

Support through mobile messaging and digital health technology for diabetes

Submission date 08/09/2020	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 18/09/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 30/12/2024	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Type 2 diabetes is a lifelong condition that causes a person's blood sugar (glucose) to become too high. It can cause serious long-term health problems. In the UK, it affects more than 4 million people. Medicines to lower blood glucose, blood pressure, and cholesterol, can stop the complications of diabetes developing, if taken as intended. However, people often face difficulties in taking medicines regularly and have concerns about starting new medicines.

The SuMMiT-D team have developed a new text messaging system that provides hints and tips about managing diabetes. We would like to test the system compared to usual diabetes care, by asking some people to use the system alongside their usual care.

The aim of this study is to help people with type 2 diabetes improve their quality of life. This is done by comparing how effective sending health-related text messages to support people with type 2 diabetes is, compared with usual care. This system may help people with type 2 diabetes improve their knowledge and understanding of type 2 diabetes and taking medicines to treat it. The system may also help GPs and other healthcare professionals provide better support for people with diabetes in the future.

Who can participate?

Participants are eligible if they are registered with a participating GP practice, aged 35 years or over, diagnosed with type 2 diabetes, have access to a mobile phone, and are prescribed tablets to lower their blood glucose, blood pressure or cholesterol levels. Potential participants will be unable to participate if they are pregnant (or have been pregnant within the last three months), or another person in the household is already taking part in this study.

What does the study involve?

Taking part in the study does not require any face to face visits with either your practice or the study team.

Participants are assigned, by chance to one of two groups, the control group will continue with usual care, the intervention group will receive 3 to 4 health-related text messages from the SuMMiT-D system each week in addition to continuing with their usual care.

Participants in both groups will be asked to complete questionnaires at the start of the study, and again after 13, 26, and 52 weeks. Participation in the study is for 52 weeks. Reviews are conducted by the study team at the start of the study and at 52 weeks.

A proportion of the participants will be invited to be interviewed either at the start or end of their participation (or both), to discuss their views about self-management of their diabetes and the system.

What are the possible benefits and risks of participating?

The possible benefits of taking part are that participants may improve their knowledge and understanding about type 2 diabetes and taking medicines to treat it but it cannot be guaranteed that participants will directly benefit from taking part in this study. Participants will be helping research by contributing towards the further development of the SuMMiT-D system.

This is a simple automated text messaging system and so no serious risks are expected. Usual caution with the use of mobile phones is needed, for example, not texting or reading text messages while driving or walking. Completing the questionnaires will take up some time.

Where is the study run from?

1. University of Oxford. (Nuffield Department of Primary Care Health Sciences and the Institute of Biomedical Engineering) (UK)
2. University of Manchester (UK)
3. Bangor University.(UK)

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

February 2020 to March 2025

Who is funding the study?

National Institute for Health Research (NIHR) (UK)

Who is the main contact?

Dr Louise Jones

louise.jones@phc.ox.ac.uk

Study website

<http://www.summit-d.org>

Contact information

Type(s)

Scientific

Contact name

Dr Louise Jones

ORCID ID

<http://orcid.org/0000-0002-0519-2334>

Contact details

Nuffield Department of Primary Care Health Sciences
University of Oxford

Radcliffe Observatory Quarter
Woodstock Road
Oxford
United Kingdom
OX2 6GG
+44 (0)1865 287849
louise.jones@phc.ox.ac.uk

Type(s)

Scientific

Contact name

Prof Andrew Farmer

ORCID ID

<http://orcid.org/0000-0002-6170-4402>

Contact details

Nuffield Department of Primary Care Health Sciences
University of Oxford
Radcliffe Observatory Quarter
Woodstock Road
Oxford
United Kingdom
OX2 6GG

-

andrew.farmer@phc.ox.ac.uk

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

280928

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

CPMS 45393, IRAS 280928

Study information

Scientific Title

Supporting people with type 2 diabetes in effective use of their medicine through a system comprising mobile health technology integrated with clinical care compared with usual care: a randomised controlled trial

Acronym

Study objectives

Brief messaging with SMS text messaging used to support patients with type 2 diabetes taking diabetes medicine (glucose, blood pressure, or lipid lowering) alongside usual care will reduce risk factors for diabetes complications compared to usual care alone

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 25/08/2020, West of Scotland REC 5 (West of Scotland Research Ethics Service, Ward 11, Dykebar Hospital, Grahamston Road, Paisley, PA2 7DE; +44 (0)141 314 0213; WoSREC5@ggc.scot.nhs.uk), ref: 20/WS/0103

Study design

Two-arm, individually (1:1) randomized, parallel-group trial with a health economic analysis and an embedded process evaluation

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Treatment

Participant information sheet

Available at <http://www.summit-d.org>

Health condition(s) or problem(s) studied

Type 2 diabetes mellitus

Interventions

Potential participants will be identified from GP clinic lists, routine GP appointments, and through response to trial promotional material online and in print displayed in various public areas. Potential participants interested in taking part will be asked to register their interest by texting the trial team. The trial team will provide further information and answer any questions the participant may have. If a potential participant is still interested in taking part, they will undergo a screening assessment to confirm suitability to take part and we will check that they have received the participant information leaflet.

Once consent has been obtained and all the baseline questionnaires have been completed, participants will be randomly allocated (1:1) to one of two groups:

1. Usual care with the addition of an individually tailored mobile device-based intervention aimed at encouraging and supporting them in developing a habit of taking their medication as

intended and providing hints and tips to help them with other aspects of living with the condition (Intervention group)

2. Usual care (Control group)

Randomisation will be done using a secure web-based randomisation programme provided by the Oxford Primary Care Clinical Trials Unit. Allocation will be carried out with a non-deterministic minimisation algorithm to ensure groups are balanced for important baseline prognostic and other factors: study site, age (<65/≥65 years), gender (M/F), duration of diabetes (<5 years/≥5 years), number of medications (<5/≥5).

Once registered on the text messaging system, participants will receive messages of different content and frequency (depending on arm allocation) for 52 weeks. Should any issues arise with the text messaging system, participants may be contacted during the follow-up period to resolve these.

Participants will be asked to complete their follow-up questionnaires at 13, 26, and 52 weeks from the day of randomisation.

Intervention Type

Behavioural

Primary outcome measure

Composite cardiovascular outcome based on the UKPDS risk engine equations calculated using measures of glycated haemoglobin (HbA1c), systolic and diastolic blood pressure, high-density lipoproteins (HDL) cholesterol, and total cholesterol measured at baseline and 52 weeks

Secondary outcome measures

1. Long term glycaemic control measured using HbA1c level in blood samples at baseline and 52 weeks
2. Systolic blood pressure measured using a sphygmomanometer at baseline and 52 weeks
3. Diastolic blood pressure measured using a sphygmomanometer at baseline and 52 weeks
4. Total and HDL cholesterol measured using blood samples at baseline and 52 weeks
5. Quality of life measured using the EQ-5D-5L questionnaire at baseline, 13, 26, and 52 weeks

Overall study start date

01/02/2020

Completion date

31/03/2025

Eligibility

Key inclusion criteria

1. Willing and able to give informed consent for participation in the trial
2. Aged ≥35 years
3. Diagnosis of type 2 diabetes
4. Taking oral glucose-lowering treatment, blood pressure-lowering treatment, or lipid-lowering treatment (diabetes treatments) either alone or in combination
5. Has access to a UK registered mobile phone and is able, if necessary, with help (e.g. relative,

friend, neighbour), to send, understand and retrieve brief SMS text-messages in the English language

6. Registered with a general practice participating in the trial

Participant type(s)

Patient

Age group

Adult

Lower age limit

35 Years

Sex

Both

Target number of participants

958 patients from 100 GP practices

Total final enrolment

1039

Key exclusion criteria

1. Pregnant, has been pregnant in the last three months or planning pregnancy during the course of the trial
2. Any other significant disease or disorder which, in the opinion of the Investigator, may either put the participants at risk because of participation in the trial, or may influence the result of the trial, or the participant's ability to participate in the trial
3. Insulin treatment without concomitant use of oral glucose lowering treatment
4. Admitted to hospital within the last three months for hyper- or hypoglycaemia (self-report)
5. Another person in the household already participates in this trial
6. Currently using a pharmacist managed monitored dosage system for supply of medication.

Date of first enrolment

23/03/2021

Date of final enrolment

08/07/2021

Locations**Countries of recruitment**

England

United Kingdom

Wales

Study participating centre

Thames Valley and South Midlands CRN

Oxford
United Kingdom
OX3 9DU

Study participating centre

Greater Manchester CRN

Manchester
United Kingdom
M13 9WL

Study participating centre

Oxford University Hospitals NHS Foundation Trust

John Radcliffe Hospital
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Study participating centre

University of Oxford

Radcliffe Observatory Quarter
Woodstock Road
Oxford
United Kingdom
OX2 6GG

Study participating centre

University of Manchester

Williamson Building
Manchester
United Kingdom
M13 9PL

Study participating centre

Bangor University

Centre for Health Economics and Medicines Evaluation
Ardudwy

Bangor
United Kingdom
LL57 2PZ

Sponsor information

Organisation

University of Oxford

Sponsor details

Research Governance
1st Floor
Boundary Brook House
Churchill Drive
Headington
Oxford
England
United Kingdom
OX3 7GB
-
ctrq@admin.ox.ac.uk

Sponsor type

University/education

Website

<http://www.ox.ac.uk/>

ROR

<https://ror.org/052gg0110>

Funder(s)

Funder type

Government

Funder Name

NIHR Central Commissioning Facility (CCF); Grant Codes: RP-PG-1214-20003

Funder Name

National Institute for Health Research (NIHR) (UK)

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

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.

Intention to publish date

31/12/2025

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in the non-publicly available Oxford University Primary Care Clinical Trials Unit repository. Requests for sharing of anonymised/de-identified individual participant data and a data dictionary defining each field in the set will be considered by the corresponding author.

IPD sharing plan summary

Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		21/02/2022	22/02/2022	Yes	No
HRA research summary			28/06/2023	No	No