Participant Information Sheet: SuMMiT-D

Understanding how the intervention will be implemented

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.

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, or your GP. Thank you for taking the time to read this information sheet.

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 could play a key part in health care. This work has included looking at the sort of 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 number of research studies.

For this study, we want to ask healthcare professionals their views on the system we develop to ensure it meets the needs of patients, and to ensure that the system will also fit with the way that health professionals work in primary care. To do this we would like to find out your views about the work we are doing.

Why have I been invited?

You have been invited to take part in this study as we are currently approaching healthcare professionals based in Thames Valley and Manchester with a potential role in the use of a messaging system. We are looking to include up to 50 staff members in total.

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, this will not affect your standing or employment with the NHS in anyway now or in the future.

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

If you decide to take part you would be asked to take part either in an individual interview or in a focus group at a local clinic with other staff members, to discuss how care for medicine use is currently delivered and how a technology system to support taking medications for type 2 diabetes medications would work in practice. We expect that most people will be interviewed in focus groups, with a smaller number of people asked to take part in individual interviews.

It is expected focus groups will be approximately 60-90 minutes and interviews will be approximately 30-60 minutes.

What are the possible benefits of taking part?

The information we gather from this study will help us in developing better care interventions to enable people with type 2 diabetes to manage their condition. Enabling people with type 2 diabetes to manage their condition may impact positively on people with diabetes and on your work.

Are there any possible disadvantages or risks from taking part?

You would be asked to take part in an interview or focus group which will take up to 90 minutes of your time.

Will my taking part in the study be kept confidential?

All information that you might give during the study would be kept strictly confidential.

Audio recordings will be transcribed and anonymised. Audio recordings will be deleted three years after the study is complete and we will store transcripts of the anonymised interviews.

What will happen to my data?

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.

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 are free to withdraw at any time without giving any reason. This will not affect your standing or employment with the NHS in anyway now or in the future

You 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 completion of the study 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: andrewfarmer@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 ctrg@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 in 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 healthcare professionals. 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 team 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

Understanding how the intervention will be implemented

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 team:

Telephone: xxxxxx
Email: xxxxxx