection points. Therefore meeting me as the researcher would have impacted on both groups and therefore irrespective of this the result of being randomised to the intervention could be examined against participants assigned to usual care. Interviews were also conducted by me, with whom participants and health care professionals had met several times. This therefore may have made them more comfortable and relaxed in conversation. I believe this allowed a more honest and open conversation to occur, for example participants felt they were able to critique the website or aspects of the study and aided the purpose of the interviews. My enthusiasm for the study should also be noted and my desire for the study to succeed and for participants to lose weight. However, I do not believe this impacted on my interpretations of the results. Weight was objectively measured and therefore I could not influence this. With regards to the study I have not been blind sighted by success and acknowledge that as it stands it would not be appropriate to take to a full trial but outline that further trialling/piloting is necessary for certain aspects of the study.

5.5 **Conclusion**

This study has added to research by providing information on the feasibility of using an internet based weight loss intervention within the NHS and UK.

Research is limited to how an internet intervention could be implemented within the UK with the majority of studies being conducted in the USA and Australia. Previous research is lacking with regards to evidence that an internet weight loss intervention could be incorporated into the current health service and used as a treatment option within weight loss referral services. This research is especially important during the current changes occurring within the NHS when time and resources are increasingly stretched. Given the lack of available services in the area of obesity, alternative modes of delivery, with the potential to reduce health professional input and time per patient whilst still enabling individual and tailored care, need to be investigated to identify if they can be effective and thus benefit the NHS by reducing cost while also maintaining or increasing quality of care to patients. The aim then would be to reach more patients than are possible through current, mainly face to face, practice.

Using data collected from this pilot study, as outlined in Table 5-1 and discussed above, would be necessary to further refine the intervention and trial protocol before conducting a full scale definitive trial to examine the clinical and cost effectiveness of implementing this, or an adapted, internet based weight loss intervention. This could be used to improve the intervention as it stands so that it is evidence based, incorporates efficient processes and the most appropriate assessment tools. It would be only after this development and further trialling that it would be possible to assess whether an internet based intervention was clinically and cost-effective. Although more development is needed I believe that an internet based intervention could advance health care within the NHS in terms of increasing accessibility to limited health professionals whilst facilitating weight loss. I acknowledge that an internet based intervention is not an appropriate treatment for everyone. As shown by this study and previous research the best solution may not be implementation of this as a standalone intervention. However, I believe there is potential to offer this as an alternative or adjunct method for weight loss. The challenge remains of how to integrate an internet weight loss intervention into primary care to best benefit health professionals, patients and the NHS.

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Appendices

A. Systematic Review Protocol

Review title

Systematic Review of interactive internet based interventions providing individualised health care programmes for weight loss in overweight and obese adults.

Review Question

Primary: To assess whether internet based contact is effective when individualised feedback and guidance is provided for weight loss in overweight and obese adults.

Secondary: To identify the behaviour change techniques in internet interventions and their relationship to effectiveness and acceptability.

Method

1. Criteria for considering studies for this review

1.1 Types of studies

Randomised controlled trials will be eligible for inclusion.

1.2 Types of participants

Men and women with a body mass index (BMI) categorised as overweight or obese (>25kg/m^2) will be included. Participants >18 years old will be included.

1.3 Types of interventions

Interventions to be included are behaviour change interventions targeting diet, physical activity or both, for weight loss.

Only interventions that include some form of internet delivered care will be included.

Only interventions that include some form of individualised feedback/contact via the internet will be included (For example by email or web based messaging).

The following definition for feedback (Michie et al's 2011 taxonomy of behaviour change techniques (Michie *et al.*, 2011)) will be used to decide whether individualised feedback was incorporated in each study.

Michie et al, 2011, pg. 9:
"Provide feedback on performance -
This involves providing the participant with data about their own recorded behaviour or commenting on a person's behavioural performance (e.g. identifying a discrepancy between behavioural performance and a set goal or a discrepancy between one's own performance in relation to others). "
Feedback will only be classified as individualised if the information received by the participant is personal to their weight loss experience. Studies including only generic feedback will be excluded. Individualised feedback can include both automatic (computer processed) feedback and feedback provided by a health care professional or other individual. These two different methods of feedback will be addressed separately in the data analysis stage.

Studies that incorporate both internet and personal contact will be included but at least some individualised feedback must be delivered via the internet. These studies will be addressed separately.

There will be no restrictions in terms of length of intervention or follow up.

Routine, non-surgical or non-pharmacological, standard care for overweight or obese individuals or alternative interventions that do not include individualised feedback via the internet will be used as comparator groups.

Types of outcome measures

Primary outcome measure will be the change in body weight post-intervention, body fat percentage (assessed by callipers or electronically), waist circumference and BMI.

Secondary outcomes will be behavioural change techniques (Michie *et al.*, 2011) and theoretical frameworks used to develop the interventions (Michie and Prestwich, 2010). Measures of effectiveness, acceptability, engagement and attrition/retention rates will also be included.

1.41 Analysis/synthesis

The data extracted from the included studies will be analysed in the following way:

The change in score from baseline to endpoint will be analysed for:

- Weight loss
- Body fat percentage
- BMI results
- Waist circumference

These data will be a mean (SD) or median (95% CI). Findings from each study will compare intervention and control group findings but will also compare studies that differ in relation to the objectives of behaviour change and features of the website (theory base, behaviour change techniques). If possible moderator analysis will be conducted to check which interventions are more likely to produce positive effects. Meta-analysis will be conducted if possible to do so. Intention–to-treat analysis and study completer analysis will be performed on each included study if possible.

- Effectiveness – number of participants showing a decrease in weight, body fat percentage, BMI or waist circumference (in comparison to the control group). Also extracted will be number of participants showing a 5-10% decrease in their original body weight (guideline recommendations to improve a person's health (National Institute for Health and Clinical Excellence clinical guidelines, 2006 updated 2014)).
- Level of engagement - average number of log-ins, how often features of the intervention were accessed, time spent on the website/each feature.
- Retention rates – number of participants remaining and adhering to randomised arm and also number of participants remaining in study for data collection (comparison to rates in the control group).
- Attrition rates – number of drop outs from allocated arm and number of participants with loss of follow up data collection (comparison to levels in the control group).

2. Search methods for identification of studies

2.1. Electronic databases

Studies will be retrieved from several databases with combinations of the key words “internet”, “web”, “computer”, “online”, “eHealth”, “nutrition”, “diet*”, “physical activity”, “exercise”, “weight”, “weight loss”, “overweight”, “obes*” and “randomi*ed controlled trial”.

Databases searched will be Scopus, Web of Science, EMBASE, MEDLINE, PsycINFO, ASSIA, IBSS, the Sociological Abstracts and CINAHL.

Clinical Trial registers and theses databases will also be searched.

2.2. Hand searching

Conference publications and relevant journals (Obesity Journal, International Journal of Obesity, Journal of Medical Internet Research, Journal of Nutrition and Dietetics) will be searched.

2.3. Reference checking

Reference lists of identified studies and citation indexes of papers citing the identified studies will be searched.

2.4. Personal communication

The authors of significant papers over the last five years and other experts in the field will be contacted and asked if they were aware of any other studies, which not have been published, relevant to the review. The authors will also be requested to send any intervention materials and to allow the authors of this systematic review to log into the web page in order to increase the available information to better describe the intervention and the behaviour change techniques used.

3. Data collection and analysis

3.1. Selection of studies

All studies generated from the previously defined search strategies will be evaluated against the pre-defined inclusion criteria by two of the review authors, Anna Sherrington and James Newham. Any disparities will be addressed by reaching an agreement via an additional review author, Vera Araujo-Soares. A record of included and excluded studies will be kept.

3.2 Data extraction

1. Study author, publication year and country where research took place.
2. Participants recruited (age, gender).
3. Intervention characteristics and comparison groups:

- Reporting of intervention components - based on Davidson et al 2003 (Davidson *et al.*, 2003) guidelines of minimal intervention detail to be described in research reports (content/elements, provider, format, setting, recipient, intensity, duration and fidelity).
- Method of selection/recruitment of participants
- Behaviour change techniques used - These will be coded based on Michie et al 2011 (Michie *et al.*, 2011) CALO-RE taxonomy of behaviour change techniques to help people change their eating and physical activity behaviours.
- Theoretical framework – Theories used to develop interventions will be recorded if mentioned by the authors. The reviewer is aware that a mixture of theories may be used in one study and authors will be contacted if any uncertainties arise. Sensitivity analysis will be performed on studies that incorporate theoretical framework into their study (Michie and Prestwich, 2010).

4. Weight loss ([non] significance), body fat percentage, waist circumference and BMI results. Any other outcome measures will also be extracted.
5. Engagement levels, recruitment, retention and attrition rates.
6. Methodological quality of the evidence.

3.3 Quality assessment

Risk of bias/validity assessment

The studies that qualify for inclusion into the review will be assessed independently for their methodological quality. In order to minimise any selection bias, both review authors will be blind to the source and the authorship of the paper.

A number of different sources of bias will be considered:

- Selection bias (differences between the groups compared)

- Performance bias (arising from participants being aware of the group they are randomised to)
- Attrition bias (arising from subjects withdrawing from the trial)
- Detection bias (which refers to problems with outcome assessments)

Studies will be assigned a quality rating of A, B or C, based on the criteria set out in the Cochrane Collaboration Handbook (Higgins and Green, 2011a). If the two review authors disagree with the rating of any study, a third review author will be available to consult in order to reach a consensus. Other aspects relating to the quality of the study will be considered in relation to the previously defined criteria, such as randomisation method, blinding, reporting of dropouts, missing data, assessing heterogeneity and intention to treat. Where possible, authors will be contacted to ask for further information (such as intervention materials), where the reporting of these was insufficient. Publication bias will also be examined using funnel plots. Statistical analysis of the data will be carried out through meta-analysis if this is deemed appropriate to use. This is will be decide by assessing the heterogeneity of the included studies. Review Manager 5.1 will be the software used to carry out the analysis.

B. Quality Assessment Form

Author & date			
Extracted by		**Checked by**	

	Domain	**Score:** Yes, No, Unclear, N/A	**Description/comments**
1	**Randomisation** Does the study report randomisation?		(If yes, note individual or group)
2	**Allocation concealment** Was allocation adequately concealed?		
3	**Blinding** Is blinding reported?	**(**If no, go to 5**)**	
3 a	**Blinding of participants** Is blinding of participants reported?		
	Was the participant adequately blinded?		
3 b	**Blinding of intervener** Is blinding of intervener reported?		
	Was the individual adequately blinded?		
3 c	**Blinding of data collector** Is blinding of data analyser reported?		
	Was the individual adequately blinded?		
4 d	**Blinding of outcome assessors** Is blinding of outcome assessors reported?		
	Was the outcome assessor adequately blinded?		
5	**Incomplete outcome data** Were incomplete outcome data adequately addressed?		
6	**Selective outcome reporting** Are reports of the study free of suggestion of selective outcome reporting?		
7	**Other sources of bias** Was the study apparently free of other problems that could put it at a high risk of bias?		

C. Feedback versus no feedback meta-analysis

Including SEM studies

Time	#	Weight Loss	#	5% Weight Loss (Risk ratio)	#	BMI change	#	Waist circumference
Total	12	-2.13 [-2.97, -1.29]*	10	2.13 [1.56, 2.90]*	8	-0.99 [-1.28, -0.70]*	8	-2.42 [-3.65, -1.19]***
3	7	-2.62 [-3.14, -2.09]*	3	8.26 [3.24, 21.07]*	5	-1.02 [-1.23, -0.81]*	5	-2.39 [-4.67, -0.11]***
6	7	-1.82 [-3.32, -0.32]***	5	2.30 [1.49, 3.55]***	3	-0.95 [-1.79, -0.11]***	4	-2.35 [-3.95, -0.76]***
12	5	-2.18 [-5.80, -1.44]	2	1.53 [0.82, 2.84]	3	-1.20 [-1.74, -0.66]**	2	-2.44 [-4.45, -0.42]***
Mean difference [95% CI] *p<0.00001, **p<0.0001, ***p<0.05 #Number of studies included in meta-analysis.								

Excluding SEM studies

Time (mths)	No #	Weight Loss	No #	5% Weight Loss (Risk ratio)	No#	BMI change	No #	Waist circumference
Total	10	-2.47 [-2.99, -1.94]*	7	2.86 [1.85, 4.41]*	7	-0.91 [-1.16, -0.65]*	7	-2.26 [-3.62, -0.89]***
3	7	-2.62 [-3.14, -2.09]*	3	8.26 [3.24, 21.07]*	5	-1.02 [-1.23, -0.81]*	5	-2.39 [-4.67, -0.11]***
6	5	-1.94 [-2.51, -1.35]*	3	2.24 [1.63, 3.06]*	3	-0.59 [-0.80, -0.39]*	3	-1.51 [-2.15, -0.87]*
12	2	-2.33 [-4.26, -0.39]***	1	2.28 [1.01, 5.13]	2	-0.80 [-1.45, -0.15]***	2	-2.44 [-4.45, -0.42]***
Mean difference (95% CI) *p<0.00001, **p<0.0001, ***p<0.05 # Number of studies included in meta-analysis.								

D. Human feedback versus no feedback meta-analysis

Including SEM studies

Time	#	Weight Loss	#	5% Weight Loss (Risk ratio)	#	BMI change	#	Waist circumference
Total	8	-2.34 [-3.38, -1.30]**	7	2.21 [1.49, 3.29]**	5	-0.90 [-1.24, -0.56]*	6	-2.70 [-4.28, -1.11]***
3	5	-2.84 [-3.56, -2.13]*	2	14.89 [2.99, 74.08]***	3	-1.03 [-1.44, -0.63]*	4	-3.03 [-5.26, -0.81]***
6	5	-1.72 [-2.73, -0.71]***	4	1.88 [1.34, 2.64]**	2	-0.59 [-0.80, -0.39]*	3	-1.51 [-2.15, -0.87]*
12	2	-2.33 [-4.26, -0.39]***	1	2.28 [1.01, 5.13]	2	-0.80 [-1.45, -0.15]***	2	-2.44 [-4.45, -0.42]***
Mean difference [95% CI] *p<0.00001, **p<0.0001, ***p<0.05 #Number of studies included in meta-analysis.								

Excluding SEM studies

Time (mths)	No #	Weight Loss	No #	5% Weight Loss (Risk ratio)	No #	BMI change	No #	Waist circumference
Total	7	-2.62 [-3.38, -1.85]*	6	2.57 [1.66, 3.98]**	5	-0.90 [-1.24, -0.56]*	6	-2.70 [-4.28, -1.11]***
3	5	-2.84 [-3.56, -2.13]*	2	14.89 [2.99, 74.08]***	3	-1.03 [-1.44, -0.63]*	4	-3.03 [-5.26, -0.81]***
6	4	-2.01 [-2.61, -1.42]*	3	2.23 [1.61, 3.08]*	2	-0.59 [-0.80, -0.39]*	3	-1.51 [-2.15, -0.87]*
12	2	-2.33 [-4.26, -0.39]***	1	2.28 [1.01, 5.13]	2	-0.80 [-1.45, -0.15]***	2	-2.44 [-4.45, -0.42]***
Mean difference (95% CI) *p<0.00001, **p<0.0001, ***p<0.05 # Number of studies included in meta-analysis.								

E. Automatic feedback versus no feedback meta-analysis

Including SEM studies

Time	#	Weight Loss	#	5% Weight Loss (Risk ratio)	#	BMI change	#	Waist circumference
Total	5	-1.85 [-4.38, 0.67]	4	1.78 [1.08, 2.95]***	3	-1.15 [-1.42, -0.89]*	2	-1.82 [-4.78, 1.15]
3	3	-2.31 [-3.18, -1.45]*	1	N/D	2	-0.99 [-1.33, -0.64]*	1	N/D
6	3	-1.83 [-5.68, 2.03]	1	N/D	1	N/D	1	N/D
12	2	-1.62 [-5.69, 2.44]	2	1.61 [0.94, 2.76]	0	N/D	1	N/D

Mean difference [95% CI] *p<0.00001, **p<0.0001, ***p<0.05
#Number of studies included in meta-analysis.
N/D = One study or no data, narrative description rather than meta-analysis.

Excluding SEM studies

Time (mths)	No #	Weight Loss	No #	5% Weight Loss (Risk ratio)	No #	BMI change	No #	Waist circumference
Total	3	-2.20 [-3.25, -1.16]**	2	2.60 [0.49, 13.79]	2	-0.99 [-1.33, -0.64]*	1	N/D
3	3	-2.31 [-3.18,-1.45]*	1	N/D	2	-0.99 [-1.33, -0.64]*	1	N/D
6	1	N/D	1	N/D	0	N/D	0	N/D
12	0	N/D	0	N/D	0	N/D	0	N/D

Mean difference (95% CI) *p<0.00001, **p<0.0001, ***p<0.05

Number of studies included in meta-analysis.

N/D = One study or no data, narrative description rather than meta-analysis.

F. Health professional Information Sheet

Evaluation of an internet-based weight loss intervention.

Anna Sherrington, Dr Ruth Bell, Professor Ashley Adamson, Dr Vera Araujo-Soares, Professor Elaine McColl.

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it will involve for you. One of our team will go through the information sheet with you and answer any questions you have. Please read this carefully and ask us if you would like any more information. Talk to others about the study if you wish.

What is the purpose of the study?

The study is being carried out to test how feasible it is to deliver a weight loss programme via the internet. The aim is to investigate whether this is an appropriate way for dietitians to administer weight management advice in primary care by comparison with usual NHS care for weight management. The study will examine the use of individualised feedback and the impact it has on patient's weight loss. Levels of recruitment, retention, attrition and engagement to the weight loss programme will be recorded.
This study is being carried out as a PhD by Anna Sherrington.

Why have I been chosen and do I have to take part?
We are recruiting two dietitians and two exercise experts to provide consultations via a website for the participants in the study. It is up to you to decide whether or not to take part. You can change your mind at any time and without giving a reason.

What will happen to me if I take part and what will I have to do?
You will first sign a consent form stating that you agree to take part in a semi-structured interview at the end of the study. The interview will be conducted by the researcher and will focus on how acceptable and feasible you found the internet based intervention as a weight loss programme. The interview will be audio recorded. The usual care group treatment will be dependent on the treatment deemed necessary for their care, with frequency and content (weight management advice) dependent on what is deemed as appropriate. The intervention group will met with their dietitian once for one face to face meeting but from then on will receive weight management information and consultations from you via the internet, through a website. Consultations from the dietitians will be given every week for the first 3 months; and then monthly for the next 9 months. You will take

part in the study for 12 months. Consultations from the exercise experts will be monthly for the first 3 months and then once every 3 months for the next 9 months.

Expenses and payments
Any travel expenses you incur solely the taking part in the interview will be reimbursed if you provide us with a receipt.

What are the risks and benefits of taking part?
There are no risks of taking part, only the possible inconvenience of giving up your time to take part. However the time and place of your interview will be arranged to minimise disruption.

What happens when the research study stops?
We will send you a report of our findings.

What will happen if I don't want to carry on with the study?
You can withdraw from the study at any time without having to give a reason.

Will my taking part in this study be kept confidential?
Yes, we will follow ethical and legal practice and all information about you will be handled in confidence. Only the research team will have access to the audio recording. All the information you give us will be anonymised so you cannot be identified. All our records will be kept securely in Newcastle University in accordance with the Data Protection Act 1998.

What if there is a problem?
Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions (0191 2223829).

What will happen to the results of the research study?
We anticipate the results will be published in a medical journal. You will not be identified in any report or publication.

Who is organising and funding the research and who has reviewed the study?
The study is being funded by the UK Clinical Research Collaboration via the Economic and Social Research Council and by Durham and Darlington NHS Foundation Trust and carried out by Newcastle University. All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by Cambridge Central Research Ethics Proportionate Review Sub-Committee.

Contact for further information
If you have any further questions about the study please contact Anna Sherrington (0191 2223829) or Dr Ruth Bell (0191 2228769).

Thank you for reading this information sheet.

G. Health professional Consent form

MyDietitian

Newcastle University

County Durham and Darlington NHS
NHS Foundation Trust

Consent Form for health professionals:

Evaluation of an internet-based weight loss intervention

Centre number:

Study number:

Name of Researcher(s): **Please initial box**

1. I confirm that I have read and understand the information sheet dated 09/08/2012 (version 2.0) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason. ☐

3. I agree to allow the researchers to audio-record the interview. I understand that direct quotes may be used in the final report or scientific publications, however these will be anonymised and no personal information which could identify me will be used. ☐

4. I understand that all data collected will remain anonymous and confidential, and will be stored in a locked filing cabinet and on password protected computers located in the Institute of Health and Society at Newcastle University. ☐

5. I understand that during the interview if any disclosures are made that would indicate malpractice or misconduct, or suggest that any individual was in danger of harm; this information will be disclosed to the appropriate personnel. ☐

6. I understand that relevant sections of my data collected during the study, may be looked at by individuals from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐

7. I agree to take part in the above study. ☐

Name of health professional	Date	Signature
Name of person taking consent	Date	Signature

When completed, 1 for health professional; 1 for researcher site file.

H. GP Practice recruitment letter

MyDietitian

Newcastle University

County Durham and Darlington NHS
NHS Foundation Trust

Dear Doctor,

We wish to invite you to take part in our research project:

Evaluation of an internet-based weight loss intervention.

Participation will involve patients, aged 18 years and above (men or women) and are obese (Body Mass Index(BMI) >≈30 and <40 kg/m^2), being randomised to either usual care for weight management or an internet weight loss intervention. Participants in the internet intervention will receive weight management advice and feedback from a dietitian and exercise expert via a website. Patients will be required to be participants for 12 months. Height and weight measurements, BMI and waist circumference will be recorded at baseline, 3 and 12 months of the study time period.

Some participants will be asked to take part in face-to-face semi-structured interviews during the study. This will assess how feasible and acceptable the internet weight loss intervention had been.

If you wished to take part then your practice would be required to assist us in a database search for eligible participants:

1. Women who have recently had a baby (from 3 months up to 2 years after childbirth) and, who currently have a BMI between >≈30 and <40 kg/m^2. Women who are breastfeeding will be eligible for inclusion as there is no evidence that weight loss advice is harmful during this period.

2. The other target group are men who have been diagnosed with type 2 diabetes and have a BMI between >≈30 and <40 kg/m^2 within the past three years.

Your practice would then need to send a letter of invitation and an information sheet, enclosed with a stamped return envelope addressed to the university, to the patients this identified, asking them to 'opt in' to being approached by the study research team.

After that it will be the research team's job to recruit participants to the study and the dietitians will be responsible for delivering the intervention.

This study has been reviewed by and given a favourable opinion by Cambridge Central Research Ethics Proportionate Review Sub-Committee.

If you have any questions about this study please contact myself (Tel 0191 2223829) or Dr Ruth Bell (Tel 0191 2228769).

Yours Faithfully

Anna Sherrington MSc BSc

FUSE ESRC PhD Student

I. Participant Invitation letter

MyDietitian

Newcastle University

County Durham and Darlington NHS
NHS Foundation Trust

[Patient name and address
to be filled in by GP practice]

Re Evaluation of a personalised weight loss programme

Dear

You have been identified as potentially suitable to take part in a new research study.
A new internet programme for weight loss is being investigated to discover more about how effective the intervention could be in the NHS compared with usual NHS care for weight management. Qualified dietitians will be involved to provide guidance and advice throughout the project. I am writing to you to ask whether you would be willing to consider helping with this research.

Participants will have an equal chance of being placed in either the usual care group (standard care through the NHS, may involve no treatment or face to face consultations) or the internet website intervention group.

The research involves a twelve month period. Measurements (weight, BMI, body fat percentage, waist circumference) and questionnaires will be conducted at the start of the project and 3, and 12 months after the project begins. An interview may take place between 6 and 12 months (end of project).

To take part in the study you must have access to the internet, this can be in any location (home, office, public location) or on any device (desktop computer, laptop or mobile phone).

All travel and parking costs will be reimbursed. There is absolutely no obligation to take part and you are free to change your mind at any stage.

If you would like to find out more about this work, please contact one of the researchers, Miss Anna Sherrington on 0191 2223829 (email

a.sherrington@ncl.ac.uk) or Dr Ruth Bell on 0191 2228769. Alternatively, please complete the reply slip and return (envelope enclosed). Sending back a reply slip does not definitely commit you to taking part you can change your mind if you wish to do so later.

Thank you for considering this research.

Yours sincerely,

Anna Sherrington
PhD Student
Newcastle University

Research into a personalised weight loss programme

Please indicate your answer by ticking the appropriate box below.

Thank you for letting me know about your research study.

☐ I am not interested in taking part in the study

Reason (optional)
……

☐ I am potentially interested in helping with the research and would like to hear more about it.

_____ _____

Signed <Patient's name> Date

Please contact me on telephone:_____

The best time to call is:

Or email: _____

J. Participant Information Sheet

Evaluation of an online personalised weight loss programme

MyDietitian

Newcastle University

County Durham and Darlington NHS
NHS Foundation Trust

Anna Sherrington, Dr Ruth Bell, Professor Ashley Adamson, Dr Vera Araujo-Soares, Professor Elaine McColl.

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it will involve for you. One of our team will go through the information sheet with you and answer any questions you have. Please read this carefully and ask us if you would like any more information. Talk to others about the study if you wish.

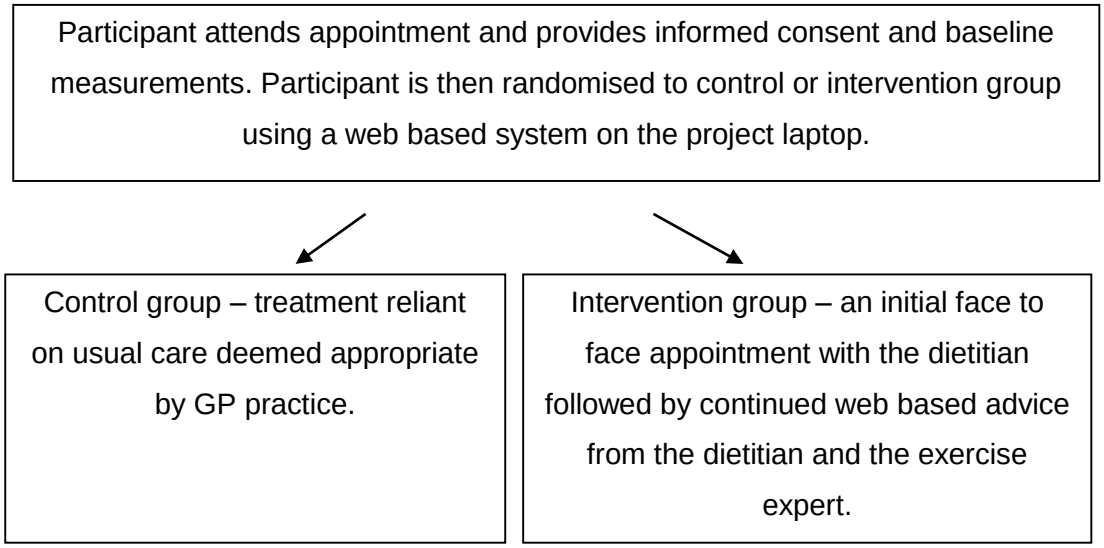
What is the purpose of the study?

The study is being carried out to test how feasible it is to deliver a weight loss programme via the internet. The aim is to investigate whether this is an appropriate way for dietitians to administer weight management advice in primary care by comparison with usual NHS care for weight management. The study will examine the use of individualised feedback and the impact it has on patient's weight loss. Participant recruitment and drop out numbers will be recorded as well as how much engagement participants have with the weight loss programme.

This study is being carried out as a PhD project by Anna Sherrington.

Why have I been chosen and do I have to take part?
We are recruiting patients aged 18 years and above (men or women) who wish to lose weight (Body Mass Index(BMI) >≈30 and <40 kg/m^2). It is up to you to decide whether or not to take part. You can change your mind at any time, without giving a reason. Whatever you decide it will not affect the care you receive.

What will happen to me if I take part and what will I have to do?
You will first sign a consent form stating that you agree to take part in the study. Your GP/health professional will be informed that you are taking part in the study. Baseline measurements will be collected. You will then have an equal chance of being placed in either the control group or the internet intervention group.



The control group will receive usual care; the nature of this will be dependent on the usual practice recommended by the primary care provider. This may consist of no specific treatment but may be weight loss services provided through the NHS, such as one to one appointments or group consultations with either a practice nurse or referral to a dietitian. The usual care group will receive the treatment that is deemed appropriate for them by the GP practice. This study will have no impact on what usual care is received. Frequency of contact will be dependent on what treatment path the GP practice decides for each patient.

The intervention group will meet with the dietitian for one face to face meeting but from then on will receive weight management information and consultations from the same dietitian via the internet, through a website using web based messaging. Consultations will be given every week for the first 3 months; frequency will then be up to the dietitian to decide for the next 9 months. Exercise expert consultations may also be provided during the study. Participant must be able to access the internet, no equipment will be provided. You will take part in the study for 12 months. Some participants from the intervention group will be asked to take part in an interview between 6 and 12 months, either in their own home or at their GP practice, to get your views on the treatment you received and how it was administered. Interviews will be audio recorded.

Weight, Body Mass Index, body fat percentage, waist circumference, questionnaires and accelerometer data will be collected from both the control and intervention group at baseline, 3 and 12 months.

Expenses and payments
Any travel expenses you incur solely for study purposes will be reimbursed if you provide us with a receipt.

What are the risks and benefits of taking part?
There is a possible inconvenience of giving up your time to take part in data collection during the course of the programme. You may lose weight during the course of the programme.

What happens when the research study stops?
The patients will stop having access to the website. We will send you a report of our findings.

What will happen if I don't want to carry on with the study?
You can withdraw from the study at any time without having to give a reason. Any data collected up to that point will be retained and used.

Will my taking part in this study be kept confidential?
Yes, we will follow ethical and legal practice and all information about you will be handled in confidence. Only the research team will have access to the audio recording. All the information you give us will be anonymised so you cannot be identified. You will only be identified by a number on questionnaires and data collection forms. All our records will be kept securely in Newcastle University in accordance with the Data Protection Act 1998. We will ask your permission to tell your General Practitioner that you have taken part in the study. If you tell us anything that suggests you have experienced malpractice or misconduct, or suggests that you are in danger of harm we would ask your permission to report this to someone who could help.

What if there is a problem?
Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions (0191 2223829). If you remain unhappy and wish to complain formally, you can do this by contacting the hospital's Patient advice and Liaison Service (0191 333 2323). If you are harmed during the research and this is due to someone's negligence you may have grounds for a legal action and compensation against Durham and Darlington NHS Foundation Trust but you may have to pay your legal costs.

What will happen to the results of the research study?
We anticipate the results will be published in a medical journal. You will not be identified in any report or publication. You will be sent a copy of a summary of findings.

Who is organising and funding the research and who has reviewed the study?
The study is being funded by the UK Clinical Research Collaboration via the Economic and Social Research Council and by Durham and Darlington NHS Foundation Trust and carried out by Newcastle University. All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by Cambridge Central Research Ethics Proportionate Review Sub-Committee.

Contact for further information
If you have any further questions about the study please contact Anna Sherrington (0191 2223829 or a.sherrington@ncl.ac.uk).

Thank you for reading this information sheet.

K. Participant Consent form

Newcastle University

MyDietitian

County Durham and Darlington NHS
NHS Foundation Trust

Participants Consent Form: Evaluation of an internet-based weight loss intervention

Centre number:

Study number:

Participant Identification Number:

Name of Researcher(s):

Please initial box

1. I confirm that I have read and understand the information sheet dated 09/08/2012 (version 2.0) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐

3. I agree that any data gained from using the website (intervention group only) could be used by the researchers of this study. ☐

4. I agree to allow the researchers to audio-record an interview if chosen to take part. I understand that direct quotes may be used in the final report or scientific publications, however these will be anonymised and no personal information which could identify me will be used. ☐

5. I understand that all data collected will remain anonymous and confidential, and will be stored in a locked filing cabinet and on password protected computers located in the Institute of Health and Society at Newcastle University. ☐

6. I understand that during the interview if any disclosures are made that would indicate malpractice or misconduct, or suggest that any individual was in danger of harm; this information will be disclosed to the appropriate personnel. ☐

7. I agree that my GP can be contacted to inform them that I am taking part in this study. ☐

8. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐

9. I agree to take part in the above study. ☐

Name of participant	Date	Signature
Name of person taking consent	Date	Signature

When completed, 1 for participant; 1 for researcher file; 1 to be kept in medical notes.

L. Ethics approval letter

NHS
Health Research Authority
NRES Committee East of England - Cambridge Central
Victoria House
Capital Park
Fulbourn
Cambridge
CB21 5XB

Telephone: 01223 597685
Facsimile: 01223 597645

09 August 2012

Anna Sherrington
Institute of Health and Society
Newcastle University
Human Nutrition Research Centre
M1.151 William Leech Building
Medical School, Framlington Place
Newcastle Upon Tyne
NE2 4HH

Dear Ms Sherrington

Study title: **Evaluation of an internet-based weight loss intervention.**
REC reference: **12/EE/0361**

Thank you for your letter of 9th August 2012, responding to the Proportionate Review Sub-Committee's request for changes to the documentation for the above study.

The revised documentation has been reviewed and approved by the sub-committee.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Confirmation should also be provided to host organisations together with relevant documentation.

Approved documents

The documents reviewed and approved by the Committee are:

Document	*Version*	*Date*
Evidence of insurance or indemnity	Newcastle University	09 August 2012
Other: CV Fiona Lowrie		23 July 2012
Other: CV Anna Sherrington		11 June 2012
Other: CV Ruth Bell		27 May 2012
Other: CV Ashley Adamson		23 July 2012
Other: CV Vera Araujo Soares		21 June 2012
Other: CV Elaine McColl		12 April 2012
Other: Research Proposal Feedback	1.0	24 July 2012
Other: GP practice recruitment letter	2.0	09 August 2012
Other: Participant invitation letter	2.0	09 August 2012
Other: GP participant confirmation letter	2.0	09 August 2012
Other: Data collection record	2.0	09 August 2012
Other: Interview topic guide for semi-structured interviews with participants in the intervention group	2.0	09 August 2012
Other: Interview topic guide for semi-structured interviews with the dieticians	2.0	09 August 2012
Other: Research Proposal feedback	2.0	09 August 2012
Other: First year review report	2.0	09 August 2012
Participant Consent Form: participant	2.0	09 August 2012
Participant Consent Form: dietician	2.0	09 August 2012
Participant Information Sheet: participant	2.0	09 August 2012
Participant Information Sheet: dietician	2.0	09 August 2012
Protocol	1.0	24 July 2012
Questionnaire: 24 hr recall	2.0	09 August 2012
Questionnaire: Quality of life	2.0	09 August 2012

Questionnaire: Precictors of behaviours change questionnaire	2.0	09 August 2012
REC application	99061/346680/1/923	24 July 2012
Response to Request for Further Information	Anna Sherrington	09 August 2012

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

Further information is available at National Research Ethics Service website > After Review

12/EE/0361 Please quote this number on all correspondence

With the Committee's best wishes for the success of this project

Yours sincerely

pp NStorey

Mrs Carolyn Read
Chair

Email: Nicky.Storey@eoe.nhs.uk

Enclosures: *"After ethical review – guidance for researchers"*

Copy to: *Mrs Lynne Williams, County Durham and Darlington NHS Foundation Trust*

Mrs Fiona Lowrie

M. Data collection record

MyDietitian

Newcastle University

County Durham and Darlington NHS
NHS Foundation Trust

Participant Number: Date of Birth:

Postcode: Gender:

Ethnicity: Age:

Work status: Occupation:

Population Group: Treatment group:

Other services used:

Number of people in your household:

Post-partum women Men with diabetes

Type of delivery: Medication:

Age of child: Date of diagnosis:

Outcome measures	Baseline	3 months	12 months
Height:			
Weight:			
BMI:			

Waist circumference:			
Body fat percentage:			
Accelerometer data:			
Completion of questionnaires: -24 hr recall -OWLQOL/WRSM -Predictors of behaviour change			

Changes to any of the above personal information during the study:

……
……
……
……
……

N. 24 hour food diary

MyDietitian

Newcastle University

County Durham and Darlington NHS
NHS Foundation Trust

Participant Number:

Please answer the following questions.

Today's date:

D	D	M	M	Y	Y	Y	Y

Which day of the week does this record?

Is this a typical day?

Yes ☐ No ☐

If not, please give an example of a typical day after yesterday's record, if you wish.

Please be as specific as possible. Include all beverages, condiments, and portion sizes.

Time	Details of Food and Drink and Method of Preparation	Quantity Eaten	Where

O. Activity Belt Diary

Participant's Name: GP Practice: Monitor no: ID No:

Please put your activity belt on EVERY day for the next seven days

The activity belt should be worn all day apart from swimming, getting washed etc. It should be worn snugly, on the right hip, under or over clothes. If it is the right way up you should be able to see the word 'TOP'.

Put the activity belt on in the morning and record when you started to wear it under "Time On".

Please ensure the belt is always taken off at bed-time and record when you stopped wearing it under "Time Off".

The monitor will stop flashing when it starts recording.

Day/Date	D/W/I*	Time on	Time off	Any other times removed e.g. 5-5.30pm for shower	Did you travel anywhere today?	How long did it take?

*D = Week Day; W = Weekend; I = ill

My Dietitian Study, Newcastle University, M1.151 Leech Building, Framlington Place, Newcastle upon Tyne, NE2 4HH
Telephone: 0191 2223829 Email: a.sherrington@ncl.ac.uk

P. Obesity Weight Loss Quality of life questionnaire and the Weight Related Symptom Measure

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Your Health

– and –

Well-Being

Obesity and Weight-Loss Quality-of-Life Instrument (OWLQOL) and Weight-Related Symptom Measure (WRSM)

This survey asks for your views about your health and your weight.

Thank you for completing these questions!

Obesity and Weight-Loss Quality-of-Life (OWLQOL) Instrument

Instructions for the completion of the quality-of-life questionnaires by study participants

1) These questionnaires are an important part of your overall medical evaluation. The questions are designed to collect information about how your health has affected your quality of life from your own point of view.

2) Complete the questionnaire using a ballpoint pen. Press firmly and print neatly when writing to ensure that the copies are clear and legible.

3) Please take the time to read and answer each question carefully. Some questions may look like others, but each one is different.

4) Please answer every question by marking an ☒ in the box that best describes your answer. You may change an answer by placing a line (☒) through the selection you wish to change and marking an ☒ in the box corresponding to the new choice.

5) There are no right or wrong answers. If you are unsure about how to answer a question, please give the best answer you can.

6) Your answers are confidential. The study coordinator will check for completeness only and not share your answers with other clinical staff.

Your Feelings About Your Weight

Below is a list of statements about your quality of life in relation to being overweight and trying to lose weight.

For each of the following statements, please mark an ☒ in the one box that best describes your answer <u>at this time</u>.

	Not at all	Hardly	Some-what	Moder-ately	A good deal	A great deal	A very great deal
1. Because of my weight, I try to wear clothes that hide my shape.	☐0	☐1	☐2	☐3	☐4	☐5	☐6
2. I feel frustrated that I have less energy because of my weight.	☐0	☐1	☐2	☐3	☐4	☐5	☐6
3. I feel guilty when I eat because of my weight.	☐0	☐1	☐2	☐3	☐4	☐5	☐6
4. I am bothered about what other people say about my weight.	☐0	☐1	☐2	☐3	☐4	☐5	☐6

(Please turn the page)

	Not at all	Hardly	Some-what	Moder-ately	A good deal	A great deal	A very great deal
5. Because of my weight, I try to avoid having my photograph taken.	☐0	☐1	☐2	☐3	☐4	☐5	☐6
6. Because of my weight, I have to pay close attention to personal hygiene.	☐0	☐1	☐2	☐3	☐4	☐5	☐6
7. My weight prevents me from doing what I want to do.	☐0	☐1	☐2	☐3	☐4	☐5	☐6
8. I worry about the physical stress that my weight puts on my body.	☐0	☐1	☐2	☐3	☐4	☐5	☐6
9. I feel frustrated that I am not able to eat what others do because of my weight.	☐0	☐1	☐2	☐3	☐4	☐5	☐6
10. I feel depressed because of my weight.	☐0	☐1	☐2	☐3	☐4	☐5	☐6

(Please turn the page)

	Not at all	Hardly	Some-what	Moder-ately	A good deal	A great deal	A very great deal
11. I feel ugly because of my weight.	☐0	☐1	☐2	☐3	☐4	☐5	☐6
12. I worry about the future because of my weight.	☐0	☐1	☐2	☐3	☐4	☐5	☐6
13. I envy people who are thin.	☐0	☐1	☐2	☐3	☐4	☐5	☐6
14. I feel that people stare at me because of my weight.	☐0	☐1	☐2	☐3	☐4	☐5	☐6
15. I have difficulty accepting my body because of my weight.	☐0	☐1	☐2	☐3	☐4	☐5	☐6
16. I am afraid that I will gain back any weight that I lose.	☐0	☐1	☐2	☐3	☐4	☐5	☐6
17. I get discouraged when I try to lose weight.	☐0	☐1	☐2	☐3	☐4	☐5	☐6

Please go back to the questions you just answered to make sure you did not miss any items

Thank you for completing these questions!

Weight-Related Symptom Measure (WRSM)

Instructions for the completion of the questionnaires by study participants

1) These questionnaires are an important part of your overall medical evaluation. The questions are designed to collect information about how your health has affected your quality of life from your own point of view.

2) Complete the questionnaire using a ballpoint pen. Press firmly and print neatly when writing to ensure that the copies are clear and legible.

3) Please take the time to read and answer each question carefully. Some questions may look like others, but each one is different.

4) Please answer every question by marking an ☒ in the box that best describes your answer. You may change an answer by placing a line (☒) through the selection you wish to change and marking an ☒ in the box corresponding to the new choice.

5) There are no right or wrong answers. If you are unsure about how to answer a question, please give the best answer you can.

6) Your answers are confidential. The study coordinator will check for completeness only and not share your answers with other clinical staff.

Weight-Related Symptoms and How Much They Bother You

For each of the following questions, read the list of symptoms below, and mark an ☒ in the one box that best describes your answer.

a. In the past 4 weeks, did you have the following symptoms?			b. If Yes, how much did these symptoms bother you?						
No	Yes	SYMPTOMS	Not at all	Hardly	Some-what	Moder-ately	A good deal	A great deal	A very great deal
☐0	☐1	Shortness of breath	☐0	☐1	☐2	☐3	☐4	☐5	☐6
☐0	☐1	Tiredness	☐0	☐1	☐2	☐3	☐4	☐5	☐6
☐0	☐1	Sleep problems	☐0	☐1	☐2	☐3	☐4	☐5	☐6
☐0	☐1	Sensitivity to cold	☐0	☐1	☐2	☐3	☐4	☐5	☐6
☐0	☐1	Increased thirst	☐0	☐1	☐2	☐3	☐4	☐5	☐6
☐0	☐1	Increased irritability	☐0	☐1	☐2	☐3	☐4	☐5	☐6
☐0	☐1	Back pain	☐0	☐1	☐2	☐3	☐4	☐5	☐6
☐0	☐1	Frequent urination	☐0	☐1	☐2	☐3	☐4	☐5	☐6
☐0	☐1	Pain in the joints (hips, knees, etc.)	☐0	☐1	☐2	☐3	☐4	☐5	☐6
☐0	☐1	Water retention	☐0	☐1	☐2	☐3	☐4	☐5	☐6
☐0	☐1	Foot problems	☐0	☐1	☐2	☐3	☐4	☐5	☐6
☐0	☐1	Sensitivity to heat	☐0	☐1	☐2	☐3	☐4	☐5	☐6
☐0	☐1	Snoring	☐0	☐1	☐2	☐3	☐4	☐5	☐6

(Please turn the page)

(Continued…)

a. In the past 4 weeks, did you have the following symptoms?			b. If Yes, how much did these symptoms bother you?						
No	Yes	SYMPTOMS	Not at all	Hardly	Some-what	Moder-ately	A good deal	A great deal	A very great deal
☐0	☐1	Increased appetite	☐0	☐1	☐2	☐3	☐4	☐5	☐6
☐0	☐1	Leakage of urine	☐0	☐1	☐2	☐3	☐4	☐5	☐6
☐0	☐1	Lightheadedness	☐0	☐1	☐2	☐3	☐4	☐5	☐6
☐0	☐1	Increased sweating	☐0	☐1	☐2	☐3	☐4	☐5	☐6
☐0	☐1	Loss of sexual desire	☐0	☐1	☐2	☐3	☐4	☐5	☐6
☐0	☐1	Decreased physical stamina	☐0	☐1	☐2	☐3	☐4	☐5	☐6
☐0	☐1	Skin irritation	☐0	☐1	☐2	☐3	☐4	☐5	☐6

Please go back to the questions you just answered to make sure you did not miss any items.

Thank you for completing these questions!

Q. Predictors of behaviour change questionnaire

MyDietitian

Newcastle University

County Durham and Darlington NHS
NHS Foundation Trust

Personal Background Information

We would like you to answer some general questions about yourself (please tick the correct box and fill in the blanks):

Gender:	❑ female (0) ❑ male (1)
Year of Birth:	19_ _
Marital Status:	❑married/relationship(0) ❑ single (1) ❑ separated / divorced (2) ❑ widowed (3)
What is your ethnic origin	❑ White (0) ❑ Black (1) ❑ Asian (2) ❑ Mixed (3) ❑ Other (4)
If other, please specify	_____
What is, or was, your job?	_____
How many years have you spent in full-time education?	_ _ years
Have you taken part in any further education or training after leaving school?	❑ Yes (0) ❑ No (1)
If yes, please specify:	_____

Which diet are you currently on?

❑ Low carbohydrate diet (0)
❑ Low fat diet (1)
❑ None (2)
❑ Not sure (3)
❑ Other: _____ (4)

If other, please specify:

Are you currently taking any weight loss medication?

❑ Yes
❑ No

If yes, which medication: _____

Your Postcode | | | | | | | |

What is your personal ideal weight? _____

Your views on your current weight

We are interested in your own personal views of how you now see your current weight problem. Please indicate how much you agree or disagree with each of the following statements about your weight problem by ticking the most suitable box.

Here is an example of where on this scale you would tick if you were a person who really does not understand your weight problem and who is not sure if your weight problem will last a long time or not.

Example

Views about your weight problem	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
I don't really understand my weight problem	❑	❑	❑	√	❑
My weight problem will last for a long time	❑	❑	√	❑	❑

Please tick the suitable answer for you:

Views about your weight problem	Strongly Disagree (1)	Disagree (2)	Neither Agree nor Disagree (3)	Agree (4)	Strongly Agree (5)
I don't really understand my weight problem	❑	❑	❑	❑	❑
My weight problem will last for a long time	❑	❑	❑	❑	❑
I get depressed when I think about my weight problem	❑	❑	❑	❑	❑
My weight problem has major consequences on my life	❑	❑	❑	❑	❑
My NHS treatment will be effective in curing my weight problem	❑	❑	❑	❑	❑

Views about your weight problem	Strongly Disagree (1)	Disagree (2)	Neither Agree nor Disagree (3)	Agree (4)	Strongly Agree (5)
Having this weight problem makes me feel anxious	❑	❑	❑	❑	❑
Nothing I do will affect my weight problem	❑	❑	❑	❑	❑
My weight problem doesn't make any sense to me	❑	❑	❑	❑	❑
My weight problem is a mystery to me	❑	❑	❑	❑	❑
My weight problem is very unpredictable	❑	❑	❑	❑	❑
Negative effects of my weight problem can be prevented by my NHS treatment	❑	❑	❑	❑	❑
My weight problem is likely to be permanent rather than temporary	❑	❑	❑	❑	❑
My weight causes difficulties for those who are close to me	❑	❑	❑	❑	❑
I have the power to influence my weight problem	❑	❑	❑	❑	❑
I lose and gain weight in cycles	❑	❑	❑	❑	❑
My weight strongly affects the way others see me	❑	❑	❑	❑	❑
My NHS treatment can control my weight problem	❑	❑	❑	❑	❑
I go through cycles in which my weight problem gets better and worse	❑	❑	❑	❑	❑
When I think about my weight problem I get upset	❑	❑	❑	❑	❑

Views about your weight problem	Strongly Disagree (1)	Disagree (2)	Neither Agree nor Disagree (3)	Agree (4)	Strongly Agree (5)
I expect to have a weight problem for the rest of my life	❑	❑	❑	❑	❑
My actions will have no effect on my weight	❑	❑	❑	❑	❑

Please list the three most important factors that you believe caused your weight problem.
The most important causes for me:-

1. _____

2. _____

3. _____

Your current physical activity

During the previous 7 days (week), how many times did you do the following kinds of exercise for more than 15 minutes during your free time (write on each line the appropriate number).

Times per week

1. Strenuous exercise
(heart beats rapidly. e.g., running, jogging, football, squash, basketball, vigorous swimming or long distance bicycling) _____

2. Moderate exercise
(not exhausting. e.g., brisk walking, cricket, easy bicycling, easy swimming, popular and dancing) _____

3. Mild exercise
(minimal effort. e.g., gardening, easy walking, yoga, shopping, bowling, golf) _____

4. How **many minutes on an average day** did you spend walking for exercise, transportation or any other purpose **over the last week**? _____ minutes.

Your views on physical activity

We are interested in your personal views on **moderate physical activity such as walking for exercise, transport or any other purpose**. There are no right or wrong answers to the following questions. Please circle the most suitable answer for you.

For me, participating in regular physical activity would be

dull	-3	-2	-1	0	1	2	3	interesting
unpleasant	-3	-2	-1	0	1	2	3	pleasant
boring	-3	-2	-1	0	1	2	3	stimulating
unhealthy	-3	-2	-1	0	1	2	3	healthy
useless	-3	-2	-1	0	1	2	3	useful
not sensible	-3	-2	-1	0	1	2	3	sensible

How confident are you that you will be able to participate in regular physical activity?

not very confident	-3	-2	-1	0	1	2	3	very confident

*People close to me think I should participate in regular physical activity**.***

disagree	-3	-2	-1	0	1	2	3	agree

To what extent do you see yourself as being capable of participating in regular physical activity?

incapable	-3	-2	-1	0	1	2	3	capable

I intend to participate in regular physical activity.

disagree	-3	-2	-1	0	1	2	3	agree

I believe that I have the ability to participate in regular physical activity.

definitely do not	-3	-2	-1	0	1	2	3	definitely do

Please circle the most suitable answers

I have made a detailed plan regarding…	disagree						agree
… *when* to participate in regular physical activity.	1	2	3	4	5	6	7
... *where* to participate in regular physical activity	1	2	3	4	5	6	7
... *how* to participate in regular physical activity.	1	2	3	4	5	6	7
... what to do if something gets in the way of my physical activity plans.	1	2	3	4	5	6	7
... how to deal with possible setbacks from regular physical activity.	1	2	3	4	5	6	7
… what to do in difficult situations to stick to my intentions for physical activity**.**	1	2	3	4	5	6	7
During the last week, I have…	disagree						agree
… checked regularly if I participate in enough physical activity.	1	2	3	4	5	6	7
…watched carefully that I participate in as much physical activity as I planned.	1	2	3	4	5	6	7
…often had my intention for physical activity on my mind.	1	2	3	4	5	6	7

... been aware of my plans for participating in physical activity.	1	2	3	4	5	6	7
… really tried hard to participate as often as I planned to in physical activity.	1	2	3	4	5	6	7
...tried my best to act in accordance with my physical activity goals.	1	2	3	4	5	6	7

Your personal views on your diet

We are keen to know your thoughts about sticking to a healthy diet to lose weight. To lose weight, the total amount of energy (calories) from this mix of food should be less than your body uses up in a day. This means eating the right mix of foods from the 5 different food groups:

- Mostly *fruit* and *vegetables* and
- *wholegrain* types of bread, rice, pasta and other starchy foods.
- Smaller amounts of *milk* and *dairy* foods and
- *meat, fish, chicken, eggs, beans, peas* and *lentils*.
- *Very small* amounts of foods and drinks high in *fat* and *sugar* and *alcoholic* drinks.

For me, sticking to a healthy weight loss diet would be…

dull	-3	-2	-1	0	1	2	3	interesting
unpleasant	-3	-2	-1	0	1	2	3	pleasant
boring	-3	-2	-1	0	1	2	3	stimulating
unhealthy	-3	-2	-1	0	1	2	3	healthy
useless	-3	-2	-1	0	1	2	3	useful
not sensible	-3	-2	-1	0	1	2	3	sensible

How confident are you that you will be able to stick to a healthy weight loss diet?

not confident	-3	-2	-1	0	1	2	3	very confident

People close to me think I should stick to a healthy weight loss diet.

disagree	-3	-2	-1	0	1	2	3	Agree

To what extent do you see yourself as being able to stick to a healthy weight loss diet?

incapable	-3	-2	-1	0	1	2	3	capable

I intend to stick to a healthy weight loss diet.

disagree	-3	-2	-1	0	1	2	3	agree

I believe that I have the ability to stick to a healthy weight loss diet.

definitely do not	-3	-2	-1	0	1	2	3	definitely do

I have made a detailed plan regarding…	disagree agree						
… how to eat a healthy breakfast.	1	2	3	4	5	6	7
... how to have a healthy lunch.	1	2	3	4	5	6	7
... how to have a healthy dinner.	1	2	3	4	5	6	7
… how to have healthy snacks and drinks between meals	1	2	3	4	5	6	7
... what to do if something makes it difficult for me to stick to a healthy weight loss diet.	1	2	3	4	5	6	7
... how to cope with possible setbacks from a healthy weight loss diet.	1	2	3	4	5	6	7
… what to do to stick to a health weight loss diet in difficult situations.	1	2	3	4	5	6	7

During the last week, I have…	disagree						agree
… checked regularly if my diet follows healthy weight loss recommendations.	1	2	3	4	5	6	7

…often had my intention for adhering to a healthy diet on my mind.	1	2	3	4	5	6	7
… really tried hard to stick to a healthy weight loss diet.	1	2	3	4	5	6	7
…watched carefully that I stick to a healthy weight loss diet.	1	2	3	4	5	6	7
... I never forgot my plans for adhering to a healthy diet.	1	2	3	4	5	6	7
...tried my best to eat and drink in accordance to a healthy weight loss diet.	1	2	3	4	5	6	7

In the following section we would like to learn more about the support you receive from others. *Please tick the suitable answer for you:*

Views about your personal diet	None of the time (1)	A little of the time (2)	Some of the time (3)	Most of the time (4)	All the time (5)
Is there someone available to you whom you can count on to listen to you when you need to talk?	❑	❑	❑	❑	❑
Is there someone available to give you good advice about a problem?	❑	❑	❑	❑	❑
Is there someone available to you who shows you love and affection?	❑	❑	❑	❑	❑
Is there someone available to help you with daily chores?	❑	❑	❑	❑	❑
Can you count on anyone to provide you with emotional support (talking over problems	❑	❑	❑	❑	❑

or helping you make a difficult decision)?					
Do you have as much contact as you would like with someone you feel close to, someone in whom you can trust and confide?	❑	❑	❑	❑	❑

On a scale from 0 [not satisfied at all] to 100 [completely satisfied] how satisfied were you with the overall programme?

Please list any other suggestions for programme improvement

……
……
……

Do you have any additional comments?

……
……
……

Thank you for taking your time to complete this questionnaire.

R. Interview topic guide for semi-structured interviews with participants in the intervention group

1. Experience of weight loss/management

- Why did you agree to take part in this study?
- What was your motivation for weight loss?
- What methods have you used previously for weight loss (any internet/website methods)?

2. Use of the website:

- How did you find using the internet/website as a weight loss programme?
- Did you go on the website regularly (on certain days/times)?
- Was it easy enough to log on or input data?
- Was the website easy to use?
- Could you access all parts of the website?

3. Acceptability of features provided:

- Did you think the information/ NHS links on the website were helpful?
- Which articles did you read?
- How did you find inputting food diaries?
- How did you find inputting exercise data?
- What features on the website did you find useful?
- Why did you find these features useful?
- Do you think any features could be removed/added to the website?

4. Interaction with others:

- Did you involve yourself in the ‘My Community’ section of the website?
- What positives or negatives did you see with being able to connect with other people on the weight loss programme?

5. **Change in health care provision:**

- How did you find receiving feedback from your dietitian via the website?
- How did you find not meeting with the dietitian face-to-face after the initial meeting?
- Did you use any other services whilst in the study? (i.e. GP, slimming club)

6. **Satisfaction with the service:**

- What did you like about having the weight loss programme via website?
- What did you dislike about having the weight loss programme via the internet?
- Why did you choose the satisfaction level you did on the questionnaire?

S. Interview topic guide for semi-structured interviews with participants in the control group

1. Experience of weight loss/management

- Why did you agree to take part in this study?
- Did you think that sending the letter through the post was a good way of getting in touch with you to let you know about the study?
- What was your motivation for weight loss?
- What methods have you used previously for weight loss (any internet/website methods)?
- When do you think it would be appropriate to approach weight loss? (after pregnancy/after being diagnosed with diabetes)

2. Randomisation to control group

- What treatment, if any, did you receive being in the usual care group?
- How did being randomised to the usual care group make you feel?
- How did you feel about the internet group?

3. Acceptability of features provided:

- Do you think using a website in the NHS is appropriate?
- Do you think information/ NHS links on a website would be helpful?
- How would you find inputting food diaries?
- How would you find inputting exercise data?

Describe the features within the current website:

- What features on the website would you find useful? Why?
- How do you think you would find getting feedback via a website?

4. Satisfaction with the service:

- What did you like about the care you received?
- What did you dislike about the care you received?
- Why did you choose the satisfaction level you did on the questionnaire?
- How did you find being part of a research study?

T. Interview topic guide for semi structured interviews with the health professionals

1. Use of the website:

- Have you any prior experience of using a web based system?
- Was the website easy to use?
- How did you find accessing participants data?
- How did you find assessing which participants needed feedback and when?

2. Acceptability of features provided:

- Which features on the website were useful for the participants?
- Do you think any features could be removed/added to the website? Why/Why not?
- Did you suggest using the NHS links to your participants? If so which ones?
- Do you think the NHS links were helpful for the participants?

3. Interaction with others:

- How do you think the ‘My Community’ section helped the participants?
- Did you suggest using this to any of your participants?

4. Change in health care provision:

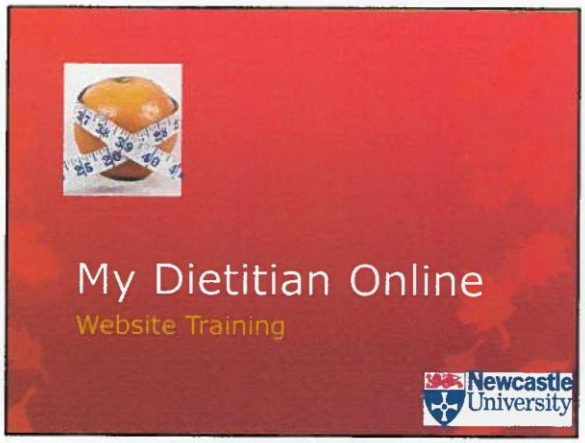
- How did you find the experience of providing weight loss/management advice via the internet?
- How did you find not meeting with the participant face-to-face after the initial meeting?
- How did you find writing e-consultations for each participant?
- How long did consultations take to create?

- What would have made it easier/quicker to write the consultations?

5. Satisfaction with the service:

- Do you think is was an appropriate way for you to advise/feedback to the participants?
- What did you like about delivering the weight loss programme via website?
- What did you dislike about delivering the weight loss programme via the internet?

U. Training presentation materials


My Dietitian Online
Website Training
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Buildings blocks of behaviour change
Self-regulation
Planning
• Action Planning
• Coping Planning
Motivation
Knowledge & Skills
Environment & Social influence
Increased likelihood of behaviour change


Buildings blocks of behaviour change
Self-regulation
Planning
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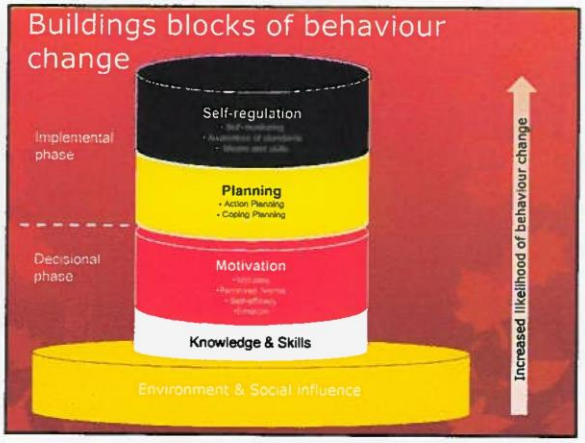
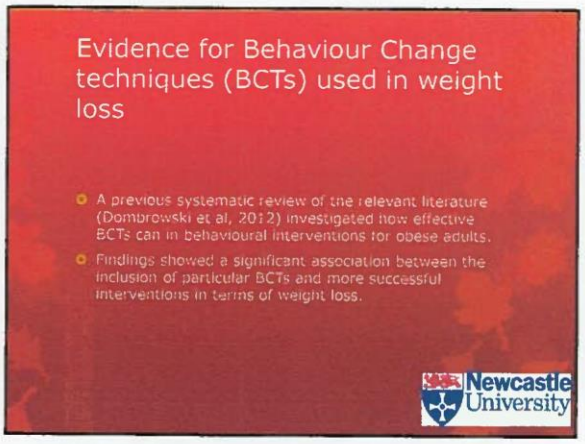

Buildings blocks of behaviour change
Implemental phase
Decisional phase
Self-regulation
Planning
• Action Planning
• Coping Planning
Motivation
Knowledge & Skills
Environment & Social influence
Increased likelihood of behaviour change


Buildings blocks of behaviour change
Implemental phase
Decisional phase
Self-regulation
Planning
• Action Planning
• Coping Planning
Motivation
Knowledge & Skills
How can I change?
Would I like to change?
Environment & Social influence
Increased likelihood of behaviour change


Evidence for Behaviour Change techniques (BCTs) used in weight loss
A previous systematic review of the relevant literature (Dombrowski et al, 2012) investigated how effective BCTs can in behavioural interventions for obese adults.
Findings showed a significant association between the inclusion of particular BCTs and more successful interventions in terms of weight loss.
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Behaviour change techniques

These core BCTs have evidence to suggest they are effective for weight loss:

- Overall goal setting
- Self monitoring of behaviour
- Goal setting
- Action Planning
- Barrier identification
- Review of behavioural goals
- Relapse Prevention/Coping planning

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Overall Goal setting

- Overall goals are things that the participants would like to achieve in the future, by changing behaviour.
- Having a concrete reason for change, and a long-term goal to aspire to helps participants to prioritise their behaviour change goal over other, often competing behaviours.
- Identifying overall goal is therefore an important source of motivation for the participant. It helps to put things into perspective and gives a purpose to the task.
- This is directed towards encouraging people to decide to change or maintain change.

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Introducing the technique to the participant

- I would like to ask you to formulate an overall goal of what it is that you want to achieve
- An overall goal can be something that is very general but it should be achievable through eating and PA
- Examples of overall goals are "Fitting into the old cloths again", "Being able to walk up the stairs without taking a break" or "Feeling healthy". Make sure that you put something down that can be achieved.
- Make also sure that you don't put yourself under too much pressure by specifying a deadline.
- Just omit any time frame on your goals and it should feel a lot easier and more realistic.
- You can check how good your overall goal is by assessing how confident you are that you can achieve it. If you are not confident in your ability to achieve the goal then it might be a better idea to choose something that you think you have a better chance of achieving.

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Where could this BCT be implemented on the website?

- E-consultation – Web based consultations sent to participants could include a reminder of the overall goal.

https://mydietician.org.uk/user/consultation

- Diary – Participants have the choice to complete diary submissions at any stage throughout the intervention. This could be used to store overall goals for the study.

https://mydietician.org.uk/socialgroups/blog/create

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Self-Monitoring of behaviour

- Self-monitoring is to keep a record of behaviour and can be done before and during behaviour change.
- Self-monitoring can be useful for people who are not sure what changes to make. Just recording your behaviour can help to change it in a desired direction.
- When a goal has been set, a diary can be used to record the changes. Using a diary can make people more aware of when they succeed, or don't succeed, in achieving their desired behaviours (for example, what situations, times of day, associated feelings etc.).
- This can help inform future plans to make behaviour change easier.

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Introducing the technique to the participant

There are many reasons why it is important to monitor what you do when you are changing your behaviour. Self-monitoring:

- 1. helps us understand what we do;
- 2. increases our motivation to change;
- 3. helps us to understand what triggers and/or reinforces potential problem
- behaviours;
- 4. helps us to become aware of our habits.
- 5. allows us to recall what we have done during the week;
- 6. helps us to be aware if we are still on track for our goals;
- 7. helps us to find solutions for our problems.

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Introducing the technique to the participant

- Inform that is hard to do all that we plan to do;
- Comment that this task per se will not lead to immediate change;
- Reinforce the commitment in trying, and not only the result.

Ask the participant:

- What thoughts come to your mind when you think of keeping monitoring pages?
- Do you think this is important/relevant for your life?
- How do you think that monitoring what you eat every day can help you?

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Where could this BCT be implemented on the website?

- Food diaries – self monitoring can take place by the participant recording their daily food intake.
- Physical activity diaries - self monitoring can take place by the participant recording their daily physical activity levels.
- My Data – personal information – Participants can complete personal information about different aspects of their life (i.e. physical activity levels, family, work) at any stage of the intervention.

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Goal Setting

- Behavioural:
- The person is encouraged to make a behavioural resolution (e.g. take more exercise next week). This is directed towards encouraging people to decide to change or maintain change.
- This does not involve planning exactly how the behaviour will be done and either when or where the behaviour or action sequence will be performed.
- This includes sub-goals or preparatory behaviours and/or specific contexts in which the behaviour will be performed.
- Outcome:
- The person is encouraged to set a general goal that can be achieved by behavioural means but is not defined in terms of behaviour, as opposed to a goal based on changing behaviour as such.
- The goal may be an expected consequence of one or more behaviours, but is not a behaviour per se.

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Introducing the technique to the participant

- The behaviour in this technique will be directly related to or be a necessary condition for the target behaviour (e.g. shopping for healthy eating; buying equipment for physical activity).
- What changes in your behaviour would be helpful to improving your health?
- Outcome goals can be set in relation to the participant's health (e.g. to reduce blood pressure or lose/maintain weight).
- Remember, you are the boss and get to decide which goals get set and which ones don't.

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Where could this BCT be implemented on the website?

- E-consultation – Web based consultations sent to participants could include a reminder of the goals set.
- Diary – Participants have the choice to complete diary submissions at any stage throughout the intervention. This could be used to goals set for the study.

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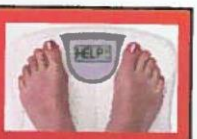
Action Planning



- Involves detailed planning of what the person will do including, as a minimum, when, in which situation and/or where to act.
- 'When' may describe frequency (such as how many times a day/week or duration (e.g. for how long).
- Formulating an action plan (i.e. SMART goal) increases the likelihood of doing what one wants to do.

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SMART stands for:

- **S**pecific – some goals can be vague and difficult to measure. It is important to set goals that are clear and precise. To help participants formulate a specific goal they should answer: What, where, how and why am I going to do it?
- **M**easurable – making the goal specific means that it should be easy to measure whether or not the goal has been achieved.
- **A**chievable – Goals should be within the participant's reach. Failing to achieve a goal can have a negative effect on motivation and decrease confidence levels. It is important that the first goals that participants set for themselves are quite easy to achieve to boost self-confidence, which encourages them to carry on.
- **R**elevant – Does the participant think that the goal is relevant? There needs to be clear link between the established goal, their health, and his/her overall goal.
- **T**ime bound – Is this goal the right thing to try to achieve at this moment in time?
- *Health Trainer Manual (2006)*

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Introducing the technique to the participant

- "I would like you to formulate your own SMART goal, which you would like to achieve over the next week."
- **Specific** – "Your goal needs to be clear and detailed, not vague. For example a vague goal would be 'eating healthily', whereas a clear, specific goal would be 'I will only eat 2 muffins a week, one when out for tea with the friends and the other on Sunday at lunch.'
- Ask yourself the following questions:

  What am I going to do?

  How am I going to do it?

  When am I going to do it?

  Where am I going to do it?

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Introducing the technique to the participant

- **Measurable** – Making the goal specific means that it should be easy to measure. The example above, 'I will only eat 2 muffins a week, one when out for tea with the friends and the other on Sunday at lunch.' is measurable.
- You can record the number of times you eat muffins in one week, and also where, when and with whom. It would be hard to measure a vague goal like 'eating healthily'.

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Introducing the technique to the participant

- **Achievable** – Try to set goals that are achievable for you. If you set yourself a really hard goal and don't achieve it, it can make you feel bad and you may want to give up.
- Make your first goal quite easy to achieve and this can give your self-confidence a boost.

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Introducing the technique to the participant

- **Relevant** – Is this an important goal for you? Is it a behaviour that you really want to change?
- You are much more likely to succeed in reaching your goal if you can see the important difference that changing this behaviour will make to your health and your overall goal that you set last week.

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Introducing the technique to the participant

- **Time bound** – Is this the right time to try to achieve this goal?
- Give yourself a set amount of time in which to complete your goal. If you don't give yourself a target date, it's easier to keep putting it off not starting to change your behaviour, and you may never reach your goal.
- If your goal is to eat 5 portions of fruit and vegetables a day, a mini goal could be to eat at least 1 portion of fruit and vegetables each day.

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Where could this BCT be implemented on the website?

- E-consultation – Web based consultations sent to participants could include a summary of the specific goals set as the participant's action plan.

- Diary – Participants have the choice to complete diary submissions at any stage throughout the intervention. This could be used for the participant to comment on specific goals set.

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Barrier Identification

- People face many barriers when they try to change their behaviour, whether they want to or not.
- These barriers are often the main reason why people give up trying to change.
- The more barriers a person faces, the more likely he/she is to fall back into old habits.
- However, once we know our barriers, we can come up with ways of overcoming these (coping planning) which makes it easier to change our behaviour.

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Introducing the technique to the participant

- *Examples of barriers*

1. Unsupportive friends/relatives;
2. A picky family that does not want to embrace your life change;
3. Situations that make it especially difficult to perform the behaviour: e.g. attending a party
4. Feeling sad and depressed and wanting to fall back into old habits;
5. Not having time to prepare for the behaviour change;
6. Not having the time to embrace your goals.

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Introducing the technique to the participant

- Everyone has times when it is difficult to do what they planned to do, so we need to be aware of these barriers and know exactly how we can deal with them.
- I would like you to think about whether these barriers would also apply to yourself?

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Introducing the technique to the participant

- *Some suggestions to overcome these barriers:*

1. Explain your goals and request their open support making sure that they understand that this is a lifestyle change, and that it would be easier with their support.
2. If your family is picky and does not want to support your lifestyle change establish clear ground rules: "I will do___ even if you're not used to it". You can also involve them in the decision process of behaviour change.
3. If you are invited to a party where you know a lot of temptations to not stick to your goal will be present, make sure that you prepare yourself for these temptations before you leave the house. Tell yourself: "If this ___ is tempting me then I will do ___"
4. You feel sad and or nervous and want to fall back into your old unhealthy habits? Then find yourself an alternative activity or a distraction. This way you will not be 'over indulging'.
5. If you feel you don't have the time to prepare for your behaviour change then think about the way you organise your day. Draw a clock or a blank page and divide this clock into the different things you have to do in a day. What are your priorities? You will see that once you have established your priorities you will be better able to stick to them, and do less of the things that you don't really need.
6. Not having the time to embrace your goals is also related to time management. Organise your day so that your goals fit into your lifestyle.

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Review of behavioural goals

- Reviewing the goals that participants set for themselves is very important. It shows clearly how the intended behaviour change is going and helps participants to compare between what they planned to do with what they have done.
- This way it is possible to see what was achieved, what was partly achieved, or what was not achieved at all.
- This process usually leads to the formulation of new goals, keeping the previous experiences in mind. These new goals can be something completely different, the same goal, or a variation of the previous goal.
- Facilitators selectively highlight any behaviour of the client that has been in line with the set goal.

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Introducing the technique to the participant

Participants can be provided with a list of questions to reflect upon for guidance.

- What did I try to do (what was my goal)?
- How much effort did I invest to achieve my goal?
- What impact/success did I have?
- What benefits have I experienced?
- What difficulties have I encountered?
- How did I manage these difficulties?
- What made it easier?
- Am I satisfied with what I did during last week?
- Am I getting enough support?
- Do I want to keep this goal or do I want to change it?

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Introducing the technique to the participant

- How did you get on over the last week?
- Did you manage to complete your food and physical activity diaries every day? If yes then praise anyone who has. If not or only partly then try and identify the barriers.
- How did people manage to integrate the monitoring into their daily routine?
- How did you get on with your eating goal last week?
- Have you managed to achieve the goals that you have set for yourself? What did it feel like on the day(s) when you achieved your goal?
- Did you encounter any barriers and/or facilitators?
- What achievements have you made this week?

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Introducing the technique to the participant

- Health professionals should reinforce any efforts made towards attaining the goal and prompt focus on how it felt when the goal was attained
- For example "When you managed to achieve your goal, how did you feel?".
- Even if participants only managed to attain the goal some of the time it should still be stressed that they are capable of achieving their goals.
- Participants should be encouraged to be more attentive to the barriers that hamper goal achievement and to plan strategies of dealing with these barriers.
- Furthermore, the facilitators that could be used to help achieve the goal should be considered.

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Where could this BCT be implemented on the website?

- E-consultation – Consultations can be used to review how the participant is doing in terms of their behaviour and also the goals that they may have set
- Graphs – Participant's can enter their weight, waist, hip measurement and steps. Graphs can then be created showing the change for days/months.
- Food diaries – as these can be used for self monitoring here participants can also view diaries from previous days/months to review their progress
- Physical activity diaries – as these can be used for self monitoring here participants can also view diaries from previous days/months to review their progress

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Relapse Prevention/Coping Planning

- This relates to planning how to maintain behaviour that has been changed.
- The person is prompted to identify in advance situations in which the changed behaviour may not be maintained and develop strategies to avoid or manage those situations.
- Behaviour change is typically not a straightforward process. After changing behaviour for a while, it often happens that old habits catch us off guard. In these cases we need to be aware of when these lapses happen, and how we can respond to avoid complete relapse.
- Relapse prevention normalises lapses, and helps clients get back on track once a lapse has occurred.

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Introducing the technique to the participant

In order to be able to recognise the risk situations for a potential lapse or relapse, it is necessary to pinpoint internal and external risk factors within each participant.

These can include (Marlatt & Donovan, 2005):

1. **Negative feelings** such as anger frustration, anxiety, depression, boredom). (Caused by intrapersonal perceptions of certain situations (e.g. feeling bored or lonely after coming home from work) or by reactions to environmental events (e.g. being made redundant))
2. **Relationship difficulties** (e.g. situations involving conflict associated with an interpersonal relationship, in particular family or friends)
3. **Social pressure** (e.g. situations in which you respond to the influence of another person or group of people who exert pressure for you to engage in a non desired behaviour)
4. **Positive feelings** (e.g. celebrations), exposure to unhealthy eating -related stimuli or cues.

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Introducing the technique to the participant

- If and when lapses happen, you should not judge or blame yourself. You are not a failure or a bad person because of this. Do not feel that all is lost once a lapse occurs. You can always learn from a lapse and relapse, and prevent it from happening again in the future.
- You should remind yourselves of the reasons why you wanted to change, as well as all the health and personal problems that your previous behaviours have caused you.
- You might find that the gains seem small in the beginning but they will accumulate bit by bit with time as a new sense of control evolves in your new way of living a healthier lifestyle.

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Where could this BCT be implemented on the website?

- Diary – Participants have the choice to complete diary submissions at any stage throughout the intervention. This could be used for the participant to identify barriers relevant to them. The participant could also then try and plan how to cope with this through relapse strategies.
- E-consultation – Web based consultations sent to participants could include reminders of the barriers identified and also the coping plans/relapse strategies that could be implemented.

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- How do you think these techniques are used in your clinical practice?

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