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Evaluating a financial incentives scheme intervention to promote healthy eating and physical activity

Submission date 10/02/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 16/02/2023	**Overall study status** Completed	
Last Edited 15/10/2024	**Condition category** Other	

Plain English Summary

Background and study aims

Healthy eating and physical activity are important for health. For example, walking, exercising, and eating fruit and vegetables regularly can all contribute to good health.

Getting rewards for healthy behaviours can help people to be healthier. For example, using rewards to help people stop smoking is known to be effective. Evidence has shown that rewards can help incentivise people to improve their physical activity and diets, although evidence is mixed on optimum value of incentive and exact details of incentive scheme design. This research will build on that evidence and show how a scheme can work in a local area.

The Behavioural Insights Team (BIT) will design and conduct an independent evaluation of an app-based financial incentive scheme to test if rewards can help people eat more healthily and be more active.

Who can participate?

All adults (18 years and above) living in Wolverhampton, UK are eligible to participate.

What does the study involve?

Participants will get free access to the Better Health: Rewards app. They will also get a free fitness tracker, if they do not already own one.

At the start, we will ask them to complete a 'baseline period' for up to 2 weeks. During this time, they can learn to use the app and fitness tracker. We will also ask them to answer questions about your diet and physical activity.

After the baseline period, they will be randomly assigned to 1 of 4 groups:

- Control group: Access to the app and the fitness tracker.
- Intervention groups: Access to the app and the fitness tracker. Individuals in these groups can also earn financial rewards. There are 3 different values:

B.1 low value rewards

B.2 medium value rewards

B.3 high value rewards

The study will last between 5 and 6 months once they have been signed up and allocated to a group. We ask that they continue using the app and wearing and syncing their fitness tracker during this time. We also ask that they answer surveys in the app during this time. They can stop being a part of the study at any time without providing a reason.

During or after the study, we may contact them about this research. Participation in any additional research is voluntary and they can decline to take part at any time without giving a reason.

What are the possible benefits and risks of participating?
All participants will get a free fitness tracker if they do not already own one. Everyone will also have free access to the Better Health: Rewards healthy lifestyle app which provides personalised physical activity and nutrition challenges and content to help with your everyday health. All participants can also earn up to £40 by answering diet questionnaires throughout the programme. Participants can use their points in a safe and secure online store to redeem a wide range of products and gift cards.

The results of this research may help to improve the services and care given to all UK residents.

This app may not be suitable for people who have or have previously had an eating disorder, or any other health concern which might stop them from changing your diet or physical activity. If they are not sure whether the app is for them, they should consult your GP or health professional before starting this programme.

We do not expect any side-effects from taking part in the study. If during the study they have any physical or mental health symptoms, they shouldspeak with a healthcare professional. They may stop using the app and participating in the trial at any point if their health status changes.

The information contained in this app is intended for education purposes only and is not intended to replace and is not professional, medical , or healthcare advice, diagnosis or treatment and should not be used for such purposes. It should not be used to prevent, detect, track, manage or to treat any medical condition, disease or injury. Better Health does not provide individual dietary advice. Better Health does not provide clinical care or clinical decision-making.

Where is the study run from?
The Behavioural Insights Team (UK)

When is the study starting and how long is it expected to run for?
February 2023 to October 2023

Who is funding the study?
HeadUp Systems Ltd are conducting this study on behalf of the Department of Health and Social Care (UK). The Department of Health and Social Care is paying for the financial rewards, the fitness tracker, the research, and all other costs.

Who is the main contact?
HeadUp Systems Ltd: betterhealthrewards@customersupport.team
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Evaluating a financial incentives scheme intervention to promote healthy eating and physical activity among adults in Wolverhamption: a randomised control trial

Study hypothesis
An app-based financial incentive scheme to provide rewards to people contingent on performing behaviours related to healthy diets and physical activity can significantly increase physical activity (PA) levels (defined as in an increase in moderate-vigorous physical activity (MVPA) minutes/day and steps/day) and improve the healthfulness of recipients' dietary intake (defined through four primary outcomes for diet: fruit and vegetables in grams/day, fibre in grams/day, sugar in % of food energy/day and saturated fat in % of food energy/day)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/01/2023, UK Health Security Agency Research Ethics and Governance Group (Nobel House, 17 Smith Square, London, SW1P 3JR; +441980 612922; RanD.OFFICE@ukhsa.gov.uk), ref: R&D 507

Study design
Interventional unmasked clustered randomized controlled trial

Primary study design
Interventional

Secondary study design

Randomised controlled trial

Study setting(s)
Community, Home

Study type(s)
Prevention

Participant information sheet
See study outputs table

Condition
Improving physical activity and diet healthfulness among general adult population

Interventions
All participants will receive access to the HeadUp app and a wearable tracker if they do not already own one. Participants will complete a baseline period during which they will familiarise themselves with the app and wearable and provide baseline data, after which they will be randomised to one of four conditions:
A. Control group: Access to the HeadUp app and the wearable tracker
B. Intervention groups: On top of the HeadUp app and the wearable tracker participants will receive a financial incentive intervention for the entire duration of the trial with:
- B.1 low value incentives, i.e. low £ per point ratio
- B.2 medium value incentives, i.e. medium £ per point ratio
- B.3 high value incentives, i.e. high £ per point ratio
Participants will be randomised at household level.

Regardless of intervention arm, each participant (including those in the control group) will receive a reward upon completion of requested data at baseline, and at the 1-, 3-, and 5-month data collection times respectively.

Explanation blinding: Participants will be aware they are participating in a randomised controlled study, as they will be asked to provide consent. However, we expect that users will not be able to figure out to which treatment arm they are assigned to (low, medium or high level of incentive) based on the information available on the app and their user journey, whilst it is likely that users in the control group will be able to correctly identify that they have been assigned to the control trial arm (no incentive). While is not possible to deliver a fully blind design for trial analysts given the differences that will be identifiable in the data at the point of analysis, datasets for each arm will be labelled neutrally (e.g. A, B, C and D instead of treatment, control).

Randomisation will be done using a computer programme. The code for this is written by HeadUp Labs' lead developer using C# and will be quality assured by BIT's in-house IT expert before launch.
Randomisation will be conducted at the household level. Users will enter randomisation only if /when they have completed the baseline phase. This implies that the day of randomisation is different across users even within the same households: it always happens at the end of their baseline phase (if successful), but the exact calendar day depends on when they have downloaded the app, when they have completed the onboarding, and how long it took them to complete the baseline phase.
The randomisation algorithm developed by HUL will then:
1. Check if another user from the same household has already been randomised based on their

full addresses (including postcode).
2. If YES, the algorithm assigns this user to the same trial arm
3. If NO, the algorithm generates a random number from 1-100 (inclusive) for the user.
4. Based on this random number users are assigned to one of the 4 trial arms: 1-61 into control, 62-76 into low incentive group, 77-88 into medium-incentive group and 89-100 into high-incentive group. Note that the control arm will be larger than the other arms. This is because at the analysis stage (5m mark), we aim at having 3 users in the control group for each user in the treatment arms. Based on our attrition estimates, at randomisation 12% of users will be assigned to the high incentive arm, 12% to the medium incentive arm, 15% to the low incentive arm, 61% to the control arm.

Intervention Type
Behavioural

Primary outcome measure
Activity outcomes:
1. Moderate and vigorous physical activity (MVPA) in minutes per day
2. Daily steps
Both measured objectively through a wearable device over a week period at baseline and week 21 (and week 19 - 23 to impute any missing data in week 21).

Dietary outcomes, daily intake of:
1. Fruit and vegetables (g/day)
2. Fibre (g/day)
3. Saturated fat (% of food energy intake)
4. Free sugars (% of food energy intake)
All measured through 24 hour dietary recalls at baseline and week 21-22.

Secondary outcome measures
1. Daily energy expenditure as measured by the wearable during week 21
2. Daily energy intake as measured by 24 hour dietary recalls (Intake24 surveys)
3. A healthy eating score based on consumption of key food groups, macro- and micronutrients
4. Self-reported weight

Overall study start date
17/02/2023

Overall study end date
17/10/2023

Eligibility

Participant inclusion criteria
1. Geographic criteria (resident in Wolverhampton)
2. Age criteria (18 years and over)

Participant type(s)
All

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
25,800

Total final enrolment
28665

Participant exclusion criteria
The app used for the trial may not be suitable for people who have had eating disorders or who have physical or mental health problems which would affect their ability to change their diet and physical activity behaviours. Prior to providing consent, prospective participants are provided with a link to further information to help support their decision about eligibility, as well as information about steps they can take if their physical or mental health changes while using the app. Prospective users are also advised to check with their health professional before starting the trial if they have any concerns about changing their diet or physical activity, or whether the app is suitable for them. Furthermore, prospective users are advised that they can stop using the app and stop participating in the trial at any point if their health status changes.

Recruitment start date
17/02/2023

Recruitment end date
03/04/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Online study
Wolverhampton
United Kingdom
-

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Funder(s)

Funder type
Government

Funder Name
Department of Health and Social Care

Alternative Name(s)
Department of Health & Social Care, DH

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Subject to DHSC’s approval, it is BIT's intention to publish the results from this study in an academic journal. Subject to DHSC’s approval, results of the trial might also be presented at conferences, public meetings, or through other platforms.

Intention to publish date
31/12/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available for data protection reasons. HUL and all sub-processors with whom identifiable data has been shared will destroy the data after 6 months. All data are stored in the UK / EEA and not transferred outside the EEA. DHSC is carrying out a data protection impact assessment with input from HUL and BIT to ensure that all data processing is minimised and has been appropriately protected. Data will be transferred securely to DHSC by HUL. The DHSC will process and store data in line with standard business as usual processes in the United Kingdom, in compliance with the Data Protection Act 2018 and the GDPR. DHSC will process and store pseudonymised data sets for the purposes of answering further policy questions in the areas of population health, health inequalities, and health behaviours. For example, this may include information such as participant demographics, health behaviours and reward redemption, however the data would not be identifiable. DHSC will destroy the data after 8 years.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		25/01/2023	17/02/2023	No	Yes
Protocol file	version 7	12/12/2022	17/02/2023	No	No
Protocol file	version 9	11/08/2023	03/01/2024	No	No