Development, validation and use of a smartphone application for weight loss.

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Intellectual Property and Publication Statements

The candidate confirms that the work submitted is her own, except where work which has formed part of jointly authored publications has been included. The contribution of the candidate and the authors to this work has been explicitly indicated below. The candidate confirms that appropriate credit has been given within the thesis where reference has been made to the work of others. Three jointly authored papers have been produced from work conducted in this thesis. All three of these papers were jointly authored with the PhD supervisors on the project Dr Victoria Burley (VB) and Professor Janet Cade (JC). Two of the papers also include Ms Camilla Nykjaer (CN) as a co-author. CN worked as a research assistant on the project during the validation study and pilot trial of the smartphone application. The papers are as follows:

1) Carter M C, Burley V J, Cade J E. Development of 'My Meal Mate' (MMM) – A smartphone intervention for weight loss. Nutrition Bulletin 2013, 38: 80-84.

2) Carter M C, Burley V J, Nykjaer C, Cade J E. 'My Meal Mate' (MMM): Validation of the diet measures captured on a smartphone application for weight loss. British Journal of Nutrition 2012, May 3:1-8

3) Carter M C, Burley V J, Nykjaer C, Cade J E. Adherence to a Smartphone Application for Weight Loss Compared to Website and Paper Diary: Pilot Randomized Controlled Trial. J Med Internet Res 2013,15(4):e32

Work from chapter 3 of this PhD thesis was used for the first paper on the development of the smartphone app. The second paper takes work from chapter 4 on the validation study of the smartphone application and paper 3 describes the results of the pilot trial of the smartphone app which is based on work included in chapters 5-8 of the thesis. In terms of individual contributions to the publications, the author of the thesis was responsible for project managing the development of the smartphone application, design and running of the validation study and pilot trial, data collection, analysis and interpretation of the data and the writing of the initial draft of the manuscripts. JC and VB assisted in supervision of the PhD work including input into; the development of the smartphone application, design of the validation study and pilot trial, interpretation of the data, supervision of the project and corrections/additions to the published papers. CN helped with data collection in the validation study and pilot trial, preparation of the data for analysis and the formatting of tables for the submitted papers. In addition Mrs Claire McLoughlin is not mentioned on the publications but worked as a clerical assistant on the project and helped with recruitment to the pilot trial, organisation and planning of the pilot trial enrolment and follow-up sessions and data collection in the pilot trial.

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Abstract

Background

The effective treatment of overweight and obesity is challenging. A smartphone application which allows self monitoring of diet and activity could give an opportunity to deliver a weight management intervention.

Methods

Multiple methods have been employed. A scoping review was conducted to explore the evidence for portable handheld electronic devices and weight loss and a smartphone application, ‘My Meal Mate’ (MMM) has been developed. MMM has a theoretical basis and has been informed by focus group research. A validation study compared the diet measures captured on MMM to a reference measure and MMM was piloted in a 6 month, 3-armed randomised trial with a sample of 128 overweight/obese adults.

Results

The literature review found no studies to date of a stand-alone smartphone app for weight loss. In the validation study, energy (kcal) recorded on MMM correlated well with 24 hour diet recalls. Day 1: r=0.77 (95% CI: 0.62-0.86) and had a small mean difference (Day 1: -16 (95% CI: -132 to 100) kcals/d (MMM-recall). Bland Altman analysis showed wide limits of agreement between the methods (+/-2SD -824 to 791kcals/d on day 1). From the pilot trial, frequency of use was statistically significantly higher in the MMM group with a median 82 (IQR: 28, 172) days of diet recorded compared to 15 (IQR: 7, 45) days in the website group and 18 (IQR: 0, 37) days in the diary group (p=<0.001). MMM was rated higher in terms of convenience and comfort of use in social settings. Mean weight change was −4.6kg (95%CI: −6.2 to −3.0) in the MMM group after 6 months (using intention to treat analysis).

Conclusion

MMM has potential as a dietary assessment tool and is an acceptable and feasible intervention. The weight loss seen in the pilot trial is promising and a full trial of MMM is warranted.

Table of Contents

List of Tables

List of Figures

Abbreviations (A-P)

ANOVA	Analysis of variance
BBC	British Broadcasting Corporation
BMI	Body mass index
BMR	Basal metabolic rate
BOCF	Baseline observation carried forward
CI	Confidence Interval
CONSORT	Consolidated Standards of Reporting Trials
DANTE	Diet And Nutrition Tool for Evaluation
EMI	Ecological momentary intervention
FFQ	Food frequency questionnaire
GPS	Global Positioning System
HDL	High density lipoprotein
HSE	Healthy Survey for England
HTA	Health Technology Assessment
ICT	Information communication technology
IPAQ	International physical activity questionnaire
IPIP	International Personality Item Pool
IQR	Interquartile range
ITT	Intention to treat
LCD	Low calorie diet
LDL	Low density lipoprotein
LOCF	Last observation carried forward
MAFF	Ministry of Agriculture, Fisheries and Food
MET	Metabolic equivalent of a task
MMM	My Meal Mate
MRC	Medical Research Council
NICE	National Institute of Clinical Excellence
NIHR	National Institute for Health Research
NHS	National Health Service
NOO	National Obesity Observatory
OFCOM	The Office of Communications
PAL	Physical activity level

Abbreviations (P-Z)

PDA	Personal digital assistant
PhD	Doctor of Philosophy
PmEB	Patient-Centred Assessment and Counselling Mobile Energy Balance
RCT	Randomised controlled trial
SD	Standard deviation
SIGN	Scottish Intercollegiate Guidelines Network
SMART	Self Monitoring and Recording with Technology
SMS	Short messaging service
SQL	Structured query language
TFEQ	Three factor eating questionnaire
TRI	Technology readiness index
USDA	United States Department of Agriculture
VLCD	Very low calorie diet
WHO	World Health Organisation
WLR	Weight Loss Resources

Chapter 1: Introduction

1.1 An overview of the problem of overweight and obesity

1.1.1 Definition of obesity

Obesity has been defined by the World Health Organisation (WHO) as *"abnormal or excessive fat accumulation that may impair health"* (WHO Media Centre, 2013). In 2000, the WHO assembled experts in obesity research to review the available epidemiological data with a view to providing recommendations for public health practice. The resulting report declared the worldwide occurrence of obesity a 'global epidemic' (WHO, 2000). The key themes arising from the report were that: obesity is a chronic condition and largely preventable through lifestyle change; obesity is a population problem rather than an individual problem; the management of obesity should not be separated from prevention of obesity and that the economic, cultural and social issues of industrialised countries have created the conditions for the wide scale spread of obesity.

Body mass index (BMI) is widely used to define and classify categories of overweight and obesity. BMI is a ratio of a persons' weight (kg) divided by their height squared (m^2). Guidelines which recommend the use of BMI to measure obesity (WHO, 2000; NICE, 2006; SIGN, 2010) acknowledge that BMI is not a direct measure of adiposity and is likely to be a less accurate indicator of disease risk in different ethnic groups and in those that are muscular. However, it has been reasoned that BMI is a crude but convenient measure for comparing body weight within and between populations (WHO, 2000).

In order to identify the proportion of a population at increased health risks due to excess adiposity, BMI 'cut-offs' are used to categorise members of a population as overweight or obese (WHO, 2004). The cut-off points proposed by the WHO in 2000 for international classification are the most widely accepted. Using the WHO classification, a BMI of 25-29.9 kg/m^2 would place a person in the overweight category and a BMI of 30 kg/m^2 or above in the obese category. Upon reviewing the available data, a WHO expert consultation concluded that Asian populations have different associations between BMI and health risks than European populations and whilst the established BMI cut-offs should remain for international classification, 'country-specific cut-offs' should be applied to Asian populations (WHO, 2004).

1.1.2 What is the prevalence of overweight and obesity?

Overweight and obesity is a global problem and although once thought to be primarily an issue with high-income nations, low and middle-income countries are also experiencing an increase in obesity (WHO Media Centre, 2013). In 2008, 1.4 billion adults across the globe were estimated to be overweight and of these over 500 million were obese (WHO Media Centre, 2013). Data collected over time suggests obesity incidence is increasing globally as can be seen in figure 1.

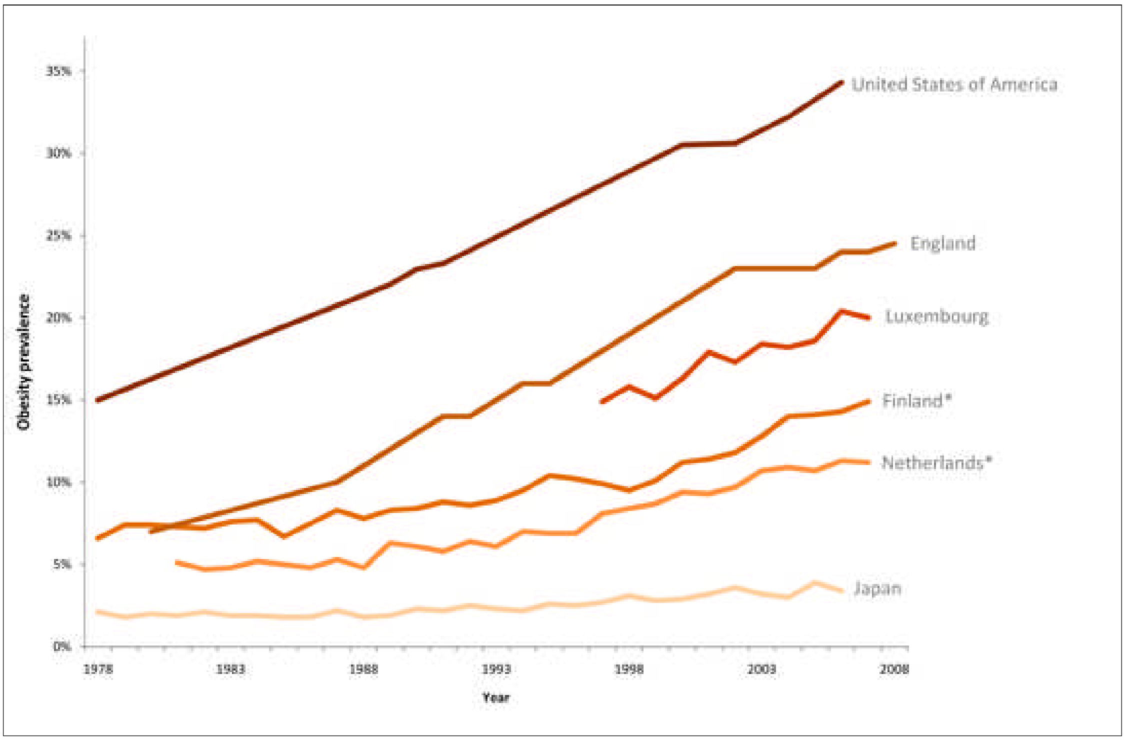


Figure 1: The percentage of adult populations assessed as obese (≥30 kg/m2) in a selection of countries over time. *self reported data. Source: National Obesity Observatory (NOO) 2013.

In 2010, just over a quarter (26%) of UK adults were reported to be obese (NHS Information Centre, 2012). In 2011, whilst a greater proportion of men (41%) were reported to be overweight than women (33%), a slightly higher proportion of women (26%) were found to be obese compared to men (24%) (HSE, 2012). The Health Survey for England (HSE) (2012) reports a marked increase in obesity between 1993 and 2011. Whilst 13% of men were obese in 1993 this has reportedly increased to nearly a quarter (24%) in 2011 (HSE, 2012). A similar increase has also been observed in women with 16% of women reported to be obese in 1993 compared to 26% in 2011 (HSE, 2012). The HSE (2012) also shows that during that time period, mean BMI has increased from 25.9kg/m^2 to 27.1kg/m^2 in men and from 25.7kgm^2 to

27.1kg/m^2 in women. Whilst the proportion of those overweight changed little between 1993 to 2011, the increase in obesity has led to a decrease in the proportion of adults in England with a 'normal' BMI with 41% of men deemed to be a normal weight in 1993 compared to 34% in 2011 and 49% of women with a 'normal' BMI in 1993 compared to 39% in 2011 (HSE, 2012). Foresight (2007) posits that for British adults, being overweight has become 'the norm'.

1.1.3 What are the consequences of obesity?

Obesity is associated with a range of serious and chronic conditions and is estimated by the WHO to be the fifth leading risk for global deaths (WHO Media Centre, 2013). Several systematic reviews and meta-analyses have shown an association between obesity and increased mortality (Allison et al., 1999; Katzmarzyk et al., 2003; Whitlock et al., 2009). An example of one of the largest cohort studies to investigate this relationship was conducted by Calle et al. (1999) using data from 1 million adults in the American Cancer Society cohort and following up for 14 years. The study showed an increased risk of mortality with increasing BMI across age groups. The lowest relative risk of mortality in those who were healthy and had never smoked was found for a BMI between 23.5 kg/m^2 and 24.9kg/m^2 in men and 22.0kg/m^2 and 23.4kg/m^2 in women. Although the association between obesity and mortality is widely accepted, the impact on health of being moderately overweight is a more contentious issue (Hu, 2008) and studies have suffered from methodological issues such as confounding by smoking (as smokers tend to be leaner but are at increased risk of mortality) and reverse causation. Reverse causation occurs when an individual in a cohort may have previously been overweight or obese but has experienced weight loss due to an underlying illness or has intentionally lost weight in order to improve their health after diagnosis with an illness. This confounds the relationship between BMI and mortality as the individual may be classified as having a 'healthy' BMI but be at an increased risk of mortality due to the disease state.

Obesity has been found to be associated with the development of a number of health conditions including; type 2 diabetes (Carey et al., 1997) coronary heart disease/ cardiovascular disease (Ni Mhurchu et al., 2004; McGee et al., 2005; Bogers et al., 2007), certain types of cancer (Hu, 2008), asthma (Beuther & Sutherland, 2007), osteoarthritis (Guh et al., 2009) and kidney disease (Wang et al., 2008). The WHO (2013) attributes overweight and obesity as the cause of 44% of the global incidence of diabetes, between 7-21% of (certain types of) cancer incidence and 23% of ischemic heart disease incidence. The economic burden to the National Health Service (NHS) is substantial, with the cost of spending on overweight and obesity estimated at £4.2 billion in 2007 (Foresight, 2007). A more recent estimate was a total spend on overweight and obesity related ill health of £5.2 billion in 2011 (Scarborough et al, 2011).   The emotional cost to the individual should also not be underestimated and there is evidence that cultural stigmatisation of overweight and obese adults and children may lead to decreased self-esteem and increased risk of depression (Latner et al., 2013).

1.2 What are the causes of overweight and obesity?

Weight gain occurs due to an energy imbalance whereby an individuals' energy intake exceeds their energy expenditure (WHO media centre, 2013). However, the factors which drive an individuals' 'energy balance' are complex and the aetiology of obesity is widely considered to be multi-factorial. Foresight, a government commissioned think-tank published 'Tackling obesities: Future Choices' in 2007 which takes a 'systems view' of obesity and identifies 108 variables which directly and indirectly influence an individual's energy balance (Foresight, 2007). Four key determinants of obesity are identified at the heart of the system; 1) the level of primary appetite control, 2) the force of dietary habits, 3) the level of physical activity and 4) the level of psychological ambivalence (Foresight, 2007). The report describes a process of 'passive obesity' whereby people in the UK are at risk of weight gain simply due to the conditions of modern life.   Sedentary lifestyles, a plentiful supply of energy dense foods and motorised transport are some of the elements implicated in creating an environment which promotes obesity, also known as an 'obesogenic environment' (Swinburn & Egger, 2002). Although discussion of all of the factors implicated in the aetiology of obesity is beyond the scope of this introduction, two of the major drivers implicated in the aetiology of obesity, genetics and the environment, are discussed below.

1.2.1 Genetic factors and obesity

Genetic factors are thought to be one contributor towards the aetiology of obesity. A few very rare conditions such as Prada-Willi syndrome and Bardet-Biedl syndrome are characterised by obesity and associated with genetic factors (Bell et al., 2005). Rather than single gene mutations, most of the genetic contribution towards obesity is thought to be polygenic involving interaction between multiple genes (which also interact with other contributors to obesity such as the environment and lifestyle) (Shriner et al., 2012).

Shriner et al. (2012) describes the three proposed metabolic pathways which genes may act upon to influence BMI: 1) food intake biochemical pathways affecting feelings of satiety and hunger, 2) energy metabolism affecting the storage and usage of energy from food and 3) body fat storage through the development of new fat storage cells. Several candidate genes have been identified from animal models which are thought to have these modes of action, for example the 'ob' gene in mice was found to encode the hormone leptin which acts on the brain to inhibit appetite (Friedman & Halaas, 1998). Whilst it is widely accepted that genetic factors have an important association with obesity, the interaction between genes and the environment is not yet fully understood. Whilst obesity appears to be highly heritable it does not necessarily follow that a predisposed individual is destined to become obese (as will be discussed in 1.2.2 below).

1.2.2 The 'obesogenic environment'

The prevalence of obesity has dramatically increased over time, which Hill & Peters (1998) argue is at a much faster rate than the likelihood of genetic change. Figure 1 as described previously, shows that in industrialised nations (such as the USA and England in particular) the increase in obesity prevalence over the past 20 years has been dramatic. Many industrialised nations have been subject to rapid advances in technology, transportation and a move towards a sedentary lifestyle, all factors which reduce an individuals' energy expenditure. Simultaneous with this reduction in energy expenditure, there has been an increase in factors which promote increased food intake. In industrialised countries, there is almost unlimited access to palatable, energy dense and nutrient poor foods (Prentice & Jebb, 2003) which in the case of fast-food may be inexpensive and convenient (DeMaria, 2003). There has also been an increase in portion sizes over time so that 'consumption norms' appear to have shifted towards larger portions (Wansink, 2012).

1.3 Treatment of overweight and obesity

The treatment of obesity in the National Health Service (NHS) is directed by national guidelines published by the National Institute for Clinical Excellence (NICE) in 2006. The guidelines state that the prevention and management of obesity is a priority for primary care trusts. In the clinical setting, *'multicomponent interventions'* are recommended to include *'behaviour change strategies to increase people's physical activity levels or decrease inactivity, improve eating behaviour and the quality of the person's diet and reduce energy intake'* (NICE, 2006). A brief discussion of different approaches to the treatment of overweight and obesity as recommended by NICE (2006) will follow.

1.3.1 Recommendations for weight loss goals

In managing obesity in the clinical setting, NICE (2006) advises health professionals to recommend to overweight/obese patients a modest initial weight loss target of 5-10% of current weight. This is based on a body of evidence which shows that modest weight loss can have large health benefits (Goldstein, 1992). In particular, the benefits of modest weight loss in preventing or delaying the onset of type 2 diabetes have been a focus of attention. For example, in the 'Diabetes Prevention Programme' trial (Knowler et al., 2002), 3234 participants with risk factors for developing type 2 diabetes (elevated fasting and post-load glucose) were randomised to receive either a lifestyle intervention (targeting 7% weight loss), drug treatment with metformin or a placebo. After an average 2.8 years of follow up, the lifestyle intervention reduced diabetes incidence by 58% (95% CI: 48-66) and the drug treatment reduced incidence by 31% (95% CI: 17-43), compared with placebo.

1.3.2 Energy deficit, low calorie diets and very low calorie diets

The NICE guidelines (2006) recommend a 600 kcal daily energy deficit or low-fat diet to lose weight. A low-calorie diet (LCD) (1000-1600 kcal/day) is also recommended as a consideration with the caveat that it is less likely to be nutritionally complete. A very low calorie diet (VLCD) (less than 1000 kcal per day) is suggested for intermittent use with an LCD for obese patients that have reached a plateau although a VLCD of less than 600kcal is only recommended with clinical supervision. The guidelines are based on the results of a systematic review by Avenell et al. (2004) which reviewed 12 randomised controlled trials and found a weight loss of approximately -5kg (95%CI -5.86kg to -4.75kg) for a 600 kcal deficit or low-fat diet at 12 months. Two studies showed an overall change in weight of approximately -6kg (95% CI -9.05 to 3.2kg) for an LCD at 12 months, whilst the evidence for using a VLCD is based on one study which found a -13.4kg (95% CI -18.4 to -8.4) weight loss at 12 months (the VLCD was administered for an 8 week period).

1.3.3 Dietary interventions with different macronutrient components

Although the overall aim of a dietary intervention for weight loss is usually to reduce energy intake, researchers have also investigated diets of different macronutrient composition. Examples of dietary interventions of different macronutrient content include very low fat diets (such as the Ornish diet) or very-low carbohydrate diets (such as the high profile Atkins diet) (Nonas & Dolins, 2012). Whilst both the Atkins and Ornish diets are commercial, dietary interventions have also been developed by researchers such as the moderate carbohydrate/moderate fat DASH (dietary approaches to stop hypertension) and Mediterranean diets. In general, when comparing diets of different macronutrient composition, studies have shown that a LCD is effective regardless of the type (Nonas & Dolins, 2012). For example, in a meta-analysis of five trials including 447 participants, Nordmann et al. (2006) found no difference in weight loss achieved by individuals assigned to a low-carbohydrate diet as compared to those assigned to a low-fat diet at 12 months. Similarly in a more recent large trial, Sacks et al. (2009) randomised 811 overweight participants to one of four diets with different percentages of energy derived from fat, protein and carbohydrate and found all groups lost a clinically meaningful amount of weight at 2 years with no significant difference between groups.

Researchers have also investigated the effectiveness of commercial weight loss organisations. For example, in the BBC diet trials, Truby et al. (2006) randomised 293 participants to one of 4 arms offering commercial interventions including Weight Watchers, the Dr Atkins diet, the Slim-Fast plan and the Rosemary Conley plan. At 6 months all groups had lost a clinically significant amount of weight (average weight loss was 5.9kg in an intention to treat analysis) and there was no difference in weight loss between the groups.

Whilst the macronutrient content of the diet does not seem to be the important factor for weight loss, there is evidence that it does have implications for cardiovascular risk factor outcomes which need to be taken into consideration when making recommendations about dietary approaches. For example, the meta-analysis by Nordmann et al. (2006) found that participants following the low-fat diet had more improvement in total cholesterol and low density lipoprotein (LDL) than those following the low-carbohydrate diet but those assigned to the low-carbohydrate diet had more improvement in high density lipoprotein (HDL) and triglyceride levels compared to the low-fat diet groups. This led the authors to conclude that low-carbohydrate diets and low-fat diets may be as effective as each other but the decision to recommend a low-carbohydrate diet needs to weigh up the costs and benefits of favourable change in high density and triglyceride levels compared to favourable changes in low density lipoproteins and total cholesterol.

1.3.4 Behavioural interventions

The behavioural approach to obesity has the underlying assumption that dietary and physical activity behaviours are learned behaviours and be modified by changing the preceding event/trigger for the behaviour and by manipulating the consequences (Wing, 2004). This builds on the well established psychological theories of classical conditioning (associative learning) and operant conditioning (where learning is reinforced by the consequences of the behaviour) (Butryn et al., 2012). A review of behavioural interventions for weight loss showed that lifestyle interventions resulted in average weight loss equivalent to 11% of initial body weight in the short term (Wadden et al., 2007). The NICE (2006) guidelines recommend a number of behavioural approaches to be incorporated in a ‘lifestyle change’ intervention, these include; self monitoring, stimulus control, goal setting, social support, reinforcement of changes and problem solving. A more in depth discussion of the components of the behavioural approach to weight loss will follow in chapter 3.

1.3.5 Physical activity interventions

The current body of evidence suggests that physical activity interventions alone are capable of producing only very small weight loss results compared to dietary change but a combined dietary and physical activity intervention can produce better weight loss results than either alone (Ashmore et al., 2012; Miller et al, 1997; Shaw et al., 2009). Although, the role of physical activity alone in initial weight loss appears to be modest, studies suggest that it has an important role to play in the maintenance of weight loss (Ashmore et al., 2012).

1.3.6. Pharmacological and surgical approaches to treatment

NICE (2006) recommend lifestyle changes as a first line approach to overweight and obesity and that treatment with the drug orlistat should be considered once these have been started and evaluated. Orlistat is a lipase inhibitor which acts to prevent digestion and absorption of fat in the diet (Bray, 2012). The evidence base for the NICE guideline on orlistat comes from a review of 14 RCTs which showed that overall, trial participants taking orlistat were 33% more likely to lose 5% of initial body weight than a placebo group at 12 months.

Bariatric surgery is recommended by NICE (2006) as a treatment option for obese adults with a BMI of ≥40 kg/m^2 or between 35 kg/m^2 and 40 kg/m^2 and other significant co-morbidities that could be improved by weight loss. If considered appropriate for surgery, bariatric surgery is recommended as a first-line option in adults with a BMI of more than 50 kg/m^2. A systematic review and meta-analysis conducted by Padwal et al. (2011) presented results from 15 RCTs (a total of 1103 patients) which compared change in BMI from baseline between standard care and bariatric surgery at one year in very obese patients (mean BMI; 42-58 kg/m2.). A range of surgical procedures were used and the range of change in BMI was -2.4 kg/m2 for adjustable gastric banding to -11.3 kg/m2 for mini-gastric banding. The authors concluded that high quality data from large RCTs is lacking but the evidence suggests bariatric surgery to be significantly more effective than standard care in producing weight loss in the very obese.

1.3.7 Limitations of research into weight loss interventions

Adherence to strict diet or exercise regimes can be challenging and weight loss trials often suffer from high attrition over time which has the potential to bias results. A review of attrition in weight loss trials has shown drop-out in the region of 30% to 60% (Douketis et al., 2005). Research suggests that participant adherence to a weight loss regime is a key determinant of its effectiveness and the more extreme and restrictive the diet the less likely people are to continue with the intervention (Nonas & Dolins, 2012). Whilst a number of studies have shown dietary interventions which restrict energy intake to be effective in the short term, it has also been observed that after treatment has stopped, weight regain is likely (Wing & Hill, 2012). For example, in a review of the area, Wadden et al. (2004) found that patients following a group lifestyle behavioural programme regained approximately a third of their weight a year after treatment. Weight recidivism over the longer term is a common problem and Douketis et al. (2005) point out that there are few trials with follow-up for longer than 3 years. This is in contrast to studies of conditions such as hypertension or diabetes which can have follow up of 4-8 years.

1.4 The potential for a smartphone intervention for weight loss

Research has turned to information communication technology (ICT) such as the internet and mobile phones as an approach to weight management. These kind of innovative approaches are intuitively appealing in that they may address some of the barriers inherent to weight management in primary care. For example, they may be an alternative route to engage with healthcare service users who are unable or unwilling to access face to face treatment. ICT may therefore be able to support self-management of weight related behaviours in the patients' natural environment. There is evidence that patients may want alternatives to face to face treatment (Sherwood et al., 1998) and there is potential for a minimal contact intervention delivered by ICT, to be disseminated to a very large audience in a relatively cost effective way.

1.4.1 What research has been conducted on web-based weight loss interventions?

Much of the research conducted to date on ICT interventions for weight loss in adults has investigated web-based systems. A short overview of findings relating to web-based systems will follow in this section and a full review of handheld electronic devices for weight loss in adults can be found in chapter 2. Neve et al. (2010) conducted a systematic review of web-based interventions for weight loss in adults and identified 18 studies which met their inclusion criteria. The duration of the included trials ranged from 6 weeks to 2 years and there was substantial heterogeneity in trial design with only 3 studies comparing a web-based intervention with a control or minimal intervention arm (other trials compared web-based programmes to face to face sessions, 'enhanced' web-based interventions, commercial slimming websites or web-based programmes plus additional elements such as email counselling or individual tailoring). The intervention components of the web-based systems varied and included such things as: educational resources and lessons (general and/or tailored); opportunities for social support (i.e. chat rooms, bulletin boards, forums); goal setting; opportunities for self monitoring with or without feedback (of diet and/or physical activity and/or weight); prescriptive physical activity and/or diet plans; emails (to/from health professionals or buddies) and online meetings.

The review by Neve et al. (2010) found mixed results. Of studies reporting percentage weight change, 3 found a 5% or greater weight change in a web-based arm at follow up where as 3 did not. Of 3 studies comparing a web-based intervention with a control or minimal contact intervention, 1 showed a statistically significantly greater change in weight with the web-based programme where as 2 studies showed no statistically significant difference between intervention and control. The evidence suggested web-based interventions with 'enhanced' features such as feedback and behavioural elements were more effective than 'education only' websites. The authors of the review concluded that web-based approaches have potential to achieve weight loss outcomes similar to other lifestyle treatments but could not yet be recommended based on available evidence.

In 2011, Manzoni et al. published an update to the review by Neve et al. (2010) and added a further 8 new studies. The authors noted that the additional studies did not build the evidence base enough to provide any conclusive statements over and above the previous review. Both reviews identified that the large heterogeneity in study design and intervention components make it difficult to amalgamate studies into a meta-analysis and provide efficacy data. Other limitations include the fact that most studies have been conducted on predominately white, educated women so cannot be generalised to other populations. The reviewed trials suffer from high rates of attrition and an overall decline in engagement over time. There is a lack of information about which specific components of internet interventions promote adherence and efficacy and whether there are individual characteristics associated with successful users. In addition, few studies investigate the cost-effectiveness of the approach. So whilst internet interventions appear to have potential, there is a need for further research and Neve et al. (2010) call for future research to focus on well-designed trials comparing web-based interventions to alternative lifestyle interventions or waiting list controls.

1.4.2 The case for a smartphone intervention

Throughout this thesis, the Oxford dictionary definitions of mobile phone and smartphone will be used. A mobile phone is defined as *'a telephone with access to a cellular radio system so it can be used over a wide area, without a physical connection to a network'* and a smartphone is defined as *'a mobile phone that is able to perform many of the functions of a computer, typically having a relatively large screen and an operating system capable of running general-purpose applications.'*

A smartphone delivered intervention may confer advantages over and above an internet delivered approach to healthcare. The portability and convenience of a smartphone allows for an intervention to be delivered in real time in a persons' natural environment. The term 'ecological momentary intervention' (EMI) is used in health psychology to describe an intervention delivered to a person as part of their everyday life (Heron & Smyth, 2010). An EMI gives a unique possibility to intervene at the moment a person is engaging in a behaviour and also allows for tailoring of feedback (Heron & Smyth, 2010).

Mobile technology has evolved quickly and the enhanced computational functionality of modern smartphones allows for a complete operating system to be run on the phone. Mobile phones are ubiquitous and a particularly acceptable and popular technology platform. Smartphones in particular have seen a dramatic increase in popularity. The most recent Office of Communications (OFCOM) report states that 39% of UK adults owned a smartphone in the first quarter of 2011 and market research company 'Kantar' put this estimate at just over 50% in January 2012 (Kantar, 2012b).

Whilst originally the preserve of 'early adopters' there is evidence that the smartphone demographic is shifting, with smartphones now constituting over half the recent handset purchases in the over-50s (Kantar, 2012a). A smartphone intervention may also address gender inequalities. Although more men are overweight than women in the UK, men have been shown to have barriers which may prevent them from engaging in traditional weight management approaches (Sabinsky et al., 2007). More men than women report to owning a smartphone (IPSOS, 2012) so may find a smartphone intervention particularly appealing. The popularity and convenience of smartphones means there is potential to deliver a wide reaching intervention in an acceptable, convenient and potentially cost effective way.

1.5 Aims and Objectives of the PhD thesis

At the time of writing there are no randomised controlled trials investigating the effectiveness of a stand-alone (i.e. not directly after or in conjunction with other forms of intervention) diet tracking smartphone application for weight loss. The aim of this PhD project is to develop, validate and pilot a smartphone intervention to support weight loss. The objectives are:

- To develop a comprehensive evidence-based smartphone application to support weight loss using qualitative research with potential users to inform the development process.

- To develop monitoring and feedback components and reminder prompts for participants, using self-regulation theories of goal setting and self-monitoring.
- To validate dietary data captured on the smartphone application.
- To implement an exploratory pilot trial using the smartphone application, assessing its feasibility and acceptability.

1.6 Structure of the PhD thesis

This chapter has provided an overview of the problem of overweight and obesity and the current approach to treatment. The potential for a smartphone intervention for weight loss has been highlighted and the aims/objectives and structure of the PhD thesis have been described. The next chapter contains a scoping review of randomised trials of handheld portable electronic devices for weight loss in overweight and obese adults. Essentially, there are three main stages of the project; development of the intervention, validation of the intervention against a reference measure of diet and a pilot trial of the intervention. Chapter 3 is concerned with the development of the intervention, chapter 4 contains the work on the validation study and chapters 5-8 present work from the pilot trial of the intervention. Chapter 9 attempts to tie all of this work together in an overall discussion and conclusion.

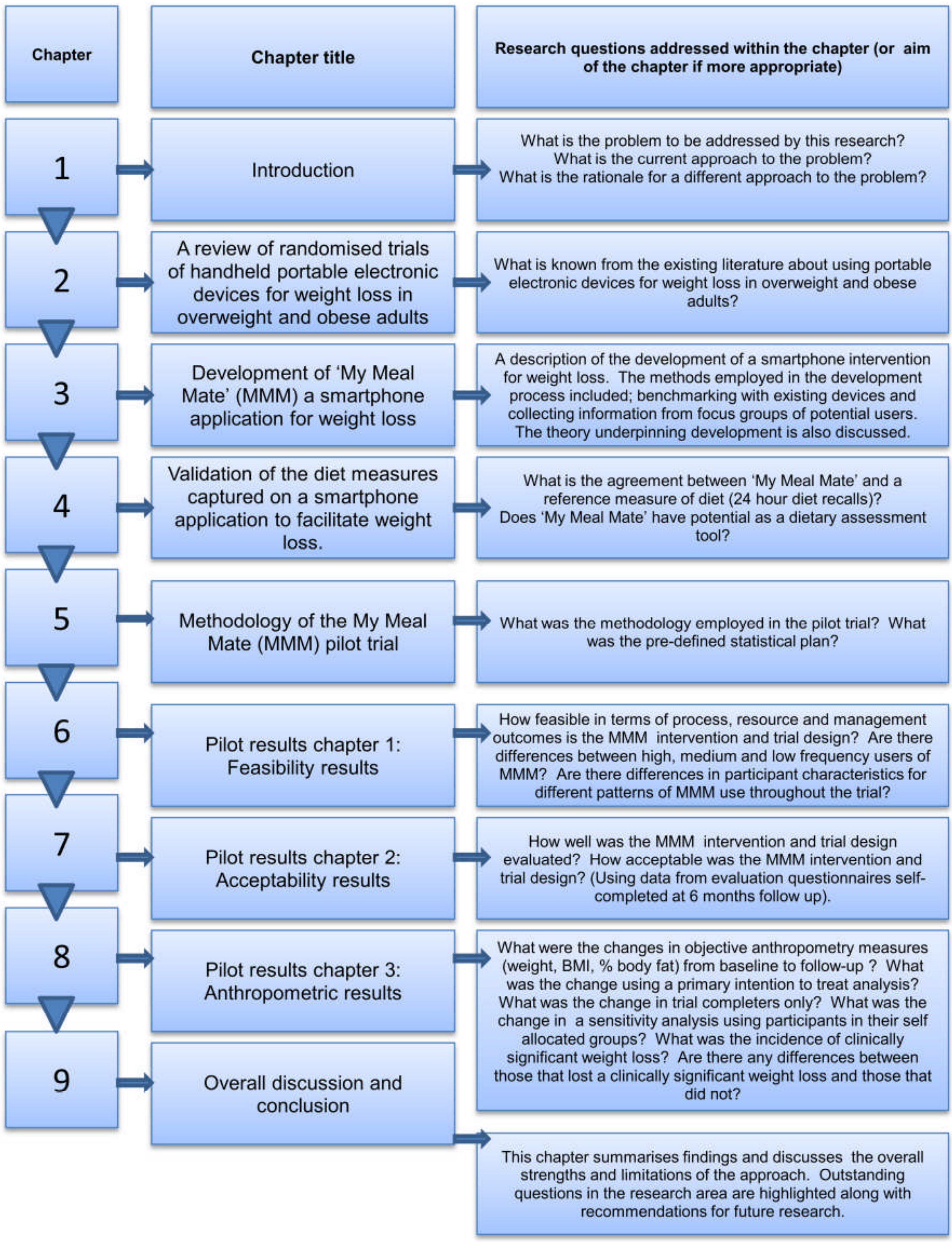


Figure 2: Flow chart to give an overview of the chapters within the thesis and the specific research questions at each stage

Chapter 2: A scoping review of randomised trials of handheld portable electronic devices for weight loss in overweight and obese adults.

2.1 Introduction

The purpose of this chapter is to conduct a scoping review (Arksey & O'Malley, 2005) of the existing evidence pertaining to handheld portable electronic devices used for weight loss in overweight and obese adults. Given that there are few trials investigating mobile phones for weight loss, this review will consider randomised trials investigating a range of different handheld electronic devices. The review will select studies based on a pre-defined inclusion and exclusion criteria and these will be presented in a results table to be followed by a discussion. This chapter fits within the overall thesis by presenting what is currently known from the existing literature about using portable electronic devices for weight loss in overweight and obese adults.

2.1.1 Mobile phone based interventions applied to healthcare

Mobile phoned based interventions have been applied to aid self management of a diverse array of health conditions such as; diabetes (Krishna & Boren, 2008), asthma (Prabhakaran et al., 2010), and HIV (Horvath et al., 2012). In addition, mobile phone based interventions have also been used to deliver behaviour change interventions including; smoking cessation (Whittaker et al., 2009), physical activity promotion (Hurling et al., 2007) and dietary behaviour change (Spring et al., 2012). Smartphones have enhanced computational abilities and typically have the capacity for text messaging, the ability to run applications (apps), a camera and global positioning system (GPS) sensing. This multi-functionality has led to them being applied by researchers to a large number of different health conditions in a variety of different ways. Klasnja and Pratt (2011) provide a useful summary of mobile health interventions and have identified five key strategies which mobile device based interventions have used across different settings. These are; 1) tracking health information (i.e. through self monitoring on an app, text messaging or automated sensing), 2) involving the healthcare team (symptom monitoring or remote coaching by a healthcare professional), 3) leveraging social influence (i.e. peer influence or social support), 4) increasing the accessibility of health information (i.e. educational messages and reminders) and 5) utilising the environment (i.e. using games and entertainment to deliver health messages).

A number of Cochrane reviews have been conducted investigating the effects of mobile interventions as applied to the management of long term conditions (de Jongh et al, 2012), smoking cessation (Whittaker et al. 2012) and for preventative health care (Vodopivec-Jamsek et al, 2012). The reviews conducted to date show that there is a large amount of diversity in this emerging area of research not only in the components of mobile interventions but also in the range of applications. In general, whilst there appears to be convincing evidence for the benefits of mobile interventions aimed at smoking cessation, there is a lack of good quality and consistent evidence for most other health conditions at present.

2.1.2 Mobile phone interventions for weight loss

Research using ICT to treat obesity was pioneered in the 1980s by advances in the portability of micro−computers (Burnett et al., 1985) and as technology has evolved new opportunities to deliver interventions have been presented. Studies have investigated the potential to deliver weight loss interventions using increasingly sophisticated technology including portable micro−computers (Burnett et al., 1985; Agras et al., 1990; Taylor et al., 1991; Burnett et al., 1992), telephone and email contact (Digenio et al., 2009), personal digital assistants (PDAs) (Yon et al., 2007; Beasley et al., 2008; Burke et al., 2011a), the internet (Gold et al., 2007; Harvey-Berino et al., 2010), Mp3 podcasts (Turner-McGrievy & Tate, 2011), text pagers (Volpp et al., 2008; John et al., 2011), mobile phone text messaging (Haapala et al., 2009; Patrick et al., 2009; Shapiro et al., 2011) and smartphone apps (Turner-McGrievy & Tate., 2011).

Bacigalupo et al. (2012) conducted an early systematic review of randomised controlled trials (RCTs) using mobile technology for overweight and obesity published between 1998 and October 2011. The reviewers applied a strict quality assessment using the Cochrane risk of bias tool (Furlan et al., 2009) and identified 7 RCTs which met their inclusion criteria. The interventions included in the systematic review were diverse (including text pagers, mobile phones and telemonitoring via weighing scales and accelerometers) and whilst some mobile devices were for tracking diet and/or physical activity, some were programmed to deliver motivational messages and some were a combination of these approaches. The self monitoring components of the interventions were also different with self monitoring of weight, diet, physical activity or a combination. The reviewers contend that the current evidence base is limited by studies with a lack of generalisability, small sample size, lack of follow-up beyond 1 year, failure to conceal treatment allocation and a focus on ‘otherwise healthy subjects’. Overall, 3 out of the 7 included studies were deemed to be at high risk of bias as assessed by the Cochrane tool. In terms of weight loss, reviewers concluded that there appears to be supportive evidence (from 3 out of 4 studies considered to be at low risk of bias) that mobile technology can lead to weight loss in overweight/obese adults in the short term.

2.1.3 Aim of this review

The aim of the present review is to take a more inclusive approach than the systematic review by Bacigalupo et al. (2012) and review a wider body of research by employing less strict criteria for study quality. The justification for this is that the body of research is largely emerging and smaller scale feasibility studies whilst at higher risk of bias may also offer some valuable contributions to the area. The present review will also focus on interventions targeting dietary change or combined diet and physical activity rather than physical activity alone and provide an update to the previously conducted systematic review by including any appropriate studies reported since its publication.

2.2 Methods

An initial scoping review was conducted at the beginning of the project in 2010. At that time there were only 8 published studies and the body of literature could largely be considered to be feasibility work. Towards the end of the project, the literature search was repeated and the present review was conducted on 15/02/2013 by searching ‘Ovid Medline 1946−2012’, ‘Ovid Medline in process and other non indexed citations’ for relevant papers. The search was not date limited. In addition to searching the electronic databases, hand searching was also carried out by looking at previous relevant reviews and reference lists. The search was performed using keyword search terms relating to electronic mobile devices which were combined with keyword search terms related to weight loss. The keyword search terms to identify handheld mobile interventions were “personal digital assistant”, “portable electronic device”, “smart phone”, “smartphone”, “smartphone app*”, “mobile phone”, “mobile app*”, “mobile device”, “handheld device”, “iPhone”, “i phone”, “iPhoneapp*”, “i phone app*”, “android app*”, “cell phone”, “electronic food diary”, “mobile electronic device”, “portable electronic device”, “multimedia messaging service”, “Text messag*”, “Texting”, “short messaging service”, “PDA phone”, “portable computer”, “handheld computer”, “m−health”, “mhealth”. These were combined with the keyword search terms “weight loss”, “obesity”, “overweight” and “diet”.

2.2.1 Inclusion and exclusion criteria

The inclusion and exclusion criteria for the review were as follows:

2.2.2 Inclusion criteria

- A handheld portable electronic device (eligible devices include: portable microcomputers; text pagers; personal digital assistants; mobile phones and smartphones)
- Interventions aimed at changing eating behaviour for weight loss (i.e. not just targeting physical activity).
- Will include overweight and obese (BMI ≥25 kg/m^2) adults (≥18 years of age) only.
- Will include devices used as the main intervention or as a component in an intervention.
- Will include participants with diabetes and hypertension as long as the intervention is aimed at weight loss (i.e. not self monitoring of blood sugars, carbohydrate counting or monitoring of sodium intake).
- English language.
- Controlled trials (will include feasibility studies and pilot trials as it’s an emerging literature so studies are often small).
- Full peer-assessed publications

2.2.3 Exclusion criteria

- Will not include telephone counselling as this is human contact led rather than self administered.
- Will not include electronic devices aimed solely at increasing physical activity.
- Will not include electronic devices which do not feature self monitoring or text messaging as strategies. This includes MP3 devices and interventions using accelerometers and digital scales.

2.3 Results

The search of Medline gave 206 hits and the search of Medline in process gave 34 hits. After screening the papers against the inclusion and exclusion criteria, 14 papers (Agras et al., 1990; Taylor et al., 1991; Burnett et al., 1992; Yon et al., 2007; Beasley et al., 2008; Volpp et al., 2008; Haapala et al., 2009; Patrick et al., 2009; John et al., 2011; Burke et al., 2011a; Acharya et al., 2011; Turner-McGrievy & Tate, 2011; Burke et al., 2012; Shapiro et al., 2012) were identified as relevant to this review, 3 of these papers (Burke et al., 2011a; Acharya et al., 2011; Burke et al., 2012) were reporting results from the same trial so in total 12 studies were identified for inclusion in the review. A detailed description of the studies included in the review can be found in table 1

A recent early systematic review of mobile technology for obesity and overweight (Bacigalupo et al., 2012) reviewed 7 studies which met their inclusion criteria, 4 of which were also included in the present review (Volpp et al., 2008; Haapala et al., 2009; Patrick et all., 2009; John et al., 2011). Of the 3 studies not included in the present review but featuring in the published systematic review, one targeted physical activity monitoring and not diet (using a combined internet and mobile phone intervention) (Hurling et al., 2007), and 2 were from the same research group which trialled a telemedicine intervention consisting of a digital scale and accelerometer. The data collected by the scale and accelerometer were transferred via Bluetooth to a 'homebox' and this was relayed by telephone to a server. Feedback was provided in the study by the researchers mailing out reports (Luley et al., 2010). Of those 2 studies whilst one was conducted with adults (Luley et al., 2010) the other was a family study using a sample of both parents and children. (Luley et al., 2010) The present review updates the previous systematic review as it includes an additional 7 studies, 3 of which were published after the systematic review by Bacigalupo et al., 2012 (Turner-McGrievy & Tate, 2011; Burke et al., 2012; Shapiro et al., 2012).

Table 1: A summary of trials using handheld portable devices for weight loss in overweight and obese adults

Author (year)	Study population (BMI, kg/m^2) (% female)	Portable electronic device intervention	Design (duration) Intervention	Duration, Attrition (% lost at follow up)	Outcome	Mean weight loss post−intervention (kg ± SD)	Adherence
Agras et al. (1990)	N=90 (25−35 kg/m^2) (100%)	Portable computer. Casio PB−700 (weighs 0.3kg). Accompanied by food code book.	RCT Handheld computer (n=30) vs. handheld computer (n=30) + group sessions vs. group sessions (n=30)	12 weeks, 0%	Weight (kg) Adherence (monthly frequency of computer use)	Computer − 2.3kg [b] Computer+ groups − 2.6kg[b] Groups sessions alone − 1.8kg [b] (p>0.05 between group difference)	70% computer +groups 29% computer 29% groups
Taylor et al. (1991)	N=57 (25−35 kg/m^2) (100%)	Hand−held Casio PB−1000 (weighs 0.4kg). Foods selected from a list of 150 common foods.	RCT Computer (n= 28) vs. 1200 kcal prescribed diet followed by computer after 5 weeks (n=28)	12 weeks, 11%	Weight (kg) Plasma lipids (Total cholesterol, HDL) Adherence (self reported percentage of days entered weekly)	Diet + Computer − 5.3kg ±2.2c Computer − 3.1kg± 2.2c (p<0.05 between group difference)	50% for both groups (p>0.05)
Burnett et al. (1992)	N=40 (25−35 kg/m^2) (100%)	Handheld computer Casio PB770 (weighs 0.5kg). Accompanied by food code book.	RCT Computer x 4 days/wk vs. computer x 4 days/wk + group sessions vs. computer 7	12 weeks, 43%	Weight (kg) Adherence (total number of days with >900kcals recorded)	Computer 4 days/wk – 0.5±1.9 [c] Computer 4 days/wk + groups – 1.6 ±1.9* [c] Computer 7 days/wk – 3.6 ±3.5*	Total number of days that computer turned on= 51 ±16

Author (year)	Study population (BMI, kg/m²) (% female)	Portable electronic device intervention	Design (duration) Intervention	Duration, Attrition (% lost at follow up)	Outcome	Mean weight loss post–intervention (kg ± SD)	Adherence
			days/wk.			c (p<0.05 difference for computer for 7 days and computer + groups compared to 4 days but not between those)	
Yon et al. (2007)	N = 176 (25–39 kg/m²) (86 %)	PDA (PalmZire21) with "Calorie King" software	RCT PDA + group sessions (n=61) vs. paper diary + group sessions from a previous study (n=115)	6 months, 15%	Weight (kg), weight change (%) Energy intake (Block FFQ) Adherence (number of weekly submissions).	ITT (BOCF) PDA – 5.8kg ±6.1 (7.0%±6.5) Diary – 5.8 ± 5.5 (8.3% (±5.8) (between groups p=0.84)	No significant differences in adherence to self monitoring (exact figures not reported)
Beasley et al. (2008)	N=174 (25–40 kg/m²) (79%)	PDA (DietMatePro) Palm Zire 21 PDA. USDA database ver.15.	RCT PDA + Ornish diet (n=89) vs. Paper diary (n=85)	4 weeks, 18%	Diet (24 hr recall) Adherence (% days with plausible energy intakes from a sample). Adherence to diet by reported calories under <15% total	Not powered to detect difference in weight.	78% for both groups assuming drop–outs non compliant (p=0.99)

Author (year)	Study population (BMI, kg/m^2) (% female)	Portable electronic device intervention	Design (duration) Intervention	Duration, Attrition (% lost at follow up)	Outcome	Mean weight loss post−intervention (kg ± SD)	Adherence
					energy from fat.		
Volpp et al. (2008)	N=57 (BMI 30−40 kg/m^2) (5%)	Text messages sent by “text pager” to the two financial incentives group but not control. Text messages were daily feedback advising on money earned and whether they were on track towards weekly weight loss of goal of a 1lb loss.	3 armed RCT design. 2 intervention arms with different financial incentives (own deposit, n=19 vs. lottery, n=19) + text message vs. control, n=19 (consultation with dietitian and monthly weigh−ins).	16 week intervention, 9% (financial incentives for weigh−ins)	Mean weight loss (authors report in lbs but for this table figures have been converted to kg) No measure of adherence to self monitoring.	ITT (BOCF) Deposit contract + Text messages −6.3 ± 4.6 kg mean weight loss. Lottery + text messages −5.9 ±5.7 kg mean weight loss. Control −1.8 ±4.1 kg mean weight loss Difference between interventions and control significant at p=≤0.05.	No measure of adherence to self monitoring.
Haapala et al. (2009)	N = 125 (26−36 kg/m^2) (77%)	Mobile phone programme called “Weight Balance”. Automatically generated text messages. Linked to website.	RCT Mobile phone (n=62) vs. control (no intervention) (n=63).	12 months, 32%	Weight (kg), weight change (%) Waist circumference (cm) Process measures	ITT (BOCF + LOCF). Phone – 4.5kg ±5 (5.4% ±5.8) Control – 1.1kg±5.8 (1.3%, ±6.5) (P<0.005 from baseline for phone and p>0.05 for control) (p<0.05	Not measured

Author (year)	Study population (BMI, kg/m²) (% female)	Portable electronic device intervention	Design (duration) Intervention	Duration, Attrition (% lost at follow up)	Outcome	Mean weight loss post−intervention (kg ± SD)	Adherence
						difference between groups for both weight outcomes).	
Patrick et al. (2009)	N = 65 (BMI >25−39.9 kg/m²) (80%)	Mobile phone text messages + monthly phone calls and print materials.	RCT design. Text message group (n=39) vs. usual care control (n=39)	4 months, 20%	Weight (kg) (% weight change) Adherence (% of messages receiving a reply that requested one)	ITT (LOCF). Phone – 2.1kg[d] (3.16%). Control−0.4kg[d] (1.01% body weight) (p=0.03 difference between groups).	Participants responded to "approximately 2/3rd of messages".
John et al. (2011)	N=66 (BMI 30−40 kg/m²) (17%)	Text messages sent by "text pager" to the two financial incentives group but not control. Text messages were daily feedback advising on money earned and whether they were on track towards weekly weight loss of goal of a 1lb loss.	3 armed RCT design. 2 intervention arms with different deposit contract financial incentives (own deposit for intervention period, n=22) + text message vs. own deposit for intervention and maintenance period, n=22) + text message vs. control, n=22	32 weeks, 11%	Mean weight loss (authors report in lbs but for this table figures have been converted to kg) No measure of adherence to self monitoring.	ITT (BOCF) Deposit contract 1 (intervention and maintenance period) + Text messages −4.4 ± 6.2 kg mean weight loss Deposit contract 2 (intervention period) + text messages −3.4 ±5.8 kg mean weight loss. Control −0.5 ±6.3kg mean weight loss	No measure of adherence to self monitoring.

Author (year)	Study population (BMI, kg/m^2) (% female)	Portable electronic device intervention	Design (duration) Intervention	Duration, Attrition (% lost at follow up)	Outcome	Mean weight loss post−intervention (kg ± SD)	Adherence
			(consultation with a dietitian and monthly weigh−ins)			Difference between interventions and control significant at p=≤0.05.	
Burke et al. (2011a), Acharya et al. (2011) Burke et al. (2012)[e]	N=210 (27−43kg/m^2) (85%)	PDA (Palm Tungsten E2) (DietMatePro) (USDA database). Feedback group received daily text messages based on % calorie goal achieved on PDA.	RCT. All participants receive weekly group sessions. Paper food diary (n=72) vs. PDA (n=68) vs. PDA with feedback (n=70).	24 months (with initial follow up at 6 months), 9% at 6 months, 14% at 24 months.	− % Weight change (kg) − Waist circumference (cm) − Adherence (measured weekly and analysed as a binary variable by categorising as adherent or non−adherent. Adherent defined as a weekly record indicated consumption of >50% of weekly calorie target). − Energy (kcal)(24 hr recall) − Dietary intake (% change from	ITT (BOCF). Reported % weight loss. Paper diary – 5.3%±5.9% at 6 months, 1.95% (95% CI: −3.9, 0.01) at 24 months. PDA− 5.5%±7% at 6 months, −1.4% (95% CI; −3.4, 0.6) at 24 months PDA with feedback – 7.3%±6.6% at 6 months, −2.3% (95% CI; −4.3, −0.4) at 24 months. Difference between baseline and F/u (P<0.01) at 6 mo. for all groups but	Paper diary − 31% PDA − 53% PDA + feedback − 60% (PDA and feedback). Statistically significant between PDA groups and diary but not between PDA group.

Author (year)	Study population (BMI, kg/m^2) (% female)	Portable electronic device intervention	Design (duration) Intervention	Duration, Attrition (% lost at follow up)	Outcome	Mean weight loss post–intervention (kg ± SD)	Adherence
					baseline, % kcal total fat, no. fruit servings, no. veg servings, no. whole grain servings, no. refined grains servings).	only for PDA+ feedback group at 24 months (p=0.02). Between group difference not statistically significant at 6 months (no p value given) or 24 months (p=0.33).	
Turner-McGrievy & Tate, (2011)	N=96 (25–45 kg/m^2) (75%)	Both groups given twice weekly podcasts for 3 months and weekly mini–podcasts for months 3–6. Podcast + mobile group downloaded a diet and physical activity tracking smartphone app called "FatSecret" and instructed how to create a twitter account.	Randomised trial with 2 intervention arms. Podcast only (n=49) vs. podcast + smartphone app for monitoring + twitter (n=47).	6 months (10% attrition, $20 incentive for completing follow–up assessment)	– Change in body weight (%) – Adherence to dietary self monitoring (self report of number of days per week with dietary monitoring). Also self reported number of podcast downloads, objective number of podcast downloads and self reported physical activity monitoring days.	ITT(BOCF) Podcast only −2.6%±3.8 Podcast + mobile −2.7%±5.6 (p=0.98 for between group difference)	Self reported days/per week. Podcast only (mean 2.4 ± 2.0 days at 0–3 months and mean 1.3 ± 1.7 days at 3–6 months).Podcast+ app (mean 2.9 ± 2.1 days at 0–3 months and mean 1.7 ± 2.0 at 3–6 months). Between group diff at 0–3 or 3–6 months (p=0.26 and p=0.39). 60%

Author (year)	Study population (BMI, kg/m^2) (% female)	Portable electronic device intervention	Design (duration) Intervention	Duration, Attrition (% lost at follow up)	Outcome	Mean weight loss post–intervention (kg ± SD)	Adherence
							24/40 in the podcast+ mobile group reported using a mobile app.
Shapiro et al. (2012)	N=170 25–39.9 kg/m^2 (65%)	Text messages	RCT intervention vs. monthly e–newsletters control.	12 months (24%) ($175 compensation, $50 for completing questionnaires).	– Mean weight loss from baseline (lbs) and weight change (%) – Adherence – response to SMS texts asking questions.	Intention to treat using multivariate imputation. Intervention (mean weight loss –1.7kg ± 5.4, weight change –1.8% ±0.06. Control (mean weight loss –1.0kg ±4.3, weight change –0.8% ±0.05. P=0.39 for between group difference in change in weight.	% response to SMS ranged from 33%–60% (depending on message query type).

Table 1: A description of the studies included in a review of randomised trials of handheld portable electronic devices for weight loss in overweight and obese adults. a)BMI not reported but states women at least 35% overweight, b) no standard deviation reported, [c)] analysis of trial completers only, [d)] reported confidence intervals but not standard deviation. 95% CI; -3.11 to -1.09, [e)] All three papers reporting on the SMART trial. Burke et al. (2011a) reported weight outcome at 6 months, Acharya et al. (2011) reported dietary outcomes at 6 months and Burke et al. (2012) reported weight outcome at 24 months. BOCF=baseline observation carried forward, LOCF=last observation carried forward.

2.3.1 Types of portable electronic devices used in weight loss interventions

Of the studies included in this review, eleven were conducted in the United States (Agras et al., 1990; Taylor et al., 1991; Burnett et al., 1992; Yon et al., 2007; Beasley et al., 2008; Volpp et al., 2008; Patrick et al., 2009; John et al., 2011; Burke et al., 2011a; Acharya et al., 2011; Turner-McGrievy & Tate, 2011; Burke et al., 2012; Shapiro et al., 2012) and one in Finland (Haapala et al., 2009). Five different types of electronic portable device have been investigated in the included studies, three trialled portable micro-computers (Agras et al., 1990; Taylor et al., 1991; Burnett et al., 1992), three investigated personal digital assistants (PDAs)(Yon et al., 2007; Beasley et al., 2008; Burke et al., 2011a), two trialled text messaging via a text pager, as an addition to an economic intervention (Volpp et al., 2008; John et al., 2011), three used text messaging via mobile phone (Haapala et al., 2009; Patrick et al., 2009; Shapiro et al., 2012) and one used a diet tracking smartphone app as part of an intervention package including podcasts and Twitter (Turner-McGrievy & Tate, 2011). Table 2 details the individual components included within the portable electronic intervention arms.

As considered chronologically, the three earliest studies (Agras et al., 1990; Taylor et al., 1991; Burnett et al., 1992) pioneered a handheld electronic approach to obesity treatment by developing portable micro-computers which one could use to self-report food intake and receive feedback. These devices were accompanied by a book of coded food items so that users could enter the appropriate food code into the device and receive instant feedback on daily calories consumed in relation to a calorie goal. Although intended to be portable, these early devices were relatively heavy and bulky to carry around (the largest weighing 0.5kg). This technology was superseded by lighter and more convenient 'personal digital assistants' (PDA's) which have been investigated in three weight loss trials (Yon et al., 2007; Beasley et al., 2008; Burke et al., 2011a; Burke et al., 2012; Acharya et al., 2011).

Two of the trials exploring PDAs used nutritional analysis software called "DietMatePro" (Beasley et al., 2008a; Burke et al., 2011a; Burke et al., 2012; Acharya et al., 2011) which contains the United States Department of Agriculture (USDA) 6,600 item food composition tables. Another study used "Calorie King" software which contains a commercial food and drink database of 70,000 food and drink items (Yon et al., 2007). In each case, the PDAs were used after a behavioural weight loss programme in order to improve adherence to dietary targets. Two were used in conjunction with initial weekly group sessions in a behavioural weight loss intervention (Yon et al., 2007;

Burke et al., 2011a; Burke et al., 2012) and one in addition to a prescribed low fat "Ornish diet" (Beasley et al., 2008). All three PDA's were intended for self monitoring of food and drink intake and provided feedback on achievement of targets. The trials by Volpp et al. (2008) and John et al. (2011) were primarily investigating economic interventions for weight loss and used daily text pager messages to inform on progress towards weight loss goals and money accumulated during the study. The financial incentives were 'deposit contract' whereby participants gave their own money which was returned and doubled if they met their weight loss goal or a 'lottery' group where participants were entered into a daily cash lottery if they had met their weight loss goal.

Three studies have used mobile phones to deliver a weight loss intervention (Haapala et al., 2009; Patrick et al., 2009; Shapiro et al., 2012). Shapiro et al. (2012) trialled a daily text message intervention called 'Text4diet' which was described as a modified version of a daily text message intervention first trialled by Patrick et al. (2009). Haapala et al. (2009) used a programme called 'Weight Balance' (Haapala et al., 2009) which automatically generated text messages advising participants to reduce food intake and increase physical activity. Rather than being an exclusively mobile phone intervention 'Weight Balance' was also linked to a website where users could keep a food diary. Only one of the included studies used a smartphone app for participants to self-monitor their diet and physical activity. The app 'FatSecret' is commercially available and was trialled alongside weekly podcasts and Twitter as part of an "enhanced intervention" package (Turner-McGrievy & Tate, 2011).

Table 2: Intervention components featuring in the electronic device intervention arms in a review of trials using handheld portable electronic devices for weight loss in overweight/obese adults

	Component included in the electronic device intervention arm											
Study	Goal setting	Self monitoring of diet	Self monitoring of physical activity	Self monitoring of weight	Motivational Messages	Prior face to face group intervention	Monthly e-newsletters	Prescriptive diet targets	Nutrition education material	Audiocassette with weight loss tips	Podcasts and Twitter	Linked website
Agras et al. (1990)	√	√			√							
Taylor et al. (1991)	√	√	√	√	√			√				
Burnett et al. (1992)	√	√	√	√	√					√		
Yon et al. (2007)	√	√	√	√				√				
Beasley et al. (2008)	√	√										
Volpp et al. (2008)	√				√							
Haapala et al. (2009)				√	√				√			√
Patrick et al. (2009)	√			√	√							
John et al. (2010)	√				√							

	Component included in the electronic device intervention arm							
Burke et al. (2011)/Acharya et al. (2011)/Burke et al. (2012)	√	√	√	√	√	√		
Turner-McGrievy & Tate (2011)		√	√	√				√
Shapiro et al. (2012)	√		√[a]	√	√		√	

Table 2: Components featured in the electronic device intervention arms included in the review of handheld electronic devices for weight loss in overweight/obese adults.

2.3.2 Study design

The limitations of the current evidence base as identified by Bacigalupo et al (2012) (small sample size, short follow-up duration, lack of treatment allocation concealment, and lack of diversity in the sample) were also apparent in many of the studies included in this review. Many of the trials described in Table 1 have a relatively small sample size, with only five investigating a sample of more than 100 people (Yon et al., 2007; Beasley et al., 2008; Haapala et al., 2009; Burke et al., 2011a; Shapiro et al., 2012). Eight studies (Yon et al., 2007; Beasley et al., 2008; Volpp et al., 2008; Haapala et al., 2009; John et al., 2011; Burke et al., 2011a; Acharya et al., 2011; Turner-McGrievy & Tate, 2011; Burke et al., 2012; Shapiro et al., 2012) detailed a power calculation to determine sample size. Of those, one did not achieve the sample size required to detect a statistically significant change in weight between groups but still drew the conclusion that there was no statistically significant difference based on the results (Yon et al., 2007). One of the most recent of the included trials, the SMART trial (Self Monitoring and Recording with Technology) stands apart with a relatively large sample size of 210 people (Burke et al., 2011a; Acharya et al., 2011; Burke et al., 2012) and a longer duration of follow up at 24 months. In comparison, the other studies all have a relatively short follow−up duration ranging from 6 weeks to 12 months. Six of the studies follow up at four months or less (Agras et al., 1990; Taylor et al., 1991; Burnett et al., 1992; Beasley et al., 2008; Patrick et al., 2009; Volpp et al., 2008), two at 6 months (Yon et al., 2007; Turner-McGrievy & Tate, 2011), one at 32 weeks (John et al., 2011) and 36 weeks (John et al., 2011) and two followed up at 12 months (Haapala et al., 2009; Shapiro et al., 2012). Most of the studies have a predominantly female sample (65% to 100%) apart from two trials of financial incentives and text messages which were conducted with American Veterans and had a predominantly male sample (Volpp et al., 2008; John et al., 2011).

Only one study used a strict 'no intervention' control group (Haapala et al., 2009) and the other studies used some kind of 'usual care' comparison group or parallel active intervention which included; monthly written materials (Patrick et al., 2009), monthly 'e-newsletters' (Shapiro et al., 2012) a prescribed low calorie diet (Taylor et al., 1991), group sessions, (Agras et al., 1990, Burnett et al., 1992) a single consultation with a Dietitian and monthly weigh-ins (Volpp et al., 2008; John et al., 2011) a paper food diary (Yon et al., 2007; Beasley et al., 2008; Burke et al., 2011a; Acharya et al., 2011; Burke et al., 2012) and weekly podcasts (Turner-McGrievy & Tate, 2011).

With regard to adequate treatment allocation concealment, although most studies gave details about the randomisation procedure, few studies provided explicit details about how treatment allocation was concealed during randomisation (i.e. how those responsible for implementing the trial were protected from knowing the randomisation sequence in advance of allocation to participants). Six studies stated that participants were randomised but did not specify the randomisation method or how allocation was concealed (Taylor et al., 1991; Burnett et al., 1992; Yon et al., 2007; Volpp et al, 2008; Haapala et al., 2009; John et al., 2011;). Four trials stated that computer generated randomisation was used to randomise (Agras et al., 1990; Patrick et al., 2009, Turner-McGrievy & Tate, 2011; Burke et al., 2012) and 1 trial stated that a randomisation table was developed and used (Beasley et al., 2008). One study stated explicitly that treatment allocation was concealed and the randomisation method was a random number generator with sealed envelopes conducted by a researcher not involved in the study (Shapiro et al, 2012). Only one other study noted that a research nurse who assigned participants was blind to the randomisation procedure (Haapala et al., 2009).

2.3.3 Attrition and handling of missing data

Attrition from the included trials ranged from 0% to 43%. As the study durations differ, table 3 shows the attrition range at different follow up points. There does not appear to be an obvious impact of study duration on attrition, the study with the longest follow up of 24 months actually had slightly less attrition (14%) than a study of only 4 weeks (18%). Eight trials used an intention to treat (ITT) analysis (Yon et al., 2007; Volpp et al., 2008; Haapala et al., 2009; Patrick et al., 2009; John et al., 2011; Burke et al., 2011a; Acharya et al., 2011; Turner-McGrievy & Tate, 2011; Burke et al., 2012; Shapiro et al., 2012). One trial imputed missing values by carrying the last observation forward (Patrick et al., 2009), five carried the baseline weight forward (Yon et al., 2007; Volpp et al., 2008; Burke et al., 2011a; John et al., 2011; Tuner-McGrievy & Tate, 2011), one used a combination of both approaches (Haapala et al., 2009) and one used multivariate imputation (Shapiro et al., 2012). Two of the very early studies only analysed trial completers (Taylor et al., 1991; Burnett et al., 1992).

Table 3: A description of the range of attrition by study duration

Trial duration	Number of studies	Attrition range
4 weeks	1	18%
12 weeks	3	0-43%
16 weeks	2	9-20%
32 weeks	1	11%
6 months	3[a]	9%-15%
12 months	2	24%-32%
24 months	1	14%

Table 3: The range of attrition at different follow up points of the studies included in a review of randomised trials of handheld portable electronic devices for weight loss in overweight and obese adults. [a] There appears to be 13 studies instead of 12 included in the review but this is because the SMART study is included twice as it has follow up points with attrition reported at 6 months and 24 months.

2.3.4 Outcome measures

Only one study did not report some kind of weight loss or weight change outcome as the trial's main outcome, choosing instead to report adherence to the dietary regime (Beasley et al., 2008). Reporting of weight change was not consistent. Outcomes were reported as; mean weight loss from baseline in kilograms (kg) (Agras et al., 1990; Taylor et al., 1991; Yon et al., 2007; 2008; Haapala et al., 2009; Patrick et al., 2009), or pounds (lbs) (Volpp et al., 2008; John et al., 2011; Shapiro et al., 2012) and percentage weight change in kilograms (kg) (Burke et al., 2011a; Turner-McGrievy & Tate, 2011; Burke et al., 2012) or pounds (lbs) (Shapiro et al., 2012).

Nine studies attempted to measure adherence to self monitoring (Agras et al., 1990; Taylor et al., 1991; Burnett et al., 1992; Yon et al., 2007; Beasley et al., 2008; Patrick et al., 2009; Burke et al., 2011a; Acharya et al., 2011; Turner-McGrievy & Tate, 2011; Burke et al., 2012; Shapiro et al., 2012). Studies also reported secondary outcomes of plasma lipids (Taylor et al., 1991), waist circumference (Haapala et al., 2009; Acharya et al., 2011; Burke et al., 2011a; Burke et al., 2012;) and change in energy and nutrient intake (Yon et al., 2007; Beasley et al., 2008; Burke et al., 2011a; Acharya et al., 2011;

Burke et al., 2012). Overall, 4 trials attempted to assess dietary intake at baseline in addition to weight (Yon et al., 2007; Haapala., 2009; Burke et al., 2011a; Turner-McGrievy & Tate, 2011). The dietary assessment measures used included a food frequency questionnaire (FFQ) (Yon et al., 2007), 3 day diet diary (Haapala et al., 2009), 2 x automated self administered 24 hour diet telephone recalls at baseline (Turner-McGrievy & Tate, 2011) and single 24 hour recalls pre and post−test (Beasley et al., 2008; Burke et al., 2011a; Acharya et al., 2011).

2.3.5 Weight loss results

The three earliest feasibility studies conducted in the 1990s using micro-computers all showed modest weight loss at 12 weeks (Agras et al., 1990; Taylor et al., 1991; Burnett et al.,1992). However, the small sample sizes, lack of ITT analysis and relatively short durations mean the results must be interpreted with caution. Both of the trials using PDA interventions (and specifically reporting a weight loss outcome) (Yon et al., 2007; Burke et al., 2011a; Burke et al., 2012) had a statistically significant weight change from baseline to follow−up at 6 months but no statistically significant difference between the self monitoring groups. Yon et al. (2007) found a mean −7% (SD ±6.5) body weight change at 6 months in the PDA group but this was not statistically significantly different from the weight loss in the paper diary comparison group (−8%, SD ±5.8 (p=0.32). In the SMART trial, (n=210) a mean clinically significant weight change (>5%) was found at 6 months in all three intervention arms but this did not differ in a statistically significant way between intervention arms (−5.3%, SD ±5.9 in the paper diary group vs. −5.5%, SD ±7.0 in the PDA group vs. −7.3%, SD± 6.6 in the PDA + feedback group, p=0.12) (Burke et al., 2011a). At the second follow up point in the SMART trial (24 months), weight recidivism was evident and only the 'PDA + feedback' group were found to have a small but statistically significant mean percentage weight change from baseline to follow-up (−2.3%, 95% CI: −4.3% to −0.4%) (Burke et al., 2012). There was not found to be a statistically significant difference in the percentage weight change between the three groups at 24 months (p=0.33).

The two studies using daily text messages via text pager alongside different financial incentives both showed statistically significantly greater weight loss in the intervention arms as compared to the control (Volpp et al., 2008; John et al., 2011). In a 16 week trial (n=57), Volpp et al. (2008) found a −6.3 (SD ± 4.6) kg mean weight loss in a deposit contract + text message intervention arm and a −5.9 (SD ± 5.7) kg mean weight loss in a lottery + text message intervention arm compared to a −1.8 (SD ± 4.1) kg mean weight loss in the control arm of monthly weigh-ins (p= ≤0.05 for difference between interventions and control group). A later trial from the same group investigated an economic intervention (John et al., 2011) alongside an arm which framed the second half of the trial as 'weight maintenance' (rather than continuous weight loss) against a 'control' group which had a single consultation with a Dietitian and monthly weigh-ins. The trial (n=66) found a statistically significantly greater weight loss in the intervention arms as compared to the control. The mean weight loss in the 'deposit contract' arm + text message intervention arm at 32 weeks (with the final 8 weeks framed as 'maintenance') was −4.4kg (± 6.2) and −3.4kg (± 5.8) in the deposit contract and text messaging arm (framed as continuous weight loss) compared to −0.5kg (±6.3) in the control group (p=<0.05 for difference between intervention and control). However in a secondary analysis at 36 weeks follow up, there appeared to be recidivism in weight and the difference in weight loss between the intervention and control groups was no longer found to be statistically significant (mean weight loss in the intervention group= −0.5kg and −0.31kg in the control group, no confidence intervals or standard deviation reported, p=0.76).

Weight change findings were mixed for the three studies investigating mobile phone based text messaging interventions (only one of which used a smartphone). Haapala et al. (2009) trialled a text message intervention in a sample of 125 participants, and found a −4.5kg (±5.0) mean weight loss from baseline at 12 months in the intervention arm compared to a mean −1.1kg (±5.8) loss in the control arm (p=0.006). Patrick et al. (2009) investigated a text message intervention for 16 weeks (n=65) and found a modest mean weight loss of −2.1kg (95% CI; −3, −1) in the group receiving daily text messages compared to −0.4kg (95% CI; −1, 1) in the control group (p=0.03 for between group difference). However, in a follow on from that study, a larger (n=170) 12 month trial using a modified version of the text messaging intervention (with extra content such as step counts via pedometer and a larger library of text messages) showed no statistically significant difference in mean weight loss between the intervention and control group at follow up (p=0.39) (Shapiro et al., 2012). The mean weight loss in the intervention group was −1.7kg (±5.4) at 12 months and −1.0kg (±4.3) in the control group.

Turner-McGrievy & Tate, (2011) randomised 96 overweight and obese participants to either a 'podcast only' arm or an 'enhanced' group which received podcasts, Twitter and a smartphone app called 'FatSecret' (for diet and physical activity self monitoring). At 6 months, the 'podcast only' group lost a mean −2.5% (±3.8) body weight compared to a mean −2.7% (± 5.6) in the 'podcast + app group'. The difference in change in body weight between group was not statistically significant (p=0.98). The weight loss results are summarised in table 4.

Table 4: Summary of weight loss in the intervention arms compared to the comparison arms in the studies included in the literature review.

Study	Weight loss in the intervention group statistically significantly greater than comparison?	
	Short term	Long term ≥ 6 months
Yon et al. (2007)	No	n/a
Beasley et al. (2008)	n/a	n/a
Volpp et al. (2008)	Yes	n/a
Haapala et al. (2009)	n/a	Yes[1]
Patrick et al. (2009)	Yes	n/a
John et al. (2010)	Yes	No
Burke et al. (2011)/Acharya et al. (2011)/Burke et al. (2012)	No	No
Turner-McGrievy & Tate (2011)	No	n/a
Shapiro et al. (2012)	n/a	No

Table 4: Details of whether weight loss in the intervention group was statistically significantly greater than the comparison arms in the studies included in a review of randomised trials of handheld portable electronic devices for weight loss in overweight and obese adults. [1] It is worth noting that this trial differs from the others in that the mobile phone intervention is also linked to a website.

2.3.6 Adherence results

There is little detail from the included trials about how participants were recommended to monitor their dietary intake using the interventions (i.e. to record daily or ad libitum). Of the PDA studies, one specified that participants were asked to record their dietary intake daily for 4 weeks (Beasley et al., 2008) and the other 2 do not state how often they asked participants to monitor but diaries were collected (and PDA records uploaded) at regular group sessions, which may have given participants the expectation that they needed to have completed records prior to sessions (Yon et al., 2007; Burke et al., 2012). Haapala et al., (2009) did not state how often participants should record their dietary intake and nor did Turner-McGrievy & Tate (2011) (although they did note that participants were asked to log-in to Twitter at least once daily).

Adherence to dietary self monitoring was measured in the following ways by different studies; total number of days with over 900 kcals recorded (Burnett et al., 1992), number of weekly submissions of food diaries and PDA records (Yon et al., 2007), as a binary variable with adherent behaviour categorised as over 50% of weekly calorie goal met (Burke et al., 2010; Burke et al., 2012), percentage of days with plausible intakes sampled for the first and last week of the study (Beasley et al., 2008), the percentage of days when a text message received a reply when requested (Patrick et al., 2009; Shapiro et al., 2012) and self−reported number of days per week with dietary self monitoring (Turner-McGrievy & Tate, 2011).

As adherence has been measured differently in each study it is difficult to describe a range of adherence across the studies. Three studies reported that adherence to dietary self monitoring was positively related to weight loss outcomes (Yon et al., 2007; Burke et al., 2012; Shapiro et al., 2012). Turner-McGrievy & Tate (2011) measured adherence to a podcast intervention and to dietary self monitoring by investigating self reported frequency of dietary recording, self reported number of podcast downloads and objectively measured number of podcast downloads from the hosting site. Although the self−reported number of podcast downloads was not found to differ between intervention groups (podcasts only vs. podcasts + smartphone app) at 3 months and 6 months ($p=0.20$ and 0.67 respectively) the objective data showed a statistically significantly greater number of total podcast downloads in the podcast and smartphone app group compared to the podcast only group at 3 months and 6 months ($p=<0.01$ and $p=<0.01$ respectively). The number of days that participants reported that they self monitored their dietary intake was not found to differ between the podcast only group and podcast + smartphone group at 3 months ($p=0.26$) or at 6 months ($p=0.39$). The average reported dietary self monitoring was 2.5 days a week by 3 months and 1.5 days/week by 6 months.

In the trials which attempted to compare adherence between different types of self monitoring intervention, one found a statistically significant greater degree of adherence to the PDA arms of the trial than the paper diary (proportion of sample meeting 50% of weekly calorie goals at 6 months was 90% in the PDA group with feedback, 80% in the PDA group and 55% in the paper diary group, p=<0.01) (Burke et al., 2011a) and four trials (Taylor et al., 1991; Yon et al., 2007; Beasley et al., 2008; Turner-McGrievy & Tate, 2011) found no statistically significant difference in adherence between intervention groups.

Burke et al. (2012) reported adherence to self monitoring at different time points throughout the 2 year trial. Adherence was found to decline over time in all three intervention arms (PDA vs. PDA + feedback vs. paper diary) but overall the proportion of participants in the most adherent groups (monitoring ≥60% of the time) was statistically significantly higher in the PDA only group (p=0.03) and the PDA + feedback group (p=0.01) than the control group. At 6 months, 33/72 (46%) of the paper diary group were adherent ≥60% of the time, 48/72 (67%) in the PDA group and 51/70 (73%) in the PDA and feedback group. By 18 months this had declined to 4/72 (6%) in the paper diary group, 8/68 (12%) in the PDA group and 8/70 (11%) in the PDA+ feedback group. Burke et al. (2012) analysed different categories of adherence and found that weight loss was greater (across groups) for those in the highest categories of adherence (≥60% adherent) than those in the lowest categories (≤30% adherent).

Shapiro et al. (2012) found that adherence to a text message intervention (measured as percentage of text messages that received a response) decreased over the 12 month study duration for some categories of message but was found to increase for messages containing knowledge testing questions. The study also reports that those with greater adherence to the text messages lost statistically significantly more weight at 6 (p=0.039) and 12 months (p=0.023) than those who were less adherent.

2.3.7 Dietary outcomes

Using pre and post test 24 hour telephone diet recalls, Beasley et al. (2008) found that the PDA group had a statistically significant reduction (p=<0.03) in the median fat intake of 31g (IQR; 8, 62) compared to 22g (IQR; 13, 45) in the paper diary group at 4 weeks. The reduction in energy intake (no standard deviation or confidence intervals reported) at 4 weeks was found to be 490 calories in the PDA group compared to 226 calories in the paper diary comparison group (p=0.005). Using an FFQ, Yon et al. (2007) reported a significant decrease in overall calorie intake, total fat intake and percentage energy from fat from baseline to follow up in all trial participants but found that this did not differ in a statistically significant way between PDA intervention group and paper diary control. The effect size of the change in dietary outcomes is not detailed.

Acharya et al. (2011) conducted a secondary analysis of the SMART trial data at 6 months and reported dietary outcomes (% change from baseline). Statistically significant reductions from baseline to follow-up were found in both the PDA and paper diary groups for energy intake (median change; −532 kcal, IQR; −966, −140 in the PDA group and median change; −343, IQR;−836, 26 in the paper diary group, p=0.20 for difference in change between the two groups), % energy (kcal) from total fat (median % change; −1.1, IQR; −8.1, 3.7 in the PDA group and −4.2, IQR; −9.8, 0.3 in the paper diary group, p=0.11 for between group difference). A similar reduction was also found in the % energy (kcal) from saturated fat. A small but statistically significant difference in change was found for the number of fruit servings (median % change, 0.06%, IQR; −0.5, 0.5 in the PDA group and −0.05%, IQR; −1.0, 0.2 in the paper diary group, p=0.02 for between group difference). Similarly the number of vegetable servings had a very slight % increase in the PDA group and slight decrease in the paper food diary group and this was statistically significantly different between the groups (p=0.04).

2.4 Discussion

This review has included randomised trials of portable handheld electronic interventions for weight loss in overweight and obese adults. In order to give a thorough overview of this emerging area, studies of varying quality have been drawn together including the formative work in the area and smaller feasibility type studies.

2.4.1 Limitations of the research conducted to date

Comparison between the studies identified in this review is difficult as there is disparity in study duration, a lack of a standard outcome measure for adherence and weight change, different combinations of components of the interventions trialled (i.e. self monitoring of diet, weight, and physical activity, feedback and motivational messages) tested across different types of device and with differing components of the entire weight loss intervention as a package. Several studies suffer from high attrition and small sample sizes. A small sample size lacks statistical power and can increase the risk of finding ‘false negatives’ in the data (Altman, 1991). Several of the trials included can largely be considered as feasibility type studies, apart from a couple of the most recent studies which stand apart with a larger sample size and longer duration (Burke et al., 2012; Shapiro et al., 2012). As is often the case with weight loss studies, most of the trials included have a predominantly female sample (77%−100%), which reduces the generalisability of the results.

Most studies fail to describe whether treatment allocation was adequately concealed. Whilst many of the studies noted the randomisation procedure they had used they did not provide sufficient detail about whether the researchers knew the randomisation schedule in advance of allocation. Shulz & Grimes (2002) state that allocation concealment does not refer to the method used to generate the randomisation procedure but rather to its implementation. A trial may be at risk of selection bias if the randomisation process is intentionally or unintentionally undermined by failure to conceal treatment allocation (Shulz & Grimes, 2002). Although most of the trials used computers to generate a randomisation schedule, most of the trials failed to provide enough detail as to whether adequate treatment allocation concealment had occurred. Torgerson (1999) argues that the most methodologically sound way to ensure concealed treatment allocation is to use a 'distance' method so an independent third party or centralised system is responsible for randomisation and allocation; none of the trials reported to have done that.

Many of the electronic interventions have been investigated as part of a wider intervention package rather than independently. For example, the PDA interventions reviewed are used after a group−based behavioural weight loss programme. This makes it difficult to tease apart what effect if any the PDA might have as a stand−alone weight loss intervention without initial dietary support and training. Similarly, the two studies which used text messages delivered by text pager (Volpp et al., 2008; John et al., 2011) featured messages alongside a financial intervention so it is difficult to understand which part of the intervention is having the effect on weight loss and whether the financial intervention would have been as effective without the messages or visa versa. The text messaging intervention by Patrick et al. (2009) is supported by monthly phone calls and written support. The one study which used a smartphone application did so as part of an intervention package containing weekly podcasts and Twitter so it's difficult to appreciate the varying contributions of each of these components (Turner-McGrievy & Tate, 2011). The heterogeneity in combinations of the entire intervention package makes it difficult to understand the potential effectiveness of a handheld intervention as a stand−alone device. There is a gap in knowledge about what kind of additional support (if any is necessary) will optimise the impact of the electronic intervention and the best combination of approaches (if a combination is necessary).

The comparison group used in the trials was mixed with only one study reporting to use a strict 'no intervention' control group (Haapala et al., 2009). Choosing an appropriate control is a contentious ethical decision in a group of overweight/obese participants who have expressed a desire to lose weight. It is also difficult in healthcare systems where there is a lack of consistency within the delivery of 'usual care' for overweight and obese adults. There is also a danger of resentful demoralisation in a 'no intervention' control arm of a trial where the intervention is viewed as desirable. It is interesting that in the one study with the 'no intervention' control, over a third of the participants did not complete follow−up at 12 months (27% attrition in the intervention arm and 35% in the control arm) (Haapala et al., 2009).

The studies also ranged considerably in their rate of attrition (0%−43%). Attrition is a serious difficulty in weight loss trials due to its potential to bias results (Ware, 2003). To put this attrition figure into context, a systematic review of long term weight loss trials in obese adults, reported losses to follow up in the range of 30−60% (Douketis et al., 2005). A review focussing specifically on web−based interventions for weight loss found most had attrition rates greater than 20% (Neve et al., 2010). As a result, the way in which missing data is handled in these types of trials is very important. Bias can arise if participants drop out of the trial because they find the intervention unacceptable or because only those that have lost weight return for follow up giving a false impression of the effectiveness of the intervention. It is interesting that retention rates varied so much in the selected studies. Several of the studies did use financial incentives for returning for follow−up which may have contributed to the range in study retention. Two of the very early studies only analysed trial completers (Taylor et al., 1991; Burnett et al., 1992) which may introduce a risk of bias. None of the included studies include any cost effectiveness analysis which would be interesting given that in theory a mobile phone intervention could allow for wide dissemination to a large audience in a minimal contact fashion so could potentially be cost effective.

Bacigalupo et al. (2012) identified several limitations of the studies in this area in their systematic review. These also hold true for the studies included in the present review, issues include: lack of researcher and participant blinding; lack of cost−effectiveness analysis; lack of follow up longer than 1 year and lack of generalisability due to a narrow participant age range and use of only a ‘healthy’ overweight sample.

2.4.2 Adherence and dietary change results

It is difficult to compare adherence to self monitoring as this variable has been measured in different ways between studies. Adherence to dietary self monitoring has been consistently linked to weight loss (Burke et al., 2011b) and is an informative process measure as there is a gap in current knowledge about how frequently a self monitoring intervention should be used for optimum effect. It is not yet known whether dietary self monitoring needs to be continuous or whether there is a ‘learning effect’ such that self monitoring needs only to occur for a short time for permanent changes to be implemented. The analysis by Burke et al. (2012) of the SMART trial data does go some way to investigating these issues. For PDA users in the SMART trial, 18 month weight loss in the two highest categories of adherence to dietary self monitoring (30−59% and ≥60%) was very similar. The researchers suggested that in this case lower levels of adherence to dietary self monitoring were sufficient in achieving the same results as higher levels after this duration of monitoring. A standard objective measure of adherence would help build the evidence base in this area.

Of the three studies attempting to measure dietary change (Yon et al. 2007; Beasley et al. 2008; Acharya et al. 2011) all reported reductions in energy intake using either an FFQ or 24 hour recall for assessment pre and post test. However, the quality of reporting of change in energy intake (kcal) in the trial by Beasley et al. (2008) was poor with no measure of spread around the mean. Both of the dietary assessment measures used are prone to measurement error when attempting to assess absolute intake (Thompson, 2008). Most studies did not attempt to measure dietary change which would be informative for understanding what kind of dietary changes are brought about by handheld devices and which changes are related to weight loss.

2.4.3 Weight loss results

The difference in interventions and trial duration of the included studies means that comparison with regard to weight loss need to be drawn with caution as although a text message intervention and a PDA for dietary self monitoring can both be delivered on a handheld electronic device they are still quite different types of intervention. There are also substantial differences within the same category of intervention. For example, the text message interventions differ in terms of message frequency, content, theoretical framework and accompanying intervention. The ‘Weight Balance’ text messaging programme (Haapala et al., 2009) is described as linking to an online food diary for self monitoring and delivering messages with advice regarding the reduction of certain foods, prompts to increase physical activity and self monitor weight. This is different to the intervention ‘Text4Diet’ trialled by Shapiro et al. (2012) (described as a modified version of the system used by Patrick et al., 2009) which was programmed to deliver 4 messages a day encouraging self monitoring of weight and step counts and giving tips, motivational statements and questions relating to behaviour change strategies. There is much less detail about the text pager interventions (Volpp et al., 2008; John et al., 2011) which are described as daily messages to indicate whether the participant is on track to achieving a monthly weight loss goal and how much money they had accrued in the study.

In summary, the earliest studies using hand−held computers in the 1990s are interesting from a historical stand−point but the small sample sizes, analysis of completers only and relatively short durations mean the results must be interpreted with caution. Overall, the weight loss results were mixed, 3 trials (2 of which were PDA interventions and 1 mobile phone reported a clinically significant (≥5%) mean weight change in the intervention group at follow up (Yon et al., 2007; Burke et al., 2011a; Haapala et al., 2009). However, over the longer term, one of these demonstrated weight recidivism by 2 years to a non-clinically significant weight change (Burke et al., 2012). Three trials (2 of text messages and 1 of a podcasting intervention) failed to find a clinically significant weight loss at follow up (Patrick et al., 2009; Shapiro et al., 2012). The two studies which used text messages alongside financial incentives reported mean weight loss rather than percentage weight change and whilst one reported a statistically significantly greater weight loss in the intervention groups compared to the control at 16 weeks (John et al., 2011), the other found a statistically significantly greater weight loss in the intervention groups compared to the control at 32 weeks but not at 36 weeks.

In terms of comparisons between groups, both PDA trials did not find a statistically significant difference in weight loss between different types of self monitoring (i.e. PDA vs. paper diary) so it appears that self monitoring was more important than the mode of self monitoring (Yon et al., 2007; Burke et al., 2011a; Turner-McGrievy & Tate., 2011).

The trial which used a smartphone application for dietary self monitoring alongside a podcast and twitter intervention found no statistically significant difference in weight loss between the podcast intervention as a stand−alone compared to the addition of the smartphone app and twitter (Turner-McGrievy & Tate., 2011).

2.4.4 The potential for a smartphone application

A difficulty of conducting research in this area is the researchers imperative to keep up with the evolution of improved technology. Micro−computers, text−pagers, PDA's and to some extent standard feature phones whilst useful in demonstrating the principles of mobile interventions are now considered to be dated in many countries and it could be argued that the population testing them may not find them as engaging, convenient or as easy to use as the now popular and familiar smartphone. Microcomputers and PDAs have now largely been superseded by smartphones in the UK. A smartphone provides an exciting opportunity to combine the self monitoring components of the PDA and micro−computer devices with text messaging feedback and provide an intervention on a device that participants will likely have on their person. The most recent Office of Communications (OFCOM) report states that 39% of UK adults owned a smartphone in the first quarter of 2011 and market research company 'Kantar' put this estimate at 51% in January 2013.

A number of smartphone applications which use the computational abilities of the phone for self monitoring rather than just the text message component have been developed by researchers (Tsai et al., 2007; Consolvo et al., 2008; Mattila et al., 2010). For example, a mobile app developed for a Nokia platform, 'Wellness Diary' allows users to record health related data such as weight, sleep and physical activity and receive feedback on input (Mattila et al., 2010). The app 'PmEB' (Patient-Centred Assessment and Counselling Mobile Energy Balance) allows users to log food intake from a limited database of foods and track calorie balance (Tsai et al., 2007). An app called 'Ubifit' has also been developed to promote change in physical activity (Consolvo et al., 2008). There are several commercially available diet and physical activity tracking smartphone applications such as 'MyFitnessPal' and 'FatSecret' but these have not been developed for research purposes so their quality is unknown. To date, none of the researcher−developed smartphone applications have been formally evaluated in an RCT and none of the commercially available applications have been tested as a stand−alone (rather than as an adjunct to another programme) weight loss intervention. It is likely that people may want to use a smartphone application as a stand−alone intervention so a future RCT of this approach is warranted.

A systematic review investigating the effect of 'e-learning' devices on dietary behaviour change was published recently (Harris et al., 2011). The review included 43 studies and found not only that e-learning devices did not bring about significant changes in diet but also that the devices were not cost-effective compared to similar interventions. The devices were informed by a large range of different theoretical frameworks and the review included a long list of different behaviour change techniques used in different combinations. The authors called for further trials of 'e-learning' devices to cease until the most effective intervention characteristics are determined.

It is worth noting that the majority of trials included in the ‘e-learning’ systematic review were web based and none used mobile phones or smartphones. These devices may offer additional advantages not conferred by other older devices given that they are portable, ubiquitous and discrete. Whilst it is beneficial to determine the most effective behaviour change techniques (in order to optimise mobile health interventions) it could be argued that the research in the area needs to be balanced with the need to keep up with the progression in technology and the pressing public health demand for effective interventions with which to tackle obesity. In the case of diet tracking smartphone applications in particular, there is evidence for large numbers of downloads by the public so whilst there is such large public demand it is within the public interest to determine whether such an intervention may be effective even if the most effective individual components of the intervention package are not yet fully understood.

2.4.5 Strengths and limitations of the review

The present review differs from the previous systematic review by Bacigalupo et al. (2012) in a number of ways; it contains three very recent studies (Turner McGrievy & Tate, 2011; Burke et al., 2012; Shapiro et al., 2012) which are important for the area given their relatively large sample sizes, long duration and innovative approach. This review considers additional outcomes of adherence and dietary changes and has not attempted to apply a quality framework. This approach was taken in order to be more inclusive given that this is an emerging area with relatively few studies published to date. A limitation of this review is that the earlier studies included have small sample sizes and are likely to be at risk of bias so the results of these have to be interpreted cautiously. As a result of this, much of the review has focussed on the more recent studies which can be considered to be of higher quality. Another limitation of this review is that it only includes interventions relating to changing diet and not physical activity based interventions. A further limitation is that the searches were performed on two databases and there may be papers that could have been retrieved in other databases which were not identified.

2.5 Conclusion

This chapter has reviewed randomised trials which investigate portable electronic handheld devices for weight loss in overweight/obese adults. The weight loss results have been mixed in this emerging area of research and whilst some relatively small trials show promising results for clinically significant weight loss in the short term (≤ 6 months), the two largest trials conducted to date have shown less promise with a text message intervention (Shapiro et al., 2012) and a PDA intervention (Burke et al., 2012). The only trial with relatively long term follow up at 2 years did not indicate the maintenance of clinically significant weight loss using a PDA for dietary self monitoring (Burke et al., 2012). The research in the area is incredibly heterogeneous and it is difficult to tease apart the sole effects of the handheld device from other aspects of the overall intervention packages and perhaps tenuous to compare results between handheld devices using different behaviour change strategies (i.e. diet tracking and motivational messages). There is currently insufficient evidence to draw a firm conclusion on whether electronic handheld devices are effective for weight loss. As devices are still in their early stages, there is scope for refinement and optimisation. In studies where no weight loss was found this could be a reflection on the quality of the specific intervention rather than on the concept of delivering an intervention by a handheld electronic device in general.

As a relatively new field, there are numerous opportunities for future research. Little is known about the optimum components of an electronic mobile intervention and outstanding questions remain. The area would benefit from further research which seeks to;

- Examine which individual behaviour change strategies (and in what combination) are the most effective to use in an electronic handheld device.
- Determine the most effective text message content and optimum frequency of delivery.

- Understand the optimum degree of tailoring and automation.
- Investigate the optimum frequency of self monitoring.
- Consider the most effective strategies for delivering electronic handheld interventions (i.e. alongside additional methods of support or stand-alone?) and how they should be used (i.e. is daily use essential?)
- Explore whether there is scope to tailor the medium of self monitoring to the individual.
- Investigate whether the drop-off in self monitoring adherence over time (which has been observed in previous trials of dietary self monitoring) could be curtailed and whether this would impact on overall weight loss.
- Examine whether particular types of people are more likely to self monitor.
- Investigate the effects of portable electronic devices for weight loss in a range of different population groups.

There are no studies testing a smartphone application (of comparable quality to those available to download) as a stand-alone weight loss intervention. Research of this nature is warranted as the devices trialled to date are now considered out-dated and have largely been superseded by new technology. This presents opportunities to deliver interventions on devices such as smartphones which people may have more familiarity with. It could be argued that a person may feel less comfortable using a PDA for dietary self monitoring than a smartphone which is likely to be less conspicuous to use in public. The potential benefit of a smartphone delivered weight loss intervention coupled with the pressing public health need for cost-effective and convenient tools with which to tackle the global obesity epidemic calls for further research in this area.

The next chapter will describe the development of ‘My Meal Mate’ (MMM); a smartphone application (app) designed to facilitate weight loss in adults. The development of the application took place in 2010, prior to the update on this literature review. The initial literature review and update to it show that there is potential for a stand-alone smartphone intervention to be developed and tested.

Chapter 3: Development of ‘My Meal Mate’ (MMM) - a smartphone intervention for weight loss.

3.1 Introduction

This chapter will describe the development of ‘My Meal Mate’ (MMM); a smartphone application (app) designed to facilitate weight loss in adults. The aim of the development process was to create a comprehensive evidence-based smartphone intervention to support weight loss. After development the application would be subject to further investigation including a validation study (chapter 4) and ultimately a randomised pilot trial (chapters 5-8). The development of MMM has been shaped by the opinions of potential system users and comparison with similar diet tracking smartphone apps already available to the public (such as ‘MyFitnessPal’ and ‘Lose it!’) and by taking an evidence based approach. This chapter will describe the app, provide an account of the intervention development process and discuss the rationale behind the key developmental and design decisions. This chapter will also describe a small focus group study which was conducted in order to investigate opinions about desirable features of a smartphone intervention. It was considered necessary to collect data from potential system users to inform the development of the intervention given the paucity of relevant evidence at the point of development.

3.2 Evolution of the intervention from a Symbian device, ‘MobileDANTE’

Although now quite different from the original precursor, the concept of MMM has evolved from a prototype mobile device called ‘MobileDANTE’ (see figures 3-5). The MobileDANTE app runs on a Symbian operating system and was prototyped using Nokia 6120 classic and Nokia 5500 smart phones. MobileDANTE incorporated the DANTE (Diet And Nutrition Tool for Evaluation) database which was developed for in-house nutritional analysis by the Nutritional Epidemiology Group at the University of Leeds. The DANTE database is based on the Royal Society of Chemistry Electronic Food Tables which use nutritional data from the ‘McCance and Widdowson food composition tables’ (McCance & Widdowson, 2002). DANTE includes data on 4000 generic food and drink items. A pilot trial of MobileDANTE as part of an MSc project revealed that the database was a major source of frustration (Albaloul, 2008). System users struggled to find the specific foods they wanted in MobileDANTE and the database was identified as a significant limiting factor in user engagement.

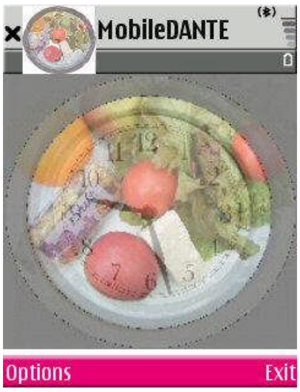


Figure 3: MobileDANTE homepage

Figure 4: MobileDANTE food entry menu

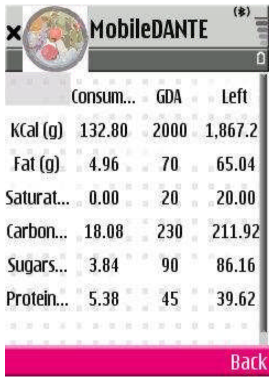


Figure 5: MobileDANTE summary page

The telecommunications market is subject to rapid evolution and as the project commenced in 2010 major changes were taking place in the sector. Smartphones were beginning to increase in popularity and in particular 'iPhones' manufactured by Apple. In comparison to other smartphone applications, the Symbian platform appeared to be facing decline. A key consideration at this point was to 'future proof' the intervention (given that the pilot trial would be at least 12 months after development) and design for a smartphone which would be engaging to users. This required reviewing other apps, to understand what smartphones users might already be familiar with. It quickly became evident that diet tracking apps available to download at that time appeared more advanced in design and functionality than mobileDANTE. The advantages and disadvantages of development options at that point in time are summarised in table 5.

The decision was made to move away from mobileDANTE and develop a new application using an Android operating system suitable to trial on a high-end smart-phone. The Android operating system is available on a range of different smartphone handsets unlike its main competitor Apple. Android is also an open source operating system which means that there are no restrictions on who can share applications for users to download. Another option under discussion was designing a website which could be optimised for a smartphone rather than an app. However, an app was felt to be more suitable as it would be available to use offline and allow for the camera functionality. Although not a particularly well known platform at the time, Android was predicted to increase in popularity as more phone handset manufacturers took advantage of the open source technology. Figures 6 and 7 show the changes in the mobile phone market since the time of development. Of particular note is the increase in popularity of the Android platform between 2010 and 2011 and the decline of Symbian.

Table 5: Options for potential MMM development platforms

Apple (IPhone) app		Android app		Developing a HTML5 website	
Advantages	**Disadvantages**	**Advantages**	**Disadvantages**	**Advantages**	**Disadvantages**
Very popular device, might encourage people to join trial.	People may only take part in a study to get an iPhone - potential to bias results with “iPhone effect”	Open source - wide range of devices from many manufacturers and many more set for release.	There is more platform variation so it is more difficult to make a single App that works on all Android phones.	Cross-platform as web hosted so Should work on iPhone, Android, and future BlackBerries.	Cannot use camera.
Has camera functionality.	Expensive to give out to participants	Device and contract cost likely to be lower than iPhone – (but cheapest devices may have smaller screens).	New technology - will it look as good as an iPhone app?	More future proof – will be less expensive to use on new devices in future.	Fully supporting all devices may require extra work – e.g. to support different screen sizes. Low cost option is to have one preferred device.
iPhone is large – makes on-screen keyboard easier to use.	Apple approval necessary on any apps developed (approx. time 2 months).	Has camera functionality.			If styled to look like an iPhone app, then it may seem odd on Android
	Must be distributed through Apple Store – but could be freely available, and then require a login when run to stop people outside pilot using	No app approval issue at all, can be deployed through a website rather than Android marketplace.			New technology – some risk of unexpected problems (e.g. there is a 5-10mb limit on database size)

Table 5: Advantages and disadvantages of three platform development options for MMM

Figure 6: Comparison of global smartphone sales by operating system between 2010 and 2011

Operating System	3Q11 Units	3Q11 Market Share (%)	3Q10 Units	3Q10 Market Share (%)
Android	60,490.4	52.5	20,544.0	25.3
Symbian	19,500.1	16.9	29,480.1	36.3
iOS	17,295.3	15.0	13,484.4	16.6
Research In Motion	12,701.1	11.0	12,508.3	15.4
Bada	2,478.5	2.2	920.6	1.1
Microsoft	1,701.9	1.5	2,203.9	2.7
Others	1,018.1	0.9	1,991.3	2.5
Total	**115,185.4**	**100**	**81,132.6**	**100**

Figure 6: Global smartphone sales by operating system in the third quarter of 2010 and 2011 (thousands of units). Android has more than doubled its market share within a year coupled with a decline in the Symbian platform. Source: Gartner (Feb, 2011).

Figure 7: Smartphone sales between the first quarter of 2007 and the first quarter of 2012 by platform

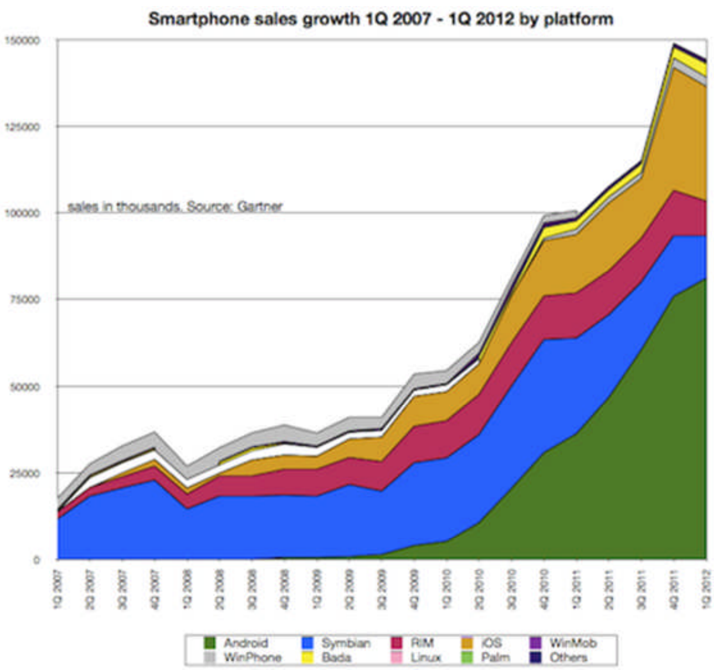


Figure 7: Global smartphone sales by operating system between 2007 and 2012 (thousands of units). Source: Guardian online (http://www.guardian.co.uk/technology/2012/may/16/android-smartphone-market-50-percent) originally sourced from Gartner.

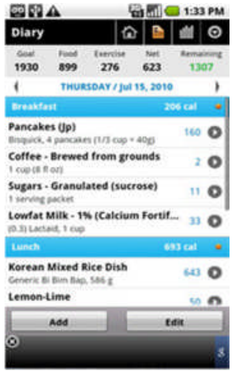
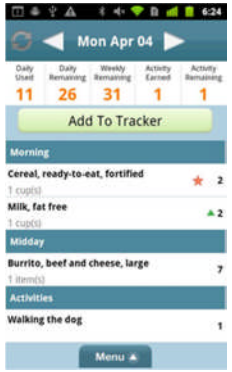
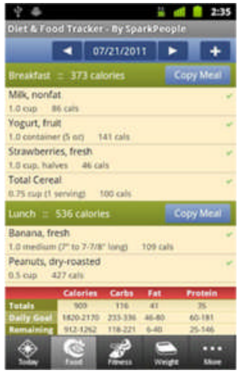
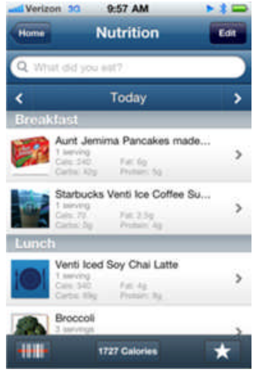
3.3 Comparison with commercially available diet tracking smartphone apps

Table 6 describes a selection of diet tracking apps that were available to download from iTunes in 2010 at the start of the MMM development process. At this point there were no diet tracking apps developed for the Android platform. There were no standard metrics available to measure the number of downloads from the iTunes store so the apps with the highest number of customer ratings were chosen for comparison. The overview of commercially available diet tracking apps was used as a reference against which the functions and lay-out of MMM would be judged. The aim was to create an app of comparable quality in terms of function and appearance to those apps that users might already be familiar with.

Each of the commercial diet tracking applications have several features in common; the user generates a daily calorie requirement for weight loss and energy is monitored towards this ‘budget’, food and drink items are selected from a database and added to a food diary in the relevant meal slot, physical activity is entered into the food diary, energy is displayed throughout the day and summarised. There were some differences between the apps, for example; some had images accompanying food items, some had banners across the top of the food diary to show the balance between energy intake and expenditure, the size of the food and drink database varied between applications, some retained control over the food database and some allowed ‘crowd-sourcing’ (system users have rights to populate the database with new food items), the apps also have different nutrient displays with some only displaying energy and others also displaying macronutrients. All of the apps had been created in the United States and in 2010 this was reflected in the foods available in the database and the portion measures (most used cups and imperial measures only).

In order to choose the most desirable features from these applications to incorporate into MMM they were used as discussion points in focus group work (see section 3.10). Over time, newer features have been added to these apps and where as in 2010 they were only available on iPhone now most are multi-platform. Several of these apps have also been updated to link into social networking via ‘Facebook’ and ‘Twitter' and also have the ability to upload items to the food diary via bar code scanning. However, the quality of the commercially available smartphone apps appears to be very mixed. A recent review (published after the development of MMM) investigated smartphone apps by looking at how they met a series of 13 evidence based criteria for weight loss including such things as; encouraging a diet rich in fruit and vegetables, recommendation of weight loss goals of 1lb-2lbs a week and a food diary facility (Breton et al., 2011). The review considered 204 weight control apps on iTunes (which were selected by searching iTunes for “weight loss” and “diet”) up to 2009. Of selected apps, only 15% met five or more of the 13 evidence-based criteria.

Table 6: Comparison of popular diet tracking apps available to download on iTunes in 2010 (at the start of the MMM development process)

Characteristic	Smartphone application				
	MyFitnessPal	Weight Watchers	SparkPeople	Lose it!	DailyBurn
Screen capture of app food diary page					
Features not common to all apps in 2010 (at the time MMM was being developed)	Online forum, blogging facility, tracking of waist and hip circumference.	Based on Weight Watchers 'points' not calorie counting, weekly email newsletters, online message-board, 1500 recipes, also available on BlackBerry	Tips and advice, fluid tracker, display of macronutrient summary on diary page, exercise video demonstrations, pie chart report of daily energy by food source, web based forum, advertisements.	Graphics of food in the diary, data can be exported to excel, reports of macronutrient intake.	Daily calorie breakdown (displays % energy from fat, protein and carbohydrate) Video clips to demonstrate exercise Food pictures next to descriptors

Characteristic			Smartphone application		
	MyFitnessPal	**Weight Watchers**	**SparkPeople**	**Lose it!**	**DailyBurn**
Rating on iTunes (17/07/2012)	4/5 (62571 ratings)	3/5 (44614 ratings)	2.5/5 (2582 ratings)	3.5/5 (310422 ratings)	4/5 (3893 ratings)
Reported food database size	250, 000 foods in 2010, 1,700,000 by 2012.	30,000 in 2010, 35,000 foods in 2012.	1,000,000	Not stated	223,000 in 2010, 350,000 by 2012.
Newer features in 2012 (17/07/2012)	Multi-platform and iPad, bar code scanning, social networking function to link to Facebook and Twitter	Multi-platform, featured daily recipes, shopping lists, share diary with friends.	Compatible with Android platform.	Social networking via Twitter and Facebook, connect to "Fitbit" accelerometer to track activity, earn fruit and vegetable 'badge' rewards.	Multi-platform, barcode scanner and "meal snap" add on to take photographs of food.

Table 6: Comparison of popular diet tracking apps available to download on iTunes in 2010 at the start of the MMM development process.

3.4 How MMM relates to national obesity guidelines

In designing MMM, the current National Institute for Clinical Excellence (NICE) guidelines for treatment of overweight/obesity in the NHS (NICE, 2006) have been considered. Although the intervention is not specifically designed for use in an NHS setting, it was designed to meet the NICE criteria for an evidence based weight loss intervention, thus giving flexibility if MMM were to be used in the NHS setting in the future. NICE recommend that weight management interventions should follow a 'multi-component' lifestyle approach aiming to reduce energy intake below energy expenditure (NICE, 2006) through a combination of increasing physical activity and changing eating behaviour. NICE also recommends that behaviour change strategies (such as self monitoring of behaviour and progress, goal setting, stimulus control) should be incorporated into behavioural interventions for overweight/obesity (NICE, 2006). By encouraging self monitoring of both diet and physical activity, MMM is 'multi-component' in its approach to behaviour change.

3.5 Theoretical underpinning of MMM

Behaviour change strategies have been incorporated into the MMM app. The behavioural approach to obesity treatment has the underlying assumption that eating and physical activity behaviours are learned and by changing the antecedents they can be modified (Wing, 2003). One aspect of this approach is to encourage changes in a target behaviour by enhancing the development of self regulatory skills. The psychological process of self regulation has been defined as *'self-generated thoughts, feelings, and actions that are planned and cyclically adapted to the attainment of personal goals'* (Zimmerman, 2005). Carver and Scheier (2011) have developed 'control theory' which is a dynamic cybernetic model of self regulation. Carver and Scheier (2011) view self regulation as a feedback loop in which a person receives feedback on a goal and attempts to minimise the gap between their own behaviour and the target behaviour. Metaphorically this is akin to the closed loop system of a household thermostat regulating temperature. In this example, a sensor monitors the temperature of the room, and this information is fed back to the thermostat and temperature maintained or adjusted accordingly (Febrero & Clum, 2008). In an informative chapter on self regulation and self-help theories, Febrero & Clum (2008) draws together the similarities in two self regulation models postulated by eminent psychologists Albert Bandura (Bandura, 1991) and Frederick Kanfer (Kanfer & Gaelick-Buys, 1991). At the heart of these models is the individuals process of goal setting, receiving feedback on the goal and evaluating his/her progress towards goal attainment. Self monitoring (direct observation and recording of the behaviour) is also seen as an important element in these models raising an individuals' awareness of behaviour (Febrero & Clum, 2008). Self regulatory processes will be discussed further in section 3.8.

3.6 Description of 'My Meal Mate' (MMM)

The development of 'My Meal Mate' (MMM) began in April 2010 and was funded by a National Prevention Research Initiative (NPRI) grant. The process of development took 9 months to complete. MMM allows the user to set a weight loss goal and self monitor daily energy intake (kcal) towards achieving the goal. Users select food and drink consumed from a large branded food database (Weight Loss Resources, 2012) and log items in an electronic food diary. Users can also select and record physical activity in the diary and receive instant feedback on their energy expenditure. Progress tracking of weight loss is provided graphically and with further support via automated tailored weekly text messages. There is also a function to take a photograph of the food eaten to serve as an *aide memoir*. For ease of use, MMM includes several usability features; such as the ability to store favourite meal combinations and recently used items. The app has an associated web interface to upload the data stored in the phone and facilitate data extraction and dietary assessment by the research team. The programming work on the application was conducted by an external software company called 'Blueberry Consultants Ltd' in collaboration with the researcher.

3.7 A complete system overview of 'My Meal Mate' (MMM)

'My Meal Mate' MMM has the following functions:

1) Creating energy targets at baseline
2) Goal setting for weight loss
3) Self monitoring of food, physical activity and weight
4) Instant nutritional feedback and feedback by SMS (short messaging service)
5) Progress tracking
6) Usability features
7) Data extraction for analysis

3.7.1 Creating energy targets at baseline

Prior to setting a goal for weight loss, system users enter data on their age, height, weight and physical activity level in order to estimate their energy requirements (at their current weight). The user navigates the 'settings menu' (figure 8) to set up a profile and enter an estimate of their physical activity level.

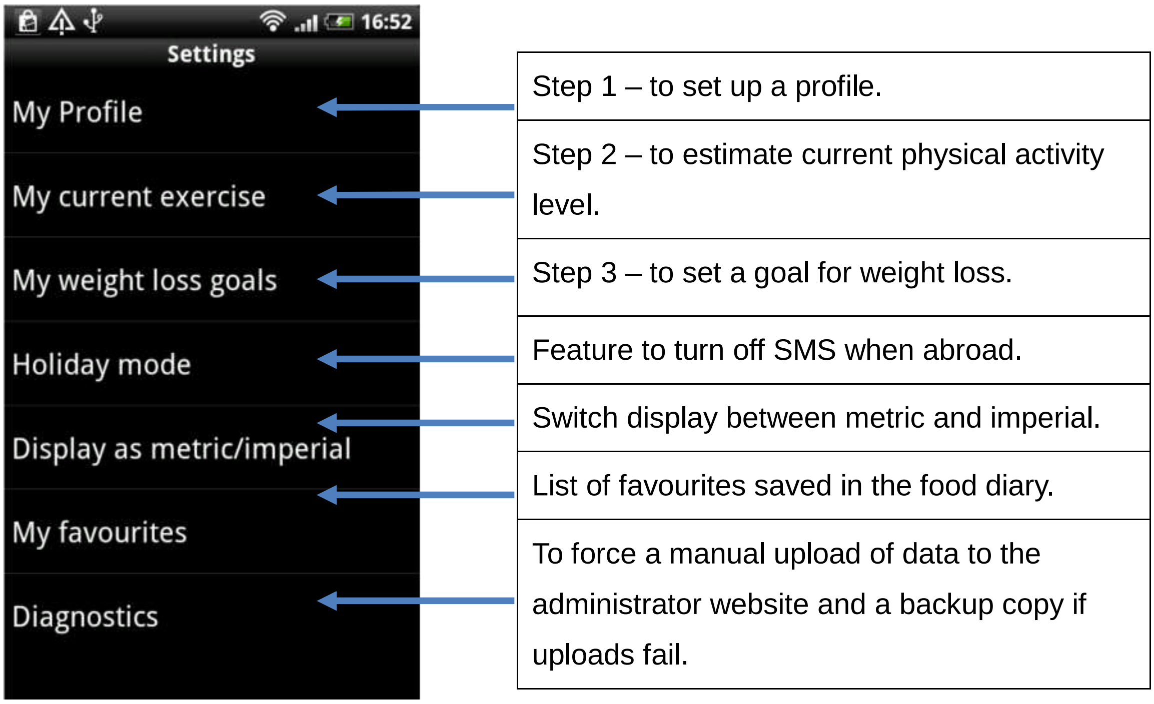


Figure 8: Screen capture of the 'settings menu' of MMM.

3.7.2 Creating a 'profile'

In order to estimate a person's daily energy requirement (measured in kcal) 2 components are required: 1) Basal metabolic rate (BMR), the energy they need to maintain bodily functions at rest and 2) Physical activity level (PAL), the energy needed to carry out physical activity

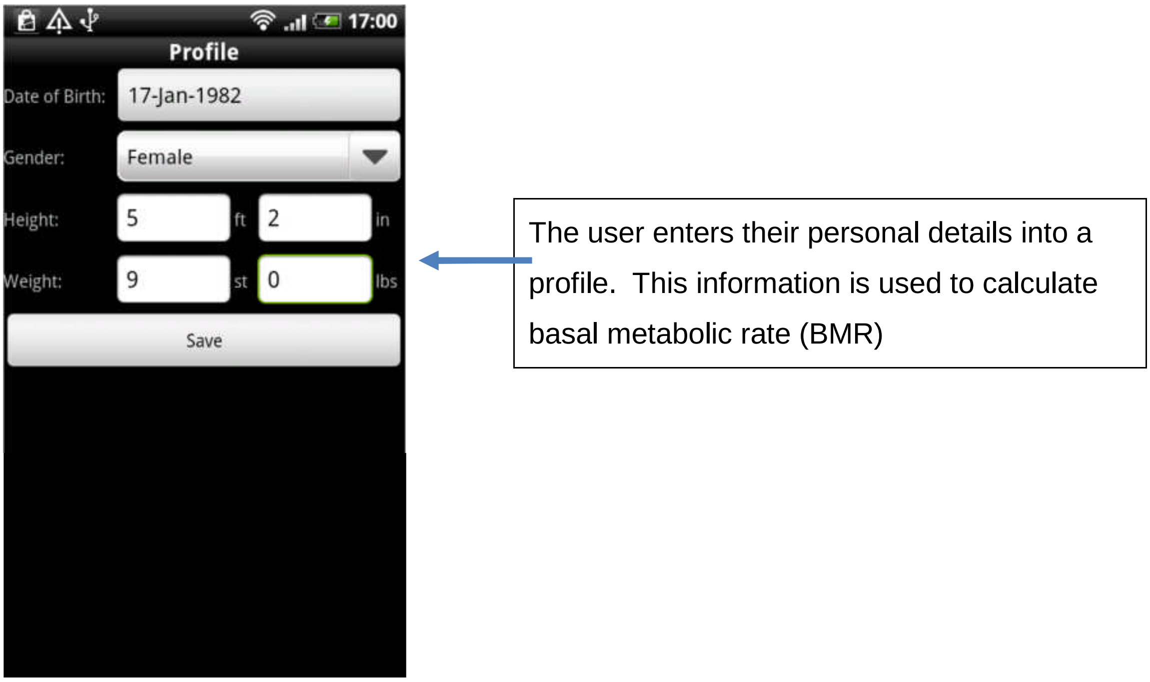


Figure 9: Screen capture of the 'profile' page of MMM.

The user enters their height, weight and age into a profile (figure 9) and this information is used to calculate basal metabolic rate (BMR). The system is programmed to predict BMR using the Harris Benedict predictive energy equation (Frankenfield et al., 1998). This is a widely used predictive equation but it has been criticised when applied to the general public as original measurements were taken on a young, healthy and entirely white sample (Frankenfield et al., 1998). This is the equation which features in similar systems including 'Nutracheck' and 'Weight Loss Resources' so the decision was made to use the same one to benchmark against. BMR is multiplied by a physical activity factor (PAL) to predict the total energy expenditure for the day.

3.7.3 Estimating physical activity

System users estimate their physical activity level by selecting from two questions (figure 10). The two questions have been modified slightly from two questions used in a study to measure physical activity by text message (used with the authors' permission) (Bexelius et al., 2011). In that study, the questions were validated against doubly labelled water in a sample of 22 women and found to have good agreement. In the first question which refers to activity during the working day, the physical activity level values were taken from a large meta-analysis of energy expenditure measurements estimated by doubly-labelled water (Black et al., 1996). The addition to the PAL estimate from leisure time physical activity is taken from the "Compendium of

Physical Activity" (Ainsworth et al., 2000) (with the authors' permission) which was developed for epidemiological research to standardise the categorisation of various different categories of activity. The Compendium is also built into the application as part of the physical activity database which will be discussed later.

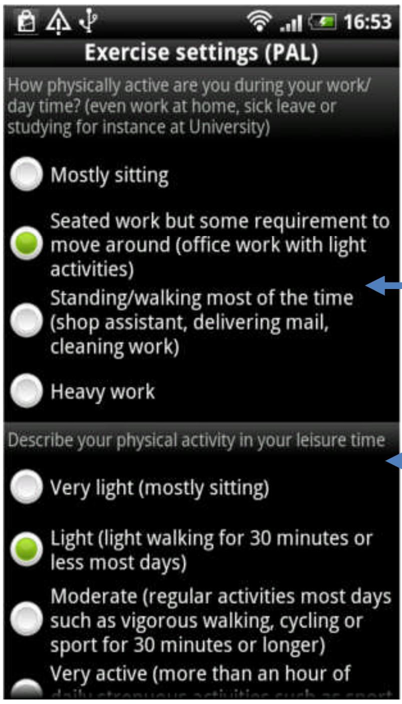


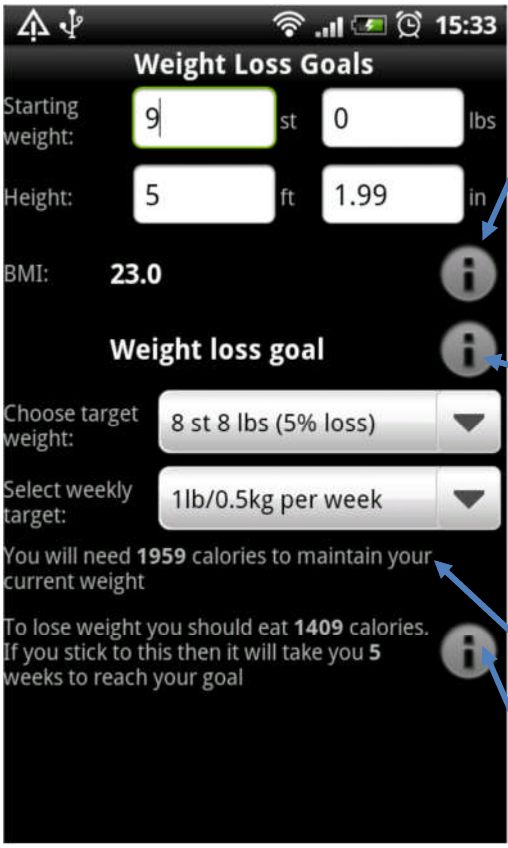
Figure 10: Screen captures of the questions to measure PAL on MMM

Questions	PAL score (as a multiple of BMR)
1) How physically active are you during your work/day time?	
Mostly sitting	1.45
Seated work but some requirement to move around (office work with light activities)	1.65
Standing/walking most of the time (shop assistant, delivering mail, cleaning work)	1.85
Heavy work	2.2
2) Describe your physical activity in your leisure time.	
Very light (mostly sitting)	+0
Light (light walking for 30 minutes or less most days)	+0.06
Moderate (regular activities most days such as vigorous walking, cycling or sport for over 30 minutes or longer)	+0.15
Very active (more than an hour of daily strenuous activities such as sport or cycling)	+0.29

In order to increase the accuracy of reported baseline physical activity a longer series of questions from a validated questionnaire to measure physical activity was initially considered. However, the need for an accurate measurement of baseline physical activity was balanced with the need for speed of setting up a profile for the system user. In similar commercially available systems a two question approach is often employed so in order to benchmark against these systems this method was considered to be adequate.

3.7.4 Goal setting for weight loss

The goal setting part of the application (figure 11) is based on the current NICE guidelines for obesity (NICE, 2006) to mimic goal setting for weight loss in NHS primary care. The system prompts users to select the percentage of their weight they would like to lose. It promotes a slow rate of weight loss so that people are more likely to set goals that generate realistic adherence in the long term. MMM advises a 10% weight loss as studies have shown that a modest weight loss can have significant health benefits in overweight people (Goldstein, 1992). Once a person has selected the rate at which they want to lose weight, the system creates an energy deficit and estimates the number of weeks to reach the goal. To lose 1lb/0.5kg per week a 500 kcal daily deficit is created, to lose 1.5lb/0.75kg per week a 750 kcal daily deficit is created and to lose 2lb/1kg per week a 1000kcal daily deficit is created. The system encourages healthy weight loss and does not allow goals which are below 18.5 kg/m^2 or more than 20% of initial weight. The goals can be modified as weight loss progresses. There is also an option to select 0% weight loss to display calories required to maintain weight.



Message to explain BMI

Body Mass Index (BMI) is a measure of how healthy your weight is for your height. The healthy range is 18.5 - 25. Everybody is different and you know at what weight you look and feel best. BMI is used as a guide to indicate your weight-related health risks.

Message to guide achievable weight loss 1

If you lose weight slowly and steadily you will be more likely to maintain your lower weight in the long term. Nutrition experts advise a safe and healthy rate of weight loss should be no more than 2lb (1kg) a week. You are more likely to succeed if you choose realistic goals that can re-visit and build on over time. If you are overweight a 10% weight loss can have significant health benefits.

These lines are not shown when 0% loss is selected

Message to achievable weight loss 2

If it's going to take you a long time to reach your ideal weight, think about setting a smaller goal first that is more achievable. Once you have achieved this you can build on your success and set another goal in the future.

Figure 11: Screen capture of goal setting user interface

3.7.5 Self monitoring of food intake

System users monitor their food intake in an electronic food diary (see figure 12). The aim is to meet daily calorie targets in order to achieve a longer term goal of weight loss.

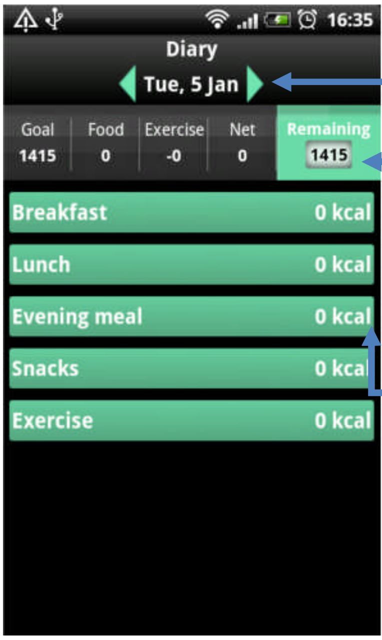


Figure 12: Screen capture of the food diary entry page of MMM

The user is able to navigate between diary dates using these green arrows.

Instant nutritional feedback is shown in this bar by running totals of energy intake and energy remaining until the goal is reached.

To enter food data, the user clicks on a meal slot and this opens up the database search form.

3.7.6 Searching the food database

The search function identifies foods by item name, brand or a combination of both. The search looks for the search term as the first word listed in the 'Weight Loss Resources' database. If the first search does not return appropriate matches the search can be expanded to look for the search term anywhere in the database. For example, to search for the breakfast cereal 'Oatibix', a search could be performed using the brand 'Weetabix' in the 'brand search' box or by 'breakfast' or an expanded search for 'Oatibix' which will look for the word anywhere in the database (see figure 13-16). Once a food is selected it is added to the food diary page (see figure 17).

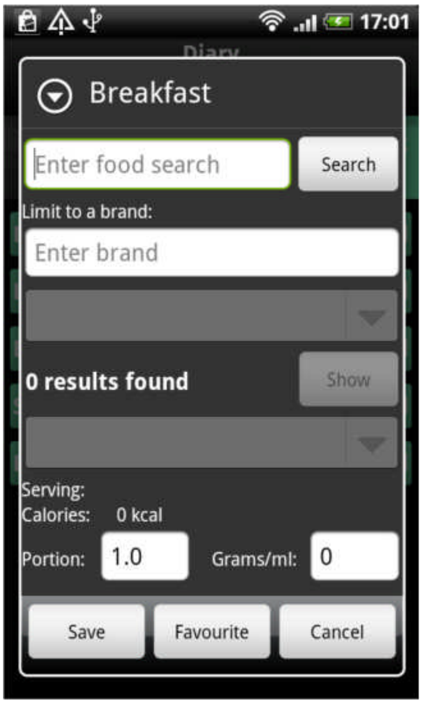


Figure 13: Screen capture of the user interface to search the database for food and drink items.

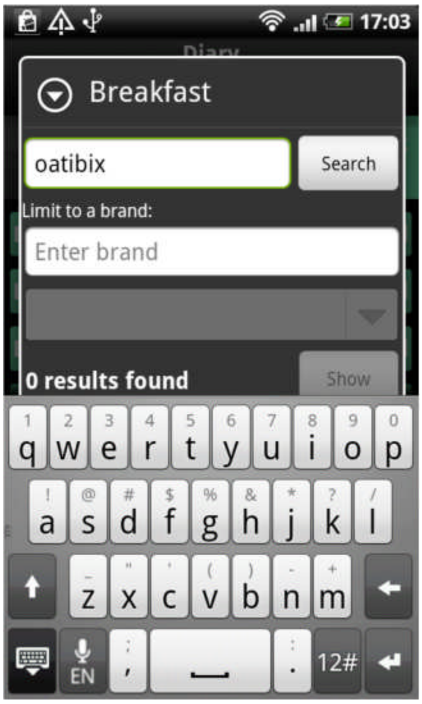


Figure 14: Screen capture to show food entry into the search form via the on screen keyboard.

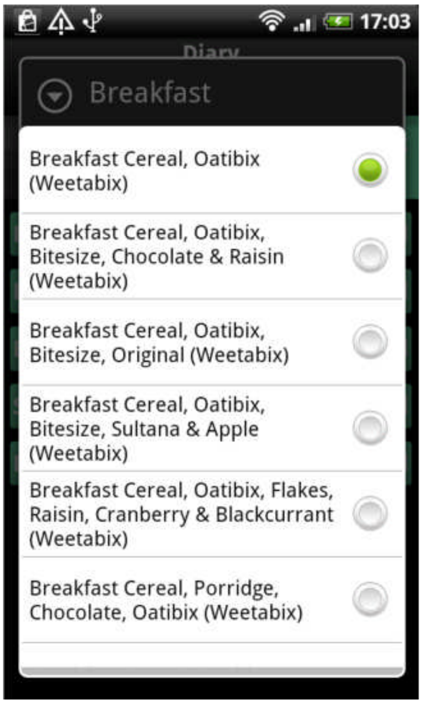


Figure 15: Screen capture to show list of potential matches to scroll through to find chosen item.

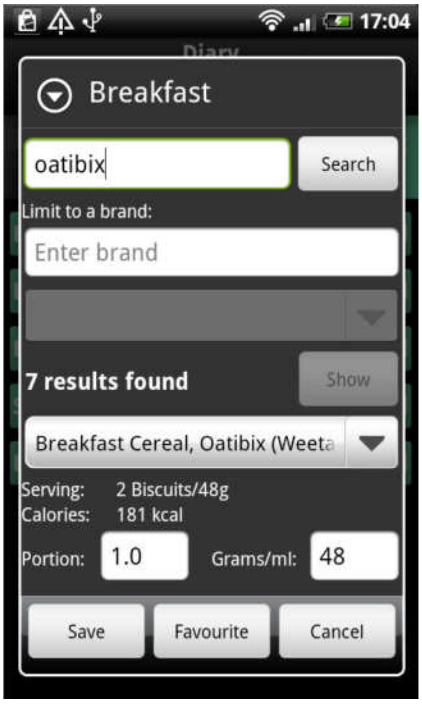


Figure 16: Screen capture of selected food and option to modify portion quantity or manually enter portion sizes.

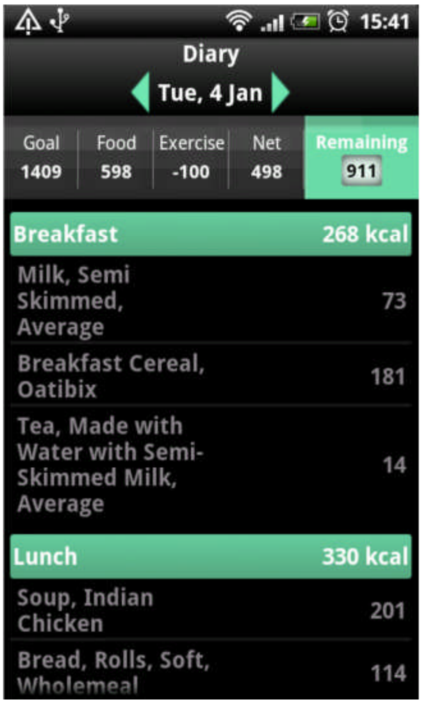


Figure 17: Screen capture of diary page with food entries

3.7.7 Self monitoring activity

System users can monitor their physical activity by selecting activities from a database (see figure 18). The activity database is from a widely used compendium of physical activities (Ainsworth et al., 2000) which assigns an estimated 'metabolic equivalent of the task' (MET) (1 MET=1 kcal/kg/hour) value to each activity. The user selects the time spent in each activity and the estimated energy expended is displayed. The MET value allows MMM to estimate how much energy (kcal) is expended on particular intensities of activity depending on the person's weight and the duration of the activity. For example, walking at a moderate speed (code 21045) is 3.3 METs. If a 76kg man walked for 45 minutes he is estimated to expend: 3.3*76*0.45 = 133 kcal. Users log physical activity which is 'over and above' the normal level set at baseline. Whilst energy intake from food is deducted from the calorie goal, the energy expended through activity is added to the net calories to display an energy balance throughout the day. This is to give system users instant feedback as to the contributions of both diet and physical activity in weight management.

3.7.8 Self monitoring weight

Monitoring of weight is a behavioural strategy which has been linked with weight loss outcomes in a systematic review of the area (Burke et al., 2011b). System users are encouraged to enter their weight weekly into MMM (see figure 19) and weight loss over time is displayed graphically.

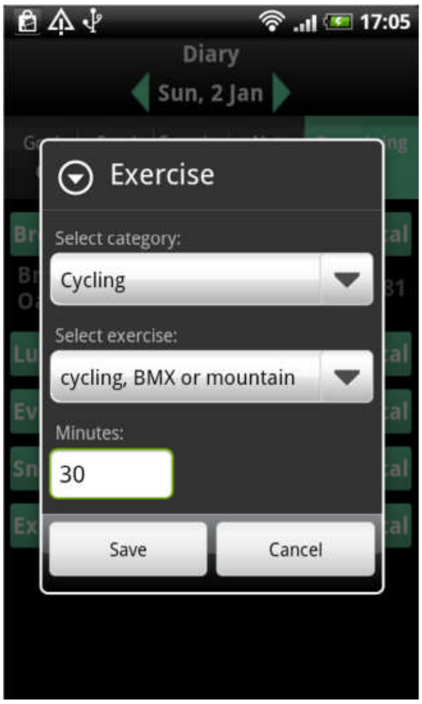


Figure 18: Screen capture of activity entry page

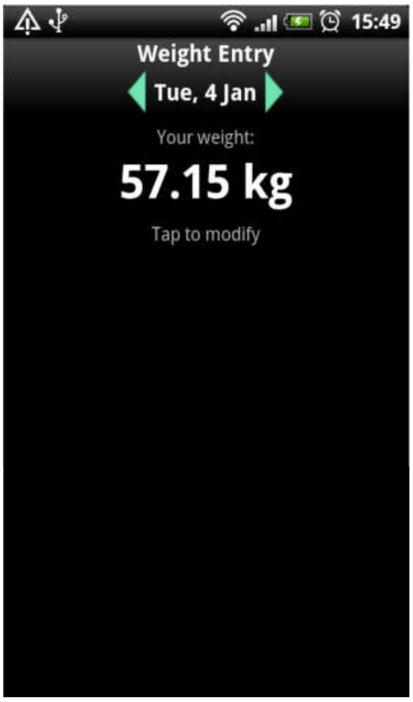


Figure 19: Screen capture of weight entry page of MMM

3.7.9 Instant nutritional feedback

Instant nutritional feedback is provided on the food diary page by a net energy display. The MMM home page displays the calories remaining each day until the calorie target is achieved. This display is green unless the calorie target is exceeded at which point the figure turns red (see figure 20).

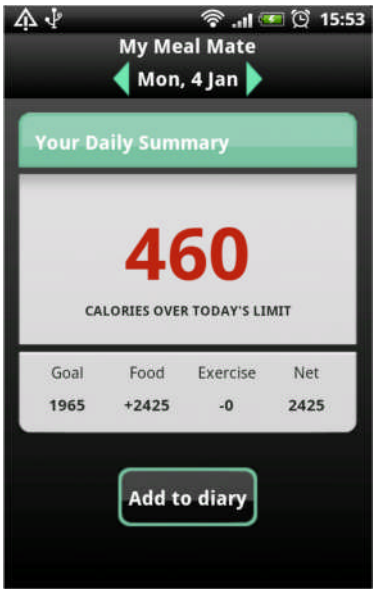


Figure 20: Screen capture of MMM home page with red display indicating that the calorie target has been exceeded for that day

3.7.10 Progress tracking

System users are able to track their progress by accessing graphs of their weight loss and achievement of calorie goals (see figure 21).

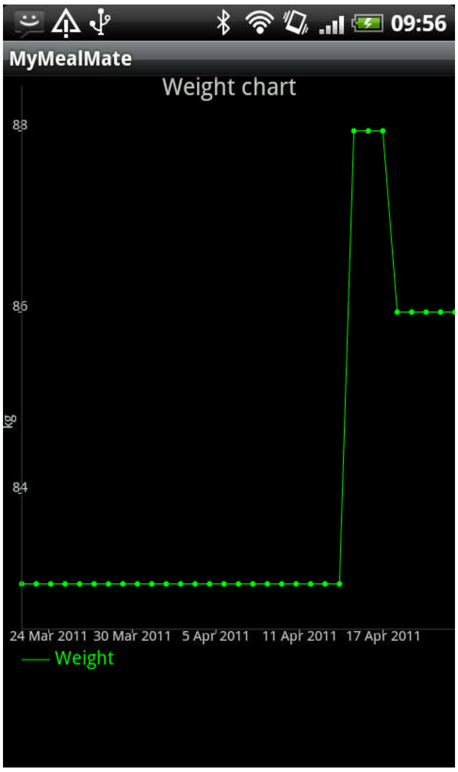


Figure 21: Screen capture of weight entry graph

3.7.11 Usability features

MMM has three features to increase ease and speed of use; 1) the ability to store food combinations as 'favourites' (see figure 22), 2) the retrieval of the previous ten individual items entered (see figure 23) and 3) the use of photos to act as memory prompts (see figure 24-27).

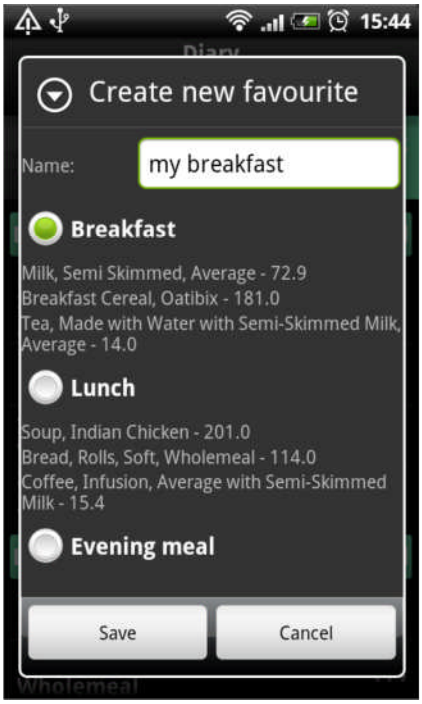


Figure 22: Screen capture of page to create a 'favourite'. The user creates a favourite by selecting the items in the appropriate meal slot, this can be saved to use later.

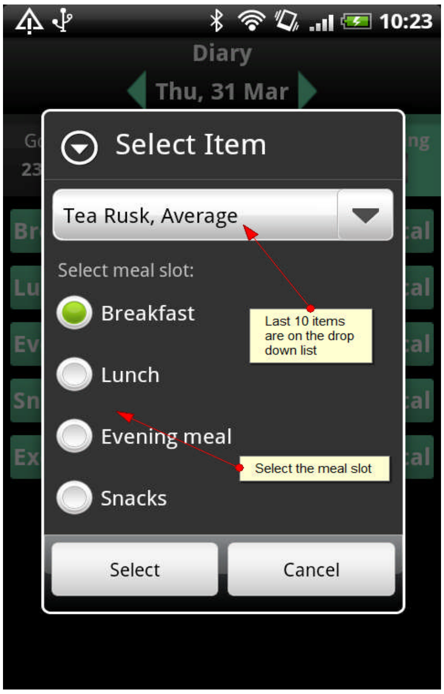


Figure 23: Screen capture of display to select recently used items. The drop down list displays the previous ten items used which can be added to the meal slot.

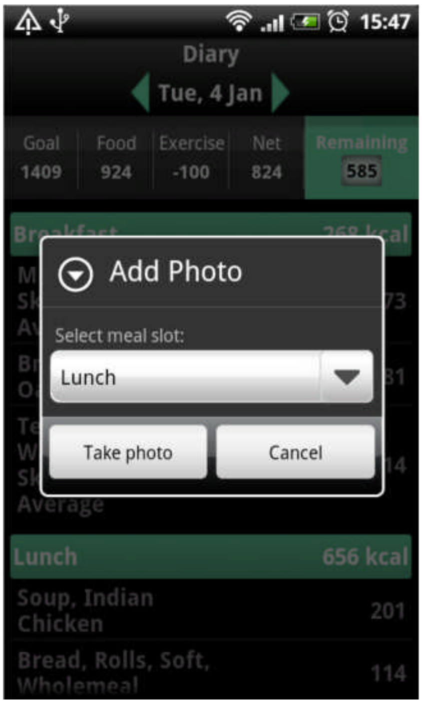


Figure 24: Screen capture of photo dialogue box to add a photo to a meal slot. Once this is selected the application opens up the in-built phone camera to take a picture.

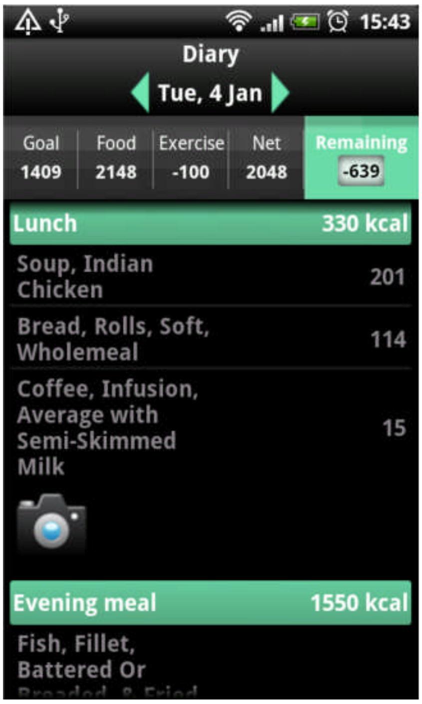


Figure 25: Example of a camera icon in the diary which serves as a reminder that a picture has been stored. Once the meal is entered the camera icon disappears.

Figure 26: Screen capture to show that when the system user is ready to add the photo to the diary they can swipe using the touch screen between the stored picture and the database search to build up a list of items.

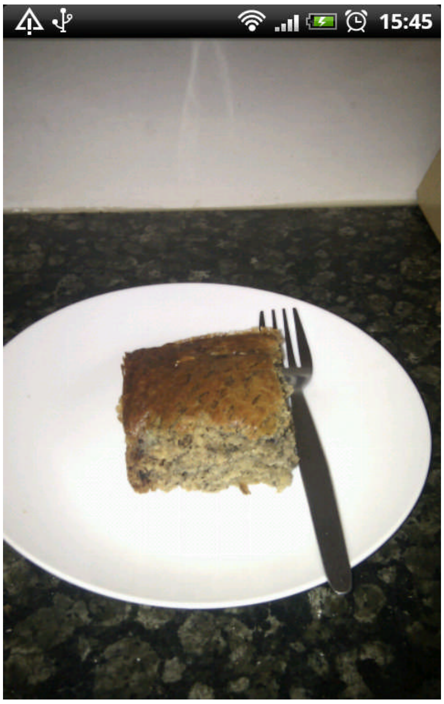


Figure 27: Example of a food photograph taken by a HTC Desire camera to act as a memory prompt in the diary.

3.7.12 Data extraction

The data recorded on MMM is uploaded to an online SQL (structured query language) database. This is then exported to a Microsoft Access database for analysis.

3.8 A description of self regulatory processes incorporated within MMM

The self regulatory processes at the heart of MMM (self monitoring, goal setting and feedback) will be discussed in the following sections.

3.8.1 Self monitoring

Self monitoring is the foundation of MMM with system users required to record their diet, physical activity and weight over time. The user also receives prompts to self monitor by weekly text message. Self monitoring has been ascribed great importance in behavioural approaches to obesity and has been described as the "centrepiece" (Burke, 2011b) and "sine qua non" (Wing, 2003) of weight management strategies.

Self monitoring requires a person to deliberately observe and record their behaviour. In the self regulatory model, self monitoring focuses attention on behaviour by raising the persons' awareness, offering them the opportunity to adjust behaviour as necessary to achieve their goal (Febrero & Clum, 2008). In weight management strategies a person may be required to self monitor their dietary intake, physical activity and/or weight (Burke et al., 2011b). Traditionally, studies have investigated dietary self monitoring using paper diaries (Baker & Kirschenbaum, 1993; Boutelle & Kirschenbaum, 1998) but as technology improves researchers have also investigated using handheld electronic devices such as personal digital assistants (PDA's) (Yon et al., 2007; Burke et al., 2009), PDA's with SIM cards (Wang et al., 2006) (Kikunaga et al., 2007) or mobile phones (Six et al., 2010).

A systematic review of the self monitoring and weight loss literature has been conducted which found 22 eligible studies published between 1993 and 2009 (Burke et al., 2011b). Of these studies, 15 investigated self monitoring of dietary behaviour, 1 exercise and 6 self-weighing. Weight loss was consistently statistically significantly associated with self monitoring across those studies investigating diet and self monitoring. However, the review highlights several methodological limitations which undermine the strength of the evidence base. There is also heterogeneity in approaches to self monitoring (i.e. by paper diary or different PDA devices) and some studies also build on previous face to face weight loss interventions or online approaches. Most of the studies were descriptive in design and some had a small sample size and poor retention. The systematic review highlighted several unknowns in the area of dietary self monitoring research. There is disparity in the way that adherence to self monitoring is measured in different studies and many are reliant on assessment by self-report leaving a paucity of information about the 'effective dose' of self monitoring required for weight loss. The review also highlights the lack of generalisability of findings given that studies predominantly consist of white women. It is questionable as to how effective and acceptable self monitoring interventions are to a more diverse audience. A limitation of the systematic review is that the inclusion criteria was limited to studies published in the United States only, which may have missed informative studies from the rest of the World.

In another review, Shay (2008) notes that it is still unknown as to whether self-monitoring causes weight loss, or whether those who consistently self-monitor are more likely to succeed for other reasons (e.g. greater self efficacy, commitment, etc.).

There is also an unanswered question about which variables are most important to monitor, for example, is it enough to record food intake or is it also important to record where food is consumed, mood at the time of eating and portion sizes? Baker and Kirschenbaum (1993) have provided some evidence on which monitoring variables might be important. Over an 18 week trial, 56 subjects who had already lost weight in a behavioural weight loss programme were encouraged to self monitor in a small paper diary. Participants were weighed weekly and self monitoring was graded for consistency by researchers on a number of individual monitoring variables including; monitoring all foods for the day, weight, energy (kcal), eating location, activity, mood, and fat consumption. At 18 weeks there were found to be statistically significant positive correlations between 6 monitoring variables and percentage weight change (r 0.54 to 0.65, $p<0.01$). In this study, monitoring water intake, situations in which foods were eaten and with whom food was eaten were not associated with weight loss. As highlighted in the systematic review of self monitoring and weight loss (Burke, 2011b), subsequent self monitoring studies have failed to evaluate self monitoring by a set criteria and so further research is still needed given the relatively small sample size, short duration of this study and reliance on researcher grading. There is potential for more objective assessment of self monitoring behaviour with time and date stamped electronic records (Burke et al., 2008). MMM was programmed so that all data is uploaded with a time and date stamp which gives an important opportunity to capture data about how people use the diary to self monitor their diet.

Despite the associations with weight loss, dietary self monitoring has often been shown to be inaccurate (Black et al., 1993) and in particular, intake is more likely to be underreported in the overweight/obese (Rennie et al., 2007). Given this observation, it may be that the process of monitoring is more important than the accuracy for weight loss effectiveness.

3.8.2 Goal setting

The initial set up process of MMM encourages the user to set a goal for weight loss. This generates a daily calorie target so that the user is monitoring towards a daily proximal calorie goal and a distal overall weight loss goal. This MMM process has been guided by the principles of ‘goal setting theory’, a theoretical approach originally described by Locke (1996). The theory originated from the field of industrial psychology, to describe the effect of goal setting on the ability to perform work tasks, but has also been applied to changing health behaviours (Strecher, et al. 1995). ‘Goal setting theory’ incorporates specific attributes of the goal setting process which have been found to enhance an individuals’ performance on a task (Locke, 1996). Attributes which have been found to enhance performance include setting a specific rather than vague goal, a proximal rather than distal goal and setting a difficult goal requiring some effort rather than an easily achieved goal. The theory also emphasises the importance of commitment to a goal, which is influenced by how important and how achievable the individual considers the goal to be. Locke (1996) describes how commitment to a goal can be strengthened in three ways: 1) by ensuring that it is within a persons’ current capacity; 2) by providing training to enhance capacity and 3) enhancing a persons’ belief and confidence in their capacity. An important concept in this third approach to goal commitment is the persons ‘self-efficacy’ (Bandura, 1977) which will be discussed later in this chapter with reference to the text messaging component of MMM. Feedback on goal performance is also an intrinsic part of the goal setting theory to be elaborated on in section 3.8.3.

A review of goal setting studies published from 1977 to 2003 found positive results supporting the effectiveness of goal setting in bringing about changes in diet and behaviour in 8 out of 13 studies on adults (Shilts et al., 2003). A more recent systematic review of the literature pertaining to goal setting in overweight/obese adults has been conducted which identified 18 studies which used goal setting as part of an intervention (Pearson, 2012). The authors concluded that whilst each of these studies did bring about positive findings with regard to weight loss, it is difficult to draw a causal relationship with goal setting exclusively given that the interventions also comprised of other elements (such as self monitoring, education) and were delivered over varying durations.

There is little evidence to suggest whether a weight loss goal will be most effective if set by the individual, assigned by someone else (i.e. researcher or health professional) or decided on collaboratively (Pearson, 2012). For this reason, MMM allows the user to set their own weight loss goal (as is the case in commercially available applications) but with some direction using drop down menu and advice to guide on an achievable and safe goal in the timeframe. The user selects the amount of weight they want to lose (in terms of % weight loss) and the difficulty level (i.e. rate of weight loss per week) which is reflected in their daily calorie target.

The goal setting guidance provided on MMM is based on the NICE recommendations that a weight loss programme should encourage realistic weight loss goals of no more than 0.5–1 kg (1–2 lb.) a week (NICE, 2006) and that people should be encouraged to set a realistic goal for weight loss of between 5-10% of initial weight section (NICE, page 32, 1.1.7.1.). Face to face, behavioural weight loss interventions typically produce weight loss of 5-10% of initial weight over 6 months (Perri et al., 2003) and losing 5% to 10% of initial body weight has been shown to have a number of clinically significant benefits (Goldstein, 1992). As a safety measure, the goal setting process does not allow the system user to lose more than 20% of their initial body weight or to choose a goal that would take them below a body mass index (BMI) at the lowest end of a healthy weight range as defined by the World Health Organisation (WHO) as 18.5kg/m^2.

3.8.3 Feedback

Feedback on performance and progress towards a goal is an important part of 'goal setting theory' and a constituent of the process of 'self regulation' (Febrero & Clum, 2008). MMM provides feedback in three ways 1) instant feedback is provided on progress towards the daily calorie target with a constant update of energy input and expenditure and calories remaining, 2) feedback is also provided graphically with a line graph of weight loss and bar charts of calorie intake and expenditure and 3) automated, tailored feedback on percentage of calorie goal achieved for the week is provided via SMS. There is evidence from 'goal setting theory' that adding feedback to a goal enhances performance (Locke, 1996).

MMM is programmed to deliver feedback via weekly text messages based on progress towards weight loss goals. The feedback aims to link the calorie target back to the original weight loss goal to reiterate and reinforce it and encourage system users to rehearse the goal. The messages are also designed to reinforce positive behavioural beliefs (about competence, confidence and mastery) and promote self efficacy. A library of 137 different text messages was constructed with an algorithm to feedback based on certain criteria (table 7). In order to limit 'message fatigue' system users should not receive the same text message more than once (there are 24 messages in each of the weekly categories so enough to receive a different message each week for 6 months).

There were several questions to consider when designing the text message feedback component of MMM such as: 1) how frequently should texts be delivered? 2) To what degree should the feedback be tailored to the individual? 3) What would be the most effective message content? There was little evidence to guide the decisions on feedback given the relative novelty of text message interventions at that time. Text message feedback is not a part of commercial applications such as 'MyFitnessPal' but given its importance and the promising results at that time from text message interventions in other health behaviours such as smoking cessation (Whittaker et al., 2009), physical activity (Hurling et al., 2007) and weight loss (Patrick et al., 2009) it was included as part of the MMM intervention package.

3.9 Consideration about degree of automation

At the extreme, a system such as MMM could allow for complete automation without any human contact or could allow for a human to provide detailed feedback specifically tailored to the individual based on the on-going diet and weight records uploaded. There was also potential for this feedback to be delivered by different mediums as an addition to the MMM intervention (i.e. email, telephone contact etc.). Given the potential wide reach of a smartphone intervention, the decision was made to automate the feedback process so that it does not require on-going human input. Utilising the text messaging feature of smartphones and creating a minimal contact intervention was pragmatic given the potential cost effectiveness if the system were to be widely disseminated in the future. This decision is supported in part by an RCT comparing automated feedback (generated on a slimming website) to email counselling (written by a human) and no counselling in an internet weight loss programme (n=192) which found automated feedback to be as effective as human counselling via email at 3 months (Tate et al., 2006).

Evidence on the type of feedback which is effective in this situation is limited given that feedback is often used in conjunction with other interventions (goal setting and self monitoring) so its effects are difficult to tease apart (Pearson, 2012). In the aforementioned systematic review of goal setting for weight loss, 12 of 18 studies incorporated a feedback component (either delivered by phone, in person, email or online) but none assessed feedback independently for its effect on outcome (Pearson, 2012).

3.9.1 Frequency of text messaging

As text messaging interventions for health behaviour was an emerging area of research at the time of MMM's development there was little to guide the decision on how frequently messages should be delivered. Cole-Lewis and Kershaw (2010) conducted a systematic review of text messaging for behaviour change studies prior to 2009 and identified 12 studies, 2 of which were investigating weight loss interventions (Haapala et al., 2009; Patrick et al., 2009). The frequency of text message delivery varied between studies ranging from once a week to 5 times a day (Cole-Lewis and Kershaw, 2010). There was heterogeneity in terms of design, duration and outcome assessed so whilst the studies supported feasibility of text messaging the authors highlighted the need for more information on what frequency and duration of text messages would be effective. Given this paucity of information, the frequency of text messages was a topic discussed at the focus groups and a pragmatic decision made to deliver messages weekly based on this.

3.9.2 Text message content

Given the paucity of evidence on what text messaging content would be effective, the messages were designed using feedback from focus group participants and by drawing from social cognitive theory (Bandura, 1991). The text message content of MMM was designed to serve several functions as listed below:

- As a prompt to continue to use MMM when use appears to wane. Given that studies show that self monitoring often declines over time (Burke et al., 2011a), this was intended as a strategy to improve adherence to self monitoring.
- As a prompt to self monitor weight.
- To enhance self efficacy by encouraging the participant to rehearse the goal and by encouraging feelings of mastery. Self efficacy is a concept from social cognitive theory as developed by Bandura (1977) and describes a persons' belief in their ability to achieve a goal. It is an important aspect of 'goal setting theory' as there is evidence that a person will perform better on a task if they believe they are able to achieve it, so enhancing self efficacy is thought to be a way to strengthen commitment to achieving a goal (Locke, 1996).
- As a safety measure if the person does not appear to be eating enough food in order to refrain from overly restrictive dieting. As this is a minimal contact intervention with no clinical supervision it was considered sensible to have some safety precautions.

- Problem solving by providing some suggestions to address common barriers to weight loss and advice on what changes the person could make to their diet to encourage weight loss (as this was desirable in the focus groups).

Table 7: Feedback algorithms which trigger the automated text message feature of MMM

Type of Feedback	Frequency	Condition	Type of Message	Category	Example message
Feedback on attainment of kcal goals	Every 7 days	Days recorded but no recorded days meet kcal goal (0%)	Not meeting goal (linking calorie target to overall goal, reminding and rehearsing goal, reminding of own reasons and motivation - why try harder?)	A1	*"It looks like your calories are over-budget this week, don't be too hard on yourself you can get back on track next week, try to stay focussed on your overall weight loss goal"*
		Under half of recorded days meet kcal goals (1% -49%)	Not meeting goal (linking calorie target to overall goal, reminding and rehearsing goal, reminding of own reasons and motivation - why try harder?)	A2	*"You've met your calorie targets some days you recorded, you are making good progress, your diary can help you to understand your diet, is there any room for improvement?"*
		Over half of recorded days meet kcal goals (50% - 99%)	Nearly meeting goal - encouragement	A3	*"Keep up the good work! Most of your recorded days last week met your calorie targets. You are on target to achieve your goal of weight loss and mastering the ability to meet goals that you set yourself."*
		All recorded days meet within kcal goals (100 %)	Positive reinforcement for goal attainment	A4	*"Success! - All of the diary entries that you recorded this week met your calorie targets. You have the will power and ability to meet your desired weight loss goal"*
Prompts to self monitor in diary	As required	No days completed diary entries over a continuous 7 day period	Prompt to self monitor and complete diary	B1	*"It looks like you haven't recorded in your diary this week. People who are successful at weight loss monitor what they eat and how active they are. It could work for you."*
Prompts to target those whose self monitoring tails off		if total number of completed diary entries submitted is less than previous month	Highlight self monitoring has declined and encourage to continue	B2	*"It appears that you recorded more diary entries last month than this month. Try to keep going with recording in your diary, it can help you to achieve your weight loss goal and maintain your weight."*
Prompts to self monitor weight	Monthly (if no weight data has been added in previous 4 weeks)	No weight data entered for month	Prompt to record weight	B3	*"Have you weighed yourself lately? Don't be too hard on yourself if you haven't lost weight. You can always re-commit to your goal and try again."*
Health feature	As required	If less than 1000 kcal is submitted as a completed days entry	highlight to person that this is a low kcal intake	C	*"You have recorded less than 1000kcal intake. Was this a mistake? It's not healthy to eat less than your body needs. Try to get closer to your calorie allowance."*

Table 7: Feedback algorithms which trigger the automated text message feature of MMM to give the user feedback on progress.

3.10 Focus group study to investigate the ideas and preferences of potential system users

3.10.1 Aim

The aim of this study was to collect qualitative data from potential users of a weight loss intervention and use this to inform the development of a smartphone application to support weight loss.

3.10.2 Materials/Subjects and Methods

3.10.2.1 Subjects and recruitment

The study was advertised in March 2010 by an email circulated around the Faculty of Medicine and Health within the University of Leeds and by posters placed around the University campus. Participants contacted the researcher to express interest and were sent further information. If interest was confirmed at this point, participants were invited to attend a pre-scheduled group meeting.

3.10.2.2 Design

Focus groups were no longer than 90 minutes. A semi-structured design was chosen and the groups were moderated by a Dietitian. Discussion within the group was allowed to flow naturally but was divided into semi-structured sections with the following questions put to the groups to guide the discussion:

- What do you think about this approach to weight loss?
- What kind of feedback would you find useful?
- How often would you like to receive feedback?
- What do you like and dislike about similar commercially available applications? (During the focus group participants were shown screen captures from four commercially available diet tracking smartphone applications for iPhone: ‘MyFitnessPal’, ‘Lose it!’, ‘SparkPeople’ and ‘calorie-counter’ to garner opinion about similar applications. The applications chosen were the most downloaded in the iTunes store at that time).

3.10.2.3 Analysis

The focus groups were audio-taped and transcribed verbatim and analysed alongside field notes taken by a research assistant. The data was examined using a basic thematic analysis and was passed through three stages of coding. Rather than a comprehensive thematic content analysis, findings are organised according to predefined questions and not data derived themes.

3.10.2.4 Ethical Approval

This study was reviewed and approved by Leeds research ethics committee. Ethical approval reference number: HSLT/09/019 (appendix 1). Participants gave written consent to take part at the start of each focus group.

3.11 Results

3.11.1 Focus group characteristics

Twelve people initially expressed interest in attending a focus group. Of these, 9 people in total attended the discussions and these were divided into three groups. The distribution of attendees in groups was as follows: Group 1 (n = 3), Group 2 (n=2), Group 3 (n=4). The mean age of focus group attendees was 36 years (SD=11) and most were female (n=7). Most of the attendees were actively trying to lose weight (n=7) and most had dieted in the past (n=6). 4 attendees owned a smartphone and 5 did not. Only the minority had used a mobile phone app before (n=2) and none had used a mobile phone app for weight loss before. The majority of attendees described how they had been interested in joining the discussion group due to the novelty of this approach to weight loss. 4 of the participants were currently involved in 'Weight Watchers' and 1 participant was a member of an online weight loss site called 'Nutracheck'.

3.11.2 Desirable features of the phone

Participants agreed unanimously that they thought they would like to use this approach to monitor their diet or to support weight loss. Most described the potential for this device to conveniently motivate them to meet their diet goals.

"if you having a bad day and you're reaching out for that chocolate bar or something like that to know that on your mobile phone you can access something that will just…you know…support you, keeping you motivated and keeping you going would be useful" (participant 7).

The majority of group members felt the convenience of being able to carry the mobile around with them was an attractive feature

"I think having it mobile on you all the time is really important, there is no way on earth I would carry around a paper diary and I certainly wouldn't fill it in at the end of the day either it would be too much hassle" (participant 3).

3.11.3 Frequency of use

The majority of the group felt that if they were using an application to track diet they would use it daily and record food intake after each meal.

"I think I would use it throughout the day. So, if I'm following some sort of programme, every time I have something to eat I will write it down…if you've actually got it there in front of you, you can sort of see what you have eaten rather than wait till the end of the day, cus I think there is a chance you would forget something" (participant 9).

"I would probably use it every time anything went in my mouth" (participant 1).

However, one person felt that they would benefit from using it less frequently and would not want to use it every day. This male participant felt that there was a gender difference in the approach to dieting.

"I don't think I would use it every day, maybe every 3 to 4 days is how I would see it because it might be boring. Nutrition, I think it's very woman led…hey I

don't see my friends you know going on their apps and putting how much food they are putting on, not every day" (participant 2).

One person expressed doubts that people with different lifestyles would use the phone after each meal.

"I'm just trying to think of some of my friends that have got really hectic jobs. You know...some that work in hospitals and can't use their phones and things like that. For them, they'd probably use it at the end of the day, but it might help them that way to plan a healthier tea the next day" (participant 7).

3.11.4 Calorie counting and dieting behaviour

A minority described how they felt that counting calories in food had become an obsession.

"I've noticed on this Weight Watchers that I've become completely obsessed with points counting" (participant 6).

"I might become obsessed with it because I know I have a tendency to be…I'd have to put everything in …" (participant 3).

However, those that felt this obsession did not seem to be concerned with it but rather described it as a natural part of dieting behaviour.

"I don't think that the application would inform that obsession or make it more so….I think when you're in that kind of diet programme that's just what you do, you kind of look at everything your gonna (sic) eat and work out what points are in it" (participant 9).

There were common themes about how people might relate to the phone. Often people appeared to cast the mobile phone in a role as something to which they would be accountable. For example:

An indulgent parent…

"something to motivate you even though you've been naughty" (participant 2).

Or several people used the metaphor of someone on your shoulder watching and passing judgement on what you are doing.

"you almost wouldn't want to enter that in (a Kit Kat) if you knew felt that somebody was looking over your shoulder and going ahh you've had a chocolate bar" (participant 9).

Or a friend,

"so someone has said…you know…your doing really well and getting towards your goal and if you just do this and this so there is almost that remote friend….that critical friend that is there on your mobile, not quite real but virtual" (participant 1).

3.11.5 Usability

Ease of use and speed of entering data were key issues that emerged from the groups as factors potentially affecting engagement with the device.

"I think this would probably be quite a useful thing to use. I suppose it depends on how it's set up because you wouldn't want to have to type every single thing in you'd want some sort of 'look up' so maybe you type the first few letters and it gives you a selection" (participant 9).

"If I was using it constantly every day which I probably would be, you'd want to use as few clicks as possible and straight in so you're not scrolling." (participant 3).

"I think you want to put thing in as quick as you can, you don't want to lose time I mean" (participant 2).

The majority of people commented that the accuracy of the information in the database was an important factor in engaging with the device. Only one person stated that they would be happy to enter in generic food items as opposed to specific brand names. There was a mixture of opinion in terms of how to enter foods. Some participants said they weigh food when following an eating plan so would want the facility to manually enter their food in grams. Several participants discussed that they would find a 'favourites' menu of commonly used items and meal combinations useful.

3.11.6 Lay-out and design

The majority of people agreed that they would find entering food into the phone via meal-slots a useful feature. One member felt that this would encourage a more balanced approach to eating.

"It probably encourages you to do a healthier way of eating. You know, three proper meals a day rather than bits" (participant 8).

However one person did express concerns that the meal slots may be too restrictive for people with less structured eating patterns.

"I've seen a lot of programmes on TV. I remember distinctly there was one woman who was asked to keep a food diary, yes kept it, she had meals and she had an occasional snack but what she was really doing is that she had another meal at 11pm at night, she'd go to bed and get up again and went had had more food so I don't know where she for example would put this….I like breakfast,

lunch and the snacks I think it would work for me but I don't think it will work for everyone" (participant 2).

3.11.7 Opinions on similar mobile applications

There were between group differences in opinion about application lay-out and design. When shown screen-caps from similar weight loss applications the groups differed in their preferences. Members of one group felt strongly that they liked the lay-out of the 'SparkPeople' application, describing how they found it engaging and attractive.

"I like this one from the start as it's more colourful than (MyFitnessPal)...I dunno (sic) it attracts me" (participant 2).

However the other two groups and majority of people felt strongly that they disliked the lay-out of 'SparkPeople' and found it too distracting. These participants favoured a plainer lay-out.

"(on SparkPeople) I can understand it but I have to look at it a bit longer than (the) other two. I think there is a lot going on with each page, I don't like the headlines at the bottom, I don't really think it's necessary" (participant 5).

"I think it's quite busy and, with the sort of celebrity gossipy bit at the bottom I'm not so keen on that. I think it would be a distraction you know, on what you're trying to achieve" (participant 7).

One group was shown screen-caps of potential designs for an application under development. Of a range of colours, the group preferred the green version. They also reacted favourably to the summary of calories consumed at each meal and the facility to 'edit' information and correct mistakes.

"because it's almost like green is for good, I think green, healthy" (participant 9).

3.11.8 Nutritional information

The groups were interested in what kind of nutritional information the phone would provide. There was a mixture of opinions as to what nutritional information would be useful. The majority of participants felt that they wanted more information on their nutrition than just calories alone.

"you know that pie chart that you could have the sections of carbs and proteins you could have that slowly filling up throughout the day" (participant 3).

Two group members stated that they always checked nutritional information for saturated fats as this was encouraged in the Weight Watchers programme

"and the more detail about the fat content and carbohydrate sort of thing would be useful, because again with saturated fat you know there's this focus on being on a healthy plan" (participant 5).

Some members felt information about calories would be adequate,

"I am a little more shallow I'd just go for calories just because I don't know the meaning of saturated fat" (participant 3).

"if I look at the content of anything in foods its calories…of my friends who are bothered about that kind of thing I've noticed that everyone, they'll tend to pick something, so for some friends it might be fat they are not really bothered about calories but for others it will be calories so I think it's different for everyone" (participant 5).

One person stated that they wanted a nutritional breakdown but was not clear about what they should be aiming for in terms of nutritional balance.

"but I'm vegetarian so it's quite important to know your carbohydrate and your protein cus its quite easy being a veggie to eat far too much carbs…and so it would just be quite good to have a nutritional breakdown. And I think quite a lot of people think I don't know what balance I should have of fat, protein and carbohydrate and other things" (participant 8).

Group members were unanimous in the opinion that information about quantity of fruit and vegetable portions eaten would be useful. One person also suggested that information on the salt in food would be useful if somebody was following a special diet and two people expressed interest in tracking their intake of water.

3.11.9 Feedback – text messaging

There were mixed requirements from group members in terms of text messaging feedback although the majority agreed that daily text messages would be too frequent.

"If it's regular it gets really annoying. I took part in someone's study once for a week and they texted me about 4 times in the week and at the end I was like not reading it any more, it just got really annoying" (participant 4).

"I would say definitely daily is too much, weekly, fortnightly is not too bad maybe" (participant 5).

"too often for me (daily), I hate text messages, maybe once or twice a week" (participant 2).

However, two people did feel they would like this frequency of messaging,

"it's like having a personal trainer who is going to stand there and give you a feedback at the end of it on a day to day basis, just a couple of lines or a sentence or something about how you'd done" (participant 1).

Participants commented that they would find graphical representation of results a useful feedback mechanism.

"something daily would be a good motivator and the graph would show you progress over that day, over the week, so you can see progress as you're going through" (participant 7).

"I found the graph (on Nutracheck online system) in terms of feedback, electronic feedback fine. You know, more reassuring and informative (than the daily email alerts)" (participant 8).

3.11.10 Automation of feedback

The automation of feedback was discussed. The majority of participants expressed a lack of engagement with automated feedback due to concerns about it being too impersonal.

"They send you emails (Nutracheck) but I felt a bit like you know, it's just a computer isn't it, kind of going 'woohoo' (sarcastic tone) "(participant 8).

"personal is nice, it means that's more caring than a machine, a machine is just like a bank or something, like 'your money has arrived'" (participant 2).

Some participants expressed a mistrust of a text with a name on it if they didn't know who that person was. Several participants agreed that they would judge the credibility of the text and a name on the bottom of the text would not necessarily imply it was from a person.

"I think I'd see an automated response, I'd feel the same as getting a response from someone I didn't know. If a message was signed off at the end of a text message 'Michelle' it could be automated anyway. You could be sending that to a group of people anyway" (participant 3).

“I suppose I’d want to know is it someone physically looking at your record and making a diagnosis or is it just computer generated and if it’s just computer generated I would not give it as much credibility as somebody sat down and physically looked at what I’d done and made a judgement as such so if it came back saying ‘Michelle’ I’d want to know that it’s actually a person as oppose to name on a computer feature as such, and I think if it came from a person I would probably take more notice of it” (participant 1).

A few people suggested that they would prefer to receive feedback from someone if they had seen them and knew them to be a real person.

“it should come from the people whom they identify with, people who were at the beginning of the study, they have a face, they know the person” (participant 4).

“I don’t want someone random in the street or in a call centre looking at it. I would want to know it's coming from someone who has expertise in the field” (participant 3).

One person suggested they would be happy with an animation providing them with feedback and one person suggested they would be happy with automated feedback if they were making good progress but would prefer a personal response if they were in need of support.

“if it was me you could have just a cartoon girl of roughly a similar age that’s quite none descript but that would be consistent every time” (participant 5).

3.11.11 Type of message

Participants seemed to discuss feedback in terms of whether their progress had been ‘good’ or ‘bad’ for that time period. Participants suggested they would want feedback on the amount of weight they had lost that week or whether they were ‘doing well’ or not.

All group members felt strongly that they would not like to receive any negative feedback or messages which they perceived as disciplining them or ‘telling them off’.

“If it’s vaguely negative or just negative at all really I don’t think people will be responsive” (participant 4).

“If you’ve had say a Kit Kat, I wouldn’t like to have a message saying, ’Ooh you know you’ve had a Kit Kat today’ (disapproving voice)” (participant 9).

Most group members suggested that they would like to hear alternative ways of doing things if they felt they had not made progress over a particular time period.

“If you were eating a lot of the wrong food that day and it came back and said you’ve just eaten too much chocolate today and give you an alternative. Don’t just say you’ve eaten far too much chocolate” (participant 1).

“If they haven’t lost weight that’s fine, this period you have maintained your weight, however this is what’s happening, have you considered doing this? That’s not a negative, not telling them off but encouraging them” (participant 4).

Some participants were concerned that messages might be patronising but found it difficult to describe what exactly would constitute a patronising message and felt that it was down to interpretation.

“I think a motivational message but not patronising, it would be hard to strike that balance but a light hearted, easy message that’s not too long” (participant 4).

“anything could be patronising if you are geared for that” (participant 2).

One person described that they would find feedback motivating if it was aimed at a group level and would feel a benefit from that kind of social support.

"I guess that would be more of a community thing as well, to know that other people are on it…looking at it and recording weight, I don't know a community feel to losing weight rather than trying to do it on my own. I guess if I was doing it alongside, maybe, if you could compare against other people and what they are doing" (participant 3).

Some people also described how they liked to see a visual equivalent as a representation of weight loss for example in terms of bags of sugar, blocks of lard or an animation of the outline of a person getting smaller.

3.11.12 Technical Support

Most participants agreed that they would not require a large amount of technical support. One group discussed that a written 'quick reference guide' would be useful or a short demonstration video. One group discussed that if the application was straightforward enough they would not need much support with its use.

"I think like the way the iphone markets itself you already know how to use it, it's that simplistic. You know exactly what to do which would be brilliant, the less instruction the better" (participant 3).

A small minority discussed that having telephone access to talk to someone with queries would be important to them. In terms of additional dietary support, the group felt that some advice would be useful such as what constitutes a good balance of food or guidance on portion size although some group members discussed that the phone itself would help people to self-educate.

3.11.13 Measures apart from weight

All members of one group mentioned they would find it useful to track progress of change in their BMI and also that they would find it useful to enter measurements such as waist and hip circumference. Participants discussed that they sometimes get frustrated looking for changes in weight but changes in measurements could be motivating. However, one person felt that if this was the case they would want support in how to take accurate measurements. Members of one group also stated that they have found instant feedback on fitness measures useful. For example, one participant described how they had used a heart monitor in the past and found this very motivating. One group member had used a pedometer to track activity and described how this encouraged them to walk more.

3.12 Discussion

3.12.1 Summary of focus group findings

Participants conceptualised the role of the application in different ways but agreed it would be something that they would want to use on the basis of its perceived convenience and ability to motivate them to monitor their diets. In terms of lay-out, opinion was divided about existing systems and some found a plainer lay-out dull while others found a more commercialised system too distracting. Participants generally agreed that daily feedback was too frequent and weekly would be adequate. People tended to discuss that a graph would be adequate for feedback on daily progress and that supportive texts would be useful about weight loss.

With regard to automation of text message feedback, participants described a general mistrust of automated message systems and the desire for reassurance of a human input. In a review of text messaging for behaviour change, all studies used automated messages but the messages were tailored (Cole-Lewis & Kershaw, 2010). Pragmatically, it would be considerably labour intensive to send personalised text messages in a large scale randomised trial but tailoring might reassure that there has been a specific human involvement. With regard to message content, group members felt supportive messages would be useful and were concerned about being criticised and chastised. If progress was not on target, participants described a desire for support via suggestions of alternatives ways of doing things. This is consistent with the findings from a focus group study of adolescents' opinions on text messages as part of a weight loss study. Woolford et al. (2011) found that adolescents expressed a preference for positive, encouraging and direct messages.

Speed of data entry, ease of use and a detailed database were cited as features which people would find important. Opinions were mixed as to how much nutritional information they desired. Some felt calories to be adequate but others wanted additional information about a range of nutrients. Some group members discussed that they found visualising weight loss useful and in addition to diet some members described their success with using devices to monitor their fitness levels. Participants felt they would not require a great deal of technical support as long as they found the device straightforward to use.

3.12.2 Strengths and limitations of the focus group research

A strength of the work is the innovative approach to weight loss and the practical use of the data to inform the application with the target population prior to piloting. Given that the use of smartphone applications for weight loss is a relatively new area there is a paucity of research into the optimum features and characteristics of these devices so formative work with potential system users is essential in developing appropriate tools.

Recruitment into the study was difficult and therefore a limitation of this study is the small sample size. This means that saturation was not reached within the study. Focus groups in general are also limited by group dynamics and the tendency of people within a group to act differently and influence and be influenced by the opinion of others (Stewart et al., 1990). Attempts were made by the moderator to ensure that participants were comfortable to voice their opinion and to give everybody a chance to speak but it is still a possibility that people's opinions within each group were influenced by other members of the group.

Given the aim of the study was to provide practical information with which to inform the development of the smartphone application, analysis has been at a superficial level and the work is not of sufficient depth to be considered a piece of comprehensive qualitative research. It was not considered appropriate or necessary to explore the data further by using an in depth grounded theory approach or a thorough exploration of data derived themes. For this reason, this study lacks several aspects of analysis which would be important for a qualitative piece of work. For example, there has been no analysis of ‘deviant cases’ and disconfirming data (which can enhance rigour in qualitative studies) (Green and Thorogood, 2005). Only one analyst was responsible for coding and analysing the transcripts so the reliability of the analysis is limited and would have been improved by using more than one analyst/coder. Unfortunately this was a pragmatic decision as there were no other analysts available to cross-check the transcripts.

3.12.3 Application of the focus group findings to the development of a smartphone application

The findings from the focus groups have been applied to the development of ‘My Meal Mate’ (MMM) a smartphone intervention for weight loss. Whilst the major components of MMM are theory driven the focus groups have helped to optimise several key aspects of the intervention content and lay-out.

3.12.4 Development of the food composition database

A key finding from the focus group was the desire to be able to find the specific branded food required in the application database. To accommodate this finding, a commercial company called ‘Weight Loss Resources’ (WLR) was approached and agreed to allow use of their database free of charge for the purposes of research on this project. WLR collects its nutrient information from supermarkets and on packet labels directly and contains 23,000 branded food and drink items. WLR is a commercial company who operate a slimming website whereby members pay a monthly fee and are able to track their food and drink intake in an online electronic diary along with accessing advice and an online forum. The WLR database contains products from major food manufacturers, supermarkets and chain restaurants. It also contains nutritional values for generic food and drink items from the McCance and Widdowson (2002) food composition tables so the user is able to select an item if they do not wish to spend time searching for the brand.

3.12.5 Nutrient display

Although the WLR database contains nutrient information for energy (kcal) and macronutrients (protein, carbohydrate and fat) the decision was made to display only energy values on the application food diary interface. This allows the system user to work towards one daily goal of maintaining energy intake below a target rather than trying to attain several nutritional goals simultaneously. There is a lack of evidence about which nutrient information is most effective to self-monitor and although one focus group participant expressed that they would like to monitor fat the majority consensus was that energy intake and expenditure alone would be desirable. As the current NICE guidelines on obesity (NICE, 2006) are based on a reduction of energy intake it was felt appropriate and sufficient to use energy display in this trial and keep the interface uncluttered. There is a possibility to extend the nutrient display in the future for other purposes if necessary.

3.12.6 Design of text message feedback

Focus group participants expressed a strong wish not to receive any feedback with a negative tone. This is also supported by research which suggests negative feedback may create self-doubt which may decrease self-efficacy in some people (Locke 1996). As there was a paucity of evidence about frequency of messaging, this was discussed and the focus groups agreed that weekly would be sufficient.

3.12.7 Usability Features

The focus groups highlighted speed of data entry and ease of use as the most important factors for engagement. Therefore, several features have been included in MMM to enhance usability. MMM allows the user to take a picture of the food item to serve as a memory prompt for later input. There is evidence that not all self monitoring is done in a timely way and that some people ‘backfill’ their food diaries (Burke et al., 2008), so the photo prompts may help people to more accurately record their intake. MMM has the function to save favourite meal combinations and recently used items so the user does not have to spend time repeating entries. The MMM search function is able to scroll very quickly through lists of options using the touch screen and the search can be broken down by item and by brand to enhance usability.

3.12.8 System lay-out and design

Of the commercially available apps, the focus groups tended to agree that ‘MyFitnessPal’ had the most desirable lay-out so the MMM lay-out has been designed to be similar in its uncluttered, simple and intuitive interface. The system primary colour is green as this was preferred by focus groups when presented with a range of initial colour options. The final design was felt to be the most ‘gender neutral’ of the colour options.

3.13 Pragmatic issues in the delivery of the MMM intervention

3.13.1 Delivery of the intervention

As there is uncertainty about how much self monitoring is necessary for weight loss, the user is not prescribed an amount of self monitoring when MMM is delivered. MMM has been designed as a ‘minimal contact’ intervention so should be able to be used without direct clinical supervision or on-going instruction. The app does link to a set of help videos on ‘YouTube’ which offer advice on estimating portion size and how to use various sections of the app.

In order not to exclude people on the basis of smartphone ownership it was felt necessary to provide participants with smartphones for use in the validation and pilot studies. A tender exercise was set up to find a telecommunications company to provide a bespoke package for the phone contract. A working smartphone with the ability to make calls, texts and use the internet was also felt important to mimic real world conditions rather than just providing participants with a handset with no functionality. The telecommunications company ‘3’ won the tender exercise as they were able to supply a bespoke package of 50 HTC Desire smartphones with a pre-paid 18 month contract providing 750 cross network minutes, 100 texts and 1GB data tariff per month. The total cost of the phone package was £27,000.

3.13.2 Hosting

MMM links to a backend administrator website where all of the data is uploaded and can be downloaded to a Microsoft Access database for analysis. The data uploaded is time and date stamped. The website is password protected and hosted on a secure server by Blueberry (although this was eventually transferred for hosting on the University of Leeds website). To set-up a new user, a log-in ID is first created on the MMM website after which the MMM application can be downloaded onto the phone from the MMM website through the phones internet browser. The user can stop data uploads by switching the app to ‘holiday mode’ which disables data transfer. This was done to avoid expensive data roaming charges if the phone was taken out of the UK.

3.13.3 Beta testing

A first iteration of MMM was developed by September 2010 and this was followed by a subsequent 5 improved releases. Each version of the app was beta tested by volunteers within the Nutritional Epidemiology Group. As there were found to be numerous software bugs several iterations of the application were developed. Each time a version was created it was tested and the software company notified of bugs. Bugs reported by participants in the validation study were fixed and the version used in the pilot trial was updated 18/04/2011.

3.14 The use of theory in developing the MMM intervention

The Medical Research Council (MRC) advises that best practice for developing public health interventions is to use the best available evidence and appropriate theory (Craig et al, 2008). One rationale for a theoretical framework is that *'the (behaviour) changes that are expected, and how change is to be achieved may not be clear at the outset (ibid)'.* Two key theories have been drawn upon in the development of the MMM intervention; control theory (Carver & Scheier, 2011) and social cognitive theory (Bandura, 1991). Within control theory there are three core self regulatory strategies of goal setting, self monitoring and feedback and the theory describes how they might link together to enable an individual to self regulate behaviour. The MMM application is based on this theory but the theory was considered much too limited when developing the content of the text messages. Therefore, social cognitive theory was drawn upon to develop appropriate content given that the text messages are designed to enhance self efficacy (a central tenant of social cognitive theory).

It was not considered appropriate to use social cognitive theory as an overarching theory as it is quite broad with no guidance on how to apply it in a pragmatic way. On the other hand, control theory, whilst a simplistic model proved too narrow to be able to apply across the board so the two theories were used together. Given the lack of practical guidance on how to apply 'control theory' to developing an intervention, 'goal setting theory' as developed by Locke (1996) was also drawn upon in order to refine the goal setting aspect of the intervention. This theory overlaps conceptually with control theory as it provides a framework for understanding the individual self regulatory strategy of goal setting which is contained within the control theory model.

This pragmatic and tailored decision to apply two theories was deemed necessary for developing the different functions of MMM. However, using more than one theory to inform the development of the intervention could be criticised on the basis that it does not allow for direct comparison with interventions based solely on one theory. If all similar interventions were designed based on the same theory it would build on a tradition of use and allow for closer comparison. Also, the researcher could be accused of 'cherry picking' aspects of theory to suit the intervention which introduces a danger of applying the theory inappropriately. However, these limitations were balanced with the practical needs of the development and the lack of a suitable overarching theory with practical guidance on how to implement it. Given the limitations inherent with the application of theory, intervention development was also based on benchmarking with similar diet tracking applications, referring current UK obesity guidelines (NICE, 2006) and by researching the ideas and opinions of potential system users.

3.15 Strengths and challenges

MMM differs from commercially available applications in that it has taken an evidence based approach and has been guided by feedback from potential system users so contains features to enhance usability (such as food photography), feedback delivered via text message, a large UK specific branded food database (with portion size information designed for a UK audience) and a back-end researcher website. By designing an application rather than testing an existing commercial application the researcher has complete control over the data collected which can be used to investigate diet and system usage.

There are a number of challenges when developing ICT based interventions, one of these is the rapid rate of technology progression. Measures were taken to 'future proof' MMM, for example by developing for the open source Android platform which allows for use on a range of handsets. However, the diet tracking apps which MMM was originally benchmarked against have developed newer features such as linking into social networking websites and cross-platform functionality. Another challenge of this approach is maintaining an updated food composition database given that food and beverage manufacturers regularly reformulate products or introduce new products to the market. As the MMM database has been provided by a commercial company, there is potential to update it with a new database download for future use when desired.

3.16 Conclusion

This chapter has described the development and provided a system overview of ‘My Meal Mate’ (MMM), a smartphone intervention for weight loss. MMM has been developed by drawing together a theoretical basis for a behavioural weight loss intervention and the opinions and desires of potential system users. A benchmarking exercise was conducted against commercially available apps to design an engaging and future proof intervention. Due to the novelty of this approach several logistical issues have been addressed during the development of the intervention. The development of MMM is the first step in a large three part project. The diet measures captured on MMM will be validated against a reference measure of 24 hour diet recalls (chapter 4) and piloted in a randomised trial (chapters 5-8).

Chapter 4: Validation of the diet measures captured on a smartphone application to facilitate weight loss.

4.1 Introduction

The ability to accurately assess diet is of paramount importance in establishing nutrition related disease risks and evaluating the effectiveness of public health interventions. Established methods of dietary assessment such as weighed food diaries, 24-hour recalls and food frequency questionnaires (FFQs) present a challenge to researchers due to their inherent limitations (Buzzard, 1998; Bingham, 1987; MacIntyre, 2007; Barrett-Connor, 1991). Retrospective methods suffer from reliance on respondent memory (MacIntyre, 2007), potential recall bias (Buzzard, 1998) and misreporting (Black et al., 1993) and prospective methods can place a high burden on the respondent and risk an alteration of habitual intake (Rebro et al., 1998). Nutritional coding of the data collected by these traditional methods requires a trained individual and can be extremely time consuming (Buzzard, 1998).

There is a growing interest in the use of information communication technology (ICT) to assist dietary assessment. Automated systems have the potential to improve the accuracy of data collected, reduce costs, provide immediate feedback and reduce respondent and researcher burden by automating the nutritional coding process (Ngo et al., 2009). Studies investigating innovative technologies for dietary assessment have included computerised methods such as automated self administered 24 hour recalls (Touvier et al., 2011; Arab et al., 2010; Zoellner et al., 2005; Subar et al., 2012) and FFQs (Slattery et al., 2008), personal digital assistants (PDAs) (Beasley et al., 2005; Yon et al., 2007; Kikunga et al., 2007; Wang et al., 2006; Boushey et al., 2009), camera-enabled cell-phones (Martin et al., 2009) and smartcards (Lambert et al., 2005). A review of ICT methods for dietary assessment concluded that these methods have potential to accurately measure dietary intakes but further work is necessary for improving and evaluating established and new tools (Ngo et al., 2009).

Handheld technology such as PDAs and mobile phones offer the particular advantage of portability allowing the user to conveniently record diet data in real time. "DietMatePro" a PDA food diary programme was found to correlate well with a 24 hour recall ($r=0.71$, $p<0.005$) in a small sample (Beasley et al., 2005) but correlated less well in a larger sample of 174 overweight adults ($r=0.54$, $p<0.05$) (Beasley et al., 2008). Another assessment tool ‘Wellnavi’ is a handheld PDA device with a mobile SIM card and camera which allows participants to photograph their food and send to a Dietitian for analysis (Wang et al., 2006). In a comparison study of the Wellnavi and a weighed food diary with 75 adults, statistically significant correlations between macronutrients and some micronutrients were reported (e.g. $r=0.62$ for energy (kcal), ($p<0.001$). However, some micronutrients were underestimated by the PDA as compared to the reference measure.

As technology evolves there is potential to develop increasingly sophisticated assessment tools and PDA devices have been improved upon by smartphones. Along with basic telephony functions, smartphones have enhanced computational abilities enabling them to connect to the internet and run a complete operating system. A smartphone application which permits self monitoring of food and drink intake offers promise as a convenient and cost effective dietary assessment tool. My Meal Mate (MMM) is a smartphone application that has been designed to facilitate weight loss. This chapter will report the findings of a validation study which aims to evaluate whether MMM has potential as a dietary assessment tool by validating it against a reference method.

4.2 Experimental methods

MMM features an electronic food diary in which users select and log foods from a 23,000 item commercial food database which includes generic and branded items. For a full overview of MMM please see chapter 3. Participants were provided with a HTC Desire smartphone (with the MMM application pre downloaded) for use during the validation study. The phone had a pre-paid data tariff in order to upload the data collected to the back-end website.

4.2.1 Subjects and recruitment

Fifty volunteers were recruited from staff and students at the University of Leeds by email advertisements and posters displayed around the campus. Upon expression of interest, participants were emailed a study information sheet to read before confirming involvement. They were not blinded to study design so as to enhance adherence given the time commitment involved. Participants were excluded if they were pregnant, lactating or unable to read and write in English (for the purposes of using the application).

4.2.2 Procedure

Volunteers were enrolled in small groups of no more than 5 people and each 90 minute study enrolment session followed a standard format. Training in the use of the smartphone and recording intake on MMM was delivered by a dietitian. The training sessions assumed no prior knowledge of smartphone use and the group had the opportunity to practice entering a day's intake on MMM with the support of two researchers. Participants were also provided with a study manual explaining the basic functioning of the smartphone and a step by step guide to using MMM. Although MMM is designed as a weight loss tool, the participants were asked not to change their normal diet and were advised that it was not necessary to restrict their food intake. Energy intake goals were therefore set for monitoring towards "weight maintenance" at current weight rather than weight loss. Participants were weighed in light clothing and without shoes on Tanita solar powered scales (Model HS-301) (maximum capacity 150kg and measuring in 200g increments). A portable stadiometer was used to measure height (without shoes) to the nearest 0.1cm. Participants were instructed to record their food and drink intake on MMM for seven consecutive days. They were advised that they might find this process easier by recording throughout the day, at the time of consumption. It was acknowledged however that some people might wish to record their intake at the end of the day, in which case they were asked to take photos of the food to act as memory prompts.

With regard to entering portion size information, although the MMM database contains default portion sizes for each item, participants were encouraged to consider when entering items whether the default portion size was appropriate. Participants were strongly encouraged to weigh foods if they had any uncertainty about their estimation and to manually enter the correct portion size. Although encouraged, weighing of every item was not a mandatory part of the procedure in order to minimise participant burden. When entering recipes, participants were instructed to break the recipe down into its constituents and enter as single items. This was the method also used during the recalls. In exceptional cases where the participant did not know the recipe constituents they had the option of entering the nearest alternative generic recipe from the database. All of the data recorded on the phone in the seven day period was uploaded to the secure website linked to the application. During the seven day recording period, participants were contacted twice at random to conduct 24 hour telephone recalls. Participants were explicitly advised at enrolment and at the beginning of each telephone recall not to use data recorded on MMM to assist them during the recall. Written consent to take part was collected from all those involved and no incentives were offered other than use of the smartphone for 7 days.

4.2.3 Reference measure – 24 hour recalls

Each 24-hour recall lasted approximately 15-20 minutes and followed a validated script procedure based on the United States Department of Agriculture (USDA) multiple pass telephone recall method to ensure consistency (USDA, 2013). The method aims to cue accurate recall by probing for food intake data in a series of "passes". In the first pass the participant is asked to give a "quick list" of foods eaten, the second pass prompts to elicit further details on cooking methods, portion sizes and commonly forgotten foods and the third pass is a review of the information. Participants were provided with a written portion size guide to aid accurate identification of food portions and were asked to have this to hand for the telephone recalls. The portion size guide was developed using a photographic atlas of portion sizes originally published by the Ministry of Agriculture Fisheries and Food (MAFF) (Nelson, 1997). The booklet contained 21 sets of photographs of six different portion sizes. Three interviewers conducted the recalls including a dietitian and trained nutrition students. Recalls were conducted at random on both weekend and week days.

4.2.4 Coding of nutritional data from the recalls

The telephone 24 hour dietary recalls were coded using a Microsoft Access based food diary analysis program custom made for the project. The Weight Loss Resources (WLR) database was incorporated into the Microsoft Access food diary analysis programme, allowing the 24 hour recalls to be coded using the same database as MMM. Data collected on MMM were downloaded from the online SQL database linked to the phone into the MMM food diary analysis database. Before coding began, a meeting was held to discuss and agree coding assumptions in order to increase consistency in coding decision making. Both coders were trained nutrition postgraduates with prior experience of food diary data entry. Coders held regular meetings to raise queries and resolve issues. After the recalls were coded, a random sample of entries was examined to cross check for consistency.

4.2.5 Data cleaning

The raw data exported from MMM and the coded recalls was manually checked for implausible outliers (<2092 kJ and >20920 kJ) (<500 kcal and >5000 kcal) and any outlying observations checked with the original records. Any errors that a participant may have made in their MMM entry were left unaltered. Individual differences between the telephone recall and MMM entries were calculated and differences above 1674 kJ (400 kcal) checked with the original records to check for errors in data entry. No outliers were removed, only obvious errors in data entry for the recalls were corrected.

4.3 Ethical approval

This study was conducted according to the guidelines laid down in the Declaration of Helsinki and all procedures involving human subjects/patients were approved by the University of Leeds, Faculty of Medicine and Health Research Ethics Committee (ethics reference number – HSLT/09/027) (appendix 1). Written informed consent was obtained from all subjects.

4.4 Statistical analysis

Analyses were performed using STATA statistical software release 11. Descriptive statistics were used to assess baseline characteristics of participants. Paired t-tests were used to compare group means of energy (kcal) and macronutrient intake as measured by the 24 hour recall and its equivalent day of subject entries on MMM. This was done separately for day 1 and day 2 of recalls.

Correlation was assessed between the two methods for each individual day collected, the average of the two days and the average of the two days as compared to the average of the 7 days on MMM. This was determined by Pearson's product-moment correlation. A Bland Altman plot (Bland &Altman, 1986) was used to analyse the limits of agreement between the two methods by calculating the standard deviation of the difference between the two. Bland Altman is the appropriate test to use in addition to correlation as a good correlation between methods does not necessarily imply a good agreement (Bland & Altman, 1986). The differences between the methods were also checked for normality of distribution.

4.5 Results

4.5.1 Characteristics of study participants

The characteristics of the study population are displayed in table 8. One participant did not record any data for the 7 day period so was excluded from analysis. Three of the 24 hour telephone recalls conducted on day 2 were excluded from analysis as the interviewer recalled the directly preceding 24 hour period rather than 6am to 6am. One further day 2 recall was missing as the person was not available to complete one with several attempts at contact. Of a possible 350 days of entry (50 people multiplied by 7 days recording) 320 entries of plausible intake were downloaded from the website meaning an overall completion of 94% of possible day's entries.

4.5.2 Accuracy of MMM compared to 24 hour recalls

Table 9 shows the daily intake of energy (kJ and kcal), protein (g), fat (g) and carbohydrate (g) as recorded by MMM and the 24 hour recall for the equivalent day. This is shown for day 1 and day 2 separately, the means of the 2 MMM days and 2 recall days combined and also the 7 day mean recorded by MMM compared to the mean of recall 1 and recall 2. As the outcome data were found to be normally distributed, paired t-tests were conducted which showed no statistically significant differences between the mean daily energy and macronutrients recorded between the methods on day 1. For day 1 of recording there was a non-significant difference in mean daily energy intake between the two methods of 68 kJ (95% CI: -553 to 418 kJ) (16 kcal, 95% CI: -127 to 100 kcal, P=0.78). On day 2, there was a statistically significant difference of 441 kJ (95% CI: -854 to -29 kJ) (105 kcal, 95% CI: (-204 to -7 kcal) between the mean daily energy recorded (P=0.04) and a statistically significant difference reported for mean daily fat intake of 7g (95% CI -13 to -1) but no statistically significant differences for protein and carbohydrate. The recalls recorded higher energy and macronutrient values than MMM.

There were no statistically significant differences between means when the mean of the recalls on day 1 and day 2 was compared to the mean of the recalls on day 1 and day 2 on MMM and when 7 days of MMM was compared to 2 days of recalls and 2 days of MMM. Energy (kJ) recorded on MMM correlated well with the recalls (Day 1: r=0.77 (95% CI: 0.62-0.86, P<0.001), day 2: r=0.85 (95% CI: 0.75-0.91, P<0.001). For the mean of MMM day1 and MMM day 2 compared to the mean of recall day 1 and recall day 2, correlations for daily energy and macronutrients were high and statistically significant ranging from r=0.69-0.86 (P<0.001).

Table 8: Baseline characteristics of the 50 participants enrolled in the validation study of 'My Meal Mate' (MMM)

Characteristic	**N**	**%**
Sex (Female)	36	72
BMI category		
Healthy weight (BMI 18.5-24.9)	32	64
Overweight (BMI 25-29.9)	15	30
Obese (BMI≥30)	3	6
Ethnicity (white)	41	82
Occupation		
Clerical or technical support	10	20
Academic, clinical and research	22	44
Professional & managerial	7	14
Postgraduate students	11	22
Use a mobile phone regularly	48	96
Use a "smartphone" for work or leisure	24	48
Used a smartphone application previously	23	46
Used a "diet" application before	7	14
Trying to lose weight	24	48
Dieted in the past	25	50
Age (years) (Mean, SD)	35	9
BMI (kg/m^2) (Mean, SD)	24	4

Table 8: Baseline characteristics of the 50 participants enrolled in a validation study of 'My Meal Mate' (MMM).

Table 9. Daily intake of energy, protein, fat and carbohydrate as recorded on MMM versus 24-hour recall.

	MMM		**Recall**		**MMM-recall**				**Correlation MMM and recall**		
	Mean	SD	Mean	SD	Mean	SD	95% CI	P value	r	95% CI	P value
Day 1 (n=49)											
Energy (kJ (kcal/d))	8355 (1997)	2523 (603)	8422 (2013)	2456 (587)	−68 (-16)	1690 (404)	-553, 418 (-127, 100)	0.78	0.77	0.62, 0.86	<0.001
Protein (g/d)	78	32	80	31	-2	18	-7, 3	0.49	0.83	0.71, 0.90	<0.001
Carbohydrate (g/d)	242	67	247	76	-5	62	-23, 13	0.57	0.63	0.42, 0.77	<0.001
Fat (g/d)	69	32	72	37	-3	26	-11, 5	0.44	0.72	0.54, 0.83	<0.001
Day 2 (n=45)											
Energy (kJ (kcal/d))	8180 (1955)	2510 (600)	8619 (2060)	2573 (615)	-441 (-105)	1372 (328)	-854, -29 (-204, -7)	0.04*	0.85	0.74, 0.91	<0.001
Protein (g/d)	73	38	77	33	-5	25	-12, 3	0.22	0.75	0.58, 0.85	<0.001
Carbohydrate (g/d)	251	69	258	71	-6	50	21, 9	0.41	0.75	0.57, 0.85)	<0.001
Fat (g/d)	70	32	77	31	-7	19	-13, -1	0.02*	0.81	(0.67, 0.89	<0.001
Mean day 1 & day 2 combined (n=45)											
Energy (kJ (kcal/d))	8196 (1959)	2146 (513)	8401 (2008)	2050 (490)	−206 (-49)	1138 (272)	-547, 136 (-131, 33)	0.23	0.85	0.74, 0.92	<0.001
Protein (g/d)	76	33	78	28	-2.5	17	-7, 3	0.32	0.86	0.76, 0.92	<0.001
Carbohydrate(g/d)	245	56	250	58	-5	45	-19, 8	0.43	0.69	0.49, 0.81	<0.001
Fat (g/d)	68	27	72	27	-3	17	-9, 1	0.15	0.80	0.66, 0.88	<0.001

	MMM		Recall		MMM-recall				Correlation MMM and recall		
	Mean	SD	Mean	SD	Mean	SD	95% CI	P value	r	95% CI	P value
MMM 7 day average vs. recalls 2 day average (n= 41)											
Energy (kJ (kcal/d))	8020 (1917)	1695 (405)	8242 (1970)	1686 (403)	−218 (-52)	1351 (323)	-640, 201 (-153, 48)	0.30	0.68	0.47, 0.81	<0.001
Protein (g/d)	72	17	76	18	-4	15	-8, 1	0.14	0.64	0.42, 0.79	<0.001
Carbohydrate (g/d)	245	47	248	56	-2	48	-18, 13	0.76	0.57	0.31, 0.74	<0.001
Fat (g/d)	66	21	70	24	-3	16	-9, 2	0.19	0.75	0.57, 0.86	<0.001

Table 9: Daily intake of energy (kJ & kcal) and macronutrients; protein, carbohydrate and fat (g) as recorded by MMM and the 24 hour recall for the equivalent day. Day 1 and day 2 are shown separately, the averages of the 2 days combined by each method and also the 7 day mean recorded by MMM compared to 2 days of recalls. Values are means ±SD with 95% CI. Correlation between MMM & 24-hour recall assessed with Pearson's correlation (r). Significance level set at p<0.05, * statistically significant difference.

4.5.3 Agreement between the two methods

Figure 28 shows the Bland Altman plot for agreement between MMM and the 24 hour recalls for day 1 and Figure 29 shows the agreement between the methods for day 2. For day 1 the mean difference is small but the 95% limits of agreement are fairly wide -3378 to 3243 kJ (-807 to 775 kcal). For day 2, the mean difference is larger (-441 kJ) (105 kcal) with limits of agreement of -3133 to 2251 kJ (-749 to 538 kcal).

Figure 28: Bland Altman plot for Day 1 MMM-Recall

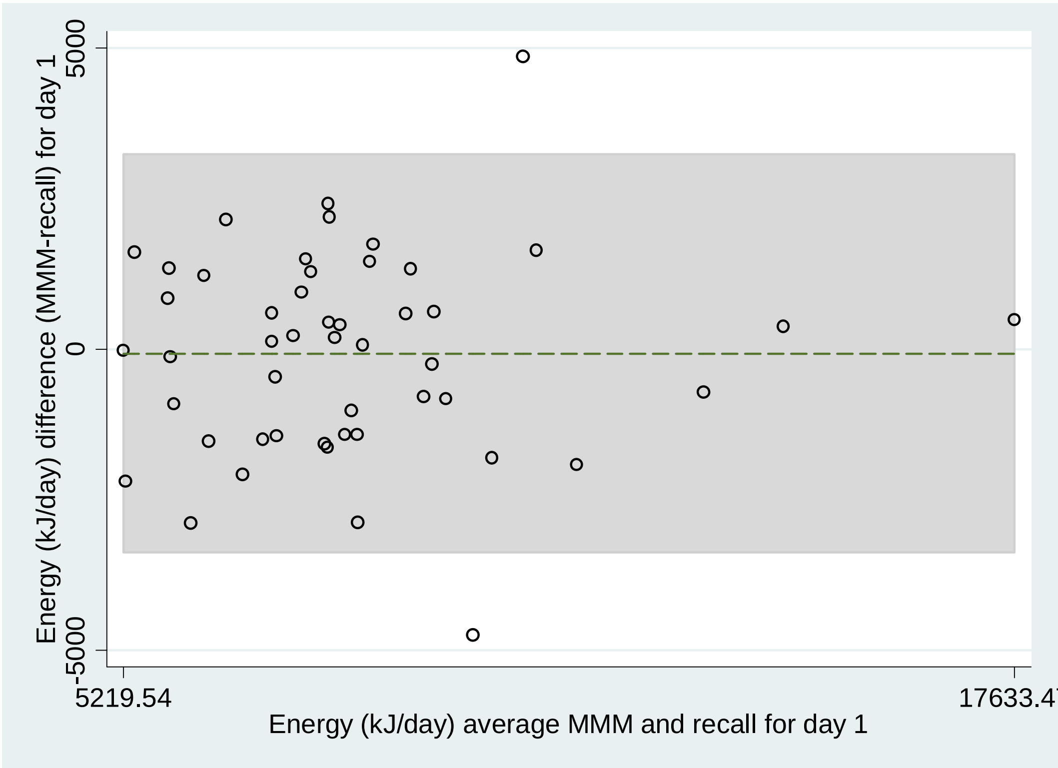


Figure 28: Plot of mean difference between participant entries on MMM and 24 hour recall for day 1 against the means of the two methods (n=49). The shaded area represents the limits of agreement of the methods: -3378 to 3243 kJ (-807 to 775 kcal). Mean difference (bias): -68 kJ (CI -553 to 418 kJ), (-16 kcal; CI -127 to 100 kcal).

Figure 29: Bland Altman plot for day 2 (MMM – Recall)

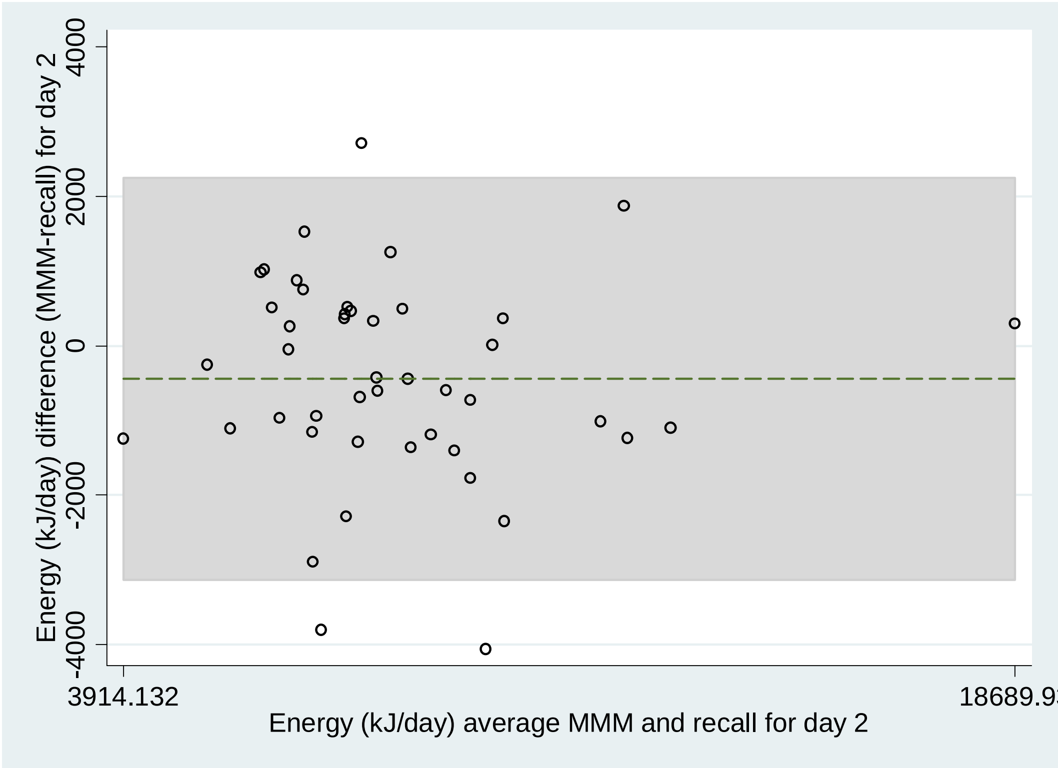


Figure 29: Plot of mean difference between participant entries on MMM and 24 hour recall for day 2 against the means of the two methods (n=45). The shaded area represents the limits of agreement of the methods: -3133 to 2251 kJ (-749 to 538 kcal). Mean difference (bias): -441 kJ (CI -854 to -29 kJ) (-105 kcal, CI -204 to -7 kcal).

Figure 30 shows the agreement for the mean of both days of recalls and the corresponding mean two days of MMM. The mean difference is 206 kJ (49 kcal) and the limits of agreement are -2434 to 2022 kJ (-582 to 483 kcal). The within-method variation (between repeated day standard deviation of the difference) was 1791 kJ (428 kcal) for MMM which was lower than the 2392 kJ (567 kcal) for the recalls.

Figure 30: Bland Altman plot for the mean two days of MMM and mean two days of recalls

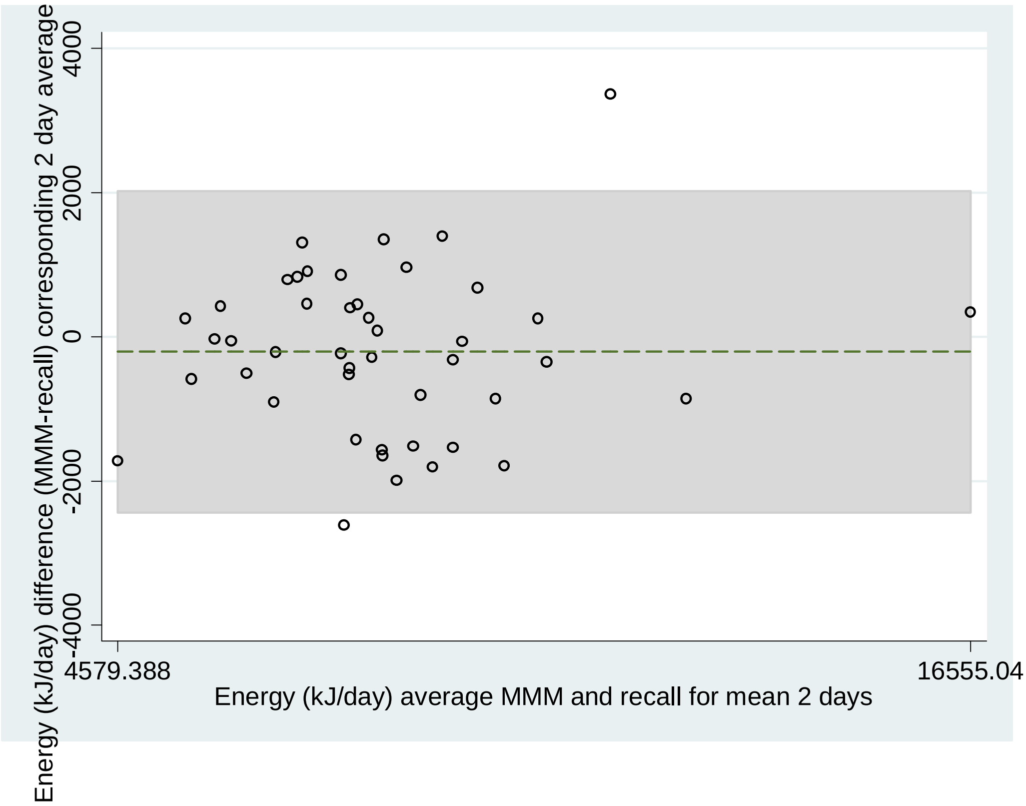


Figure 30: Plot of mean difference between mean participant entries on 2 days of MMM and mean 2 days 24 hour recall against the means of the two methods (n=45). The shaded area represents the limits of agreement of the methods: -2434 to 2022 kJ (-582 to 483 kcal). Mean difference (bias): -206 kJ, CI -547 to 136 kJ (-49 kcal, CI -131 to 33 kcal).

4.6 Discussion

This is, to the author's knowledge, the first study to assess the validity of nutrient intake data collected on a smartphone application as compared to a reference measure. The correlations between MMM and the 24 hour recalls for energy and macronutrients were moderate to high (r=0.63 to 0.83) and were found to be statistically significant. Bland Altman plots showed fairly wide limits of agreement on an individual level (day 1:-3378 to 3243 kJ (-807 to 775 kcal) and day 2:-3133 to 2251 kJ (-749 to 538 kcal)). At the group level, the group mean totals for energy and macronutrients were not found to be statistically significantly different on day 1 but the daily energy and fat intakes were found to have a statistically significant difference on day 2. Bland Altman plots showed that the bias between the methods appeared consistent over different levels of energy intake.

Although there are no studies comparing the food diary from a smartphone application with a reference measure, the correlation coefficients compare favourably to studies validating PDA food diaries against 24 hour recalls. Fukuo et al. (2009) compared a PDA food diary programme to a 24 hour recall and found Pearson's correlations of r=0.72 to 0.85 for energy and macronutrients. However, the agreement between methods was not reported in that study. Beasley et al. (2005) found Pearson's correlations of r= 0.71 for energy comparing the PDA programme DietMatePro to a 24 hour recall in a sample of 39 but found a lower correlation coefficient of r=0.54 in a further study with a larger sample of 174 (Beasley et al., 2008).

Most previous studies comparing electronic devices to a reference measure report group means and rarely report agreement as analysed by Bland Altman analysis. One exception is the aforementioned validation of DietMatePro (Beasley et al., 2005) where the researchers carried out a Bland Altman plot of agreement between DietMatePro and a 24 hour recall in a sample of 28 adults and the limits of agreement were -6694 to 6694 kJ (-1600 to 1600 kcal) which is fairly wide. The limits of agreement in this study of MMM although wide, are narrower than those seen for DietMatePro. The limits of agreement for DietMatePro as compared to a weighed food diary also appear to be fairly wide and look to be approximately -1674 to 2092 kJ (-400 to 500 kcal). The wide limits of agreement seen in this study are consistent with the validation of DietMatePro and given the number of potential sources of error in the reference measure it does seem prudent to expect wide agreement when comparing a new method to a reference measure which is not in itself a true reflection of absolute intakes.

A disadvantage of 24-hr recalls as a reference measure is the reliance on participant memory and potential for recall bias. Recalls were chosen as a reference measure in this study as they were a sufficiently different method to a food diary in an attempt to minimise correlated errors. In general, previous studies that have compared energy intake reported by food diaries and 24 hour dietary recalls have found lower intakes for the recalls ranging from 0% to 16% (Buzzard, 1998). In this case, the mean energy intakes were slightly higher in the recalls than MMM. It could be argued that using MMM might have actually improved participant performance in the recall as prospectively recording intake potentially raised awareness of consumption and increased the likelihood that respondents would weigh portions and increase the accuracy of portion estimation in the recalls. However, the recalls were unannounced during the 7 day recording period so participants were not aware of the days they would be required to provide a recall in advance.

The ability to access information about the nutritional content of food consumed in advance of the recall may have also increased nutrition knowledge and inadvertently enhanced any potential social desirability bias. It is also worth considering that the energy goal display on the MMM food diary page may have encouraged restrained eating. In an effort to avoid this, participants were encouraged to set their energy display to weight maintenance rather than weight loss. However, recording foods with a goal of not exceeding the energy display may be another explanation for the lower energy reported on MMM when compared to the recall. It is not known to what extent this may have affected reporting but further investigations with MMM as a dietary assessment tool would possibly benefit from removing the energy target display from the food diary page.

The differing results for the group means between day 1 and day 2 could be due to a number of factors. Day 2 had a smaller sample size due to exclusions of several of the recalls and there were some significant outliers where the differences in energy measured were as much as 4184 kJ (1000 kcal) between methods. One of these instances appeared to be where a participant had misinterpreted one of the portion size pictures used to aid the 24 hour recalls and another where a person appeared to have relied on the standard portion sizes in the MMM database rather than manually selecting the appropriate portion size. Despite guidance, both methods put the estimation of portion sizes into the hand of the respondent. There may also be an effect of time spent using MMM. By the second recall the participants may have experienced a ‘training effect’ on MMM and be more able to find foods readily and record with greater precision. On the other hand, 'respondent fatigue' has been associated with recording periods of greater than four consecutive days (Gersovitz et al., 1978) so it may be as the week progressed participant recording on MMM became less accurate. This might be another possible explanation for the difference in the result seen on day 2.

The sample in this study was mostly female and white and nearly a third of participants were educated in nutrition or food science, limiting generalisability to other populations. The volunteers were self selecting so likely to be a motivated sample. It also seems reasonable to assume that this approach needs a degree of technological literacy to be able to use the smartphone although it is worth noting that the study had a good adherence rate with 92% of entries submitted despite only half of the participants reporting to have ever used a smartphone before. Another limitation with the study was the lack of micronutrient intake assessment as the database was limited to macronutrient data only.

Using a smartphone application for dietary assessment does have a number of strengths, not least the speed of data entry. Respondents reported taking an average 7 minutes to enter a meal which compares favourably with the 8.5 minutes reported by respondents in the study of DietMatePro (Beasley et al., 2005) and the 5 minutes reported in the validation of the Wellnavi PDA device (Wang et al., 2006). Participants reported an average of 22 minutes spent each day using the application and although this is about the same length of time spent conducting a 24 hour recall, the amount of time spent manually coding the recall for analysis is considerably longer than this. Obviously no additional coding time is required for the MMM application. The direct transfer of food and drink data collected on MMM to nutrient output for analysis is a substantial benefit of this approach to dietary assessment.

Whilst this validation study of MMM showed a very small mean difference in energy intake recorded between MMM and the reference measure of 24 hour dietary recalls (MMM-recall, Day 1: −16 kcal (95% CI:−132 to 100 kcals/d); Day 2: −105 kcal (95% CI:−204 to −7 kcal) at the group level, the limits of agreement on the days of recording were wide (Day 1: −807 to 775 kcal; Day 2: −749 to 538 kcal). In order to record accurately on MMM, the user is required to select the correct food or drink item from the database and then to accurately estimate the portion size. Portion size estimation is notoriously difficult and recognised as a source of error in common to data collection from both food diaries and 24 hour dietary recall methods (Buzzard, 1998).

Given that the 24 hour dietary recall itself is not a measure of absolute intake it is difficult to draw conclusions about the accuracy of MMM for the individual recording their dietary intake. For this reason, a further small scale validation study of MMM was conducted by a Masters student at the University of Leeds comparing food and drink items entered into MMM against known weighed items (Frary, 2011). This study recruited a sub-sample of 22 volunteers from the larger validation study of MMM (by email) and asked them to use MMM to record a selection of 18 items presented as three meals across two hypothetical days. The food and drink items were a mixture of generic and branded (i.e. sometimes the packaging was displayed alongside the foods). The food and drinks were selected by reviewing the dietary records from the main validation study and choosing those which were frequently consumed, this included items such as: porridge oats with semi-skimmed milk, orange juice, sausage and mashed potato, Doritos's crisps and chocolate cake. The data collection sessions lasted no longer than 30 minutes and were conducted in a sensory laboratory. The participants were required only to look at the items and not to consume them as the test was just of their ability to select the correct food and estimate the portion size. The data collected on MMM was compared to the known weighed values as a reference measure.

This smaller validation study found similar results to the larger MMM validation study. Whilst the overall mean difference between energy recorded on MMM and the known weighed food and drinks was relatively small (MMM-recall, Day 1: 2 kcal (95% CI: −141 to 137 kcals/d); Day 2: 183 kcal (95% CI: 58 to 308 kcal), when analysed with a Bland Altman plot the limits of agreement were wide (Day 1: −628 to 624 kcal; Day 2: −349 to 715 kcal). This additional study is useful in that it uses a more accurate reference measure of diet than 24 hour dietary recalls (as there is no reliance on participant memory or conceptualisation of portion sizes after the event) and also may negate some of the social desirability bias associated with diet recalls given that the food was not consumed. However, it is limited in that the sample size is small and although the foods chosen were common items in the British diet they may not have been frequently consumed items by all of the participants. Also, the experiment was not conducted in natural settings so may have influenced the participants responses. As the participants had originally taken part in the previous validation study they had prior knowledge of using the MMM app and it may be that this had increased their ability to record accurately and they were also likely to be the most motivated as they had volunteered to test the app a second time.

Where individual large differences were observed on the Bland Altman plots for energy and macronutrients (fat, protein, carbohydrate) between MMM and the weighed items, the following sources of error were found: entering raw food rather than cooked; choosing a different food or drink item from the database; inaccurately estimating portion size; selecting the default 'average' serving size displayed in the database and omitting the item completely.

Using a smartphone application for dietary assessment is a unique and innovative approach with the advantage that as a prospective method it does not rely on memory and can collect data in real time. Smartphones are popular items which people carry around so can be conveniently used throughout the day. Mobile phones are a particularly widely accepted technology platform with 89% of the UK population claiming to use or have used a mobile phone (OFCOM, 2010). Mobile phone technology has evolved rapidly and there has been a surge in "smartphone" ownership. Over a quarter of the UK population (26.5%) reported to owning a smartphone in 2010 which is more than double the number two years previously (OFCOM, 2010). A strength of MMM in particular is the extensive database with generic and branded food items for people to choose from. Early focus group work informed the decision to use a branded food database to reflect the consensus that people wanted to select the exact food that they had eaten. As consumption of processed food increases, branded foods become more important and can give a greater degree of accuracy as the nutrient composition of a branded item can vary considerably within the same product category (Buzzard, 1998).

Although the validation study has shown variation in results at the individual level it does show the potential of a smartphone application as a dietary assessment tool. Automating the process of dietary assessment could save time and money whilst giving the flexibility of a prospective method in terms of open ended reporting of foods and flexible analysis at the level of nutrient or individual food. An automated dietary assessment method can standardise the data collection process and eliminate the manual coding necessary for analysis. Researchers are currently investigating computer based repeat 24 hour recalls for epidemiological studies (Arab et al., 2010; Touvier et al., 2011; Subar et al., 2012). A handheld, portable device has the advantage of convenience for reporting and portability and prospective reporting as it is less reliant on memory. This study has only looked at the accuracy of two particular days so measures on repeat days would need to be investigated in order to measure habitual diet. Further research into MMM is needed with an extended database to include micronutrients and in a wider range of population groups.

4.7 Conclusion

This chapter has presented the findings of a validation study of MMM. MMM has been developed as a tool to support weight loss, however this validation study shows the potential for MMM as a dietary assessment tool as it correlates favourably with 24 hour recalls for estimating group means. However, the agreement on daily energy totals between methods at the individual level is wide. The largest outlying differences between individuals appeared to be mistakes in estimating portion sizes on both methods. Training on estimating portion sizes and features to help with this might be useful additions in a future programme. Further research is warranted in establishing the accuracy of MMM in other population groups and with a wider range of nutrients. The next chapters of the thesis will describe the methods and results of a 6 month pilot trial of the MMM application. The overall discussion chapter (chapter 9) will attempt to bring the results from each stage of the project together.

Chapter 5: Methodology of the My Meal Mate (MMM) pilot trial.

5.1 Introduction

This chapter will describe the methodology used in the 6 month pilot trial of the "My Meal Mate" (MMM) smartphone intervention. Previous chapters have demonstrated the potential for a smartphone application for weight loss (chapter 1) and the gaps in the current evidence base (chapter 2). The development of a smartphone intervention for weight loss has been described (chapter 3) and the MMM app has been validated against a reference measure of diet and shown to have potential as a dietary assessment tool (chapter 4). From this point in the thesis, the work will focus on a 6 month pilot trial of the 'My Meal Mate' app. This chapter will describe the MMM pilot methodology and will include a description of how the participants were selected, trial design, trial procedure, data collection instruments and statistical analysis plan.

5.1.1 Definition of a pilot trial

In 2008 the Medical Research Council (MRC) published guidelines on developing and implementing complex interventions. The guidelines state that evaluation of large trials can be undermined by problems of "*intervention acceptability, compliance, delivery of the intervention, recruitment and retention and smaller than expected effect sizes".* This is important given that large randomised controlled trials (RCTs) to investigate the efficacy of an intervention are often costly and time consuming (Lancaster et al., 2004). The MRC guidelines recommend that a pilot trial is an important prerequisite in anticipating and exploring issues which may arise in the main trial. The definition of a pilot trial as distinct from a feasibility study is a contentious issue and the two terms have often been used in varied ways or interchangeably in the literature. This led Arain et al (2010) to call for distinct definitions and outcome reporting of the two types of trial. The National Institute for Health Research (NIHR) (2012) has attempted to distinguish between pilot trials and feasibility studies and defined a pilot trial as;

*"a version of the main study that is run in miniature 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 recruitment, randomisation, treatment, and follow-up assessments all run smoothly". (*Source: NIHR Evaluation, Trials and Studies Coordinating Centre*)*

This is distinct from a feasibility study which addresses the question of *"can this be done?"* by exploring the individual components which would come together in the main trial. Where as a feasibility study focuses on individual parameters such as recruitment rate and willingness of participants to be randomised, a pilot trial is concerned with how all the individual components work together as a small-scale version of the main study. To this end, Eldridge and Kerry (2012) contend that a pilot trial should always be conducted with the intention of carrying out a full trial.

A number of authors have discussed the reasons for conducting pilot trials and the most appropriate outcomes to report. Van Teijlingen et al. (2001) posit that a pilot trial can forewarn about potential problems likely to arise in a larger trial and identify where methods are inappropriate or the protocol may not be followed. Lancaster et al. (2004) identify a number of reasons for conducting a pilot trial such as: to determine a sample size for a larger trial; as a dummy run of procedures for a larger trial; to test data collection forms and the randomisation process; to highlight recruitment and consent rates; to understand the acceptability of the intervention and to select the most appropriate primary outcome measure. Thabane et al. (2010) identify similar reasons and classify them into four themes as follows; 1) Process (to assess feasibility, for example recruitment and retention rate), 2) Resources (assessing time, budget and identifying problems which may occur), 3) Management (human and data organisation problems), 4) Scientific (determination of treatment effect and its variance).

With regard to the choice of outcomes to report from a pilot trial, Lancaster et al. (2004) have written a useful discussion of recommendations for good practice in which they suggest that analysis should be descriptive and that hypothesis testing should be interpreted with caution given the absence of a formal power calculation. They go on to recommend that pilot trials should have well-defined aims and objectives *a priori*. Loscalzo (2009) draws a distinction between trials that are designed *a priori* and those that are redefined by the investigators after the trial has been conducted. He claims that clinical pilot trials are often "over interpreted, misleading and misguide researchers and interested readers" given that they lack adequate statistical power. Eldridge and Kerry (2012) support this idea and point out that there has been a tendency in the literature to inappropriately describe a small trial as a pilot trial in order to justify a small sample size, lack of statistical power or lack of sample size calculation. This problem has also been given attention by Arain et al. (2010) who conducted a review of 54 pilot or feasibility studies published in 2007-2008 and concluded that many of the studies put inappropriate emphasis on hypothesis testing.

5.1.2 Implications for the pilot trial of MMM

Given the issues that have been highlighted in the literature, clear aims and objectives of the pilot trial will be defined *a priori*. Although at the time of conducting this pilot trial there was no funding in place for the definitive trial, the intention was that the data collected in the pilot trial should inform a definitive trial. Therefore, the trial can be defined as a pilot and not a feasibility study although the focus will be feasibility outcomes. The trial of MMM is a stand-alone external pilot so not intended to be part of a future main study. The advantage of this is flexibility should major changes need to be made to the design for a definitive study. Given that a formal sample size calculation has not been conducted, the pilot trial primary analysis will focus on feasibility outcomes which will be defined in advance. As there are currently no agreed standard guidelines on which individual feasibility outcomes should be reported, the classification of process outcomes into four groups (process, resources, management and scientific) by Thabane et al. (2010) will be used as a framework. Some hypothesis testing will be conducted as secondary analysis although this is to explore the data as part of the PhD work and results should be interpreted with caution.

5.2 Pilot trial aim

To implement an exploratory pilot trial investigating the acceptability and feasibility of the “My Meal Mate” (MMM) intervention in order to inform a definitive trial.

5.3 Pilot trial objectives

- To obtain evidence of potential recruitment rates that could be applied to a definitive trial.
- To pilot instruments for outcome assessment of diet, physical activity, attitudes towards self monitoring and technology and physical activity which could be used in a definitive trial.
- To asses adherence to the trial and intervention arms and overall acceptability of the interventions.
- To estimate effect size (change in anthropometric measures).

5.4 Study population

The target population was overweight/obese (BMI ≥ 27kg/m^2) (but otherwise healthy) working age (18-65 years) men and women. Leeds City Council was contacted with details about the study and they agreed to advertise for volunteers on behalf of the University. This was a pragmatic decision in order to give a sufficiently large and diverse sample given that Leeds City Council is the largest employer in Leeds with 30,000 employees (Leeds City Council, 2012) and has a hierarchical structure employing people within a range of services at different levels.

5.5 Pilot trial inclusion criteria

The pilot trial inclusion criteria were as follows;

- Body mass index (BMI) equal to or greater than 27 kg/m^2.
- Willing to commit the necessary time and effort to the study. This includes time spent each day to record food intake (whether on the phone, website or paper diary, estimated to take 30 minutes initially with but with practice could be done in 5-10 minutes).
- Employed by a large employer in Leeds (and expected to continue to be employed there for the next 12 months).
- Aged 18-65.
- Not pregnant, not breast-feeding, and not planning on a pregnancy in the next 12 months.
- Not taking anti-obesity medication (orlistat/xenical) or medications or insulin for diabetes.
- Not had surgery for weight loss.
- Not taking the antidepressant sertraline (due to associations with weight gain).
- Able to read and write in English.
- Able to access the internet.
- Willing to be randomised to one of three groups with the understanding that they might not necessarily receive a smartphone for the trial.

An inclusion cut-off BMI of ≥ 27kg/m^2 as opposed to the more familiar cut-off point for overweight of 25kg/m^2 (as defined by the World Health Organisation) was used. The trial purposefully selected participants with more weight to lose given that the intervention is 6 months without clinical supervision and with only minimal contact. This was to ensure that participants had a reasonable amount of weight to lose in 6 months before maintenance of weight loss and also as a safety measure so that they would be unlikely to lose so much weight that they fell below the defined 'healthy' BMI range.

5.6 Sample Size

Since this is a pilot trial and not a phase III trial of efficacy a formal sample size calculation was not appropriate (Thabane et al., 2010). A total sample of 135 was chosen to give a reasonable estimate of expected response and drop-out rates. This was a pragmatic decision based on randomising 45 people to each arm. The project budget allowed for 50 HTC Desire phones to use in the trial so 45 phones allowed for five phones to be held in reserve in case of theft, loss or damage. Logistically, this number of people was also expected to be manageable to allow for interim follow up at 6 weeks and support on the forums.

5.7 Advertisement and Recruitment

Leeds City Council printed an advertisement in their staff newsletter and also posted on their intranet. Although initially agreed upon, they were unwilling to circulate a staff-wide email internally due to a policy regarding unsolicited emails. The study was also advertised using a 'health communication' email distribution list and snowball emailing from the communication list to other colleagues. The study was advertised on the 7/03/2011 in the March internal newsletter and staff intranet for one month. After one month, the advert was extended to posters and re-circulated via the health communication email and blog. Due to a lower than expected response rate participants were also recruited from other large employers in Leeds. Several large employers were contacted by email with details about the study and the following agreed to circulate an advert:

- Faculty Deans at the University of Leeds were contacted and 3 out of 8 agreed to circulate an email around their faculty.
- Leeds Metropolitan University (by internal email and staff intranet).
- Npower (by internal email within the call centre in Leeds).
- Morrisons (by internal email within the head office in Bradford).
- Asda (by internal email within the head office in Leeds).

- Walker Morris (a legal firm in central Leeds, by internal email).

In addition, advertisement fliers were distributed at Leeds Central Library. As a final strategy, participants were recruited by word of mouth and snowball sampling by including leaflets to advertise the study in the information packs given to participants at the enrolment sessions.

5.8 Recruitment Procedure

A specific study inbox was created (smartphonestudy@leeds.ac.uk) and advertising material advised participants to email the study inbox to express an interest. To maintain a standardised procedure, potential participants enquiring by telephone were advised to email the study inbox to express interest. Upon expression of interest, participants were sent a standard email (containing ten questions to assess eligibility) and a trial information document (appendix 2).Participants were assessed for eligibility and those found to be eligible were invited to attend an appointment to enrol. They were also emailed the first of three baseline questionnaires and asked to complete and bring it to the enrolment appointment. The first baseline questionnaire contained the International Physical Activity Questionnaire (IPAQ) short-form (Craig et al., 2003) and the Three Factor Eating Questionnaire (Stunkard and Messick, 1984). Those found to be ineligible were informed by email. Participants who confirmed attendance were booked into a suitable session and were contacted 2-3 days in advance to confirm attendance.

5.9 Trial design

The pilot trial consisted of three parallel intervention arms with participants randomised to one of three diet and physical activity self-monitoring interventions. Comparison arms were investigated rather than a ‘do nothing’ control in order to minimise resentful demoralisation in a population who had expressed a desire to lose weight and were seeking treatment. Trial duration was 6 months.

5.9.1 Interventions

The three intervention arms involve the self monitoring of weight, food and drink intake and physical activity and each draws its food data from the ‘Weight Loss Resources’

(WLR) food database and physical activity from a compendium of physical activities (Ainsworth et al., 2000). The WLR database has 23,000 food and drink items and contains nutrient data for energy (kcal), protein (g), carbohydrate (g) and fat (g). The interventions present an opportunity to explore similar self monitoring tools delivered by different mediums; smartphone application, online and on paper. The three intervention arms are comparable in that the user begins by setting an individual goal for weight loss which generates a daily energy target. The user monitors dietary intake and physical activity towards this daily target. Each intervention also encourages the user to record their weight weekly. The MMM app and WLR website provide feedback automatically where as the paper diary group manually calculate their energy intake using a book and have a facility to plot their own progress charts. The three intervention groups will be described in more detail below.

5.9.2 Arm 1 – "My Meal Mate" (MMM)

Participants in the 'My Meal Mate' (MMM) group received a 'HTC Desire' smartphone with the MMM application pre-downloaded on to it. The participants were provided with a smartphone with a pre-paid data contract so that they could use the internet and make calls and texts. This was to done to encourage the participants to use the smartphone as they would their own phone to emulate real life conditions. Participants were provided with a handset so as not to exclude any participants on the basis of not having a smartphone with an Android operating system. There may have been a risk of bias if only smartphone owners had been recruited into the trial. Please see chapter 3 for a full overview of the MMM intervention. For consistency the smartphones were set up according to a standard protocol.

5.9.3 Arm 2 – "Weight Loss Resources" (WLR) website (online food diary)

The 'Weight Loss Resources' (WLR) group received a voucher (containing a link to the website and log-in ID and password) entitling them to free access to the WLR slimming website for 6 months. WLR are a commercial slimming organisation and the website allows the user to keep an electronic food diary by selecting and logging foods from the WLR database. Each participant had a unique ID and the website guided them through a goal setting process based upon their height, weight, age and personal weight loss goal (similar to the MMM goal setting process). System users could also monitor their physical activity and weight and track progress over time graphically. The WLR website has the facility to save favourite meal combinations (as does MMM).

The website also has a support forum which was disabled for the trial participants in order to standardise across intervention arms. The usual cost of membership to the website at the time of the trial was £9.95 per month. All participant data was downloaded to an excel spreadsheet by WLR and forwarded to the researcher at the end of the trial. At the time of the pilot trial, WLR did not allow for social networking but since then it has been updated to link with Facebook and Twitter. Figures 31-34 show screenshots of the WLR website as it appeared at the time of the pilot trial.

Figures 31-34: Screen captures of the Weight Loss Resources website at the time of the pilot trial

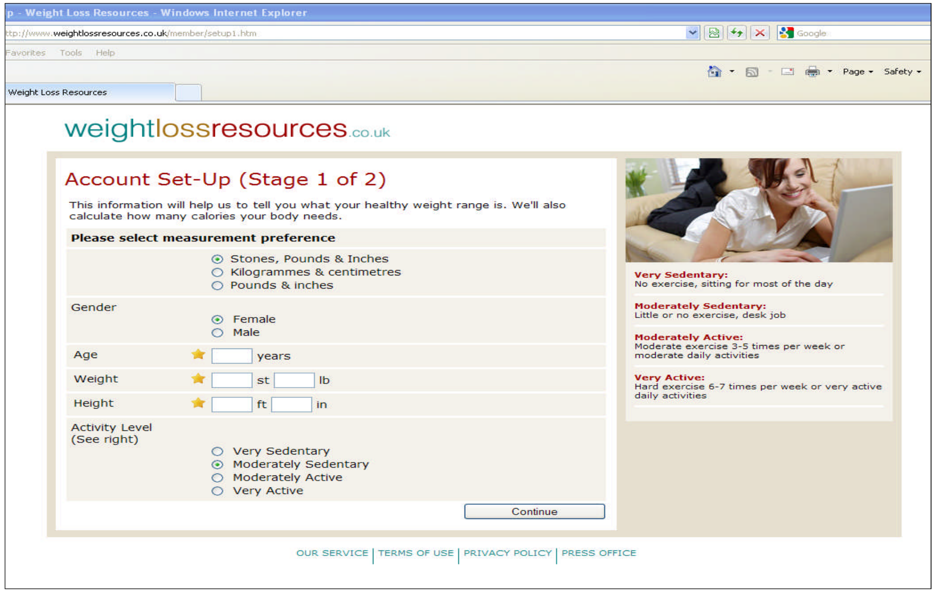


Figure 31: Screen capture of the goal setting page of the 'Weight Loss Resources' Website (accessed 7/08/2012).

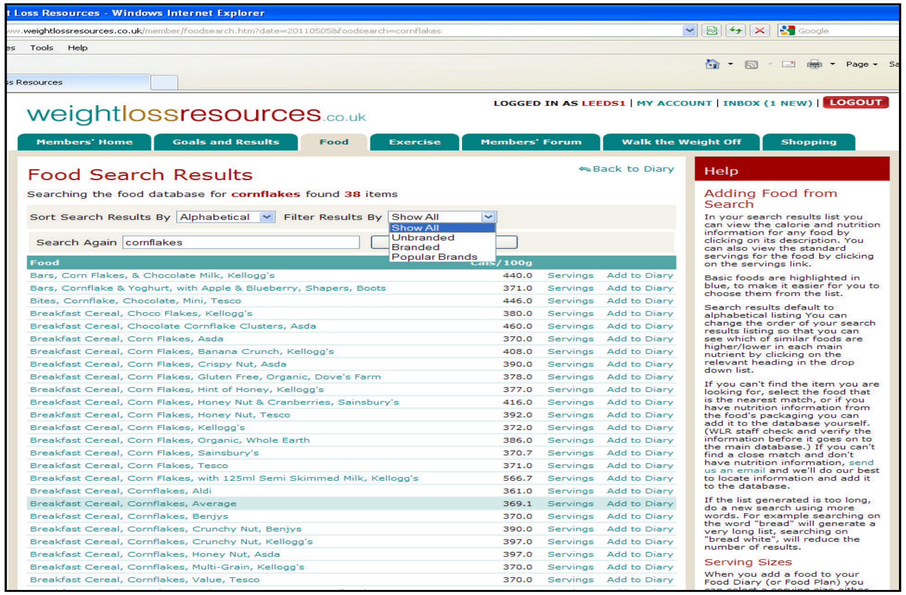


Figure 32: Screen capture of the list of foods returned when searching for a food item in the 'Weight Loss Resources' database (accessed 7/08/2012).

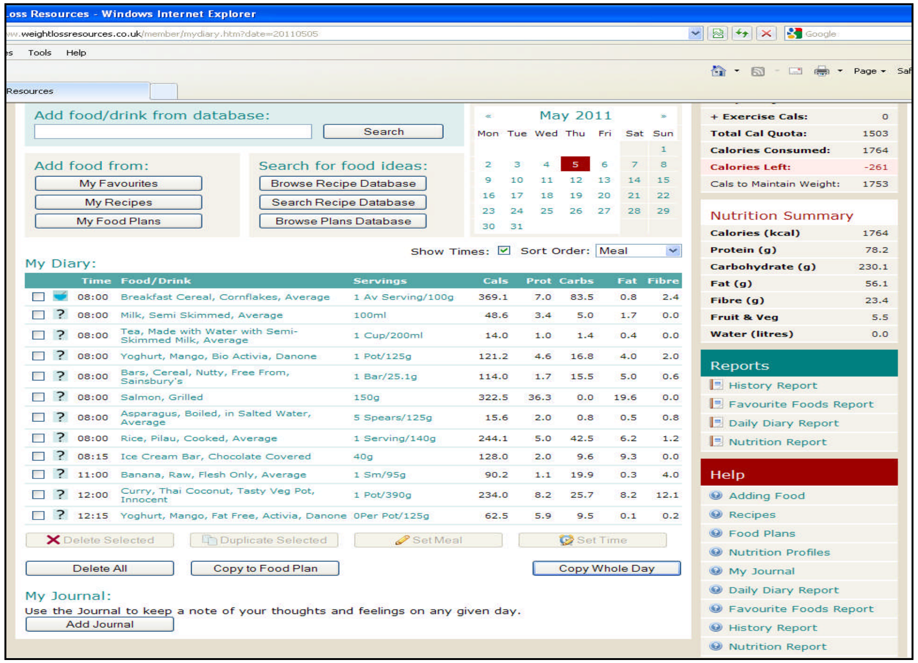


Figure 33: Screen capture of the food and activity diary page of the 'Weight Loss Resources' website (accessed 7/08/2012).

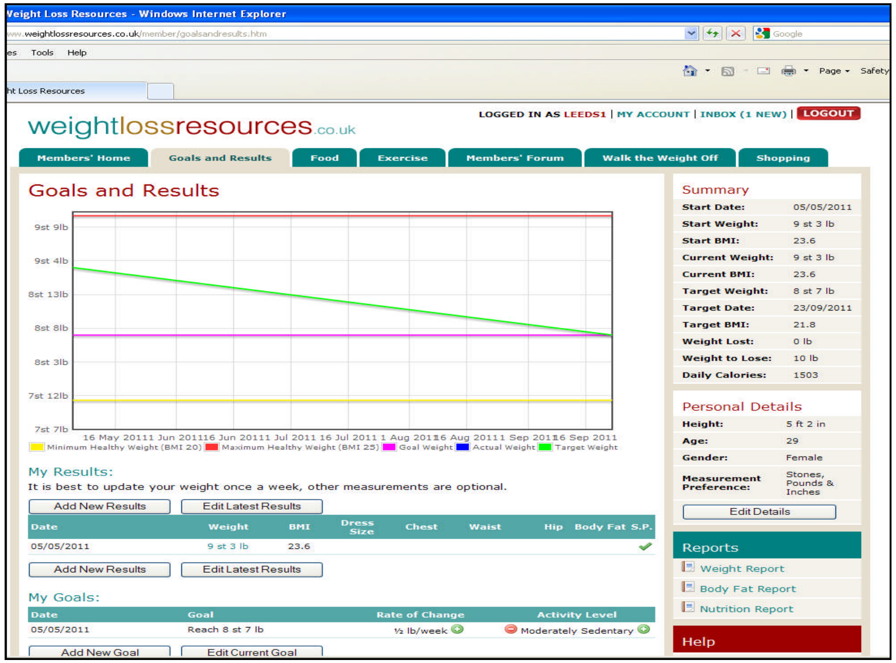


Figure 34: Screen capture of graphical tracking of weight change over time on the 'Weight Loss Resources' website (accessed 7/08/2012).

5.9.4 Arm 3 – WLR paper food diary

This group received a calorie counting book published by WLR called 'The Calorie, Carb, and Fat Bible (2011)' (a hardcopy version of the WLR electronic food database), a calculator and two blank paper food diaries (each with space to record for 3 months). Figure 35 is a picture of the diary group intervention package. Users write down their intake in the diary and use the book to find the corresponding energy value (kcal) for the food. The user then manually calculates the energy in their particular portion and totals this for the day. There is also a database of common physical activities. At the end of each week there is a summary page to record net calories for the week and space to record weekly weights. There is also a blank graph page so the user can manually graph their weight trajectory.

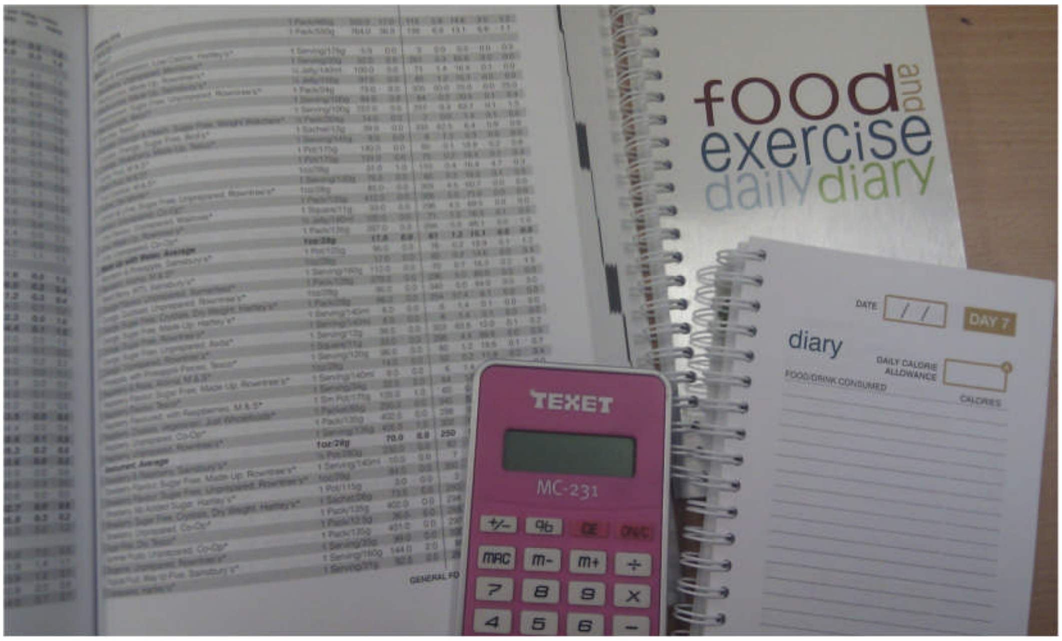


Figure 35: Photograph of the diary group intervention package, including paper diary, "Calorie, carb and fat bible" and calculator.

5.10 Online forum

All participants had access to an online forum which was set up by liaising with the University IT Department. The forum consisted of a general discussion thread and three intervention specific threads. The rationale for the forum was to provide an area for participants to ask questions in a consistent way rather than contacting the researcher individually and asking for advice.

5.11 Randomisation

Participants were allocated to groups by a process of minimisation. An MS-Dos program called 'minim' was used which has been created by the University of York for use in clinical trials (Evans, Royston & Day, 2004). Bland and Altman (2005) describe minimisation as a process whereby the first participants in the trial are randomly allocated and every subsequent participant is allocated in such a way as to minimise imbalance between groups on important prognostic factors. Minimisation balanced equally at the medians on three factors; starting BMI, age and gender. The median for age was 39 years and BMI 32 kg/m^2 (calculated in advance from the self report data provided at enrolment). Minimisation was used as this method has an advantage over simple or stratified randomisation of providing very similar balanced groups in small samples (Altman, 1991).

5.12 Blinding

Although it was not feasible to blind participants to their intervention, efforts were made to ensure blinding where possible. The fieldworkers responsible for weighing participants were different at baseline, 6 weeks and 6 months so they were blinded to the intervention the participant had been allocated to. Participants were asked at enrolment not to discuss which group they had been allocated to with the fieldworker weighing them when they returned for follow-up. When participants arrived for follow up they were met initially to collect questionnaires and then taken to be measured in a separate room where the fieldworker was waiting. In this way, if they were returning equipment or wanted to ask any questions related to their group the fieldworker measuring would not be involved and able to deduce which group they belonged to. The minimisation was performed in a separate room by an independent researcher using only unique ID number, age, gender and BMI. The statistical analysis was initially blinded with each group allocated a code which would be broken at the end of the analysis.

5.13 Withdrawal procedure

A standard withdrawal procedure was in place. If a participant made contact to withdraw they were asked whether they wanted to withdraw with the knowledge that they did not have to use the study equipment every day. Participants were informed that they were entitled to remain in the study until the end even if they did not want to use the study equipment frequently. This was reiterated in case it was not clear from the enrolment session, given that a lot of instruction had been delivered at that time. If they still wished to withdraw, they were asked to complete a withdrawal questionnaire and asked whether they would still be willing to return for follow-up measurements.

5.14 Pilot trial procedure

5.14.1 Baseline enrolment sessions

The pilot study enrolment sessions were held between 12/05/11 and 9/06/11 and took approximately four weeks to complete. Figure 36 shows a flowchart of the enrolment session procedure. Participants were enrolled in nine separate groups ranging in size from 6-25 people. The enrolments took place in groups with sessions scheduled for evenings, weekends and daytime to accommodate work schedules. The group sessions lasted approximately two hours and followed a set procedure. If a participant did not attend a session they were contacted to check whether they were still interested and to reschedule their appointment.

On arrival at a session, participants were given a sticker with their pre-allocated ID number and provided with a pack of information. The first part of the questionnaires was collected and labelled with the appropriate ID. Four measuring stations were set up in the four corners of the Food Technology Laboratory within the School of Food Science. This ensured that participants were measured in privacy from others involved in the trial but fieldworkers were not isolated from each other.

Participants were measured by research assistants who had received training in using the equipment prior to the session. Weight (without shoes) and body fat (%) were measured using ‘Weight Watchers 8958U: Body analyser’ portable weighing scales (weight capacity up to 182kg). Height without shoes was measured using a portable stadiometer to the nearest 0.1cm. The scales were purchased on the week of start of the trial and were calibrated with a 10kg weight placed on each scale to test that each was accurate. Participants were also asked by the research assistant how they had heard about the study and this information was recorded. Measurements were taken at the start of the session for convenience in case a participant needed to be excluded based on their BMI. After measurements were taken, the participants were asked to complete the two remaining baseline questionnaires and a consent form. A short presentation was delivered consisting of an overview of the trial. This was scripted in order to ensure standardisation across groups. This presentation also included advice for self monitoring, instructions for follow-up, withdrawal procedure and instructions for accessing the forum.

Whilst participants completed questionnaires, they were allocated to an intervention group by a process of minimisation conducted in a different room. The researcher conducting the minimisation was blinded to the participant details and the groups to which people were allocated. Participants were randomised using the unique ID, gender and body measurement data collected on paper records to an anonymous group (A, B or C).

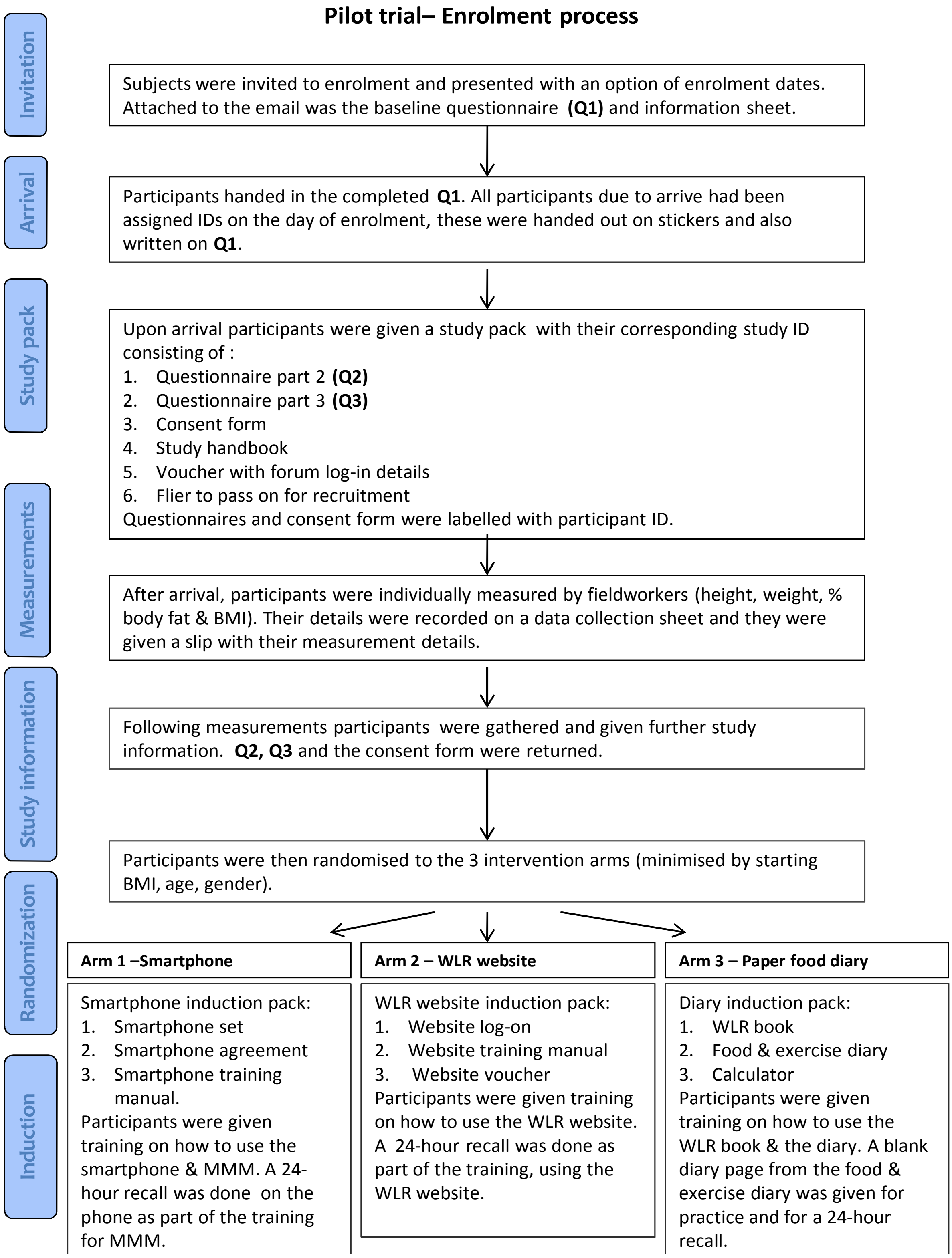


Figure 36: Flow chart of the MMM pilot trial enrolment procedure

5.14.2 Enrolment information pack

The enrolment pack given to participants at baseline contained:

- Questionnaire part 2 (appendix 3)
- Questionnaire part 3 (the data from which has not been used in this thesis)
- Consent form (appendix 2)
- Study handbook. The study handbook contained basic instructions for self monitoring, one page outlining current healthy eating guidelines (NICE; 2006) and the portion size pictures used in the validation study (Chapter 4) to help with estimation of portion sizes.
- Voucher with forum log-in details
- Flier to pass on for recruitment

5.14.3 Intervention training

After minimisation, participants were informed of their group allocation and the groups were taken to three separate rooms. Training was delivered for a maximum of one hour on how to use the specific interventions including a demonstration of the equipment. Each training session was managed by two research assistants who had been trained together in order to give a standardised process. The training sessions were designed to cover identical information as far as possible. During the training session, participants were asked to input the previous day's intake (6am -6am) on to their study equipment to give an approximate 24 hour recall (the website training was conducted in a room where participants could sit at a computer). This allowed participants to practice the equipment with help from researchers. The smartphone group was given an MMM instruction manual and asked to sign an agreement to return the phones at the end of the trial. The WLR website group was given a WLR instruction manual and the paper diary group was given an example of a completed diary day.

5.14.4 Instructions for use

The participants were instructed to use the equipment as often as they wished throughout the trial. However, participants were encouraged to attempt to use the equipment for 7 days at least in order to practice and familiarise themselves with it.

5.15 Data collection instruments

5.15.1 Design of baseline questionnaires

A number of psychosocial scales which may be associated with self monitoring and weight related behaviour were piloted for use with this population. The scales were all self-administered and participants were asked to complete them at baseline. There is potential to tailor the MMM intervention in the future so the rationale behind these measures is that they could be used to investigate whether certain factors predict success with the intervention. The scales incorporated into the questionnaires are described in table 10. Physical activity, nutrition knowledge and confidence, demographic data, technology readiness, usage and confidence were also measured. Participants were also asked about their attitudes towards different methods of self monitoring, their previous weight loss attempts and attitudes towards various methods for weight loss (using 7 point Likert scales).

Prior to the start of the trial, the questionnaires were piloted on a convenience sample of five people in the Nutritional Epidemiology Group office and the consensus was that they took too long to complete and that some of the wording was difficult to follow. In order to reduce participant burden, a decision was made to break the questionnaires into three parts. The first questionnaire was sent to participants in advance by email to bring along with them to the enrolment session.

Table 10: A description of the scales used in the three questionnaires administered to participants at baseline of the 'My Meal Mate' (MMM) pilot trial

Scale	Location	Description	Outcome
International physical activity questionnaire (IPAQ – short version) (Craig et al., 2003)	Questionnaire 1, Section 1 (Questions 1-7)	The IPAQ comprises of 7 questions (short version) designed to give a self-reported energy expenditure (MET-minutes per week) score by assessing physical activity in four domains (vigorous and moderate activity, walking and sitting). The respondent is required to estimate how many days and the duration of time they spent in the four activity domains during the preceding 7 days. The short version has been chosen for use in the pilot study in order to reduce respondent burden given that the short version has been validated against the long-form and found to be comparable in accuracy (Craig et al., 2003). The IPAQ is a well-established physical activity questionnaire which has been found to have good test-retest reliability and has been validated against accelerometer data in 12 countries and found to have comparable validity to other self-report physical activity instruments (Craig et al., 2003). The benefit of using this self-report tool is that it is relatively quick and easy to administer, however the tool has primarily been developed for use in national and regional surveys so the results will need to be interpreted with caution.	Continuous (MET-mins/per week).
Three factor eating questionnaire (TFEQ) (Stunkard and Messick, 1984).	Questionnaire 1 (Second part) called "Eating Behaviours" (Questions 1-60)	The TFEQ is a 51-item scale purported to measure three domains of eating behaviours with sub-scales for 1) cognitive restraint of eating, 2) disinhibition and 3) hunger (Stunkard and Messick, 1984). Respondents are presented with a list of statements such as *"When I feel anxious, I find myself eating"* and required to indicate whether they believe it to be true or false. Restraint theory (Herman and Polivy, 2011) contends that purposefully restricting eating through dieting behaviour is a psychological determinant of both under-eating and overeating. Overeating in restrained eaters has been associated with triggers to disinhibition (loosening of dietary restraint) such as lowered mood, alcohol or a high calorie pre-load (Ogden, 2011). The scale has been found to have good internal consistency (Cronbach's alpha, 0.82-0.9) (Stunkard and Messick, 1984).	Scores in the three domains of restraint, disinhibition and perception of hunger (ordinal).
Short Form Food Frequency Questionnaire (SFFQ) (Cleghorn et al., 2011)	Questionnaire 1 ("Food and Drink").	The SFFQ is a 20-item tool which has been developed by the University of Leeds (Cleghorn et al., 2011, unpublished) to indicate diet quality. It focuses on indicators of a healthy diet including 'fruit, vegetables, fibre rich foods, high fat and high sugar foods, meat, meat products and fish'	Diet quality score (ordinal).

Scale	Location	Description	Outcome
Technology Readiness Index (TRI) (Parasuraman, 2000).	Questionnaire 2 Section B (Q 1 - 10)	The TRI is a 10-item scale that has been developed to measure the *'propensity to adopt and embrace technology for accomplishing goals in home life or work'* (Parasuraman, 2000). It is based on the technology acceptance model which is related to the theory of reasoned action. The respondent is asked to indicate how strongly they agree with statements regarding their attitudes towards technology on a Likert scale of 1-5. An example of an item is, "*in general, you are among the first in your circle of friends to acquire new technology when it appears".* The index was originally developed to investigate consumer preferences and enhance understanding for the role of technology in marketing and customer service. The index is made up of four domains; optimism (a positive view that technology helps in daily life), innovativeness (tendency to adopt new technologies early on), discomfort (perceived lack of control over new technology) and insecurity (distrust and scepticism about new technology) (Parasuraman, 2000). The scores in these domains give an overall score of technology readiness. Parasuraman (2000) contends that optimism and innovativeness are drivers of technology readiness whilst discomfort and insecurity are inhibitors and that the total technology readiness score is a good predictor of technology usage. The scale has been found to have good internal reliability (Cronbach's alpha=0.74 to 0.81) (Parasuraman, 2000) and whilst the index has mostly been applied to consumer use of technology some studies have been conduced assessing technology readiness in other areas such as health care settings (Caison et al., 2008) and education (Van der Rhee et al., 2007).	Technology readiness score (ordinal).
Conscientiousness Scale. 20 item scale on a 5 item Likert rating (Goldberg et al., 2006).	Questionnaire 2 Section C (Q1-20)	A 20-item scale was used to measure conscientiousness. The scale was taken from the International Personality Item Pool (IPIP) website which hosts a freely available inventory of personality measures (Goldberg et al., 2006). Participants were requested to self-report how much they agree with each item (for example, *"I pay attention to detail")* on a Likert scale of 1-5. Conscientiousness is one of five domains which make up the five-factor model of personality (along with extroversion, agreeableness, neuroticism and openness) (McCrae and John, 1992). This model assumes that individuals can be classified on a range of personality traits which can be measured and are fairly stable across different situations. (McCrae & Costa, 2008). Conscientiousness has been described as *"a tendency to be organised, strong-willed, persistent, reliable, and a follower of rules and ethical principles"* (Terracciano et al., 2009). The internal consistency (the coherence of components of the scale) of the scale has been found to be high (Cronbach's alpha=0.88) (IPIP, 2012).	Continuous (higher score indicates greater conscientious).

Scale	Location	Description	Outcome
Consideration of future consequences (CFC) (Strathman et al., 1994).	Questionnaire 3, Section D (Questions 1-12)	The CFC scale is a 12-item scale which proposes to measure *"the extent to which people consider the potential distant outcomes of their current behaviors (sic) and the extent to which they are influenced by these potential outcomes"* (Strathman et al., 1994). Respondents are asked to rate how characteristic of them a particular behaviour is on a Likert scale of 1-5. The items are statements such as *"I only act to satisfy immediate concerns, figuring the future will take care of itself".* The scale has been used in a range of areas including research into; aggression, pro-social organisational behaviour, pro-environmental behaviour (for example propensity to recycle) and health behaviour (including risk taking and academic achievement) (Joireman et al., 2006). Studies have shown the CFC scale to have good internal validity (Cronbach's alpha 0.8-0.86) (Strathman, 1994) and high levels of CFC have been found to be associated with less risky healthy behaviours (such as less cigarette and alcohol consumption) and an expression of greater concern for health (Joireman et al., 2006).	Continuous – (higher score indicates greater consideration of future consequences).

Table 10: A description of the scales used in the three questionnaires administered to participants at baseline of the 'My Meal Mate' (MMM) pilot trial

5.16 Follow-up procedure

Follow-up measurements occurred at 6 weeks and 6 months. At 6 weeks participants were invited back to the University of Leeds for a short appointment to be weighed and complete an evaluation questionnaire. Follow-up appointments were available daytime, evenings and weekends to give everybody the opportunity to return. At 6 weeks, each participant was contacted a maximum of three times by email and then by telephone (if there was no response to email) to invite them to come back at 6 weeks. At 6 months, participants were invited back to be weighed and repeat some of the rating scales administered at baseline (see appendix 4). At this point the smartphone and diary group were also asked to return their study equipment. At 6 months, participants were sent a maximum of three emails to invite them back for follow up. For those that did not reply to email, one telephone contact attempt was made and voice messages left if the person did not answer. Remaining participants who had not responded by this point were sent a letter in the post inviting them to return. The letter also contained hard copies of the follow-up questionnaires and a stamped self-addressed envelope and participants were asked to return these even if they did not intend to come back and be measured. A fortnight after the letters were sent, one final attempt was made to gather self report data by sending a text message asking the participant to self-report their current weight.

5.17 Ethical approval

The pilot trial was conducted according to the guidelines laid down in the Declaration of Helsinki and all procedures involving human subjects were approved by the University of Leeds, Faculty of Medicine and Health Research ethics committee (ethics reference no: HSLTLM/10/002) (appendix 1). Written informed consent was obtained from all trial participants. The trial consent form can be found in appendix 2.

5.18 A priori statistical analysis plan for the pilot trial data

A statistical analysis plan was written prior to conducting the trial. Key aspects of the plan in its original form will follow in this section.

5.18.1 Data entry and cleaning

Data will be entered into the MMM tracking database, a Microsoft Access database which has been specifically designed by the Database Manager. Categorical data from questionnaires will be consistently entered with “1” for yes or “2” for no and “99” for missing. Data validation will be set up on the data entry cells so that only appropriate categories can be entered. Data will be cleaned to look for implausible values which will then be cross checked with the original data collection records. Outliers and influential observations will be left in the analysis unless values are clearly incorrect when checked with original raw data. The psychosocial scales rely on all of the questions being answered to give a score so if data is missing from a scale then the complete result for that scale will need to be removed from analysis.

5.18.2 Presentation of pilot trial findings

The findings of the pilot trial will be presented in three results chapters. The first results chapter will present findings relating to the feasibility of the trial (and the MMM intervention), the second will present the results relating to the acceptability of the trial (and the MMM intervention) and the third chapter will focus on changes in anthropometry over the course of the trial.

5.18.3 Feasibility outcomes

Thabane et al. (2010) have published a detailed tutorial article on conducting pilot studies and contend that a pilot trial should focus on ‘feasibility’ of the intervention. They categorise the desirable outcomes from a pilot study as follows;

1) Process (i.e. recruitment rates, adherence rates, retention rates).
2) Resources (i.e. determining process times, what happens in case of loss or theft?)
3) Management (i.e. human and data management issues).

4) Scientific (i.e. do patients respond to the intervention? What is the estimate of treatment effect?).

Due to a lack of agreed outcomes to present in a pilot trial, the criteria above will be used to guide the presentation of results. Table 11 provides details on the feasibility outcomes to be measured and how they will be reported. It is worth noting that there are two types of adherence outcomes to consider. The first is adherence to the trial and the second is adherence to dietary self monitoring within each intervention. It is possible that a participant may stop adhering to their intervention (i.e. discontinue self monitoring in the diary) but may still adhere to the trial by returning for follow-up. Participants have not been given a prescriptive number of days to record over the 6 months so they are free to adhere as much or as little as they like to their allocated intervention. To make the distinction between types of adherence, adherence to the trial and adherence to dietary self monitoring (frequency of use) will be considered separately.

5.18.4 Acceptability outcomes

At 6 month follow up, participants were asked to complete questionnaires relating to satisfaction and use of the study equipment in order to assess acceptability (appendix 4). The majority of these items were measured on Likert scales. Participants were also asked to complete a separate questionnaire relating to their satisfaction and evaluation of the overall trial. Descriptive statistics will be used to present these results in the second results chapter.

Table 11: Feasibility outcomes to be reported in the 'My Meal Mate' (MMM) pilot trial

Criteria	Outcome	How will it be reported?
Process	Success of recruitment strategy	To be evidenced with a CONSORT flow chart and descriptive statistics.
	Adherence to the trial	• Number of withdrawal contacts and reasons for withdrawal • Adherence to the trial will be reported as the number of trial completers within each group. A completer will be considered to be a participant who attends follow up appointments to be measured. This will be reported for 6 weeks and 6 months. Differences between trial completers and non completers will be investigated within each group.
	Frequency of intervention use (adherence to dietary self monitoring)	• Frequency of use of the interventions will be measured as a continuous variable over the 6 months (number of days recorded in the diary, website and phone that fall within a biologically plausible range i.e. 500-5000kcals). For the diary group this will involve manually checking through the paper diaries returned and counting the days completed. For the smartphone group this data will be uploaded to the administrator website and for the website group the number of days will be exported to an excel spreadsheet by "Weight Loss Resources". Frequency of use will be plotted graphically to show the pattern of usage between groups. • Further regression analysis will investigate whether certain factors predict frequency of use within the smartphone group.
	Success of data collection	To be reported as number of diaries returned, number of questionnaires returned and how successful data transfer is from the smartphones to the administrator website.
Resources	Determining process	A description of the time taken at critical stages during the running of the trial (i.e. recruitment, enrolment and follow

Criteria	Outcome	How will it be reported?
	times	up).
	Technical issues with using the intervention	A description of logistical issues encountered with study equipment at set-up, deployment and during the course of the trial.
	Determining capacity	A summary of the numbers of research assistants needed at various points in the trial.
Management	What challenges do study personnel have?	An evaluative discussion of challenges faced during the study.
	What are the challenges with managing the study?	An evaluative discussion of challenges faced during the management of the study.
Scientific	What is the estimate of treatment effect?	The pilot trial is not adequately powered to detect a change in anthropometric measures, however this will be analysed to give an idea of effect size. Changes in anthropometric measures (weight (kg), BMI (kgm^2), % body fat) at 6 weeks and 6 months after entry into the study will be reported. This will be reported in five analyses (described in the statistical analysis plan). Differences between those that do and do not lose a clinically significant amount of weight (5%) will also be investigated.

Table 11: Feasibility outcomes to be reported in the 'My Meal Mate' (MMM) pilot trial

5.18.5 Statistical analysis

Statistical analysis will be conducted using Stata 11 (Stata corp). As this is a pilot trial with feasibility and acceptability outcomes, the majority of analyses will be descriptive. The pilot trial is not statistically powered to detect differences between groups and analyses will be conducted in an exploratory way in order to generate potential hypotheses for future investigation rather than to test hypotheses. The effectiveness of the minimisation procedure will be assessed by determining baseline balance between the groups. In general, when an outcome is continuous: means, standard deviation, confidence intervals, frequency and proportions will be presented. When the variable is categorical: medians, interquartile range and proportions in the highest categories will be presented as appropriate.

5.18.6 Investigating differences between groups

When analysing differences between the three intervention groups, one-way ANOVA will be used for continuous outcomes found to be normally distributed (and other assumptions of the test met) or Kruskal Wallis equality of population rank test where not normally distributed (and not improved by log transformation). For the analysis of completers vs. non completers, independent two sample t-tests will be used for continuous outcomes which are normally distributed and the Wilcoxon rank sum test for non-normally distributed outcomes. Where data is collected on the same individual at two different time points a paired t-test will be used (if the outcome is continuous, normally distributed and all other assumptions of the test met) or the non-parametric equivalent Mann Whitney U-test test as appropriate. Where tests have investigated differences in the number of participants within different categories Chi squared (X^2) tests will be used (where assumptions met) or the Fisher's exact test where numbers are too small for X^2. Detail about the specific statistical tests used will be provided in the legends of the tables within the results chapters.

5.18.7 Analysis of items measured on Likert scales

Items measured on a Likert scale will be treated as ordinal variables and analysed using appropriate non parametric tests. Medians, interquartile ranges and proportions in the highest categories will be presented.

5.18.8 Regression analysis

If assumptions are met, regression analysis will be used to investigate whether adherence to dietary self monitoring is predictive of follow up weight (adjusted for baseline weight) in the MMM group. The regression analysis will use an intention to treat principle with baseline observation carried forward for missing data in follow up weight at 6 months.

5.18.9 Analysis of change in anthropometric measures

The pilot trial is not statistically powered to detect a change in anthropometric measures within or between groups; however results are displayed to give an idea of effect size. Two types of anthropometric outcome will be considered; difference in change between groups and difference in endpoint at follow up (adjusting for baseline and balancing variables). The balancing variables are gender, age and baseline BMI. Vickers and Altman (2001) give a useful overview of the relative advantages and disadvantages of analysis using either comparison of follow up scores (adjusted for baseline) or comparison of change scores (follow up-baseline). They posit that if average baseline scores are similar and groups are well balanced then intervention effect will not differ much whichever analysis approach is used.

The analysis of difference between intervention groups will be conducted using the comparison of follow up scores as this allows for a regression analysis and the ability to adjust for group and the balancing variables at baseline. Adjusting for balancing variables is considered to be best practice in analysing trial results where the randomisation has been balanced by minimisation (Kahan and Morris, 2012). There is evidence that balancing the randomisation may introduce correlation between the treatment groups so that failure to adjust may lead to decreased statistical power and p values that are too large (Kahan and Morris, 2012). Even if the groups are found to be well balanced at baseline in order to be conservative the analysis will be conducted using comparison of follow up values (adjusted for baseline) as this method of analysis is less affected by baseline imbalance (Vickers and Altman, 2011).

Vickers and Altman (2001) contend that if the correlation between baseline and follow up is high (as is often the case in weight loss trials) then using just the follow up score can lose information and change score is more likely to be significant. For these reasons although the analysis is conducted using difference in follow up (adjusted for starting weight and balancing variables), the results for overall mean weight change will also be presented.

The anthropometric analyses will be presented in five tables in the third results chapter (Chapter 8). The first is a primary intention to treat analysis which displays results within and between groups in all of those who were randomised at baseline using baseline observation carried forward (BOCF) for missing data. Baseline observation carried forward will be used rather than last observation carried forward (LOCF) as it is a more conservative approach. An assumption is being made in this case that participants who did not return for follow up have not lost or gained weight since the baseline appointment. The purpose of the intention to treat analysis is to maintain the benefits of the randomisation at baseline so that known and unknown confounders are as balanced as possible between groups.

The second analysis presents the mean weight change in each group (in all participants using baseline observation carried forward and in completers). The third table will be a sub-analysis which shows the results within and between groups for only those that completed 6 month follow up. A further two sub analyses will be conducted which show the results within and between groups if participants are analysed in the groups to which they allocated themselves (i.e. if a participant reports at follow up that they used a different intervention other than the one assigned). This analysis will be conducted for all participants in the trial using baseline observation carried forward for missing data and for trial completers only.

After each regression analysis, the residuals will be plotted to check that they meet the assumption of a normal distribution. Weight at follow up is adjusted for the baseline balancing variables.

5.18.10 Statistical significance

As this is an exploratory pilot trial which is hypothesis generating, there is a potential danger of multiple testing and a Type 1 statistical error arising by chance. For this reason, the statistical analysis plan has outlined the outcomes *a priori*. A significance level of ($p<0.05$) will be set for investigating differences in outcomes between groups and over time although given the danger of multiple testing on a small sample size results must be interpreted with caution.

5.19 Conclusion

This chapter has described the methodology used in the 6 month ‘My Meal Mate’ (MMM) pilot trial including the recruitment of participants, trial design, trial procedure, data collection methods and statistical analysis plan. The findings of the trial will be presented in chapters 6 -8. The pilot trial and other elements of the overall project will be brought together in the overall discussion chapter (chapter 9) at the end of the thesis.

Chapter 6: Feasibility results of the ‘My Meal Mate’ (MMM) pilot trial.

6.1 Introduction

Previous chapters have demonstrated the potential for a smartphone application for weight loss (chapter 1) and the gaps in the current evidence base (chapter 2). The development of a smartphone intervention for weight loss has been described (chapter 3) and the MMM app has been validated against a reference measure of diet and shown to have potential as a dietary assessment tool (chapter 4). A 6 month pilot trial of MMM has been conducted and the methodology has been described in the previous chapter (chapter 5).

The findings of the ‘My Meal Mate’ (MMM) pilot trial have been divided into three chapters in order to consider results related to feasibility, acceptability and changes in anthropometry. The following is the first of the three results chapters which will present the feasibility results of the ‘My Meal Mate’ (MMM) intervention and the pilot trial. This chapter will include a description of the sample at baseline and the presentation of the feasibility outcomes in accordance with pre-defined criteria (process, resource and management) as described in Chapter 5, section 5.18.3.

6.2 Methods

For a description of the MMM intervention please see Chapter 3. The methodology of the pilot trial has been previously described in Chapter 5. The statistical analysis in this chapter was conducted using Stata 11 (Stata corp) and analysis conducted in accordance with the statistical analysis plan (Chapter 5, section 5.18).

6.3 Results

6.3.1 Characteristics of the MMM pilot trial sample at baseline

Table 12 shows the baseline characteristics of the pilot study participants by intervention group. There were no statistically significant differences found between the three intervention groups for the factors balanced on at minimisation; gender (p=0.97), age (p=0.8) and BMI (kg/m^2) (p =0.7). Of the 128 adults enrolled, 99/128 (71%) were female and 117/128 (91%) of white ethnic origin. The mean age of participants was 42 (SD: 9) years and 74/128 (58%) were employed in managerial and professional occupations. The mean participant BMI was 34 (SD: 5) kg/m^2 with over three quarters of participants (77%) classified as obese (BMI ≥30 kg/m^2). The mean self reported BMI was 33 kg/m^2 which was found to be statistically significantly different compared to the measured BMI (mean difference: 0.9 kg/m^2, 95% CI: -1.2,-0.6, p=<0.001).   With regard to smoking behaviour, 12/128 (10%) of the sample described themselves as current smokers and 97/128 (76%) described their health status in the preceding 12 months as good, very good or excellent.

Table 12: Baseline characteristics of participants enrolled in a randomised, three armed (smartphone application, website, paper diary) pilot trial of "My Meal Mate" (MMM)

	Total (n=128)		**Smartphone (n=43)**		**Diary (n=43)**		**Online (n=42)**		
	Mean	**SD**	**Mean**	**SD**	**Mean**	**SD**	**Mean**	**SD**	***P*[2]**
Age (years)	41.9	9.1	41.2	8.5	42.4	8.3	41.9	10.6	0.8
Actual weight (kg)	97.0	18.1	96.4	16.0	97.9	18.7	96.4	19.9	0.9
Self-reported BMI (kg/m^2)	33.4	7.7	33.3	3.9	33.4	5.5	33.4	4.7	0.9
Actual BMI (kg/m^2)	34.2	5.2	33.7	4.2	34.5	5.7	34.5	5.6	0.7
% Body fat	36.0	4.1	35.9	3.8	35.9	4.8	36.2	3.9	0.9
Reported no. of previous weight loss attempts	9	12	9	13	9	12	8	10	0.9
	%	**N**	**%**	**N**	**%**	**N**	**%**	**N**	
Female (%)	77	99	77	33	77	33	79	33	0.1
Obese (BMI≥30)	77	98	81	35	74	32	74	31	0.7
Current smoker	10	12	5	2	19	8	5	2	0.03
Ethnicity (white)	92	117	100	43	83	35	93	39	0.02
Occupation (managerial & professional)[3]	58	74	74	32	51	22	49	20	0.02
Has a University degree	60	77	72	31	56	24	53	22	0.2
Health status in past 12 months(Excellent/v. good/good)	76	97	81	35	70	30	76	32	0.5
Has diabetes (yes)	1	1	0	0	0	0	3	1	0.3
Has hypertension (yes)	22	28	26	11	19	8	22	9	0.7
Main shopper (yes)	81	103	84	36	79	34	79	33	0.8
Main preparer (yes)	73	94	72	31	74	32	74	31	0.9
Currently dieting (yes)	73	94	70	30	74	32	76	32	0.8
Constant dieter (yes)	49	62	45	19	52	22	50	21	0.8
Ever kept a food diary (yes)	60	77	65	28	53	23	62	26	0.5
Lost more than 7lb in past year (yes)	39	49	40	17	30	13	45	19	0.4
Unintentional weight gain of ≥ 7lb in past year (yes)	72	91	67	28	81	35	68	28	0.3

Table 12: Baseline characteristics of participants enrolled in a randomised, three armed (smartphone application, website, paper diary) pilot trial of "My Meal Mate" (MMM) (N=128). Values are means ±SD or frequency & %.[2]Significant difference between groups assessed by one-way ANOVA, the Kruskal-Wallis equality-of-populations rank test, chi-square or Fisher's exact test; significant difference at *P*<0.05. [3]The occupation variable was measured as a) Managerial and professional, b) Intermediate, c) Small Employers and own account workers, d) Lower supervisory and technical, e) Semi-routine and routine occupations (categories b-e have been combined). Where numbers do not total 128, this is due to a small proportion of missing data.

6.3.2 Technology experience of the sample at baseline

Table 13 shows the participant responses at baseline to questions about technology usage. With regard to smartphone ownership, 51/128 (40%) of participants reported to owning a smartphone and 77/128 (60%) had used a smartphone application before. Of those that reported to owning a smartphone, Android and Apple were the most popular operating systems with 24/62 (39%) owning an Android phone and 25/62 (40%) an Apple phone. In terms of internet usage, 124/128 (97%) of the sample had internet access at home and 110/128 (86%) reported to using the internet daily. The intervention groups were well balanced with regard to technology attitudes and usage with no statistically significant differences found between intervention groups in confidence in using technology (p=0.9), smartphone ownership (p=0.6), internet access at home (p=0.7) and frequency of internet usage (p=0.08).

6.3.3 Differences between men and women in the sample at baseline

Although there was not found to be a statistically significant difference between the proportion of men and women that reported to having used a smartphone application before (p=0.13) there was found to be a statistically significant difference between men and women in terms of owning a smartphone with 18/29 (62%) of the men owning a smartphone and 33/99 (33%) of the women (p=0.003). There was not found to be a statistically significant difference in the type of smartphone owned by men or women (p=0.9). Similarly, the frequency of internet use was not found to differ in a statistically significant way by gender (p=0.2). The sample reported high confidence in using technology with a median score of 9 (IQR; 8 to 10) (on a 10-point Likert scale with 1=not confident at all and 10=extremely confident).

Table 13: Technology characteristics of 128 adults enrolled in the MMM pilot trial[1]

	Total (n=128)		Smartphone (n=43)		Diary (n=43)		Website (n=42)		
	Median	**IQR**	**Median**	**IQR**	**Median**	**IQR**	**Median**	**IQR**	***P*[2]**
Confidence in using technology[3]	9	8, 10	9	9, 10	9	8, 10	9	8, 10	0.9
	N	**%**	**N**	**%**	**N**	**%**	**N**	**%**	
Own a smartphone? (yes)	51	40	18	42	19	44	14	34	0.6
Use a smartphone? (yes)	59	46	24	56	20	47	15	36	0.2
Ever used a smartphone app? (yes)	77	60	31	72	24	56	22	54	0.2
Type of smartphone?									
Android (i.e. Google, HTC)	24	38	9	36	10	48	5	31	0.1
Apple (i.e. I-phone)	25	40	14	56	5	24	6	38	
RIM (i.e. BlackBerry)	5	8	1	4	2	10	2	13	
Internet access at home? (yes)	124	97	42	98	41	95	41	98	0.7
Uses internet daily (yes)	110	86	36	84	34	79	40	95	0.08

Table 13: Technology characteristics measured at baseline in a randomised, three armed (smartphone application, website, paper diary) pilot trial of "My Meal Mate" (MMM) (N=128). Values are medians, interquartile range, frequency and %. [2]Significant difference between groups assessed by the Kruskal-Wallis equality-of-populations rank test, chi-square or Fisher's exact test; significant difference at $P<0.05$. [3]Based on a 10-point scale (1=not confident at all; 10=extremely confident). Where numbers do not total 128, this is due to a small proportion of missing data.

6.4 Outcome: Process measures

6.4.1 Recruitment

Recruitment to the pilot trial took three months. Figure 37 is a CONSORT diagram (Shulz et al., 2010) showing the participant flow through the trial. A total of 336 (74% female) people initially expressed an interest in taking part in the trial and 231 (69%) of these were assessed for eligibility to take part. A large proportion, 145/336 (43%) of people responding to express an interest were from Leeds City Council and the second largest proportion 92/336 (27%) were from the University of Leeds. Figure 38 shows the recruitment sources of those who expressed an interest in taking part in the trial. Of those screened, 49/231 (21%) were excluded for not meeting the inclusion criteria, with just under half (49%) because their self reported BMI was less than 27 kg/m^2.

In total, 182 people met the eligibility criteria and were invited to a baseline appointment. Of those invited, 21 (12%) declined to participate, 13 (7%) did not respond and 19 (10%) agreed to attend but did not. This left 129 people who attended baseline appointments. One person was excluded at baseline because their BMI was found to be below 27 kg/m^2 when measured. In total, 128 people were allocated by minimisation to one of the three groups. This was 38% (128/336) of those that had originally expressed an interest in taking part and 71% (128/182) of those who had been invited to take part who met the eligibility criteria. With regard to sources of recruitment, the University of Leeds provided the most trial participants (54/128, 42%) and Leeds City Council provided the second highest proportion (50/128, 39%). Figure 39 shows the breakdown of recruitment sources of those enrolled in the trial. Regardless of employer, the majority of participants (107/128, 84%) had heard about the study from an electronic source either by email (79/128, 62%) or intranet (28/128, 22%).

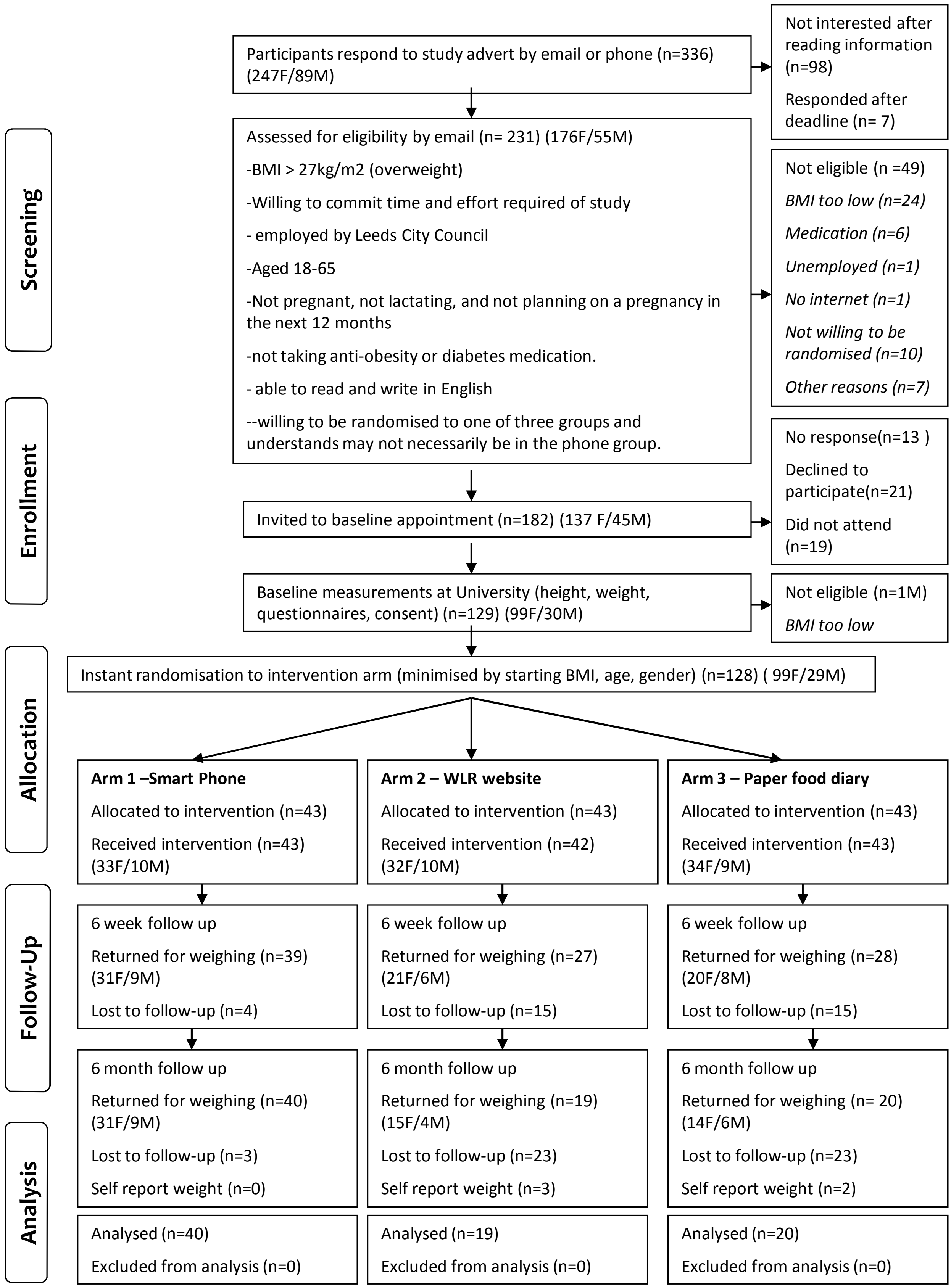


Figure 37: Flow of participants through a randomised, three armed, 6 month, pilot trial of "My Meal Mate" (MMM) a smartphone application for weight loss (N=128).

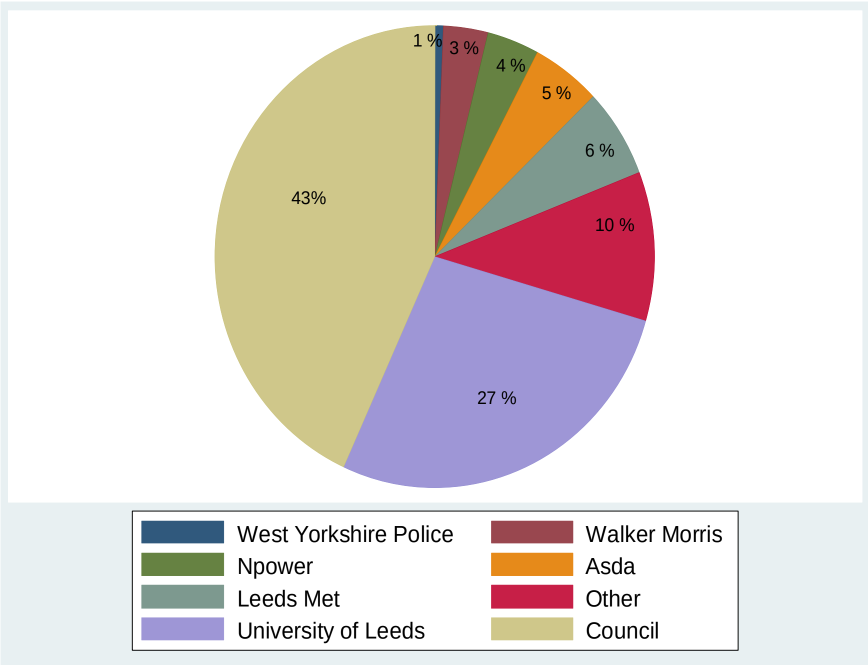


Figure 38: Proportion of expressions of interest to advertisement from each recruitment source (n=336) in the MMM pilot trial

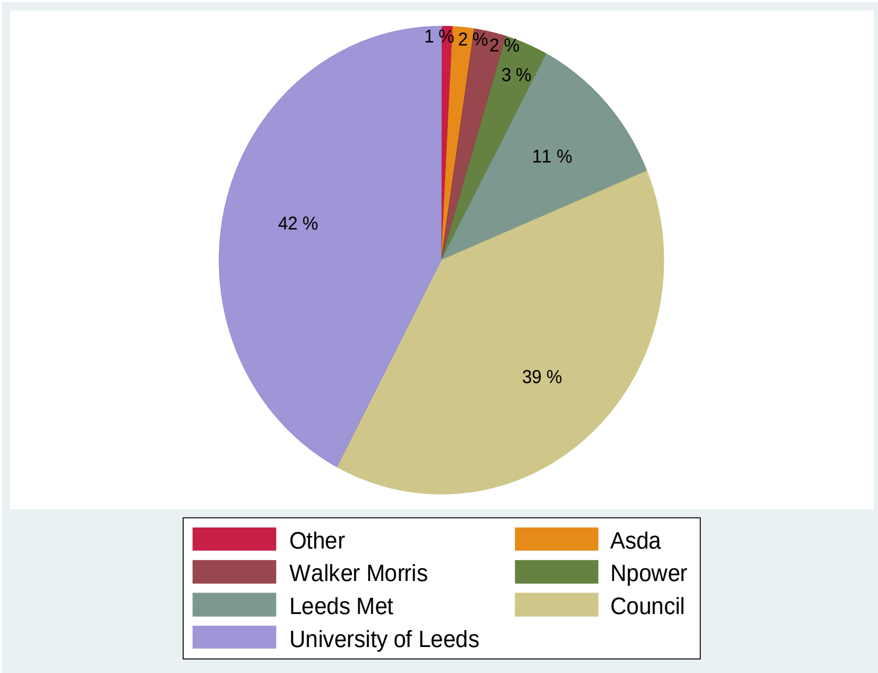


Figure 39: Sources of recruitment for the 128 participants enrolled in the MMM pilot trial

6.4.2 Adherence to the trial

Adherence to the pilot trial and adherence to the individual interventions (frequency of intervention use) are considered separately. In terms of trial retention, 94/128 (73%) people returned for 6 week follow up measurements and 79/128 (62%) returned at 6 months. The differences between completers and non completers at 6 months have been reported in table 14. Compared to trial completers, non-completers had a statistically significantly greater baseline BMI (completers initial BMI=33.1 kg/m^2, SD: 5, non completers initial BMI=36.1 kg/m^2 SD: 6, p=0.001) and initial % body fat (completers initial body fat =35.3%, SD: 4, non completers initial body fat =37.4%, SD: 4, p=0.01). There was a statistically significant difference in self-reported health status at baseline between completers and non-completers with 86% of completers reporting their health status as good or excellent compared to 59% of non completers (p=0.001).

Trial drop-out was statistically significantly different between the groups (p=0.001) with 3 people not attending 6 month follow up in the smartphone group compared to 23 people not attending 6 month follow up in the paper diary group and 23 people not attending 6 month follow up in the website group. In terms of retention rates, retention was 93% (95% CI; 81-99) in the smartphone group, 45% (95% CI; 30-61%) in the website group and 47% (95% CI; 31 to 62) in the paper diary group at 6 months.

The website group was investigated separately with regard to variables specific to technology usage (table 15) but there were not found to be any statistically significant differences between trial completers and non completers in these variables. The reasons that the participants gave for non attendance at follow up are shown in table 16. The most popular reasons given for non attendance were a dislike of the study equipment (n=12) and personal issues (n=6).

Table 14: Differences in baseline characteristics between trial completers and non completers at 6 months[1]

	Non-completers (n=45)	Completers (n=79)	*P* [2]
Age (years), mean (SD)	43.2 (9.0)	41.2 (9.3)	0.2
BMI (kg/m2), mean (SD)	36.1 (5.8)	33.1 (4.5)	0.001
% Body fat, mean (SD)	37.4 (4.2)	35.3 (4.0)	0.01
Motivation to lose weight [3], mean (SD)	8 (2)	8 (1)	0.4
Confidence in ability to lose weight [4], mean (SD)	7 (2)	7 (2)	0.7
Number of previous weight loss attempts, mean (SD)	11.9 (16.1)	6.9 (7.9)	0.1
Consideration of future consequence score [5], mean (SD)	32.5 (8.5)	30.7 (7.2)	0.2
Conscientiousness score [6], mean (SD)	79.6 (11.8)	76.3 (11.3)	0.1
Female, n (%)	38 (78)	61 (77)	0.9
Obese (BMI≥30) (yes), n (%)	39 (86.7)	55 (69.6)	0.05
Ethnicity (white), n (%)	39 (88.6)	74 (93.7)	0.3
Smoking status (current smokers), n (%)	7 (15.9)	5 (6.4)	0.09
Occupation (managerial professions), n (%)	21 (46.7)	50 (64.1)	0.06
Reported health status as excellent/v.good/good, n (%)	26 (59.1)	68 (86.1)	0.001
Main shopper (yes), n (%)	34 (75.6)	66 (83.5)	0.3
Main preparer (yes), n (%)	33 (73.3)	58 (73.4)	0.9
Constant dieter (yes), n (%)	25 (56.8)	36 (46.2)	0.3
Ever kept a food diary (yes), n (%)	26 (57.8)	47 (59.5)	0.9

Table 14: Differences in baseline characteristics between trial completers and non-completers in a randomised, three armed (smartphone application, website, diary) 6 month pilot trial of "My Meal Mate" (MMM); a smartphone application for weight loss (N=128). Values are means and standard deviation or frequency and percentage. [2] Significant differences between completers and non completers assessed by one-way t-test. [3] Based on a 10-point scale (1=not motivated at all; 10=extremely motivated). [4] Based on a 10-point scale (1=not confident at all; 10=extremely confident). [5] Measured by consideration of future consequences scale. [6] Measured by "International Personality Item Pool" (IPIP) conscientiousness scale.

Table 15: Attitudes towards technology as measured at baseline according to follow-up status at 6 months for 42 adults enrolled in the online group of the MMM pilot trial[1]

	Online group (n=42)				
	Non-completers (n=25)		**Completers (n=17)**		
	Median	**IQR**	**Median**	**IQR**	***P*[2]**
Confidence in using technology[3]	9	9, 10	9	8, 10	0.4
Like gadgets and new technology?[4]	3	3, 4	3	3, 3	0.7
Ability with the internet[5]	1	1, 2	1	1, 2	0.9
	N	**%**	**N**	**%**	
Internet access at home? (yes)	25	100	16	94	0.4
Internet usage? (yes)					0.5
Daily	23	92	17	100	
2-6 times/week	2	8	0	0	
Less than once/week	0	0	0	0	
Less than once/month	0	0	0	0	

Table 15: Differences in technology characteristics between trial completers and non-completers in the online/website group of a randomised, three armed (smartphone application, website, diary) 6 month pilot trial of "My Meal Mate" (MMM); a smartphone application for weight loss (N=128). Values are medians & IQR or frequency & %. [2]Significant difference between groups assessed by the two-sample Wilcoxon ranksum (Mann-Whitney) test, chi-square or Fisher's exact test; significant difference at $P<0.05$. [3]Based on a 10-point scale (1=not confident at all, 10=extremely confident). [4]Based on a 4-point scale (1=not like me; 4=describes me perfectly).[5]Based on a 5-point scale (1=Excellent; 5=Poor).

Table 16: Reasons for non attendance at 6 month follow-up in MMM pilot trial non-completers at 6 months[1]

Reason for non attendance[2]	**Smartphone (n=43)**	**Diary (n=43)**	**Online (n=42)**	**Total (n=128)**
Unable to contact to determine reason, n (%)	0 (0)	9 (20.9)	9 (21.4)	18 (14.1)
Did not like study equipment, n (%)	3 (6.9)	5 (11.6)	4 (9.5)	12 (9.4)
Holiday during follow up, n (%)	0 (0)	2 (4.6)	0 (0)	2 (1.6)
Illness, n (%)	0 (0)	2 (4.6)	2 (4.7)	4 (3.1)
Personal issues, n (%)	0 (0)	3 (6.9)	3 (7.1)	6 (4.7)
Study too time consuming, n (%)	0 (0)	1 (2.3)	1 (2.4)	2 (1.6)
Pregnancy, n (%)	0 (0)	0 (0)	1 (2.4)	1 (0.8)
Willing to self-report weight only, n (%)	0 (0)	1 (2.3)	3 (7.1)	4 (3.1)
Total	3	23	23	49

Table 16: Reasons for non attendance at 6 month follow up in a randomised, three armed (smartphone application, website, diary) 6 month pilot trial of "My Meal Mate" (MMM); a smartphone application for weight loss (N=128). [1]Values are frequency and percentage of participants responding with a particular reason.[2]Data collected from withdrawal questionnaires completed by the participants (n=14) or by direct email/telephone contact.

6.4.3 Participant withdrawal from the pilot trial

In total, 26 people made contact to withdraw, 20 of these were pre-6 week follow up and 6 people withdrew between 6 weeks and 6 months. All 26 participants were asked to complete a withdrawal questionnaire and 14 of those were returned. Of the 20 people who withdrew prior to the 6 week follow up date, 4 returned for 6 week follow up and 1 also attended 6 month follow-up. Of the 6 who withdrew post 6 week follow-up, one came back for 6 month follow-up.

6.4.4 Balance on randomisation factors at 6 weeks and 6 months between the groups

There were no statistically significant differences between the intervention groups in those completing follow-up at 6 weeks and 6 months, on the baseline 'balancing variables'; age (p=0.73 and p=0.1 respectively), baseline BMI (kg/m^2) (p=0.61 and p=0.4 respectively), gender (p=0.7 and p=0.97 respectively). The balance between groups on these important balancing variables was preserved at follow up despite unequal drop out between groups. Table 17 shows the balance between the minimisation variables at 6 weeks and 6 months.

Table 17: Balance on randomisation factors at 6 weeks and 6 months between the groups in the MMM pilot trial[1]

	6 weeks							6 months						
	Smartphone (n= 39)		**Diary (n=28)**		**Website (n=27)**			**Smartphone (n=40)**		**Diary (n=20)**		**Website (n=19)**		
	Mean	**95% CI**	**Mean**	**95% CI**	**Mean**	**95% CI**	***P***	**Mean**	**95% CI**	**Mean**	**95% CI**	**Mean**	**95% CI**	***P***
Age (years)[2]	41.2	38.3, 43.9	42.5	38.9, 46.2	40.5	35.9, 45.1	0.74	41.2	38.5, 43.9	44.1	40.0, 48.2	38.0	32.9, 43.1	0.1
Baseline BMI (kg/m^2)[2]	33.6	32.2, 34.9	33.8	31.4, 36.3	34.9	32.4, 37.4	0.61	33.8	32.4, 35.1	32.6	30.5, 34.7	32.0	29.5, 34.5	0.4
	N	**%**	**N**	**%**	**N**	**%**		**N**	**%**	**N**	**%**	**N**	**%**	
Gender (%female)[3]	30	77	18	75	21	69	0.7	31	77.5	14	70.0	16	84.2	0.1

Table 17: Age, baseline BMI and gender in trial completers at 6 weeks and 6 months in the randomised, three armed (smartphone application, website, diary), pilot trial of "My Meal Mate" (MMM). 1Values are means and 95% confidence intervals. [2]Significant difference between the three groups for age and baseline BMI assessed by one-way ANOVA. [3]Significant differences between the three groups for gender assessed by Chi square.

6.4.5 Frequency of use of the interventions

Table 18 shows the total number of days the interventions were used for each group at 6 weeks and 6 months (a complete day is considered as a day with ≥500 and ≤5000 kcal energy intake recorded). Intervention usage was highest in the smartphone group at 6 months with a median of 82 (IQR: 28, 172) days completed compared to 18 (IQR: 0, 37) days in the paper diary group and 15 (IQR: 7, 45) in the website group. There was found to be a statistically significant difference in the number of days usage between the groups at 6 weeks (p <0.001) and 6 months (p =<0.001). Pairwise comparison showed that this difference lies between the smartphone group and the paper diary group (p<0.0001), between the smartphone group and the website group (p <0.0001) but not between the website group and the paper diary group (p =0.14). Table 19 shows the number of participants in each group who have recorded a certain number of days on their allocated intervention. The table shows a decline in the number of self monitoring days completed in each group over time. At 6 months, 7 people had completed the smartphone electronic diary every day, no participants were found to have complete daily usage in the website and paper diary groups. Figure 40 also displays the decline in self monitoring within each intervention arm over time. In the smartphone group, 2 people recorded ≤7 days of food entry compared to 19 in the paper diary group (assuming 0 entries for 16 non-returned diaries at 6 weeks) and 10 people in the website group.

Table 18: Total number of days that the interventions were used in the MMM pilot trial[1]

	Smartphone (n=43)	**Diary (n=43)**	**Website (n=42)**	***P*[2]**
Total number of days intervention used				
6 weeks (42 days), median (IQR)	36 (21, 42)	29 (0, 38)	15 (6, 33)	0.004
Completing every day, n (%)	14 (33)	8 (19)	3 (7)	
6 months (184 days), Median (IQR)	82 (28, 172)	18 (0, 37)	15 (7, 45)	<0.001
Completing every day, n (%)	7 (16)	0 (0)	0 (0)	
Completing 0 days/not returning paper diary, n (%)	0 (0)	17 (40)	3(7)	

Table 18: Frequency of daily use of the interventions in a randomised, three armed (smartphone application, website, paper diary) pilot trial of "My Meal Mate" (MMM) (N=128). [1] Values are median days with interquartile range, frequency and proportion of participants completing every day for 6 weeks and 6 months and frequency and proportion of those completing zero days. (A day of dietary self monitoring is considered to be a day with ≥500 and ≤5000 kcal energy recorded.) [2]Significant difference between groups assessed by Kruskal-Wallis equality-of-populations rank test as variable not normally distributed and not improved after log transformation, significant difference at *P*<0.05.

Table 19: Breakdown of frequency of days of intervention usage by different time points throughout the MMM trial period (by intervention group)[1]

	Smartphone (n=43)		Diary (n=43)[2]		Website (n=42)	
Number of entries completed by participants	Freq.	%	Freq.	%	Freq.	%
Participants (%) completing 0 entries	0	0	17	40	3	7
Participants (%)completing ≥ 7 days	41	95	24	56	32	76
Participants (%)completing ≥ 14 days	38	88	24	56	21	50
Participants (%)completing ≥ 21 days	36	84	20	47	19	45
Participants (%)completing ≥ 28 days	33	77	20	47	16	38
Participants (%)completing ≥ 35 days (5 weeks)	31	72	14	33	14	33
Participants (%)completing ≥ 42 days (6 weeks)	30	70	9	21	13	31
Participants (%)completing ≥ 62 days (2 months)	23	53	5	12	8	19
Participants (%)completing ≥ 93 days (3 months)	20	47	4	9	5	12
Participants(%)completing ≥ 124 days (4months)	15	35	2	5	4	10
Participants (%)completing ≥ 155 days (5 months)	12	28	1	2	1	2
Participants (%)completing ≥ 184 days (6 months)	7	16	0	0	0	0

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Table 19: Intervention use at different time points throughout a randomised, three armed (smartphone application, website, diary) 6 month pilot trial of "My Meal Mate" (MMM); a smartphone application for weight loss (N=128). [1]Values are frequency and percentage of participants completing a number of days at each time point. A complete day is considered to be one with ≥500 and ≤5000 kcal energy recorded. [2]Assumption of 0 days completed for those diaries not returned at 6 week follow up (16 diaries missing).

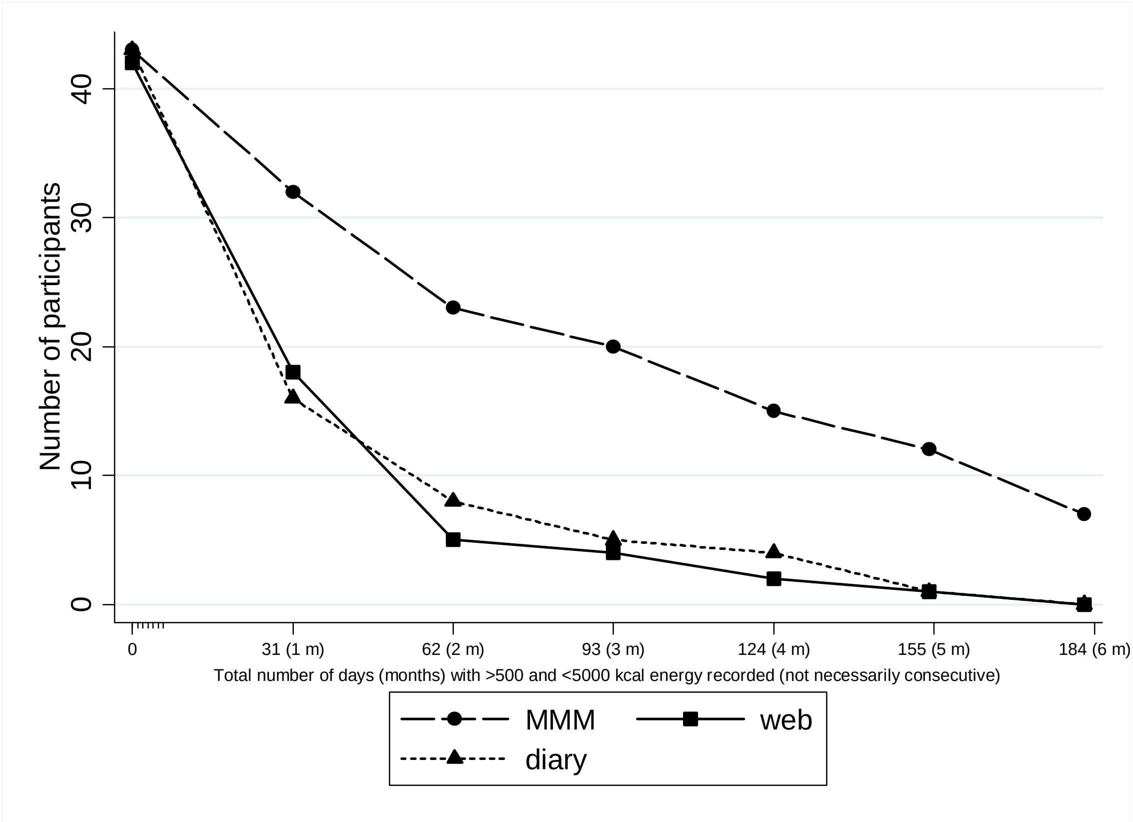

Figure 40: Intervention use in a randomised three arm pilot trial (N=128) of "My Meal Mate" (MMM). Adherence to the intervention arms (smartphone application, website, paper diary) over the trial duration (6 months) is shown by total number of days completed in e ach intervention group. Data collection was conducted over Summer 2011 which was 4 months of 31 days and 2 months of 30 days giving a total 184 days for complete 6 months usage. A complete day is considered to be one with ≥500 and ≤5000 kcal energy recorded. Intervention use is for overall total days completed and not necessarily consecutive days.

6.5 Differences between high, moderate and low frequency MMM users

The differences between those participants who displayed high adherence to dietary self monitoring and recorded in the MMM electronic diary frequently and those who had low adherence to self monitoring and recorded in the MMM electronic diary less frequently have been investigated. The 'frequency of use' variable for the MMM group (number of days using the equipment) is a continuous variable however its distribution was found to be u-shaped and not improved after log transformation making it unsuitable to be used in a regression analysis. For analysis, the variable has been split so that it can be treated as a categorical variable. Due to the distribution of the data, the variable was cut at three points to make categories (low, moderate and high adherence frequency of use). The variable was cut automatically by STATA at three points which gave an equal number of participants in each group. In this case it means a definition of low frequency over 6 months use as ≤42 days (22% of total days) (13 people), moderate frequency use as ≥43 days to 128 days (23%-69% of total days) (15 people) and high frequency use as ≥129 days (70% of total days) (15 people) with dietary data recorded (≥500 and ≤5000 kcal).

Table 20 presents differences in key variables measured at baseline between the different categories of frequency of MMM daily use. There were no statistically significant differences found between different categories of user for these key variables. Table 21 presents the results of a regression analysis which uses weight at follow up (with baseline observation carried forward) as the outcome variable and the adherence category as a predictor variable. The model was adjusted for baseline weight but no other adjustments were made given that no variables were found to differ in a statistically significant way between the categories.

The results of the regression analysis show that those in the highest adherence category (recorded ≥129 days on the app) had a −6.4kg (95% CI; −10.0, −2.9) lower follow up weight (adjusted for baseline weight) than those in the lowest adherence category who recorded ≤42 days. This difference was found to be statistically significant (p=0.001). The difference in follow up weight was not found to be statistically significantly different between those in the moderate category of adherence and those in the low category of adherence (p=0.325). If the dummy variable is recoded so that the medium adherence category is the reference category, the high adherence category is found to have a −4.7kg (95% CI: −8.2, −1.1) lower follow up weight (adjusted for baseline weight) (p=0.01). However, it is worth noting that although still significant as the sample is very small the confidence intervals are fairly wide.

Table 20: Investigation of the differences between categories of MMM use for key variables measured at baseline in the MMM group[1]

	Category of frequency of MMM use for dietary self monitoring[2]						
	Low (n=13)		Moderate (n=15)		High (n=15)		
Variable	Mean	95% CI	Mean	95% CI	Mean	95% CI	P value
Age (years)[3]	39.1	34.4, 43.8	40.4	34.9, 45.8	44.1	39.7, 48.4	0.27
Baseline weight (kg)[3]	96.8	88.2, 105.3	100.5	90.1, 110.9	93.5	84.8, 102.1	0.51
Baseline BMI (kg/m^2)[3]	33.8	31.1, 36.4	34.8	32.3, 37.2	32.7	30.6, 34.9	0.44
Conscientiousness score[3,5]	76.5	66.1, 84.8	76.1	70.0, 82.2	81.2	76.0, 86.5	0.43
Score for CFC[3,6]	31.9	28.2, 35.6	33.7	29.4, 38.0	28.2	23.8, 32.5	0.12
Weight change 6 weeks[3]	−1.8	−2.7, −0.8	−3.4	−5.0, −1.7	−3.6	−5.0, −2.2	0.10
	N	**%**	**N**	**%**	**N**	**%**	
Female (%)[4]	11	79	10	71	12	80	0.85
Ethnicity (White)[4]	14	100	14	100	15	100	1.00
Managerial & professional occupation[4]	10	71	10	71	12	80	0.90
Has a University degree[4]	12	86	8	57	11	73	0.43

Table 20: Differences in baseline characteristics for those in the MMM group between different categories of adherence in a randomised, three armed (smartphone application, website, diary) 6 month pilot trial of "My Meal Mate" (MMM); a smartphone application for weight loss (N=128). [1] Values are means, 95% CI, frequency and percentages. [2]Low frequency is defined as ≤42 days of dietary self monitoring (n=14), moderate frequency use is ≥43 days to ≤128 days and high frequency use is ≥129 day. A day of self monitoring is one with ≥500 and ≤5000 kcal energy recorded. [3]Significant difference between the three categories of adherence assessed by one-way ANOVA. [4]Signficiant differences assessed by Kruskal Wallis. [5]Measured by "International Personality Item Pool" (IPIP) conscientiousness scale. [6]Measured by consideration of future consequences scale.

Table 21: Regression analysis of category of MMM use as a predictor of follow up weight (adjusted for baseline weight) in the MMM arm of the MMM pilot trial

Category of adherence	N	Coefficient	95% CI	p
Low	14	reference		
Moderate	14	−1.8	−5.3, 1.8	0.325
High	15	−6.4	−10.0, −2.9	0.001

Table 21: Investigation of the relationship between frequency of use category and follow up weight (adjusted for baseline weight) in the MMM group of a randomised, three armed (smartphone application, website, diary) 6 month pilot trial of "My Meal Mate" (MMM); a smartphone application for weight loss. Low frequency is defined as ≤42 days of dietary self monitoring (n=14), moderate frequency use is ≥43 days to 128 days and high frequency use is ≥129 day. A day of self monitoring is one with ≥500 and ≤5000 kcal energy recorded. No other variables were included as adjustments. Using the 'testparm' command the overall significance for adherence category variable is p=0.0019.

6.6 Pattern of MMM use over the course of the trial

As the frequency of MMM use is an overall count of total days with dietary self monitoring over the course of the trial it misses information about the distribution of the days. For example, person A and B may have both recorded 50 days on the MMM app but person A may have monitored consecutively at the beginning of the trial for 50 days and then stopped where as person B may have recorded 50 days intermittently over the course of the 6 month period. The pattern of monitoring in relation to weight loss has been investigated. Figure 41 shows the distribution of dietary self recording over the course of the trial. The distribution of data in figure 41 has been visually inspected and used to divide the participants into discrete patterns of self monitoring. The four assigned patterns of monitoring are described in table 22 below.

Table 22: Description of the categories of types of dietary self monitoring

Category	Name	Definition
1	Stopped early	Last diary entry before 31 days
2	Moderate term monitoring	Last entry before 92 days (approx. 3 months)
3	Long term intermittent monitoring	Monitored over the long term (3-6 months) but intermittently with breaks
4	Long term consecutive monitoring	Monitored mostly consecutively over the long term (no more than 4 breaks, and breaks never longer than 10 days)

Table 22: Categories of types of dietary self monitoring in the MMM arm of a randomised, three armed (smartphone application, website, diary) 6 month pilot trial of "My Meal Mate" (MMM); a smartphone application for weight loss (N=128).

The differences between the patterns of dietary self monitoring in a number of key variables at baseline were investigated in table 23. A regression analysis was conducted to account for baseline weight. The regression output can be seen in table 24.

Figure 41: Plot of daily use of MMM for dietary self monitoring in a randomised, three armed (smartphone application, website, and diary) 6 month pilot trial of "My Meal Mate" (MMM); a smartphone application for weight loss (N=128). The X axis is the MMM ID number that was automatically assigned to the participant and the y axis is dietary self monitoring in days. Each green shaded box is a day with ≥500 and ≤5000 kcal energy recorded on MMM.

Table 23: Investigation of the differences between patterns of MMM use for key variables measured at baseline in the MMM group[1]

	Pattern of MMM use[2]							
	Stopped early (n=11)		Stopped before 92 days (n=9)		Intermittent over long term (n=11)		Consecutive over long term (n=12)	
Variable	**Mean**	**95% CI**	**Mean**	**95% CI**	**Mean**	**95% CI**	**Mean**	**95% CI**
Age (years)	36.7	31.6, 41.9	42.2	34.2, 50.3	42.8	37.7, 48.0	43.2	38.1, 48.3
Baseline weight (kg)	96.4	84.8, 107.9	94.5	80.4, 108.6	96.3	85.2, 107.5	99.5	90.4, 108.6
Baseline BMI (kg/m^2)	33.9	30.9, 37.0	31.2	29.9, 32.6	33.6	30.5, 36.7	35.5	32.7, 38.2
Conscientiousness score[3]	75.6	64.4, 86.8	78.0	67.9, 88.1	79.6	72.9, 86.4	78.2	73.2, 83.2
Score for CFC[4]	33.0	30.4, 35.6	30.6	24.3, 36.9	29.1	23.6, 34.6	32.5	26.9, 38.2
Weight change 6 weeks	−1.4	−2.9, −0.1	−2.6	−3.9, −1.4	−4.2	−6.5, −1.9	−3.4	−4.4, −2.4
	N	**%**	**N**	**%**	**N**	**%**	**N**	**%**
Female (%)	9	81	5	56	9	81	10	83
Ethnicity (White)	11	100	9	100	11	100	12	100
Managerial & professional occupation	8	73	9	100	10	91	5	42
Has a University degree	7	64	7	78	9	82	8	67

Table 23: Differences in baseline characteristics for those in the MMM group between different patterns of MMM use in a randomised, three armed (smartphone application, website, diary) 6 month pilot trial of "My Meal Mate" (MMM); a smartphone application for weight loss (N=128). A day of self monitoring is one with ≥500 and ≤5000 kcal energy recorded. [1] Values are means, 95% CI, frequency and percentages. [2] "stopped early" have recorded less than 31 days, "consecutive over the long term" monitored over the 6 month period with no more than 4 breaks of no more than 10 days at a time. A day of self monitoring is one with ≥500 and ≤5000 kcal energy recorded. [3]Measured by "International Personality Item Pool" (IPIP) conscientiousness scale. [4]Measured by consideration of future consequences scale

Table 24: Regression analysis of pattern of MMM use as a predictor of follow up weight (adjusted for baseline weight) in the MMM arm of the MMM pilot trial

Pattern of adherence	N	Coefficient	95% CI	p
Stopped early	11	reference		
Moderate	9	-3.1	−7.4, 1.2	0.157
Long but intermittent	11	-7.5	−11.6, −3.4	0.001
Long consecutive	12	-3.2	−7.2, 0.8	0.116

Table 24: Investigation of the relationship between adherence category and follow up weight (adjusted for baseline weight) in the MMM group of a randomised, three armed (smartphone application, website, diary) 6 month pilot trial of "My Meal Mate" (MMM); a smartphone application for weight loss. A day of self monitoring is one with ≥500 and ≤5000 kcal energy recorded. No other variables were included as adjustments in the regression given that no key variables were found to be statistically significant at baseline. Using the testparm command the overall significance for the pattern of monitoring is p=0.007.

The results of the regression analysis show that those who monitored intermittently over the long term had a −7.5kg (95% CI; −11.6, −3.4) lower follow up weight (adjusted for baseline weight) than those who stopped monitoring completely before 31 days (p=0.001). The difference in follow up weight was not found to be statistically significantly different between the other two categories as compared to the 'early stoppers' reference group. The confidence intervals around the coefficients are wide which is likely to be reflective of the small sample size within categories once the variable is split.

6.7 A description of entry times on MMM

Figure 42 shows the total number of food and drink items entered into the MMM electronic diary for all participants by hour of entry. The graph is of interest as it shows three peaks around morning, midday and evening when it is likely items are entered as eaten at meal times. More items appear to be entered in the evening which may reflect the quantity eaten in the evening or may reflect entering food items in a 'batch' to reflect the days intake. As the actual time and date an item is entered into MMM by the participant is time-stamped with a 'created on date' separately from the 'diary date' which the entry is allotted to, it allows for investigation of the number of days where 'created on date' and 'diary date' do not match. The number of entries where the 'created date' and 'diary date' were not matched was investigated, and it was found that not all food and drink entries are added to the diary on the date to which they apply and this varies by individual participant. Of all individual food and drink items entered onto MMM over the course of the trial, 6391/32581 (20%) had a 'created on' date on a day after the 'diary date', 1113/32581 (3%) had a 'created on' date on a day prior to the 'diary date' and 25066/32581 (77%) items had a 'created on' date the same as the 'diary date'.

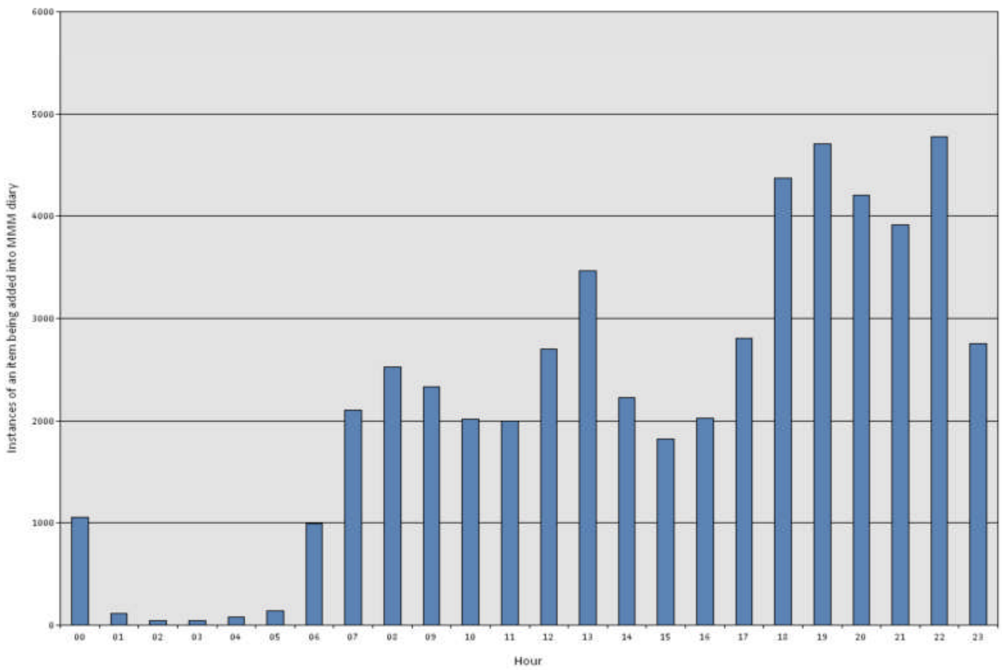

Figure 42: Total number of food and drink items entered into MMM by hour of the day in a randomised, three armed (smartphone application, website, and diary) 6 month pilot trial of 'My Meal Mate' (MMM); a smartphone application for weight loss (N=128).

6.8 Website usage

The median number of log-ins to the website over the 6 month period was 33 (IQR: 11, 75). The frequency of website log-ins ranged from 2-375. Figure 43 shows the frequency of website log-ins by individual participant.

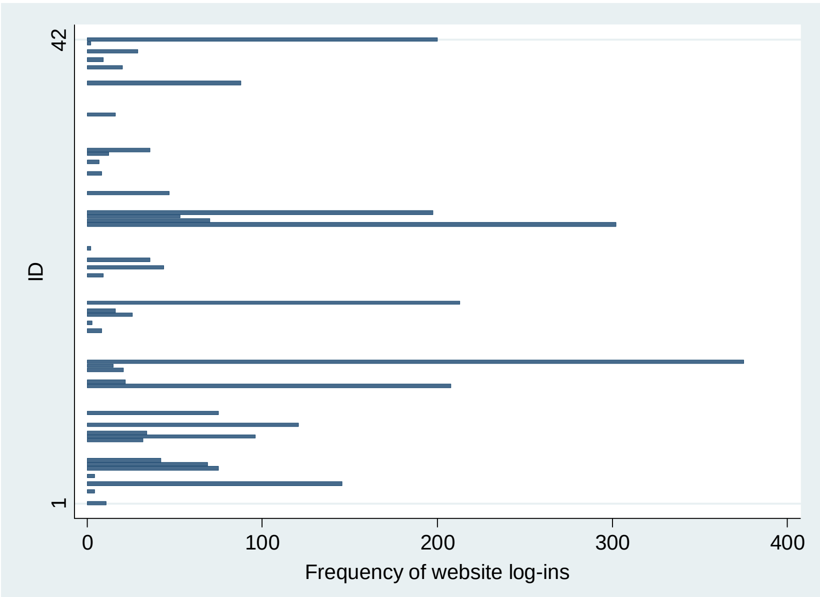

Figure 43: Frequency of log-ins to the WLR over the course of the trial by individual participant ID (n=42). Number of log-ins collected automatically by "Weight Loss Resources".

6.9 Frequency of forum use

There were a total of 62 posts to the online forum which was set up for participants to access support over the course of the trial. The last post in the forum was on October 12 2011, two months before the end of the trial. Table 25 below shows the number of views and posts to the forum.

Table 25: Frequency of forum posts and views during the MMM pilot trial [1]

Forum thread	Freq. of topics	Freq. of posts	Freq. of views
General	12	16	253
Smartphone	10	25	301
Website	6	17	133
Diary	2	4	60
Total	30	62	747

Table 25: Frequency of posts and views to the online forum set up to support participants during the trial. All participants were given a log-in to access the forum at the start of the trial and encouraged to do so to ask questions of the research team and for social support. [1]Frequency is a count of overall posts and views and does not account for individual participants (so could be the same participant multiple times).

6.10 Outcome: Resources

6.10.1 Equipment and questionnaire return

All 43 smartphones were returned undamaged. Of the three participants in the smartphone group that declined to be weighed, two returned the smartphones at the 6 week follow up appointment and one declined to attend the 6 week follow up appointment and the phone was collected from her directly. With regard to the paper diaries, 27/43 diaries were returned at 6 weeks and 12/43 diaries were returned at 6 months. At baseline all but one participant brought the questionnaires with them which they had been asked to complete in advance. At 6 weeks, 93/128 questionnaires were returned (39 in the smartphone group, 28 in the website group and 26 in the paper diary group) and at 6 months, 77/128 questionnaires were returned (38 in the smartphone group, 19 in the website group and 20 in the paper diary group).

The individual scales used in the baseline questionnaires were designed for large population samples and the pilot trial was not adequately statistically powered to detect moderate changes over time in these measures. However, the scales were piloted for feasibility and ease of use with the sample. Each scale was completed by over 80% of the sample. The IPAQ was the least well completed and several participants asked questions whilst completing the questions and some appeared to find it challenging. The three factor eating questionnaire was completed by 114/128 participants and several participants mentioned to the research team that they found the questionnaire repetitious and tedious to complete. Table 26 below shows the number of scales successfully completed at baseline.

Table 26: Numbers completing individual scales at baseline in the MMM pilot trial

Scale	Completed	
	Freq.	%
International physical activity questionnaire (IPAQ)	105	82
Three factor eating questionnaire (TFEQ)	114	89
Consideration of future consequences (CFC)	115	90
Technology readiness index (TRI)	121	94
Short form food frequency questionnaire (SFFQ)	125	98

Table 26: Frequency and proportion (of total sample) of participants completing individual scales at baseline. A scale is considered to be complete if it is suitable to be included in an analysis as per the individual guidelines relating to each scale.

6.10.2 Time taken and study personnel required

The recruitment period took longer than planned due to a lower than expected response rate from Leeds City Council. After one month, recruitment was extended to other large employers in order to get an adequate number and recruitment took 3 months in total (recruitment continued during the enrolment phase of the trial). The trial enrolment period took one month. Four research assistants were sufficient to take baseline measurements at these sessions and two members of staff were in each post-randomisation intervention training session. Although the number of staff used in the trial was sufficient, a difficulty arose in trying to use different volunteers to weigh participants at 6 weeks and 6 months to ensure blinding to participant group and previous measurements. This was accommodated by recruiting and training volunteer nutrition students to take follow up measurements. Several enrolment sessions suffered from poor attendance despite contacting participants in advance to remind them of their intention to attend. Extra enrolment sessions were held for those who did not attend their original appointment time.

6.11 Outcome: Management

6.11.1 Synching of phone contacts

In order to track smartphones in the event of loss or theft, a GPS tracking app called ‘where’s my droid?’ was downloaded onto the smartphones prior to the trial. A ‘Google’ account was created as part of this process. Unfortunately, this shared Google account had the unforeseen consequence of syncing contact data stored in the address book on the phones. This was discovered during a training session. As this was a breach of participant confidentiality all of the contacts were immediately deleted. Within the hour a text message was sent out to all of the participants in the smartphone group with instructions about how to 'un-sync' the contacts and the Google account was deactivated. This involved simply un-ticking a box in the 'settings menu' on the phone. This was also followed up with a more detailed apology and explanatory email later that day. At this stage, 25 smartphones had been rolled out in the smartphone group.

6.11.2 Problems with downloading applications

The test Google account which had been initially set-up, led to a further complication with the phone. The HTC Desire phone would not allow two Google accounts to exist on the phone simultaneously; this appeared to be a technical glitch with this particular model. A Google account is necessary to download apps onto the phone so despite the fact that the account was deactivated the phone defaults back to this account when trying to download apps from the market. The impact of this was that the participants were unable to download other new apps once the account was deactivated. The only way to create a new Google account on the phone is to re-set the phone to factory settings. This means a loss of apps already downloaded on the phone (including MMM).

Four participants got in touch to query this and were given an explanation and instructions on how to re-set the phone to factory settings and reinstall the MMM app using their unique ID code. As the data is uploaded from MMM to a website, re-installing the app did not affect the data already recorded. When the participants were invited back for 6 week follow up they were encouraged to bring their phones back so that the researchers could re-set the phone so that they could download apps. The majority declined this offer and were happy to continue with the phones without downloading apps. It is possible that these technical difficulties impacted on satisfaction with the smartphone.

6.11.3 Lack of agreed 'top-ups' to credit

The original agreement with the network provider '3' that participants would be able to top-up credit on an individual basis by contacting '3' customer services was not upheld. The customer service team at '3' would only speak to the person named as the designated contact for the entire contract and would not allow individual top-ups.

Participants were advised that to top-up they would need to get in contact with the study team who would contact ‘3’ on their behalf. This was not the agreed process and several participants got in touch to complain that ‘3’ were slow to contact them.

6.11.4 Phone and application difficulties

One participant deleted the MMM app by accident but this was remedied by talking them through the application installation process by telephone. One person reported that the trial phone was broken and would not switch on. The network provider ‘3’ was contacted and they delivered a replacement under warranty.

6.11.5 Website difficulties

One person contacted the team to report that their website log-in did not work. This was reported to ‘Weight Loss Resources’ who fixed the problem within the same day.

6.12 Contamination

At 6 month follow up, participants were asked whether they had used a smartphone app, website or paper diary to monitor their intake regularly during the preceding 6 month period (regardless of initial group allocation). There was found to be a degree of contamination in the trial with 20 participants reporting to have used different interventions to those assigned, of these; 7 smartphone participants used a website, 7 paper diary participants used a website and 4 used a smartphone app and 2 website participants used a smartphone app. As a result of this, a sub-analysis has been conducted in the analysis of change in anthropometry to be discussed further in Chapter 8.

6.13 Discussion

Whilst in general the pilot trial has shown the MMM app to be a feasible intervention to deliver, important issues regarding the feasibility of the design of the trial have emerged and will be discussed as follows.

6.13.1 Recruitment and sample characteristics

The trial recruited 128 participants which was 95% of the original recruitment target. The initial response rate was lower than expected. Although Leeds City Council had originally agreed to circulate an email to advertise the study they were reluctant to do so and the recruitment period had to be extended from 1 month to 3 months, this was accommodated within the project timeline and did not cause a delay to project completion. Despite recruiting from a range of employers the majority of participants were either from Leeds City Council or the University of Leeds. Perhaps as a reflection of these two predominant recruitment sources, the sample was generally well educated (60% with a University degree or higher) and over half worked in managerial/professional occupations. Both employers recruit staff at a range of levels of employment so the sample did have some diversity in this regard. A limitation of recruiting from employers was that no unemployed people were represented in the sample.

A large proportion of the sample (77%) was female and of white ethnic origin (91%), this is a sample structure common to many weight loss trials (Douketis et al., 2005). In terms of characteristics relating to technology usage and attitudes, the number of participants reporting to own a smartphone at baseline (40%) was higher than the national average at that time (24%) (OFCOM, 2011). Over half (60%) of participants had used a smartphone application before and their median self-rated confidence in using technology was high. The feasibility and acceptability of the intervention and trial must be interpreted within the confines of this particular sample. Therefore, generalisability to different populations is limited.

6.13.2 Trial Retention

The pilot trial suffered from 38% attrition overall. Attrition is a serious difficulty in weight loss trials because of its potential to bias results (Ware, 2003). Missing data may reflect dissatisfaction with the intervention and a rebound in weight. To put this attrition figure into context, a systematic review of long-term weight loss trials in obese adults reported losses to follow-up in the range of 30% to 60% (Douketis et al., 2005). A review focusing specifically on web-based interventions for weight loss found most had attrition rates greater than 20% (Neve et al., 2010). In this pilot trial, attrition was not equal among the groups, with more non-completers at follow-up in the paper diary and online groups compared to the smartphone group ($p<.001$). In fact, the smartphone group had extremely high retention with 93% returning for follow-up at 6 months (compared with 53% in the diary group and 55% in the website group).

Unequal dropout among groups is likely to be intervention-related (Altman, 1991) and a dislike of the study equipment was the most popular reason given for nonattendance at follow-up. Unequal dropout is a potential source of bias in a large RCT so this will need to be considered for the full trial. Another explanation for differences in group retention may be that the smartphone group felt a greater sense of responsibility to the trial given that they had been provided with a costly piece of study equipment and had signed an agreement that they would return it. The paper diary and online group may have felt less obliged to return for follow-up because they did not have the same obligation to return equipment.

Although participants were enrolled into the trial with the knowledge that they would be randomised and may not be assigned to the group of their choice, the high attrition in the comparison arms may also be due to ‘resentful demoralisation’ at not receiving a smartphone. Despite at least three attempts at contact to invite for follow up, the attrition rate in the trial is high and measures would be needed to address this in a definitive trial. In a future trial, strategies to improve retention could include; providing incentives for follow up, by visiting participants in their homes to measure their weight, or by providing a ‘delayed control’ arm so that eventually all participants would receive the smartphone app. However, the high attrition in this trial may be less of an issue in a future trial when it is likely that a larger proportion of the population will own a smartphone (given the rising trend in smartphone ownership in the United Kingdom) so the MMM app could be downloaded onto existing phones. This may reduce ‘resentful demoralisation’ relating to not receiving a smartphone from comparison arms and relieve unequal drop-out given that the smartphone app group would not feel under such obligation to return expensive equipment.

A range of variables were investigated to identify potential differences between trial completers and non completers. The non completers in the trial were found to have a statistically significantly higher BMI and percentage body fat at baseline and self- report a poorer health status. Other studies have shown mixed results with regard to attrition and initial body weight and a review of the behavioural approach to weight loss reports that both a higher and lower initial BMI have been linked to attrition in weight loss trials (Wing, 2003). It may be that this minimal care approach is more acceptable to patients with a lower initial baseline BMI and a perception of good health, but interpretation should be cautious given the small sample size.

6.13.3 Frequency of usage of the interventions

Frequency of intervention use for dietary self monitoring (number of days with ≥500-≤5000 kcal recorded) was higher in the smartphone group (mean 92 days, SD: 67) than the paper diary (mean 29 days, SD: 39) and website group (35 days, SD: 44) (p=<0.001). Participants were free to use the study equipment as often as they liked so the relatively high usage in the smartphone group is interesting. In similar trials which attempted to compare adherence between different types of self monitoring intervention, one found a statistically significant greater degree of adherence to a PDA arm than a paper diary (proportion of sample meeting 50% of weekly calorie goals at 6 months was 90% in the PDA group with feedback, 80% in the PDA group and 55% in the paper diary group, p=<0.01) (Burke et al., 2011a) and four trials (Taylor et al., 1991; Yon et al., 2007; Beasley et al., 2008; Turner-McGrievy & Tate, 2011) found no statistically significant difference in adherence between intervention groups. However it is worth noting that all of these trials used a PDA which although similar to a smartphone is potentially less familiar to users and less likely to be conveniently carried around at all times in the same way as a smartphone.

6.13.4 The relationship between frequency of dietary self monitoring and weight loss

Adherence to dietary self-monitoring is an important process outcome because it has been consistently linked to weight loss (Boutelle and Kirschenbaum, 1998; Wadden, 2005; Burke et al., 2011b). In the MMM arm of the trial, those who were classified as high frequency users (used MMM for ≥129 days) had a statistically significantly greater reduction in follow up weight (adjusted for baseline) than low and moderate frequency users. These findings are supported by Burke et al. (2012) who analysed different categories of adherence to a PDA, PDA with feedback and a paper diary and found that weight loss was greater (across groups) for those in the highest categories of adherence (≥60% adherent) than those in the lowest categories (≤30% adherent). Two other studies have also reported adherence to electronic dietary self monitoring to be positively related to weight loss outcome (Yon et al., 2007) (Shapiro et al., 2012)

However, as researchers have taken different approaches to measuring adherence in studies investigating technology for weight loss direct comparison of results is difficult.

A unique aspect of this trial is that the pattern of self monitoring has also been considered. Unfortunately the numbers in the MMM group are very small so attempting to classify users into categories is difficult producing very small numbers in each category. This makes parametric tests inappropriate. However, a descriptive analysis does seem to suggest that intermittent use of the app over the long term gave the best weight loss outcome even compared to those that had used the app consecutively with very few breaks over the 6 months. The small groups do have wide confidence intervals though so results are exploratory only and must be interpreted with caution. There is a gap in knowledge about how much dietary self monitoring is necessary for successful weight loss. This finding seems to suggest that there may be some kind of 'learning effect' whereby in the intermittent group users did not need to use the MMM app to track calories every single day but were perhaps self managing the days when they needed extra help to track over the long term. The automated time and date stamped information collected by the MMM app is a strength as it allows for this kind of analysis.

If more is known about how much self monitoring is effective, participants in weight loss trials could be given more prescriptive advice about how best to track their diet and supported in adherence to self monitoring. It could be speculated that the group of individuals who monitored consecutively every day relied on the phone to self monitor but were not learning as much about their intake or feeling as confident about having days of non tracking when they were responsible for their own instinctive self-management. Perhaps those that monitored intermittently over the 6 months were still sufficiently invested in the process of self monitoring to carry it out over the long term but during this time their awareness of their dietary intake and self-sufficiency had increased so that they could identify when they needed some more support and could use the diet tracking as and when they needed it. At this stage, this interpretation is conjecture and in a definitive trial with larger numbers an attempt to classify type of self monitoring in this way would be useful to further investigate how much dietary self monitoring is necessary and what is the optimal way to incorporate it.

It is worth noting that although dietary self monitoring has been found to be positively associated with weight loss it does not follow that self monitoring alone is necessarily the causative factor for weight loss. Individuals who are more willing to self monitor their diet may share dispositional traits which are difficult to capture in the studies conducted to date. Boutelle & Kirschenbaum (1998) speculate that people who self monitor well could be those with better ‘coping skills’ or ‘frustration tolerance’ or could simply be those more able to make appropriate changes based on their self monitoring.

6.13.5 Adherence to dietary self monitoring over time

Adherence to dietary self monitoring declined over time in all three groups but less so in the smartphone group. By 6 months only 7 participants in the smartphone group had managed to record their dietary intake every day (none in the paper diary or online group had done this). A similar decline in adherence to dietary self-monitoring over time has been reported in other studies. In a recent RCT (Burke et al., 2009) comparing a PDA, a PDA with feedback, and a paper diary, 53% of the PDA group were adherent at 6 months compared with 60% of the PDA with feedback group and 31% of the paper diary group. Adherence was measured in that study as >50% of weekly calorie goal achieved so although the result is not directly comparable, the trend is similar.

6.13.6 A suitable adherence outcome

The number of days with a plausible energy intake gives a continuous variable which is useful for exploratory analysis but it is a crude measure of adherence to dietary self monitoring. Adherence has been measured differently by other researchers. Burke et al. (2012) for example create a binary variable of adherent or non adherent which is based on the person achieving 50% of their weekly calorie goal. This gives a week by week pattern of adherence over time. However, it is quite an arbitrary cut-off as so little is known about how much self monitoring is necessary for weight loss success. It is also measuring adherence to dietary goals rather than adherence to the act of recording intake. Under this definition, if somebody has recorded their diet but their intake has not met their dietary target they would be considered non-adherent. The differing approaches to measuring adherence to dietary self monitoring make comparison between studies difficult and a standard approach is warranted.

6.13.7 Timeliness of MMM entries

A strength of the MMM app is the automatic data uploads which give a time and date stamp for every food and drink entry created. Of all food and drink items entered into MMM over the course of the trial, 20% of entries were created on a day after the reported day of consumption, 3% were created on a day before and 77% were added to the MMM electronic diary on the same day as reported consumption. 'Back-filling' and 'forward filling' has been previously demonstrated in studies using electronic diaries. For example, Stone et al. (2003) asked 40 participants to complete electronic diaries related to pain assessment at three specific points during the day for 21 days. On approximately 30% of the days participants reported that they had self monitored but the diary had not actually been opened. Burke et al. (2008) used instrumented paper diaries for dietary recording and also found that participants had reported that they had self monitored even on days when the diary had not been opened. Entry into the instrumented paper diaries was not timely with a mean 6.4 (SE: 3.0) hours between reporting an eating behaviour and recording it in the first 6 months of the study.

This finding has important implications for the use of a smartphone app as a dietary assessment tool. Although a diary is considered to be a prospective method of dietary assessment if recording takes place retrospectively it is still reliant on memory and subject to similar limitations as a retrospective measure. Burke et al. (2008) found that weight loss was positively correlated ($r=-0.53$, $p= 0.002$) with dietary self monitoring made within 15 minutes of eating which indicates that timely self monitoring does appear to be important.

6.13.8 Resource and management

Smartphone and website data collection was successful in that all data recorded by the participants was uploaded for analysis. Data collection in the paper diary group was less successful with 27/43 diaries returned at 6 weeks and 12/43 returned at 6 months. A limitation of this is that for diaries not returned an assumption had to be made that no dietary self monitoring had taken place in the diary although it may be that the case that the participant had self monitored to a point and stopped.

6.13.9 Limitations relating to feasibility

Generalisability of the pilot results is limited given that the sample is predominantly white, female and employed in managerial/professional occupations. MMM was a prototype app and participants reported that they frequently encountered bugs which caused the app to close. This may have affected participant engagement. Several unforeseen challenges arose from using novel technology. In particular a Google account which had been created in order to download an app which would allow the phones to be tracked by GPS had the unforeseen consequence of synching some phone contacts and preventing participants from downloading their own apps. Participants also reported problems with the network provider “3” in terms of adding extra credit to the phones as agreed. Although efforts were made to rectify these issues promptly it is possible that they may have impacted on participant engagement with the smartphone. Although these were difficulties at the time, the pilot trial has served to highlight these issues so that they can be addressed before a definitive trial.

A number of people in the trial reported that they had used another intervention (either instead of or as well as their originally allocated intervention) during the trial. One participant originally randomised to the paper diary group reported to enjoy self monitoring but wanted to make it more convenient so downloaded the commercially available ‘MyFitnessPal’ and used this for the duration of the trial. This person went on to lose 32kg and has had a strong influence on the mean weight change seen in the diary group. The degree of contamination seen in the trial is a serious issue and has implications for the design of a definitive RCT. In the pilot trial, participants knew what interventions were available in the trial and although they had all agreed to sign up with the understanding that they would be randomised to a group and not necessarily receive the intervention of their choice it is a possibility that the trial raised their awareness of newer ICT based methods of weight loss which they may not have already been aware of. In a definitive trial, the design would need to be altered in order to address contamination.

6.13.10 Strengths relating to feasibility

This pilot trial has several strengths including its randomised design. Whilst researchers have investigated dietary self monitoring as an adjunct or follow-up to a behavioural weight loss intervention (Burke et al., 2011a) or used a smartphone app to enhance adherence to another intervention (Turner-McGrievy et al., 2009), this pilot trial has taken a minimal contact approach with no dietary advice at baseline. This was considered to be the most logical first step as if disseminated widely a minimal contact approach could be logistically convenient to deliver and potentially cost effective. This approach could also be especially beneficial to those who would prefer not to attend face to face meetings. Another strength of the trial is the up to date app for tracking diet and physical activity which was comparable in appearance and functionality to commercial diet tracking apps available at that time. Despite their apparent popularity these commercial ‘diet tracking apps’ have not been comprehensively evaluated. Developing a new app specifically for research purposes has allowed for an evidence based approach and an extensive amount of data to be automatically uploaded. The MMM app has large potential for use in future research. Now that the app has been developed it would be relatively easy to modify it to facilitate research into dietary tracking for a range of different health conditions.

6.14 Conclusion

The results of the MMM pilot trial relating to feasibility have been presented and summarised in this chapter. The MMM app was successfully deployed to all participants in the appropriate arm and appears to be a feasible intervention. The trial attrition rate was high and efforts will need to be made in a definitive trial to reduce this. Other feasibility issues which have been highlighted include unequal drop-out, contamination and technical issues associated with using novel ICT. A key strength of the pilot trial is that it has served the purpose of identifying several important limitations of the trial design which will need to be seriously considered when designing the full trial. MMM was used more frequently than the comparison group interventions but the amount of dietary self monitoring in all three groups declined over time. Exploratory analysis suggests that those who used MMM for dietary self monitoring more had the most weight loss and the optimum type of use was to monitor intermittently over the long term. The next chapter aims to present findings from a participant evaluation conducted at 6 months follow-up relating to acceptability of the interventions and the trial itself.

Chapter 7: Acceptability of the 'My Meal Mate' (MMM) pilot trial.

7.1 Introduction

Previous chapters have demonstrated the potential for a smartphone application for weight loss (chapter 1) and the gaps in the current evidence base (chapter 2). The development of a smartphone intervention for weight loss has been described (chapter 3) and the MMM app has been validated against a reference measure of diet and shown to have potential as a dietary assessment tool (chapter 4). A 6 month pilot trial of MMM has been conducted and the methodology has been described in chapter 5. The findings of the 'My Meal Mate' (MMM) pilot trial have been divided into three chapters in order to consider results related to feasibility, acceptability and changes in anthropometry. This is the second of the three 'My Meal Mate' (MMM) pilot trial results chapters. This chapter aims to present findings from a participant evaluation conducted at 6 months follow-up relating to acceptability of the interventions and the trial itself. Please see Chapter 3 for an overview of the MMM intervention

7.2 Method

The data presented in this chapter was collected by questionnaires which participants self-completed at 6 month follow up (appendix 4). The questionnaires were related to satisfaction, use of the study equipment and evaluation of the trial, as a means to assess acceptability. The methodology of the pilot trial has been previously described in chapter 5. Questionnaire items have been measured on a Likert scale so have been treated as ordinal variables and analysed using appropriate non parametric tests (described in the table legends). Medians, interquartile ranges and proportions in the highest categories have been presented. Statistical analysis was carried out using Stata 11 (Stata corp) and in accordance with the statistical analysis plan (Chapter 5, section 5.18).

7.3 Results

At 6 months 77/128 (60%) follow-up questionnaires were collected from participants. The results of the questionnaires have been presented in a series of tables as follows.

7.3.1 Acceptability of the study equipment

Table 27 presents descriptive statistics for a range of self-reported acceptability measures collected in those that returned questionnaires at 6 month follow up (n=77). Each item was measured on a Likert scale of 1 to 5 (1=strongly disagree, 5-strongly agree), an exception being 'satisfaction with study equipment' which was measured on a Likert scale of 1 to 5 (1=very unsatisfied, 5=very satisfied). Satisfaction with study equipment at 6 months was found to differ in a slight but statistically significant way between the three groups. The smartphone group had a median score of 4 (IQR; 3 to 5) compared to a median of 3.5 (IQR; 2 to 5) in the paper diary group and a median of 3 (IQR; 2 to 4) in the website group (p=0.045). In terms of proportions in the highest categories, 63% of smartphone participants were 'satisfied' or 'very satisfied' with the study equipment compared to 50% in the diary group and 42% in the website group.

Convenience of using study equipment was also found to be statistically significantly different between the groups. The smartphone group had a median score of 4 (IQR; 3 to 5) compared to a median of 2 (IQR; 2 to 4) in the paper diary group and a median of 4 (IQR; 2 to 4) in the website group (p=0.006). In terms of proportions in the highest categories, 65% of smartphone participants 'agreed' or 'strongly agreed' that the study equipment was convenient to use compared to 35% in the diary group and 53% in the website group.

With regard to perceived comfort of using study equipment in social settings, the smartphone group had a median score of 4 (IQR; 4 to 4), the paper diary group had a median score of 3 (IQR; 2 to 4) and the website group had a median score of 3 (IQR; 2 to 3) (p=0.006). In the smartphone group, 76% of participants 'agreed' or 'strongly agreed' that they were comfortable using the study equipment in social settings compared to 40% in the dairy group and 21% in the website group.

The item 'I would like to continue to use the study equipment' had low median scores for the paper diary (median =2, IQR; 2 to 4) and website group (median=2, IQR; 1 to 4) and a slightly higher median of 4 (IQR; 3 to 5) in the smartphone group (p=0.009). The item 'I would recommend this approach to a friend or family member' had a median of 4 in each group but the IQR was wider for the diary group (IQR; 2 to 4.5) and website group (IQR, 2 to 4) than the smartphone group (IQR 4 to 5) indicating a slightly wider range of responses (p=0.008).

There was no statistically significant difference between the groups with regard to whether the study equipment was easy to use (p=0.6) and each group had a median score of 4. There were also no statistically significant differences between the groups for whether participants liked recording their food and exercise using the study equipment (p=0.2), whether they found the study equipment motivating (p=0.07) or whether participants thought people could lose weight with the approach (p=0.6).

7.3.2 Attitudes towards general use of study equipment

There were few statistically significant differences found between the groups in terms of attitudes towards the individual functions and overall usability of the study equipment (table 28). With regard to the self monitoring function of the study equipment, responses to the item ‘I find it useful to record weight weekly’ did not differ in a statistically significant way between the intervention groups (p=0.2) with each having a median score of 4. Similarly there was no statistically significant difference between responses to the item ‘I find it useful to see how closely daily calories are met’ (p=0.5), (smartphone median=4, diary median=5, website median=4).

In terms of reported changes made to diet and physical activity during the trial. There was found to be a small but statistically significant difference between the groups for the item ‘the study equipment has helped me to make changes to diet’ (p=0.04). The smartphone group had a median score of 4 (IQR; 3 to 5) compared to a median of 4 (IQR; 2 to 5) in the paper diary group and a median of 3 (IQR; 2 to 4) in the website group. The median scores were slightly lower for changes in physical activity (median=3 for each group) and not statistically significant between the groups (p=0.2).

Just under half of the paper diary group participants (45%) agreed or strongly agreed that they found the length of time it takes to record a day of dietary intake acceptable (58% in the smartphone group and 58% in the website group). However the median scores (smartphone median=4, diary median=3, website median=4) were not found to be statistically significantly different between the groups (p=0.4).

7.3.3 Items relating to the database components of the interventions

Table 29 presents results related to opinions on the food and activity databases. Only 34% of smartphone participants agreed or strongly agreed that it was easy to find foods in the database (45% in the diary group and 63% in the website group).

However the difference between the group median scores was not found to be statistically significant (smartphone median=3, diary median=3, website median=4, p=0.08). With regard to the activity database, 58% of smartphone participants agreed or strongly agreed that it was easy to find physical activity in the database compared to 30% in the diary group and 90% in the website groups. There was a small but statistically significant difference between the median scores (smartphone median=4, diary median =3, website median=4, p=0.002).

There was a small but statistically significant difference in the participants' confidence in the suitability of a generic food or drink item (if they could not find the specific branded food) in the database (smartphone median=3, diary median =4, website median =4, p=0.05). In terms of reported method of portion size estimation, items were measured on a 4-point Likert scale (1=never, 4=all of the time). Looking at nutritional information on packaging appears to be the most popular means of estimating portion sizes with 97% of smartphone users agreeing or strongly agreeing that they did that (79% in the diary group and 79% in the website group). The median score was 3 in each group and not found to differ in a statistically significant way between groups (p=0.5). Median scores were low for the other methods of portion estimation. There were no participants in either group that agreed or strongly agreed that they used the help videos on 'YouTube' to estimate portion sizes. The median score for 'rely on average portion sizes from the database' as a means of estimating portion size was 2 (disagree) in each group (p=0.3).

Table 27: Acceptability of the study equipment at 6 month follow-up according to group allocation of 77 adults enrolled in the MMM pilot trial[1]

	Smartphone (n= 38) (31F/9M)			Diary (n=20) (14F/6M)			Website (n=19) (16F/3M)			
	Median	**IQR**	**% agreed/ strongly agreed**	**Median**	**IQR**	**% agreed/ strongly agreed**	**Median**	**IQR**	**% agreed/ strongly agreed**	***P*[2]**
Acceptability measures[3]										
Satisfied with study equipment[4]	4	3,5	63	4	2,5	50	3	2,4	42	0.045
Find study equipment easy to use	4	4, 5	87	4	3, 5	65	4	4, 5	83	0.6
Find study equipment convenient to use	4	3, 5	65	2	2, 4	35	4	2, 4	53	0.006
Feel comfortable using study equipment in social settings	4	4, 4	76	3	2, 4	40	3	2, 3	21	0.002
Find study equipment motivating	4	3, 5	55	4	2, 4	50	3	2, 4	42	0.07
Like recording food and exercise using study equipment	4	3, 4	54	3	2.5, 4	40	4	2, 4	53	0.2
Think people can lose weight with this approach	4	4, 5	90	4	3, 5	70	4	4, 4	90	0.6
Would like to continue to use equipment	4	3, 5	55	2	2, 4	30	2	1, 4	32	0.009
Would recommend this approach to a friend or family member	4	4, 5	84	4	2, 4.5	60	4	2, 4	68	0.008

Table 27: 1Items to measure acceptability of study equipment in those completing 6 month follow up questionnaires (n=77) in the randomised, three armed (smartphone application, website, diary), pilot trial of "My Meal Mate" (MMM). Values are medians, IQR and % agreed/strongly agreed. [2]Significant difference between groups assessed by the Kruskal-Wallis equality-of-populations rank test; Significant difference at *P*<0.05. [3]Based on a 5-point Likert scale (1=strongly disagree; 5=strongly agree). [4]Based on a 5-point Likert scale (1=very unsatisfied; 5=very satisfied).

Table 28: Attitudes towards using the study equipment at 6 month follow-up according to group allocation of 77 adults enrolled in the MMM pilot trial[1]

	Smartphone (n= 38) (31F/9M)			Diary (n=20) (14F/6M)			Website (n=19) (16F/3M)			
	Median	IQR	% agreed/ strongly agreed	Median	IQR	% agreed/ strongly agreed	Median	IQR	% agreed/ strongly agreed	P^2
Attitudes towards use[3]										
Find it useful to record weight weekly	4	3, 4	53	4	3, 5	70	4	2, 4	63	0.2
Find it useful to see how closely daily calories are met	4	4, 5	84	5	3.5, 5	75	4	2, 5	68	0.5
Had enough training to be able to use equipment	4	4, 5	87	5	4, 5	85	4	4, 5	95	0.3
Find length of time it takes to complete a day's entry acceptable	4	3, 4	58	3	2, 4	45	4	2, 4	58	0.4
The study equipment has helped to make changes to diet	4	3, 5	68	4	2, 5	55	3	2, 4	42	0.04
The study equipment has helped to make changes to activity	3	3, 4	37	3	2, 4	30	3	2, 3	21	0.2

Table 28: 1Items to measure attitudes towards the use of study equipment in those completing 6 month follow up questionnaires (n=77) in the randomised, three armed (smartphone application, website, diary), pilot trial of "My Meal Mate" (MMM). Values are medians, IQR and % agreed/strongly agreed. [2] Significant difference between groups assessed by the Kruskal-Wallis equality-of-populations rank test. Significant difference at P<0.05. [3]Based on a 5-point Likert scale (1=strongly disagree; 5=strongly agree).

Table 29: Attitudes towards the food and activity databases at 6 month follow-up according to group allocation of 77 adults enrolled in the MMM pilot trial[1]

	Smartphone (n= 38) (31F/9M)			Diary (n=20) (14F/6M)			Website (n=19) (16F/3M)			
	Median	IQR	% agree/strongly agree	Median	IQR	% agree/strongly agree	Median	IQR	% agree/strongly agree	P^2
Attitudes towards database[3]										
It is easy to find most foods in database	3	2, 4	34	3	2, 4	45	4	3, 4	63	0.08
It is easy to find most activities in database	4	3, 4	58	3	2, 4	30	4	4, 4	90	0.002
Confident in generic value suitability[4]	3	2, 4	32	4	3, 4	58	4	3, 4	58	0.045
Methods of portion estimation[5]										
Weigh foods	2	1, 3	32	2	2, 3	47	2	2, 3	32	0.2
Look at nutritional information on packaging	3	2, 3	97	3	3, 4	79	3	3, 3	79	0.5
Use "help video" on portion sizes	1	1, 1	0	1	1, 1	0	1	1, 1	0	0.5
Use own estimate	2	2, 3	41	2	2, 2	10	2	2, 3	44	0.05
Rely on average portion sizes from database	2	1, 3	24	2	1, 2	20	2	1, 3	33	0.3
Use portion size pictures in study handbook	1	1, 2	8	1	1, 2	11	1	1, 2	11	0.6

Table 29: [1]Items to measure attitudes towards use of the food and activity database components in those completing 6 month follow up questionnaires (n=77) in the randomised, three armed (smartphone application, website, diary), pilot trial of "My Meal Mate" (MMM). Values are medians, IQR and % agreed/strongly agreed. [2]Significant difference between groups assessed by the Kruskal-Wallis equality-of-populations rank test; Significant difference at $P<0.05$. [3]Based on a 5-point Likert scale (1=strongly disagree; 5=strongly agree). [4]Based on a 5-point scale (1=not confident; 5=extremely confident). [5]Based on a 4-point scale (1=never; 4=all of the time).

Table 30: Self reported time spent using the study equipment at 6 month follow-up according to group allocation of 77 adults enrolled in the MMM pilot trial[1]

	Smartphone (n= 38) (31F/9M)			Diary (n=20) (14F/6M)			Website (n=19) (16F/3M)			
	Median	**Mean**	**95% CI**	**Median**	**Mean**	**95% CI**	**Median**	**Mean**	**95% CI**	***P*[2]**
Time[3]										
Time to enter an evening meal (mins)	5	7.0	4.7, 9.3	10	11.7	6.1, 17.2	10	10.0	6.8, 13.1	0.05
Time each day using equipment (mins)	10	16.3	9.6, 23.0	15	15.0	8.1, 21.9	20	19.4	11.8, 26.9	0.4
No. days until felt comfortable using (days)	2	4.7	1.4, 7.9	2	7.1	1.8, 12.3	2	3.1	1.6, 4.5	0.8
Use of study equipment[4]	**N**	**%**		**N**	**%**		**N**	**%**		0.2
Daily	16	42		6	30		3	16		
2-6 times a week	3	8		2	10		1	5		
Less than once a week	2	3		0	0		2	11		
Less than once a month	0	0		0	0		1	5		
Used it to start with but have now stopped	18	47		11	55		12	63		
Haven't used it since enrolment session	0	0		1	5		0	0		
Completing a day's entry[4]										
As I go along	20	57		6	38		10	59		0.3
In one sitting at the end of the day	13	37		7	44		5	29		
Backfill entering data from previous day	0	0		1	6		1	6		
Enter more than 1 day at a time in a batch	2	6		2	16		1	6		

Table 30: [1]Self reported time spent using the study equipment in those completing 6 month follow up questionnaires (n=77) in the randomised, three armed (smartphone application, website, diary), pilot trial of "My Meal Mate" (MMM). Values are medians, mean and 95% confidence intervals. [2]Significant difference at $P<0.05$. [3] As these are continuous variables (minutes and days), the distribution was checked and found to be skewed even after log transformation so the non parametric test Kruskal-Wallis equality-of-populations rank test was used. [4]Significant differences between groups assessed by Fisher's exact test.

7.3.4 Reported frequency of use of study equipment

At 6 months, participants were asked about the time they spent using the study equipment (table 30). There was found to be a statistically significant difference between the groups for reported time spent entering an evening meal (smartphone mean=7.0 mins, 95% CI: 5 to 9, paper diary mean=11.7 mins, 95% CI: 6 to 17, website mean=10.0 mins, 95% CI: 7 to 13, p=0.05). However, the overall reported amount of time per day spent using the equipment was not found to differ in a statistically significant way (smartphone mean=16.3 mins, 95% CI: 10 to 23, paper diary mean=15.0 mins, 95% CI: 8 to 22, website mean=19.4 mins, 95% CI: 12 to 27, p=0.4). Participants reported to entering their dietary data in several ways (e.g. prospectively throughout the day, 'backfilling at the end of the day) but there was not found to be a statistically significant different between the groups in method of reporting (p=0.3).

7.3.5 Participant evaluation of the pilot trial

Table 31 presents results on the perceived usefulness of additional weight loss support options (which were not part of this pilot trial). Of a range of options, the item 'regular feedback and advice on your diet by email' appeared the most popular with 41/77 (53%) participants reporting that they 'agreed' or 'strongly agreed' that this would have been useful. The least popular option was 'regular podcasts or videos with advice about diet' with 13/77 (17%) participants reporting that they 'agreed' or 'strongly agreed' that this would have been useful. There were no statistically significant differences between the groups on their rating of any of the options for support presented.

Participants were presented with a range of options regarding the potential learning that could be garnered from using the interventions (including new knowledge about portion sizes, calories in food and drink, energy expended during physical activity and meal patterns) and asked whether the study equipment had helped them to learn any new information related to these areas. The results are presented in table 32. In each intervention group over half the participants reported that they had learnt about the individual items listed and there were no statistically significant differences found between the groups on each of the items. In the smartphone group 33/38 participants reported that they had learnt about the 'calories in food' and 32/38 reported that they had learnt about 'calories used in physical activity'.

Table 33 presents results on the changes to weight related behaviour reported by the participants. The three most popular changes which participants reporting to having made over the course of the trial were 'reduced portion sizes' (68/77), 'lower calorie options' (58/77) and 'decreased snacking' (54/77). These three were also the most popular within the smartphone group (35/38, 28/38, 26/38 participants selecting these options respectively). There were no statistically significant differences found between the groups in the reported changes to their weight related behaviours.

Participants were asked about their feeling of comfort with the idea that researchers could view their diet records (table 34). On a 5 point Likert scale (1=extremely uncomfortable, 5=extremely comfortable), the item scored a median of 5 overall for the total sample (IQR; 4-5) and 68/77 (88%) reported that they were 'comfortable' or 'extremely comfortable' with researchers viewing their diet records. There was not found to be a statistically significant difference between the intervention groups with regard to this item (p=0.9).

Table 31: Perceived usefulness of additional weight loss support options at 6 month follow-up according to group allocation of 77 adults enrolled in the MMM pilot trial[1]

	Smartphone (n= 38) (31F/9M)			Diary (n=20) (14F/6M)			Website (n=19) (16F/3M)			Total sample (n=77)			
	Median	IQR	% agreed/ strongly agreed	Median	IQR	% agreed/ strongly agreed	Median	IQR	% agreed/ strongly agreed	Median	IQR	% agreed/ strongly agreed	P^2
To what extent do you agree you would have liked any of the following throughout the trial?[3]													
Regular group meetings with trial members led by a nutrition expert	3	2, 4	43	3	2, 4	35	3	2, 4	47	3	2, 4	42	0.9
Regular feedback and advice on your diet by telephone	3	2, 4	32	3	2, 3.5	25	3	1, 4	37	3	2, 4	31	0.5
Regular feedback and advice on your diet by email	4	2, 4	61	3	2.5, 4	40	4	2, 4	53	4	2, 4	53	0.9
Regular written materials with advice about diet	3	2, 4	32	3	2, 3	20	3	2, 4	42	3	2, 4	31	0.8
Regular podcasts or videos with advice about diet	2	2, 3	16	3	2, 3	15	2	2, 3	17	2	2, 3	17	0.9

Table 31: [1]Items to measure perceived usefulness of additional weight loss support options in those completing 6 month follow up questionnaires (n=77) in the randomised, three armed (smartphone application, website, diary), pilot trial of "My Meal Mate" (MMM). Values are medians, IQR and % agreed/strongly agreed. [2]Significant difference between groups assessed by the Kruskal-Wallis equality-of-populations rank test; Significant difference at $P<0.05$. [3]Based on a 5-point Likert scale (1=strongly disagree; 5=strongly agree). [4] Based on a 5-point scale (1=extremely uncomfortable; 5=comfortable).

Table 32: Perception of learning on a number of weight related items at 6 month follow-up according to group allocation of 77 adults enrolled in the MMM pilot trial[1]

	Smartphone (n= 38) (31F/9M)		Diary (n=20) (14F/6M)		Website (n=19) (16F/3M)		
Have you learnt anything new about the following? (yes)	**N**	**%**	**N**	**%**	**N**	**%**	**P**
Portion sizes[2]	24	63	14	70	13	68	0.8
Calories in food[3]	33	87	15	75	16	84	0.5
Calories in drinks[2]	28	74	15	75	13	68	0.9
Your patterns of eating[3]	28	76	13	65	15	80	0.6
Calories used in physical activity[3]	32	87	16	80	16	84	0.9

Table 32: [1]Items to measure perception of changes in knowledge about weight related items in those completing 6 month follow up questionnaires (n=77) in the randomised, three armed (smartphone application, website, diary), pilot trial of "My Meal Mate" (MMM). Values are frequency and percentage who agreed. [2]Significant difference between groups assessed by the Chi Squared test. [3]Significant difference between groups assessed by the Fisher's exact test due to an expected cell count value of 5 or less. Significant difference at P<0.05.

Table 33: Self reported changes made to weight related behaviours throughout the trial at 6 month follow-up according to group allocation of 77 adults enrolled in the MMM pilot trial[1]

	Smartphone (n= 38) (31F/9M)		Diary (n=20) (14F/6M)		Website (n=19) (16F/3M)		
Have you made any of the following changes during the trial? (N and % answering yes)	**N**	**%**	**N**	**%**	**N**	**%**	P
Reduced portion sizes[4]	35	92	18	90	15	79	0.3
More regular meal pattern[4]	13	36	7	35	4	21	0.5
Choose lower calorie options[4]	28	76	16	80	14	74	0.9
Decreased snacking[4]	26	70	16	80	12	63	0.5
Increased physical activity[3]	27	73	11	55	12	63	0.4
Increased fruit and vegetable consumption[3]	23	62	10	50	8	42	0.3
Reduced alcohol[3]	15	41	9	47	6	32	0.6
Less eating out or takeaways[3]	23	62	14	70	11	58	0.7
Other[4]	3	25	1	25	1	33	1.0

Table 12: [1]Self reported changes to weight related behaviour in those completing 6 month follow up questionnaires (n=77) in the randomised, three armed (smartphone application, website, diary), pilot trial of "My Meal Mate" (MMM). Values are frequency and percentage who agreed. [2]Significant difference between groups assessed by the Chi Squared test. [3]Significant difference between groups assessed by the Fisher's exact test due to an expected cell count value of 5 or less. Significant difference at *P*<0.05.

Table 34: Level of comfort with the knowledge that participant diet records would be viewed by researchers at 6 month follow-up according to group allocation of 77 adults enrolled in the MMM pilot trial[1]

	Smartphone (n= 38) (31F/9M)			Diary (n=20) (14F/6M)			Website (n=19) (16F/3M)			Total sample (n=77)			
	Median	**IQR**	**% comfortable/ very comfortable**	**Median**	**IQR**	**% comfortable/ very comfortable**	**Median**	**IQR**	**% comfortable/ very comfortable**	**Median**	**IQR**	**% comfortable/ very comfortable**	***P*[2]**
Comfort with the idea that diet records could be reviewed by the researchers in the trial[3]	5	4, 5	92	5	4, 5	80	5	4, 5	88	5	4, 5	90	0.9

Table 34: [1]Item to measure level of comfort with the prospect of diet records being reviewed by researchers in those completing 6 month follow up questionnaires (n=77) in the randomised, three armed (smartphone application, website, diary), pilot trial of "My Meal Mate" (MMM). Values are medians, IQR and % agreed/strongly agreed. [2]Significant difference between groups assessed by the Kruskal-Wallis equality-of-populations rank test; Significant difference at $P<0.05$. [3]Based on a 5-point Likert scale (1=very uncomfortable; 5=very comfortable).

7.3.6 Participant acceptability and satisfaction with the MMM app

At 6 month follow up, participants in the smartphone group were given evaluation questions relating specifically to the MMM app. The results of this evaluation are presented in table 35. With regard to 'ease of navigating around the app' on a 5-point Likert scale (1=very difficult, 5=very easy) participants gave a median rating of 4 (IRQ; 4 to 5). In terms of encountering software bugs in the MMM app, 16/38 (42%) reported that they had encountered bugs 'most of the time' or 'all of the time' over the course of the trial.

The text message feature of the app was rated on a 5-point Likert scale (1=extremely unhelpful; 5=extremely helpful). At 6 months the median rating for message content was 3 (IQR; 3 to 4) with 16/38 (42%) rating the message content as 'helpful' or 'extremely helpful'. The median score for message frequency was 3 (IQR; 3 to 4) and only 13/38 (34%) rated the frequency of text messages as 'helpful' or 'extremely helpful'.

Using the same 5-point Likert scale as above, participants were asked to rate the MMM usability features independently with regard to how helpful they had found them. The ability to save 'favourite' food combinations was rated highly with a median score of 4 (IQR;4 to 5) with 32/38 (84%) participants at 6 months reporting that they had found the "favourites" feature 'helpful' or 'extremely helpful'. The photo prompts and help videos on 'YouTube' appear to be the least popular usability features with 6/38 (17%) rating the photo prompts as 'helpful' or 'extremely helpful' at 6 months and 2/38 (6%) rating the help videos as 'helpful' or 'extremely helpful'. With regard to the trial phone itself, 15/38 (40%) reported that they had used the trial phone as their main phone over the course of the 6 months and 13/38 (34%) reported that they would have preferred an 'iPhone' handset to the HTC Desire.

Table 35: Acceptability and satisfaction with the MMM app at 6 month follow-up for 38 adults enrolled in the MMM pilot study[1]

	Median	IQR	% highest categories
Ease of use[2]	5	4, 5	92
Satisfaction with content of text messages[3]	3	3, 4	42
Satisfaction with frequency of text messages[3]	3	3, 4	34
Acceptability of usability features[4]			
Favourites	4	4, 5	84
Recent items	4	3, 4	70
Photo prompts	3	3, 3	17
Help videos	3	2.5, 3	6
Graphs of weight loss progress	4	3, 4	58
Graphs of when calorie goals met	4	3, 4	63
Frequency of bugs encountered[5]	2	2, 3	42
Ease of navigating around the app[2]	4	4, 5	87
	N	**%**	
Used trial phone as main phone (yes)	15	40	
Would have preferred an iPhone (yes)	13	34	

Table 35: [1]Items to measure acceptability of the 'My Meal Mate' intervention in those completing 6 month follow up questionnaires in the MMM arm of the randomised, three armed (smartphone application, website, diary), pilot trial of MMM. Values are medians, IQR, %in highest categories, frequency and percentage. [2]Based on a 5-point scale (1=very difficult; 5=very easy). [3]Based on a 5-point scale (1=very unsatisfied; 5=very satisfied). [4]Based on a 5-point scale (1=extremely unhelpful; 5=extremely helpful). [5]Based on a 4-point scale (1=never; 4=all of the time).

7.3.7 Desirable future adaptations to MMM

A range of potential future adaptations to MMM were presented to participants and they were asked to rate the extent to which they agreed that these features would be helpful to the application (on a 5 point Likert scale) (table 36). The most popular adaptations were; 'barcode scanning' (27/38 'agreed' or 'strongly agreed' that this would be helpful), 'searching the database by keyword' (31/38 'agreed' or 'strongly agreed' that this would be helpful), and 'manually entering the known calorie values for foods and activities' (29/38 'agreed' or 'strongly agreed' that this would be helpful). The least highly rated option was 'display of vitamin and minerals consumed' (11/38 'agreed' or 'strongly agreed' that this would be helpful).

Table 36: Perception of usefulness of possible future adaptations to MMM at 6 month follow-up for 38 adults enrolled in the MMM pilot study[1]

	Median	**IQR**	**% agree/s. agree**
Usefulness of possible future features[2]			
Bar code scanning	4	3, 5	70
Picture database to select portion sizes visually	3	3, 4	49
Searching the database by 'keywords'	4	4, 5	82
Manually entering known kcal values for foods and activities	4	4, 5	76
Display of grams of carbohydrates consumed	3	2, 4	32
Display of grams of protein consumed	3	2, 4	34
Display of grams of fat consumed	3	3, 4	45
Display of vitamins & minerals consumed	3	2, 4	29
Display of fruit & vegetable portions consumed	3	2, 4	49
Display of total fluid intake	3	2, 4	45
Weekly calorie targets in addition to daily	4	3, 5	58

Table 36: [1]Items to measure desirable future adaptations to the 'My Meal Mate' intervention in those completing 6 month follow up questionnaires in the MMM arm of the randomised, three armed (smartphone application, website, diary), pilot trial of MMM. Values are medians, IQR and % agreed/strongly agreed. [2]Based on a 5-point scale (1=strongly disagree; 5=strongly agree).

7.3.8 Qualitative results from open-ended questions administered to the smartphone group

Participants in the smartphone group were asked seven open ended questions about what they liked and disliked about the trial, the MMM app and the trial phone handset. They were also asked about their ideas for improvements. The responses were categorised by themes which emerged. Participants reported that the aspects of the trial they most enjoyed were; 1) gaining new nutrition knowledge (n=12), 2) increasing awareness of eating patterns (n=11), 3) awareness of energy intake and the process of calorie counting (n=11) and the convenience and ease of use of the MMM app (n=11). With regard to less favourable aspects of the trial, several participants suggested that they would have liked more support with their weight loss attempt in addition to the provision of the study equipment (n=14). Difficulty in finding food and drink items in the database was also cited by 8 people as a limitation of the trial.

In terms of the MMM app itself, participants liked that it was convenient (n=10) and easy to use (n=7). The frequency of the app crashing and software bugs were cited as less appealing aspect of the app (n=12). Several participants reported that the HTC Desire trial phone was easy to use (n=7) but the network coverage from the provider ‘3’ was reported to be poor by 4 participants. Participants responded with a range of suggestions to improve the trial including; more human contact (n=3), ability to add items of known calorie value to the database (n=3) fix the graph function (n=1) and reduce the number of software bugs (n=1).

7.4 Discussion

The MMM pilot trial findings relating to acceptability of the trial and the individual interventions as collected by questionnaires at 6 months have been presented in this chapter.

7.4.1 Acceptability of the study equipment and attitudes towards use

In terms of acceptability of the interventions, at 6 months the MMM app was more highly rated in comparison to the diary and website on a range of key measures including overall satisfaction, convenience and acceptability of use in social settings. For some of these measures the difference in rating was quite striking. For example, with regard to 'comfort of use in social settings', 76% (29/38) of the MMM group reported that they felt 'comfortable' or 'very comfortable' using their study equipment in social settings compared to 40% (8/20) of the paper diary group and 21% (4/19) of the website group (p=0.0002). Comfort of use in social settings could be a key advantage of a smartphone intervention and could be expected given that a smartphone is portable, discrete and a gadget that is ubiquitous in the public domain.

It is interesting that some key satisfaction items were not found to differ in a statistically significant way between the groups. It could be hypothesised that a smartphone weight loss intervention might be easier to use than a paper diary given that the total energy consumed and expended for the day is automatically calculated and summarised. However, the 'ease of use' of the study equipment was rated highly in each group (median = 4 in each group) and not found to differ in a statistically significant way between the groups (p=0.6). It could be that after 6 months of using the equipment all groups found it sufficiently easy to use. It may also be that the participants in the paper diary and website groups who did not find the equipment easy to use did not continue to use it and did not complete questionnaires at follow-up thus making the medians higher in completers only.

For the item, 'would like to continue to use equipment', the MMM group had a median of 4 (IQR; 3 to 5) compared to a median of 2 (IQR; 2 to 4) in the diary group and a median of 2 (IQR; 1 to 4) in the website group, p=0.009. Although it is not known how many participants would have continued to use the equipment past the 6 months in this trial, the intention to continue to use the equipment is higher in the MMM group and it could be hypothesised that this approach to self monitoring may be more engaging over the long term.

7.4.2 Attitudes towards the food database

Despite the large size of the Weight Loss Resources food database contained within the MMM app it is evident that participants were not easily able to find the items they required in the database. Only 34% of smartphone participants (45% in the diary group and 63% in the website group) agreed or strongly agreed that it was easy to find foods in the database, although the difference between the group median scores was not found to be statistically significant (smartphone median=3, diary median=3, website median=4, p=0.08). The search engine function of the MMM database was limited and the search worked by finding the specific term at the start of the word rather than searching by keyword. It was also dependent on correct spelling and although the phone does have predictive text to aid this, it does not work for brand names as they are not in the dictionary. Some brand names could be considered difficult to spell or are not spelt as expected (for example “Kellogg’s” and “Sainsbury’s” are difficult to find if not spelt precisely). It could be argued that most people are accustomed to working with intuitive and efficient search engines when browsing the web (such as Google and Yahoo) so the extra thought and effort required to search the MMM database may have been difficult. This may have affected participant engagement with the intervention and the database search function would likely need to be improved for future work with the app.

7.4.3 Time spent using the study equipment

Although smartphone participants reported to being able to complete an evening meal entry more quickly than the comparison groups (smartphone mean=7.0 mins, 95% CI: 5 to 9, paper diary mean=11.7 mins, 95% CI: 6 to 17, website mean=10 mins, 95% CI: 7 to 13, p=0.05), the overall reported amount of time per day spent using the equipment was not found to differ in a statistically significant way between the groups (smartphone mean=16.3 mins, 95% CI: 10 to 23, paper diary mean=15.0 mins, 95% CI: 8 to 22, website mean=19.4 mins, 95% CI: 12 to 27, p=0.4). This is an interesting finding, as although using technology to record a day’s diet would certainly speed up the processing of nutrient data by the researcher for dietary assessment (removing the need for manual coding) these results suggest that the speed of data entry for the participant would not be that different to the traditional method of recording in a paper diary. However these results are collected from trial completers only and therefore must be interpreted with caution. There was larger drop-out in the diary and website group and it may be that only those who were able to complete a record quickly were engaged with the trial and more likely to return for follow up. The time spent is also a self reported estimate so its accuracy is questionable.

The self reported time spent using the MMM app is similar to the findings from the previous validation study of MMM (chapter 4).   In the validation study, after using the MMM app for 7 days (n=50), participants estimated that it took a mean of 7 minutes to enter a meal and a mean of 22 minutes to enter a full days' intake (Carter et al. 2012). The self reported time spent entering a meal is comparable to the reported time spent using similar PDA devices that have previously been investigated. For example, users of the 'DietMatePro' PDA reported a mean 8.5 minutes to enter a meal (Beasley, 2005) and 'Wellnavi' users reported 5 minutes to enter a meal (Fukuo, 2009) (Kikunaga, 2007) (Wang, 2006).

The number of participants who agreed or strongly agreed that they found the length of time to complete a days' entry as acceptable was moderate (45% in the paper diary group, 58% in the smartphone group and 58% in the website group). It is interesting that despite the paper diary group reporting to spend less time than the other two groups to complete a days' entry fewer people agreed or strongly agreed that the time it took them was acceptable. Perhaps the time spent was perceived as less acceptable due to the extra effort required to manually write down and summarise energy values or a perception that this process should have been quicker.

7.4.4 Participant evaluation of the pilot trial

Over half the participants in each intervention group reported that they had learnt something new during the trial across a range of factors including: learning about portion sizes, calories in food and drink and energy expended during physical activity. Across these items there were no statistically significant differences between the groups. There were also found to be no statistically significant differences between the groups in the reported changes to their weight related behaviours.   It may be the case that despite the mode of delivery of the intervention the underlying behaviour change processes of goal setting, self monitoring and feedback led to similar learning and reported changes in behaviour.

The MMM pilot trial was minimal contact in that participants only met with the researcher at baseline and at 2 follow up points at 6 weeks and 6 months with no on-going support in the interim (other than the online forum). When asked about a range of potential additional support measures which could have been provided, the only option where over half (53%) the participants agreed or strongly agreed on desirability was ‘regular feedback and advice on diet by email’. This is worth noting as it could be incorporated into a future trial whereby the MMM intervention along with email support could be tested against the MMM intervention alone to see if its effectiveness could be enhanced. It is also worth noting that the participants who may have really benefitted from extra support in order to continue to engage with the trial could have already dropped out so were not able to register their opinion.

7.4.5 Additional evaluation measures for the MMM app

In terms of usability, MMM was rated highly for ‘ease of navigating around the app’. On a 5-point Likert scale (1=very difficult, 5=very easy) participants gave a median rating of 4 (IRQ; 4 to 5). However, it is evident from the evaluation that some aspects of the MMM app were less favourable. The app was a prototype and 16/38 (42%) reported that they had encountered bugs ‘most of the time’ or ‘all of the time’ over the course of the trial. This aspect also came out in the open ended questions with the frequency of the app crashing and software bugs cited by 12 participants as an undesirable feature. Although participants were informed at the start of the trial that the app was a prototype and that bugs were likely it is still possible that the frequency of bugs may have affected participant engagement and if MMM is to be used in a future trial it will need further bug testing.

Satisfaction with the text message feature of the app was also rated quite low. The low scores for satisfaction may be due to a bug in the text message algorithm. As time went on the messages appeared to be being sent more than once a week and occasionally at inappropriate times of the day. This was fixed by the software company at the end of the trial and an option added to turn the text messages off if required. If MMM were to be used in a future trial it is likely that improvements to the text message content and frequency would be necessary. Although the MMM text messages were developed with advice from a psychologist and from consulting with small focus group there is scope for improvement. As a new area of research, at the time of intervention development there was little guidance from similar trials on what kind of text messages would be most appropriate. The MMM app would benefit from some further formative work on the text messages and perhaps piloting a range of different styles of messages with focus groups to enhance the effectiveness of this aspect.

It is interesting to note that less than half of the smartphone group (15/48) actually used the trial phone as their main phone. Participants were supplied with a handset capable of making calls and texts in order to encourage them to use the trial phone with the MMM app pre-downloaded as their main phone in order to emulate 'real life' use of the app. In the qualitative evaluation questions, a number of participants who already owned a smartphone stated that they found it too much of an inconvenience to transfer their existing contacts and apps to a new handset. It could be the case that engagement with the app may have been different in those who were not using it as their primary handset. This issue could be ameliorated in a future trial where due to an increasing number of people in the UK owning a smartphone it may be possible to allow participants to download the app directly onto their own phone. If the MMM app was also to be developed for an Apple operating platform or perhaps online as mobile web content it could be used across platforms and have greater scope to be downloadable directly onto people's existing smartphones.

7.4.6 Suggested future improvements to the MMM app based on participant evaluation

Smartphone technology evolves quickly and although at the time of development the MMM app was comparable to similar diet tracking apps such as 'MyFitnessPal' and 'Lose it!', these apps have had continued investment and development and now have newer features such as barcode scanning and links to social network sites. Of suggested improvements to the MMM app, the most popular adaptations were; 'barcode scanning' (27/38 'agreed' or 'strongly agreed' that this would be helpful), 'searching the database by keyword' (31/38 'agreed' or 'strongly agreed' that this would be helpful), and 'manually entering the known calorie values for foods and activities' (29/38 'agreed' or 'strongly agreed' that this would be helpful). These adaptations may be useful in a future version of MMM in order to create an up to date intervention and engage with users who are familiar with current diet tracking apps.

7.4.7 Limitations

A limitation of the evaluation data collected is that it is only represents the views of those that completed the questionnaires at follow-up. At 6 months, 77/128 (60%) questionnaires were returned (38/43 in the smartphone group, 20/43 in the diary group and 19/42 in the website group). This has the potential to introduce a source of bias particularly in the diary group and website group where it is likely that the more motivated and engaged participants (and potentially those that lost the most weight) are those willing to return to follow up. The sample size is also reduced and there are small numbers in each group which could lead to a type 2 statistical error. There has also been multiple testing which increases the chance of a statistically significant result occurring by chance. For these reasons results must be interpreted with caution.

7.4.8 Strengths

Whilst several assumptions have been made in the literature about the perceived advantages of mobile interventions for weight loss, this trial has provided a large amount of data about participants' actual experiences of using a diet tracking app over a moderate length of time. This is unique data and gives a valuable insight into the acceptability of this relatively new approach.

7.5 Conclusion

The MMM pilot trial findings relating to acceptability of the trial and the individual interventions as collected by questionnaires at 6 months have been presented in this chapter. MMM was rated more highly than the paper diary and online interventions in terms of satisfaction, convenience of use, comfort of use in social settings and desire to continue to use study equipment. However, there were no statistically significant differences found between the groups with regard to ease of use of study equipment, whether participants found equipment motivating, whether participants liked the study equipment and whether they thought people could lose weight with the approach. The evaluation data must be interpreted with caution given that it only represents the views of completers and the sample size is small.

The evaluation data has highlighted a number of suggested improvements to the MMM app. Although the MMM app was rated highly for satisfaction, there is scope to improve the text messages and the food database search function. A large number of participants reported that they frequently encountered software bugs and these will need to be fixed if the app is to be used again. Some of these issues may have affected participant engagement with the intervention. A number of future research avenues for further optimisation of the MMM intervention have been highlighted such as a need for further work to enhance the effectiveness of the text message component and a need to investigate whether additional methods of support such as feedback emails could enhance the effectiveness of the application.

The next chapter will present the anthropometric outcomes of the "My Meal Mate" (MMM) pilot trial. The pilot trial was not statistically powered to detect a specific difference between trial arms and analyses have been conducted in an exploratory way in order to generate potential hypotheses for future investigation and to give an idea of effect size.

Chapter 8: Anthropometric results of the ‘My Meal Mate’ (MMM) pilot trial.

8.1 Introduction

Previous chapters have demonstrated the potential for a smartphone application for weight loss (chapter 1) and the gaps in the current evidence base (chapter 2). The development of a smartphone intervention for weight loss has been described (chapter 3) and the MMM app has been validated against a reference measure of diet and shown to have potential as a dietary assessment tool (chapter 4). A 6 month pilot trial of MMM has been conducted and the methodology has been described in chapter 5. The findings of the “My Meal Mate” (MMM) pilot trial have been divided into three chapters in order to consider results related to feasibility, acceptability and changes in anthropometry. This is the third of the three pilot trial results chapters which will present the anthropometric outcomes of the “My Meal Mate” (MMM) pilot trial. The pilot trial was not statistically powered to detect small/meaningful differences between group and analyses have been conducted in an exploratory way in order to generate potential hypotheses for future investigation and to give an idea of effect size.

8.2 Methods

The methodology of the pilot trial has been previously described in Chapter 5. The anthropometric results presented in this chapter (weight, BMI and % body fat) were objectively measured at baseline, 6 weeks and 6 months. Statistical analysis was carried out using Stata 11 (Stata corp) and in accordance with the statistical analysis plan (Chapter 5, section 5.18).

8.2.1 Presentation of results tables

The anthropometric results have been displayed in 5 tables. Table 37 is the primary anthropometric analysis and takes an intention to treat approach which presents results within and between groups in all those who were randomised at baseline using baseline observation carried forward (BOCF) for missing data. Table 38 is a summary of the mean weight change within each group (in all participants in the trial and in completers only). Table 39 is a sub−analysis which shows the results within and between groups for only those that completed 6 month follow up. Table 40 and 41 are also sub analyses which show the results within and between groups for participants analysed in the groups which they allocated themselves to (i.e. if someone declared that they used a slimming app over the course of the trial even though they were initially randomised to the paper diary group, they would be analysed in the smartphone group). This has been presented for all participants in the trial using baseline observation carried forward for missing data (table 40) and for trial completers only (table 41). After each regression analysis, the residuals were plotted (to check that the assumption of a normal distribution had been met) to confirm that a regression was an appropriate test to perform.

8.3 Results

8.3.1 Intention to treat analysis with baseline observation carried forward for missing data

An intention to treat analysis was conducted (with all participants included in the original group to which they were assigned) using baseline observations carried forward for missing data (table 37).

8.3.1.1 Intention to treat: Comparison of endpoints

A regression analysis was performed to investigate difference in mean follow up weight adjusting for starting weight, group and the 3 covariates minimised on at baseline (age, baseline BMI and gender). At the end of the trial, the mean follow up weights in each group were not found to be statistically significantly different between the smartphone and diary group (p=0.12) but smartphone participants lost a mean −3.3kg (95% CI; −5.4, −1.2) more weight than the website group (p=0.001). Each analysis was repeated for the BMI and body fat (%) measurements and a similar trend in results was found.

8.3.1.2 Intention to treat: Mean weight change

In the intention to treat analysis, the overall mean weight change (follow-up−baseline) was −4.6kg (95% CI: −6.2 to −3.0) in the smartphone group, −2.9kg (95% CI: −4.7 to −1.1) in the paper diary group and −1.3kg (95% CI: −2.7 to 0.1) in the website group.

8.3.1.3 Intention to treat: Removal of an extreme outlier

There is a large outlying value in the dataset as one participant in the paper diary group lost 32kg, this was checked back to the original paper records and found to be accurate. This person reported that they had actually used a commercially available slimming smartphone app during the trial rather than the paper diary. As this participant did not follow the study protocol and is having an extreme effect on the group mean there is a justification to exclude the measurements from the analysis. If this participant is excluded and the analysis repeated the difference in follow up scores between the smartphone and diary group is statistically significant. A −2.4kg (−4.4, −0.4) greater weight loss is found for the smartphone group than the paper diary group (p=0.009). The difference in change between the paper diary and online group is still not statistically significantly different when the outlier is excluded (p=0.3160). The mean weight change in the diary group with the extreme outlier excluded is −2.2 kg (95% CI; −3.4, −1.0).

8.3.2 Sub−analysis: Results in trial completers only

8.3.2.1 Completer analysis: Comparison of endpoints

A regression analysis was performed to investigate difference in mean follow up weight adjusting for starting weight, group and the 3 covariates minimised on at baseline (age, baseline BMI and gender) in those that completed follow-up (40/43 in the smartphone group, 20/43 in the diary group and 19/42 in the website group). Group allocation was not found to be statistically significant at 6 months (p=0.628). At the end of the trial, the mean follow up weights in each group were not found to be statistically significantly different between the groups (smartphone−diary: mean difference in weight=1.3kg, 95% CI= −2.1, 4.6, p=0.62; smartphone−website: mean difference in weight=−2.1kg, 95% CI=−5.2, 1.0, p=0.40; diary−website: mean difference in weight=−3.4, 95% CI=−7.9, 1.1, p=0.48). Each analysis was repeated for the BMI and body fat (%) measurements and a similar trend in results was found.

8.3.2.2 Completer analysis: Mean weight change

In the analysis of completers, the overall mean weight change (follow-up−baseline) was −5.0kg (95% CI: −6.7kg to −3.3kg) in the smartphone group, −6.2kg (95% CI: −9.8kg to −2.7kg) in the paper diary group and −2.8kg (95% CI: −5.9 to 0.2kg) in the website group.

8.3.2.3 Completer analysis: Removal of an extreme outlier

If the outlying participant in the paper diary group who lost 32kg is excluded from the analysis the mean weight change in paper diary group completers is −4.8kg (95% CI: −7.1kg to −2.7kg) and the 6 month follow up mean weight is 85.4kg (95% CI: 77.0, 93.8). The difference in difference in change over time between the groups is still not found to be statistically significant; (phone−diary) −0.1kg (95% CI: −2.9, 2.7) (p=0.95), (diary−web) −2.0kg (95%CI: − 5.6, 1.6) (p=0.26).

8.3.3 Sensitivity analysis: Results in participant self−allocated groups

A sub−analysis has been conducted in an attempt to address the group contamination evident within the trial. As several participants reported at the end of the trial that they had used different interventions to the ones they had been originally assigned, participants have been analysed in the self selected group which they reported at follow-up. Each participant that swapped group was analysed in the group they reported giving 43 smartphone participants, 35 paper diary participants and 50 website participants.

8.3.3.1 Sensitivity analysis: Comparison of endpoints in self-allocated groups

A regression analysis was performed to investigate difference in mean follow up weight adjusting for starting weight, self−allocated group and the 3 covariates minimised on at baseline (age, baseline BMI and gender). Self−allocated group was not found to be a statistically significant predictor of follow-up weight (adjusted for starting weight) at 6 weeks (p=0.60) and 6 months (p=0.40). At the end of the trial, the self allocated smartphone participants lost a mean −3.9kg (95% CI; −6.5, −1.4) more weight than the self−allocated diary group (p=0.002) and a mean −3.2 (−5.6, −0.8) more weight than the self−allocated website group (p=0.01). Each analysis was repeated for the BMI and body fat (%) measurements and a similar trend in results was found.

8.3.3.2 Sensitivity analysis: Mean weight change in self-allocated groups

When all participants are considered in their self−allocated groups, the mean weight change in each group was as follows; smartphone −5.3kg (95% CI: −7.4, −3.1), diary −1.3kg (95% CI; −2.4, −0.3) and the website −2.1kg (95% CI; −3.3, −0.8).

8.3.3.3 Sensitivity analysis: Comparison of endpoints in self-allocated groups (trial completers only)

A regression analysis was performed to investigate difference in mean follow up weight adjusting for starting weight, self−allocated group and the 3 covariates minimised on at baseline (age, baseline BMI and gender). Self−allocated group was not found to be statistically significant at 6 months (p=0.30). At the end of the trial, the mean follow up weights in each self−allocated group were not found to be statistically significantly different between the groups (smartphone−diary, p=0.4; smartphone−website, p=0.3; diary−website, p=0.9). Each analysis was repeated for the BMI and body fat (%) measurements and a similar trend in results was found.

8.3.3.4 Sensitivity analysis: Mean weight change in completers

When completers are considered in their self−allocated groups, the mean weight change in each group was as follows; smartphone −5.7kg (95% CI: −7.9, −3.4), diary −3.4kg (95% CI; −6.6, −1.2) and the website −3.9kg (95% CI; −6.0, −1.7).

Table 37: Change in anthropometric measures within and between groups at 6 weeks and 6 months (using baseline observation carried forward for missing data) in the MMM pilot trial.

	Smartphone		**Diary**		**Website**		**P for between group diff in endpoint**	**Phone−Diary diff in change**		**Phone−Website diff in change**		**Diary−Website diff in change**	
	N	Mean (95% CI)	N	Mean (95% CI)	N	Mean (95% CI)		Mean (95% CI)	P	Mean (95% CI)	P	Mean (95% CI)	P
Weight (kg)													
Baseline	43	96.8 (91.9−101.8)	43	97.9 (92.2−103.6)	42	96.4 (90.2, 102.6)							
6 wk	43	93.9[1] (89.0, 99.0)	43	95.9[1] (89.8, 101.7)	42	95.1[1] (89.0, 101.2)	0.001[2]	−0.8 (−1.9, 0.3)	0.106	−1.6 (−2.7 −0.6)	0.001[3]	−0.8 (−1.9, 0.3)	0.152
6 mt	43	92.2[1] (87.0, 97.4)	43	95.0[1] (89.0, 101.0)	42	95.1 (89.0, 101.3)	0.004[2]	−1.7 (−4.1, 0.7)	0.120	−3.3 (−5.4, −1.2)	0.001[3]	−1.6 (−3.9, 0.7)	0.183
BMI (kg/m^2)													
Baseline	43	33.7 (32.4, 35.0)	43	34.5 (32.7, 36.2)	42	34.5 (32.7, 36.2)							
6 wk	43	32.6[1] (31.3, 33.9)	43	33.7[1] (31.9, 35.5)	42	34.0 (32.3, 35.7)	0.002[2]	−0.3 (−0.7, 0.1)	0.107	−0.6 (−1.0, −0.2)	0.002[3]	−0.3 (−0.7,−0.1)	0.154
6 mt	43	32.1[1] (30.7, 33.5)	43	33.4 (31.5, 35.4)	42	34.0 (32.3, 35.8)	0.002[2]	−0.6 (−1.4, 0.2)	0.098[3]	−1.2 (−1.9, −0.4)	0.002[3]	−0.6 (−1.3, 0.2)	0.154

	Smartphone		Diary		Website		P for between group diff in endpoint	Phone−Diary diff in change		Phone−Website diff in change		Diary−Website diff in change	
	N	Mean (95% CI)	N	Mean (95% CI)	N	Mean (95% CI)		Mean (95% CI)	P	Mean (95% CI)	P	Mean (95% CI)	P
Body fat (%)													
Baseline	42	35.9(34.7, 37.1)	42	36.0(34.5, 37.5)	42	36.3 (35.1, 37.5)							
6 wk	42	35.0[1] (33.7, 36.2)	42	35.3[1] (33.8, 36.9)	42	36.0 (34.7, 37.2)	0.010[2]	−0.2 (−0.6, 0.1)	0.163	−0.5 (−0.9,−0.1)	0.008[3]	−0.25 (−0.6 ,0.1)	0.208
6 mt	42	34.7[1] (33.5, 35.9)	42	35.1 (33.4, 36.7)	42	35.9 (34.5, 37.2)	0.019	−0.3 (−1.1, 0.4)	0.303	−0.8 (−1.4, −0.2)	0.014[3]	−0.5 (−1.2, 0.2)	0.211

Table 37: Change in recorded anthropometric measures at 6 weeks and 6 months in all participants (N=128) in the randomised, three armed (smartphone application, website, diary), pilot trial of "My Meal Mate" (MMM). Values are means and 95% confidence intervals. The baseline measures recorded have been carried forward for missing data. Significant difference between baseline and 6 week & 6 month follow-up assessed by paired t-test. The regression analysis for difference in endpoints between the groups adjusts for starting weight and the 3 covariates randomised on at baseline (age, baseline BMI and gender). [1]Statistically significant difference within group from baseline value, *P* =<0.01. [2] Statistically significant difference for follow up weight (adjusted for baseline weight) between group endpoints, *P* =<0.01. [3] Statistically significant difference in weight change between groups, *P* =<0.01.

Table 38: Mean weight change (Follow/up−baseline) at 6 months within each group

Group	Intention to treat (using baseline observation carried forward)			Completers only		
	N	Mean weight change (kg)	95% CI (kg)	N	Mean weight change (kg)	95% CI (kg)
Smartphone	43	−4.6	−6.2, −3.0	40	−5.0	−6.7, −3.3
Diary	43	−2.9	−4.7, −1.1	20	−6.2	−9.8, −2.7
Diary (excluding extreme outlier)	42	−2.2	−3.4, −1.0	19	−4.8	−7.1, −2.7
Website	42	−1.3	−2.7, 0.1	19	−2.8	−5.9, 0.2

Table 38: Mean weight change by 6 months (follow up−baseline) in the randomised, three armed (smartphone application, website, diary), pilot trial of "My Meal Mate" (MMM). Results displayed using baseline observation carried forward for missing values (N=128) and in completers only (N=79). Values are means and 95% confidence intervals. As one participant in the diary group is an extreme outlier and did not follow the study protocol results have also been presented with this person excluded

Table 39: Change in anthropometric measures within and between groups at 6 months in participants who completed follow up in the MMM pilot trial.

	Smartphone		Diary		Website		P for between group diff in endpoint	Phone–Diary diff in change		Phone–Website diff in change		Diary–Website diff in change	
	N	Mean (95% CI)	N	Mean (95% CI)	N	Mean (95% CI)		Mean (95% CI)	P	Mean (95% CI)	P	Mean (95% CI)	P
Weight (kg)													
Baseline	40	96.8 (91.9–101.8)	20	97.9 (92.2–103.6)	19	96.4 (90.2, 102.6)							
6 mt	40	92.1[1] (86.6, 97.6)	20	86.1[1](78.1, 94.2)	19	87.0 (79.5, 94.6)	0.628	1.3 (−2.1, 4.6)	0.618	−2.1 (−5.2, 1.0)	0.400	−3.4 (−7.9, 1.1)	0.478
BMI (kg/m^2)													
Baseline	40	33.7 (32.4, 35.0)	20	34.5 (32.7, 36.2)	19	34.5 (32.7, 36.2)							
6 mt	40	32.0[1](30.5, 33.5)	20	30.4 (28.2, 32.6)	19	31.0 (28.9, 33.2)	0.588	0.5(−0.7, 1.6)	0.607	−0.7(−1.8, 0.4)	0.291	−1.2 (−2.7, 0.3)	0.372
Body fat (%)													
Baseline	39	35.9(34.7, 37.1)	20	36.0(34.5, 37.5)	19	36.3 (35.1, 37.5)							
6 mt	39	34.6[1] (33.4, 35.9)	20	32.5 (30.1, 34.8)	19	33.7 (31.7, 35.8)	0.894	0.6 (−0.4, 1.5)	0.478	−0.4 (−1.3,0.6)	0.563	−0.9 (−2.3, 0.4)	0.551

Table 39: Change in recorded anthropometric measures at 6 months (N=79) in those that completed follow up in the pilot, three armed (smartphone application, website, diary), randomised trial of "My Meal Mate" (MMM); a smartphone application to facilitate weight loss. Values are means and 95% confidence intervals. Significant difference between baseline and 6 month follow-up assessed by paired t–test. The regression analysis for difference in endpoints between the groups adjusts for starting weight and the 3 covariates randomised on at baseline (age, baseline BMI and gender). [1]Statistically significant difference within group from baseline value, *P* =≤0.01. [2] Statistically significant difference for follow up weight (adjusted for baseline weight) between group endpoints, *P* =≤0.01. [3] Statistically significant difference in weight change between groups, *P* =≤0.01.

Table 40: Change in anthropometric measures within and between groups at 6 weeks and 6 months (with people who swapped groups in self-selected groups using baseline observation carried forward for missing data) in the MMM pilot trial.

	Smartphone		Diary		Website		P for between group diff in endpoint	Phone−Diary diff in change		Phone−Website diff in change		Diary−Website diff in change	
	N	Mean (95% CI)	N	Mean (95% CI)	N	Mean (95% CI)		Mean (95% CI)	P	Mean (95% CI)	P	Mean (95% CI)	P
Weight (kg)													
Baseline	43	97.5 (92.2, 102.8)	35	98.9 (92.5, 105.4)	50	95.3 (90.0, 100.6)	0.7						
6 wk	43	94.6[1] (89.3, 99.8)	35	97.5[1] (90.8, 104.2)	50	93.5[1] (88.2, 98.7)	0.6	−1.5 (−2.6, −0.3)	0.01[3]	−1.1 (−2.2, −0.01)	0.047	0.4 (−0.7, 1.4)	0.5
6 mt	43	92.2[1] (86.9, 97.6)	35	97.6[1] (90.7, 104.6)	50	93.2[1] (87.9, 98.5)	0.4	−3.9 (−6.5, −1.4)	0.002[3]	−3.2 (−5.6, −0.8)	0.01[3]	0.7 (−0.9, 2.5)	0.4
BMI (kg/m^2)													
Baseline	43	33.5 (32.2, 34.8)	35	34.9 (32.9, 36.9)	50	34.4 (32.8, 35.9)	0.5						
6 wk	43	32.4[1] (31.2, 33.7)	35	34.3[1] (32.2, 36.4)	50	33.6[1] (32.1, 35.2)	0.3	−0.5 (−0.9, −0.1)	0.02	−0.4 (−0.8, 0.02)	0.06	0.1 (−0.3, 0.5)	0.5
6 mt	43	31.7[1] (30.3, 33.1)	35	34.4* (32.2, 36.6)	50	33.6[1] (32.1, 35.2)	0.07	−1.3 (−2.2, 0.5)	0.003[3]	−1.1 (−1.9, −0.3)	0.01[3]	0.2 (−0.4, 0.8)	0.5
Fat (%)													
Baseline	42	35.5 (34.3, 36.7)	34	36.3 (34.5, 38.0)	50	36.4 (35.3, 37.5)	0.6						
6 wk	42	34.5[1] (33.3, 35.8)	34	35.8[1] (33.9, 37.7)	50	35.8[1] (34.7, 36.9)	0.3	−0.5 (−0.9, −0.1)	0.02	−0.4 (−0.8, −0.4)	0.03	0.1 (−0.3, 0.5)	0.6
6 mt	42	34.0[1] (32.8, 35.3)	34	35.8[1] (33.8, 37.7)	50	35.8[1] (34.6, 36.9)	0.1	−1.0 (−1.8, −0.3)	0.01[3]	−0.9 (−1.6, −0.2)	0.01[3]	0.1 (−0.4, 0.7)	0.6

Table 40: Change in recorded anthropometric measures at 6 weeks and 6 months in all participants (N=128) in the randomised, three armed (smartphone application, website, diary), pilot trial of "My Meal Mate" (MMM). Values are means and 95% confidence intervals. Participants have been analysed in the groups they allocated themselves to (which were reported on the 6 month follow up questionnaires). Significant difference between baseline and 6 week & 6 month follow-up assessed by paired t–test. The regression analysis for difference in endpoints between the groups adjusts for starting weight and the 3 covariates randomised on at baseline (age, baseline BMI and gender). [1]Statistically significant difference within group from baseline value, *P* =≤0.01. [2] Statistically significant difference for follow up weight (adjusted for baseline weight) between group endpoints, *P* =≤0.01. [3] Statistically significant difference in weight change between groups, *P* =≤0.01.

Table 41: Change in anthropometric measures within and between groups at 6 months (trial completers with participants who swapped groups in self-selected groups) in the MMM pilot trial.

	Smartphone		Diary		Website		P for between group diff in endpoint	Phone−Diary diff in change		Phone−Website diff in change		Diary−Website diff in change	
	N	Mean (95% CI)	N	Mean (95% CI)	N	Mean (95% CI)		Mean (95% CI)	P	Mean (95% CI)	P	Mean (95% CI)	P
Weight (kg)													
Baseline	40	97.5 (92.2, 102.8)	12	98.9 (92.5, 105.4)	27	95.3 (90.0, 100.6)	0.7						
6 mt	40	92.1[1] (86.4, 97.8)	12	87.8[1] (74.8, 100.8)	27	85.9[1] (80.7, 91.2)	0.3	−1.8 (−6.1, 2.6)	0.4	−1.8 (−5.0, 1.4)	0.3	−0.04 (−3.6, 3.6)	0.9
BMI (kg/m^2)													
Baseline	40	33.5 (32.2, 34.8)	12	34.9 (32.9, 36.9)	27	34.4 (32.8, 35.9)	0.5						
6 mt	40	31.6[1] (30.1, 33.0)	12	31.1[1] (27.6, 34.7)	27	31.2[1] (29.4, 32.9)	0.9	−0.5 (−1.9, 0.9)	0.5	−0.6 (−1.7, 0.5)	0.3	−0.1 (−1.4, 1.2)	0.8
Fat (%)													
Baseline	39	35.5 (34.3, 36.7)	12	36.3 (34.5, 38.0)	27	36.4 (35.3, 37.5)	0.6						
6 mt	39	33.9[1] (32.7, 35.2)	12	32.8[1] (28.9, 36.6)	27	34.2[1] (32.6, 35.8)	0.6	−0.3 (−1.6, 1.01)	0.7	−0.5 (−1.5, 0.4)	0.3	−0.2 (−1.4, 0.9)	0.7

Table 41: Change in recorded anthropometric measures at 6 months (N=79) in those that completed follow up in the pilot, three armed (smartphone application, website, diary), randomised trial of "My Meal Mate" (MMM); a smartphone application to facilitate weight loss. Values are means and 95% confidence intervals. Participants have been analysed in the groups they allocated themselves to (which were reported on the 6 month follow up questionnaires). Significant difference between baseline and 6 month follow-up assessed by paired t–test. The regression analysis for difference in endpoints between the groups adjusts for starting weight and the 3 covariates randomised on at baseline (age, baseline BMI and gender). [1]Statistically significant difference within group from baseline value, *P* =≤0.01. [2] Statistically significant difference for follow up weight (adjusted for baseline weight) between group endpoints, *P* =≤0.01. [3] Statistically significant difference in weight change between groups, *P* =≤0.01.

8.4 Incidence of clinically significant weight loss (≥5%) 6 months after enrolment in the MMM pilot trial

Table 42 shows the number of trial participants that lost ≥5% of their initial body weight by 6 months. Assuming baseline observation carried forward for those who did not return for follow up at 6 months, 35/128 (27% of all participants randomised) achieved a clinically significant weight loss (≥5% of initial weight). This included 16/43 participants (37%) in the smartphone group, 12/43 (28%) participants in the paper diary group and 7/42 (17%) participants in the website group. This difference was not found to be statistically significant between the groups (X^2=4.5, p=0.10). If only trial completers are considered, the frequency of participants who lost 5% of their initial body weight was also not found to be statistically significantly different between the groups using a chi squared test (X^2=2.7, p=0.26).

Table 42: Frequency and proportion within each group who lost ≥5% of initial body weight by 6 months in the MMM pilot trial

	Smartphone		Paper diary		Web		Total	Pearson's Chi	P
	N	**%**	**N**	**%**	**N**	**%**	**N**		
Lost ≥5% weight (BOCF)[1]	16/43	37	12/43	28	7/42	17	35/128	4.5	0.10
Did not lose ≥5% weight (BOCF)[1]	27/43	63	31/43	72	35/42	83	93/128		
Lost ≥5% weight (Completers)[2]	16/40	40	12/20	60	7/19	37	35/79	2.7	0.26
Did not lose ≥5% weight (Completers)[2]	24/40	60	8/20	40	12/19	63	44/79		

Table 42: Frequency and proportion within each group who lost ≥5% of initial body weight by 6 months in the MMM pilot trial. [1] Intention to treat with all participants in their original groups and baseline observation carried forward (BOCF) for missing values. [2.] Results for only those participants who completed follow up at 6 months. Values are frequency and %.

8.5 Differences between completers in the smartphone group who had a clinically significant weight loss and those who did not.

Table 43 presents an investigation of the differences between the completers in the smartphone group (n=40) who lost ≥5% of their initial body weight (n=16) and those that did not (n=24). There were not found to be any statistically significant differences between those that did and did not lose a clinically significant amount of weight for a range of variables including age ($p=0.6$), gender ($p=0.3$) and initial BMI ($p=0.8$). A statistically significant difference was found in the total number of days that the MMM app was used to record intake ($p=0.02$). The mean number of days the smartphone electronic diary was used for dietary recording in the participants (within the smartphone completers) who lost weight was 127 (95% CI; 93−162) days compared to 78 (95% CI; 53−102) days in those who did not lose a clinically significant amount of weight ($p=0.02$). In terms of attitude towards technology, the completers who lost 5% of their weight had initially rated their confidence with technology 1 Likert point lower than those who did not (median=10 (IQR; 9, 10) in those who lost <5% weight and median=9 (IQR; 8, 9) in those that lost ≥5% weight (On a Likert scale of 1−10, 1=very unconfident, 10=very confident). The median scores for initial confidence with technology were very high in both groups although the difference was found to be statistically significant ($p=0.03$).

Table 43: Baseline characteristics according to clinically significant weight loss at 6 months of 40 adults enrolled in the MMM pilot trial

	Smartphone group (n=40)						
	Did not lose 5% of weight (n=24)			**≥5% weight loss (n=16)**			
	Mean	**SD**	**95% CI**	**Mean**	**SD**	**95% CI**	**P**
Age (years)	40.6	8.9	36.8, 44.4	42.2	8.3	37.7, 46.6	0.6
Anthropometrics							
Actual weight (kg)	98.6	17.7	91.1, 106.0	94.8	14.5	87.1, 102.5	0.5
Actual BMI (kg/m2)	33.9	4.0	32.2, 35.6	33.5	4.7	31.0, 36.0	0.8
% Body fat	35.7	3.7	34.2, 37.3	36.2	4.2	33.9, 38.6	0.7
Number of previous weight loss attempts	7	6	4, 10	9	12	2, 15	0.9
Conscientiousness score	77	11	72, 82	81	10	76, 86	0.3
Score for Consideration of Future Consequences	32	8	28, 35	30	7	27, 34	0.6
Adherence (days)	77.5	57.9	53.0, 101.9	127.3	64.6	92.8, 161.7	0.02
	Median	**IQR**		**Median**	**IQR**		
Motivation to lose weight[3]	8	8, 9		8	7, 10		0.5
Confidence in ability to lose weight[4]	8	6, 9		8	6, 9.5		0.8
Confidence in using technology[4]	10	9, 10		9	8, 9		0.03
Like gadgets and new technology?[5]	4	2.5, 4		3	2.5, 3		0.08
Ability with the internet[6]	1	1, 2		1	1, 1.5		0.6

	Smartphone group (n=40)						
	Did not lose 5% of weight (n=24)			**≥5% weight loss (n=16)**			
	N	**%**		**N**	**%**		
Female (%)	17	71		14	88		0.3
Own a smartphone? (yes)	9	38		7	44		0.7
Use a smartphone? (yes)	13	54		9	56		0.9
Ever used a smartphone app? (yes)	18	75		11	69		0.7
Internet access at home? (yes)	24	100		15	94		0.4
	Mean	**SD**	**95% CI**	**Mean**	**SD**	**95% CI**	**P**
Ethnicity (White)	24	100		16	100		-
Smoking status							
Current smoker	1	4		1	6		0.8
Ex smoker	6	26		3	19		
Never smoked more than 100 cigarettes	16	70		12	75		
Occupation[7]							0.1
Managerial & professional	16	67		14	88		
Highest qualification							0.3
Has a University degree	16	67		13	81		
	n						

	Smartphone group (n=40)				
	Did not lose 5% of weight (n=24)		**≥5% weight loss (n=16)**		
Health status in past 12 months					0.9
Excellent	4	17	3	19	
Very good	10	42	7	44	
Good	6	25	3	19	
Fair	4	17	3	19	
Constant dieter (yes)	13	57	4	25	0.09
Ever kept a food diary (yes)	16	67	10	63	0.8

Table 43: [1]Baseline characteristics according to clinically significant weight loss at 6 months for 40 adult completers enrolled in the MMM arm of the MMM pilot trial. Values are means ±SD & 95% CI, median, IQR or frequency.[2]Significant difference between groups assessed by the independent two sample t-test (2 sided p), the two sample Wilcoxon ranksum (Mann Whitney) test, chi-square or Fisher's exact test. Significant difference at p=<0.05. [3]Based on a 10-point scale (1=not motivated at all; 10=extremely motivated). [4] Based on a 10 point scale (1=not confident at all; 10=extremely confident). [5] Based on a 4-point scale (1=not like me; 4=describes me perfectly). [6] Based on a 5-point scale (1=excellent; 5=poor). [7] The occupation variable was originally measured as: a) Managerial and professional occupations; b) Intermediate occupations; c) Small employers and own account workers; d) Lower supervisory and technical occupation; e) Semi-routine and routine occupations (categories a-e have been combined). Where numbers do not total to 40, this is due to a small proportion of missing data.

8.6 Discussion

Although the pilot trial was not statistically powered to detect a useful difference in weight change it did detect statistically significant differences in change between the groups and it has provided data on effect size. However, there is a danger of a type 2 statistical error given the multiple testing in this analysis on a relatively small sample. For this reason, results must be treated with caution and are for exploratory purposes only.

8.6.1 Comparison between groups

Using data from all participants randomised at baseline (with baseline observation carried forward for missing data), the mean follow up weight (adjusted for starting weight) in each group was not found to be statistically significantly different between the smartphone and diary group (p=0.12) but smartphone participants had a mean −3.3kg (95% CI; −5.4, −1.2) greater weight loss than the website group (p=0.001). However, when a significant outlier who did not follow the study protocol is excluded the results in the intention to treat analysis are different. A −2.4kg (−4.4, −0.4) greater weight loss is found for the smartphone group than the paper diary group (p=0.009) and the mean weight change in the diary group is more modest (−2.2kg, 95% CI; −3.4, 1.0).

If only those who completed the trial (returned for 6 month follow-up) are considered there are no statistically significant differences found in weight loss between the groups. Each group of completers had lost a comparable amount of weight regardless of their mode of self monitoring. This is a similar finding to the SMART trial by Burke et al. (2011a) who compared self monitoring using a PDA, PDA with feedback and paper diary at 6 months and found all three groups had a mean clinically significant weight loss but this was not statistically significant between the groups. Both the website and diary group had high losses to follow up compared to the smartphone group and it could be argued that the participants who returned to be measured are those most likely to have lost weight. This may introduce a source of bias in the results so even though the smartphone group appears equal in terms of weight loss for completers, double the number of participants returned in this group compared to the other two groups. Therefore the smartphone group is likely to include more of those that returned despite not losing weight unlike the other two groups. As so many participants (who potentially did not lose weight) are not considered in the completers analysis the weight loss results look impressive, however using baseline observation carried forward for missing data shows much more modest weight loss results in the comparison groups.

8.6.2 Weight change in the smartphone group

The mean weight change in the smartphone group at 6 months using an intention to treat analysis was −4.6kg (95% CI: −6.2 to −3.0) and − 5.0kg (95% CI: − 6.7 to −3.3) in the analysis of completers. Weight loss seen in similar trials of portable handheld electronic devices have had mixed results and direct comparison between different trials is difficult given the different devices trialled. Two trials which have been conducted with a PDA for self monitoring demonstrated a mean clinically significant weight change at 6 months using the PDA (Yon et al, 2007) (Burke et al, 2011a).

In two trials of text messaging interventions, one trial reported a clinically significant % mean weight change (≥5%) by 1 year in the intervention group which was statistically significantly greater than the control (p=<0.05) (Haapala et al., 2009). Two other trials of text messaging interventions failed to demonstrate a clinically significant mean percentage weight change in the intervention group at 4 months (−3.16% mean change in the intervention group) (Patrick et al., 2009) and at 1 year (−1.8%± 0.06 weight change) (Shapiro et al., 2012). Two studies which used text messages alongside financial incentives reported mean weight loss rather than percentage weight change and whilst one reported a statistically significantly greater weight loss in the intervention groups compared to the control at 16 weeks (John et al., 2011), the other found a statistically significantly greater weight loss in the intervention groups compared to the control at 32 weeks but not at 36 weeks.

The only trial which has been conducted to date using a smartphone application for dietary self monitoring (alongside a podcast and twitter intervention) failed to find a clinically significant percentage weight change at 6 months (−2.7% ±3.8) (Turner-McGrievy & Tate., 2011). However, the app used in that trial ‘FatSecret’ was a commercial one so of unknown quality and was used in addition to podcast and twitter intervention rather than as a stand alone intervention.

8.6.3 Sensitivity analysis

Contamination was an issue in this trial as participants reported using other interventions during the course of the trial. To address this, participants were analysed in groups according to the intervention they reported they had used. Using data from all participants enrolled in the trial in this ‘actual treatment’ analysis, weight loss was statistically significantly higher in the ‘self−allocated’ smartphone app group compared to the website and diary groups. The self allocated smartphone participants lost a mean −3.9kg (95% CI: −6.5, −1.4) more weight than the self−allocated diary group (p=0.002) and a mean −3.2 (95% CI: −5.6, −0.8) more weight than the self−allocated website group (p=0.01). In completers only, the results were similar for self−allocated groups as the groups randomised to at baseline in that there were no statistically significant differences found for weight loss between groups (smartphone−diary: mean difference in weight=−1.8kg, 95% CI: −6.1, 2.6, p=0.4; smartphone−website: mean difference in weight=−1.8kg, 95% CI: −5.0, 1.4, p=0.3; diary−website: mean difference in weight=−0.04, 95% CI: −3.6, 3.6, p=0.9).

8.6.4 Implications of the results

Considering that the MMM intervention is minimal contact the −4.6kg (95% CI: −6.2 to −3.0) weight loss seen in the smartphone group is very encouraging. To put this figure into context, a large multi-centered RCT (n=293) of popular face to face commercial diet programmes such as Weight Watchers and Rosemary Conley reported an average weight loss of − 5.9kg at 6 months across all diets (Truby et al, 2006). It could be hypothesised that a minimal contact intervention such as MMM would be more cost effective than an on-going face to face intervention and as the effect size is promising, further research is warranted into the efficacy and cost effectiveness of this approach. Although in the short term, weight loss has been observed in the MMM group it is not known whether this effect size would be sustained in the long term. Weight maintenance in the long term is notoriously challenging (Wing & Hill, 2012) and a comparable trial of a PDA over 24 months showed that most of the weight lost at 6 months was regained over the long term (Burke et al, 2012). The National Obesity Observatory recommend that weight loss trials should have a minimum of 1 year follow up (NOO, 2009) and a definitive RCT of MMM would benefit from a period of long term follow up beyond 6 months.

8.6.5 Strengths and limitations

The strengths and limitations of the interventions and trial design have been discussed in the previous two results chapters. A strength relating to this particular analysis is that the data collected on weight, % fat and BMI was objectively measured by fieldworkers blinded to the participants' group allocation. The analysis is limited in that although an encouraging weight loss result has been seen, the pilot trial was not powered to detect a particular weight loss as being statistically significant so more evidence is still necessary to determine whether MMM is effective as a weight loss intervention in overweight and obese adults. With regard to sample size, a post-hoc power calculation shows that based on the follow-up values from the smartphone and diary group, the sample size in this trial had 90% power to detect a statistically significant difference of 13kg in follow up weight between two groups and 80% power to detect a difference of 11kg (at the 5% significance level). The sample size in the trial (n=43 in each arm) had 10% power to detect the actual difference in follow up weight found between the smartphone and diary group.

8.7 Conclusion

The results of the MMM pilot trial relating to anthropometry have been presented and summarised in this chapter. Change in anthropometry is not the primary outcome of this pilot trial however the weight loss seen in the MMM group is interesting and encouraging. If all participants are considered in their original groups, the weight loss in the MMM group is statistically significantly greater than the website group but not the paper diary group. However, a large outlying value from a participant who did not follow the protocol in the paper diary group is having an impact on the results and if this person is excluded the weight loss in the MMM group is statistically significantly greater than both of the other two groups. The weight loss seen in the MMM arm is comparable to weight loss demonstrated in face to face interventions at 6 months. Given these findings, a full trial of MMM is warranted in order to determine whether MMM is an effective weight loss intervention. The next chapter will attempt to bring all of the chapters presented thus far together in an overall discussion of the work conducted.

Chapter 9: Overall discussion

9.1 Introduction

Previous chapters have demonstrated the potential for a smartphone application for weight loss (chapter 1) and the gaps in the current evidence base (chapter 2). The development of a smartphone intervention for weight loss has been described (chapter 3) and the MMM app has been validated against a reference measure of diet and shown to have potential as a dietary assessment tool (chapter 4). A 6 month pilot trial of MMM has been conducted and the methodology has been described in chapter 5. Three results chapters have been included, which consider the pilot trial results in terms of feasibility, acceptability and changes in anthropometry. This final chapter attempts to critically reflect on the work conducted and bring all of the elements of the PhD thesis together in an overall discussion.

9.2 Summary of findings

An evidence based smartphone application called 'My Meal Mate' (MMM) has been developed, validated and piloted. The development and design of MMM was informed by qualitative research with potential system users and guided by behaviour change theories of self-regulation including goal setting, self monitoring and feedback. A validation study comparing MMM to a reference measure of diet (2 x 24hr diet recalls) found fairly wide limits of agreement between the two methods at the individual level (-824 to 791 kcals/d on day 1) but a small mean difference at the group level (Day 1: -16 (95% CI: -132 to 100) kcals/d (MMM-recall). It was discussed that the MMM app may have some potential as a dietary assessment tool.

The MMM app was piloted in a 6 month randomised controlled trial and found to be a feasible and acceptable weight loss intervention in overweight and obese adults. Trial retention was 93% in the smartphone group, 55% in the website group and 53% in the diary group at 6 months. Adherence was statistically significantly higher in the smartphone group with a mean 92 (SD: 67) days recorded compared to 35 (SD: 44) days in the website group and 29 (SD: 39) days in the diary group (*P* =<0.001). Self monitoring declined over time in all groups. In an intention to treat analysis (with baseline observation carried forward for missing values) the overall mean weight change (follow up−baseline) was −4.6kg (95% CI: −6.2 to −3.0) in the smartphone group, −2.9kg (95% CI: −4.7 to −1.1) in the paper diary group and −1.3kg (95% CI:

−2.7 to 0.1) in the website group. Although the trial was not powered to detect differences of this magnitude. MMM was rated more highly in terms of convenience and comfort of use in social settings than the comparator groups.

The MMM app was designed to be of comparable quality and design to commercially available diet tracking apps such as 'MyFitnessPal' and 'Lose it!' and to be used on a modern Android smartphone handset. It appears that such apps are widely downloaded despite being of unknown quality and with no information about their effectiveness. Although comparable, MMM does differ from commercially available apps. The unique features and advantages of MMM are highlighted in table 44. By designing an application rather than testing an existing commercial application the researcher has complete control over the data collected which can be used to investigate self reported dietary intake, self reported physical activity patterns and system usage.

Table 44: Unique features of the 'My Meal Mate' (MMM) application

- Evidence based design (theory driven and guided by qualitative research).
- UK specific branded food database.
- Quality control over the database (i.e. users are not permitted to add in their own foods which can sometimes lead to duplicates in food records or erroneous nutritional information).
- Regular feedback via SMS.
- Usability features such as the ability for the user to take photographs to serve as memory prompts.
- Automatic upload of dietary records for analysis by the researcher.

Table 44: Unique features of the 'My Meal Mate' (MMM) app as compared to similar commercially available diet tracking apps.

9.3 The original contribution of this work to the existing knowledge

At the time of development (to the researcher's knowledge) there were no trials investigating diet tracking smartphone apps of this quality as stand-alone interventions. Comparable researcher designed systems at that point were for use on personal digital assistants or older handsets such as Nokia feature phones. The work in this thesis has made an original contribution to the research base in the following ways:

- The development process has created an evidence based intervention which has the potential to be easily adapted and applied to other areas of health research in the future. The intervention also offers an opportunity as a research tool due to its capacity to collect large amounts of dietary data.
- The validation study was the first published study to validate a smartphone app of comparable quality to popular diet tracking apps against a reference measure of diet in adults. The data highlights the potential for a smartphone app to be used in dietary assessment of adults and adds to the existing evidence in this field, most of which has been on online systems, personal digital assistants or mobile devices in children and adolescents.
- The pilot trial was the first to pilot a smartphone app of comparable quality to popular diet tracking apps as a stand-alone (as opposed to an adjunct to an additional weight management intervention such as group sessions or podcasting) minimal-contact intervention in overweight and obese adults. This has built on the data collected by trials of electronic mobile devices such as personal digital assistants and older style applications. The literature review highlighted that the only published trial using a smartphone app for weight used a commercially available diet tracking app called 'FatSecret' alongside a podcasting intervention and did not test the app as an intervention in its own right.
- The exploratory work has provided some new insight into the relationship between dietary self monitoring on a handheld electronic device and weight loss.
- The pilot trial has provided valuable data to inform a definitive trial and has shown the intervention to be a feasible and acceptable approach.

9.4 The context of the thesis within the wider research area

In terms of the previous work conducted in this field, the validation study and pilot trial have produced interesting findings which make an original contribution to the literature. However, given the multi-factorial nature of obesity aetiology, a smartphone app for weight loss as a potential obesity treatment is only a very small part of the overall 'big picture'. This type of intervention is individualistic and puts the responsibility for behaviour change into the hands of the patient only, which is just one type of approach to obesity treatment and prevention. Given the number of drivers of overweight and obesity, interventions which also consider environmental and societal contributors are important. It could also be argued that for some overweight and obese patients seeking treatment, medications and surgery may be a more suitable and effective treatment strategy.

None the less, as the options available to treat obesity in primary care are currently very limited, there is a need for different tailored approaches for those seeking support. If a general practitioner had more effective interventions in their obesity 'tool-kit' it may mean they are able to offer something different to those for whom group support or face to face contact is not appropriate/acceptable. Therefore, whilst there is unlikely to be a 'magic bullet' one size fits all approach to treatment there is still a place for interventions such as this which help to support an individual to make more nutritionally informed food and drink choices within the confines of an obesogenic environment.

9.5 Strengths and limitations

The strengths and limitations of the three individual stages of the project (development of the intervention, validation study and pilot trial) have been discussed within the relevant chapters. General strengths and limitations of the overall approach and PhD work will be discussed as follows.

9.5.1 Strengths of the approach

There are many potential advantages to the use of a smartphone intervention for weight loss. Smartphones are ubiquitous and portable and it is encouraging that the app was rated highly in the pilot trial for convenience of use and comfort in social settings. The approach may be useful in those who are unable or unwilling to engage with traditional methods of weight management such as one to one appointments with health professionals or group sessions. An effective minimal contact intervention may also be convenient for wide dissemination and may potentially be cost effective (although more research would be needed to understand the economic implications of a smartphone app for weight loss in adults).

The MMM intervention has been developed and although it has scope for further optimisation and improvement it is a potentially useful research tool given that it allows for dietary data to be collected prospectively. A strength of the MMM app is that it is evidence based having been designed with a theoretical basis and guided by qualitative research conducted with potential system users. A wealth of data has been collected in the trial and there is an opportunity for further investigation into the dietary and physical activity habits of the sample (although this is outside the scope of this thesis). As a pilot study, conclusions cannot be drawn from the findings about the effectiveness of the MMM app for weight loss however data has been provided which it is hoped will improve the quality of a definitive trial and save money and time on challenges which may have been costly in a much larger sample. The lessons learned in the pilot trial should help to optimise the intervention and trial design for a definitive trial of this app or similar studies in the future. The MMM app has been uploaded onto the Google Play store for free download and currently has a 4/5 star rating with a total of 11,581 downloads (between 21/04/13 and 12/07/13). The link for the app is:

(https://play.google.com/store/apps/details?id=com.mymealmate&hl=en). The MMM app also has a link featured on the NHS Choices website (NHS Choices, 2013) so the research has provided a tangible output which the general public are free to use.

9.5.2 Limitations of the approach and the thesis

9.5.2.1 The potential influence of the researcher

The PhD candidate responsible for conducting this research is a State Registered Dietitian. It should be considered that the candidates' background may influence the research conducted in both positive and negative ways. In terms of strengths, dietetic training and experience of working directly with overweight and obese patients within the NHS has given the candidate the advantage of having first-hand knowledge of current obesity treatment within primary care. This aided the candidate in developing the intervention in line with national obesity guidelines. It could also be argued that prior experience of working with overweight and obese patients has enhanced the candidates' communication and empathy skills which has been a strength when working directly with trial participants. However, it might also be the case that the participants' knowledge of the researcher's background may have led them to feel pressure to report intake or act in a socially desirable way. As a result they may have felt less comfortable in the trial due to perceived judgements from a nutrition professional. The candidate was mindful of this effect and efforts were made to avoid this by maintaining a professional, open and non-judgemental demeanour throughout the trial. Dietitians whilst having a background in working clinically with individuals, in general have less training in public health nutrition and wider population strategies so the candidate has had to read around this topic more widely to gain the relevant expertise.

It could also be argued that there is a risk of bias in the fact that the researcher was responsible for both developing and trialling the intervention. In an ideal situation these two processes would be conducted by separate researchers. If the researcher has become ‘personally invested’ in the intervention then they may be more likely to want the intervention to perform well in the trial and could intentionally or unintentionally influence the trial in this way. Whilst pragmatically it was not possible to separate development from trialling given the nature of the project, the researcher did take measures to protect against bias. For example, the researcher was not involved in any of the objective outcome measures and measurements were done by fieldworkers blinded to the participants’ allocation. The researcher was also removed from the randomisation process which was done by a third party in a separate room using participant ID. A research assistant was responsible for data entry and for coding the STATA dataset for analysis so that groups were not identifiable during analysis. These measures were taken in order to create a fair test of the intervention as the aim was to generate pilot data in order to conduct a sound definitive trial. In order to reduce the risk of bias, it would be best practice for the researcher not to be involved in a definitive trial of the MMM intervention if there were to be one in the future.

9.5.2.2 The use of multiple methods

Given the innovative nature of the project and paucity of previous research, the researcher chose to use multiple methods and combine non quantitative methods (discussions with focus groups to help develop the intervention) with the quantitative validation and trialling of the intervention. Using mixed methods has strengths and limitations. The strength for this project was that the focus groups did add an extra dimension to the research in that they allowed for the intervention to be tailored to the needs of potential system users. A limitation was that the researcher was less well versed in qualitative methods and had not had the same level of training with this approach as the quantitative methods. The research spans several disciplines including health psychology, health informatics and nutrition but as the researcher and supervisors primarily had nutrition and epidemiological expertise the work could be criticised for lacking the same level of depth within the other disciplines. The researcher did attempt to mitigate this by reading as widely as possible within the other disciplines and by consulting with experts where feasible. For example, the researcher did have several conversations with health psychologists during the initial development of the intervention. However, the research may have benefitted from more input from researchers from the other relevant disciplines.

9.5.2.3 Considerations of e-health literacy and health inequality

The MMM pilot trial has tested the app in a relatively well educated, employed, white, predominantly female sample so little is known about the feasibility and acceptability of the approach as applied to other populations. Obesity is a condition where health inequalities are evident in the UK and lower social economic status and deprivation have been found to be associated with risk of obesity, especially in women (NOO, 2012). In order to address health inequalities, if MMM is found to be effective in a definitive trial, further research may seek to investigate the use of MMM in lower social economic status groups. Socio-economic group has been shown to be a factor in smartphone ownership. In the most recent statistics from OFCOM, in 2012, 29% of all smartphone users were in social group AB, 32% in C1, 17% in C2 and 21% in DE. Most smartphone manufacturers have extended their range to include lower price handsets, and smartphone prices continue to drop so accessibility among lower income groups may increase over time. However, price and accessibility are only pertinent if the user has the skills to be able to adequately engage with the intervention. Therefore, for future development it is worthwhile considering the MMM app in the context of individuals with differing 'health literacy'. 'Health literacy' has been defined by the European Health Literacy Consortium in 2012 as:

'linked to literacy and entails people's knowledge, motivation and competences to access, understand, appraise and apply health information in order to make judgements and take decisions in everyday life concerning health care, disease prevention and health promotion to maintain or improve quality of life during the life course.' (Source: WHO, 2013).

There is evidence that lower levels of health literacy are associated with poorer health outcomes (WHO, 2013). A European Health Literacy Survey conducted between 2009 and 2012 across 8 European countries with approximately 8000 respondents found that nearly half of all Europeans had inadequate or problematic health literacy skills (HLS-EU Consortium, 2012). Whilst the UK was not included in this survey, it is estimated that 1 in 6 adults in England struggle with general literacy having a reading age below the level expected of an eleven year old (National literacy trust, 2013) and 24% of adults have numeracy skills equivalent to a child aged nine or younger (for example, they might struggle to count up to 1000) (Department for Business, Innovation and Skills, 2012). General numeracy and literacy skills are likely to be important in terms of searching the food database and estimating portion sizes.

As health interventions are developed using ICT as a mode of delivery, the concept of health literacy has been expanded further to consider 'e-health literacy.' E-health literacy has been defined by Neter and Brainin (2012) as *'the ability of people to use emerging information and communications technologies to improve or enable health and health care'.* Norman et al. (2006) has developed a model for e-health literacy which contains 6 components: traditional literacy (basic reading and writing skills); information literacy (how to find and use information); media literacy (critically reflecting on the media source and placing information in a social and cultural context); health literacy (ability to interact with the healthcare system and engage in self-care); computer literacy (ability to adapt to and use technology) and scientific literacy (understanding the processes of creating scientific knowledge and placing health findings in the appropriate context).

Given the complexity of e-health literacy and the high rates of poor general literacy and numeracy in the UK, it may be worth considering in the future whether there is a requirement and scope to modify MMM for population groups with differing levels of e-health literacy. E-health literacy may be particularly important in a diet tracking app such as MMM where participants are required to have fundamental literacy and numeracy skills in order to understand the written content of the application (i.e. goal setting, text message content and searching the database for foods) and numeracy skills (in order to estimate portion sizes, input body weight, and understand calorie counting). Studies investigating health literacy in the area of nutrition have shown lower literacy and numeracy to be linked to poorer accuracy of portion size estimation (Huizinga et al., 2009) and less understanding of nutritional food labelling (Rothman et al., 2006). Food and activity diaries in particular have been criticised in a health literacy context for being *'minimally interactive and requiring high-user motivation for use'* (Zarcadoolas et al., 2011).

Strategies to tailor health interventions in order to support lower health literate populations have tended to focus primarily on 2 approaches, 1) simplifying written material so that it is written in plain language or 2) education and training (Xie, 2011).

When improving e-health interventions for lower literacy populations, researchers have additionally used audio-visual information and consistency in website navigation to engage with individuals with lower literacy levels (Mackert et al., 2009). Given that the use of mobile devices for overweight/obese adults is an emerging area there is little evidence to guide how such an intervention might be tailored to populations with lower e-health literacy (and indeed how effective such tailoring might be). However, theoretically there are numerous ways in which the MMM app could possibly be tailored to target users with lower literacy and numeracy skills. For example;

- Instead of (or in addition to) searching the database by typing in foods, as technology evolves it may be possible to employ voice recognition or barcode scanning. Alternatively users could search the database using food images rather than words (in a similar way to self service check-outs at supermarkets within the UK). For example, the online dietary assessment tool 'DietDay' developed in the US has taken this approach with a library of images of food pictures for the user to drill down through higher level food categories to find the specific image (Arab et al., 2010).
- The language used throughout the MMM app and the text message feedback could be assessed and simplified if appropriate.
- More audio-visual components could be included, for example, within a help section or in the form of additional training which could be included as a user begins the app. The online dietary assessment tool 'ASA24' (Subar et al., 2012) uses an avatar of a cartoon penguin which talks to the user and guides them through the system, which may be helpful for adults with lower literacy levels.
- With regard to the numerical components of the MMM app, participants are encouraged to manually enter their weight weekly into the app but this step in the process could be automated if the app was linked via wireless network or Bluetooth to digital scales which could automatically upload the weight to the app. Weight loss progress may be tracked in a more visual way rather than by a graph. For example, one person in the focus groups conducted at the start of the project, suggested that they might like to track their weight loss with an image of a person becoming slimmer over time. Alternatively, users may wish to upload their own photos documenting their weight loss.
- As the calorie counting aspect of MMM is automatic it does not require the user to add up the calories themselves. However, the calorie counting does include large numbers and daily energy targets are likely to be in the thousands so this element may lend itself to adaptation so that smaller numbers could be used.

For example a nutrition scoring system using smaller numbers could be devised similar to that employed by the 'Weight Watchers' points system.

- Since e-health literacy includes several domains, a user's information literacy skills may also need to be considered independently and perhaps could be assessed prior to a trial. In this case, training on use of the phone and app could be targeted to those individuals with lower information literacy skills.
- Although the technology is still in its infancy, researchers are investigating means of identifying foods and estimating portion sizes by using photographic images rather than manually selecting the food from a database (Boushey et al., 2009; Zhu et al., 2010). This might be useful not only for improving the accuracy of dietary assessment but also could be employed in a diet tracking apps such as MMM to aid those with lower literacy and numeracy skills.

In summary, further investigation of MMM should consider the e-health literacy of different test populations and seek to understand whether there is a need for and a scope to modify MMM in the future for use in populations with lower e-health literacy and whether any of the ideas above may be appropriate to test.

9.5.2.4 Challenges of using ICT

There are a number of challenges when developing ICT based interventions, one of these is the rapid rate of technology progression. Measures were taken to 'future-proof' MMM, for example by selecting the open source Android platform which allows for use on a range of handsets. However, the diet tracking apps which MMM was benchmarked against originally have developed newer features such as linking into social networking websites, bar code scanning and cross-platform functionality. Another challenge of this approach is maintaining an up to date food composition database given that food and beverage manufacturers regularly reformulate products or introduce new products to the market. As the MMM database has been provided by a commercial company, there is potential to update it with a new database download for future use when desired. However, in order to keep the MMM app up to date and engaging, on-going funding and input is required.

9.5.2.5 Accuracy of energy intake recorded on MMM

The two validation studies have implications for the use of MMM as a weight loss tool as they raise the question of whether the MMM app can help the individual to record their energy intake sufficiently for weight loss. The NICE obesity guidelines recommend a 600kcal deficit to daily intake to achieve a 1lb a week weight loss (NICE, 2006). If the MMM app could potentially be under or over reporting energy intake by as much as 600kcal in an individual (as suggested by the limits of agreement observed in the two validation studies) then this is important. Given that the mean BMI of participants in the validation study was 24 kg/m^2 (SD: 4) it could be speculated that even larger limits of agreement might be found if the validation study were to be conducted on a sample of overweight/obese participants considering that overweight/obese individuals have been shown to underreport intake compared to healthy weight individuals (Rennie et al., 2007).

Whilst there is evidence that frequency of dietary self monitoring is associated with weight loss (Burke et al., 2011) it is not known whether the self monitoring of diet also needs to be accurate in order to be effective. In the pilot trial, 16/43 (37%) of the MMM group were able to lose a clinically significant amount of weight (≥5%) using the MMM app. It would appear in those individuals at least MMM was able to help them to record their intake sufficiently to lose weight. Whilst it appears that in the pilot those who self monitored the most frequently lost the most weight, it is not known whether they were also recording their intake the most accurately. One mode of action of dietary self monitoring could be through the accurate tracking of energy intake and adjusting food choices accordingly throughout the day to meet the target. However it could be the simple act of frequent recording of food and drink alone regardless of accuracy is enough to develop ‘mindful’ rather than ‘mindless’ eating and that by raising awareness in this way the individual is prompted to make different food and drink choices. If the mode of action is the former then inaccurate reporting could lead a person to continue to record on MMM and believe they are meeting the energy target but not see any weight loss and this could be a reason for disengaging with the trial.

It would be interesting to further investigate whether accuracy of reporting on MMM is important for weight loss. If a larger trial was conducted then it may be possible to test a sample of users in a validation study and attempt to classify them in some way in terms of their accuracy of reporting compared to a reference measure. It may then be possible to investigate whether accurate reporters lose more weight or indeed adhere to the trial more. However, it must also be considered that accuracy of recording may not be static over the duration of use. Whilst there is a chance accuracy may improve over the course of time as the user becomes more familiar with the use of the app, it is also possible that it might decline due to 'recording fatigue'.

MMM was designed for weight loss and not accurate dietary assessment therefore speed of entry of food and drink items and ease of use were priorities. However the validation study has shown that there is room for improvement in helping participants to increase the accuracy of their recording if this was considered important. Portion size estimates in particular appear to be a source of error on MMM, and the current portion estimation facility on MMM is very limited (currently the user is presented with a default serving size or is required to manually enter the weight of how much they consumed). One option to increase accuracy may be to offer portion size photographs, although this is limited by the small screen architecture of smartphones. Also, the WLR database itself could be improved by filling in some gaps where the default serving sizes are poor. As WLR have obtained serving sizes from 'back of pack' nutritional labelling these may often be smaller than an actual portion size as consumed.

Spending time on making sure that the database search is as efficient as possible could also be useful for engagement with the app and improved accuracy of reporting. Whilst measures were taken to make searching the database efficient (generic items displayed first, spell check function on the search term as it is entered) more could be done to make it more intuitive as only 34% of participants in the smartphone group agreed or strongly agreed that it was easy to find foods. As MMM is used by more people, frequently selected items could move to the top of the search and the database could be populated with misspellings, synonyms and keywords which could be used as search terms so if the food item or brand is not spelt correctly it may still be found. However, finding the correct food and estimating an accurate portion size must be balanced with the need for speed and convenience of use.

9.5.2.6 Lack of reporting on dietary change

A large amount of data has been generated in the pilot trial including the nutritional data entered onto the apps throughout the trial (energy, protein, carbohydrate and fat) which would have been interesting to examine. Although the participants in the trial self-reported on the changes to the eating related behaviour it is not known objectively what changes participants made to their diets using the interventions. The traditional methods available for dietary assessment include multiple 24 hour recalls, food frequency questionnaires and diet records. There were considered to be several limitations to using these methods to collect dietary data from participants in the pilot trial. Food frequency questionnaires are designed for ranking individuals in terms of food consumption habits in large epidemiological studies (Patterson and Pietinen, 2004) so it was not felt appropriate in this instance given the small sample size and aim to detect change over time. Multiple 24 hour recalls were not considered plausible logistically given the size of the pilot sample as they involve high subject and researcher burden (Buzzard, 1998) and a minimum of three recalls are recommended to assess normal diet (Bingham, 1987). This would have required 384 recalls to be conducted prior to the study and additional time spent doing the nutritional coding. A paper food diary was not possible to deliver in a consistent way across the groups given that those in the paper food diary group were already keeping a diary and to ask the smartphone and website group to keep a diary alongside recording their intake electronically would have been high participant burden.

Although an earlier idea was to use the diet records collected on the MMM app itself to assess dietary change this proved difficult in practice. Few participants recorded daily for the entire 6 month period so taking a cross section of the sample at different time points was difficult as some participants may or may not have recorded intake over the course of the week at one particular point. If a reduction in energy intake was observed in the nutrient data it is difficult to tell whether that was due to a genuine reduction in intake or through 'reporting fatigue' due to the lengthy 6 month recording period. Participants in the validation study were aware that the aim of the study was to assess accuracy of reporting and they recorded for 7 days only. No stipulations about accuracy of recording were made to pilot trial participants who were free to record at the level of accuracy they desired. Therefore it is questionable whether participants in the pilot trial would have been reporting their intake accurately enough for adequate dietary assessment throughout the entire 6 months. The validation study of MMM also showed the MMM app to have very wide limits of agreement at the individual level so it was not felt appropriate to detect dietary change over time for the individual in a sample of this size.

9.5.2.7 Scope for optimisation of the intervention

There is scope for further investigation regarding optimisation of the intervention package. The focus groups attracted only very small numbers and it would have been interesting to capture a wider range of opinions on the intervention. Given the length of the project and the need to fit in a development phase, validation study and pilot trial whilst working with an external contractor the timescale to make the decisions about development were limited. There is large scope to further investigate the optimum components of the app, in particular the SMS component was not rated highly in the pilot trial evaluation and more time and effort could be spent on improving this component. Future research could explore the tone and type of message with focus groups and perhaps even conduct a small trial to compare and evaluate several iterations of the MMM app with different frequency/content of text message.

9.6 Balancing the need to optimise the intervention with future research

A recent systematic review of 'e-learning' devices (Harris et al. 2011) found no evidence of their effectiveness for improving dietary behaviour and also stated that such interventions were no more cost-effective than other methods. Given this lack of evidence of effectiveness, the large number of different theoretical frameworks and the long and disparate list of different behaviour change strategies which had informed the interventions, the authors called for trials in the area to desist until the most effective intervention characteristics are determined. However it is worth noting that most of the studies in the 'e-learning' review looked at online systems and only mobile devices other than smartphones were considered. Smartphones as a behaviour change delivery medium may offer additional advantages not conferred by other older devices given that they are portable, ubiquitous and discrete.

Whilst it is certainly beneficial to determine the most effective behaviour change techniques to optimise a smart phone based obesity intervention it could be argued that the research in the area needs to be balanced with the need to keep up with the progression in technology and the pressing public health demand for effective interventions with which to tackle the obesity epidemic. In the case of diet tracking smartphone applications in particular, there is evidence for large numbers of downloads by the public so whilst there is such large public demand it is within the public interest to determine whether such an intervention as a complete package may be effective, even if the most effective individual components are not fully understood. There is already evidence for the effectiveness of the behaviour change components of MMM. A recent meta-regression showed that self monitoring along with one other self-regulatory technique from control theory (Carver & Scheier, 2011) (i.e. prompting of specific goal setting, providing feedback, reviewing behavioural goals) was more effective than other behaviour change techniques used in healthy eating and physical activity interventions (Michie et al., 2009).

The promising results seen in the MMM pilot trial justify a call for a definitive trial of the intervention. A recent systematic review (Bacigalupo et al., 2012) looking at handheld devices and obesity showed that trials in the area had a number of shortcomings including short duration of follow up, lack of allocation concealment, small sample sizes and lack of diversity in samples and there is a need for well designed trials to explore the potential of a smartphone app as a means to deliver a weight management intervention. The literature review in chapter 2 of this thesis which also includes some more recent studies also showed mixed evidence of effect and methodological flaws in the existing evidence. The pilot trial of MMM is good groundwork to design a methodologically rigorous definitive trial of the intervention. This call for a definitive trial is not disputing that there is still scope to improve the MMM intervention as there may be additional behaviour change techniques which could be incorporated which may make the intervention more effective and the ideal combination of techniques is not yet known. However, future research with MMM must balance the need for formative work to optimise the intervention with the need for a definitive trial of a diet tracking smartphone app. These priorities must be considered against a climate of public demand for mobile health apps (which are as yet not well evaluated) and the public health imperative for a range of options with which to support the efforts of overweight and obese people to manage their weight.

9.7 How could the work have been improved?

In terms of the development of the intervention, the feedback received from the evaluation questionnaires suggests that participants were dissatisfied with the text messages. Although the MMM text messages were developed with advice from a psychologist and from consulting with small focus groups there is scope for improvement. As a new area of research, at the time of intervention development there was little guidance from similar trials on what kind of text messages would be most appropriate. The MMM app would have benefitted from some further formative work on the text messages and perhaps piloting a range of different styles of messages with focus groups to enhance the effectiveness of this aspect. It is also not clear which individual behaviour change strategies are the most effective to incorporate into the intervention and in which combination. Although there was a rationale for incorporating the strategies chosen, there are other strategies which are recommended in the NICE Obesity guidelines (2006) which may have also been interesting to test, i.e. stimulus control, advice on how to cope with ‘lapses’ and high risk situations, problem solving and cognitive restructuring. A different approach to the overall project might have been to develop several iterations of the intervention with different behaviour change strategies incorporated and pilot test these against each other with small groups of participants to produce the best possible intervention. This would mean taking a step back from the validation and pilot work and spending the time and resource on formative work on the intervention itself. Pragmatically however, this was not appropriate given that the PhD work was conducted alongside a prescriptive project outline.

9.8 Recommendations for future research

Given the encouraging feasibility, acceptability and anthropometric findings seen in the pilot trial a definitive trial of MMM is warranted. However, it would be beneficial to modify the trial design based on the learning from the pilot trial. For example, the pilot trial suffered from high loss to follow up in the comparison arms which would need to be avoided in a larger trial. There may be several ways that this could be addressed;

1) By providing a ‘delayed control’ so that participants would eventually receive the intervention.
2) By providing incentives for follow up or by following up at home
3) In a future trial it is likely that more of the population will own a smartphone so it may not be necessary to give all participants a phone handset which may reduce ‘resentful demoralisation’ in a comparison arm who do not receive a smartphone. In order to achieve this it would be important to develop the MMM app for other popular smartphone platforms. This would also help to test the app in real life conditions as it was clear from the pilot trial that some participants were still carrying two phones about and not using the trial phone as their main phone.

It may also be beneficial to consider using a different comparison arm in a definitive trial of MMM as three arms would be unnecessary if the research question is focused on comparing a smartphone app for weight loss against ‘usual care’ rather than different approaches to self monitoring. It is difficult to provide a ‘usual care’ intervention given that NHS ‘usual care’ tends to be varied depending on the NHS primary care trust and in the community the general public are likely to use a variety of different sources of support. One approach might be to provide a control group which receives monthly SMS which links to healthy eating advice. This would allow for an important inclusion criteria of owning a smartphone to be met but without any of the MMM active intervention components.

There is also potential to modify the MMM app to support other diet related health conditions such as hypertension and diabetes. To aid this, the display on the app could be modified to track additional or alternative nutrients to energy and could be used as an intervention to improve dietary quality or self monitor a range of different nutrients. The app could also be modified to investigate whether it might be effective in the long term maintenance of dietary change or weight loss. Although the pilot trial tested the MMM app in the general public, it would be interesting to investigate the effectiveness of this approach in primary care. Although the pilot trial has tested a minimal contact approach, as the diet records on MMM are automatically uploaded it provides the ability for a health professional such as a GP or Dietitian to be able to review dietary self monitoring with patients and offer feedback. This gives flexibility in the way in which MMM might be used in the primary care setting and offers more opportunities for further investigation.

9.9 Outstanding questions

There are several outstanding questions which have not been addressed in this pilot but may be interesting to look at in a future trial. For example, it is not known whether self monitoring needs to be accurate to be effective or whether there are certain associated dispositional traits of those who display high levels of self monitoring. It is not known how much self monitoring is necessary for effectiveness and if the trial had gone on for a longer period whether the self monitoring would have also needed to continue at the same level for effectiveness. It is also worth considering whether anything could have been done to improve the drop-off in adherence seen over time or whether more could have been done for those who stopped immediately.

In addition, given the minimal contact nature of the MMM approach it could be assumed that the approach would be cost effective compared to other more intensive interventions. However one needs to be careful with this assumption given that so little cost effectiveness evaluation been carried out to date on smartphone applications for weight loss and such a component would be necessary in the definitive trial. Although behavioural weight loss interventions have been shown to be effective in the short term there is less evidence of effective interventions for weight loss maintenance. A 6 month pilot trial is a short period and gives no indication of how effective the app may be over the longer term. Frequency of use of the intervention waned over the 6 month period so that only a small number were still using the app at the end of the trial. If the app were to be trialled over the long term it is unknown whether this trend would have continued and whether the app has a ‘learning effect’ so that possible lifestyle changes made at the beginning of the trial are maintained over the longer term without the need for continuous monitoring. In planning a longer term trial it is worth considering the results of the SMART trial by Burke et al (2012) who tested a PDA device for self monitoring and found initial loss at 6 months but weight recidivism by 2 years. It could be argued that smartphone apps are different to PDA's and could be engaged with and used differently, however the underlying processes of goal setting, self monitoring and feedback are comparable so in a further trial there may need to be consideration of whether there are appropriate strategies which could be employed to discourage the drop-off in monitoring seen over time.

9.10 The need for a societal approach to obesity

The multi-factorial nature of obesity means that there is unlikely to be a 'magic bullet' one size fits all approach to treatment. The pilot trial has found some interesting results and if a definitive trial of MMM provides evidence of effectiveness for weight loss, the app could be one of a number of tools that overweight/obese adults may choose to use to facilitate their weight management efforts. Trialling new technologies for dietary recording is particularly appealing in an 'obesogenic environment' where energy dense foods are often cheap and convenient and growing portion size norms can make it difficult to keep track of intake.

However, whilst new technology may be investigated as one means of helping individuals to self-regulate their own behaviour, this is only one approach to addressing the problem. Current government policy on obesity in England asserts that obesity is 'everyone's responsibility' and calls for action across society involving the individual, health professionals, the food industry and local authorities (Department of Health, 2011). In the White Paper 'Healthy Lives, Healthy People: A call to action on obesity in England' the Department of Health sets out a national 'ambition' (rather than target) to see a *'downward trend in the level of excess weight averaged across all adults by 2020.'* The document puts an emphasis on *'eating and drinking too much'* as the key cause of overweight and obesity and states that reducing national energy intake (relative to expenditure) is a key priority. The report sets a challenge to collectively reduce national energy intake by 5 billion calories a day.

The key ways in which the government sees this being achieved is through: investment in 'Change4life'; giving local government a leading role in local weight management initiatives; helping people to make healthy choices (for example, by improving nutritional labelling), encouraging physical activity (for example, by linking initiatives to the London 2012 Olympics) and in particular, the government highlights the role of working with industry in the 'responsibility deal' which is based on voluntary pledges to develop strategies to improve public health from industry themselves rather than government regulation. The responsibility deal pledges encourage the food and drink industry to: reduce harmful ingredients in their products; encourage uptake of fruit and vegetables and display calories on menus of fast food outlets and restaurants.

In a press release, The Association for the Study of Obesity (ASO, 2011) responded to this report by welcoming its focus in highlighting the seriousness of obesity but emphasised the *“clear and pressing need for governmental leadership in the co-ordination of the response to the obesity crisis”.* The report was criticised in the media by some academics and by voluntary organisations such as the National Obesity Forum (NOF, 2011) for not doing enough and for a lack of a coordinated and committed government effort to tackle the obesity problem. So whilst a smartphone app for weight loss may be one tool for the public to use in their weight management efforts and to create a calorie reduction there is still a need for a more coordinated government effort in addressing the obesogenic environment at the societal level to support people in making healthy choices.

9.11 Conclusion

This thesis has reported on the development, validation and pilot trial of ‘My Meal Mate’ (MMM) a smartphone application for weight loss. MMM has been developed as an evidence based approach and the initial validation study shows promise for MMM as a dietary assessment tool. The pilot trial of a smartphone app for weight loss has shown that it is both an acceptable and feasible intervention and has provided data to inform a definitive trial. Adherence to the intervention and to the trial was greater in the smartphone group than the comparator groups and the app was rated highly in terms of satisfaction and acceptability. There is scope to improve and update the MMM app and to investigate the best means of delivering it.

Although MMM was comparable to diet tracking apps commercially available at the time of the trial these now have newer features to improve functionality due to the evolution of technology (such as bar code scanning and linking to social networking) so these improvements might be appropriate in a future trial. If the MMM app were to be taken forward and used in future studies on-going funding is needed in order to keep the database up to date and the technology itself relevant. There is evidence that commercially available diet tracking apps are popular and a smartphone intervention for weight loss could be one of a number of tools that individuals may wish to use to manage their weight. To the author’s knowledge there have been no large RCTs of smartphone apps for weight loss and this pilot trial provides valuable data which could be used to inform such a trial. The promising feasibility, acceptability and effect size data found in this trial warrant further research.

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Appendix 1: Favourable outcome letters for ethical approval for three separate stages of the project.

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Prof Janet Cade
Nutritional Epidemiology Group
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Room 8.001, level 8, Worsley Building
University of Leeds
LEEDS LS2 9NL

28 April 2010

Dear Janet

Re ref no: HSLT/09/019
Title: Smartphone: promoting weight loss and improved health using mobile phone technology - Part 1: initial development work

I am pleased to inform you that the above research application has been reviewed by the Leeds Institute of Health Sciences and Leeds Institute of Genetics, Health and Therapeutics (LIHS/LIGHT) joint ethics committee and following receipt of reviewers' comments (enclosed for your information), I can confirm a favourable ethical opinion on the basis described in the application form, protocol and supporting documentation at submitted at date of this letter.

Please notify the committee if you intend to make any amendments to the original research as submitted.

I wish you every success with the project.

Yours sincerely

Laura Stroud

Professor Alastair Hay/Mrs Laura Stroud
Chairs, LIHS/LIGHT REC

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Prof Janet Cade
c/o Michelle Carter
Nutritional Epidemiology Group
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11 June 2010

Dear Janet

Re ref no: HSLT/09/ 027
Title: Smartphone: promoting weight loss and improved health using mobile phone technology - Part 2: Validation of diet and physical activity measures

I am pleased to inform you that the above research application has been reviewed by the Leeds Institute of Health Sciences and Leeds Institute of Genetics, Health and Therapeutics (LIHS/LIGHT) joint ethics committee and following receipt of the amendments requested, I can confirm a favourable ethical opinion on the basis described in the application form, protocol and supporting documentation at submitted at date of this letter.

Please notify the committee if you intend to make any amendments to the original research as submitted at date of this approval. This includes recruitment methodology and all changes must be ethically approved prior to implementation. Please contact the Faculty Research Ethics and Governance Administrator for further information (r.e.desouza@leeds.ac.uk)

I wish you every success with the project.

Yours sincerely

Laura Stroud

Professor Alastair Hay/Mrs Laura Stroud
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Michelle Carter
Research Dietitian
Nutritional Epidemiology Group
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University of Leeds
Leeds, LS2 9JT

14 October 2010

Dear Michelle

Re ref no: HSLTLM/10/ 002
Title: Smartphone: promoting weight loss and improved health using mobile phone technology– Part 3: Pilot RCT

I am pleased to inform you that the above research application has been reviewed by the Leeds Institute of Health Sciences and Leeds Institute of Genetics, Health and Therapeutics (LIHS/LIGHT) joint ethics committee and following receipt of the amendments requested, I can confirm a favourable ethical opinion on the basis described in the application form, protocol and supporting documentation at submitted at date of this letter.

Please notify the committee if you intend to make any amendments to the original research as submitted at date of this approval. This includes recruitment methodology and all changes must be ethically approved prior to implementation. Please contact the Faculty Research Ethics and Governance Administrator for further information (r.e.desouza@leeds.ac.uk)

I wish you every success with the project.

Yours sincerely

Laura Stroud

Professor Alastair Hay/Mrs Laura Stroud
Chairs, LIHS/LIGHT REC

Appendix 2. MMM pilot trial information sheets and consent form

Nutritional Epidemiology Group
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UNIVERSITY OF LEEDS

FLIP Pilot Trial

Facilitating Lifestyle Improvement by Phone

Information Sheet

Please take your time to read the following information. This will hopefully answer any questions you may have, but if you feel you need more information please feel free to get in touch with Michelle Carter (Research Dietitian) on 0113 343 8908 or email m.carter@leeds.ac.uk

1) What is the purpose of this study?

This trial aims to find out whether mobile phone technology can be used to support weight loss. There is no "quick fix" for weight loss but we are investigating tools which might help to support you if you are trying to lose weight. The University of Leeds has designed an innovative smart-phone application called "My Meal Mate" which will be tested as a weight loss support tool. "My Meal Mate" allows the user to set a personal weight loss goal and monitor food and activity levels in an electronic food diary. The application tracks daily calories and provides feedback on progress towards weight loss goals. We want to compare three different approaches to using technology for weight loss to see which is the most effective. One group will be provided with a HTC Desire smart-phone to test the weight loss application, one group will be given free access to a weight loss website and one group will trial a traditional written food diary. The study will last for 6 months and will explore how useful each method is and whether there is any potential for mobile phone technology to be tested in a much larger study in the future.

2) Do I have to take part?

No it is entirely up to you. We will ask you to read and to sign a written consent form stating that you are happy to take part. You are still free to back out of the study at any time and you do not have to give a reason. However if you withdraw from the trial we will need to have the study equipment returned.

Information Sheet

3) What do I have to do?

This study is a randomised controlled trial which means you will be randomly assigned to one of three groups (smartphone, website or food diary). Allocation to a group is by chance – a bit like tossing a coin so there is an equal chance that you could be in any of the groups. Neither you nor the researcher will be able to choose which of the groups to put you in.

- <u>Smartphone group</u>

If you are in the "smartphone" group you will be given a HTC Desire smartphone to use for the 6 month trial. We want you to use the trial phone as you would a normal phone so you will have credit to make free calls, texts and access the internet. The phone will be the property of the University of Leeds at all times and at the end of the trial we will ask for you to return the phone. You can use the weight loss application as you wish and the phone will upload the information you have entered to a secure website which only the researcher will have access to. The application allows you to keep a food and activity diary and helps you to keep track of your calories throughout the day in order to meet calorie goals for weight loss. The application allows you to take photographs of your food if you do not have time to enter the food then and there, this can serve as a memory prompt later. It also provides you with feedback on your progress towards goals via messages.

- <u>Website group</u>

If you are allocated to the "website" group you will be given free access to the "Weight Loss Resources" website which is a commercial online slimming website for which people would normally pay a monthly fee.

- <u>Food diary group</u>

If you are allocated to the "food diary" group you will receive a blank food diary and a book called the "calorie bible" which contains information on the calorie values of 22,000 UK foods. This allows you to keep a written record of the food you eat and count your calories. Each group will have access to an online forum to ask questions and share ideas with other participants and the research team.

At the beginning of the trial we will ask you to attend an appointment at the University of Leeds where we will take your measurements (weight and height). We will try to arrange evening and weekend appointment sessions as well as daytime. We will also ask you to fill out some questionnaires which will ask about your attitudes towards your diet, weight and using mobile phones. You will be asked to use the phone/website/diary daily for 6 weeks and then you will be invited back to the University to be re-weighed. Then you will continue to use the phone/website/diary for the rest of the study period so that after 6 months we would like you to return and repeat final measurements. This means in total you will be making 3 visits to the University for measurements (on day 1, after 6 weeks and after 6 months). At the end of the trial we will ask people in the "smartphone" group to return the phones and diary group to return books.

Information Sheet

4) Will my taking part in the study be kept confidential?

All information will be held in the strictest confidence and will not be available to anyone outside of the research team. You will not be identified by name in any reports of results.

5) What's in it for me?

If you are monitoring your food intake be it on the phone or in a diary it may help you to become more aware of dietary patterns and could promote weight loss. Even a modest weight loss can have a range of health benefits. Those in the "smartphone" group will benefit by receiving a top of the range smartphone (HTC Desire) to use for 6 months (with a data package for 3G internet connection and calls and texts included), those in the "website" group will benefit by receiving access to a specialist slimming website which would normally charge a monthly fee, and those in the "food diary" group will benefit from receiving a free calorie bible and blank food diary which would normally be commercially available. There is no "magic formula" for weight loss but it is hoped that these tools might help to support you if you want to lose weight. Whichever group you are assigned to, by taking part you will be in a trial which is helping to develop a new approach to weight loss and could help people to improve their health in the future.

6) What are the possible disadvantages and risks?

Participating in a research study can be an inconvenience to your daily life. You will be asked to take time to attend an appointment at the beginning, after 6 weeks and end of the 6 month period. You will also be asked to spend time over the 6 months using whichever method you have been allocated (i.e. using the smart-phone, accessing the website or using the food diaries). When considering whether to take part you should think carefully about the responsibilities required by the study and whether you feel that now is the right time for you to attempt to lose weight and whether you feel motivated to try these approaches and monitor your food intake by these methods. There is no "magic formula" for weight loss so these methods are tools to help you if you feel that now is a good time for you to try to lose weight.

Information Sheet

7) Who has funded the study ?

The study is funded by a grant from the National Prevention Research Initiative (a national initiative made up of government departments, research councils and major medical charities that are working together to encourage and support research into chronic disease prevention. It is administered by the Medical Research Council (MRC).

8) How will the results of the study be used?

The final results will be assessed and a report will be written regarding how well the mobile phone compares to the other groups. This will not include any individual information or names. This report will be submitted for publication in a journal.

9) Who has reviewed the study?

The study has been reviewed by Leeds University Research Ethics Committee

10) What do I do now?

To take part you need to reply to the study team with your answers to the eligibility questions. If you have any queries or would like to talk to someone for more details about this study please contact us at "smartphonestudy@leeds.ac.uk.. We will be happy to answer any queries. Once we have your responses we will get in touch to let you know if you are eligible to take part.

Thank you for your help

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UNIVERSITY OF LEEDS

FLIP Consent form

Facilitating Lifestyle Improvement by Phone

Please initial to confirm	**Initials**
I confirm that I have read the information sheet for the study	……
I have had the opportunity to ask questions about the study and to discuss it, if I wanted to, with family and friends.	……
I understand the purpose of the study and how I will be involved.	……
I understand, and accept, that if I take part in the study I may not gain any personal benefit from it.	……
I understand that all information collected in the study will be held in confidence and that, if it is presented or published, all my personal details will be removed.	……
I understand that my participation is voluntary and that I am free to withdraw from the study at any time without giving a reason.	……
I confirm that I will be taking part in this study of my own free will and I understand that I may withdraw from it, at any time and for any reason, without my medical care or my legal rights being affected.	……
I agree to take part in the above study.	……

Name (please print)

……………………………………………………………………………………

Signed…………………………………………… Date……………………

Appendix 3: Baseline questionnaire 2 (self-administered at the start of the MMM pilot trial)

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ID Number ....

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FLIP **Part 2 - Baseline questionnaire**
Facilitating Lifestyle Improvement by Phone

Thank you for taking the time to help us with our research. These questions are designed to find out about your characteristics and your attitudes towards technology. Your responses are really important to us and can help us to develop ways for people to manage their weight and improve their health in the future. Please answer every question even if it might not seem relevant to you. If you are uncertain about how to answer a question then do the best you can but please do not leave any questions blank.

Your answers will be treated in the strictest confidence and only used for the purposes of this research.

Please turn over page

Section A – About you

It would be helpful if you could give us some information about yourself so that we can put your answers into context. This is anonymous data and will be held in the strictest confidence.

1) What sex are you ? *(please tick box)* **Male** ☐ **Female** ☐

2) How old are you ? ____________

3) What is your ethnicity? *(please tick box)*

White ☐

Asian or Asian British

Indian ☐ *Pakistani* ☐
Bangladeshi ☐ *Other Asian* ☐

Black or Black British

Black Caribbean ☐ *Black African* ☐
Black other ☐

Chinese ☐
Mixed ☐
Other ☐

4) Regarding smoking, are you? *(please tick box)*

a) A current smoker	
b) An ex smoker	
c) Never smoked more than 100 cigarettes	

Section A – About you

5) Occupation – what best describes the work you do? (please tick in box)

a) Managerial and professional Occupations – e.g. teacher, nurse, physiotherapist, finance manager, accountant, solicitor, civil/mechanical engineer, chief executive	
b) Intermediate Occupations – e.g. secretary, personal assistant, clerical worker, call centre agent, nursery nurse, nursing auxiliary	
c) Small Employers and own account workers	
d) Lower supervisory and technical occupation - e.g. motor mechanic, fitter, inspector, plumber, printer, electrician, train driver	
e) Semi-routine and routine occupations – e.g. receptionist, sales assistant, farm worker, HGV/van driver, caretaker	

6) What is the highest level of education you have completed? (please tick in box)

a) None	
b) NVQ / GNVQ	
c) CSEs	
d) O Levels/GCSEs	
e) AS / A Levels	
f) City and Guilds Technical or Trade Certificate	
g) Post Graduate / Higher Degree /Teaching Qualification	

Section A – About you

7) Over the past 12 months would you say that your health on the whole has been? *(please tick one box)*

a) Excellent		b) Very Good		c) Good	
d) Fair		e) Poor			

8) Do you now, or have you ever had ? *(please tick box)*

	Yes	No
a) Diabetes		
b) High blood pressure		

9) On a scale of 1 to 10 how **motivated** are you to lose weight? (Please circle a number from 1 to 10, 1 being not motivated at all and 10 being extremely motivated)

Not motivated **Extremely motivated**

1 2 3 4 5 6 7 8 9 10

10) On a scale of 1 to 10 how **confident** do you feel that you can lose weight ? (Please circle a number from 1 to 10, 1 being not confident at all and 10 being extremely confident)

Not confident **Extremely confident**

1 2 3 4 5 6 7 8 9 10

Section A – About your household

11) How many people aged 18 years or over live in your household in total? _______

12) How many people under 18 years old live in your household in total? _______

13) Are you the person in your household who does most (i.e. more than half the time) of the shopping for food ? **Yes** ☐ **No** ☐

14) With regard to meals eaten within the home. Are you the person in your household who does most (i.e. more than half the time) of the food preparation and cooking? **Yes** ☐ **No** ☐

15) The following is a list of options for evening meals that people might cook/prepare. Please write the number of days each week that you would prepare food in this way next to each method. *For example, if you cooked meals from scratch every day you would put "7" next to option (c).*

a) Convenience foods and ready meals	
b) Ready-made ingredients put together to make a complete meal (e.g. using ready-made sauces)	
c) Dishes prepared from basic ingredients	
d) Meals eaten outside of the home (e.g. restaurant, cafeteria, canteen foods)	
e) Fast-food, take away meals	

Section A – About you

16) Are you currently trying to lose weight? *(please tick box)* **Yes** ☐ **No** ☐

17) In the past year have you lost more than 7lb in weight? (7lb is equal to ½ stone or approximately 3kg) *(please tick box)* **Yes** ☐ **No** ☐

18) Are you a constant "dieter" whose weight often fluctuates? *(please tick box)* **Yes** ☐ **No** ☐

19) Have you ever recorded your food intake in a food diary of some sort (including paper and electronically)? *(please tick box)* **Yes** ☐ **No** ☐

20) In the past year have you gained more than 7lb in weight ? (7lb is equal to 1/2 stone or approximately 3kg) *(please tick box)* **Yes** ☐ **No** ☐

21) Was this weight gain intentional? *(please tick box)* **Yes** ☐ **No** ☐

22) If you answered yes to question 20, what do you attribute your weight gain to? *(please tick as many boxes as apply below)*

Less exercise or general activity	
More snacks	
Medication or illness	
Larger meals or portion sizes	
Getting older	
Eating out/socialising	
Weight gain after pregnancy	
Other *(please state)*	

23) On the next page there is a list of different things that a person might try to lose weight. Please tick whether you have tried any of these methods to lose weight in the past and whether you are currently trying any of them *(tick as many as appropriate)*

Question 23 continued *(please tick all that apply)*

		Tried in past	Doing now
Slimming clubs with group meetings	a) Weight Watchers		
	b) Rosemary Conley/Slimming World or other slimming group with face to face meetings		
A diet plan from a book	c) Atkins Diet , "zone diet" or other carbohydrate reduced diet		
	d) The Ornish , South Beach, Dukan diet or other food combining diet		
	e) Detox , fasting diet or only eating one type of food (e.g. cabbage soup diet)		
Websites and online methods	f) Nutracheck		
	g) Weight Loss Resources		
	h) Weight Watchers online		
	i) Other slimming website (please specify) ___________________________________		
A smartphone app for weight loss	j) My fitness pal		
	k) Other smartphone app (please specify) ___________________________________		
Meal replacement plans	l) Lighter life or Cambridge diet		
	m) Slim fast or shop brought meal replacement products		
Medications	n) Slimming pills (without GP prescription) e.g. "alli", "adios", "lipobind", "slim-nite"		
	o) Weight loss medication prescribed by your GP (e.g. "xenical/orlistat", "reductil")		
Consultations with a health care professional	p) GP, Nurse or Health Trainer, NHS group weight management sessions		
	q) Dietitian		
Surgery	r) Including gastric band or gastric bypass		
Physical Activity	s) Increased physical activity and exercise		
Others (please specify)			7

Section A – About you

24) Approximately how many times have you attempted to lose weight (by restricting /changing your intake of food in some way on purpose for a period of time) in the past? *(please write the number of times on the line below, if never please put a zero)*

Number of previous weight loss attempts = __________

25) Weight Loss Preference – Please rank the following weight loss methods in order of preference for what you think would work best for you personally in the future.

Please rank these from 1-7. **1** being the method you would **most prefer** to use to try to lose weight and **7** being the method that you would **least prefer.** *(Please put the number that you rank each item in the box next to it)*

a) Slimming club with group meetings (e.g. Weight Watchers, Slimming World)	
b) A diet plan from a book (e.g. Atkins, Zone diet)	
c) Recording intake in a paper food diary	
d) Slimming website (e.g. Weight Loss Resources, Nutracheck, Tesco diet)	
e) Smartphone application for weight loss (e.g. My fitness pal, lose it)	
f) Meal replacement plans (e.g. Lighter life, Cambridge diet)	
g) Medications and surgery	

8

Section B – Your attitudes towards technology

We would like to know about your attitudes towards technology. Please indicate for each statement whether you 1.Strongly disagree, 2. Somewhat disagree, 3.Neutral, 4.Somewhat agree, or 5. Strongly agree.

	Strongly Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Strongly Agree
1) In general, you are among the first in your circle of friends to acquire new technology when it appears	1	2	3	4	5
2) You can usually figure out new high-tech products and services without help from others	1	2	3	4	5
3) You find new technologies to be mentally stimulating	1	2	3	4	5
4) If you provide information to a machine or over the internet, you can never be sure it really gets to the right place	1	2	3	4	5
5) You like computer programs that allow you to tailor things to fit your own needs	1	2	3	4	5
6) Other people come to you for advice on new technologies	1	2	3	4	5
7) You do not consider it safe to do any kind of financial business online	1	2	3	4	5
8) You worry that information you send over the internet will be seen by other people	1	2	3	4	5
9) When you get technical support from a provider of a high-tech product or service , you sometimes feel as if you are being taken advantage of by someone who knows more than you do	1	2	3	4	5
10) It is embarrassing when you have trouble with a high-tech gadget while people are watching	1	2	3	4	5

9

Section B –Your attitudes towards technology

The following questions are about your technology usage and "smartphone" experience. There is no industry standard definition of a "smartphone" but it can be thought of as a phone which can run an operating system (e.g. Apple, Google Android, Windows mobile, RIM) download applications and has enhanced computer abilities. There are many different types of smartphone handsets including I-phone, Blackberry, HTC, Samsung, Sony, Nokia and Palm.

	Yes	**No**
11) Do you **own** a smartphone?		
12) Do you **use** a smartphone?		
13) Have you ever used a smartphone application?		

14) If you answered yes to question 11 or 12, please put a tick in the box next to the type of smartphone you have. *(These are options for the phones operating system rather than the handset. If you do not know, its ok to leave this question blank.)*

a)Android (i.e. Google, most HTC)	
b) Apple (i.e. I-phone)	
c) RIM (i.e. Blackberry)	
d) Windows mobile	
e) Other (please specify)	

15) Do you use a mobile phone for any of the these things?

	Yes	**No**
a) Voice calls		
b) Texts		
c) Camera		
d) Internet		
e) Applications		
f) Emails		

16) Do you have internet access at home? **Yes** ☐ **No** ☐

17) How often do you access the internet? (please tick box)

a) Daily	
b) 2-6 times a week	
c) Less than once a week	
d) Less than once a month	

18) On a scale of 1 to 10 how confident do you feel in general about using technology (Please circle a number from 1 to 10, 1 being not confident at all and 10 being extremely confident)

Not confident **Extremely confident**

1 2 3 4 5 6 7 8 9 10

19) How would you rate your ability to use the internet ? (please tick box)

a) Excellent	
b) Very good	
c) Good	
d) Fair	
e) Poor	

20) To what extent would you agree with this statement below? *(please tick box)*

"I like gadgets and new technology"

Not like me ☐ Little like me ☐ Pretty good description of me ☐ Describes me perfectly ☐

Please turn over for last page

Section C – Describing yourself

Please indicate for each statement whether it is an accurate description of you

	Very inaccurate	Moderately inaccurate	Neither accurate nor inaccurate	Moderately accurate	Very accurate
1) I am always prepared.	1	2	3	4	5
2) I leave my belongings around.	1	2	3	4	5
3) I pay attention to details.	1	2	3	4	5
4) I make a mess of things.	1	2	3	4	5
5) I get chores done right away	1	2	3	4	5
6) I often forget to put things back in their proper place.	1	2	3	4	5
7) I like order.	1	2	3	4	5
8) I shirk my duties.	1	2	3	4	5
9) I follow a schedule.	1	2	3	4	5
10) I neglect my duties.	1	2	3	4	5
11) I am exacting in my work.	1	2	3	4	5
12) I waste my time.	1	2	3	4	5
13) I do things according to a plan	1	2	3	4	5
14) I do things in a half-way manner.	1	2	3	4	5
15) I continue until everything is perfect.	1	2	3	4	5
16) I find it difficult to get down to work.	1	2	3	4	5
17) I make plans and stick to them.	1	2	3	4	5
18) I leave a mess in my room.	1	2	3	4	5
19) I love order and regularity.	1	2	3	4	5
20) I like to tidy up.	1	2	3	4	5

Appendix 4. Example pages from the follow up questionnaire (self administered at 6 months)

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FLIP 6 month evaluation
Facilitating Lifestyle Improvement by Phone

Thank you for taking the time to help us with our research. These questions are designed to find out about your experiences within this study at six months. Your responses are really important to us and can help us to develop ways for people to manage their weight and improve their health in the future. Please answer every question even if it might not seem relevant to you. If you are uncertain about how to answer a question then do the best you can but please do not leave any questions blank.

Your answers will be treated in the strictest confidence and only used for the purposes of this research.

Please turn over page

Section C

Please note – These evaluation questions are relevant to participants in all three study groups. If the question asks you about using your "study equipment" this refers to either the phone app, website or food diary depending on your group.

1) How satisfied have you been over the past 6 months with your study equipment (website, phone or diary)? Please rate your satisfaction on a scale of 1-5 by circling a number below.

Very unsatisfied — Very satisfied

1 2 3 4 5

2) On average, how frequently are you using the study equipment? (study equipment refers to either the app, website or food diary) (please tick box)

a) Daily		1
b) 2-6 times a week		2
c) Less than once a week		3
d) Less than once a month		4
e) I used it to start with but have now stopped		5
f) I haven't used it since the enrolment session		6

3) On a scale of 1 to 10 how **motivated** are you to lose weight? (Please circle a number from 1 to 10, 1 being not motivated at all and 10 being extremely motivated)

Not motivated — Extremely motivated

1 2 3 4 5 6 7 8 9 10

4) On a scale of 1 to 10 how **confident** do you feel that you can lose weight ? (Please circle a number from 1 to 10, 1 being not confident at all and 10 being extremely confident)

Not confident — Extremely confident

1 2 3 4 5 6 7 8 9 10

5) On a scale of 1 to 10 how **confident** do you feel in general about using technology (Please circle a number from 1 to 10, 1 being not confident at all and 10 being extremely confident)

Not confident — Extremely confident

1 2 3 4 5 6 7 8 9 10

Please circle the following items from 1-5 (1 = strongly disagree, 5 = strongly agree)

	Strongly Disagree	Disagree	Neither	Agree	Strongly Agree
6) I found the study equipment (phone, website or diary) easy to use	1	2	3	4	5
7) I found the study equipment (phone, website or diary) convenient to use	1	2	3	4	5
8) I liked recording my food and exercise using my study equipment	1	2	3	4	5
9) I think people can lose weight with this approach	1	2	3	4	5
10) I found it useful to record my weight weekly	1	2	3	4	5
11) I found it useful to see how closely I meet my daily calorie target	1	2	3	4	5
12) It was easy to find most of my foods in the food database	1	2	3	4	5
13) It was easy to find most of my activities in the activity database	1	2	3	4	5
14) I had enough training to be able to use my study equipment	1	2	3	4	5
15) I found the length of time it takes me to complete a day's intake acceptable	1	2	3	4	5
16) I would like to continue to use the equipment	1	2	3	4	5

Please circle the following items from 1-5 (1 = strongly disagree, 5 = strongly agree)

	Strongly Disagree	Disagree	Neither	Agree	Strongly Agree
17) I felt comfortable using my study equipment in social settings	1	2	3	4	5
18) The study equipment has helped me to make changes to my diet	1	2	3	4	5
19) The study equipment has helped me to make changes to my physical activity	1	2	3	4	5
20) I would recommend this approach to a friend or family member	1	2	3	4	5
21) I found the study equipment motivating	1	2	3	4	5

22) Would you still have been likely to volunteer for this study had there been no offer of a smartphone? (please tick box below)

a) Yes		1
b) No		2

23) How comfortable were you with the idea that your diet records could be reviewed by the researchers in the trial?

Extremely uncomfortable				Extremely comfortable
1	2	3	4	5

These questions are about your time spent using the study equipment

24) How many times a day on average do you use your study equipment?

I do not use it daily		1
Once a day		2
Twice a day		3
Three times a day		4
Four times a day		5
More than 4 times a day		6

25) On average, how long does it take you to enter an evening meal? ______ **mins**

26) On average, how long do you spend each day using the equipment? (if you are not using the equipment daily then please leave blank) _______

27) How many days did it take until you felt comfortable using the equipment? ____ **days**

28) In general, how do you complete a day's entry? (please tick box)

a) I enter foods as I go along throughout the day		1
b) I enter foods in one sitting at the end of the day		2
c) I enter foods from the previous day the next day		3
d) I enter more than one day at a time in a batch		4

These questions are about finding the information about your foods

29) On average are you able to find the specific food you are looking for? *(please circle from options below)*

NEVER	OCCASIONALLY	MOST OF THE TIME	ALL OF THE TIME
1	2	3	4

30) If I can't find the specific food I want....... *(please finish this sentence by ticking appropriate box)*

a) I tend to enter the generic/average value		1
b) I tend to choose a similar branded product instead		2
c) I tend to create my own meal by breaking it down into individual parts		3
d) I tend not to enter it if I can't find it		4

31) If you can not find the specific branded food you are looking for in the database how confident are you that the average (generic) value is a suitable alternative? (Please mark your satisfaction on the scale below by circling from 1-5 with 1 being extremely unconfident and 5 being extremely confident)

Extremely unconfident				**Extremely confident**
1	2	3	4	5

10

32) How do you estimate the portion sizes of the foods you are eating? (please tick in the boxes below)

	Never	**Occasionally**	**Most of the time**	**All of the time**
a) I weigh foods	1	2	3	4
b) I look at nutritional information on the food packaging	1	2	3	4
c) I use the "help video" on portion sizes to estimate	1	2	3	4
d) I used my own best estimates	1	2	3	4
e) I rely on the average portion sizes from the database	1	2	3	4
f) I use the portion size pictures in the study handbook	1	2	3	4

33) We would like to know if you have been using any methods similar to the groups we allocated people to. **Regardless of your group** have you done any of the following regularly (at least 2-3 times a week) over the past 6 months? (please tick box)

	Yes	No
a) Used any kind of website to help with weight loss?	1	2
b) Used any kind of smartphone app for weight loss?	1	2

11

The following questions are about whether you have found the study equipment educational in any way.

34) Have you learnt anything new about any of these areas by using the study equipment? (please tick box next to any that apply)

	Yes	No
a) Portion sizes	1	2
b) Calories in food	1	2
c) Calories in drink	1	2
d) Your patterns of eating	1	2
e) Calories used in physical activity	1	2

35) We are interested in the types of changes that people might make to their diets when they are trying to lose weight. Have you made any of the following changes to your intake over the past 6 months? (please tick box next to any that apply)

	Yes	No
a) Reduced portion sizes	1	2
b) More regular meal pattern	1	2
c) Lower calorie options	1	2
d) Decreased snacking	1	2
e) Increased physical activity	1	2
f) Increased fruit and vegetables	1	2
g) Reduced alcohol	1	2
h) Less eating out or takeaway foods	1	2
i) Other, please state.....	1	2

12

This trial had very limited human contact. We would like to know whether you would have preferred additional human contact.

36) To what extent do you agree that you would have liked any of the following options over the course of the trial ?

	Strongly Disagree	Disagree	Neither	Agree	Strongly Agree
a) Regular group meetings with other members of the trial led by a nutrition expert	1	2	3	4	5
b) Regular feedback and advice on your diet by telephone	1	2	3	4	5
c) Regular feedback and advice on your diet by email	1	2	3	4	5
d) Regular written materials with advice about diet	1	2	3	4	5
e) Regular podcasts or videos with advice about diet	1	2	3	4	5

37) What have you liked about this trial?

38) What have you liked least about this trial?

39) Any other comments?

The next page of questions is specific to those in the smartphone group. If you are in the website or the diary group the questionnaire is now finished, thank you for your time. For those in the smartphone group please continue for the last section.

Please only answer these questions if you are in the smartphone group

1) How would you rate the ease of use of the HTC Desire smartphone? (Please circle below on a scale of 1-5 with 1 being very difficult and 5 being very easy)

Very difficult				Very easy
1	2	3	4	5

2) Did you use the trial phone as your "main phone" (i.e. did you take the phone about with you and use it for calls and texts?)

a) Yes		1
b) No		2

3) If you answered no to question 2, why did you not use it as your main phone? (please write in box)

4) Would you have preferred to use an I-phone in the trial rather than the HTC Desire?

a) Yes		1
b) No		2
b) No preference		3

5) Please rate your satisfaction with the text messages received in the study

	Very unsatisfied	Unsatisfied	Neutral	Satisfied	Very satisfied
a) How satisfied are you with the **content** of the text messages?	**1**	**2**	**3**	**4**	**5**
b) How satisfied are you with the **frequency** of the text messages	**1**	**2**	**3**	**4**	**5**

6) Do you have any thoughts on how the text messaging could be improved?

7) To what extent do you agree that you would have found the following features helpful in the application ?

	Strongly Disagree	Disagree	Neither	Agree	Strongly Agree
a) Bar code scanning to enter foods into the diary	**1**	**2**	**3**	**4**	**5**
b) Picture database on the phone to select portion sizes visually.	**1**	**2**	**3**	**4**	**5**
c) Searching the database by "keywords"	**1**	**2**	**3**	**4**	**5**
d) Manually entering known calories values for foods and activities.	**1**	**2**	**3**	**4**	**5**
e) Display of grams of carbohydrate consumed	**1**	**2**	**3**	**4**	**5**
f) Display of grams of protein consumed	**1**	**2**	**3**	**4**	**5**
g) Display of grams of fat consumed	**1**	**2**	**3**	**4**	**5**
h) Display of vitamins and minerals consumed	**1**	**2**	**3**	**4**	**5**
i) Display of fruit and vegetable portions consumed	**1**	**2**	**3**	**4**	**5**
j) Display of total fluid intake	**1**	**2**	**3**	**4**	**5**
k) Weekly calorie targets in addition to daily	**1**	**2**	**3**	**4**	**5**

Please only answer these questions if you are in the smartphone group

8) Please rate how helpful you find the following usability features of the phone ? (please circle the appropriate number on the scale)

	Extremely unhelpful	Unhelpful	Neutral	Helpful	Extremely helpful
a) Favourites	1	2	3	4	5
b) Recent items	1	2	3	4	5
c) Photo prompts	1	2	3	4	5
d) Help videos	1	2	3	4	5
e) Graphs of weight loss progress	1	2	3	4	5
f) Graphs of when calorie goals met	1	2	3	4	5

9) How frequently do you encounter bugs with the software? (i.e. when you receive an error message and the app closes). (Please tick box below)

a) Never		1
b) Occasionally		2
c) Most of the time		3
d) All of the time		4

10) How easy do you find it to navigate around the app? (Please circle below on a scale of 1-5 with 1 being very difficult and 5 being very easy).

Very difficult **Very easy**

1 2 3 4 5

11) What did you like most about the phone?

12) What did you like least about the phone?

13) Any other comments or suggestions for improvements are gratefully received (please write in space below)

Thank you for your time and efforts in helping with this research

Appendix 5: Conference presentations featuring research on 'My Meal Mate' (MMM)

Presentation title	Conference	Date
'My Meal Mate' (MMM): Development and acceptability of a smartphone application to promote weight loss and improved health. *(Poster)*	'Advancing Science and Knowledge Translation'. United Kingdom Society for Behavioural Medicine (UKSBM) 6th Annual Scientific Meeting, Leeds Institute of Health Sciences, Leeds, UK.	14-15th Dec, 2010
'My Meal Mate' (MMM): Development and acceptability of a smartphone application to promote weight loss and improved health. *(Poster)*	'New approaches to diet and lifestyle monitoring at the individual and population level'. Association for the Study of Obesity (ASO),University of London, UK	12th April, 2011
'My Meal Mate' (MMM) – a smartphone tool for dietary assessment and weight management. *(Oral)*	'Motivating, enabling and promoting behaviour change for health' United Kingdom Society for Behavioural Medicine (UKSBM) 7th Annual Scientific Meeting, Stirling University, UK	13-14th Dec, 2011
'My Meal Mate' (MMM) a new smartphone application for weight loss: evaluation of its potential as a dietary assessment tool. *(Poster)*	International Conference of Dietary Assessment methods (ICDAM) Rome, Italy	14th – 17th May, 2012
Using information and communication technology to improve dietary assessment and tackle obesity. *(Poster, presented by colleague).*	Public Health Science. A national conference dedicated to new research in public health. Royal Society of Medicine, London, UK	23rd Nov, 2012
Results of a pilot trial of 'My Meal Mate' (MMM) – a smartphone app for weight loss. *(Oral)*	'New Developments in the Theory and application of Behavioural Medicine' United Kingdom Society for Behavioural Medicine (UKSBM) 8th Annual Scientific Meeting, University of Manchester, UK	10th – 11th Dec, 2012
Results of a pilot trial of My Meal Mate (MMM) – a smartphone app for weight loss. *(Oral, presented by colleague)*	10th European Congress on Obesity (ECO), Liverpool, UK.	12th-15th May 2013

Appendix 6: Specification of the contributions of the PhD candidate to the thesis

This PhD research was conducted alongside a project funded by the National Prevention Research Initiative (NPRI). The PhD candidate began working on the project as the Project Manager in January 2010. Due to the innovative and interdisciplinary nature of the project, several academics (from within the University of Leeds) with different areas of expertise had input in developing the original NPRI grant application and project proposal. Once the project had begun, their input was limited and all of the work conducted on the thesis was done by the PhD candidate alone (under the supervision of the PhD supervisors). In the interests of transparency, the contributions from various people are as follows:

Dr Alison Marshall (School of Computing) and Dr Joan Ransley (previously of the Nutritional Epidemiology Group) worked on the development of the original "MobileDANTE" device for a Symbian operating system. 'My Meal Mate' (MMM) has veered significantly from this path being developed as a smartphone app for an Android operating system with different functionality and a different food composition database. Both Dr Marshall and Dr Ransley ceased to have input in the project once "MobileDANTE" was replaced with the idea of developing an application and its development was outsourced to an external company. Dr Karen Birch (Faculty of Biological Sciences) advised on the compendium of physical activity to use in the physical activity database within the application. Dr Birch also supported on the validation of physical activity on the phone which is not part of this PhD project. Professor Mark Connor (Institute of Psychological Sciences) advised on a range of validated scales with which to measure psychosocial characteristics of participants, in particular "conscientiousness" and "consideration of future consequences". The PhD candidate put together a library of text messages and feedback algorithms and Dr Siobhan Hugh-Jones (Institute of Psychological Sciences) reviewed this and provided feedback. Minor changes to the messages were made as a result of this. Dr Darren Greenwood (Centre for Epidemiology and Biostatistics) has provided feedback on the statistical plan which the PhD candidate wrote for the project. Dr Greenwood has also provided feedback on aspects of the pilot trial design including the randomisation process and sample size.

The PhD candidate has made a number of changes to the original project proposal. The intervention was altered based on the opinions of potential system users and the design of the validation and pilot trial are significantly different. The original validation study planned to use food diaries as a reference measure of diet and the original pilot trial had a food diary only comparison arm and planned to recruit participants from local NHS Teaching Hospitals. The rationale for these changes is detailed in the relevant chapters. The project has required input from several external organisations. A software development company called "Blueberry Consultants" was employed through the University tender process and was project managed by the PhD candidate. The PhD candidate initiated and designed the specification for the tender. Blueberry Consultants carried out the programming of the application and administrator website based on the specification for the design, features and functions of the application. At the end of the development phase all intellectual property on the application was delivered back to the University.

The food and drink database contained within the application has been supplied free of charge by a commercial company called "Weight Loss Resources" (WLR) for the purposes of the project. The PhD candidate approached WLR and also arranged for them to provide materials for the two comparison arms in the pilot. The PhD candidate set up another tender exercise with help from the University Procurement team to find a telecommunications company to provide the phone call and data packages.