SuMMiT-D Feasibility: Support through mobile messaging & digital health technology for diabetes

PARTICIPANT INFORMATION LEAFLET

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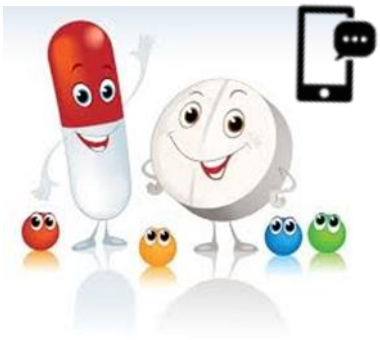
We would like to invite you to take part in the SuMMiT-D Feasibility study!

We are a team of researchers developing a tool that could help people with type 2 diabetes improve their health.
This tool could offer you hints and tips about your treatment and other aspects of managing your diabetes.
Our aim is to help you, and other patients with type 2 diabetes, improve your quality of life.
The tool may also help GPs and other healthcare professionals provide better support for people with diabetes in the future.

Continue reading to learn more about the study and find out how you can help!



Before you decide if you would like to take part, it is important that you understand why we are doing this research and what your involvement would be.

Please take time to read the following information carefully and decide if you wish to take part.

You may like to talk to others, friends or family members about this study.

If there is anything that is not clear or if you would like more information, please ask us.

Study team contact details can be found at the back of this leaflet.

What is the purpose of this study?

What we know about diabetes

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 3.4 million people - that's more than 1 in 16.

Taking medicines as intended

Medicines to lower blood glucose, blood pressure and cholesterol, can stop complications developing, if taken as intended. However, people often have concerns about starting new medicines and face difficulties in taking them regularly.

Text messages for health support

Previous research has shown that brief mobile text messages have been effective in improving health for some conditions. They can be sent to large numbers of people at low cost and could be a useful way of supporting people with type 2 diabetes.

Receiving brief messages may contribute to improved health, but more research is needed so they work better and are relevant to different groups of people.

The SuMMiT-D feasibility health management support tool

SuMMiT-D feasibility draws on patients' experiences and suggestions that mobile phone text-messages could be used to provide information and support.

We have developed a system for sending text messages that aims to encourage and support people with type 2 diabetes by providing hints and tips about treatments and other aspects of living with the condition.

The messages were put together by a group of health psychology researchers and have been reviewed by patients.

We are now ready to move on to the next stage of the development process and involve people like you in using this tool and interacting with it in daily life.

Aim of the study

The study you are being invited to join is testing the processes for a large-scale clinical trial to follow on from this work. The study involves receiving either brief health-related messages linked to your health condition and medication (intervention group) using the system or receiving brief non-health related messages (control group). Participants will be assigned randomly to these two groups.

We want to find out if this text messaging system could be used to support people with type 2 diabetes and also understand how it can be best introduced to usual medical care.

We need your help!

Why have I been invited?

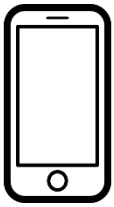
You have been invited to take part as you are over 35, have type 2 diabetes, have access to a mobile phone and have been recently prescribed new medication for diabetes, blood pressure or cholesterol. Your practice needs to be taking part in the study.

You cannot take part if you are pregnant or are within three months after having a baby. You cannot participate if another person in the household already participates in this study.

Our aim is to include 200 participants in this feasibility study.

From this group we are also aiming to recruit up to 30 participants to take part in interviews. Further information about the interviews is provided at the end of this booklet.
We are also speaking to doctors and nurses from your GP practice about their experience of the text-messaging system.

What will happen if I decide to take part?



You can let us know that you're interested in taking part by simply texting **Register** and your **first name** and **surname** to **074 2212 8690.** You may also contact the trial team via email or phone (See contact details at the back of this leaflet).

A member of our team will call you to check that you are registered with a GP practice taking part in the study and collect some information from you (including GP practice name, email address, mailing address) and answer any questions you might have.

We will send you all the information you need to take part and ask for your consent. We will also ask you to fill in five questionnaires (online or on paper, your choice). Once we have confirmed you are eligible, you have provided consent and submitted your questionnaires, we will let your GP know that you are taking part. Then, you will be allocated to either the group which receives health-related text messages or the group that receives non-health related text messages.

For six months, you will either receive health-related messages or non-health related messages. You will be given a user guide to help you decide which messages you want to receive and when. At the end, we will send you some follow-up questionnaires. When we receive these, we'll send you a £10 thank you voucher.

What will happen if I decide to take part?
Further details

Expressing your interest

You may have received information about this study through different sources. For example, your doctor might have let you know that you are potentially eligible, you might have seen one of our adverts online or a poster in your practice's waiting area.

If you are interested in taking part, text **Register** and your full name to **074 2212 8690** to express your interest. You may also contact the trial team via email or phone (See contact details at the back of this leaflet).

First steps and eligibility

We will contact you to answer any questions you may have so you can make an informed decision about taking part in the study.

We will then ask you a few questions to confirm you are eligible to take part, such as the name of your GP practice (so we can check if your practice is taking part in the study). If you are not eligible to take part due to your practice not having signed up to the study, we may ask to keep some basic contact information (such as name, preferred phone number and email address) so we can contact you if your GP practice signs up to the study in the future.

After we have confirmed you are eligible, all your questions are answered, and you are happy to continue, we will ask you for some further information, including preferred contact number, mailing address and email address.

If you choose to take part in the study, you will have a choice of completing forms and questionnaires using the internet or on paper. The online system is secure. Paper forms can be returned by prepaid post.

Consent

You will be asked to sign a consent form (either online or a paper form) to confirm that you have understood what your participation involves, that you consent for us accessing your medical notes to retrieve information such as your smoking status, in order to send you messages that are more relevant to your medical history and that you are voluntarily taking part in this study.

If you need help, we can talk you through how to sign your consent form.

Registration and randomisation

Once you have completed your eligibility and consent forms you will fill in some questionnaires and answer a series of questions about your health, the management of your condition, any challenges you may be experiencing with taking your medication etc. We will also be asking for your NHS number. Your NHS number can be found on prescription labels or on letters from your GP. Completion of the questionnaires should take approximately 20 minutes.

Once we have received your questionnaires, we will register you onto the text messaging system (you will not need to do anything). We will ask your practice to let us look at information in your medical records about your treatment, appointments and blood tests.

You will then be allocated to one of two groups. We will randomly allocate you to one or the other group. This means that you will have an equal chance of being in either group. You will not be able to choose the group you will be in.

The **intervention group** will include your usual medical care plus health-related SMS text messages. You will be able to indicate your preferences for the sort of messages you might receive.

The **control group** will include your usual medical care plus non-health related SMS text messages.

Six month follow-up

Once randomised you will receive text messages for six months.

If you are in the **intervention group**: You will receive text messages approximately three to four times a week. You will be able to interact with the messages, for example, you will be able to text 'LIKE' or 'DISLIKE' to ask for more or fewer messages of different types. You will be given a guide to help you get used to interacting with the system and you are always welcome to contact us for assistance.

If you are in the **control group**: You will receive a text message approximately every four weeks. You will be able to use the same commands as the intervention group to interact with the system.

For both intervention and control group participants:

Approximately one week before the end of the six-month follow-up period, you will be asked to complete some follow-up questionnaires. The follow-up questionnaires will take approximately 20 minutes to complete.

You will be invited to complete these either online or by post and return them to us. Once we receive them, we will send you a £10 thank you voucher.

Subsequent contacts and reminders

If we have not received your questionnaires one week after your 6-month study follow-up end date, a study team member will contact you to remind you to complete and return these to us. We will also ask your GP for information about your health and treatment for a further 18 months.

Do I have to take part?

No. **It is entirely up to you if you wish to take part**. You should take part only if you want to. You can withdraw at any time. This will not affect the standard of care you receive.

What will happen if I don't want to carry on with the study?

If you decide that you no longer wish to take part in the study you would be free to withdraw at any time without giving any reason. The clinical care you receive now and in the future would not be affected.

You can withdraw from the study but information collected up to that point may still be used.

If you wish to withdraw, please contact the study team via email or phone using the contact details on the back page of this leaflet.

How have patients been involved in developing this study?

This study is based on formative work during which we invited people with type 2 diabetes to share their views with us about the challenges they face with taking medication and how a digital health system could support them. Approximately 200 patients with type 2 diabetes have contributed to the development of this project. A Patient and Public Involvement panel member is attending our monthly study update meetings and is a co-applicant who will continue to be involved in the study. People with type 2 diabetes have also been involved in reviewing this document and other patient documentation.

Are there any disadvantages or risks from taking part?

This is a simple text messaging system and so we do not expect any serious risks occurring from your participation. Usual caution with the use of mobile phones is needed, for example, not texting or reading text messages while driving, walking. Completing the baseline and follow-up questionnaires will take up some of your time.

What are the possible benefits of taking part?

You may improve your knowledge and understanding about type 2 diabetes and taking medicines to treat it but we cannot guarantee that you will directly benefit from taking part in this study. You will be helping research by contributing towards the further development of the text messaging tool.

Will my GP know I'm taking part? Yes, we will write to your GP to inform them of your participation, we will also ask them to provide some clinical information, like your HbA1c, that only your GP will be able to provide.

Whether you choose to take part in this research or not will not affect the care you receive at your surgery.

Will I be reimbursed for taking part?

You will receive a £10 voucher to thank you for your participation after we receive your completed six-month questionnaires, at the end of the follow-up period.

Will my taking part in the study be kept confidential?

Personal identifiable data (e.g. name, date of birth, NHS number) will be collected so we can contact you e.g. to help with your enrolment in the study and registration on the text messaging system. This data will be stored in a secure encrypted database separate from your clinical data collected for research purposes. Your clinical information will be coded with a participant identification number so you will not be able to be identified by anyone other than the study team. Access to both databases is restricted to study team members only. Responsible members of the University of Oxford and the relevant NHS Trust(s) may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

What will happen to my data and what happens at the end of the study?

We will be using information from you and your medical records to undertake this study. Research is a task that we perform in the public interest. The University of Oxford, as study Sponsor, is the data controller. This means that we, as University of Oxford researchers, are responsible for looking after your information and using it properly. We will use the minimum personally-identifiable information possible. We will keep identifiable information about you (including your name, address and contact numbers) for six to twelve months after the study has finished and will use it to stay in touch with you and ensure the quality of the study. Once the study has finished we will store anonymised research data and any research documents with personal information, such as consent forms, securely at the University of Oxford for twenty years after the end of the study.

The local study team will use the following information from your medical records (and it will continue to be stored on an NHS computer): full name, NHS number, date of birth, prescribing information, blood tests and other health data to make sure that the information provided in the text messages is relevant to you.

The following information will be requested from your GP to test this data collection method for the clinical trial to follow:
HbA1c measurements, total and HDL cholesterol, systolic and diastolic blood pressure, weight, height, current medication and diabetes drugs and medical history of myocardial infarction (heart attack), stroke, transient ischemic attack (TIA), heart failure, peripheral vascular disease, and renal failure.
The study team will keep identifiable information about you from this study for six to twelve months after the study has finished.
The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details. Interview data that may be collected

during the trial by our collaborators will be returned to the sponsor, the University of Oxford, by the end of the trial period.

Your rights to access, change, or move your personal information may be limited, as we need to manage your information in specific ways for the research to be reliable and accurate.

Further information about your rights with respect to your personal data is available at http://www.admin.ox.ac.uk/councilsec/compliance/gdpr/individualrights/

The results of this study will be presented in academic and professional journals, and conferences to inform other professionals of the work we have been doing. Some of the data may also be used for educational purposes, such as teaching research students. Neither your individual data nor you would be identified in any report or publication.

What if there is a problem?

Given the nature of this study, it is highly unlikely that you would suffer harm by taking part. However, the University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study.

If you wish to complain about any aspect of the way in which you have been approached or treated during the course of this study, you should contact Professor Andrew Farmer by phone: 01865 617942 or email: patoandrewfarmer@phc.ox.ac.uk or you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 616480, or the head of CTRG, email: ctrg@admin.ox.ac.uk.

The Patient Advisory Liaison Service (PALS) is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. PALS is unable to provide information about this research study. If you wish to contact the PALS team, please contact (01865 221473).

Who is organising and funding the study?

The sponsor of this study is the University of Oxford. This research study is organised by the Nuffield Department of Primary Care Health Sciences and the Institute of Biomedical Engineering at the University of Oxford. Collaborators include the University of Manchester, Bangor University, National University of Ireland Galway, University of Aberdeen with Oxford University Hospitals NHS Foundation Trust and Oxford Health NHS Foundation Trust.
The research is funded by the NIHR Programme Grants for Applied Research. The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health and Social Care.

Interviews

We are aiming to recruit up to 30 participants to take part in interviews. The study team will ask to speak with you before you start the study and again after you have completed the study. Each interview will be conducted over the phone, last no more than one hour and will be arranged at a time that suits you.

If you agree to take part in these interviews, you will be interviewed twice. At the initial interview, you will be asked questions such as any challenges you may be facing with taking your diabetes medication, other challenges with managing your condition etc.
At the final interview, you will be asked a few questions about using the system, your opinion of the messages, if the system influenced how you are taking your medication and self-management of your diabetes etc.

Audio recordings of these interviews will be transcribed verbatim and the anonymised transcripts will be stored securely on Oxford University servers. Audio recordings will be deleted at the end of the study and anonymised transcripts will be kept for up to 20 years after completion of the study.

Who has reviewed the SuMMiT-D feasibility study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given favourable opinion by the West of Scotland Research Ethics Committee 5.

Thank you for taking the time to read this leaflet!

If you would like any further information about the study you can contact the SuMMiT-D Feasibility team here:

Interested in taking part?

Text your full name to 074 2212 8690

Oxford Study Team

Tel.: 0808 164 2521

E.: summit-d@phc.ox.ac.uk

Study Address:
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http://www.summit-d.org

OUR COLLABORATORS

Oxford University Hospitals NHS NHS Foundation Trust

Oxford Health NHS NHS Foundation Trust

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OÉ Gaillimh NUI Galway