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Abstract

Background

There is growing interest in the use of information communication technologies to treat obesity. An intervention delivered by smartphone could be a convenient, potentially cost effective and wide reaching weight management strategy. Whilst there have been studies of SMS based interventions and smartphone apps used as adjuncts to other treatments there are currently no randomised controlled trials (RCT) of a "stand alone" smartphone application for weight loss which primarily focuses on self monitoring of diet and physical activity.

Objectives

This trial is a pilot aiming to collect acceptability and feasibility outcomes of a self-monitoring weight management intervention delivered by a smartphone app.

Methods

A sample of 128 overweight volunteers were randomised to receive a weight management intervention either delivered by smartphone app, website or paper diary. The smartphone app intervention "My Meal Mate" (MMM) was developed by the research team using an evidence based behavioural approach. The app incorporates goal setting, self monitoring of diet and activity and feedback via weekly text message. The website group used an existing commercially available slimming website from a company called "Weight Loss Resources" who also provided the paper diaries. The comparator groups delivered a similar self-monitoring intervention to the app but by different modes of delivery. Participants were recruited by email, intranet, newsletters and posters from large local employers. Trial duration was 6 months. The intervention and comparator groups were self-directed with no ongoing human input from the research team. The only face to face components were at baseline enrolment and brief follow up sessions at 6 weeks and 6 months to take anthropometric measures and administer questionnaires.

Results

Trial retention was 40/43 (93%) in the smartphone group, 19/42 (55%) in the website group and 20/43 (53%) in the diary group at 6 months. Adherence was statistically significantly higher in the smartphone group with a mean 92 (SD: 67) days of dietary recording 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 using baseline observation carried forward for missing data mean weight change at 6 months was 4.6kg (95% CI: -6.2 to -3.0) in the smartphone app group, -2.9kg (95% CI: -4.7 to -1.1) in the diary group and -1.3kg (95% CI: -2.7 to 0.1) in the website group. BMI change (kg/m^2) at 6 months was -1.6 kg/m^2 (95% CI; -2.2, -1.1) in the smartphone group, -1.0 kg/m^2 (95% CI; -1.6, -0.4) in the diary group and -0.5 kg/m^2 (95% CI; -0.9, 0.0). Change in body fat (%) was -1.3 % (95% CI; -1.7, -0.8) in the smartphone group, -0.9% (95% CI; -1.5, -0.4) in the diary group and -0.5 % (95% CI; -0.9, -0.0) in the website group.

Conclusion

MMM is an acceptable and feasible weight loss intervention and a full RCT of this approach is warranted.

Registration: Clinicaltrials.gov NCT 01744535, http://clinicaltrials.gov/show/NCT01744535.

Introduction

Associated with a range of serious and difficult to treat conditions such as diabetes, some cancers and heart disease, obesity is estimated by the World Health Organisation to be the fifth leading risk for global deaths[1]. In the UK, obesity is a major public health concern reported to affect a quarter of the adult population[2]. The economic burden to the NHS is significant, with the direct cost of spending on overweight and obesity estimated at $4.2 billion in 2007[3]. The effective treatment of obesity and overweight is challenging and NHS primary care struggles to provide effective support to meet demand[4]. A large community based survey showed that individuals desire alternatives to face to face weight loss

treatments and if given the choice some would be interested in engaging with minimal contact weight management programmes[5].

Information communication technology (ICT) based weight management interventions provide an opportunity to engage a wide audience in a potentially flexible and cost effective way. In recent years, research into mobile devices to facilitate dietary and physical activity self monitoring and weight related behavior change has grown. Mobile phones, in particular, are an intuitively appealing intervention platform given that they are ubiquitous, engaging and portable[6]. Researchers have investigated text message interventions (SMS) to promote change in diet [7-9] and physical activity [10, 11]. For example, in a small randomised controlled trial (RCT) (N=75) an SMS intervention lasting 16 weeks led to a 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[7]. However, in a follow on from that study, a larger 12 month RCT of an SMS intervention in 170 overweight and obese adults showed no statistically significant difference in weight loss between the intervention and control group (Shapiro et al, 2012). In that study, adherence to the text messaging intervention was found to be related to greater weight loss and the authors concluded that text messages might be a useful adjunct to a weight loss programme. Researchers have also investigated dietary self monitoring based electronic interventions using personal digital assistants (PDAs). PDAs are electronic portable devices so share some of the features of mobile phones. A 6 month RCT compared a PDA and PDA with feedback to a paper diary in a sample of 210 overweight adults. The PDA group (combined with feedback) had the highest proportion of participants achieving >5% weight loss (63% compared to 46% in the PDA alone and 49% in the food diary alone) after 6 months[12].

A number of smartphone apps which use the computational abilities of the phone for self monitoring rather than just the SMS component have been developed (13-15, Lee, 2010)using different approaches to health behaviour and weight management have been developed and tested. 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[13-15]. The app "PmEB" allows users to log food intake from a limited database of foods and track calorie balance[16]. An app called "Ubifit" has also been developed to promote change in physical activity[17]. However, none of these apps have been formally evaluated in an RCT. In a recent 6 month RCT, Turner McGreivey et al, (2011) randomised 96 overweight and obese participants to either a group receiving podcasts only or an "enhanced" group using the podcasts, twitter and a smartphone app called "fat secret" for self monitoring. In this study, the "enhanced" group were not found to have greater weight loss than the podcast only group.

We have developed a smartphone app for weight loss called "My Meal Mate" (MMM). The enhanced computational ability of a smartphone allows detailed self monitoring (of diet, physical activity and weight) and feedback via text message to be combined in one intervention. MMM uses an Android operating system so can be trialled on an up to date and popular handset. The app has been benchmarked against commercially available systems such as "my fitness pal"[18] and contains a large detailed UK branded food database[19]. These factors are important in order to engage users with the app in a real-life setting. Although there have been RCTs using text messaging interventions for weight management, personal digital assistants for self monitoring and smartphone apps as adjuncts to other weight management interventions, to our knowledge there have been no RCTs of a smartphone app as a weight loss intervention in itself using both self monitoring and text messaging functions. A trial of this type is necessary as smartphone apps are readily available to the public to download and likely to be used as a "stand alone" intervention rather than as an adjunct to another intervention (such as podcasts or face to

face advice). The aim of this pilot is to test the acceptability and feasibility (including; recruitment, drop-out and adherence) of MMM with a view to informing a larger trial.

Methods

Recruitment strategy

Participants were recruited from large employers within Leeds, UK, by advertising via email; intranet; posters and newsletters. Advertising material encouraged participants to contact the research team, following which they were emailed information sheets and an eligibility questionnaire. The eligibility criteria was a body mass index (BMI)≥27kg/m^2 ; aged 18-65; willing to commit the necessary time and effort to the study; employed by a large employer in Leeds; not pregnant, breast-feeding or planning a pregnancy; not taking anti-obesity medication or medication/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. An inclusion cut-off BMI of ≥ 27kg/m^2 as opposed to the more familiar cut-off point of 25kg/m^2 was chosen in order 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 given that the app would be used for 6 months without any clinical supervision.

Interventions

The researchers have developed a smartphone app for weight loss called "My Meal Mate" (MMM) which uses an Android operating system. Figure 1 and 2 are screen captures of the app. During development of MMM, several commercially available systems such as "my fitness pal" and "calorie counter" were informally evaluated by the researchers and by discussion in focus groups with potential system users. MMM was "benchmarked" in this way in order to produce an app of equivalent appearance and functionality as apps available

to the general public to download. Current UK evidence based obesity guidelines advocate a "lifestyle change" approach to treatment[20] so in line with this the key behavioural strategies of goal setting, self monitoring and feedback underpin the MMM app. MMM allows system users to set a weight loss goal and self monitor daily calorie intake towards achieving the goal. Users select food and drink consumed from a database and log items in an electronic food diary. Physical activity can also be recorded in the diary enabling the user to receive instant feedback on their energy expenditure. Progress is tracked graphically and further support is provided via tailored weekly text messages. A library of text messages was created and each message was triggered according to progress towards the users' calorie targets. The messages aimed to enhance the users self efficacy by encouraging the user to rehearse their weight loss goal and reinforce positive behavioural beliefs (about competence, confidence and mastery). MMM has several usability features such as the ability to take photographs of food to serve as an *aide memoir* and store favourite meal combinations and recently used items. The app has an associated web interface to upload the data recorded. A unique feature of MMM is the large UK specific branded food database which has been provided by a commercial company, "Weight Loss Resources" (WLR)[19]. The database contains 23,000 food and drink records which reflect both generic and branded items. The diet measures captured on MMM have been found to correlate well with a reference measure of diet[21]. There are a series of "youtube" videos which give a detailed account of each feature of the MMM app which participants were able to directly link to for help [22].

MMM was compared against two other self-monitoring interventions to allow comparison of self-monitoring on a mobile phone against other approaches. The comparison groups used either a self-monitoring slimming website[19]; or a food diary accompanied by a calorie counting book[23]. The comparison interventions provided an opportunity to deliver a similar

self monitoring intervention by different mediums as each provides goal setting, and self monitoring using the same “Weight Loss Resources” food database.

Procedure

The trial design was a three armed parallel group randomised trial. As a pilot trial the primary outcomes were feasibility and acceptability outcomes of adherence to the trial and adherence to the interventions (frequency of use). Secondary outcomes were anthropometric which were objectively measured to give an idea of effect size. Eligible participants were invited to attend a baseline enrolment session at the University of Leeds, where height, weight and percentage body fat were measured by research assistants, and baseline questionnaires completed. The questionnaires were designed to collect information on; demographics, technology usage, attitudes towards weight loss, physical activity[24], eating behaviour[25] and a variety of psychosocial variables[26, 27]. Weight (without shoes) and body fat (%) were measured using “Weight Watchers 8958U: Body Analyser scale” portable weighing scales. Height (without shoes) was measured using a portable stadiometer to the nearest 0.1cm. After measurements had been taken participants were randomised by a process of minimisation using the software package “minim”[28] to one of three groups. The minimisation balanced equally at the medians on three factors; starting BMI, age and gender. Minimisation was used as this method has the advantage over simple or stratified randomisation of providing very similar balanced groups in small samples[29].

After randomisation, groups of participants were taken to separate rooms to receive standardised training in their allocated study equipment. Participants were instructed to use the study equipment every day for a week and then to use it as much as they desired over the trial period. The smartphone group were given a “HTC Desire” smartphone with the MMM pre-downloaded, the website group were given a voucher providing 6 months access

to the WLR website and the food diary group were given a paper food diary, calorie counting book and calculator. All participants were given access to an internet forum for social support. The baseline enrolment sessions took place over the course of one month with participants enrolling in small groups at a time. Participants returned for repeat measures at 6 weeks and 6 months after randomisation. Evaluation questionnaires were also administered at 6 weeks and 6 months. At 6 months study equipment was returned. Due to the nature of the interventions it was not possible to blind participants to their assignment. Fieldworkers carrying out measurements on participants were blinded to group assignment and participants were asked not to discuss their group allocation when measurements were taken.

Sample size determination

Since this is not a phase III trial a formal sample size calculation is not appropriate and there are few published guidelines on recommended sample sizes for pilot trials. The trial aimed to recruit a sample size of 135 which was a pragmatic decision based partly on the amount of available study equipment.

Statistical analysis

Statistical analysis was carried out using Stata 11 (Stata corp). As this is a pilot trial and not powered to detect weight change, most analysis is descriptive. The effectiveness of the minimisation procedure was assessed by determining baseline balance between the groups. Where analysing differences between the three intervention groups, oneway anova was used for continuous outcomes found to be normally distributed or kruskal wallis where not normally distributed. For the analysis of completers vs. non completers, t-tests were used for continuous outcomes which were normally distributed and the Wilcoxon rank sum test for non normally distributed outcomes. Differences between groups for categorical data were analysed using chi squared tests.

The pilot trial is not statistically powered to detect change in anthropometric measures however results are displayed for interest and to provide information on effect size. A regression analysis was used to test between group difference in change in anthropometric measures adjusting for the three factors used in randomisation at baseline (age, gender and starting BMI). As there is a proportion of missing data and unequal drop-out between groups, two analyses have been conducted; an intention to treat analysis in which all are included but using baseline weight carried forward for missing data and an analysis in just those who completed 6 month follow up.

Ethical approval

The present 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). Written informed consent was obtained from all trial participants.

Results

Baseline characteristics

Table 1 shows the baseline characteristics of the pilot study participants by 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, 71% were female and 89% of white ethnic origin. The mean age of participants was 42 (SD: 9) years and over half (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).

Table 1: Baseline characteristics of the participants enrolled in the pilot trial

	Smartphone	**Diary (n=43)**	**Website (n=42)**

	(n=43) (33F/10M)	**(33F/10M)**	**(33F/9M)**
Age (years), mean (SD)	41.2 (8.5)	42.5 (8.3)	41.9 (10.6)
Weight (kg), mean (SD)	96.4 (16.0)	97.9 (18.7)	96.4 (19.9)
Body mass index (kg/m2), mean (SD)	33.7 (4.2)	34.5 (5.7)	34.5 (5.6)
% Body fat, mean (SD)	35.9 (3.8)	35.9 (4.8)	36.2 (3.9)
Gender (female), n (%)	33 (77)	33 (77)	33 (79)
Ethnicity (white), n (%)	43 (100)	35 (83)	39 (92)
Smoking status (current smokers), n (%)	2 (5)	8 (19)	2 (5)
Occupation (managerial professions), n (%)	32 (74)	22 (51)	20 (49)
Has a university degree, n (%)	31 (72)	24 (56)	22 (53)
Owns a smartphone, n (%)	18 (42)	19 (44)	14 (34)

Table 1: Baseline characteristics of 128 participants enrolled in a randomised, three armed (smartphone application, website, diary), 6 month pilot trial of “My Meal Mate” (MMM); a smartphone application designed to facilitate weight loss. The occupation variable as been dichotomised, it 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.

Recruitment

Recruitment to the trial took three months. Figure 3 is a CONSORT diagram[30] 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 (43%) of people responding to express an interest were from Leeds City Council and the second largest proportion (27%) were from the University of Leeds. Of those screened, 49 (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 show up to appointments. 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. In total, 128 people were randomly allocated to one of the three groups. This was 38% of those that had originally expressed an interest in taking part and 71% 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 study participants (42%) and Leeds City Council provided the second highest proportion (39%). The majority of participants (84%) had heard about the study from an electronic source either by email (62%) or intranet (22%).

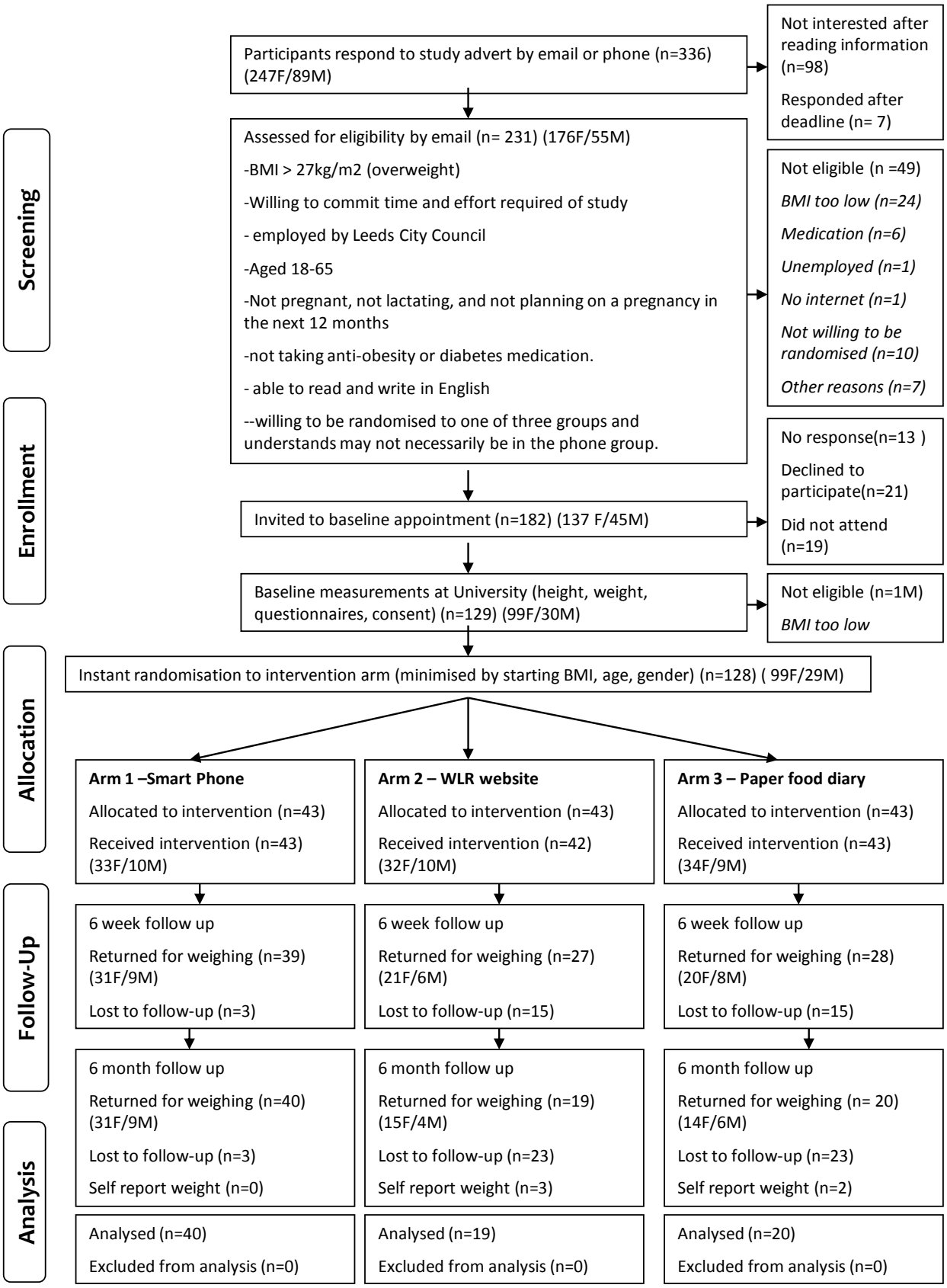

Figure 3: Flow of participants through a randomised, three armed, 6 month, pilot trial of "My Meal Mate" (MMM) a smartphone application for weight loss (N=128).

Adherence to the trial

In terms of trial retention, 94 (73%) people returned for 6 week follow up measurements and 79 (62%) returned at 6 months. Table 2 shows the differences between those that completed 6 month follow up compared to non-completers. Compared to trial completers, non-completers had a statistically significantly greater baseline BMI and % body fat. There was a statistically significant difference in self-reported health status at baseline between completers and non-completers with more completers reporting their health status as good or excellent (*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 diary group and 23 people not attending 6 month follow up in the website group. The reasons given for non attendance are shown in table 3. The most popular reasons given for non attendance were dislike of the study equipment (n=12) and personal issues (n=6).

Table 2: Differences in baseline characteristics between trial completers and non completers at 6 months

	Non-completers (n=45)	**Completers (n=79)**	***P*** [a]
Age (years), mean (SD)	43.2 (9.0)	41.2 (9.3)	0.2
Weight (kg), mean (SD)	101.5 (18.9)	94.1 (17.1)	0.03
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
Baseline physical activity (Met/mins/wk) [b], mean (SD)	1468.8 (1207.9)	1638.5 (1412.3)	0.6
Motivation to lose weight [c], mean (SD)	8 (2)	8 (1)	0.4
Confidence in ability to lose weight [d], 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 [e], mean (SD)	32.5 (8.5)	30.7 (7.2)	0.2
Conscientiousness score [f], 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 or 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
Currently dieting (yes), n (%)	31 (68.9)	59 (74.7)	0.5
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 2: 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). [a] Significant difference between completers and non completers assessed by oneway t-test. [b]Measured by International Physical Activity Questionnaire (IPAQ). [c] Based on a 10-point scale (1=not motivated at all; 10=extremely motivated). [d] Based on a 10-point scale (1=not confident at all; 10=extremely confident).[e] Measured by consideration of future consequences scale. [f] Measured by "International Personality Item Pool"(IPIP) conscientiousness scale.

Table 3: Reasons for non attendance at 6 month follow-up in trial non-completers

Reason for non attendance	**Smartphone (n=43)**	**Diary (n=43)**	**Website (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 3: Reasons given for non attendance at 6 month follow up in a randomised, three armed (smartphone application, website, diary) pilot trial of "My Meal Mate" (MMM) (N=128).

Frequency of use of the interventions

Table 4 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-≤5000 kcal energy recorded). Intervention usage was highest in the smartphone group at 6 months with a mean 92 (SD: 67) days completed compared to 29 (SD: 39) days in the diary group and 35 (SD: 44) 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 =0.0001). Pairwise comparison showed that this difference lies between the smartphone

group and the diary group (*P* <0.0001), between the smartphone group and the website group (*P* <0.0001) but not between the website group and the diary group (*P* =0.14). 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 diary groups. Usage within each intervention arm declined over time as shown in figure 4. In the smartphone group, 2 people recorded ≤7 days of food entry of compared to 19 in the diary group (assuming 0 entries for 16 non-returned diaries at 6 weeks) and 10 people in the website group. 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.

Table 4: Total number of days that the interventions were used

	Smartphone (n=43)	**Diary (n=43)**	**Website (n=42)**	***P*[b]**
Total number of days intervention used [a]				
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 (%)	1 (2)	31 (78)	3(7)	

Table 4: Frequency of daily use of the interventions in a randomised, three armed (smartphone application, website, diary) pilot trial of "My Meal Mate" (MMM) (N=128). [a]A usage day is considered to be a day with ≥500 and ≤5000 kcal energy recorded. [b]Significant difference between groups assessed by Kruskal-Wallis equality-of-populations rank test as adherence variable not normally distributed and not improved after log transformation, significant difference at *P*<0.05.

Figure 4: Intervention use over 6 months in each trial arm

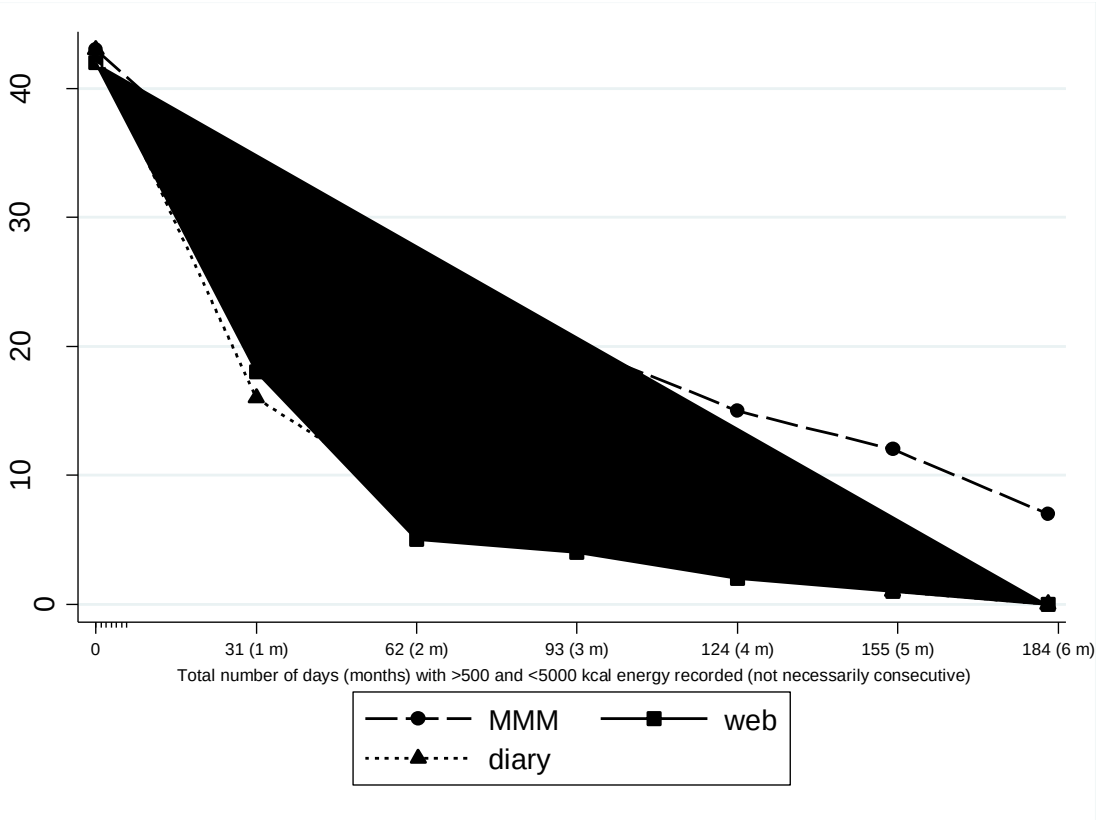

Figure 4: Intervention use in a randomised three arm pilot trial (N=128) of "My Meal Mate" (MMM). Adherence to the intervention arms (smartphone application, website, diary) over the trial duration (6 months) is shown by total number of days completed in each intervention group. Data collection was conducted 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.

Acceptability of randomisation and satisfaction with equipment

Of those that completed 6 week questionnaires (n=93), 91% of smartphone participants reported that they were initially "satisfied" or "very satisfied" with their group allocation at baseline compared to 23% in the diary group and 71% in the website group (*P* =0.01). When asked about how satisfied they were with the study equipment at 6 weeks, 87% reported that they were "satisfied" or "very satisfied" with the smartphone, compared to 58% in the diary group and 50% in the website group (*P* =0.02). At 6 months, of those that completed questionnaires (n=77), 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 (*P* =0.05). At 6 months, 23 (30%) completers reported that they would not have volunteered for the trial if there had been no offer of using a smartphone.

No statistically significant difference was seen between the groups for self reported ease of use of study equipment. In the smartphone group, 87% reported that they found the smartphone easy to use, compared to 65% in the diary group and 83% in the website group (*P* =0.6). However, a statistically significant difference between the groups was found for self reported convenience of use with 65% reporting that they found the smartphone convenient, (compared to 35% in the diary group and 53% in the website group, *P* =0.006). In the smartphone group 76% of participants agreed or strongly agreed that they felt comfortable using the study equipment to record their diet in social settings compared to 40% in the diary group and 21% in the website group (*P* =0.0002).

Change in anthropometric measures

The pilot trial is not statistically powered to detect change in anthropometric measures, however results are displayed to give an idea of effect size. As there is a proportion of missing data and unequal drop-out an intention to treat analysis was completed with baseline observations carried forward for missing data (table 5). In the intention to treat analysis using all of the participants assigned to their original group, the mean weight change 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 diary group and -1.3kg (95% CI: -2.7 to 0.1) in the website group. There was found to be a statistically significant difference in follow-up weight between the groups at 6 months (*P* =0.004). At 6 months, weight change over time was statistically significantly greater in the smartphone group as compared to the website group (-3.3kg, 95%CI: -5.4 to 1.2) but not when the smartphone group was compared to the diary group (*P* =0.12).

In the intention to treat analysis with baseline observation carried forward, change in BMI (kg/m^2) at 6 months was -1.6 kg/m^2 (95% CI; -2.2, -1.1) in the smartphone group, -1.0 kg/m^2

(95% CI; -1.6, -0.4) in the diary group and -0.5 kg/m^2 (95% CI; -0.9, 0.0). Change in fat (%) was -1.3 % (95% CI; -1.7, -0.8) in the smartphone group, -0.9% (95% CI; -1.5, -0.4) in the diary group and -0.5 % (95% CI; -0.9, -0.0) in the website group.

Table 6 is a sub-analysis which shows the anthropometric measures for study completers only (participants who attended follow up at 6 months). In just those that completed the trial, the mean weight change 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 diary group and -2.8kg (95% CI: -5.9 to 0.2kg) in the website group. One person allocated to the diary group reported that they had actually used a commercially available slimming smartphone app during the trial rather than the paper diary. This person lost 32kg overall and if they are excluded from the diary group analysis the mean weight change in completers is -4.8kg (95% CI: -7.1kg to -2.7kg). There were not found to be statistically significant differences in follow-up weight between the groups at 6 months (*P* =0.63) or in difference in change over time (smartphone-diary; *P* =0.99, smartphone-website; *P* =0.40, diary-website; *P* =0.47). A similar trend in results was seen for BMI and % fat.

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 diary group and 7/42 (17%) participants in the website group.

Table 5: Change in anthropometric measures using an intention to treat analysis[a]

	Smartphone		**Diary**		**Website**		***P* for between group diff in endpoint[b]**
	N	Mean (95% CI)	N	Mean (95% CI)	N	Mean (95% CI)	
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[c] (89.0, 99.0)	43	95.9[c] (89.8, 101.7)	42	95.1[c] (89.0, 101.2)	0.001
6 mt	43	92.2[c] (87.0, 97.4)	43	95.0[c] (89.0, 101.0)	42	95.1 (89.0, 101.3)	0.004
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[c] (31.3, 33.9)	43	33.7[c] (31.9, 35.5)	42	34.0 (32.3, 35.7)	0.002
6 mt	43	32.1[c] (30.7, 33.5)	43	33.4 (31.5, 35.4)	42	34.0 (32.3, 35.8)	0.002
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[c] (33.7, 36.2)	42	35.3[c] (33.8, 36.9)	42	36.0 (34.7, 37.2)	0.010
6 mt	42	34.7[c] (33.5, 35.9)	42	35.1 (33.4, 36.7)	42	35.9 (34.5, 37.2)	0.019

Table 6: 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). An intention to treat analysis has been performed with baseline observation carried forward for missing data. [a] The baseline measures recorded have been carried forward for missing data. [b] 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). [c]=statistically significant *P* value of <0.01.

Table 6: Change in anthropometric measures at 6 weeks and 6 months in trial completers

	Smartphone		Diary		Website		*P* for between group diff in endpoint[a]
	N	Mean (95% CI)	N	Mean (95% CI)	N	Mean (95% CI)	
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[b] (86.6, 97.6)	20	86.1[b] (78.1, 94.2)	19	87.0 (79.5, 94.6)	0.62
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[b] (30.5, 33.5)	20	30.4 (28.2, 32.6)	19	31.0 (28.9, 33.2)	0.58
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[b] (33.4, 35.9)	20	32.5 (30.1, 34.8)	19	33.7 (31.7, 35.8)	0.89

Table 5: Change in recorded anthropometric measures at 6 weeks (N=95) and 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.[a] 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). [b]=statistically significant *P* value of <0.01.

Discussion

This pilot trial has shown "My Meal Mate" (MMM) to be a feasible and acceptable weight loss intervention.

Recruitment and response

In terms of recruitment and response, we were able to recruit 128 participants to the pilot which was 95% of the original recruitment target. As is common to many weight loss trials, a

large proportion of the sample (77%) were women and of white ethnic origin (91%). The initial response rate was lower than expected and the recruitment period was extended to three months. Electronic media was the most successful recruitment strategy.

Trial retention

The pilot trial suffered from 38% attrition overall. Attrition is a serious difficulty in weight loss trials due to its potential to bias results[31]. Missing data may reflect a person's dissatisfaction with the dietary intervention and a rebound in weight loss. 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%[32]. A review focussing specifically on web-based interventions for weight loss found most had attrition rates greater than 20%[33]. In this trial, attrition was not equal between the groups, with more non-completers at follow up in the diary and web group compared to the smartphone group (P = <0.0001). In fact, the smartphone group had extremely high retention with 93% returning for follow up at 6 months (compared to 53% in the diary group and 55% in the website group).

Unequal drop-out between groups is likely to be intervention related [29] and a dislike of the study equipment was the most popular reason given for non attendance at follow up. Questionnaire data collected at follow-up also supports dissatisfaction with treatment group as at 6 weeks and 6 months satisfaction with group allocation was statistically significantly lower in the diary and web groups. Unequal drop-out 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 diary and website group may have felt less obliged to return for follow up as they did not need to physically return equipment. This may be avoidable in a future study when it is likely that a large proportion of the population

will own a smartphone (given the rising trend in smartphone ownership in the UK) so the app could be downloaded onto existing phones.

The non-completers in the trial were more likely to have a higher BMI at baseline and report 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[34]. 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.

Frequency of usage of the interventions

Adherence to dietary self monitoring was found to be statistically significantly higher in the smartphone group than the website and paper diary group (*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 all three groups, self monitoring declined over time so that by 6 months only 7 participants (16% of the group) in the smartphone group had managed to record their dietary intake every day (no participants in the diary and web group had done this). Adherence to self monitoring is an important process outcome as it has been consistently linked to weight loss[35]. Researchers have taken different approaches to measuring adherence in studies investigating technology for weight loss so direct comparison of results is difficult.

A similar decline in adherence to dietary self monitoring over time has been reported in other studies. In a recent RCT[12] comparing a PDA, PDA with feedback and a paper diary, 53% of the PDA group were adherent at 6 months, 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. Also

supporting the results of this pilot trial, the aforementioned study found that the PDA groups were statistically significantly more adherent to self monitoring than the paper diary groups. However, in another study of dietary self monitoring via PDA, no statistically significant difference in adherence was found between a PDA and a paper diary[36].

A key strength of this pilot is the use of a smartphone app for a high end smartphone which is able to build on the research with PDAs (having similar self monitoring functions) but is likely to be a more familiar technology to users. There has been a recent surge in smartphone ownership in the UK with 51% of the population reporting to own a smartphone[37]. It is evident that there is consumer demand for diet tracking apps due to the popularity of commercial systems such as “my fitness pal”[18] and “lose-it”[38]. Investigating a researcher developed app gives a unique opportunity to collect data on usage directly from the participants. In terms of acceptability, MMM was more highly rated in comparison to the diary and website on a range of acceptability measures including overall satisfaction, convenience and acceptability of use in social settings.

Weight loss

Although the pilot trial was not statistically powered to detect a difference in weight change between the groups it has provided some data on effect size. Completers in the smartphone group had a mean weight loss of - 5.0kg (95% CI: - 6.7kg to -3.3kg) after 6 months. This is comparable to the weight loss achieved in a large multi-centred RCT of popular commercial diet programmes which reported an average weight loss of - 5.9kg at 6 months across all diets[39]. The diary and website group had a comparable mean weight change at 6 months in those that returned for 6 month follow up. When an intention to treat analysis is used with baseline observation carried forward for missing data the mean weight change in the diary and web groups is more modest.

Strengths

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[40] or used a smartphone app to enhance adherence to another intervention[41], this pilot trial has taken a minimal contact approach with no dietary advice at baseline. The weight loss seen in the smartphone arm is encouraging given that a minimal contact approach could be a cost effective and wide reaching strategy. 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 is comparable in appearance and functionality to commercial diet tracking apps. Despite their apparent popularity these commercial apps have not been comprehensively evaluated to date.

Limitations

Generalisability of the pilot results is limited given that the sample are 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. Twenty people in the trial also reported that they had used another intervention (either instead of or as well as their originally allocated intervention) during the trial. Seven participants from the smartphone group reported using a slimming website, 7 people from the diary group reporting using a website and 4 using a smartphone app and 2 from the website group reported to have used a smartphone app. One participant originally randomised to the diary group reported to enjoy self monitoring but wanted to make it more convenient so downloaded the commercially available “my fitness pal” 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. A delayed control may be used so that participants in the control group could be asked not to use other weight management interventions during the trial and participants would be recruited in such a way that did not reveal what other groups were receiving.

Implications

Further analysis will be performed on the pilot data to investigate the characteristics of successful users in the trial to see if there is any scope for tailoring this approach. Given that some participants have more success in behavioural weight loss programmes than others[34], knowing who will do well with this smartphone approach is key to tailoring it appropriately. This pilot trial has several implications for a future trial. Given the unequal drop-out in the comparator group a larger trial may need to consider what if any retention strategies are appropriate. Two control groups were used in the pilot but as participants had comparable adherence and weight loss in the diary group this may be the most cost effective for a full trial. Further research would also benefit from an economic analysis to investigate the cost of implementing a smartphone app intervention compared to other types of weight management intervention.

Conclusion

This pilot trial of a smartphone app for weight loss has shown that it is both an acceptable and feasible intervention. 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. To our 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.

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Conflict of interests

The authors developed the "My Meal Mate" (MMM) application for the purposes of this trial by working with a software company called Blueberry Consultants (www.bbconsult.co.uk). The University of Leeds owns full intellectual property of the MMM app which is not currently available for download. The researchers developed the application and objectively evaluated it but have no commercial intent with the app which is planned to be available for free download in the future.

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