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Support through mobile messaging and digital health technology for diabetes

Submission date
08/09/2020

Recruitment status
No longer recruiting

Registration date
18/09/2020

Overall study status
Completed

Last Edited
30/12/2024

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
280928

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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
SuMMiT-D

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

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
35 years

Sex
All

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
United Kingdom

England

Wales

Study participating centre
Thames Valley and South Midlands CRN
Oxford
United Kingdom
OX3 9DU

Study participating centre
Greater Manchester CRN
Manchester
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M13 9WL

Study participating centre

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Sponsor information

Organisation
University of Oxford

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

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes