Developing a Core Outcome Set for Medication Adherence Trials

An invitation to take part in a study to develop a set of outcomes for medication adherence trials

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What is the study about?

Some people who are prescribed medicines struggle to take them, for example because they forget, or because the medicines get in the way of doing other things. It is important that we develop and test new and better ways of supporting people to take their medicines as prescribed. The things that we measure when testing whether these new ways have worked, are called 'outcomes'. An agreed list of the important outcomes that should be measured is called a Core Outcome Set. In this study we are asking patients and their informal carers, staff from GP surgeries and researchers, to agree on which outcomes should be included in a Core Outcome Set for seeing if a new way of supporting people to take their medicines as prescribed has worked.

Why am I being invited to take part?

We are inviting all GP surgeries in England to take part. We are inviting general practitioners, nurses, pharmacists and healthcare managers, employed by a primary care organisation, to participate in this study. We are also inviting academic researchers with relevant expertise in medication adherence or medication management to take part.

Do I have to take part?

No, it is entirely up to you if you take part. If you do decide to take part in the study, you can change your mind at any time without giving a reason.

What will happen if I take part?

We will ask you to complete an online consent form. Once we get your completed consent form, we will ask you to complete two online questionnaires about 1 to 2 months apart. Each questionnaire should take around 15 minutes to complete.

The first questionnaire will give you a list of outcomes that might be important to measure in trials testing new ways of supporting people to take their medicines as prescribed. We will ask you to score each of these outcomes based on how important you think they are. We will also ask you to add any additional outcomes that you think are missing.

We will add the scores that we get from everyone. We will remove outcomes that most people agreed were not important to measure. We will put the outcomes that most people agreed were important in the Core Outcome Set. We will put the remaining outcomes into the second questionnaire to be looked at again. For each outcome in the second questionnaire, you will be able to see the average score from everyone who took part the first time, and you will be asked to score the outcomes again.

After we have looked at the completed questionnaires, we will invite some people to take part in an online discussion about what we have found. If you are interested in being invited to the online discussion, there is a box on the consent form for this study that you can tick to let us know. We only have limited spaces for the online discussion so if we get lots of interest, we will pick people to have a mixture of different patients, family members, staff from GP surgeries, and researchers. We will let you know either way whether you have been picked. You do not have to take part. It is optional and will last no more than 2 hours. At the online discussion, we will ask people for their thoughts on the best ways to measure the outcomes that were scored as important. We will use the information from the online discussion to help us decide which outcomes to include in the Core Outcome Set and how to measure them.

What will happen to the results of this study?

We will share the results of the study at conferences and in scientific journals. We may use direct quotations from the online discussion in publications but we will remove all personal information so that you cannot be identified from the quotations. We will also produce a summary of the findings to share with the study participants. If you would like to receive a summary of the findings you can tell us on the consent form.

How will we use information about you?

For this research project we will ask you to tell us a little bit about yourself so that we can describe the range of people who complete the questionnaire. We will ask you for your professional role, number of years in your profession and your organisation details. We will also ask you for your name and contact details but only use these to send you the questionnaires and invite you to take part in the online discussion if you agree to this. People who do not need to know will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure on a password protected university storage space. Paper copies of your study data will be kept in a secure office environment at the University of Leicester. Once we have finished the study, we will keep some of the data so we can check the results.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

If you wish to withdraw, please contact the research team. A decision to withdraw at any time or a decision not to take part will not affect your legal rights.

Where can I find out more about how my information is used?

You can find out more about how we use your information at:

- at www.hra.nhs.uk/information-about-patients/

- on the following website: www.le.ac.uk/patient-gdpr-guidance
- by asking one of the research team
- by contacting us via the e-mail address or phone number at the end of this sheet
- by contacting the University's Data Protection Officer, University of Leicester, University Road, Leicester, LE1 7RH please email ias@leicester.ac.uk.

Will my participation be kept confidential?

The University of Leicester is the Sponsor for this study based in the United Kingdom. The University of Leicester will be responsible for looking after your information and using it properly. We will keep your information in a secure password protected storage space at the University of Leicester, and only the research team will have access to it. Notes will be typed up from the audio-recordings of the online discussion and then the recording will be deleted. No names or information that would allow anyone to be identified will be typed up.

Some of your coded information may be shared with and analysed by researchers at the University of East Anglia. Identifiable data like name and address will only be seen by select members of the study team, the Sponsor, Research Ethics Committee, NHS trust, or other regulatory authorities for auditing and monitoring purposes. The University of Leicester will keep identifiable information about you for six years after the study has ended.

What are the benefits of taking part?

There are no direct benefits to you from taking part. The things you tell us will help towards developing a list of important outcomes to be measured in future trials testing new ways of supporting people to take their medicines as prescribed.

What are the drawbacks of taking part?

We need participants to complete the questionnaire two times. This means being involved in the study for 1 to 2 months and being contacted by us more than once. To minimise the number of times we contact you, we will send one reminder at each stage. If we do not hear from you after the reminders, we won't contact you again unless you ask us to.

Who is organising and paying for the research?

The study is organised by a team of researchers from the University of Leicester and University of East Anglia. The research is paid for by the National Institute for Health Research Programme Development Grant stream (award ID PDG 203303). The researchers will not be paid for your participation in this study.

What if something goes wrong?

If you have a concern about any aspect of this study, you should ask to speak with a member of the study team who will do their best to answer your questions.

If you have any complaints about the study, you can contact the Deputy Head of School and Director of Research of the School of Allied Health Professions, University of Leicester, Associate Professor Seth O'Neill on 0116 252 5141 or at so59@leicester.ac.uk.

It is very unlikely that you would be harmed by taking part in this type of research study. In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against University of Leicester but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

Who has reviewed the study?

This research was reviewed and approved by the London – Camberwell St Giles Research Ethics Committee (reference 22/PR/0449) and the Health Research Authority (reference IRAS ID 313087).

How do I take part?

If you would like to take part in this study, please visit the weblink listed on your invitation letter. The link will take you to an online form where you can express your interest in taking part in the study. You can get in touch with a member of the research team, as listed on your invitation letter, to discuss the study and answer any queries that you may have.

Contacting the research team

If you have any questions or would like further information about this study, please contact one of the study researchers:

Kumud Kantilal
Telephone: 0116 252 5992
Email: k.kantilal@leicester.ac.uk

If you would like to find out more about the research programme, please contact the lead investigators:

Prof Debi Bhattacharya
Email: d.bhattacharya@leicester.ac.uk

Dr Sion Scott
Email: s.scott@leicester.ac.uk

Thank you for taking the time to read this information sheet