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Support through mobile messaging and digital health technology for diabetes

Submission date	Recruitment status	[X] Prospectively registered
08/10/2018	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
10/10/2018	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
30/01/2024	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol

Background and study aims
Type 2 diabetes is a lifelong condition that causes a person's blood sugar to become too high. In the UK, it affects more than 3.4 million people. It can cause serious long-term health problems. Medicines to lower blood glucose, blood pressure and cholesterol can stop complications developing, if taken as intended. However, people are often concerned about starting new medicines and face difficulties in taking them regularly. This study has drawn on patients' experiences and suggestions and previous research which has shown that mobile text messages can be effective for some conditions. Based on these messages have been developed that aim to encourage and support people with type 2 diabetes in taking their medication and managing their condition. The messages were put together by health psychologists and have been reviewed by patients. The aim of this study is to test recruitment methods, feasibility of data collection and the processes of a clinical trial to follow.

Current Who can participate? as of 04/01/2019
Patients aged 35 and over with type 2 diabetes who are taking diabetes-related oral medication.

Previous Who can participate?
Patients aged 35 and over with type 2 diabetes who have started or had a change in their diabetes-related oral medication recently

What does the study involve?
Participants are randomly allocated to receive either tailored condition specific text messages or non-health related messages for 6 months. They are asked to complete questionnaires at the start of the study and the end of the six-month period. Notes reviews are conducted at the start of the study and at 6 and 24 months. 30 participants also take part in interviews. 2: 12 to 30 healthcare professionals are invited to share their experiences of taking part in this trial.

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 text messaging

tool. This is a simple 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 of the participant's time.

Where is the study run from?
1. Thames Valley and South Midlands NIHR CRN (UK)
2. Greater Manchester NIHR CRN (UK)
3. West Midlands NIHR CRN (UK)
4. South West Peninsula NIHR CRN (UK)

When is the study starting and how long is it expected to run for?
April 2018 to August 2021

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
https://www.summit-d.org

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
38220

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 feasibility trial

Acronym
SuMMiT-D: feasibility

Study objectives
The aim of this feasibility trial is to test recruitment methods, feasibility of data collection and the processes of a clinical trial to follow.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West of Scotland REC 5, West of Scotland Research Ethics Service, 27/09/2018, ref: 18/WS/0173

Study design
Randomised; Both; Design type: Treatment, Process of Care, Education or Self-Management, Psychological & Behavioural, Qualitative

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
The patient information sheet will be made available on the study's website https://www.summit-d.org

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

Interventions

Current interventions as of 04/01/2019:
This feasibility trial is a two-arm, individually randomised, parallel group trial aiming to recruit 200 participants across approximately 20 practices. Patients with type 2 diabetes (Cohort 1) who are taking diabetes-related oral medication will be randomised to one of two groups:
1. Usual care with the addition of an individually tailored mobile phone-based intervention aiming to support them with taking their medication (approx. 3 per week) (intervention group)
2. Usual care with the addition of infrequent non-health related messages (approx. one every four weeks) (control group)

FEASIBILITY TRIAL RECRUITMENT (baseline and 26-week follow-up procedures) (Cohort 1):
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, phoning or emailing 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 eligibility is confirmed, the participant will be asked if they would prefer to complete their baseline forms (consent form and baseline questionnaires) online or on paper. Some preliminary information will be collected in order to send the forms to the participants to complete. (The same information that is ordinarily collected in a reply slip, e.g. participant mailing address, email address, alternative phone number, preferred contact time etc.)

Participants that decide to complete their forms on paper will receive their baseline forms and freepost envelopes via post.

Participants that opt to complete their forms online will be sent an email with the information needed for them to access their forms. Participants will need to enter their full name and a unique access code to access their forms.

Once consent has been obtained and all the baseline questionnaires have been completed, participants will be randomly allocated to either the treatment or the control arm and will be registered on the text messaging system.
Once registered, participants will receive messages of different content and frequency (depending on arm allocation) for 26 weeks following randomisation.

Participants will be contacted at least 48 hours after they have been provided with their baseline forms to confirm they have received them. If the forms have not been submitted or received by the trial team 7-14 days from the date they were sent by the team, further contacts will be made.

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 26 weeks from the day of randomisation.

If the follow-up forms have not been completed a week after the 26-week period end date, reminders will be sent. Multiple contacts for collection will be made up to 4 weeks after the end of the participants' 26 week follow-up period.

Qualitative part of the feasibility trial with trial participants (Cohort 1):
30 participants who have consented to taking part in a qualitative study at baseline, and are in the intervention arm, will be invited to take part in two interviews. After consent has been taken, the first interview will take place before participants receive their first message. The final interview/a debriefing phone call will take place at the end of the 26 week follow-up period (± 4 weeks). A total number of 30 participants will be taking part in this study.

In addition to the above interviews, a participant may be invited to an interview if they decide to stop receiving messages during the six-month follow-up period. Participants invited to this interview may not necessarily be part of the 30-participant sample originally selected for the above qualitative interviews.

Interviews will be audio recorded and transcribed verbatim.

Qualitative study with a cohort of healthcare staff (Cohort 2):
A minimum of 12 and up to 30 healthcare staff from practices recruiting for the feasibility trial will be participating in focus groups (or individual interviews) to discuss their experience of recruiting for this trial and share their views on the implementation of the intervention.

Consent and qualitative data will be audio recorded and transcribed verbatim.

Previous interventions:
This feasibility trial is a two-arm, individually randomised, parallel group trial aiming to recruit 200 participants across approximately 20 practices. Patients with type 2 diabetes (Cohort 1) who have started or had a change in medication in the last three months will be randomised to one of two groups:
1. Usual care with the addition of an individually tailored mobile phone-based intervention aiming to support them with taking their medication (approx. 3 per week) (intervention group)
2. Usual care with the addition of infrequent non-health related messages (approx. one every four weeks) (control group)

FEASIBILITY TRIAL RECRUITMENT (baseline and 26-week follow-up procedures) (Cohort 1):
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, phoning or emailing 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 eligibility is confirmed, the participant will be asked if they would prefer to complete their baseline forms (consent form and baseline questionnaires) online or on paper. Some preliminary information will be collected in order to send the forms to the participants to complete. (The same information that is ordinarily collected in a reply slip, e.g. participant mailing address, email address, alternative phone number, preferred contact time etc.)

Participants that decide to complete their forms on paper will receive their baseline forms and freepost envelopes via post.

Participants that opt to complete their forms online will be sent an email with the information needed for them to access their forms. Participants will need to enter their full name and a unique access code to access their forms.

Once consent has been obtained and all the baseline questionnaires have been completed, participants will be randomly allocated to either the treatment or the control arm and will be registered on the text messaging system.
Once registered, participants will receive messages of different content and frequency (depending on arm allocation) for 26 weeks following randomisation.
Participants will be contacted at least 48 hours after they have been provided with their baseline forms to confirm they have received them. If the forms have not been submitted or received by the trial team 7-14 days from the date they were sent by the team, further contacts will be made.

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 26 weeks from the day of randomisation.

If the follow-up forms have not been completed a week after the 26-week period end date, reminders will be sent. Multiple contacts for collection will be made up to 4 weeks after the end of the participants' 26 week follow-up period.

Qualitative part of the feasibility trial with trial participants (Cohort 1):
30 participants who have consented to taking part in a qualitative study at baseline, and are in the intervention arm, will be invited to take part in two interviews. After consent has been taken, the first interview will take place before participants receive their first message. The second and final interview/a debriefing phone call will take place at the end of the 26 week follow-up period (± 4 weeks). A total number of 30 participants will be taking part in this study.

Interviews will be audio recorded and transcribed verbatim.

Qualitative study with a cohort of healthcare staff (Cohort 2):
A minimum of 12 and up to 30 healthcare staff from practices recruiting for the feasibility trial will be participating in focus groups (or individual interviews) to discuss their experience of recruiting for this trial and share their views on the implementation of the intervention.

Consent and qualitative data will be audio recorded and transcribed verbatim.

Intervention Type
Behavioural

Primary outcome measure
Participant recruitment to trial and willingness to be randomised. Outcome measure: Recruitment against planned recruitment rates. Number of people showing an interest and not proceeding or those who withdraw from the control group and give a reason; Timepoint(s): End of recruitment period

Secondary outcome measures

1. The feasibility of collection of clinical measurement data for the proposed 15-month clinical trial, with particular interest in 15 months prior to trial entry or following trial entry measurement collection of participant's HbA1c, systolic blood pressure and cholesterol. Outcome measure: Completeness of data collection of HbA1c, systolic blood pressure and total to HDL cholesterol ratio; Timepoint(s): End of follow-up period
2. The willingness of participants to be followed up over the 26-week period post randomisation. Outcome measure: Retention and follow-up rates; Timepoint(s): End of follow-up period
3. The collection of prescribing data on trial participants. Outcome measure: Proportion of medication possession ratio for glucose, blood pressure and lipid lowering medication obtainable; Timepoint(s): End of follow-up period
4. The collection of self-reported questionnaire data. Outcome measure: Proportion of completed self-reported measures; Timepoint(s): End of follow-up period
5. The feasibility and acceptability of the intervention for patients and healthcare professionals (including general practitioners, nurses, receptionists and pharmacists). Outcome measure: Data obtained through focus groups/qualitative interviews with patients and recruiting healthcare staff; Timepoint(s): Baseline and end of follow-up for patients and throughout the trial period for healthcare staff
6. The mechanisms of action of brief health related messages on self-reported adherence. Outcome measure: Change in quantitative process measures and relationship between changes in these measures and self-reported adherence; Timepoint(s): End of follow up period qualitative interviews/survey/telephone contacts with trial participants
7. The feasibility and acceptability of self-completion of the resource use questionnaire. Outcome measure: Proportion of completed resource use questionnaire; Timepoint(s): End of follow-up period
8. Exploratory measures: (a) Outcome measure: Changes in primary and secondary measures that will be used in the main trial. (b) Outcome measure: Information on message delivery and interaction with participants; Timepoint(s): (a) Differences between timepoints obtained from baseline to 26 weeks (b) Automated reports from messaging service on messages delivered and interactive messaging

Overall study start date
01/04/2018

Completion date
31/08/2021

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 04/01/2019:
COHORT 1 (people with diabetes):
1. Participant is willing and able to give informed consent for participation in the trial
2. Male or female, ≥35 years of age
3. Type 2 diabetes
4. Taking oral glucose lowering treatment, blood pressure lowering treatment or lipid lowering treatment either alone or in combination
5. Has access to a 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. The participant's practice is taking part in the trial

COHORT 2 (health care professionals):
Any health care professionals (including doctors, nurses, receptionists, practices managers and pharmacists) involved in the care of patients recruited to the trial.

Previous participant inclusion criteria:
COHORT 1 (people with diabetes):
1. Participant is willing and able to give informed consent for participation in the trial
2. Male or female, ≥35 years of age
3. Type 2 diabetes
4. Taking oral glucose lowering treatment, blood pressure lowering treatment or lipid lowering treatment either alone or in combination
5. Has started one or more of these medications or had a change in one of these medications within the last three months
6. Has access to a 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
7. The participant's practice is taking part in the trial

COHORT 2 (health care professionals):
Any health care professionals (including doctors, nurses, receptionists, practices managers and pharmacists) involved in the care of patients recruited to the trial.

Participant type(s)
Mixed

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 212; UK Sample Size: 212

Total final enrolment
209

Key exclusion criteria
COHORT 1 (people with diabetes):
1. Female participant who is pregnant, within three months post-partum or planning pregnancy during the course of the trial
2. A serious medical condition that, in the opinion of the investigator makes them ineligible
3. Insulin treatment without also concomitant use of oral glucose lowering treatment
4. Another person in the household already participates in the trial
5. Patient has been admitted to hospital within the last three months for hyper- or hypoglycaemia (self-report)

COHORT 2 (health care professionals):
No exclusions

Date of first enrolment
29/10/2018

Date of final enrolment
07/08/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Thames Valley and South Midlands NIHR CRN
John Radcliffe Hospital
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Study participating centre
Greater Manchester NIHR CRN
Central Manchester University Hospitals NHS Foundation Trust
North Road
Manchester
United Kingdom
M13 9WL

Study participating centre
West Midlands NIHR CRN
First Floor
Murray Learning Centre
University of Birmingham
Birmingham
United Kingdom
B15 2TT

Study participating centre
South West Peninsula NIHR CRN
Plymouth Science Park
Research Way
Plymouth
United Kingdom
PL6 8BX

Sponsor information

Organisation
University of Oxford

Sponsor details
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Churchill Drive, Headington
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United Kingdom
OX3 7LQ
-
ctrg@admin.ox.ac.uk

Sponsor type
University/education

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

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

Results and Publications

Publication and dissemination plan
The trial protocol, statistical analysis plan and other trial documentation will be made available. Availability will be added when arrangements have been finalised. The investigators will be involved in reviewing drafts of the manuscripts, abstracts, press releases and any other publications arising from the study. Authors will acknowledge that the study was funded by NIHR Programme Grants for Applied Health Research, give the appropriate 28-day notice and carry the standard disclaimer. Authorship will be determined in accordance with the ICMJE guidelines and other contributors will be acknowledged. Publication is planned in a high-impact

peer reviewed journal. The researchers intend to publish data by August 2022, which is one year after the overall trial end date.

Intention to publish date
31/08/2022

Individual participant data (IPD) sharing plan
The datasets for this trial will be made available following trial completion. This record will be updated when arrangements for this have been finalised.

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?
Basic results		13/10/2020	13/10/2020	No	No
Other publications	describes the SMS-based system developed for and evaluated in SuMMiT-D	26/03/2021	29/03/2021	Yes	No
Results article	influence on psychological constructs that predict adherence	29/04/2022	03/05/2022	Yes	No
HRA research summary			28/06/2023	No	No
Protocol article		29/12/2019	17/11/2023	Yes	No
Results article	feasibility results	25/01/2024	30/01/2024	Yes	No