Original paper

Effect of a unique web-based behaviour change program on weight loss and cardiovascular risk factors in overweight and obese adults at high risk of developing cardiovascular disease. A randomised controlled trial.

Sinead Watson[1,2], BSc, MSc, PhD; Jayne V Woodside[1], MA, PhD; Lisa J Ware[3], BSc, MSc, PhD; Steven J Hunter[4], MB, BCh, MD, FRCP; Alanna McGrath[1], BSc, Christopher R Cardwell[1], BSc, MSc, PhD; Katherine M Appleton[5], BSc, PhD; Ian S Young[1], BSc, MB, BCh, MD, FRCP; Michelle C McKinley[1], BSc, PhD.

[1]Centre for Public Health, Queen's University Belfast, School of Medicine, Dentistry and Biomedical Sciences, Belfast, UK
[2]Institute for Global Food Security, Queen's University Belfast, School of Biological Sciences, Belfast, UK
[3]Hypertension in Africa Research Team (HART), Faculty of Health Sciences, North-West University, South Africa
[4]Regional Centre for Endocrinology and Diabetes, Royal Victoria Hospital, Belfast, UK
[5]Department of Psychology, Faculty of Science and Technology, Bournemouth University, Poole, Dorset, UK1

Corresponding Author:

Michelle McKinley, PhD

Centre for Public Health
School of Medicine, Dentistry & Biomedical Sciences
Queen's University Belfast
Institute of Clinical Science Block B
Grosvenor Road
Belfast BT12 6BJ
Phone: +44 (0)28 9063 2685
Fax: +44 (0)28 90235900
Email: m.mckinley@qub.ac.uk

Abstract

Background

Web-based programs (WBPs) offer potential as a medium for supporting weight loss, owing to their easy accessibility, anonymity and capacity for wide reach. However, further research is warranted to determine the shorter- and longer-term effects of these WBPs, not only in relation to weight loss, but other health outcomes and, specifically, to determine effects in comparison with a 'true control' group.

Objective

To evaluate the effects of a web-based component of a service '*Imperative Health'* on weight loss in an overweight/obese population at high risk of cardiovascular disease (CVD) using a randomised controlled design and a 'true control' group.

Methods

Sixty-five overweight/obese adults at high risk of CVD were randomly allocated to one of two groups. Group one (n=32) were provided with the web-based program. This WBP supports positive dietary and physical activity changes and assists in managing weight and other cardiovascular risk factors. It combines objective monitoring of weight and physical activity with automated, tailored feedback. Group two were asked to continue with their usual self-care (n=33). Assessments were carried out face-to-face. The primary outcome was between-group change in weight at 3 months. Secondary outcomes included between-group change in anthropometric measurements, blood pressure, lipid measurements, physical activity and energy intake at 3, 6 and 12 months. Interviews were conducted to explore participants' views of the WBP.

Results

Retention rates for the intervention and control groups at 3 months were (78% vs. 97%), at 6 months (66% vs. 94%) and at 12 months (53% vs. 88%), respectively. Intention-to-treat analysis, using a single imputation method (baseline observation carried forward), revealed that the intervention group lost more weight relative to the control group at 3 months (-3.41 kg vs. -0.52 kg; $P<.001$, respectively), at 6 months (-3.47 kg *vs.* -0.81; $P=.02$, respectively), but not at 12 months (-2.38 *vs.* -1.80 kg; $P=.77$). More intervention group participants compared with the control group lost 5% or more of their baseline body weight at 3 months (34.4% *vs.* 3.0%, $P<.001$) and 6 months (40.6% *vs.* 18.2%, $P=.047$), but not at 12 months (21.9% *vs.* 21.2%, $P=.95$). The intervention group showed improvements in total cholesterol ($P=.003$) and triglyceride ($P=.003$) concentrations, and adopted more positive dietary ($P=.005$) and physical activity ($P=.03$) behaviours for up to 3 months compared with the control group; however, these improvements were not sustained in the longer-term.

Conclusions

Although high levels of attrition were evident in the intervention group, this study provides evidence that this WBP can be used to initiate clinically relevant weight loss and lower CVD risk up to 3-6 months based on the proportion of participants losing 5% or more of their body

weight in the WBP group relative to the true control group. It also highlights a need for augmenting WBPs with further interventions, such as telephone, email or in-person support in the longer-term to enhance engagement and maintain these changes.

Trial Registration

ClinicalTrials.gov identifier: NCT01472276;
http://clinicaltrials.gov/ct2/show/study/NCT01472276

Keywords: web-based; randomised controlled trial; behaviour change; weight loss; cardiovascular risk factors; diet; physical activity; obesity

Introduction

The prevalence of obesity has been increasing progressively throughout the world [1]. Identifying effective and cost-effective treatment and prevention strategies is a top priority for all healthcare systems. Over the past few decades the internet has increasingly been used to deliver behavioural modification programs owing to its easy accessibility and anonymity, potential for wide reach and penetration, and its ability to provide a source of continuous support to large segments of the population [2,3,4].

There is growing evidence suggesting that the internet may be a viable medium for encouraging weight loss. However, several systematic reviews and meta-analysis, conducted in this area have found it difficult to draw definitive conclusions regarding its effectiveness owing to heterogeneity in study designs, methods employed and the lack of 'true control' groups used [5,6,7,8,9]. Most of the evidence to date comes from randomised controlled trials (RCTs) conducted in the USA. Many only included short-term follow-up and lacked 'true control' groups (no support provided), making it challenging to accurately evaluate the true effectiveness of web-based programs (WBPs). Instead, minimal support groups are often employed to help boost recruitment and decrease attrition, although this approach may attenuate the relationship between groups and limits the ability of the findings to inform cost-effectiveness and healthcare models. Research is also limited regarding the effect of these WBPs on other health outcomes that co-exist with weight loss, such as cardiovascular disease (CVD) risk factors. Therefore, the aim of this study was to evaluate the effects of an interactive web-based component of a service called *Imperative Health* on weight loss (primary outcome) and CVD risk factors (secondary outcomes) in an overweight and obese population at high risk of CVD using a randomised controlled design and a 'true control' group. It was hypothesised that weight loss would be greater in the WBP intervention group compared to the usual care control group.

Methods

Recruitment

Ethical approval was obtained from the Office for Research Ethics Committees Northern Ireland. The trial was registered (ClinicalTrials.gov identifier: NCT01472276) and is reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT) - ehealth checklist (Multimedia Appendix 1) [10]. Participants were recruited from April to December 2011 using posters in public places in the greater Belfast area, and intranet advertisements via

staff updates in the Belfast Health and Social Care Trust and Queen's University Belfast (QUB). Patients from the Regional Centre for Diabetes and Endocrinology at the Royal Victoria Hospital Belfast were also sent a letter informing them about the study. Participants were eligible if they were aged over 18 years, had a BMI between 27 to 40 kg/m^2, were inactive or moderately inactive assessed by the General Practice Physical Activity Questionnaire (GPPAQ) [11] and had one or more CVD risk factor: high blood pressure ≥ 140/90 mmHg, cholesterol ≥ 5.0 mmol/l or type 2 diabetes. All participants were required to have access to the internet, email, and a telephone and were asked not to participate in another behavioural change weight loss program throughout the study period. Participants were excluded if they had established CVD, type 1 diabetes, were pregnant or consumed excessive amounts of alcohol. Computer literacy was not assessed. All participants at the screening appointment provided written informed consent.

Study design

After completion of the baseline assessments, conducted face-to-face, at the Regional Centre for Diabetes and Endocrinology at the Royal Victoria Hospital Belfast, participants were randomly allocated to one of two parallel groups (1:1 allocation ratio) using a block randomisation approach (block size = 10) with computer-generated numbers (**figure 1**). A researcher independent from the study prepared the randomisation schedule. Opaque sealed envelopes were used to conceal the sequence until groups were allocated. Participants were recruited and enrolled by the researcher, who was unaware of the randomisation schedule until after the baseline assessments when the sealed envelope containing the allocation outcome was opened by the participant. Group one (intervention group) was provided with the WBP known as *Imperative Health*, excluding telephone and email support and group two (control group) was requested to continue with their usual self and medical care. All participants were followed up 3 months, 6 months and 12 months after randomisation for assessment of primary and secondary outcomes. Based on a standard deviation of weight loss at 3 months of 3.0 kg, observed in a number of internet-based weight loss studies in the literature [12,13,14,15], it was estimated that a sample size of 60 (30 per group) would give the study 90% power at the 5% significance level to detect a difference of 2.6 kg between groups at the 3 month follow-up. Allowing for a 10% drop out rate at the first 3 month follow-up, it was aimed to recruit 66 participants. With only one researcher on the ground, it was not possible to blind the researcher or participants to group allocation but laboratory analysis was performed blind.

Intervention (*Imperative Health* WBP)

Imperative Health is a service, owned by AXA PPP Healthcare Limited, that consists of a WBP and human (email and telephone) support that assists in lifestyle change; with a particular focus on improving diet and nutrition, increasing physical activity and managing weight and other CVD risk factors. It combines objective monitoring of weight and physical activity with automated, tailored feedback and support by physiologists by telephone and email. Previous versions of this WBP have been evaluated by Hurling *et al.* [16,17] and Ware *et al.* [18]; this program has since been modified to be more relevant to individuals that have independent risk factors for CVD such as hypertension, dyslipidemia (high cholesterol and triglycerides) and type 2 diabetes. For this particular study only the WBP component of the service was evaluated in order to determine its specific impact, i.e. the human support (telephone and email) component of the service was removed for the purposes of this trial.

Initial set-up of Imperative Health (WBP)

At the end of the baseline appointment the intervention group participants were provided with the *Imperative Health* package that contained the self-monitoring devices (Bluetooth enabled weighing scales and an accelerometer activity band) and basic written instructions to set up an online account at home. To access the online program participants were instructed to go to the *Imperative health* website [19] and enter a unique code to create their own personal password-protected free account. To complete registration and to enable the setup of the monitoring devices participants were advised to follow the online instructions. The intervention group was informed at the baseline appointment that if any problems occurred throughout the study period after the initial set-up regarding the technology they were instructed to contact *Imperative Health* rather than the researcher. This current study wanted to evaluate this WBP in a real life setting in order to determine realistic levels of engagement and their relationship with weight loss, therefore, no instructions were provided by the researcher as to how often the participants should login to use the website components and the self-monitoring devices. The WBP, however, does itself encourage daily engagement by allowing the upload of daily weight and physical activity data and by the entry of daily food diaries (see below for more detail).

Web-based behaviour change program

Once the online account was set up the participants were required to complete a series of online introductory health questionnaires that enabled *Imperative Health* to collect information on their height, weight, waist circumference, blood pressure and blood biomarkers (total cholesterol, HDL cholesterol, fasting blood glucose and triglycerides), as well as information on past and current health status, dietary intake, physical activity level and stated goals. This self-reported information was not used by the researcher to evaluate the effects of this WBP; instead, it was used by the Imperative Health system to generate personalised daily targets (weight loss, physical activity and dietary targets) for each participant to achieve over 12 weeks. Automated weekly feedback on their performance, assessed by the self-monitoring devices (weighing scales and accelerometer), as well as the food diary was provided and also after 12 weeks in the form of an overall review. After 12 weeks, in order to encourage further progress, it was requested that the participants start a new program by completing the same introductory health questionnaires again and setting new goals. The WBP encompasses supportive components to help facilitate lifestyle change (See Table 1). These WBP components were developed based on well recognised behaviour change strategies such as: planning, self-monitoring, goal setting and structured feedback, which were all used within the Diabetes Prevention Program [20] to promote weight loss.

Table 1 Imperative Health WBP components to support behaviour change

Behaviour Change strategy	WBP component	Description of component
Goal setting	- Daily dietary targets - Daily physical activity targets - Weekly weight loss targets - Clinical targets	Personalised daily dietary, physical activity (see Multimedia Appendix 2), weight and clinical (blood pressure/ glucose/ lipids) targets were created based on the health questionnaire responses (see above). Targets were reviewed every 12 weeks.
Planning	Exercise weekly schedule	A weekly schedule for planning physical activity was provided. Icons (representing light, moderate or vigorous activities) could be dragged to specific days. Start times and duration of the activity could be selected (see Multimedia Appendix 2).
	Daily meal planners	Meal suggestions for breakfast, lunch, dinner and snacks were provided to help meet personalised dietary targets set by the WBP.
Self-monitoring	- Bluetooth weighing scales - Bluetooth accelerometer activity band - Food diary (calorie uploads) - Clinical measurements (blood pressure, glucose, blood lipids uploads).	Monitoring devices included Bluetooth enabled weighing scales and an activity band. Data from the weighing scales was transmitted to the activity band and subsequently blue toothed to the user's online profile page. The activity band provided daily feedback on minutes of moderate, high and very high activity (see Multimedia Appendix 3). Daily calorie intake, blood pressure, glucose and blood lipid measurements could be entered and uploaded onto coloured charts (see Multimedia Appendix 3 and 4) to demonstrate daily, weekly and monthly results and if targets were achieved.
Personalised feedback	Coaching session – automated weekly feedback	Automated tailored feedback on progress was provided weekly.
Push reminders	Email/ SMS texts	Text messages or emails were sent daily and weekly to help remind participants to login and to weigh themselves.
Social support	Community forum	Online discussion forums.
The Decision balance	Habit breaker component	Solutions for barriers perceived as preventing healthier behaviours (e.g. eating breakfast) being adopted were provided.

Theory

Outcome measures

Assessments were carried out face-to-face at the Regional Centre for Endocrinology and Diabetes at the Royal Victoria Hospital Belfast at baseline, 3 months, 6 months and 12 months.

Primary outcome

The primary outcome for this study was between-group change in body weight (kg) at 3 months. Weight was measured, without shoes and in light clothing, to the nearest 0.1 kg using calibrated Salter 994 digital weighing scales (Salter Housewares Ltd, Tonbridge, UK).

Secondary outcomes

Secondary outcomes were between-group change in weight loss at 6 and 12 months and between-group change in the following risk markers at each follow-up: Body mass index (BMI) calculated as weight (kg) divided by height (m) squared; height was measured to the nearest 0.1 cm using a Leicester portable height measure (CMS Weighing equipment Ltd, London, UK); waist circumference was measured to the nearest 0.5 cm using a tape measure at the middle point between the lower rib margin and iliac crest at normal expiration.

Blood pressure (mmHg) was measured using an automated Omron M3 sphygmomanometer (Omron Healthcare, Hoofddorp, The Netherlands).

Fasting serum lipid profile included measurements of total cholesterol, high density lipoprotein (HDL) cholesterol and triglycerides and were measured using standard assays on an automated ILab 600 Chemistry system (Instrumentation Laboratory, Cheshire, UK). Plasma hs-CRP (CRP) was measured using an ultra-sensitive assay (quantex CRP ultra-sensitive; Instrumentation Laboratory, Cheshire, UK) on an automated machine, (ILab 600 Chemistry System).

Dietary intake was assessed using a diet history interview [21], which is a retrospective dietary assessment method used to gather information regarding the habitual food intake of all the participants over the previous 3 months. The diet history method has been shown to have good repeatability in previous studies and is also able to pick up dietary changes over time [22]. Quantities of food and food portion sizes (household measures) were converted into weights (grams) by using Crawley's Food Portion Sizes (Food Standards Agency) [23]. The food type, preparation method if relevant, and weight of food were entered into a computerised food analysis database (WISP, Weighed Intake Software Program; Tinuviel Software, Warrington, UK). For the purpose of this current study total daily energy intake (kcal) was calculated.

Physical activity was assessed using the validated Recent Physical Activity Questionnaire (RPAQ) [24]. Participants were asked to provide descriptions of their habitual physical activity performed in four domains: home, work, travel and recreation over the last four weeks. For the purpose of this current study time (min/day) spent participating in moderate and vigorous activities (> 3.5 METs) was calculated.

A self-reported questionnaire was distributed at the baseline appointment to collect socio-demographic information including past and current occupation. Socioeconomic status was classified according to National Statistics Socio-economic Classification (NE-SEC, Hampshire, UK, 2010) into three occupational classes: the highest included higher managerial, administrative and professional occupations; the second class was intermediate occupations; and the third class included routine and manual occupations.

Website usage

Data on frequency of logins, the total number of completed food diaries and the number of weight and physical activity uploads from the monitoring devices were provided by *Imperative Health* and were used to determine level of engagement.

Qualitative – Interviews

To gain in-depth feedback on the intervention group's experiences of using the WBP these participants were asked if they would be willing to take part in an interview conducted by the researcher towards the end of the study. This was an optional part of the study and for this reason a convenience sampling technique was utilised. The interviews were conducted between July and August 2012, in the Centre for Public Health, QUB, within an informal setting and lasted ~25–30 minutes. Semi-structured open-ended questions were used throughout to ensure that a consistent approach was utilised. The researcher used a style of probing to extract more information or clarify meaning.
All the interviews were audio-recorded and transcribed verbatim. NVivo 8 was used to assist in the management and analysis of the transcripts. To analyse the transcripts a template approach, outlined by Cabtree and Miller [25] was utilised. This process involved the naming, defining and describing of the codes based on research questions. Three broad categories formed the code template: views on their experiences of using *Imperative Health* (WBP), views on *Imperative Health's* website components that support behaviour change and suggested improvements that *Imperative Health* should implement. The template of codes was then applied to all transcripts. Given that the data were qualitative, frequencies were used in the broadest sense (e.g. majority, some and few). Quotations were used to demonstrate typical views within each code category.

Statistical Analysis

All analyses were performed using SPSS for Windows version 21.0 (SPSS Inc, Chicago, IL). Results are expressed as mean and standard deviation for normally distributed variables and median and inter-quartile range for variables that did not satisfy normality criteria. Categorical data are expressed as frequencies and percentages. To compare baseline characteristics between the control and intervention groups, for continuous variables, the appropriate parametric (Independent samples t-test) and non-parametric tests (Mann Whitney U test) were utilised. For categorical variables the Chi-square test was used. Between-group differences in the primary outcome (weight change at 3 months) and secondary outcomes from baseline to 3 months, 6 months and 12 months were investigated using the analysis of covariance (ANCOVA) adjusted for baseline measurements [26]. Analyses were carried out by an intention-to-treat (ITT) approach using a single imputation method (baseline observation carried forward, BOCF) to deal with missing data and losses to follow-up [27],

and a complete-case analysis on weight change was conducted using information on all individuals with available data at each time point. C-reactive protein, triglycerides and physical activity distributions were skewed and therefore log transformed. Adjusted differences in log-transformed means between groups from ANCOVA were converted to, and reported as, ratios of geometric means and 95% confidence intervals. Within-group changes (intervention or control) in weight loss were analysed using paired sample t-test. As the WBP usage data was not normally distributed, Spearman correlations were performed to investigate the relationship between weight change and WBP usage at each time point (intervention group only).

Results

Participant Flow

Eighty-one individuals were screened for eligibility. Sixteen were ineligible; the other 65 participants (29 males, 34 females) were randomised to the control (n=33) or intervention (n=32) groups (see **Figure 1**). Retention rates significantly differed between the control and intervention groups at 3 months (n=32 (97%) *vs.* n=25 (78%), *P*=.03), at 6 months (n=31 (94%) *vs.* n=21 (66%), *P*=.004) and at 12 months (n=29 (88%) *vs.* n=17 (53%), *P*=.002), respectively. Baseline characteristics, including socio-economic status, did not differ significantly between those who dropped-out of the study and those who completed the study in either group at any time point.

Baseline characteristics

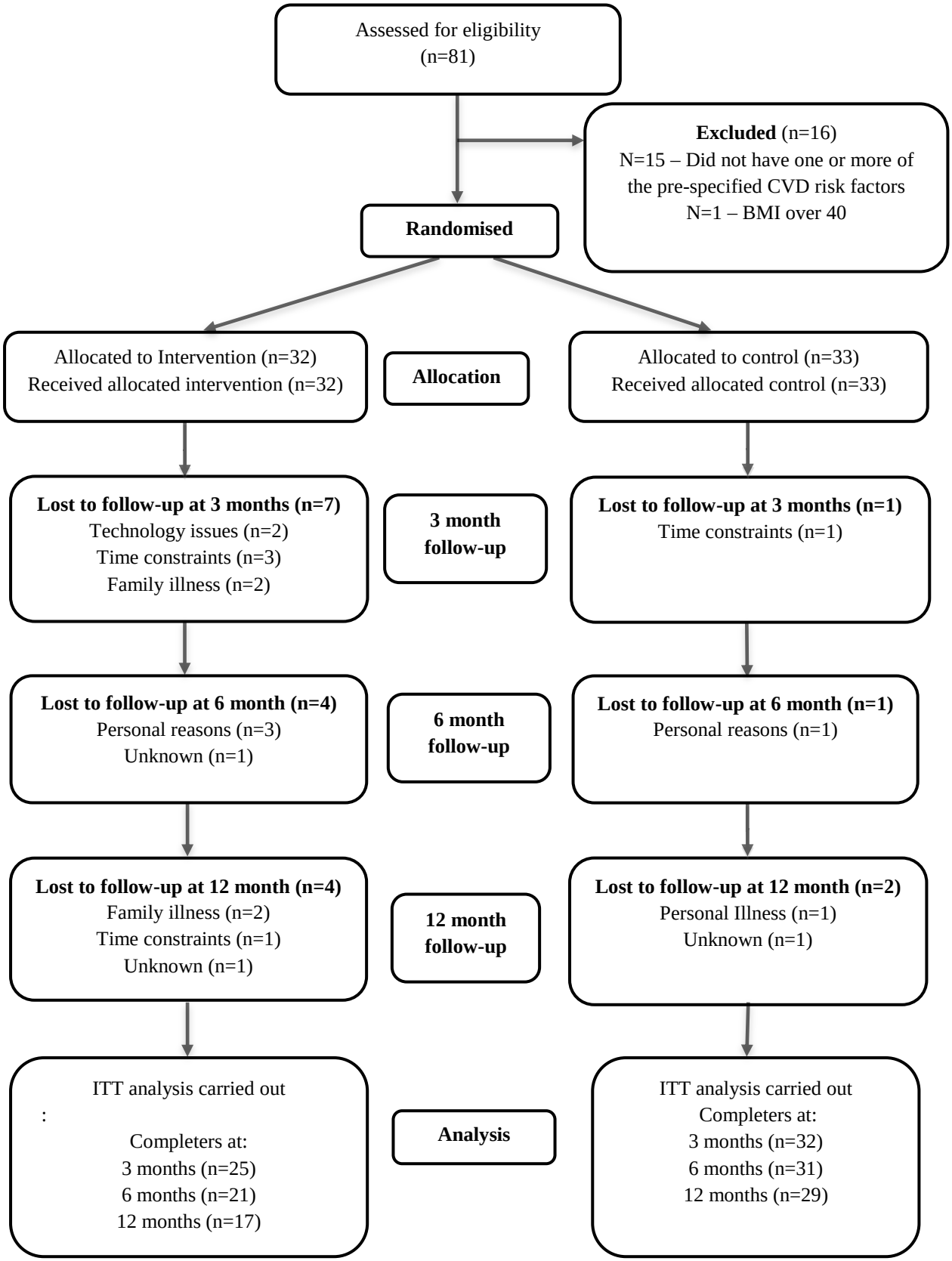
Mean age was 52.1 ± 7.4 years and mean BMI at baseline was 32.7 kg/m^2. According to WHO criteria [28], 20% of the sample were overweight, 58.5% were obese category I and 21.5% were obese category II. Socio-economic status (SES) was determined by occupational class (NS-SEC): Class 1 included higher managerial, administrative and professional occupations which approximately half the sample (50.3%) lay within; Class 2 included intermediate occupations of which 38.5 % of the sample lay within; and Class 3 included routine and manual occupations, and applied to 10.8% of the sample. There were no significant differences in any of the baseline characteristics between the control and intervention group (**Table 2**).

Table 2 Baseline characteristics of overweight and obese participants, according to control and intervention group

	Intervention (n = 32)	**Control (n = 33)**	
	Mean (SD)	**Mean (SD)**	***P* value**
Gender, male n(%)	16 (50)	13 (39)	
female n(%)	16 (50)	20 (61)	.39
Age (years)	51.4 (7.59)	52.9 (7.27)	.43
Weight (kg)	95.2 (16.7)	91.9 (13.4)	.39
Height (cm)	169.4 (9.44)	168.1 (9.35)	.57
BMI (kg/m^2)	32.9 (3.07)	32.4 (2.74)	.50
Waist circumference (cm)	103.5 (11.2)	102.5 (9.47)	.69
Systolic Blood pressure (mmHg)	129.8 (17.8)	129.1 (18.3)	.88
Diastolic Blood pressure (mmHg)	85.5 (9.54)	86.0 (11.4)	.85
Total cholesterol (mmol/l)	4.87 (1.44)	5.16 (1.02)	.35
HDL (mmol/l)	1.33 (0.39)	1.36 (0.31)	.77
Triglycerides[1] (mmol/l)	1.49 (1.18-1.86)	1.48 (1.01-2.02)	.75
CRP[1] (mg/l)	1.73 (0.67-2.90)	2.11 (1.11-4.35)	.22
Energy (kcal)	1949.6 (545.1)	1893.6 (477.2)	.66
Physical Activity[1] (mins/day)	15.5 (6.4-45.3)	17.40 (7.5-46.9)	.72

Continuous data presented as mean (SD) for normally distributed data and [1]median (IQ) for skewed data. Between-group differences analysed using independent samples t-test for normal data and Mann Whitney test for skewed data. Categorical data presented as frequencies (%). Differences between categories analysed using Chi-squared test (X^2 test) Abbreviations: BMI, body mass index; HDL, high-density lipoprotein cholesterol; CRP, C-reactive protein.

Figure 1 CONSORT diagram showing the flow of participants through the trial and analysed for weight loss at 3 months, 6 months and 12 months


Assessed for eligibility
(n=81)
Excluded (n=16)
N=15 – Did not have one or more of the pre-specified CVD risk factors
N=1 – BMI over 40
Randomised
Allocated to Intervention (n=32)
Received allocated intervention (n=32)
Allocation
Allocated to control (n=33)
Received allocated control (n=33)
Lost to follow-up at 3 months (n=7)
Technology issues (n=2)
Time constraints (n=3)
Family illness (n=2)
3 month follow-up
Lost to follow-up at 3 months (n=1)
Time constraints (n=1)
Lost to follow-up at 6 month (n=4)
Personal reasons (n=3)
Unknown (n=1)
6 month follow-up
Lost to follow-up at 6 month (n=1)
Personal reasons (n=1)
Lost to follow-up at 12 month (n=4)
Family illness (n=2)
Time constraints (n=1)
Unknown (n=1)
12 month follow-up
Lost to follow-up at 12 month (n=2)
Personal Illness (n=1)
Unknown (n=1)
ITT analysis carried out
:
Completers at:
3 months (n=25)
6 months (n=21)
12 months (n=17)
Analysis
ITT analysis carried out
Completers at:
3 months (n=32)
6 months (n=31)
12 months (n=29)

Change in body weight (primary outcome)

As shown in **Table 3**, both approaches (ITT and complete-case) demonstrated significant mean weight loss difference between groups at 3 months; however the magnitude of weight lost was slightly higher using the complete-case analysis approach. ITT analysis revealed that the Intervention group participants had a mean weight loss of -3.41 kg at 3 months; the control group lost -0.52 kg, overall this accounted for a significant mean weight difference between groups of -2.70 kg after adjusting for baseline weight (*P* <.001).

Table 3 Weight (kg) outcome differences between and within study groups from baseline to 3, 6 and 12 months (ITT and complete-case analysis)

		Change from baseline Mean (95% CI)		Difference between groups	Between-group
	Month	Intervention	Control	Mean (95% CI)	*P* value
ITT	3	-3.41 (-4.70, -2.13)[c]	-0.52 (-1.55, 0.52)	-2.70 (-4.27, -1.13)	.001
	6	-3.47 (-4.95, -1.98)[c]	-0.81 (-2.23, 0.61)	-2.49 (-4.50, -0.48)	.02
	12	-2.38 (-3.48, -0.97)[b]	-1.80 (-3.15, -0.44)[a]	-0.27 (-2.16, 1.61)	.77
Complete-case	3	-4.37 (-5.80, -2.94)[c]	-0.53 (-1.60, 0.54)	-3.66 (-5.28, -2.05)	< .001
	6	-5.28 (-7.12, -3.44)[c]	-0.86 (-2.38, 0.65)	-4.16 (-6.46, –1.86)	.001
	12	-4.48 (-7.34, -2.37)[b]	-2.16 (-4.58, -0.62)[a]	-1.89 (-4.42, 0.64)	.14

Difference between groups analysed using ANCOVA and adjusted for baseline weight. Abbreviations: ITT, intention to treat. ITT analysis: control group (n=33) and intervention group (n=32) at 3, 6 and 12 months. For the complete-case analysis: control group (n=32) at 3 months, (n=30) at 6 months and (n=29) at 12 months. Intervention group (n= 25) at 3 months, (n=21) at 6 months and (n=17) at 12 months. Within-group weight changes were analysed using paired sample t-test and only significant results are presented [a]$P \leq 0.05$, [b]$P \leq 0.01$, [c]$P \leq 0.001$

Change in body weight at 6 and 12 months (Secondary outcome)

Intention-to-treat analysis (**Table 3**) demonstrated that the intervention group lost significantly more weight compared to the control group from baseline to 6 months (-3.47 kg *vs.* -0.81 kg; *P*=.02, respectively) but not from baseline to 12 months (-2.38 kg *vs.* -1.80; *P*=.77). There were significant changes in weight between baseline and each time point within the intervention group (3 months, *P* <.001; 6 months, *P* <.001 and 12 months, *P*=.002). However, between 6 months and 12 months the intervention group gained 1.08 kg, reducing the overall mean weight loss at 12 months in this group. There was a significant weight loss from baseline to 12 months within the control group (-1.80 kg; *P*=.01) but not for the 3 month (*P*=.32) and 6 month (*P*=.25) time points.

Percentage weight loss

Weight loss as a percentage of baseline weight was calculated using the ITT data. The mean percentage weight loss in the intervention and the control group was: from baseline to 3 months -3.62% *vs.* -0.34%, respectively (*P* <.001); from baseline to 6 months -3.73% *vs.* -0.63% respectively (*P*=.004); and from baseline to 12 months -2.42% *vs*. -1.94%, respectively (*P*=.56). Significantly more participants in the intervention group compared with the control group lost 5% or more of their baseline body weight at 3 months (34.4% *vs.* 3.0%, *P* <.001) and at 6 months (40.6% *vs.* 18.2%, *P*=.047), but not at 12 months (21.9% *vs.* 21.2%, *P*=.95).

Change in other Secondary Outcomes

Table 4 shows the intervention group had significantly reduced their BMI and waist circumference measurements relative to the control group from baseline to 3 months (*P* <.001 and *P*=.006, respectively) and to 6 months (*P*=.003 and *P*=.02, respectively), but not at 12

months. There were no between-group differences in blood pressure observed during the study. For lipid measurements, larger reductions were observed in total cholesterol and triglyceride concentrations in the intervention group compared to the control group, but only during the first 3 months (*P*=.003 and *P*=.003; respectively). Similar patterns were identified for health behaviours: the intervention group significantly decreased their energy intake and increased their time spent exercising at an intensity > 3.5 METs relative to the control group from baseline to 3 months (*P*=.005 and *P*=.03). These behaviours were not sustained over the longer term, at 6 and 12 months.

Table 4 Clinical outcome differences between study groups from baseline to 3, 6 and 12 months (ITT)

	Treatment Groups				
		Mean change from baseline (95% CI)		Between-group difference	
	Month	Intervention (n=32)	Control (n=33)	Adjusted mean (95% CI)[2]	*P*
BMI	3	-1.16 (-1.60, -0.73)	-0.14 (-0.47, 0.19)	-0.99 (-1.53, -0.46)	<.001
(kg/m^2)	6	-1.20 (-1.70, -0.70)	-0.18 (-0.64, 0.27)	-1.02 (-1.69, -0.35)	.003
	12	-0.78 (-1.26, -0.31)	-0.65 (-1.12, 0.19)	-0.10 (-0.75, 0.55)	.76
WC	3	-2.73 (-3.98, -1.49)	-0.67 (-1.44, 0.11)	-2.04 (-3.47, -0.61)	.006
(cm)	6	-3.05 (-4.68, -1.41)	-0.83 (-1.95, 0.28)	-2.18 (-4.11, -0.24)	.02
	12	-2.31 (-3.84, -0.79)	-1.80 (-3.02, -0.58)	-0.42 (-2.29, 1.45)	.66
SBP	3	-2.69 (-6.48, 1.10)	-1.64 (-6.02, 2.75)	-0.81 (-5.61, 3.99)	.74
(mmHg)	6	-1.31 (-4.83, 2.20)	0.88 (-3.79, 5.55)	-1.92 (-6.48, 2.65)	.40
	12	-1.22 (-4.33, 1.90)	-2.12 (-2.25, 6.49)	-3.13 (-7.69, 1.43)	.18
DPB	3	-3.03 (-5.14, -0.92)	-2.36 (-5.02, 0.29)	-0.83 (-3.76, 2.10)	.58
(mmHg)	6	-2.63 (-5.05, -0.20)	-1.73 (-5.26, 1.81)	-1.14 (-4.55, 2.27)	.51
	12	-1.78 (-3.52, -0.05)	-1.55 (-4.57, 1.48)	-0.38 (-3.52, 2.76)	.81
TC	3	-0.49 (-0.70, -0.28)	-0.06 (-0.31, 0.19)	-0.48 (-0.79, -0.18)	.003
(mmol/l)	6	-0.30 (-0.53, -0.08)	-0.24 (-0.46, -0.02)	-0.07 (-0.38, 0.24)	.64
	12	-0.19 (-0.38, -0.01)	-0.13 (-0.36, 0.10)	-0.09 (-0.38, 0.20)	.56
HDL	3	-0.02 (-0.08, 0.04)	0.00 (-0.07, 0.07)	-0.03 (-0.11, 0.06)	.51
(mmol/l)	6	-0.01 (-0.07, 0.06)	-0.03 (-0.10, 0.04)	0.02 (-0.07, 0.12)	.62
	12	-0.02 (-0.07, 0.02)	0.02 (-0.06, 0.10)	-0.04 (-0.13, 0.04)	.32
TG[1]	3	0.89 (0.82, 0.96)	1.03 (0.96, 1.10)	0.87 (0.80, 0.95)	.003
(mmol/l)	6	0.96 (0.89, 1.04)	0.98 (0.91, 1.04)	0.99 (0.90, 1.09)	.79
	12	0.97 (0.91, 1.02)	0.97 (0.90, 1.05)	1.00 (0.92, 1.09)	.93
CRP	3	0.93 (0.84, 1.03)	1.01 (0.87, 1.18)	0.88 (0.74, 0.96)	.13
(mg/l)[1]	6	0.89 (0.83, 0.95)	1.03 (0.86, 1.24)	0.83 (0.69, 1.01)	.06
	12	0.99 (0.80, 1.23)	0.99 (0.81, 1.21)	0.93 (0.71, 1.21)	.58
Energy	3	-487.6 (-640.7, -334.5)	-241.4 (-375.8, -106.9)	-216.3 (-364.0, -68.7)	.005
Intake	6	-314.8 (-466.2, -163.5)	-243.2 (-393.6, -92.8)	-47.8 (-228.5, 133.0)	.60
(Kcal)	12	-221.6 (-363.5, -79.8)	-204.2 (-384.5, 23.9)	7.20 (-191.0, 205.4)	.94
Physical	3	2.85 (1.64, 4.94)	1.43 (0.92, 2.21)	1.98 (1.09, 3.60)	.03
Activity[1]	6	1.43 (1.00, 2.06)	1.00 (0.61, 1.64)	1.43 (0.84, 2.44)	.19
(min/day)	12	1.52 (0.95, 2.43)	1.18 (0.74, 1.89)	1.28 (0.72, 2.27)	.40

Data presented as mean and 95% CI for normal distributed variables and [1]ratios of geometric mean and 95% confidence for log transformed variables. [2]Difference between groups analysed using ANCOVA and adjusted for baseline measurements. Abbreviations: BMI, body mass index; WC, waist circumference; SBP, systolic blood pressure; DBP, diastolic blood pressure; TC, total cholesterol; HDL, high density lipoprotein cholesterol; TG, triglycerides; CRP, C - reactive protein. Physical activity calculated as time in minutes spent exercising >3.5 METS daily.

Website usage and weight change (Intervention group only)

Website utilisation data is presented in **Table 5**. Participants in the intervention group tended to login, upload their weight measurement and make food diary entries more frequently during the first 3 months of the intervention, website usage declined thereafter.

Table 5 Website utilisation from baseline to 3, 6 and 12 months (intervention group only)

	Baseline to 3 months (13 weeks)	3 to 6 months (13 weeks)	6 to 12months (26 weeks)
	Median (IQ)	Median (IQ)	Median (IQ)
Number of logins	69.0 (25.5 – 122.0)	12.0 (2.00 – 47.5)	27.0 (2.00 – 96.8)
Food diary entries	18.0 (0.00 – 77.0)	0.00 (0.00 – 38.5)	0.00 (0.00 – 156.5)
Weight uploads	15.0 (9.0 – 46.0)	11.0 (1.0 – 30.0)	4.0 (0.0 – 29.8)
Physical activity uploads	13.0 (10.0 – 13.0)	12.0 (3.0 – 13.0)	15.0 (0.00 – 24.5)

Data presented as median (IQ) due to data being skewed. Sample size at 3 months (n=25), at 6 months (n=21) and at 12 months (n=17).

Correlation analyses (**Table 6**) demonstrated that weight change from baseline to the 3 month follow-up was significantly positively related to the number of logins (*P*=.04) and the number of weight uploads (*P*=.007) at 3 months. A positive relationship was observed between weight change from baseline to 6 months and the amount of physical activity uploads over the same time period (*P*=.048). The number of daily food diaries entered was not related to weight change throughout the course of the study.

Table 6 Correlations between weight change and website components usage from baseline (intervention group only)

	Weight change from baseline					
Website component usage	**3 months (*r*)**	***P* value**	**6 months (*r*)**	***P* value**	**12 months (*r*)**	***P* value**
Number of logins	0.42	.04	0.28	.21	0.21	.42
Food diary entries	0.01	.96	0.00	.99	-0.20	.53
Physical activity uploads	0.33	.14	0.47	.048	0.12	.67
Weight uploads	0.53	.007	0.20	.39	0.10	.70

Data analysed by Spearman's correlation.

Interview feedback (intervention group only)

A total of seven participants (four males and three females) from the intervention group were recruited using a convenience sampling approach. Three broad categories formed the code template: views on their experiences of using *Imperative Health* (WBP), views on *Imperative Health's* website components (see Table 1) that support behaviour change and suggested improvements that *Imperative Health* should implement. Below are some of the quotations used to demonstrate typical views within each code category.

Experiences using Imperative Health (WBP)

All of the interviewees stated that they were keen to use this WBP to help them lose weight and manage their chronic condition. They found the initial set up of their *Imperative Health* accounts relatively straightforward.

"It was very straightforward. I don't think I had any difficulty at all with it."

Some of the interviewees perceived using the WBP as time consuming and quite burdensome, specifically, the tasks that involved uploading and manually entering measurements as well as working through the weekly feedback.

"I don't know whether people who would be employed full time would have enough time to do that ... If you're running out to work in the morning and you have to be out for 7 o'clock, you're not going to be standing there weighing yourself, and again, when you come back home again, typing in what you have done"

And

"If you wanted a quick consult it was taking you 10 minutes to get through ..."

Website components that support behaviour change

The majority of interviewees found the personalised targets (weight loss, physical activity and dietary targets) provided by the WBP as realistic and motivating.

"It did give me the motivation to say 'right, I'm supposed to go walking 60 minutes a day. I'll try and keep to that target of 60 minutes a day'.

And

"They weren't tough; the calories I was being allowed were okay..."

The majority of interviewees were not impressed with the WBP planning components (meal planner and exercise schedule). Accessibility issues and aversions to the recommended foods in the meal plans were commented.

"If it had of been pre-packaged food or something that I would have actually liked but there was none of the stuff that really appealed to me. So I never used the meal planner..."

And

"But they were all foods that were for supermarkets, say, in England and a lot of the stuff that you wouldn't get here maybe."

All the interviewees felt that the WBP's self-monitoring components (weighing scales and accelerometer activity band – data from these devices were uploaded onto coloured charts to track progress) helped them to evaluate their progress and at the same time acted as facilitators for motivating them to keep continuing towards their targets.

"With regard to the weight one, it encouraged you to do better, because it showed if you were flattening out or, at worst, going the wrong way off your target."

And

"I found the activity useful because when I would sync up at the end of the week I would have a look and say 'I was low on Tuesday and Wednesday this week. I'll maybe do a boost on Friday. I'll go for an hour and a half walk just to make sure my average for the week is up'. So I found that a little bit, slightly motivating."

All of the interviewees provided negative feedback regarding the dietary self-monitoring element of this WBP (food diary). They felt the process was time consuming and burdensome as a result of having to look up all the calories of the foods they consumed and then enter them manually into the food diary.

"I found getting the nutritional values of things awkward because you had to go into a separate wee thing in the background and then you had to write it down and then you go back to something else."

Most of the interviewees claimed they did not use the component for monitoring their clinical measurements, as they were unable to get these health risk factors measured regularly.

"... the average person doesn't have that information. I might get that done twice a year."

The majority of the participants were not impressed with the automated feedback and coaching sessions provided weekly. They felt that it was too generic and repetitive; hence not encouraging or constructive.

"The other thing that irritated me intensely is the standard messages that you would get at every stage of the bloody feedback! I suppose it's a computer system, what can you expect, but I just got cheesed off because it said the same thing all the time."

And

"It was more generic in the sense. They were just basically saying 'we haven't got enough information' or 'you have not met your target.'

Most participants stated that they did browse the community forum but did not contribute anything. They generally felt that there was not enough activity.

"I occasionally dipped in and out to see what it was but there was very little action or interest, and I don't get involved in anything like that at all."

Suggested improvements

A common suggestion for improvement was more personalised interaction and feedback specifically from a human rather than an automated machine as this may provide them with more focus and motivation. This would be in line with the full *Imperative Health* service that has physiologists supporting participants by telephone and email.

"... some more personalised interaction in terms of somebody perhaps phoning you on your mobile to give you a kick start or perhaps an email..."

And

"I tried at the start, and because there is not actually a person involved in it you're not worried about what the machine tells you then, you don't care what it says to you. So you go off track a wee bit..."

Discussion

Weight loss (primary and secondary outcome)

In comparison to a 'true control' group, access to a WBP resulted in significantly greater weight loss in the intervention group after 3 and 6 months. However, longer-term follow-up indicated that the difference in weight loss between the intervention and control group was not sustained at 12 months. The reasons for this were twofold: weight regain in the intervention group between the 6 and 12 month time point and an increase in weight loss in the control group over the same time period. In terms of clinically significant weight loss (weight loss of ≥ 5% of baseline body weight), significantly more participants in the intervention group compared with the control group lost 5% or more of their baseline body weight at 3 months (34.4% *vs.* 3.0%, P <.001) and at 6 months (40.6% *vs.* 18.2%, P=.047), but not at 12 months (21.9% vs. 21.2%, P=.95).

Engagement, non-usage attrition and attrition

This study was designed to evaluate this WBP in a real life setting in order to observe real levels of engagement and their relationship with weight loss; hence, no instructions were given to participants regarding how often they should login to use the website and the self-monitoring devices. The *Imperative Health* program does itself encourage daily engagement by allowing the upload of daily weight and physical activity data, captured by the accelerometer activity band and by the entry of daily food diaries. Some studies have suggested that an unstructured 'self-care' approach may limit the potential benefit of internet programs [29,30], however, prescriptive dosage studies are likely to represent efficacy rather than effectiveness and do not help to understand the likely true public health impact of these novel modes of delivery. Studies that have provided dosage instructions have found positive effects. For example, participants that comply with the dosage instructions tend to lose significantly more weight than non-compliers [14,31,32,33]. The majority of these prescriptive dose studies, however, were conducted over the short term (6 months or less). Sustaining engagement levels in the long term is undoubtedly more of a challenge. Weight change (3 months) in this current study had a positive moderate correlation with the number of logins and weight uploads but engagement levels tended to diminish with time, particularly after 6 months. Web-based programs in general tend to have problems with long-term sustainability and non-usage attrition tends to be a common characteristic that increases steadily over time [2,30]. Participants are likely to disengage over time, perhaps due to motivational issues and, particularly, if they are failing to lose weight or have reached a plateau [34]. Furthermore, depending on the WBP itself and what it has to offer in terms of interactivity and level of intensity, participants may simply get bored and lose interest in the WBP.

Attrition rates are generally high in web-based weight loss studies and have been reported to range between 0 and 70%, with a mean attrition rate of 22.5% [7]. Furthermore, attrition rates have been reported to be higher within the web-based intervention group [29,31,35,36,37] relative to the control group, as was the case in this current study.

Interactivity is essential for high engagement and low attrition, furthermore, it is well accepted that WBPs with enhanced interactive features promote greater weight reductions than those that provide information only [5]. The WBP described in this current study encompassed an interactive design by encouraging self-monitoring and providing automated feedback yet high levels of attrition and long-term disengagement levels were evident. Incorporation of more individualised personal support rather than automated feedback may have helped engagement levels, particularly at the 6 month juncture. The majority of participants who took part in an interview suggested that the addition of more personalised interaction, by a phone call or email, rather than an automated machine providing standard feedback would be more motivating and help preserve their interest to keep using the program. Similar studies evaluating the effect of WBPs on weight loss have reported higher effect sizes and usage when face-to-face contact is incorporated into the intervention [4]. This would be in line with the complete *Imperative Health* service; however, it was important to assess the WBP on its own in order to understand its specific contribution.

Incorporation of WBPs into traditional care pathways for weight loss has generally taken the approach of comparing standard healthcare with standard healthcare plus WBP over a defined period of time. An alternative model of care that may be worth further investigation is to use WBPs for initiation of weight loss and then add in further interventions, rather than using WBPs alongside other interventions from the outset. Addition of more interpersonal interventions, at the later stage would perhaps encourage sustained behaviour change, prevent attrition from the 6 month time point onwards and support the weight loss maintenance stage. Such a model has particular relevance for healthcare systems, for example, waiting lists to be seen by Dieticians in the UK National Health Service can be many weeks; referral to use a WBP during this time would be a useful way of initiating weight loss and may be particularly appealing for patients who do not feel comfortable attending weight loss groups.

Secondary outcomes

In terms of cardiovascular risk, between-group analyses demonstrated that the intervention group significantly improved their BMI and waist circumference at 3 months and 6 months and their total cholesterol and triglycerides from baseline to 3 months in comparison with the control group, however, these significant between-group changes were not sustained at 12 months. The WBP did provide a self-monitoring tool for tracking blood pressure, lipids and lipoprotein levels but intervention group participants did not avail of this part of the program. When this was discussed at the interview sessions, the majority of participants stated that the main reason they didn't access this part of the program was that they weren't able to have these risk factors measured regularly. This is a general disadvantage of WBPs that do encourage the monitoring of other health risk factors but don't provide the means to conduct the measurements at the participant's own convenience.

It was evident that the intervention group adopted healthier behaviours specifically in the short term. The significant increase in time spent exercising moderately and above (> 3.5 METs) and the decrease in energy intake observed in the intervention group in comparison with the control group was likely to be attributable to the self-monitoring components of the web-based program. Usages of these self-monitoring features were also correlated with short-term weight change (baseline to 3 and 6 months). Physical activity levels were not sustained in the longer term and the number of weekly physical activity uploads notably decreased between 6 and 12 months. These findings are consistent with those already reported in the literature [38,39]. A systematic review examining the effects of self-monitoring diet, physical activity and weight on weight loss [38] found a consistent and positive significant association between the

frequency of the self-monitoring behaviours and weight loss compared to less frequent self-monitoring. It was also reported in this review that a gradual decline over time in adherence to self-monitoring weight management behaviours is common [38].

Strengths and limitations

The strengths of this study included its robust study design, the objectively measured primary outcome and the mixed method research approaches (qualitative and quantitative) used throughout the evaluation process. Furthermore this study included a 'true control group'; the majority of studies in this area tend to use a minimal support group in order to boost recruitment and decrease attrition, however, this may attenuate the relationship between groups. This study was conducted within a real life setting and participants were not provided with strict instructions as to how often they should use the program, therefore making the results more generalisable to overweight populations accessing these WBPs at home for their own self-care.

This study did have some limitations, for example, all participants had contact with the researcher during clinical assessments, and knew this was a weight loss study, which in itself may have triggered a behaviour change response, and this 'Hawthorne effect' [40] appears to be evident within the control group. The researcher, however, did not give any advice during the assessment period to either group.

Issues of attrition or loss to follow-up and non-usage attrition steadily increased over time, but this phenomenon is commonly reported in the literature in relation to weight loss management [34] and is not unique to WBPs. From a scientific perspective, attrition and non-usage attrition can impact on the likelihood of detecting a difference between groups when evaluating the treatments over longer periods of time, from a clinical perspective it highlights the challenge of maintaining interest, motivation and weight loss in the medium to long term. Another limitation is the fact that the study was powered on weight loss at the three month time point; therefore, the sample size may have been too small to detect a significant difference between groups for some of the secondary outcomes, particularly at the later follow-up time points.

Owing to the routes of recruitment and the fact that people volunteered themselves for this study, the majority of the sample was from a higher social economic background. This could have potentially affected levels of engagement and attrition. This, however, is not unique to similar studies in the literature (Weinstein and Neville) but does suggest the sample is not entirely representative of the general overweight and obese population. This will need to be borne in mind when considering the potential wider or larger scale impact of the web-based behaviour change intervention.

Conclusion

This study provides evidence that this WBP can be used to initiate clinically relevant weight loss of 5% or more and promote improvements in total cholesterol and triglyceride concentrations in the short term (3- 6 months) in comparison with usual care. These changes, however, were not sustained by the WBP alone in the longer term (up to 12 months) and this appeared to correspond with a general decline in usage of the WBP over time. The fact that the study was powered on weight loss at the 3 month juncture and the high attrition rates at the 12 month time point in the intervention group could have also prevented significant differences between the groups being identified, specifically at the later time point. Nevertheless, results of this study highlights a need to augment WBPs with further interventions after 6 months of

usage, for example phone or email or face-to-face support, in order to enhance engagement, prevent relapses and encourage maintenance of weight loss in the longer-term. The effectiveness and cost-effectiveness of such a model of weight management is worth further exploration.

Acknowledgments

Funding source: This study was supported by a PhD studentship provided by the Northern Ireland Department for Employment and Learning (DEL). Imperative Health (AXA PPP Healthcare Ltd) provided the web-based program and monitoring devices without charge. The authors would like to acknowledge the Imperative Health team; specifically, John Crudgington and Chris Tomkins, for their contribution, assistance and support throughout this project. As well as acknowledge Dr Caroline Mercer for undertaking the serum lipid and CRP analysis. We would like to thank all the participating volunteers for giving up their time and for their co-operation.

Authors' contributions

MCM, JVW and LJW were all involved in the conception of this piece of research. All authors listed (SW, JVW, LJW, SJH, AM, ISY, CRC, KMA and MCM) were involved in designing this research. SW with the assistance of AM conducted the research. SW with the guidance and assistance of CRC analysed the data. SW wrote the manuscript and all authors were involved in reading, revising it critically, editing, and approving the final manuscript.

Conflicts of Interest

L Ware was involved in developing the nutrition and behaviour change elements of the web-based program. All other authors listed on the manuscript are distinct from the developers and sponsors of the intervention.

Multimedia Appendix 1

CONSORT-eHealth checklist [9].

Multimedia Appendix 2

Imperative Health screenshots (Meal and activity planners).

Multimedia Appendix 3

Imperative Health screenshots (Activity and calorie feedback charts).

Multimedia Appendix 4

Imperative Health screenshots (Clinical measurement feedback chart).

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Abbreviations

ANCOVA: analysis of covariance
BMI: body mass index
CRP: C-reactive protein
CVD: cardiovascular disease
GPPAQ: General Practice Physical Activity Questionnaire
HDL: high-density lipoprotein
ITT: Intention-to-treat
MET: metabolic equivalent
QUB: Queen's University Belfast
RCT: randomised controlled trial
RPAQ: Recent physical activity questionnaire
WBP: web-based program