ISRCTN14335124 https://doi.org/10.1186/ISRCTN14335124

Mobile health for type 2 diabetes

Submission date	Recruitment status	[X] Prospectively registered
19/10/2020	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/10/2020	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
21/06/2024	Nutritional, Metabolic, Endocrine	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Type 2 diabetes is a common condition that causes the level of sugar (glucose) in the blood to become too high. Being physically active and exercising is very important in the treatment of Type 2 diabetes (T2D), with it helping to control blood sugar and prevent complications. Nevertheless, lots of people with T2D find it hard to be physically active and/or stick to an exercise programme, even when doctors and diabetes nurses have told them to exercise as part of their treatment. Research is needed to identify more effective methods to help people with T2D increase their everyday physical activity levels, start exercising regularly and stick too the right amount of exercise to benefit their T2D management, particularly in the early stages after diagnosis.

In this project we want to see if mobile health technology (i.e. the use of smartphones, wearable technology and apps to support the delivery of interventions) when added into exercise advice makes it easier for people with T2D to begin and maintain a physically active lifestyle, which includes exercising regularly.

Who can participate?
People aged 40 - 75 years, who have been diagnosed with T2D in the last 5 - 24 months.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group work with an exercise specialist to co-design a 6-month structured exercise and physical activity programme. The programme is supported by 5 meetings with the exercise specialist and regular text messages encouraging exercise and physical activity. Those in the second group (mHealth) receive the same 6-month exercise and physical activity programme supported by an exercise specialist, but participants also receive a fitness watch linked to a mobile phone application (App). The fitness watch and mobile App allow the exercise specialist to provide greater support and feedback throughout the programme. Participants in both groups are sent a home testing kit to measure their own body composition, blood pressure, cholesterol and control of blood sugar before, after and 6-months following the exercise programme. The study lasts one year in total.

What are the possible benefits and risks of participating?
All participants co-design their own 6-month personalised exercise and physical activity

programme, supported by 5 meetings with an exercise specialist. Participants also complete three basic health assessments. To do these assessments participants are given, to keep, a tape measure, set of scales and a blood pressure monitor.
Participants in the mHealth group are given a wrist worn fitness watch, to keep, and access to a free online training application. The fitness monitor will act as a personal trainer on participants wrist providing live feedback on how to exercise. The training app will track participants exercise and enable the exercise specialist to follow progression and provide regular personalised feedback.
Participants will collect a finger prick blood sample at three time points. Some sensitivity may be felt where the sample is taken from, but this will be short lived (normally 24h). Participants will experience fatigue during exercise sessions.

Where is the study run from?
1. Liverpool John Moores University (UK)
2. University of British Columbia (Canada)

When is the study starting and how long is it expected to run for?
April 2020 to May 2023

Who is funding the study?
Medical Research Council (UK)

Who is the main contact?
(UK contact) Dr Matthew Cocks, m.s.cocks@ljmu.ac.uk
(Canada contact) Dr Ali McManus, AliMcManus@UBC.ca

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
283225

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 46893, IRAS 283225

Study information

Scientific Title
mHealth Biometrics for Type 2 Diabetes (MOTIVATE T2D)

Acronym
MOTIVATE T2D

Study objectives
The study aims to have an evidence-based exercise and PA intervention ready to evaluate in a future randomised controlled trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/10/2020, South East Scotland Research Ethics Committee 01 (Waverley Gate, 2-4 Waterloo Place, Edinburgh, EH1 3EG; 44+ (0)131 465 5473; Sandra.Wyllie@nhslothian.scot.nhs.uk), ref: 20/SS/0101

Study design
Pilot multicentre interventional unblinded randomized control trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Treatment

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Type 2 diabetes

Interventions
Participants will be randomised to an active control (exercise counselling) or intervention (exercise counselling and mobile health (mHealth)) groups. Patients will be randomised in a 1:1 ratio using an online randomisation service administered by the Centre for Health and Evaluation and Outcome Sciences (University of British Columbia, CA).

Participants in both groups will undertake a 6-month structured exercise and physical activity intervention.

Active control (exercise counselling): Participants will have 5 exercise consultations with an exercise specialist. Exercise consultations will be supported by behaviour change text messages (weekly for first 3-months and bi-weekly for second 3-months).

Intervention (exercise counselling and mHealth): Participants will have 5 exercise consultations with an exercise specialist. Exercise consultations will be supported by 3 mHealth elements; 1) a wrist worn fitness watch, featuring a 3d accelerometer and optical heart rate monitor, 2) a smartphone app for patients, and 3) a coaching website for the exercise specialist, and behaviour change text messages influenced by patients exercise adherence (following each exercise session for the first month, weekly from month 2-3 and bi-weekly for the final 3-months).

Intervention Type
Behavioural

Primary outcome measure
Feasibility outcomes:
1. The number of adults with newly diagnosed T2D that are eligible to participate

2. The proportion of these who would be willing to take part in this trial (i.e. recruitment rate), and their characteristics
3. The number of participants retained at 12-months (i.e. participant drop-out)

Secondary outcome measures

1. Estimate precision of potential outcome measures required for sample size estimations for the definitive RCT:
1.1. Adherence to structure exercise, measured using heart rate monitoring of all structured exercise sessions, measured throughout the 12-month study period
1.2. Self reported leisure-time exercise, measured using the Godin Leisure-Time Exercise Questionnaire (GLEEQ), measured monthly over 12-month study period
1.3. Device assessed physical activity, measured using a GENEActiv physical activity monitor for 14 days at baseline, post-intervention (6-months) and follow-up (12-months)
1.4. HbA1c, measured using a finger prick blood sample at baseline, post-intervention (6-months) and follow-up (12-months)
1.5. 14-day glycaemic control, measured using Flash Glucose Monitoring for 14-days at baseline, post-intervention (6-months) and follow-up (12-months)
1.6. Body composition, measured using BMI and waist circumference at baseline, post-intervention (6-months) and follow-up (12-months)
1.7. Blood pressure, measured using automated blood pressure monitor at baseline, post-intervention (6-months) and follow-up (12-months)
1.8. Blood Lipids (total cholesterol, HDL cholesterol, LDL cholesterol and triglycerides), measured using a finger prick blood sample at baseline, post-intervention (6-months) and follow-up (12-months)
1.9. Health related quality of life, measured using the SF-12 health survey at baseline, post-intervention (6-months) and follow-up (12-months)
1.10. Diabetes Treatment Satisfaction using the Diabetes Treatment Satisfaction Questionnaire status version at baseline, post-intervention (6-months) and follow-up (12-months), and Diabetes Treatment Satisfaction Questionnaire change version at post-intervention (6-months)
1.11. Exercise motivation, measured through the Behavioural Regulation in Exercise Questionnaire at baseline, post-intervention (6-months) and follow-up (12-months)
1.12. Patient rapport with counsellor, measured through the Patient Rapport with Counsellor Questionnaire at baseline, post-intervention (6-months) and follow-up (12-months)

2. Evaluate the acceptability of the intervention to patients, assessing the feasibility of implementing the intervention:
2.1. Patient experiences of the intervention, measured using semi-structured interviews post-intervention (6-months)
2.2. Continuity of physical activity after intervention the concluded, measured using semi-structured interviews at follow-up (12-months)

3. Pilot methods for collecting outcome measures and ensure that our plans for recruitment, randomisation, treatment, and follow-up all run smoothly:
3.1. Acceptability of the virtual testing procedures, measured using semi-structured interviews at baseline
3.2. Acceptability of research process, measured using semi-structured interviews post-intervention (6-months)

4. Determine availability and completeness of economic data
4.1. Health related quality of life, measured using the 5-Level EQ-5D at baseline, post-

intervention (6-months) and follow-up (12-months)
4.2. Healthcare usage, measured using a study specific questionnaire assessing Healthcare Usage Over the Previous 12-weeks at baseline, post-intervention (6-months) and follow-up (12-months)

Overall study start date
01/04/2020

Completion date
01/05/2023

Eligibility

Key inclusion criteria
1. Clinical Diagnosis of T2D within the previous 5–24 months
2. Aged 40 - 75 years
3. Treating diabetes with only Metformin or lifestyle modifications (diet and exercise)
4. For those prescribed Metformin: Stable dose for 3-months or more

Participant type(s)
Patient

Age group
Adult

Lower age limit
40 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
120 (UK arm n=60; Canadian arm n=60)

Total final enrolment
125

Key exclusion criteria
1. HbA1c >10% (>86mmol/mol)
2. Blood pressure >160/100 mmHg
3. Prescription of oral antidiabetic drug other than Metformin
4. Prescription of Insulin
5. Unstable angina
6. Myocardial infarction within the previous 3 months
7. Transient ischemic attack (TIA) in the previous 6 months
8. Heart failure >= class 2
9. Inability to increase level of activity
10. Pregnancy or planning to become pregnant

11. <6 months postpartum or stopped breastfeeding <1 month before recruitment
12. Not owning a smartphone/ or having no data plan or access to WiFi
13. Currently meeting the recommended exercise guidelines (150 min of moderate intensity exercise per week)

Date of first enrolment
01/11/2020

Date of final enrolment
01/12/2021

Locations

Countries of recruitment
Canada

England

United Kingdom

Study participating centre
Liverpool John Moores University
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Study participating centre
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Sponsor type
University/education

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ROR
https://ror.org/04zfme737

Funder(s)

Funder type
Government

Funder Name
Medical Research Council; Grant Codes: MR/T032189/1

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Our intended policy is that the research team will have exclusive use of the data for a period of 12 months or until the data is published. Following this data will be publicly available through the LJMU Data Repository, published under a permissive re-use license. A CC BY NC license will be applied to openly available data, this creative commons license permits others to distribute, and build upon the work for non-commercial purposes. Data will be stored in this repository for a minimum of 10 years or for 10 years from the last date of access

Intention to publish date
01/01/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publically available repository

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version v2	08/10/2020	21/10/2020	No	Yes
Protocol article		26/11/2021	29/11/2021	Yes	No
HRA research summary			28/06/2023	No	No