Supporting behaviour change in sedentary adults via real-time multidimensional physical activity feedback: A mixed-methods randomized controlled trial

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Table of Contents

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Abstract

Background: Increasing physical activity (PA) behaviour remains a public health priority and wearable technology is increasingly being used to support behaviour change efforts. Using wearables to capture and provide comprehensive, visually persuasive, multidimensional feedback with realtime support may be a promising way to increase PA in inactive individuals.

Objective: To test whether a six-week self-monitoring intervention using composite web-based multidimensional PA feedback with real-time daily support increased PA in adults.

Methods: A six-week, mixed-methods, two-armed pilot randomized controlled trial (RCT) with six-week follow-up was used, whereby fifty-one low to moderately active (physical activity Level (PAL)<2.0) adults (mean age = 51.3 years; %female = 55) were randomly assigned to receive the self-monitoring intervention (n=36) or waiting-list control (n=15). Assessment of PA across multiple health-harnessing PA dimensions (e.g. PAL, weekly moderate-to-vigorous intensity physical activity (MVPA), sedentary time, steps), psychosocial cognitions (e.g. behavioral regulation, barrier self-efficacy, habit strength) and health were made at pre-randomisation baseline, 6 and 12 weeks. An exploratory analysis of mean difference and confidence intervals was made using the ANCOVA model. After the 12-week assessment intervention participants were interviewed to explore their views on the programme.

Results: There were no notable differences in any PA outcome immediately post-intervention, but at 12-weeks moderate-to-large effects were observed with a mean (95% CI) difference in PAL of 0.09 (0.02 – 0.15), effect size (Hedges' g)=0.8; daily moderate-intensity PA of 24 minutes (0 – 45), g=0.6; weekly MVPA of 195 minutes (58 – 331), g=0.8; and steps of 1545 (581 – 2553), g=0.7. Descriptive analyses suggested the differences in PA at 12 weeks were more pronounced in females, and participants with lower baseline PA levels. Immediately post intervention there were favourable difference in autonomous motivation, controlled motivation, perceived competence for PA, and barrier self-efficacy, with the latter sustained at follow-up. Qualitative data implied that the intervention washighly informative for participants and that the realtime feedback element was particularly useful in providing tangible, daily, behavioural support.

Conclusions: Using wearable trackers to capture and present sophisticated multidimensional PA feedback combined with discrete realtime support may be a useful way to facilitate changes in behaviour. Further investigation into the ways to optimise the use of wearables in inactive participants and test the efficacy of this approach via a robust study design is warranted. Clinical Trial: www.clinicaltrials.gov REF: NCT02432924

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Conclusions: Using wearable trackers to capture and present sophisticated multidimensional PA feedback combined with discrete real-time support may be a useful way to facilitate changes in behaviour. Further investigation into the ways to optimise the use of wearables in inactive participants and test the efficacy of this approach via a robust study design is warranted.

Trial Registration: www.clinicaltrials.gov REF: NCT02432924

Keywords: physical activity; feedback, wearables, behaviour change, sedentary time

INTRODUCTION

The health benefits of leading a physically active life are well established with higher volumes of physical activity (PA) reducing the risk of numerous chronic diseases, mood disorders and premature mortality [1-3]. In contrast, physical inactivity and prolonged sedentary time have been shown to be an independent risk factor for non-communicable conditions including type 2 diabetes, cardiovascular disease, cancer and musculoskeletal disease [4-6]. In addition to health and wellbeing ramifications, it is estimated that physical inactivity costs $53.8 billion to healthcare systems around the world [7]. Collectively, such data stresses the need for wide-reaching, cost-effective solutions. The availability, accuracy, and popularity of wearable technology for capturing PA behaviour has surged in recent years and presents a potentially useful, affordable, and accessible tool for driving increases in PA levels [8, 9]. Yet, commercial activity monitors are typically marketed at, and used by, young adults who have relatively high baseline PA levels as a means to monitor exercise performance. Thus, the effectiveness of PA monitoring for inactive populations remains understudied and undetermined [10]. Sophisticated monitoring technology enables personalised motivational and persuasive feedback for individuals who would benefit from an increase in PA [11].

There are multiple dimensions to PA behaviour that can independently impact on our health and wellbeing [12, 13]. Analysis of wearable-derived data shows that individuals can score high and low on any number of these health-harnessing dimensions such as sedentary time, moderate-to-vigorous physical activity and overall energy expenditure [14, 15], which could present a challenge when providing feedback on the appropriateness of one's behaviour. However, this understanding could also be beneficial, as each dimension can be presented as a unique opportunity for behaviour change and in principle help individuals find bespoke solutions across a person's day that can help them to overcome personal barriers or anchor to their particular health goals [16]. Moreover, recipients can use reliable multidimensional PA feedback to understand and mitigate against compensatory changes in one aspect of their behaviour in response to an attempt to alter another (e.g., replacing moderate habitual activity with sedentary time in response to a new exercise regime). Preliminary qualitative data suggests that presenting multiple health harnessing dimensions to adults is an acceptable, comprehensible, and motivating means of communication that could be readily implemented to support behaviour change [17].

The Multidimensional Individualised Physical ACTivity (MIPACT) trial [18] examined whether a 12-week self-monitoring intervention incorporating multidimensional feedback alongside brief trainer support, led to increases in PA behaviour among adults at risk of chronic disease. After 3- and 12-months, there was very little change in behaviour using this approach despite excellent compliance and adherence [19]. In MIPACT, participants received personal feedback on their multidimensional PA profile and both time spent and energy expended at different PA intensities, via the manual upload of data from the monitor to a web-based "app" for viewing retrospectively. While this approach is educational and might raise awareness about past behaviour [20, 21], other persuasive behavioural techniques to support ongoing, acute regulation of behaviour or habit formation may be important precursors of sustained change [22, 23].

Interventions that have utilised continuous 'real-time' PA feedback (e.g., pedometers) have shown promise for supporting changes in PA behaviour [24-27]. Extending such work, real-time feedback provided across multiple PA dimensions might compliment a more holistic composite of PA to provide both a 'bigger picture' as well as a time-segmented appreciation of PA within the context of people's daily lives. In other words, providing informative data about their progress towards a discrete and achievable activity target in real-time can allow people to make quick behavioural adjustments and work towards their overall weekly health goal. Key to such an endeavour is the use of wearable technologies to provide informational feedback and primes based on real-time assessments so as to best capitalize on within activity motivation 'quality' [28].

To best utilise technological advancements to improve health and wellbeing, the use of appropriate motivational theory is a necessity [28]. Self-determination theory (SDT) is a broad and empirically based theory of motivation that provides insight into how to translate informational feedback [29]. At the heart of SDT is the proposition that people have three universal and essential necessities to wellness, healthy functioning, development, and growth, namely the satisfaction of the psychological needs for autonomy, competence, and relatedness [28]. In PA and exercise settings, empirical research has supported the role of need satisfaction in supporting high quality forms of motivation (i.e. autonomous wherein intrinsic enjoyment and value of the behaviour or identified congruence with self-identity guide behaviour), better experiences, and higher well-being [cf. [28]].

Research has also shown autonomous motivation towards exercise to positively predict objectively assessed exercise bouts [30].

Within SDT, it is postulated that when social inputs such as those inherent within interpersonal interactions and/or embedded in informational ‘real-time’ feedback satisfy basic psychological needs for autonomy, competence, and relatedness, people are motivated into action for high quality reasons and experience greater wellbeing, and better experiential outcomes [31]. Applied to the current work, the use of sophisticated PA data visualisations with light touch trainer support, self-monitoring, and real-time feedback were designed to support autonomy (e.g. via the provision of choice, exploring new activities/options, and use of meaningful rationales), competence (e.g. through the promotion of self-monitoring and clear, constructive, and relevant feedback), and relatedness (e.g. demonstrating interest in people and acknowledging and respecting their perspectives and feelings).

The primary aim of the present work was to explore whether the provision of sophisticated visual feedback with additional real-time feedback across multiple dimensions of PA supports changes in PA behaviour. Secondary aims were to examine whether any changes in behaviour led to meaningful change to health status over 12-weeks, or whether any psychological variables changed in response to the intervention. A supplementary aim was to explore the thoughts and feelings of intervention participants to further understand and explain their engagement with and impact of the programme.

METHODS

Study Design

To explore the efficacy of using combined, multidimensional, composite and real-time PA feedback on behaviour change a pilot 12-week, two-armed randomized controlled trial (RCT) design with quantitative and qualitative evaluation was employed. The study is registered at clinicaltrials.gov (Ref: NCT02432924) and received ethical approval from the University of Bath Research Ethics Approval Committee for Health (REACH, reference number: EP 14/15 10). Study outcomes were assessed on three occasions. The first two assessments were taken before and after a six-week self-monitoring intervention (or usual behaviour if control) with the third assessment following a further six-week follow-up period in which participants were without feedback. Control participants were offered the 6-week feedback intervention after their third assessment, while the intervention group participants were invited to undertake a one-to-one, semi-structured interview to provide rich insight into their experience of the intervention.

Participants

Participants were males and females aged between 40 to 70 years who responded to adverts through the external university web pages, twitter and in local newspaper articles for people who did not feel they were currently very active. All participants who enquired were sent a participant information sheet and subsequently screened for eligibility via a telephone call. Volunteers were deemed ineligible if they were actively being treated for a chronic disease that might impede their ability to change their PA (coronary heart disease, chronic kidney disease (stages 3-5), diabetes mellitus, stroke, heart failure, and peripheral arterial disease) or if they had a physical activity level (PAL: total energy expenditure/resting metabolic rate) of <2.0 METS, which has been categorised by the World Health Organisation as representing a highly active lifestyle [32]. The exploratory nature of this study meant that no formal sample size calculation was undertaken.

Intervention

Waiting-list control arm

The waiting-list control group were encouraged to carry on with their usual behaviour until they had had 2 further assessments in line with those of the intervention group (i.e., 6- and 12-weeks post randomisation). At the time of revealing their allocation, wait-list participants were informed that upon completion of the third assessment they would be able to receive the 6-week self-monitoring intervention in full (without any further follow-up assessment), but to carry on as normal in the meantime.

Intervention arm (6-week active intervention and 6-week follow-up)

Participants randomised to the intervention group returned to the University of Bath at their earliest convenience to undertake a set-up session. Here, participants were shown multidimensional feedback on their weekly PA using the MIPACT web-platform as described in Peacock et al. [18]. Briefly, the website provides informational feedback in the form of visual representations of their behaviour across a 7-day period. To this end, the feedback encompasses five key health targets (Figure 1-a): daily calorie burn, sedentary time, accumulated daily minutes of moderate-intensity activity, weekly MVPA in at least 10-minute bouts and weekly vigorous-intensity activity accumulated in at least 10-minute bouts. Using a simplified and more detailed graphic, participants were shown each target attainment using a traffic light system where green would indicate a hit target, amber close to target, and red a missed target.

Additional feedback was provided in the form of 24-hour PA patterns that were colour coded to indicate the intensity of activity at a given minute of the day (Figure 1-b). The web platform also included two interactive tabs whereby participants could tag activities to learn about and explore the specific intensity and energy expenditure of a given activity or period of time (Figure 1-c); and forward plan future activities that could be superimposed on a given weeks physical activity patterns to visualise and/or explore the impact of adding new or existing activities on their health targets (Figure 1-d). The Ainsworth Compendium of Physical Activities [33] was used as the basis for calculating the intensity category and personalised energy expenditure for each added activity in the menu of physical activities.

[Figure 1 – about here]

For the real-time feedback element, participants were provided with a Bodymedia mini monitor (Pittsburgh, USA), a smaller model that use the same algorithms and sensors as the Bodymedia Core used for the assessments, and an accompanying real-time analogue display that synced data directly from the armband. The small clip-on display provided feedback on daily-accumulated minutes of moderate-intensity activity and minutes of vigorous-intensity activity, calories, and steps that were contextualised alongside the web-platforms moderate, vigorous, calorie burn, and non-sedentary time goals, respectively. In addition to real-time data, the display also stores the total 24-hour values for the previous day and enables users to set personalised targets for each of the four-activity metrics. If targets were met, a congratulatory message was displayed on the screen and an alarm sounded to inform the user of their success.

Participants were given an operating manual for the device and encouraged to use it as often as they felt necessary during the six-week period. Over the course of the intervention period, the participant and researcher met a further three times to upload new data from the armband to the MIPACT web platform at weeks 2, 4 and 6. These 15-minute informal sessions afforded each participant the opportunity to troubleshoot any technical queries, get help interpreting their personal multidimensional web feedback and discuss new plans of action for change. Each session was delivered in a need-supportive manner, encompassing the provision of participant choice, exploration of new activities/plans, promotion of self-monitoring with clear, constructive, and relevant feedback, while taking a clear interest in the perspectives and feelings of the participant [34].

Measurement procedures

The baseline laboratory session lasted approximately 45 minutes and involved the signing of informed consent, completion of a questionnaire pack, the measurement of brachial seated blood pressure, anthropometric measurements, and retrieval of a fasting venous blood sample from the antecubital vein. Participants were asked to attend the session having abstained from food or caffeine for a minimum of 10-hours. At the end of the session, participants were provided with a physical activity monitor and instructed to wear the device for 7 consecutive days, removing solely for water-based activities. Participants were also provided with a pre-addressed envelope with which to return the activity monitor. Index of multiple deprivation was calculated using participants postcode on the UK government English indices of deprivation web-tool [35], and deprivation decile was extracted for each participant [36]. All procedures were replicated at the six- and twelve-week follow-up assessment time points.

Primary Outcome: Physical Activity

Physical activity was measured using the Bodymedia Mini (Sensewear v8.0), which has been shown to accurately measure minute-by-minute energy expenditure [37, 38]. To be included in the analysis participants required a minimum of 6-valid days that included 80% of an assumed 16-hour waking day. On occasions where participants removed the device during sleep or at other times, estimated resting metabolic rate [39] was assigned to missing data points to complete the 24-hour period. Minute-by-minute energy expenditure was used to determine time (minutes) spent in each of the activity intensity thresholds (sedentary, <1.8 METs; light, ≥1.8, <3.0 METs; moderate, ≥3.0, <6.0

METs and vigorous, ≥6.0 METs) [40]. These data were used to determine changes in each of the key health harnessing physical activity dimensions utilised in the feedback including: 1) physical activity level (PAL) (total energy expenditure /resting metabolic rate); 2) sedentary time (% of waking day); accumulated 1-minute bouts of moderate-intensity activity (minutes per day); 3) moderate-to-vigorous-intensity physical activity accumulated in bouts of 10-minutes or greater (minutes per week); and 5) vigorous-intensity activity accumulated in bouts of 10-minutes or greater (minutes per week). Mean daily steps were also determined at each assessment.

Secondary Outcomes: Health markers

Blood pressure was measured using an automatic sphygmomanometer immediately after 15 minutes of isolated rest. Three measurements were taken at least one minute apart, and the mean of the readings used as the recorded value. Height was measured without shoes to the nearest millimetre using a Seca (222, Birmingham, UK) Stadiometer, and weight to the nearest 100 grams using a set of digital Tanita (BC-543, Tokyo, Japan) scales. These measures were used to calculate body mass index (kg/m^2) for each participant. Waist circumference measurements were taken to the nearest millimetre using a Hoechstmass tape measure placed parallel to the floor at the mid-point between the iliac crest and the lowest palpable rib after a gentle exhalation. The mean of 3 measurements was taken providing they were within 0.5 centimetres of one another. A 10ml fasted venous blood sample was taken at each assessment and used to measure concentrations of plasma glucose, insulin, total cholesterol, HDL cholesterol, LDL cholesterol, triglycerides, and C-reactive protein. These metabolic biomarkers were quantified via commercially available spectrophotometric assays (Randox Laboratories, Co., Antrim, UK) and enzyme-linked immunosorbent assay (serum insulin only: Mercodia AB, Uppsala, Sweden). The homeostasis model assessment calculator was used estimate insulin resistance (HOMA-IR2).

Each participant also completed the EQ-5D-5L [41], which measures quality of life across 5 dimensions, namely: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. An EQ visual analogue scale is used to record patients' overall perception of their health from 0 (worst imaginable) to 100 (best imaginable). The SF-36 Health Survey Questionnaire was also used to determine any changes in perceived physical and mental health [42]. In total, 8 health concepts are measured by the SF-36 with 4 scales each loading onto 2 higher order factors: physical (physical functioning, physical impact on role, bodily pain, and general health) and mental (i.e., vitality, social functioning, emotional impact on role, and mental health) health [cf. 43]. Using the standardized scoring algorithms outlined by Ware et al [43], component summary scores were computed for physical and mental health ranging from 0 to 100, with higher scores representing better health status.

Secondary Outcomes: Motivation and psychological variables

The questionnaire pack included a collection of instruments for which the reliability and validity of the scores have been described at length by the respective cited authors. Where necessary, the stem of the respective questions was altered from its original wording to refer to '*physical activity'* rather than '*exercise'*. To measure participant's motivation as propagated within SDT: the Psychological Need Satisfaction in Exercise scale [44] was used to measure; autonomy, competence and relatedness and the Behavioural Regulation in Exercise Questionnaire – 2 [45] to explore the participants motivation for engaging in physical activity (i.e., autonomous and controlled reasons). The Perceived Competence in Physical Activity [46] was also included as a more specific measure of an individual's self-belief. The Barrier Self-Efficacy scale [47] was included to determine whether the intervention changed people's confidence to undergo physical activity in the face of common obstacles and the Self-Report Habit Index [48] used to determine the automaticity of physical activity behaviour. The Subjective Vitality Scale [49] was used to detect changes in vitality.

Post intervention interviews

Participants who successfully completed the intervention were invited to attend a one-to-one semi-structured interview to discuss their experience with the programme once all follow-up assessments were complete. The topic guide for these interviews (shown in full in Supplementary file 2) included questions to capture participants' views on the utility, and retrospective and prospective impact of the intervention for them, and unpick the aspects that were most useful and those that might be improved. The interviews typically lasted between 15 and 25 minutes and were recorded on an Olympus digital voice recorder. In addition, all intervention participants completed a feedback form that included rating scales for aspects of the real-time display (overall, personal targets, calories, steps, moderate and vigorous activity) and web-based feedback (overall, health targets, activity patterns, review function, planning function). Scores ranged from 1- not useful at all, 3- somewhat useful, to 5- extremely useful, with a 0 option if the element in question was not used.

Analysis

Mean differences between intervention and control group participants for 6- and 12-week PA and 95% confidence intervals across each of the six feedback dimensions were calculated using an analysis of covariance (ANCOVA) model [50]. Covariates included baseline values of each outcome variable to control for chance imbalances at baseline (accounting for any unequal variance due to the unequal group allocation) and the factors used in balancing the groups (sex and weight status) [51]. Bias corrected and accelerated bootstrapping were used to verify confidence intervals via 5000 replications, as this approach has been recommended to provide more accurate estimates of standard errors and confidence intervals with smaller sample sizes [52-54]. The same analysis was used to explore differences in health outcomes and psychosocial variables at six and twelve weeks. Effect sizes (Hedges g) are provided for the mean difference between intervention and control across each variable, which are interpreted as .2, .5 and .8 for small, moderate and large effects [55]. A *Posthoc* subgroup analysis to explore interactions with covariates observed at 12 weeks was made whereby unadjusted mean and standard deviations were calculated to explore whether male vs. female and participants with low vs. high baseline PA had more pronounced changes in PA data.

Qualitative Interviews were interpreted using descriptive deductive and inductive qualitative analysis based on the principles of thematic analysis [56]. Audio files were transcribed verbatim and uploaded to NVivo (version 11, QRS International, Australia) for coding and analysis. The lead author, who conducted the interviews, reread through each participant transcript for familiarisation, and then coded themes within the data. When all transcripts were coded the themes were compared between participants, and common recurring viewpoints and other important insights were presented in the Results as themes.

RESULTS

Figure 2 shows the flow of participants through the study. Of the 57 eligible participants out of 102 enquiries, 5 were excluded for being too active (PAL ≥2.0) at baseline, and 1 withdrew due to an allergic reaction to the PA assessment device. Therefore, fifty-one participants were randomised into either the intervention group or waiting-list control group at a 2:1 allocation ratio to learn more about the intervention. A statistician external to the research team completed randomisation and did not disclose any of the details prior to completion of recruitment. The statistician stratified by sex (male or female) and weight status (with BMI ≥30 kg/m^2 as the binary cut point) using a block size of six (which was revealed to the researcher team after the study) giving an overall allocation of 36:15 in favour of the intervention group. No participant withdrew from the study although one intervention participant declined to undergo the end of intervention interview. Baseline characteristics of participants are displayed in Table 1.

Table 1 - Baseline characteristics of study participants

Characteristic **N (%) *unless specified***	**All** **(n = 51)**	**Intervention** **(n = 36)**	**Control** **(n = 15)**
Age (years) *Mean (SD)*	*51.3 (8.4)*	*52.3 (8.2)*	*50.1 (8.3)*
40-55	33 (65%)	23 (64%)	10 (67%)
55-70	18 (35%)	13 (36%)	5 (33%)
Female	28 (55%)	20 (55%)	8 (53%)
Ethnicity (white British)	46 (90%)	32 (88%)	14 (93%)
Marital status			
Married/cohabiting etc.	42 (82%)	30 (83%)	12 (80%)
Single/divorced/widowed	9 (18%)	6 (17%)	3 (20%)
Education			
GCSE	3 (6%)	3 (8%)	0 (0%)
A-Level	4 (8%)	3 (8%)	1 (7%)
First degree	24 (47%)	17 (47%)	7 (47%)
Higher degree	20 (39%)	13 (36%)	7 (47%)
Index of Multiple Deprivation[a] Decile *Mean (SD)*	*8.0 (2.4)*	*7.9 (2.3)*	*8.2 (2.6)*
1-5	11 (22%)	8 (23%)	3 (20%)
6-10	39 (78%)	27 (77%)	12 (80%
Smoker	2 (4%)	0 (0%)	2 (13%)

a = Index of Multiple Deprivation (based on postcode calculated at http://imd-by-postcode.opendatacommunities.org)

[Figure 2 about here]

Primary outcome – Physical activity

All 51 participants provided complete PA data at the six- and twelve-week time-points and baseline and were therefore included in the exploratory analysis of the primary outcome. The baseline characteristics of participants are shown in table 1. Total 24-hour wear time across the week for the three assessment time points was, on average, 98%, 96% and 95% in the intervention group and 95%, 95% and 95% in the control group. Table 2 shows the adjusted mean difference (95% confidence intervals) between the intervention and control group at the 6- and 12-week timepoints and effect sizes for each physical activity outcome.

There were no observed differences in any PA outcome at the six-week end of intervention assessment. At 12-weeks, relative to control participants, the intervention group reduced their mean (95%CI) daily sedentary time by -40 (-76 to -4) minutes per day, increased their light-intensity activity by 14 (-78 to 45) minutes per day, their moderate-intensity activity by 22 (1 to 45) minutes per day and their vigorous-intensity activity by 2 (-1 to 6) minutes per day. *Posthoc* descriptive analysis of subgroups indicated that changes in physical activity were more pronounced in female participants relative to males, and for individuals with lower baseline physical activity levels at 12 weeks (Supplementary file 1, Table S1 and S2).

Table 2 Mean scores, adjusted mean difference between intervention and control and effect sizes (with 95% confidence intervals) across physical activity dimensions at 6 and 12 weeks.

Outcome	Time point	Intervention (n=36)[f]	Control (n=15)[f]	Adjusted mean difference [fg]	Effect size (*Hedges g*)
PAL [a] (TEE/RMR)	Baseline	1.61 (1.55,1.66)	1.62 (1.55,1.68)	-	-
	Week 6	1.62 (1.57,1.67)	1.65 (1.58,1.72)	-0.02 (-0.10,0.04)	-0.2 (-0.8,0.4)
	Week 12	1.67 (1.63,1.72)	1.58 (1.52,1.64)	0.09 (0.02,0.15)	0.8 (0.2,1.4)
Sedentary time [b] (% waking day)	Baseline	69 (66,73)	69 (64,73)	-	-
	Week 6	69 (66,72)	66 (62,70)	3 (-2,8)	0.3 (-3,0.9)
	Week 12	66 (63,69)	70 (65,74)	-4 (-8,1)	-0.5 (-1.1,0.1)
Moderate activity [c] (mins/day)	Baseline	111 (94,129)	117 (99,135)	-	-
	Week 6	118 (105,130)	127 (107,148)	-10 (-28,8)	-0.3 (-0.9,0.3)
	Week 12	132 (118,147)	109 (89,131)	24 (0,45)	0.6 (0.0,1.2)
Vigorous bouts [d] (mins/week)	Baseline	42 (23,65)	26 (12,43)	-	-
	Week 6	48 (30,70)	46 (24,71)	2 (-24,28)	0.0 (-0.6,0.6)
	Week 12	50 (30,73)	33 (14,55)	18 (-5,41)	0.4 (-0.2,1.0)
MVPA bouts [d] (mins/week)	Baseline	539 (435,646)	509 (400,622)	-	-
	Week 6	584 (495,675)	580 (441,725)	4 (-126,136)	0.0 (-0.6,0.6)
	Week 12	658 (571,750)	462 (340,587)	195 (58,331)	0.8 (0.2,1.4)
Steps [e] (steps/day)	Baseline	7403 (6705,8093)	7767 (6626,8884)	-	-
	Week 6	8207 (7269,9114)	8280 (7268,9114)	-73 (-1122,1017)	0.0 (-0.6,0.6)
	Week 12	8782 (7987,9656)	7236 (6496,7991)	1545 (581,2553)	0.7 (0.1,1.3)

a = mean total daily energy expenditure/daily resting metabolic rate; b = percentage of waking day; c = all minutes ≥3 METS;

d = activity ≥3 METS (MVPA) or ≥6 METS (vigorous) accumulated in 10 minutes or greater is counted; e = mean daily step count

PAL = physical activity level; MVPA = Moderate to vigorous intensity physical activity

f Confidence intervals are verified using a bias-corrected and accelerated bootstrap with 5000 replications g Covariates include stratified randomisation factors (BMI at baseline and sex) and baseline score for respective outcome variable

Secondary outcomes: Health and wellbeing

There were no six- or 12-week differences in any of the cardiometabolic health outcomes measured between intervention and control groups, except for insulin resistance calculated at week 12. The mental health component summary of the SF-36 improved in the intervention group at 12 weeks, but that, nor the physical component summary or EQ-5D-5L or visual analogue scale scores were different at any other time point. Baseline, 6-week and 12-week scores for all variables are shown in Table 3.

Secondary outcomes: Motivation and psychosocial variables

Relative to the control group, the intervention group had a reduction in controlled behavioural regulation [introjected and external regulation and increases in autonomous behavioural perceived competence for physical activity and habit strength at the six-week assessment but not at 12 weeks. Barrier self-efficacy was increased in the intervention group at six weeks and sustained at twelve-week follow-up. Subjective vitality was also increased in the intervention group at six weeks but not sustained to twelve weeks. No changes to overall psychological need satisfaction or its subscales were observed (Table 3).

Table 3 Secondary health and psychosocial outcomes at six and 12 weeks.

Outcome	Baseline (n=51)		Intervention mean (95% CI)	Control mean (95% CI)	Adjusted mean diff. (95% CI)	Effect size Hedges g
Health and wellbeing						
Systolic Blood Pressure (mmHg)	124	6W	123 (118,128)	123 (118,128)	0.2 (-4.69,4.86)	0.02
		12W	124 (120,127)	120 (113,127)	4.33 (-3.33,11.43)	0.43
Diastolic Blood pressure (mmHg)	86	6W	86 (83,90)	88 (83,93)	-1.53 (-6.03,3.21)	-0.20
		12W	88 (85,91)	86 (81,91)	1.85 (-3.88,7.79)	0.21
Body Mass (kg)	81.9	6W	81.6 (77.8,85.4)	82.3 (78.6,86.1)	-0.74 (-1.86,0.49)	-0.44
		12W	81.8 (78.2,85.4)	82.6 (79,86.4)	-0.81 (-2,0.36)	-0.33
Waist Circumf. (cm)	91.8	6W	89.9 (86.6,93.3)	90.8 (87.3,94.4)	-0.93 (-2.47,0.81)	-0.32
		12W	89.2 (86.1,92.4)	89.2 (85.7,92.9)	0.01 (-1.67,1.77)	0.00
Glucose (mmol/L)	5.3	6W	5.3 (5.1,5.5)	5.4 (5.2,5.6)	-0.08 (-0.32,0.17)	-0.22
		12W	5.3 (5.1,5.5)	5.5 (5.3,5.7)	-0.15 (-0.43,0.13)	-0.36
Insulin (mIU/mL)	6.7	6W	6.4 (5.2,7.7)	6.6 (5.3,8)	-0.18 (-1.85,1.7)	-0.06
		12W	6.1 (5.1,7.3)	7.3 (6,8.9)	-1.25 (-2.4,-0.16)	-0.50
Insulin resistance	1.6	6W	1.5 (1.2,1.9)	1.6 (1.3,2.0)	-0.07 -0.48,0.34)	-0.09
		12W	1.5 (1.2,1.7)	1.8 (1.5,2.1)	-0.34 (-0.61,-0.62)	-1.23
Total Cholesterol (mmol/L)	5.6	6W	5.3 (5,5.6)	5.5 (5.1,5.9)	-0.16 (-0.56,0.22)	-0.23
		12W	5.4 (5.2,5.6)	5.5 (5.1,6)	-0.14 (-0.65,0.32)	-0.23
HDL Cholesterol (mmol/L)	1.3	6W	1.4 (1.2,1.5)	1.4 (1.3,1.5)	-0.04 (-0.17,0.11)	-0.18
		12W	1.4 (1.2,1.5)	1.4 (1.3,1.6)	-0.06 (-0.17,0.04)	-0.38
LDL Cholesterol	3.7	6W	3.5 (3.2,3.7)	3.5 (3.2,3.8)	-0.07 (-0.38,0.25)	-0.11

(mmol/L)		12W	3.5 (3.3,3.7)	3.5 (3.1,3.9)	0.01 (-0.39,0.36)	0.03
Triglycerides (mmol/L)	1.4	6W	1.2 (1,1.4)	1.3 (1.1,1.6)	-0.12 (-0.39,0.14)	-0.27
		12W	1.2 (1.1,1.4)	1.5 (1.2,1.7)	-0.23 (-0.55,0.08)	-0.54
CRP (mg/L)	2.0	6W	2.4 (1.5,3.5)	1.6 (0.9,2.2)	0.89 (1.11,0.18)	0.32
		12W	1.9 (1.3,2.7)	3 (1.6,4.5)	-1.09 (-2.8,0.51)	-0.48
EQ-5D VAS	65.2	6W	72.2 (66.8,77.3)	71.7 (63.4,79.6)	0.45 (-7.57,8.45)	0.03
		12W	69.5 (62.5,75.7)	71.7 (66.6,76.7)	-2.12 (-11.23,6.47)	-0.12
EQ-5D-5L Score	0.90	6W	0.92 (0.89,0.95)	0.89 (0.85,0.93)	0.03 (-0.01,0.07)	0.38
		12W	0.89 (0.85,0.92)	0.9 (0.85,0.95)	-0.01 (-0.06,0.04)	-0.16
SF36 Physical Health^	47.4	6W	51.1 (48.3,53.9)	48.5 (45.2,51.5)	2.52 (-1.63,7.17)	0.39
		12W	47.5 (43.8,51.1)	50.1 (46.3,53.5)	-2.6 (-7.58,2.79)	-0.28
SF36 Mental Health	49.0	6W	50.8 (48.4,53)	48.9 (45.3,52.6)	1.86 (-2.29,6.03)	0.26
		12W	51.7 (47,56.3)	43.8 (38,49.4)	7.93 (0.74,15.18)	**0.**60
Motivation and Psychosocial						
Autonomous Motivation	2.9	6W	3.1 (3,3.3)	2.9 (2.7,3)	0.26 (0.04,0.49)	0.79
		12W	3.1 (2.9,3.3)	3 (2.8,3.2)	0.1 (-0.1,0.3)	0.30
Controlled Motivation	1.5	6W	1.4 (1.2,1.6)	1.7 (1.4,1.9)	-0.28 (-0.55,-0.01)	-0.63
		12W	1.3 (1.2,1.5)	1.6 (1.3,1.8)	-0.2 (-0.5,0.09)	-0.42
Overall Need Satisfaction	4.7	6W	4.6 (4.2,4.9)	4.6 (4.3,5)	-0.03 (-0.57,0.39)	-0.03
		12W	4.7 (4.5,4.9)	4.6 (4.2,4.9)	0.12 (-0.21,0.43)	0.16
Autonomy	5.4	6W	5.3 (5.1,5.5)	5.4 (5.1,5.7)	-0.07 (-0.39,0.26)	-0.12
		12W	5.5 (5.3,5.7)	5.6 (5.4,5.7)	-0.09 (-0.32,0.16)	-0.17
Competence	4.1	6W	4.5 (4.2,4.7)	4.1 (3.7,4.5)	0.36 (-0.1,0.77)	0.47
		12W	4.3 (3.9,4.6)	4 (3.5,4.4)	0.32 (-0.18,0.8)	0.36
Relatedness	4.3	6W	4.2 (3.7,4.6)	4.5 (4.1,4.9)	-0.35 (-0.88,0.16)	-0.37
		12W	4.4 (3.9,4.8)	4.4 (3.9,4.8)	0 (-0.74,0.72)	0.00
Barrier Self-efficacy	49.7	6W	52.3 (47.6,57)	41 (35.1,46.8)	11.35 (3.24,19.37)	0.84
		12W	53.3 (48,58.8)	43.9 (37.3,50.3)	9.38 (1.67,17.18)	0.68
Vitality	4.4	6W	5.1 (4.8,5.4)	4.3 (3.7,4.9)	0.77 (0.17,1.37)	0.81
		12W	5.1 (4.7,5.5)	4.5 (3.8,5.1)	0.57 (-0.04,1.2)	0.51
Perceived Competence	5.0	6W	5.3 (4.9,5.6)	4.8 (4.4,5.1)	0.51 (0.14,0.92)	0.70
		12W	5.2 (4.8,5.7)	5 (4.6,5.5)	0.2 (-0.41,0.9)	0.19
Habit	1.6	6W	2.1 (1.8,2.4)	1.5 (1.2,1.9)	0.56 (0.16,0.97)	0.84
		12W	2.1 (1.8,2.3)	1.7 (1.3,2)	0.41 (-0.04,0.86)	0.58

a = covariates include baseline score for each parameter (as indicated in the pooled mean baseline column), BMI and sex.
b = Confidence intervals verified using bias corrected and accelerated bootstrapping with 5000 repetitions

Intervention component evaluation

Participants were asked to provide their subjective ratings of the 'usefulness'' of intervention features at the six-week assessment and qualitative feedback following their 12-week assessment. From the subjective ratings (Table 4), receiving clear and constructive feedback in real-time was recognised to have been the single most useful feature, with each aspect of the real-time display consistently rated as more useful than the features of the web-platform. The lowest ranked features were the more interactive web-based tools, namely the review and planning sections of the Mi-PACT website.

TABLE 4 - Mean (SD) scores[a] for each evaluated intervention component.

REAL-TIME DISPLAY					WEB PLATFORM				
Overall score	Calorie data	Step counter	Mod. /Vig. Activity	Personal Targets	Overall score	Health target	Activity pattern	Review /tagging	Planning function

4.5 (0.8)	4.0 (0.9)	4.6 (0.7)	4.3 (1.2)	4.0 (1.5)	3.3 (1.5)	3.6 (1.5)	3.7 (1.5)	2.3 (2.0)	2.0 (1.9)

a = Participants scored each component from 1 (not at all useful) to 5 (very useful) or 0 (did not use).

Mod. = Moderate-intensity activity; Vig. = Vigorous-intensity activity

Qualitative Evaluation

The qualitative feedback offers further insight into these ratings. Table 5 provides a summary of the key themes identified in the analysis of intervention participants interviews and quotations to illustrate each one. All intervention participants championed the feedback as useful for raising their consciousness and awareness of their own PA behaviour with many mentioning an improved understanding of the time they spend inactive (T1). More than half of the intervention participants postulated that PA was now more of a priority having been through the programme and that it reinforced their belief that PA was a means to improve health (T2). The self-monitoring element helped individuals gauge how much PA was required to meet certain health recommendations (T3). According to many of the participants, the programme inspired them to increase their PA levels and two thirds alluded to the fact that the multidimensional nature of the feedback assisted them in finding personal solutions (T4). Some participants said that during the six-week programme they would consciously go out of their way to achieve the targets and many put added emphasis on steps as a key, achievable daily motivator (T5).

The majority of the intervention group felt that they were now being more proactive about fitting PA into their routine after the intervention (T6), while a handful of participants alleged to have had and illness or injury during the programme that hampered their progress (T7). Two-thirds of participants expressed further intentions to take up new, or perform more, PA and approximately half of the group felt confident that they could maintain their PA levels after the programme and/or had made lasting behavioural changes (T8). In addition, some participants felt that they had improved their confidence and sense of competence for PA, and others expressed a greater enjoyment for PA and an improved sense of health and wellbeing (T9).There were many participants who said that they missed not having the real-time activity monitor once it was removed after six weeks and by the time the interview around a third of participants had purchased a commercial PA tracker for personal use with many more considering acquiring a device (T10).

For many of the intervention participants, the real-time display was a favourable component for the self-monitoring of activity and more important than the website feedback (T11). That said, there were still a reasonable proportion of participants, who made reference to the multidimensional feedback as being a useful way of viewing the overall picture and some even described it as the wake-up call (T12). Some participants suggested that their engagement with the feedback on the web-platform may have been improved if it was more readily available, and that sitting down at a computer felt counterintuitive to being [more] physically active (T13). Data also revealed that for certain participants there were minor issues with the device itself in terms of either trusting the feedback or its wearability (T14). Finally, a handful of participants made recommendations for improved utility of the monitor and feedback system, which included the need for more prompts and guidance or links to their health data collected at assessment sessions to help them evaluate the impact of more PA or for motivation (T15).

TABLE 5 – Key themes identified in the qualitative analysis and example quotations

Theme	Example quotation(s) [Participant information provided as sex, age, baseline PAL]
T1. Personalised feedback improved understanding of one's own behaviour	*"I think it's, it's changed, it's changed my day-to-day activity, and I am a lot more conscious of the fact that I am sitting a lot, and part of it, there was a realisation that I wasn't very active."* ***[Male, 46, 1.48]*** *"Yeah, I think I was probably overestimating what I was doing, I thought I was more active than I was in a way so... when you see it it's like oh you are actually doing as much as I thought I'd probably on my feet but I'm not necessarily so doing anything that is going to benefit me stop so yeah it's definitely made me more aware of the need."* ***[Female, 42, 1.42]***
T2. Physical activity now more of a priority/ reinforced importance	*"Um, well it certainly hasn't become any less important. I probably would say that it has become more important because the awareness breeds that sort of feeling, you know, that this is something that is not just a one-off, you know. Over a three-month period, it's, it's life and it should continue."* ***[Male, 59, 1.72]*** *"And then hopefully, my hope is, as i.e., as I lose weight... Because that's one thing I haven't done is lost weight... um, is once I have lost more weight that I will feel fitter and then I can up that target. But I don't want to try and do too much, too soon."* ***[Female 62, 1.25]***
T3. Feedback helped people understand how to meet recommendations	*"I found it interesting, you know? Because I know how many steps it takes me to go down our town and round and back to the house it's at about 1800, I think. And I know how many is to go to the railway and things like that."* ***[Female, 63, 1.37]*** *"But of course, that whole thing then tipped me nicely over and I was... So, it had that useful upturn, and equally, as I said before, it helps me gauge just exactly how much distance I need to be covering to meet a, sort of a standard target."* ***[Male, 48, 1.65]***
T4. Feedback helped motivate and find personalised solutions to	*"So, I knew that I had to just get back into doing something... And having that monitor was almost like a critical friend, it was there to say "you can do this"."* ***[Female, 48, 1.55]*** *"Yes, that really helped and then over the six-week period, every week I was trying to do a little bit more and*

increase PA	*like I say, it's not very difficult to do it it's just that now you are conscious of it and you are aware of it that you have to achieve so many steps per day.”* ***[Male, 48, 1.87]*** *“Definitely. Anything is worth it. Any… Any activity, it doesn’t have to be gym five days a week. If I wasn’t doing five days a week at the gym, I didn’t consider myself to be active, basically. So now I know that because I wasn’t training five days a week, and I was actually able to show some green lights when I wasn’t doing the fi… it makes me realise that all of it counts. It’s completely changed. I’m actually more active because I’m down on myself for not doing five days a week at the gym.”* ***[Female, 44, 1.52]*** *“And it’s achievable without knocking myself flat you know I can do it in little steps and I can move myself forward in little ways rather than try and charge at a wall and break through a wall. It is much easier that way. So again, using the word empowerment it has sort of empowered me into thinking I could do this.”* ***[Male, 54, 1.39]***
T5. Realtime feedback prompted attainment of acute daily goals.	*“Um, and I did find it motivating, and I did, um, you know, I was known to leave the house at kind of five minutes to bedtime to walk around the block at the time … Or spend five minutes doing star jumps to try and get vigorous activity in. So yes, having the targets I found very helpful, and yeah, and motivating and interesting and fun.”* ***[Female, 56, 1.56]*** *“Um, I did actually, I surprised myself in how easy it was to make step goals. I didn't think I walked that much but as soon as I was just tracking it, it was like "actually I'm not far off daily amounts if I just do a little bit more and better hit that target.”* ***[Male, 41, 1.53]***
T6. Now able to fit more PA in to routine	*“Making a conscious almost, not a plan, plan is probably a bit too grand, but saying "right each week I must do a certain amount of activity” and I plan that and think about it and so… The type of person I am, I'm quite a sort of structured and quite organised person so just building that into my routine is a change in my behaviour.”* ***[Male, 53, 1.86]***
T7. Injury and illness hampered progress during intervention	*“Right, um, it was slightly complicated by the fact that I was ill right in the middle of it so… I started off really motivated and felt really good about it and it was building very well. And then unfortunately, after about a month I guess, I got this fluey type thing, which really did kick in and, made it a bit of a struggle to do as much and build as much as I wanted to do it. And then of course it's sort of came to the end of the programme really so I don't feel like I did it as much justice as I would have liked to have done.”* ***[Female, 67, 1.58]***
T8. Felt confident to keep up or increase PA further	*“Yeah, it definitely made me think a bit more about the moderate bouts of activity and how important they are. And it made me more keen to do things like walking the dogs and, you know, walks to school and I wouldn't the thought that to be useful before. And I think ‘oh they are quite a useful way of getting in extra steps’."* ***[Female, 43, 1.71]***
T9. Intervention led to improved confidence and enjoyment of PA	*“Yeah. I mean, variety… yeah, I think that’s been really helpful, actually. Because it’s less boring and, um, you don’t perceive it as… I think my perception of what exercise was and what it actually is very different now. So now activity isn’t exercise. Activity is just anything.”* ***[Female, 45, 1.52]*** *“Knowing how more confident I am, which I, perhaps if I wasn’t recording it somewhere I wouldn’t have been aware of that…So that’s erm, yeah that’s a nice position to be in, having seen confidence increase with various things, various types of activities, it’s a nice position to be in for sort of in the future.”* ***[Female, 48, 1.51]***
T10. Intervention prompted participants to (consider) purchase(ing) a real-time feedback	*“It has spurred me on to get one of these, to actually buy one of these Fitbits. Which is just going to continue to let me know in real-time exactly what I’m doing and very similar in fact it is in steps and calories burnt off and what have you and the fact everyone else in the office have got one.”* ***[Female, 60, 1.52]***

device	*"Which I suppose sounds really obvious when you say it, but it hadn't ever linked with me before. And, I now have a little Fitbit because I want to now... I've become slightly obsessed with steps."* ***[Female, 63, 1.37]***
T11. Real-time feedback element considered the most useful element of intervention	*The instant display I think is what... I mean, I did go online that that's in retrospect, you didn't get to see that until you had already done it. Whereas in today's society we want instant answers so having the display and being able to look at it, um, was, you know, was motivating."* ***[Female, 62, 1.25]*** *Um, the, the monitoring device, I found I used the little tiny daily, daily monitor, all the time...that was almost obsessive!* ***[Male, 46, 1.48]***
T12. Web-based feedback useful initial picture	*"You see on the computer screen and it was just flat line, I think that that is, visually, or when you look at it and you look at the figures and you look at that... that had probably quite an impact. And I think that that is... Probably the wake-up call which will remain with me, yeah, visually seeing it."* ***[Male, 64, 1.72]***
T13. Web-based component could be improved	*"Because I could only look at it at certain times at home without being able to do it when I wanted to do it was frustrating...If you see what I mean? So, just only having a sort of biweekly uploaded my information... I wish I could have just done it as and when and seen more feedback."* ***[Male, 41, 1.53]*** *"I think to be perfectly honest it was....it was sort of time element of it. I didn't feel that I had the time just to sit and...and look at it, which I probably should have done, but it felt as if the more instantaneous response from the monitor was actually....or the display was...was what I needed on a day-to-day basis."* ***[Female, 52, 1.64]***
T14. Some issues with device comfort or data trust	*"The exercise I tend to do is like cycling and the bottom half of my body it probably won't show a great deal of vigorous activity. Which, okay it is the limitation of the technology and the technology at that time, but I was mildly irritated by that."* ***[Male, 55, 1.50]***
T15. Suggested improvements	*"10,000 steps is nice and easy cause that's just walking, you can just incorporate that into your daily activity, but then the vigorous activity, I could do it if I go for a run, but any other way I wouldn't know. I only had ideas of cycling and rowing and though there are suggestions, but a programme of how you can achieve them would have been helpful."* ***[Female, 45, 1.60]*** *"So, if you said to me your cholesterol is 5 at the end of the study you told me my cholesterol...well...I found out my cholesterol...because you know cholesterol response to exercise had dropped to 3.5 that would have been a big encouragement."* ***[Female, 55, 1.61]***

DISCUSSION

Summary of findings

In this exploratory-RCT we evaluated a 6-week intervention using personalised real-time digital PA feedback and sophisticated web-based multidimensional PA feedback combined with brief trainer support. Exploratory analysis demonstrated no change in PA between groups immediately post-intervention, but improvements were found for several PA metrics that formed part of the feedback at 12 weeks follow-up. Subgroup analysis suggests that this effect was more pronounced in female participants and those with lower baseline activity levels. Very little changed in respect to secondary health outcomes with the exception of insulin resistance and self-reported mental health, which showed signs of improvement after 12-weeks. Qualitative data suggests that participants found the multicomponent intervention informative and motivating, with the real-time feedback being heralded as the single most memorable and supportive component within the context of the overall treatment package.

Comparison with other literature

A novel aspect of the present study was the multidimensional approach that, we hypothesised, helps individuals to understand their behaviour and find bespoke behavioural solutions for increasing their PA [16]. We hypothesised that using a multidimensional approach to PA promotion and feedback would provide options and self-endorsed choice to foster autonomous motivation and would satisfy the needs for autonomy and competence. Following the 6-week active phase of the intervention we witnessed favourable improvements in autonomous vs. controlled motivation, perceived competence, and barrier self-efficacy, which offers support for this proposed mechanism and the multidimensional approach. Moreover, the qualitative evaluation aligns with our previous development work, which found that receiving detailed, visual multidimensional PA feedback is helpful for raising awareness, understanding and intention to change [17, 20]. We hypothesised that the addition of real-time feedback may help translate those intentions into behaviour [57, 58]. However, beneficial differences in PA were only observed after a six-week period in which the whole treatment package (including the real-time display) was removed, rather than immediately after the active intervention. Participants valued the real-time feedback at interview more than other components of the intervention and highlighted that it empowered them to adjust their behaviour on a more discrete basis as they strive towards a desired daily target (e.g., served as a prompt to take an additional 1000 step walk if they were short towards the end of a day).

Other studies have observed real-time feedback to be an effective tool for increasing physical activity when used in conjunction with detailed web-based feedback and trainer support. Vandelenotte *et al*. demonstrated that adding a Fitbit device to their theory informed, web-based physical activity intervention increased total physical activity and MVPA by up to three times relative to a non-tracker web-only group [27]. Their study, whose website went beyond the provision of feedback to provide individually tailored advice on a number of self-regulation strategies, found that the real-time monitoring also improved engagement and adherence to the main web-content and the overall package of behavioural support. Similarly, a large RCT by Harris and colleagues found that combining brief nurse support, retrospective accelerometer feedback and continuous pedometer feedback led to significant, sustained, changes in physical activity in the intervention vs. control groups at 3 and 12 months [25]. In another trial, the same research team demonstrated that continuous pedometer feedback provided effective support both with and without trainer input vs a control with no feedback or trainer [24]. The effects observed in these studies, albeit modest in size, were maintained after 3-4 year follow-up periods [59], suggesting that technology based physical activity interventions such as the one used in the present study, can help individuals make long-lasting changes.

Our qualitative findings corroborated key findings from the PACE-UP and PACE-LIFT studies that were conducted by Harris and colleagues [24, 25, 58]. Specifically, participants who were in receipt of the nurse-led pedometer intervention experienced greater awareness of the PA guidelines and their own PA levels. They also placed more importance on being active and helping participants to embed PA into their own routines [25, 60, 61]. Participants also found the real-time feedback useful for initiating and monitoring behaviour change in relation to personalised goals, and mirroring the findings reported in the present work, some went on to invest in other wearable trackers after their intervention, although distrust in the accuracy was identified as a potential barrier to effectiveness [60]. One set of themes deriving from the present study (e.g., illness and injury) and the work of Harris et al. (e.g. weather, lack of time) was the fact that common external barriers still existed for participants that could not be overcome by the real-time feedback interventions. Recommendations from participants in these and other qualitative studies suggest that more interpersonal prompts and guidance, resources for planning activities, meaningful challenges, and linking into health data may be avenues to overcome barriers, enhance intrinsic motivation and behavioural maintenance in real-time feedback-based interventions [62-64].

Indeed, the incongruent findings observed at six (immediately post intervention, no difference) and twelve weeks (after a 6-week follow-up, moderate to large effects) warrants further consideration. The assessment used in the present study, and the majority of RCTs with device-based PA outcomes, rely on weekly snapshots of participants' behaviour. The small sample size and variability around the mean scores of the control group suggest that any fluctuations might be due to noise in the assessment. In the intervention group, a weekly snapshot may not give an accurate representation of a person's true behaviour [65]. Continuous measurement in both intervention and control groups would help decipher if the six-week observation is, for example, indicative of a dip in behaviour following the removal of feedback, or if the twelve-week observations is, for example, indicative of the intervention participants learned rather than new habitual behaviour. Given the advancing technology that enables long-term data capture, future studies would do well to investigate the stability and representativeness of PA behaviour to guide trials on the most appropriate assessment window.

Strengths and limitations

Strengths of the present study include the almost complete 24-7 objective, physical activity assessment and high compliance to the intervention, measured as the completeness of attendance to upload sessions and PA monitor wear time in the intervention group, and assessments in all groups (all 100%). The use of quantitative and qualitative evaluation also provides rich insight on the effectiveness of this approach. Limitations include the small sample size, short follow-up period, and use of a non-clinical population, which prevents the performance of more robust statistical analyses and means any interpretations of these results should be viewed as preliminary rather than definitive and generalisable.

There is also a need to improve the synchronicity of the wearable devices as, in the present study, technical issues meant the global web-based feedback could not be fully self-monitored without the trainer needing to re-calibrate the personal targets and user profile used within the real-time display. This lack of autonomy over the web-platform use may contribute to the more favourable evaluation of the real-time feedback element. Accordingly, we cannot determine the respective contribution of the real-time, web-based, or indeed the trainer on individual participants behaviour change, nor whether favourable perceptions of the real-time element would have been the same without the more comprehensive web-based feedback. Recent meta-analyses of self-determination theory-based techniques support the notion that different self-regulatory and trainer-delivered strategies may be useful for optimising an individual's motivation for physical activity [66, 67]. It is unlikely, therefore, that any single component will be effective in isolation and that multicomponent interventions are required to provide optimal behavioural support. Nonetheless, future trials using more adaptable, multiple-group, designs such as the multiphase optimization strategy would be advised to augment the complex intervention and evaluate the relative and complimentary importance of the different elements [68].

Conclusions

In conclusion, this exploratory RCT represents the first attempt at combining multidimensional feedback with real-time data and light touch trainer support across several important health harnessing dimensions of physical activity as a means to help individuals change their behaviour. Results suggest that this approach may be a useful strategy to help individuals with low levels of physical activity change their behaviour. These findings can inform the design of future studies with larger and more diverse sample sizes, detailed process evaluation and longer follow-up periods to explore the effectiveness of real-time, multidimensional feedback.

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Conflicts of Interest

None declared.

References

1. Kyu, H.H., et al., *Physical activity and risk of breast cancer, colon cancer, diabetes, ischemic heart disease, and ischemic stroke events: systematic review and dose-response meta-analysis for the Global Burden of Disease Study 2013.* BMJ, 2016. **354**: p. i3857.
2. Lear, S.A., et al., *The effect of physical activity on mortality and cardiovascular disease in 130 000 people from 17 high-income, middle-income, and low-income countries: the PURE*

study. The Lancet, 2017. **390**(10113): p. 2643-2654.
3. Teychenne, M., K. Ball, and J. Salmon, *Physical activity and likelihood of depression in adults: A review.* Preventive Medicine, 2008. **46**(5): p. 397-411.
4. Owen, N., et al., *Sedentary Behavior and Public Health: Integrating the Evidence and Identifying Potential Solutions.* Annu Rev Public Health, 2020.
5. Tremblay, M.S., et al., *Physiological and health implications of a sedentary lifestyle.* Appl Physiol Nutr Metab, 2010. **35**(6): p. 725-40.
6. Chomistek, A.K., et al., *Relationship of sedentary behavior and physical activity to incident cardiovascular disease: results from the Women's Health Initiative.* J Am Coll Cardiol, 2013. **61**(23): p. 2346-54.
7. Ding, D., et al., *The economic burden of physical inactivity: a global analysis of major non-communicable diseases.* Lancet, 2016. **388**(10051): p. 1311-24.
8. Chiauzzi, E., C. Rodarte, and P. DasMahapatra, *Patient-centered activity monitoring in the self-management of chronic health conditions.* BMC Med, 2015. **13**(1): p. 77.
9. Piwek, L., et al., *The Rise of Consumer Health Wearables: Promises and Barriers.* PLoS Med, 2016. **13**(2): p. e1001953.
10. Patel, M.S., D.A. Asch, and K.G. Volpp, *Wearable devices as facilitators, not drivers, of health behavior change.* JAMA, 2015. **313**(5): p. 459-460.
11. Standage, M., T. Curran, and P. Rouse, *Self-determination-based theories of sport, exercise, and physical activity motivation.*, in *Advances in Sport and Exercise Psychology (4th Edition)*, T.S. Horn and A.L. Smith, Editors. 2019, Human Kinetics: Champaign, IL. p. 289-311.
12. Gabriel, K.K.P., J.R. Morrow, and A.L.T. Woolsey, *Framework for Physical Activity as a Complex and Multidimensional Behavior.* Journal of Physical Activity & Health, 2012. **9**: p. S11-S18.
13. Thompson, D. and A.M. Batterham, *Towards integrated physical activity profiling.* PLoS One, 2013. **8**(2): p. e56427.
14. Thompson, D., et al., *Confusion and conflict in assessing the physical activity status of middle-aged men.* PLoS One, 2009. **4**(2): p. e4337.
15. Scheers, T., R. Philippaerts, and J. Lefevre, *Compliance with different physical activity recommendations and its association with socio-demographic characteristics using an objective measure.* Bmc Public Health, 2013. **13**.
16. Thompson, D., et al., *Multidimensional Physical Activity: An Opportunity, Not a Problem.* Exercise and Sport Sciences Reviews, 2015. **43**(2): p. 67-74.
17. Western, M.J., et al., *The understanding and interpretation of innovative technology-enabled multidimensional physical activity feedback in patients at risk of future chronic disease.* PLoS One, 2015. **10**(5): p. e0126156.
18. Peacock, O.J., et al., *Multidimensional individualised Physical ACTivity (Mi-PACT) - a technology-enabled intervention to promote physical activity in primary care: study protocol for a randomised controlled trial.* Trials, 2015. **16**.
19. Peacock, O.J., et al., *Effect of novel technology-enabled multidimensional physical activity feedback in primary care patients at risk of chronic disease – the MIPACT study: a randomised controlled trial.* International Journal of Behavioral Nutrition and Physical Activity, 2020. **17**(1): p. 99.
20. Western, M.J., et al., *The impact of multidimensional physical activity feedback on healthcare practitioners and patients.* BJGP Open, 2019. **3**(1): p. bjgpopen18X101628.
21. Godino, J.G., et al., *Impact of personalised feedback about physical activity on change in objectively measured physical activity (the FAB study): a randomised controlled trial.* PLoS One, 2013. **8**(9): p. e75398.

22. Rhodes, R.E. and C.A. Yao, *Models accounting for intention-behavior discordance in the physical activity domain: a user's guide, content overview, and review of current evidence.* Int J Behav Nutr Phys Act, 2015. **12**: p. 9.
23. French, D.P., et al., *Can Communicating Personalised Disease Risk Promote Healthy Behaviour Change? A Systematic Review of Systematic Reviews.* Annals of Behavioral Medicine, 2017. **51**(5): p. 718-729.
24. Harris, T., et al., *Effect of a Primary Care Walking Intervention with and without Nurse Support on Physical Activity Levels in 45- to 75-Year-Olds: The Pedometer And Consultation Evaluation (PACE-UP) Cluster Randomised Clinical Trial.* PLOS Medicine, 2017. **14**(1): p. e1002210.
25. Harris, T., et al., *A primary care nurse-delivered walking intervention in older adults: PACE (pedometer accelerometer consultation evaluation)-Lift cluster randomised controlled trial.* PLoS Med, 2015. **12**(2): p. e1001783.
26. Bravata, D.M., et al., *Using pedometers to increase physical activity and improve health: a systematic review.* Jama, 2007. **298**(19): p. 2296-304.
27. Vandelanotte, C., et al., *The Effectiveness of a Web-Based Computer-Tailored Physical Activity Intervention Using Fitbit Activity Trackers: Randomized Trial.* J Med Internet Res, 2018. **20**(12): p. e11321.
28. Standage, M. and R.M. Ryan, *Self-determination theory in sport and exercise.* Handbook of sport psychology (4th ed., pp. 352-378). Hoboken, NJ: Wiley, 2019.
29. Ryan, R.M. and E.L. Deci, *Self-determination theory and the facilitation of intrinsic motivation, social development, and well-being.* Am Psychol, 2000. **55**(1): p. 68-78.
30. Teixeira, P.J., et al., *Exercise, physical activity, and self-determination theory: a systematic review.* Int J Behav Nutr Phys Act, 2012. **9**: p. 78.
31. Standage, M., S.J. Sebire, and T. Loney, *Does exercise motivation predict engagement in objectively assessed bouts of moderate-intensity exercise?: A self-determination theory perspective.* Journal of Sport and exercise Psychology, 2008. **30**(4): p. 337-352.
32. FAO/WHO/UNU, *Human Energy Requirements: Report of a Joint FAO/WHO/UNU Expert Consultation: Rome, 17-24 October 2001*. Vol. 1. 2004: Food & Agriculture Org.
33. Ainsworth, B.E., et al., *2011 Compendium of Physical Activities: a second update of codes and MET values.* Medicine & science in sports & exercise, 2011. **43**(8): p. 1575-1581.
34. Teixeira, P.J., et al., *A Classification of Motivation and Behavior Change Techniques Used in Self-Determination Theory-Based Interventions in Health Contexts.* Motivation Science, 2020.
35. Ministry of Housing Communities & Local Government. *English indices of deprivation 2015*. 2015; Available from: https://imd-by-postcode.opendatacommunities.org/imd/2015.
36. Smith, T., et al., *The English indices of deprivation 2015.* London: Department for Communities and Local Government, 2015.
37. Lee, J.M., Y. Kim, and G.J. Welk, *Validity of consumer-based physical activity monitors.* Med Sci Sports Exerc, 2014. **46**(9): p. 1840-8.
38. Johannsen, D.L., et al., *Accuracy of armband monitors for measuring daily energy expenditure in healthy adults.* Med Sci Sports Exerc, 2010. **42**(11): p. 2134-40.
39. Schofield, W.N., *Predicting basal metabolic rate, new standards and review of previous work.* Hum Nutr Clin Nutr, 1985. **39 Suppl 1**: p. 5-41.
40. Haskell, W.L., et al., *Physical activity and public health: updated recommendation for adults from the American College of Sports Medicine and the American Heart Association.* Circulation, 2007. **116**(9): p. 1081.
41. Rabin, R. and F.d. Charro, *EQ-SD: a measure of health status from the EuroQol Group.*

Annals of medicine, 2001. **33**(5): p. 337-343.
42. Ware, J.E., Jr. and C.D. Sherbourne, *The MOS 36-ltem Short-Form Health Survey (SF-36): I. Conceptual Framework and Item Selection.* Medical Care, 1992. **30**(6).
43. Ware, J., M. Kosinski, and S. Keller, *SF-36 physical and mental health summary scales.* A user's manual, 2001: p. 1994.
44. Philip, M.W., et al., *The Psychological Need Satisfaction in Exercise Scale.* Journal of Sport and Exercise Psychology, 2006. **28**(3): p. 231-251.
45. Markland, D. and V. Tobin, *A modification to the behavioural regulation in exercise questionnaire to include an assessment of amotivation.* Journal of Sport and Exercise Psychology, 2004. **26**(2): p. 191-196.
46. Williams, G.C., Z.R. Freedman, and E.L. Deci, *Supporting Autonomy to Motivate Patients With Diabetes for Glucose Control.* Diabetes Care, 1998. **21**(10): p. 1644-1651.
47. McAuley, E., *The role of efficacy cognitions in the prediction of exercise behavior in middle-aged adults.* J Behav Med, 1992. **15**(1): p. 65-88.
48. Verplanken, B. and S. Orbell, *Reflections on Past Behavior: A Self-Report Index of Habit Strength1.* Journal of Applied Social Psychology, 2003. **33**(6): p. 1313-1330.
49. Ryan, R.M. and C. Frederick, *On energy, personality, and health: Subjective vitality as a dynamic reflection of well-being.* Journal of personality, 1997. **65**(3): p. 529-565.
50. Laird, N., *Further comparative analyses of pretest-posttest research designs.* The American Statistician, 1983. **37**(4a): p. 329-330.
51. Scott, N.W., et al., *The method of minimization for allocation to clinical trials: a review.* Controlled clinical trials, 2002. **23**(6): p. 662-674.
52. Efron, B. and R.J. Tibshirani, *An introduction to the bootstrap*. 1994: CRC press.
53. Kelley, K., *The Effects of Nonnormal Distributions on Confidence Intervals Around the Standardized Mean Difference: Bootstrap and Parametric Confidence Intervals.* Educational and Psychological Measurement, 2005. **65**(1): p. 51-69.
54. Chen, L.-T. and C.-Y.J. Peng, *The sensitivity of three methods to nonnormality and unequal variances in interval estimation of effect sizes.* Behavior Research Methods, 2015. **47**(1): p. 107-126.
55. Cohen, J., *Statistical power analysis for the behavioral sciences*. 2013: Academic press.
56. Clarke, V. and V. Braun, *Thematic Analysis*, in *Encyclopedia of Critical Psychology*, T. Teo, Editor. 2014, Springer New York: New York, NY. p. 1947-1952.
57. Rhodes, R.E. and L. Dickau, *Moderators of the intention-behaviour relationship in the physical activity domain: a systematic review.* British Journal of Sports Medicine, 2012: p. bjsports-2011-090411.
58. Sniehotta, F.F., U. Scholz, and R. Schwarzer, *Bridging the intention-behaviour gap: Planning, self-efficacy, and action control in the adoption and maintenance of physical exercise.* Psychology & Health, 2005. **20**(2): p. 143-160.
59. Harris, T., et al., *Physical activity levels in adults and older adults 3-4 years after pedometer-based walking interventions: Long-term follow-up of participants from two randomised controlled trials in UK primary care.* PLoS Med, 2018. **15**(3): p. e1002526.
60. Wahlich, C., et al., *'You started something ... then I continued by myself': a qualitative study of physical activity maintenance.* Primary Health Care Research & Development, 2017. **18**(6): p. 574-590.
61. Normansell, R., et al., *Numbers are not the whole story: a qualitative exploration of barriers and facilitators to increased physical activity in a primary care based walking intervention.* BMC Public Health, 2014. **14**: p. 1272.
62. Lewis, Z.H., et al., *The utility of wearable fitness trackers and implications for increased engagement: An exploratory, mixed methods observational study.* Digital health, 2020. **6**:

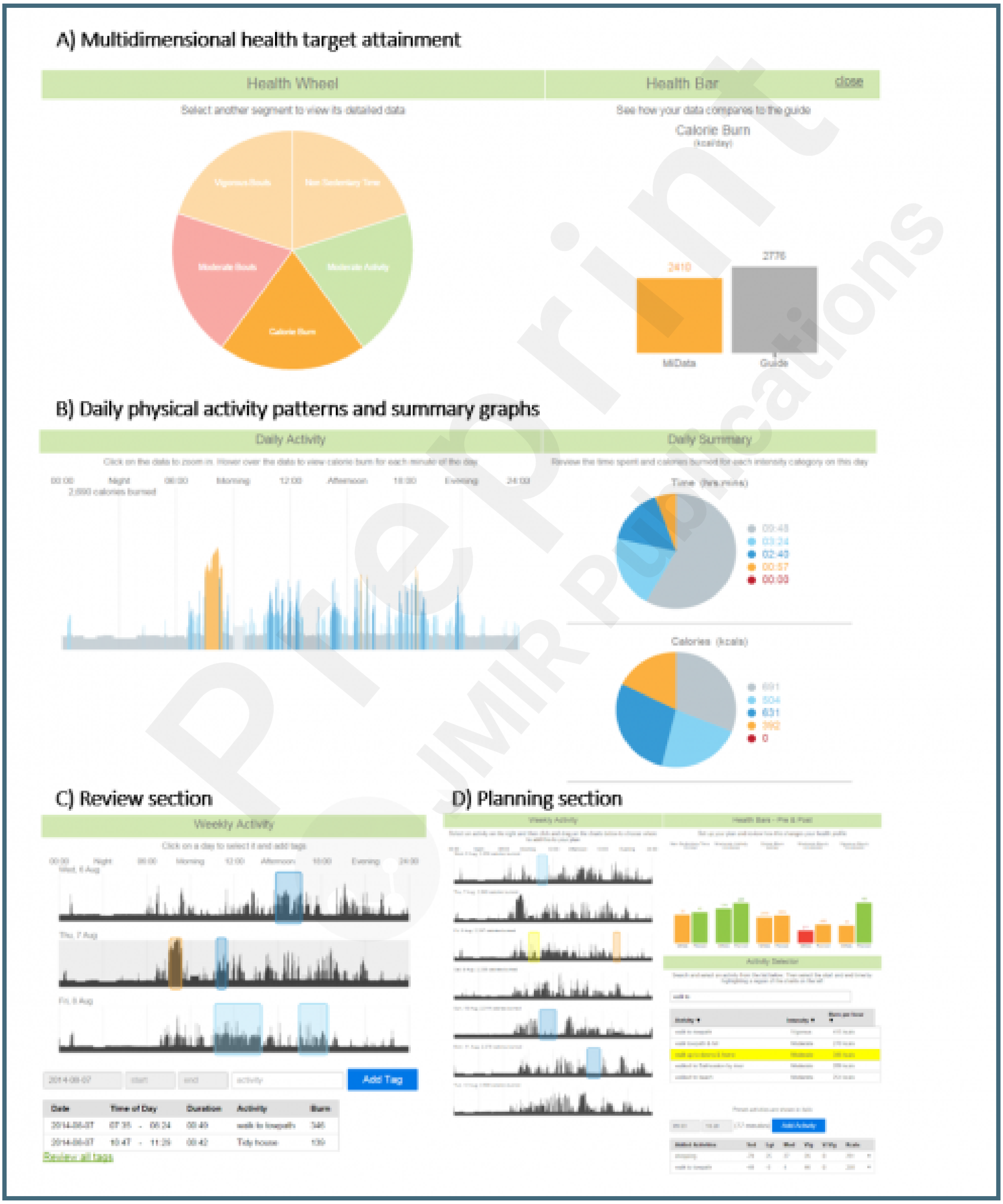
p. 2055207619900059.

63. Kononova, A., et al., *The Use of Wearable Activity Trackers Among Older Adults: Focus Group Study of Tracker Perceptions, Motivators, and Barriers in the Maintenance Stage of Behavior Change.* JMIR Mhealth Uhealth, 2019. **7**(4): p. e9832.
64. Peng, W., et al., *Habit Formation in Wearable Activity Tracker Use Among Older Adults: Qualitative Study.* JMIR Mhealth Uhealth, 2021. **9**(1): p. e22488.
65. Bergman, P., *The number of repeated observations needed to estimate the habitual physical activity of an individual to a given level of precision.* PLOS ONE, 2018. **13**(2): p. e0192117.
66. Gillison, F.B., et al., *A meta-analysis of techniques to promote motivation for health behaviour change from a self-determination theory perspective.* Health Psychology Review, 2019. **13**(1): p. 110-130.
67. Ntoumanis, N., et al., *A meta-analysis of self-determination theory-informed intervention studies in the health domain: effects on motivation, health behavior, physical, and psychological health.* Health Psychology Review, 2020(just-accepted): p. 1-85.
68. Collins, L.M., S.A. Murphy, and V. Strecher, *The multiphase optimization strategy (MOST) and the sequential multiple assignment randomized trial (SMART): new methods for more potent eHealth interventions.* American journal of preventive medicine, 2007. **32**(5 Suppl): p. S112-S118.

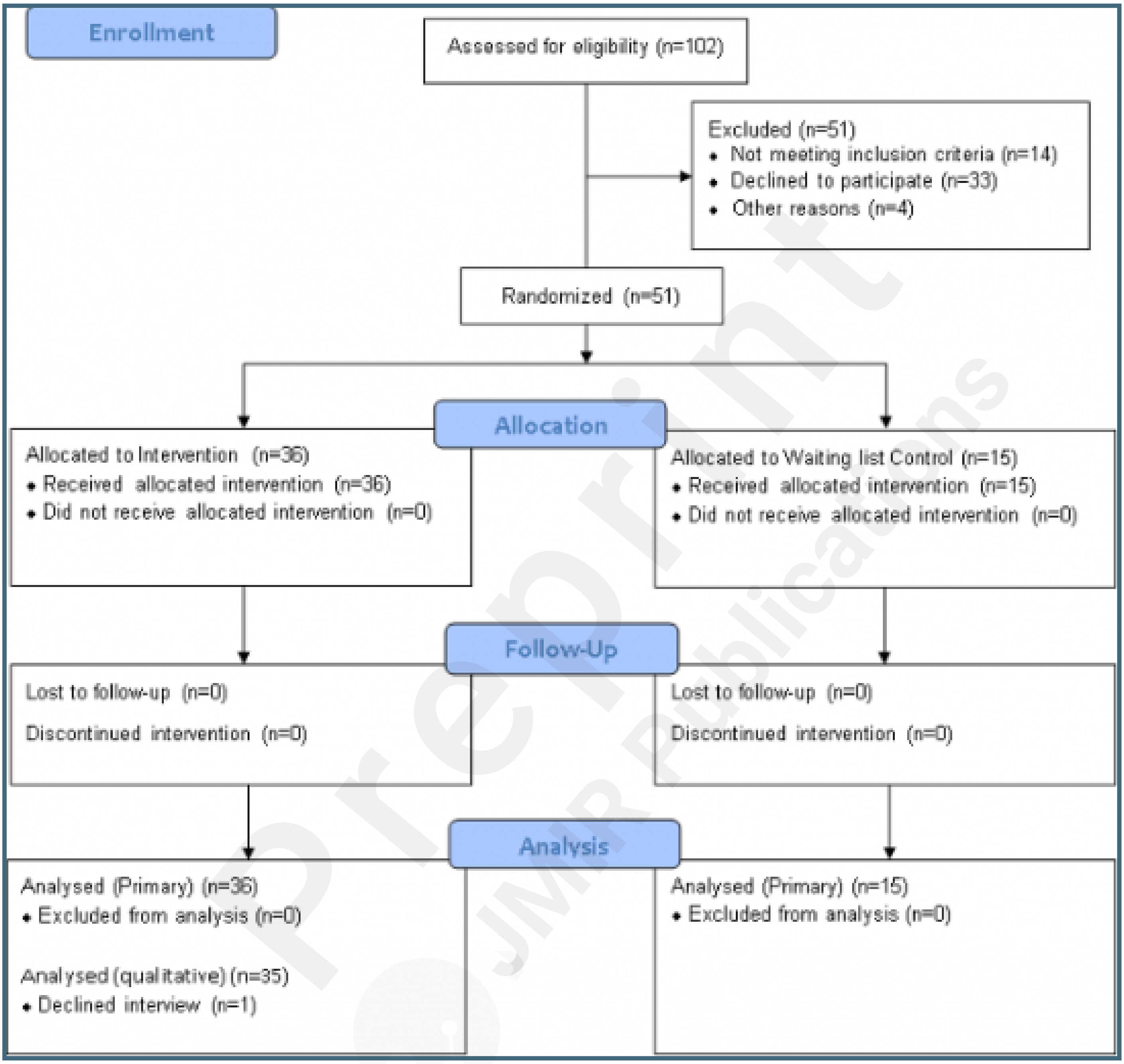
Supplementary Files

Figures

Features and examples of feedback and functions included on the MIPACT web-based platform. Participants were provided feedback using a traffic light coloured health target attainment schematic across the five dimensions (A) and detailed activity patterns and time use summaries coloured in accordance with the intensity of activity during each given minute (B). Participants were also able to review specific segments of a day to learn about the energy cost and intensity of particular activities (C) and provided with a planning section where they could see how the addition of new activities, derived from the Ainsworth compendium [33], would impact their health targets if imposed over their existing week (D).



Consolidated Standards of Reporting Trials flow diagram, demonstrating participants progress through the study.



Multimedia Appendixes

End of Study semi-structured interview topic guide and evaluation form.
URL: http://asset.jmir.pub/assets/61a46b8ffff91b4c651a5b1878bd5542.docx

Subgroup data for physical activity outcomes.
URL: http://asset.jmir.pub/assets/de045006a9589fb88c9af97e742c688b.docx