Pharmacist Participant Information Sheet

PPhoCUs: Polypharmacy, Pharmacists and Clinical Uncertainty (Phase 1)

Large font version available if required

Invitation and brief summary

You are being invited to take part in a research study. You do not have to take part but before you decide, it is important for you to understand why the research study is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. My name is Tom Kallis, I am a Clinical Pharmacist undertaking a PhD at the University of Exeter. I am doing this research study as part of my degree. Ask me (t.j.kallis@exeter.ac.uk) if there is anything that is not clear or if you would like more information.

This study looks at how pharmacists review patients with significant polypharmacy (prescribed ten or more medications) in general practice and how they deal with clinical uncertainty. Patients with polypharmacy are more likely to be admitted to hospital, suffer a life-changing fall or be generally more unwell, than people who do not regularly take a large number of medicines. The more co-morbidities a person has and the greater number of medicines a person is prescribed, the more difficult decision making can become for healthcare professionals giving advice or treating that patient. When the next best step for a patient is unclear, this is referred to as 'clinical uncertainty.'

It is the purpose of this study to understand how pharmacists make decisions when reviewing polypharmacy and dealing with clinical uncertainty. This will be done through audio recording of medication review appointments and interviews with both patients and pharmacists.

What would taking part involve?

If you decide to take part you will be invited to an online Microsoft Teams briefing with me (Tom Kallis) at a pre-arranged time of your convenience. The briefing will last for no longer than one hour in total and we will discuss in full how to use audio recorders to capture your structured medication reviews (SMRs) with patients. You will have the opportunity to ask any questions about the research here also. You will be sent an audio recorder from the research team and will need to invite and consent patients to participate in having their SMR audio recorded. You will record seven polypharmacy SMR appointments. Once completed, the audio recorder will be collected by research team. The chief investigator conducting the research is a registered pharmacist and has a professional duty to highlight any professional misconduct or negligence to their

registered body where this has not already occurred. Whilst unlikely, if any disclosures are made of practice that would result in harm to patients or the general public, are obliged to highlight this to the GPhC.

What are the possible benefits of taking part?

Whilst there are no direct benefits to taking part in the study, participating in the research may include opportunities for reflection on your practice which could contribute to or initiate a CPD cycle. The GP practice you are based at will be paid for participating in the research study.

What are the possible disadvantages and risks of taking part?

You may feel uncomfortable having your clinic recorded. We are not aware of any disadvantages or risks to you in taking part in the study.

What happens if something goes wrong?

You can contact me (Tom Kallis) if you wish to complain or have any concerns about any aspect about any way you have been approached or treated during the course of this study. If you feel that your complaint has not been handled to your satisfaction you can contact Prof Rupert Payne r.a.payne@exeter.ac.uk.

Who has reviewed the study?

The research study has been approved by a HRA Research Ethics Committee. The study has been peer reviewed by external academics.

Who is organising and funding the research?

The study is being organised by Tom Kallis at the University of Exeter and funded by the NIHR School for Primary Care Research.

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

Patients and members of the public have been involved in this study from the point of applying for funding. Plain English summaries and the research programme structure have been reviewed by members of the public and patients. A dedicated Patient Advisory Group (PAG) will support and inform the research throughout the PPhoCUs study.

How will we use information about you?

We will need to use information from you for this research project. We will ask you about where your practice is located and your ethnicity. People will use this information to do the research or to check your records to make sure that the research is being done properly. 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 recordings will be anonymised and transcribed. Third party transcription services may be used to transcribe recordings taken. Once we have finished the study, we will keep some of the data so we can check the results. Anonymised information collected (including transcriptions) about you may be used to support other research in the future. This data will be retained for up to 10 years following recording. We will write our reports in a way that no-one can work out that you took part in the study.

Do I have to take part?
It is up to you to decide whether or not to take part. If you choose to take part you will first be asked to confirm your consent and you can still withdraw at any time prior to audio recording. You do not have to give a reason.

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.

How will my information be kept confidential?
All of the personally identifiable information that we collect about you during the course of the research will be kept strictly confidential and no one outside the University of Exeter will be allowed access to it. Electronic data containing personally identifiable information about you will only be stored on a password-protected, encrypted Sharepoint that only I and my supervisory group have access to. Hardcopies of data and other documentation containing personally identifiable information about you will be kept secure in a locked cupboard that only I have access to. The recorded audio will be retained for 10 years following data collection, at which point it will be destroyed by Prof Rupert Payne. You will not be able to be identified in any reports or publications

Where can you find out more about how your information is used?
You can find out more about how we use your information at www.hra.nhs.uk/information-about-patients/, via the University of Exeter Data Protection officer informationgovernance@exeter.ac.uk or by sending an email to the researcher t.j.kallis@exeter.ac.uk