

Participant Information Sheet: SuMMiT-D

Designing the messaging system

We would like to invite you to take part in a research study. Before you decide to take part you need to understand why this research is being undertaken and what it would involve for you.

Please take time to read the following information carefully and, if you wish, talk to friends or family about the study as this may help in your decision-making.

If anything is unclear or you require further information feel free to contact us, our details can be found at the end of this leaflet. Thank you for taking the time to read this information leaflet.

What is the purpose of the study?

This study forms part of a wider programme of work that aims to understand how mobile phones and other digital devices can be used to provide information and advice about medicines and their best use for people with type 2 diabetes. In the future, new communication and computing technologies will play a key part in health care. The research team, working with people with diabetes, is developing a system that may play a key part in health care. This work has included looking at the sort of messages, containing information and advice, that people might find helpful, finding ways to make the information personally relevant, and looking at the design of the system so it is easy to use. We want to test this system with a large



number of patients in a research study.

For this study we want to work with a group of people who have diabetes as the system is developed by the research team. We are keen to ensure that the system is user-friendly, easy to use and meets the needs of people with diabetes.

Why have I been invited?

You have been invited to take part in this study as we are currently approaching people living with type 2 diabetes and are registered with a general practice within the Thames Valley and Greater Manchester areas.

We are looking to include up to 10 patients with type two diabetes to help us design the messaging system.

Do I have to take part?

No. It is up to you to decide as any participation is entirely voluntary. If you do decide to take part, we would ask you to sign a consent form to show that you have agreed to take part. You would be free to withdraw at any time without giving a reason.

If you decide not to take part or to withdraw from the study, the clinical care you receive now and in the future will not be affected.

What will happen to me if I decide to take part?

If you decide to take part we would ask you to take part in up to six group meetings (each lasting around one hour) over a six-month period. These meetings will include other patients and some of our research staff and will be held at a local clinic or other community centre. These will be informal meetings where we will be discussing how our research team are designing the messaging system and you will be given the opportunity to share your thoughts on our ideas during this development phase. We may also audio record these interviews so we do not have to take notes during the discussions.

What should I consider?

This research is intended to develop a system that will be of help to most people with type 2 diabetes. Type 2 diabetes (sometimes also called maturity onset diabetes) can occur at any age, although usually after the age of 30 years, and is treated with tablets to lower blood sugar levels, although sometimes injections are also needed alongside tablets. We would like you to share your personal thoughts on our ideas

during this development phase of the system. You may be able to take part in this study even if you have other medical conditions or are taking part in other research studies.

What are the possible benefits of taking part?

You will help us in designing this intervention to make sure patients with diabetes find it easy to use. We also hope that everyone taking part will improve their knowledge and understanding about type 2 diabetes and taking medicines to treat it. However, we cannot guarantee this. The information we gain from this study may help us to treat patients with type 2 diabetes better in the future.

Are there any possible disadvantages or risks from taking part?

You would be asked to take part in up to six group interviews, each lasting around an hour.

Will my General Practitioner/family doctor (GP) be informed of my participation?

We will tell your general practitioner that you are taking part in this study. Please let us know if you would not want us to do this. Whether you choose to take part in this research or not will not affect the care you receive from your GP.

Will my taking part in the study be kept confidential?

All information that you might give during the study would be kept strictly confidential. Information that would help with your health care will be stored on NHS computer systems (including GP systems and NHS Hospital computer systems). Information collected for research purposes will not include identifiable personal data and will be securely stored on University or NHS computer systems accessed only by members of the research team, or in a safe, lockable place at University premises, and only the researchers on this research project will have access to it.

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.

Where relevant, audio recordings of the interviews will be transcribed and anonymised. Audio recordings will be deleted three years after the study is complete

and kept as anonymised transcripts. We will also ask all members of the interview groups that they should not share details of the messaging system as it is developed over the period of this study.

What will happen to my data?

All interviews recordings will be transcribed. These transcripts will be stored as explained in the previous section. We would also ask you whether we can use some of the interview data for educational purposes, such as teaching research students.

Will I be reimbursed for taking part?

Any reasonable travel expenses incurred as a result of participation in this study will be reimbursed upon production of receipts for fares or a mileage claim as appropriate.

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

If you should decide that you no longer wished 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.

Participants will be able to withdraw from participating in the focus group at any time. However, any comments made at the focus group up to that point will be included in the transcript and analysis, as (a) it will not be possible to uniquely attribute any comments to a specific individual, and (b) any comments made by an individual are part of discussion and are likely to influence the comments made by another participant.

What will happen to the results of the study?

The results of this study will be presented in both academic and professional journals as well as conferences to inform other professionals of the work we have been doing. We will also provide a summary of the work to those who have taken part, and hold meetings where people who have taken part will be invited to attend.

We may use some of the things you might tell us during this study at conferences or in published articles. However your name will not mentioned nor will we give any other identifiable details of you. Audio recordings will be deleted three years after the study is complete and kept as anonymised transcripts.

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. NHS indemnity operates in respect of any advice or information which is provided.

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 on 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 572224, or the head of CTRG, email ctrq@admin.ox.ac.uk. The NHS Patient Advice and Liaison Service (PALS) is also available at <http://www.pals.nhs.uk> (Oxford telephone 01865 221473 / Manchester telephone 0161 276 8686). 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.

How have patients and the public been involved in this study?

This study was designed following discussions with patients with type 2 diabetes and a group of patients have reviewed this form. There is also a patient representative as part of the study team.

Who is organising and funding the research?

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, University of Exeter, National University of Ireland Galway, University College London, 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.

Who has reviewed this 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 _____ Research Ethics Committee.

Participation in future research:

If you chose to take part in this study, we would keep your name and contact details in a secure university computer system and may approach you to take part in further related research (for example to test further development of this system). If you did not wish to do this, your name would not be kept on our computer system.

What will I have to do if I would like to take part in the study?

If you would like to take part in the study, we would ask you to complete and return the reply slip at the end of this information sheet in the prepaid envelope with your contact details completed or alternatively contact the SuMMiT-D research office on

phone: xxxxxx

email: xxxxxx

If you do not want to take part in the study at all, you need to do nothing more.

Further information and contact details

Oxford Contact details:

Local study team: xxxxxx

Phone: xxxxxx

Email: xxxxxx

Chief Investigator: Prof Andrew Farmer

Phone: 01865 617942

Email: patoandrewfarmer@phc.ox.ac.uk

Manchester Contact details:

Local study team: xxxxxx

Phone: xxxxxx

Email: xxxxxx

Investigator: Prof David French

Phone: 0161 275 2605

Email: david.french@manchester.ac.uk

THANK YOU FOR CONSIDERING TAKING PART IN THE STUDY.





Designing the messaging system

REPLY-SLIP

Your name _____

Your address:

1st Line _____

2nd Line _____

Town/City _____

County _____

Post code _____

I am interested in taking part in the above study and would like to be contacted.

My preferred contact details are

Mobile _____

Home _____

Work _____

Best time to call _____

Email _____

Please post this slip in the FREEPOST envelope provided to

SuMMiT-D study, University address details

or alternatively contact the research office:

Telephone: xxxxxx

Email: xxxxxx