

# Mobile health for type 2 diabetes

<b>Submission date</b> 19/10/2020	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 21/10/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 19/11/2025	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data

## 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 to 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](mailto:m.s.cocks@ljmu.ac.uk)

(Canada contact) Dr Ali McManus, [AliMcManus@UBC.ca](mailto:AliMcManus@UBC.ca)

## Contact information

### Type(s)

Scientific

### Contact name

Dr Matthew Cocks

### ORCID ID

<https://orcid.org/0000-0003-1671-8714>

### Contact details

Research Institute for Sport and Exercise Sciences

Tom Reilly Building

Liverpool John Moores University

Byrom Street

Liverpool

United Kingdom

L3 3AF

+44 (0)151 9046243

[m.s.cocks@ljmu.ac.uk](mailto:m.s.cocks@ljmu.ac.uk)

### Type(s)

Public

**Contact name**

Dr Katie Hesketh

**ORCID ID**

<https://orcid.org/0000-0003-3409-3906>

**Contact details**

Research Institute for Sport and Exercise Sciences  
Tom Reilly Building  
Liverpool John Moores University  
Byrom Street  
Liverpool  
United Kingdom  
L3 3AF  
+44 (0)151 9046243  
K.Hesketh@2012.LJMU.ac.uk

**Additional identifiers****Clinical Trials Information System (CTIS)**

Nil known

**Integrated Research Application System (IRAS)**

283225

**Protocol serial number**

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

## **Study type(s)**

Treatment

## **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(s)**

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)

## **Key secondary outcome(s)**

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)

## **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

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Lower age limit**

40 years

**Upper age limit**

75 years

**Sex**

All

**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  $\geq$  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**

United Kingdom

England

Canada

**Study participating centre**

**Liverpool John Moores University**

Research Institute for Sport and Exercise Sciences

Tom Reilly Building

Liverpool John Moores University

Byrom Street

Liverpool

England

L3 3AF

**Study participating centre**

**The University of British Columbia**

School of Health and Exercise Sciences

Faculty of Health and Social Development

ART360 (Arts Building)

1147 Research Road

Kelowna

Canada

V1V 1V7

## **Sponsor information**

**Organisation**

Liverpool John Moores University

**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, Medical Research Committee and Advisory Council, MRC

### Funding Body Type

Government organisation

### Funding Body Subtype

National government

### Location

United Kingdom

## Results and Publications

### 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?
<a href="#">Results article</a>		26/03/2025	19/11/2025	Yes	No
<a href="#">Protocol article</a>		26/11/2021	29/11/2021	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Participant information sheet</a>	version v2	08/10/2020	21/10/2020	No	Yes