Optimising StruCtured medicAtion Reviews

The OSCAR study

PARTICIPANT INFORMATION LEAFLET

We would like to invite you to take part in our research study. Joining the study is entirely up to you. Before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through this information leaflet with you, to help you decide whether or not you would like to take part and answer any questions you may have. We suggest this should take about 10 minutes. Please feel free to talk to others about the study if you wish.

The first part of the Participant Information Leaflet tells you the purpose of the study and what will happen if you take part. Then we give you more detailed information about how the study is conducted. Do ask if anything is unclear, the contact details for the team are at the bottom of this document.

Our study will be exploring structured medication reviews for patients who take multiple different medicines and/or have multiple different conditions. The reviews are conversations between patients and their clinical pharmacists for GP's about the medicines they are taking. Their family or caregivers may also be present. We seek to record real examples of these reviews and how they are documented to understand how they work and what they achieve. We will also be talking to some patients about their experiences to understand how to optimise the process in the future.

What is the purpose of the study?

Structured medication reviews (SMRs) are dedicated appointments where a clinical pharmacist or GP meets face-to-face (or remotely) with a patient and discusses the medicines they are taking in one session. SMRs aim to reduce medicines-related harm and are being introduced in the NHS across England. They aim to target people with several different health conditions and/or people who are taking many different medicines. The aim of this study is to understand how SMRs work, what they achieve, and how to optimise the process. We are seeking around 40 people registered in GP surgeries in different parts of England to join our study.

Why have I been invited?

We are inviting you to take part in our study because you have been invited to have a structured medication review and your GP Surgery is taking part in our study. We are interested in hearing and understanding your views on the process.

What would taking part involve?

Taking part in our study is entirely voluntary. If you accept this invitation you will be telephoned by a member of the research team to discuss the study and answer any questions you might have. If you are happy to proceed we will seek your consent for your structured medication review, and any entries made in your health record about it, to be audio or video recorded and used in our study. We will send you a copy of your consent form to keep. Following your structured medication review conversation we may also ask you to take part in an interview conducted by a member of the research team so we can ask you about your experience. We will conduct the interview at a time convenient to you either in person, or on the telephone, or remotely. The interviews will be audio-recorded by the researcher and last no longer than one hour.

Do I have to take part?

No. Taking part in our study is entirely voluntary. You can stop being part of the study at any time, without giving a reason.

Are there any possible disadvantages and risks from taking part?

We do not anticipate any possible disadvantage or risks in taking part in our study.

What are the possible benefits of taking part?

Most people find the experience of taking part in this type of study positive and rewarding. Your involvement will help us to understand the pros and cons of SMRs from the patient perspective and to suggest changes, which may improve the quality of many people's lives.

Will my taking part in the study be kept confidential?

We will be using information from you in order to undertake this study and will use the minimum personally-identifiable information possible. People who do not need to know who you are 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. The SMR recordings and interviews will be transcribed and the transcripts de-identified.

Responsible members of the University of Oxford may be given access to your data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

Once we have finished the study, we will keep all research data and documents with personal information, such as consent forms, for three years so we can check the results. It is possible that we might share de-identified transcripts of your consultation with other researchers in the future; for peer scrutiny, to optimise the use of good quality research data and to support policy and other decision-making. With your consent, we might also share the recording, unchanged, but with all spoken identifiers redacted. If the Structured Medication Review was video-recorded, you may request to have your face blurred.

How will my data be protected?

UK data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest.' The

University of Oxford is the sponsor for this study, based in the United Kingdom, is the data controller and is responsible for looking after your information and using it properly.

We will be using information from you in order to undertake this study and will use the minimum personally-identifiable information possible; this will include your name, contact details and basic demographic information. We will keep all research data and documents with personal information securely at the University of Oxford for three years after the end of the study. We will retain the de-identified transcripts, and with your specific consent the original review recording (unchanged but with all spoken identifiers redacted), indefinitely for future research purposes. If you agree to your original recording being held regarding future research, we will retain a copy of your consent form until such time as your data are removed from our database but will keep the consent form and your data separate.

The person who does the transcription may be external to the University of Oxford. If so, they will have completed the University's Information Security for Third Party Security Assessment and will be bound by a confidentiality agreement.

Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at https://compliance.web.ox.ac.uk/individual-rights

You can find out more about how we use your information by contacting Dr Aduku Agwunobi at aduku.agwunobi@phc.ox.ac.uk.

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

Participating is voluntary and you can change your mind at any stage. If you leave the study we will destroy all your identifiable research data, but will use the data collected up to that point.

What will happen to the results of this study?

We will write our reports in a way that does not identify the individuals who took part. We plan to disseminate our results to the public and participants in the following ways:

- Summarising research findings on our study website;
- Publishing research findings in academic journals;
- Presenting our findings at conferences;
- Feeding back findings to study practices to help optimise SMRs.

What if there is a problem?

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.

If you wish to complain about any aspect of the way in which you have been approached or treated, or how your information is handled during the course of this study, you should contact the study lead Professor Richard McManus on 01865 617852 or richard.mcmanus@phc.ox.ac.uk or you may contact the University of Oxford Research Governance, Ethics and Assurance team on 01865 616480, or email RGEA.Sponsor@admin.ox.ac.uk.

Who is organising and funding this study?

The University of Oxford is the sponsor for this study. The study is funded by National Institute for Health Research via the East Midlands Applied Research Collaboration.

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 your interests. This study has been reviewed and given favourable opinion by South Central - Hampshire A Research Ethics Committee.

Further information and contact details

For specific information about this study please contact the study team by emailing oscarstudy@phc.ox.ac.uk. For independent advice on taking part in this study please contact heather.house@admin.ox.ac.uk. For more general information about participating in research please email bepartofresearch@nihr.ac.uk.

Thank you for reading this information.