Participant Information Sheet: SuMMiT-D

How acceptable are text messages about medication to patients

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 could play a key part in health care. The work so far 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 ways in which we might design 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 find out your views on the messages that we plan to send to people as part of the system. We want to ensure that these messages are clear, friendly and meet 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 in the Thames Valley and Greater Manchester areas.

We are looking to include up to 30 patients with type 2 diabetes to tell us what they think of the brief messages (for example they could be in the form of mobile phone SMS text-messages. Each person taking part in the study will read up to 100 messages, and complete four questions in relation to each message, to indicate how acceptable it would be to receive each message. Depending on which you prefer, a paper copy of the questionnaire can be sent to you or you could complete it electronically online.

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 indicate that you have given your consent and agreed to take part.

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 or if you have any questions about this research, you should return the brief questionnaire and reply slip. If you have any questions about this research, indicate on the reply slip whether you would prefer us to contact you by email or telephone. We will then get in touch to answer any questions you may have.

If you are willing to take part, please indicate on the reply slip whether you prefer to evaluate the brief messages online or on a paper copy of these. We will then send you a link to the online questionnaire and a unique identification password, or a paper copy of the text messages and the questionnaire, along with an envelope addressed to us that will not require stamps or other payment to return to us.

Completing the questionnaire should take no longer than 90 minutes. You will have the option of pausing the questionnaire and returning to it at a later time if you complete it online.

What should I consider?

The intellectual property (IP) in relation to the messages being developed resides with the research team. Further, the content of all messages developed is to be regarded as confidential.

This part of the research programme is intended to contribute to a system that will help 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. 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?

We 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?

A possible disadvantage of taking part in this research is the time commitment of up to 90 minutes to read the brief messages and complete the questionnaire.

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?

When you agree to take part, you will be allocated a study code. Your contact details with this study code 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. Everything that you put on the questionnaires would be stored electronically with only your study code and not your personal details attached. Once data collection has finished for this study, we will destroy the files containing your contact details.

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?

The responses to the questionnaires will be analysed to help develop the text (SMS) messages. The analysis will be used to help make sure that the text (SMS) messages are acceptable to people who might use it. We would also ask you whether we can use some of the data for educational purposes, such as teaching research students.

Will I be reimbursed for taking part?

There is no payment for taking part in this research.

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

You would be free to withdraw from the research up to one week after completing the questionnaire without giving any reason. Withdrawal after that point would be difficult, as we will aim to recruit study participants who vary as much as possible in terms of age, duration of diabetes, other health conditions, etc. Your participation would mean that we would then aim to recruit fewer people who are like you. The clinical care you receive now and in the future would not be affected if you decide to withdraw.

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 and we will not keep any details that would allow you to be identified.

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 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 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 the North West – Greater Manchester West Research Ethics Committee (ref: 17/NW/0224).

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, or have some questions you would like to ask, 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: 01865 617877 (Oxford) / 01613 065436 (Manchester)

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

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

Further information and contact details

Manchester Contact details:

Local study team: Manchester Centre for Health Psychology, University of Manchester
Dr Kiera Bartlett
Phone: 01613 065436
Email: kiera.bartlett@manchester.ac.uk

Investigator: Prof David French
Phone: 0161 275 2605
Email: david.french@manchester.ac.uk

Oxford Contact details:
Local study team: Nuffield Department of Primary Care Health Sciences, University of Oxford
Jenny Riga
Phone: 01865 617959
Email: summit-d@phc.ox.ac.uk
Chief Investigator: Prof Andrew Farmer
Phone: 01865 617942
Email: patoandrewfarmer@phc.ox.ac.uk

THANK YOU FOR CONSIDERING TAKING PART IN THE STUDY.

How acceptable are text messages about medication to patients

Study ID: ☐☐-☐☐☐-☐☐☐☐

REPLY-SLIP

Your name_____

Your address:

1st Line_____

2nd Line_____

Town/City_____

County_____

Post code_____

GP surgery _____

I have some questions about the above study and would like to be contacted.

My preferred contact details are

Mobile _____

Home _____

Work_____

Best time to call _____

Email_____

I would like to part in the study, and would like to complete the questionnaire (please tick which applies):

□ online (please send weblink to questionnaire and password. please ensure your email address is correct above)

□ paper copy (please send questionnaire and reply-paid envelope)

Please post this slip in the FREEPOST envelope provided to

SuMMiT-D Study

Manchester Centre for Health Psychology
University of Manchester
Coupland 1 Building
Oxford Road
Manchester
M13 9PL

Or

Nuffield Department of Primary Care Health Sciences
University of Oxford
Radcliffe Observatory Quarter
Woodstock Road
Oxford
OX2 6GG

or alternatively contact the research office:

Telephone: 01865 617877 (Oxford) / 01613 065436 (Manchester)
Email: summit-d@phc.ox.ac.uk