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How do proposed messages map to behaviour change theories?

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 work so far includes looking at the sort of information and advice that could be given, 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 are currently optimising this system so it can be tested with a large number of patients in a research study.



For the present study, we are keen to get input from people with relevant expertise to help us carry out a formal process to test whether the messages we have developed have fidelity to their intended content.

Why have I been invited?

You have been invited to take part in this study as we are currently approaching people who have expertise in behavioural interventions, and 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 have this expertise.

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 would like to take part in the study or if you have any questions about this research, 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.

If you were willing to take part, we would then send you a link to the online questionnaire and a unique identification password. The online questionnaire will begin with an online consent form. You would then be presented with 200 text messages of up to 160 characters each. You would be asked to answer two questions in relation to each of these text messages. Completing the questionnaire should take no longer than 120 minutes. You will have the option of pausing the questionnaire and returning to it at a later time.

What should I consider?

The intellectual property (IP) in relation to the messages being evaluated resides with the research team. Further, the contents of all messages evaluated 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 the task interesting. 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 complete the online questionnaire.

Will my taking part in the study be kept confidential?

We will keep records of all your responses, and these will be linked with a unique code. We will store your name in relation to the unique code in a separate online document that will be stored securely in a password-protected file. 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.

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 help select the text (SMS) messages to be used in the next stage of the research, to evaluate the impact on medication adherence of receiving these messages.

Will I be reimbursed for taking part?

We will pay an honorarium of £250 upon completion of the questionnaire.

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

You will be able to withdraw from completing the questionnaire at any time up to one week after you complete the online survey, without giving any reason. At one week after completion of the online survey, we will use information about your gender and geographical location to inform the sampling of other experts that are less represented.

What will happen to the results of the study?

The results of this study will help select the text (SMS) messages to be used in the next stage of the research, to evaluate the impact on medication adherence of receiving these messages. It will also be used to provide evidence about the extent to which messages have fidelity to the intended content.

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

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; 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 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 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?

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: 0161 306 5436

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, 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

Phone: 0161 306 5436

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

Dr Veronika Williams

Phone: 01865 617940

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

Chief Investigator: Prof Andrew Farmer

Phone: 01865 617942

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THANK YOU FOR CONSIDERING TAKING PART IN THE STUDY.