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## **Identifying theory-based messages in type 2 diabetes**

### **Participant Information Sheet**

**Ethical Approval Reference: R50752/RE001**

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. 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. A system is being developed to do this. The wider programme of work includes looking at the sort of information and advice that could be given, finding ways to make the information personally relevant, and looking at the



design of the system so it is easy to use. We are currently optimising this system so it can be tested with a large number of patients in a research study.

For this study, we want to obtain input from people with relevant expertise to develop high-quality text messages based on what we know already can be refined in the next stages of the research programme.

### **Why have I been invited?**

You have been invited to take part in this study as we are currently approaching clinicians with a range of clinical experience (e.g. GPs, pharmacists, diabetologists, nurses), and psychologists with experience of behavioural interventions, experience of working with people with diabetes, or working in the area of medication adherence. We are looking to include up to 20 people who are clinicians or research psychologists.

### **Do I have to take part?**

No. It is up to you to decide as any participation is entirely voluntary. You can ask questions about the study before deciding whether or not to participate. If you do decide to take part, you may withdraw from the study at any time, without giving a reason and without penalty, by advising the researchers of this decision.

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

If you decide to take part we will ask you to indicate your availability to attend a single day workshop in Manchester, of maximum 8 hours total duration, assuming that a day that is convenient to you can be found.

After signing a consent form, you will participate in four groups throughout the day, facilitated by members of the research team. In each group, you will be asked to work on producing text messages employing one Behaviour Change Technique, such as goal setting or eliciting social support for medication taking. You will be given a definition of the Behaviour Change Technique and some explanatory text to help with this.

In each group, you will first be asked to individually generate a set of 160-character messages. You will then share your messages as a group, and suggest refinements to messages produced by other members of the group to produce a final set of brief messages. You will then be asked to rate how well the brief messages generated by another group meet the definitions that they were working with.

You will be rotated to different groups throughout the day, so that you will work with a different set of participants in each of your four groups. You will be provided with lunch and refreshments throughout the day.

### **What should I consider?**

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

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.

### **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 better which may also impact positively on your work. We also hope you will find attending the workshop to be interesting, and you may learn from other attendees. We will acknowledge the contribution of all participants in message development in subsequent publications, unless you request that we do not.

### **Are there any possible disadvantages or risks from taking part?**

The main drawback of participation is finding the time to attend the workshop in Manchester for eight hours total.

### **Will my taking part in the study be kept confidential?**

We will keep records of all messages generated, and refinements to these produced throughout the duration of the workshop. We will store your name in relation to the messages you generated and those of the groups you work in, and these will be stored securely. However, we will not link your name with the messages you generated in any publication or other method of dissemination. We will recognise your contribution to message development in subsequent publications, but you can opt out of this if you wish.

Responsible members of the research team at University of Oxford 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?**

All research and personal data will be stored securely and confidentially on password protected University computer systems accessed only by members of the research team, and in a safe lockable place at University premises. Only the researchers on this research project will have access to them.

All research and personal data records will be stored for a minimum retention period of five (5) years after publication or public release of the work of the research.

Your input will develop the text (SMS) messages from a list of Behaviour Change Techniques identified from previous research, and that will be refined and evaluated in subsequent research.

### **Will I be reimbursed for taking part?**

We will pay an honorarium of £250 to all attendees. Any reasonable travel or accommodation expenses incurred as a result of participation in this study will also be reimbursed upon production of receipts as appropriate.

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

You will be able to withdraw from participating in the workshop at any time, without giving any reason. However, any input into message development at the focus group up to that point will be included, as (a) it will not be possible to uniquely attribute any messages to a specific individual, and (b) any messages generated by an individual will be discussed 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 refined, and form the basis for a subsequent evaluation of the effectiveness and cost-effectiveness of sending text messages to people with type 2 diabetes.

The results will also 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.

### **What if there is a problem?**

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](mailto:patoandrewfarmer@phc.ox.ac.uk)

The researcher should acknowledge your concern within 10 working days and give you an indication of how they intend to deal with it. If you remain unhappy or wish to make a formal complaint, please contact the relevant chair of the Research Ethics Committee at the University of Oxford who will seek to resolve the matter in a reasonably expeditious manner:

Chair, Medical Sciences Inter-Divisional Research Ethics Committee; Email: [ethics@medsci.ox.ac.uk](mailto:ethics@medsci.ox.ac.uk); Address: Research Services, University of Oxford, Wellington Square, Oxford OX1 2JD

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

This study was designed following discussions with patients with type 2 diabetes. There is also a patient representative as part of the study team.

### **Who is organising and funding the research?**

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 and National University of Ireland Galway.

The work is part of a research programme 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?**

This project has been reviewed by and received ethics clearance through the University of Oxford Central University Research Ethics Committee [reference number R50752/RE001].

### **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, please indicate this in a reply to the email you have been sent, and a member of the SuMMiT-D research team will contact you

directly about your participation. Please reply to the email invitation or other people whose contact details are included below should you want any further information, or alternatively contact the SuMMiT-D research office on

phone: 01613 065436 (Manchester)

email: kiera.bartlett@manchester.ac.uk

If you do not want to take part in the study at all, you need to do nothing more, or you can reply to this email indicating you do not wish to take part. If we do not hear from you, we will send one more email about your potential participation.

### **Further information and contact details**

#### Manchester Contact details:

**Local study team: Manchester Centre for Health Psychology, University of Manchester**

**Dr Kiera Bartlett**

Phone: 0161 306 5436

Email: kiera.bartlett@manchester.ac.uk

**Investigator: Prof David French**

Phone: 0161 275 2605

Email: david.french@manchester.ac.uk

**THANK YOU FOR CONSIDERING TAKING PART IN THE STUDY.**