Evaluating an incentive-based mHealth application for physical activity promotion using the ORBIT Model (Study Protocol)

NCT05294692

October 25, 2024

METHODS

Study Design

This was a 12-week single-arm pilot study that examined an incentive-based mHealth PA intervention in the UK. This trial was registered at clinicaltrials.gov (NCT05294692) and local research ethics board approval was obtained (120615). The Strengthening the reporting of observational studies in epidemiology (STROBE) checklist was also used to standardize reporting.[43]

Procedures

The ORBIT model guided the development of the Caterpillar Health app (Caterpillar Health Inc., Leeds, UK), a multi-component healthy living app that includes FIs (points redeemable for consumer goods like movies or gym passes). This model provides a framework for developing behavioural treatments, from initial innovation to efficacy testing (Figure 1). The ORBIT model helped shape key questions at each development stage, informed our methodological choices, and established milestones for pre-efficacy development and testing. This pilot trial outlines the stages of development, including: (1) identifying a significant clinical question, (2) designing and refining the behavioral treatment using theory and targeted treatment goals, and (3) conducting a pilot trial to test for the preliminary efficiency and acceptability among UK residents. We conducted a literature review, applied relevant theories, and engaged stakeholders through qualitative methods such as customer discovery and user testing to ensure the app addresses user needs and overcomes issues of low uptake. Future development stages will involve expanding the app's capabilities with advanced tracking (e.g., activity and wellness logs) and goal-setting tools (e.g., virtual coaching), and incorporating social support elements (e.g., group challenges) to enhance user engagement. Additionally, we will conduct a fully

powered randomized controlled trials (RCT) to test the app's effectiveness and usability while exploring partnerships with additional reward partners to broaden the scope of available reward options that may meet the interests of potential users. Methods were chosen based on ORBIT model recommendations to develop an effective, pragmatic, and sustainable behaviour change solution.

ORBIT Model: Identification of a Significant Clinical Question

The first step in the ORBIT model is to identify and articulate a health need or clinical problem requiring a solution and generate a specific hypothesis. Literature review, analysis of epidemiological data, and surveys from target populations, and expert consensus were used to understand the clinical problem and articulate the app's hypothesized unique value proposition relative to alternative interventions. The goals of explicitly identifying the clinical problem are to (1) include primary behavioural or clinical endpoints in Phase II Preliminary Testing, (2) prepare the Phase III Efficacy trial to test the benefit of the treatment on a clinically meaningful outcome, and (3) commit to achieving a sufficient, meaningful change.

ORBIT Phase I: Design

The goal of Phase I was to design the essential features of a behavioural treatment. Phase I is divided into two phases: Ia (Define) defines the scientific foundation and basic elements of the behavioral treatment and milestones for judging success, and Ib (Refine) refines the treatment to optimize efficiency and feasibility while promoting the intended clinical change. Following the identification of the clinical gaps we gathered feedback from various stakeholders (i.e., app developers, public health agencies) to make iterative adjustments, such as simplifying the user interface and integrating relevant content primarily covering healthy eating and PA guidelines in line with the National Health Service (NHS) "Live Well" guidelines. This process ensured that

the final intervention was both user-friendly and effective before advancing to more rigorous testing.

ORBIT Phase II: Preliminary Testing

The goal of Phase II is to conduct preliminary testing of the behavioural treatment. Phase II is divided into two stages: IIa (Proof of Concept) and IIb (Pilot). In Phase IIa, the core components of the intervention will be tested to confirm that they produced the desired behavioural changes under controlled conditions. This stage is meant to provide initial evidence of the intervention's effectiveness and validate its fundamental design. In Phase IIb, a pilot study is being conducted to evaluate the feasibility, acceptability, and preliminary effectiveness of the intervention in real-world settings. The pilot involves a diverse participant group and tests the intervention's scalability, identifying any practical issues that could arise during implementation. Feedback from the pilot study may lead to further refinements, ensuring the intervention is well-prepared for subsequent efficacy testing.

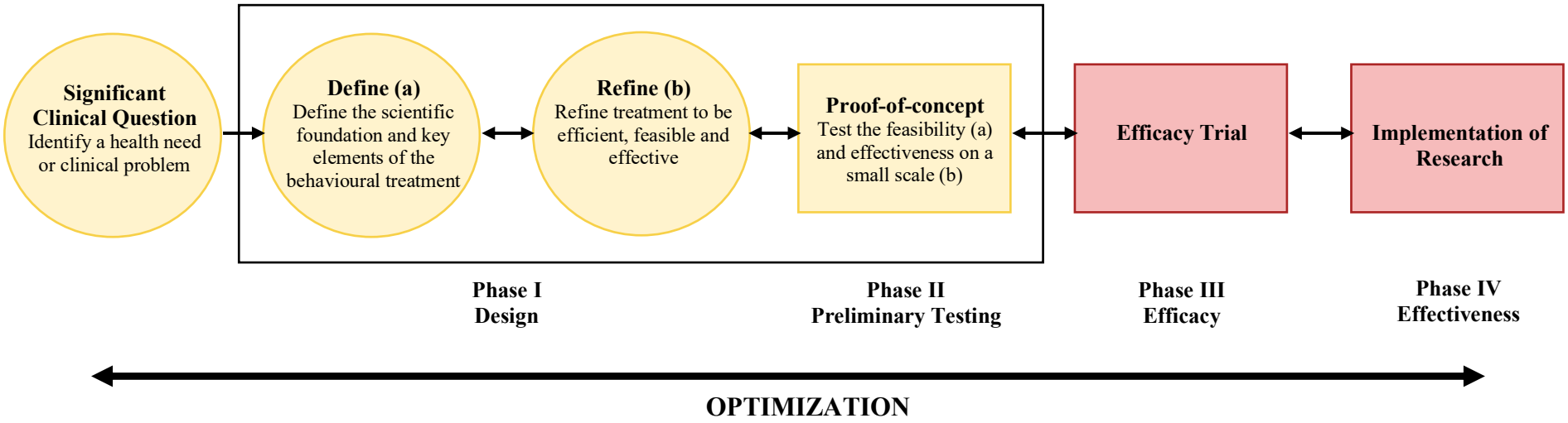

Figure 1. Application of the ORBIT Model for Caterpillar Health Development. Yellow boxes indicate completed research; red boxes are future research. Figure adapted from Czajkowski et al.

Theoretical Underpinning

In the development of the Caterpillar Health app, the research team utilized the COM-B model[46] as the theoretical foundation of the app to identify and address potential barriers and enablers to encourage users to increase daily step counts and enhance overall engagement. In implementing the COM-B (Capability, Opportunity, Motivation- Behaviour) model, the research team identified potential influencing factors (i.e., lack of motivation, time constrains) and facilitators (i.e., social support, user-friendly interfaces) to determine how the apps features could be designed to best elicit behaviour change. The app's functions were designed to enhance perceived capabilities (i.e., health information content, 'Education'), opportunities (i.e., integration with Wearable Devices, 'Enablement') and boosting motivation (i.e., incentives, 'Persuasion'). Behaviour change techniques[46] guided the selection of specific strategies, implementing additional techniques such as real-time feedback (i.e., prompts) and personalized goal-setting (i.e., individualized daily step targets), which further informed the design of app features.

Intervention Overview

Caterpillar Health was made available to Leeds, UK residents on the Apple iTunes/App Store and Google Play app stores on August 8, 2022 (Figure 2). The app was later made available to all of the UK as of October 3, 2022. To offer a variety of popular incentives, Caterpillar Health Inc. formed partnerships with two major UK based companies, Vue Cinema and Hussle (a gym network system), allowing users to redeem points for free movie and gym passes. Additionally, the company collaborated with a UK health agency (Active Leeds via Leeds City Council) to assist in the development and approval of educational health quiz content. To aid in the launch of the app in Leeds, the company leveraged the marketing assets of their

loyalty partners by utilizing email campaigns sent to Leeds City Council and KPMG employees as well as Hussle gym members living in Leeds, UK. The app was made available for download through two methods: organically (i.e., discovering and installing the app without paid advertising) or through above mentioned partner email invitations. Following initial partnership outreach, paid advertising campaigns on social media (Facebook, Instagram, Twitter) began on August 1, 2022. A public relations campaign began on August 9, 2022.

Prior to download, users were required to have an app compatible smartphone (i.e., iPhone 5S model or higher; Android version must support step counting i.e., include a 'built-in' accelerometer) and have the Health Kit or Google Fit application (or equivalent) downloaded. According to UK law, individuals under the age of 13 are not eligible to participate in loyalty rewards programs and were therefore excluded from this study.[44] To complete app registration, participants were asked to enter their birth year, gender, and postal code. After registration, users were instructed to (a) enable step count tracking and (b) 'carry their phone' as much as possible over a five-day baseline period. Users first personalized daily step goal was calculated using the median step count of the five-day baseline. A goal was given once five days of step data were collected; if the median was <2500 steps per day, the first goal was 2500 steps. A goal was given once five days of step data were collected; if the median was <2500 steps per day, the first goal was 2500 steps. Afterwards, step count goals were reassessed weekly and new step goals (past 30-day median) were introduced to the user on Sunday night.[45] There was no increase in addition to the median (e.g., +500 steps/day) to promote goal consistency and reduce the number of days with step counts lower than the 30-day median.

After the baseline period, participants earned FIs in the form of 'points' ($0.10 USD per day) for reaching personalized daily step goals. Since people tend to overvalue points

("numerosity" concept),[32] this is valuable to make smaller FIs more effective. Points could be redeemed for movie tickets and gym passes. Users could opt-in and participate in a weekly step goal challenge (i.e., complete 5/7 daily goals) for points ($0.25 USD). For the first 12 weeks, users could complete ~2-4 health knowledge questionnaires or surveys per week, for points (~$0.25 USD per quiz); this served as an educational feature. After Week 12, health knowledge questionnaire frequency drops to once a week. Users could earn a maximum of $23.65 within the 12 weeks. The health knowledge questionnaires primarily covered healthy eating and meeting PA guidelines (in line with the National Health Service (NHS), "Live Well" guidelines).

Measures

Two main groups are reported on: (a) 'users' and (b) 'participants' and are distinguished for data collection/analysis purposes. Users are those who created an account on the *Caterpillar Health* app and agreed to the analysis of aggregate app data (via Caterpillar Health app's Terms and Conditions). Participants are users that have also (a) agreed to an in-app consent survey to participate in a more detailed study, including individualized data collection (i.e., demographics, health characteristics, and step counts), (b) 'enabled step tracking' and (c) consistently recorded at least 1000 steps per day for a minimum of three days at baseline.

Physical activity. Physical activity was measured objectively using built-in smartphone and wearable fitness tracker accelerometers integrated with Apple Health and/or Google Fit with enabled step tracking. Participants were instructed to carry their smartphones and wear their fitness trackers as much as possible throughout the day during to allow for precise and reliable analysis of participants' daily step patterns at baseline and during intervention. To further enhance the reliability of collected step data, only days with step counts between 1,000 and 40,000 were considered 'valid days'.

Uptake. App uptake (i.e., number of downloads and app store visits) was measured using Google Analytics and Firebase tools. The representativeness of the sample population of study participants (users consenting to sharing of individual user data) was collected through an in-app demographic survey. Process of delivery (i.e., number of email campaigns, emails sent, paid social media advertisements, posts via the app's social media accounts), changes to intervention (i.e., size of incentives offered), and app partnerships (i.e., Leeds City Council, Hussle Gym, Vue Cinemas) were reported narratively.

Engagement. Engagement was measured using Google Analytics and Firebase tools from September 12th, 2022, to December 12th, 2022, providing objective insight into the actual use of the app after installing. Data included the number of unique users and frequency of use, number of page visits within the app, usage time per app visit, as well as new and recurrent use of the app. Individual data on app usage was collected from participants data, which examined the app's educational quizzes and surveys according to what was made available to the users and participants over a five-week period.

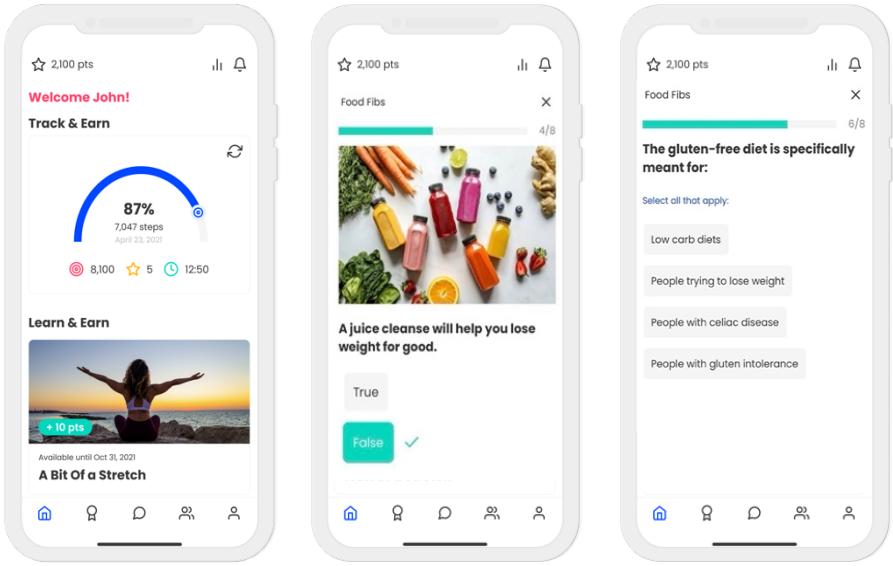

Figure 2. Caterpillar Health user interface

Outcomes

The primary outcomes were change in PA (i.e., mean daily steps and step goal achievement) from baseline to the end of the intervention period, five weeks after baseline. We also report the change in PA by engagement and PA subgroups (n=14) (i.e., high engagement defined as completing more than 50% of health quizzes; low PA defined as taking fewer than 5,000 daily steps at baseline).

The secondary outcomes were app uptake at baseline and changes in app engagement from baseline to 12 weeks. App uptake included demographics data (i.e., household income, chronic disease status, use of wearable fitness trackers). Engagement outcomes were changes in number of page visits within the app, usage time per app visit, new and recurrent use of the app, and individual quiz and survey completion data.

Statistical Analysis

Statistical analysis was performed using SPSS (version 28.0.1.0). Descriptive statistics were also used to report on primary and secondary outcomes. To assess preliminary efficacy of the app, paired-samples t-tests were used to examine change in weekly mean daily step count from the five-day baseline (vs. Study Week 5) for the total sample (n=47) as well as by engagement and PA subgroups (n=14). Time was coded as a categorical variable (baseline = 0, week 1 = 1, …, week 5 = 5) to allow for the non-linear trajectory of the primary outcome (i.e., daily step count). A mixed-effects model was used to examine change in daily step counts across weeks. Missing data was assessed for randomness prior to data analysis. As results from previous work at *Carrot Rewards*, 12-week analyses indicated that engagement and PA status had significant moderating effects on changes in weekly mean daily step counts over time. Therefore, we fit the results separately for physically active and physically inactive participants and

separately for engagement groups. As this is a preliminary analysis, no sample size was calculated; however, results will be used to inform future, larger studies sample size calculations. Cohen's f^2 for local effect sizes of weekly mean daily step counts within the mixed-effects models were calculated, with $f^2 \geq 0.02$, $f^2 \geq 0.15$, and $f^2 \geq 0.35$ representing small, medium, and large effect sizes, respectively. Statistical significance levels were set at $P < 0.05$.