NIHR | Applied Research Collaboration Oxford and Thames Valley

NUFFIELD DEPARTMENT OF PRIMARY CARE HEALTH SCIENCES

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 clinical pharmacist or GP-led structured medication reviews (SMRs) for patients who take multiple different medicines and/or have multiple different conditions. These reviews are conversations between patients or family members / caregivers about their medicines. 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 clinical pharmacists, and GP's about their experiences to understand how to optimise the process in the future.

What is the purpose of the study?

Structured medication reviews are dedicated appointments where a clinical pharmacist or GP meets face-to-face (or remotely) with a patient and discusses all the medications they are taking in one session. SMR's aim to reduce medicines-related harm and are being introduced in the NHS across England and while they seem sensible, little is known about how they work and what they achieve. They aim to particularly target people with several different medical conditions (called multimorbidity), and/or people on many different medicines (called polypharmacy), and/or people who are particularly frail, and/or people in care homes. The goal of these to reviews is to improve the quality of prescribing. This project is concentrating on multi-morbidity where people have at least two conditions. We are seeking approximately 20 HCPs working in GP surgeries and care homes 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 work for a Primary Care Network or GP Surgery who are participating as a case study in our research and you have been conducting structured medication reviews with our target patient group.

What would taking part involve?

Taking part in our study is entirely voluntary. If you accept this invitation you will be given an opportunity to discuss the study and answer any questions with a member of our research team and if you are happy to proceed, please send us a completed consent form, making sure you keep a copy for your records, or we will send you a copy. We will ask you to share examples of SMR documentation with us e.g. any templates for letters of invitation, process checklists or data input, and support you to audio or video record up to 6 structured medication reviews with consenting patients for our study.

You would also be interviewed by a member of the research team and asked to reflect on structured medication reviews and how they are being implemented. We will conduct the interview at a time convenient to you either in person, on the telephone, or online. The interviews will be audio-recorded by the researcher with your agreement 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 a qualitative study to be a positive one. Your involvement will help us to understand the pro's and con's of these new reviews and if any changes might be made to improve it in the future.

Will my taking part in the study be kept confidential?

We will need to use information from you for this research project. This information will include your name and contact details. 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 interview recordings will be transcribed and the transcripts de-identified. Confidentiality will be maintained unless there are clear and overriding reasons to do otherwise – for example in relation to safeguarding issues or subpoena by a court.

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 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 original recording, unchanged, but with all spoken identifiers redacted. If the Structured Medication Review is being 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. 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 original recordings (unchanged but with all spoken identifiers redacted), indefinitely for future research purposes. If you agree to your original recordings 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 Anna Seeley at anna.seeley@worc.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.