ISRCTN14925701 https://doi.org/10.1186/ISRCTN14925701

Evaluating the effectiveness of a digital health and financial incentive scheme intervention to promote physical activity in patients living with type 2 diabetes

Submission date
05/10/2023

Recruitment status
Suspended

Registration date
30/10/2023

Overall study status
Ongoing

Last Edited
09/01/2025

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Currently, 3.7 million people are living with type 2 diabetes in the UK and there are a further 12 million people at high risk of developing it. There is strong evidence that being active helps people to manage type 2 diabetes as well as being good for their overall health.

Current guidance states that adults should, over the week, complete at least 150 minutes of moderate to vigorous physical activity, however, few manage to achieve this target.

Given a large number of people with type 2 diabetes are inactive, new interventions are needed to help these people become more active. One potential solution is the use of wearable technology, health apps and financial incentives to encourage people to be more active.

We are proposing to test the effectiveness of one such scheme: the Exi App (a mobile phone-based app that encourages and supports people to achieve a personalised prescription of physical activity), a wearable device that monitors physical activity, and a set of financial incentives (vouchers).

We will use a randomised controlled trial to test its impact on clinical outcomes (e.g. HbA1c) and patient-reported outcomes (quality of life).

Who can participate?
We will aim to recruit people aged 18 years or older living with type 2 diabetes via primary care, during their annual diabetes review with their GP or diabetes nurse.

What does the study involve?
Participants will be randomised to receive standard advice about physical activity (national guidance) or provided with a wearable (apple watch), health app (EXi) and financial rewards on goal achievement.

The trial will run for 24 months and we will measure health outcomes and patient-reported outcomes at baseline, 12 months and 24 months. The usual care group will be a waitlist control group and will receive the intervention at 12 months.

What are the possible benefits and risks of participating?
Possible benefits.
We hope the study will help those living with type 2 diabetes to be more physically active and it may improve their health and diabetes.
Disadvantages and risks
We do not expect any risks or disadvantages from taking part in this study. Participants will need to give up some of their time to fill out the study documents and take part in the study. The intervention is aimed at encouraging those living with type 2 diabetes to be more active and to do this in a gradual way. However, sometimes there are risks when increasing physical activity too quickly, such as feeling tired or developing muscle or joint stiffness or pain; these symptoms are normally minor and should not last long.

Where is the study run from?
Milton Keynes Hospital NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
August 2023 to September 2026

Who is funding the study?
Apple (USA)

Who is the main contact?
Dr Joanne Turner, Joanne.Turner@mkuh.nhs.uk
Trial team, DiabetesTrial@mkuh.nhs.uk

Study website
https://www.mkuh.nhs.uk/news/activate-trial-notice-thursday-10-october-2024

Contact information

Type(s)
Public, Scientific

Contact name
Dr Trial team -

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
326885

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 57291, IRAS 326885

Study information

Scientific Title
ACTIVATE Study - Digital Incentive Scheme to optimise movement in T2DM

Acronym
ACTIVATE

Study objectives
To test the effectiveness and cost effectiveness of a digital health incentive scheme (physical activity behaviour change smartphone app paired with a physical activity tracker and financial incentives) designed to increase physical activity on HbA1c and quality of life amongst people living with type 2 diabetes in Milton Keynes (MK), UK

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 30/08/2023, West Midlands- Black Country REC (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8388; blackcountry.rec@hra.nhs.uk), ref: 23/WM/0167

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Quality of life

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied
Diabetes

Interventions
Randomisation
Once participants have provided informed consent, they will be randomised at the level of the individual in a 1:1 ratio to receive either the intervention or be in the usual care waitlist control arm. A variable block randomisation (block size of 6) algorithm will be used on the secure trial management system.

Intervention: After participants have been randomised to either the intervention or usual care group, they will attend their NHS annual diabetes review. HCPs may be reminded of the patient's involvement in the intervention in one of three ways. Participants may be asked to remind their HCP that they are taking part in the study at the start of their consultation either verbally or by presenting the HCP with a study prompt card at the beginning of the consultation.
Secondly, the administration team at the participating health service may add an electronic prompt to the participant's notes ahead of the consultation. Lastly, the research team may email the HCP to inform them of their patient's involvement. In some instances, one method may be preferred over the other or it may be that all three methods are used.

During the annual diabetes review, the GP or HCP will:
- Describe the importance of physical activity in the management of type 2 diabetes through NHS consultations with an NHS health professional.
- Discuss the EXi app and how it can help them to increase their physical activity.
The purpose of the EXi app and the Apple watch for facilitating self-monitoring and feedback on physical activity will be discussed and the use of the technology will be specifically encouraged.
- HCPs will be asked to highlight to participants that increases in physical activity may be helped if they develop habits or routines and 'what needs to change' to achieve this.

EXi Intervention
The EXi app is evidence-based and analyses patient health, fitness, and disease status to prescribe a personalised physical activity programme which is calibrated at the right frequency, intensity, and duration for each participant. As a participant progresses, the algorithm adapts to encourage each person in an effective, measurable, and safe manner in line with international physical activity guidelines.
The EXi app can specifically tailor the participant's physical activity programme according to several variables including age, gender, current physical activity levels, fitness and disease status. The EXi platform also consists of the EXi Rewards Programme (ERP). The ERP is built on the Vitality incentive scheme data and evidence, and is integrated with wearable technology to measure activity duration and intensity, so validating that the physical activity prescription has been achieved. The ERP has been designed for a population who are sedentary, at risk of developing a long-term condition or already have a diagnosis of a chronic disease such as type 2 diabetes. The ERP 'starts where you're at', creating an ability for everyone to achieve rewards, regardless of current fitness level. For example, participants' prescriptions can start with as little as 10 minutes of low-intensity activity three times per week and build up gradually over time. The EXi app is built for iOS. The app connects to wearable technology (Apple watch). The ERP is driven by the data captured from the wearable technology such as heart rate, steps, distance covered, and active minutes (including low, moderate, and vigorous

activity). Participants can also receive up to £350 in financial incentives for completing their goals.

Usual care: All those randomised to usual care waitlist control group will receive the current guidance for physical activity within their annual diabetes review and at 12 months will be provided with the intervention.

Intervention Type
Behavioural

Primary outcome measure
%HbA1c measured by blood test at 12 months post-randomisation

Secondary outcome measures
1. Quality of Life as measured by EQ-5D-5L at 12 months.
2. Composite endpoint of HbA1c reduction >0.5% + weight loss >3% and SBP reduction >3mmHg at 12 months measured during the participants NHS Annual Diabetes Check
3. Composite endpoint of HbA1c reduction >0.5% + weight loss >3% and SBP reduction >3mmHg measured during the participants NHS Annual Diabetes Check pre and post-intervention delivery in the waitlist usual care group.
4. Other blood biomarkers including blood lipid panel, blood glucose, and kidney function tests at 12 months.
5. Healthcare utilisation (visits to primary or secondary healthcare) measured using a modified version of the Client Services Receipt Inventory as well as linkage to NHS healthcare records via systmone at 12 months.
6. Diabetes medication used measured using a modified version of the Client Services Receipt Inventory as well as linkage to NHS healthcare records via systmone at 12 months.
7. Problem Areas in Diabetes Score / EQ-5D-5L scores at 12 months.
8. Changes in physical activity (Total physical activity, MVPA, Light physical activity, minutes sedentary) over the intervention period as measured by the Apple watch

Overall study start date
30/08/2023

Completion date
04/09/2026

Eligibility

Key inclusion criteria
1. Aged > = 18 years.
2. Diagnosis of type 2 diabetes (based on WHO criteria e.g., HbA1c > = 48 mmol/mol or 6.5%)
3. Time since their last HbA1c measure: less than three months
4. Able to provide informed consent.
5. Own and use a mobile phone capable of hosting the EXi app (i.e., Apple iOS 14.3 or above)
6. Agreement that the study team can notify their healthcare practitioner of their involvement in the study (if applicable).
7. Physically mobile/able to be physically active
8. MK resident and registered with an MK GP or the MK Integrated Diabetes Services

Participant type(s)

Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 1,018; UK Sample Size: 1,018

Key exclusion criteria
1. Unable to understand English sufficiently to complete the trial assessments.
2. Women known to be pregnant or breastfeeding
3. Do not own/ cannot operate a smartphone.
4. Life-limiting condition.
5. Chronic health conditions significantly affecting mobility.
6. Meeting physical activity guidelines of 150 minutes of moderate-to-vigorous physical activity as measured by the physical activity vital signs questionnaire.

Date of first enrolment
31/10/2023

Date of final enrolment
30/04/2025

Locations

Countries of recruitment
United Kingdom

Study participating centre
Milton Keynes University Hospital
Standing Way
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MK6 5LD

Sponsor information

Organisation

Milton Keynes Hospital NHS Foundation Trust

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Sponsor type
Hospital/treatment centre

Website
http://www.mkhospital.nhs.uk/

ROR
https://ror.org/03r1qk590

Funder(s)

Funder type
Industry

Funder Name
Apple

Alternative Name(s)
Apple Inc.

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Publication and dissemination plan

Dissemination of the results is intended to be in high impact peer reviewed scientific journals, internal reports, conference presentations, Publication on the website.

Intention to publish date
30/09/2027

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		12/11/2024	15/11/2024	Yes	No