Participant Information Sheet

Invitation to take part in a research study

As we get older, our bodies are less able to handle some medicines. Medicines that were once effective and safe, may no longer work as well but could still cause side effects.

With the help of patients, family members, hospital doctors and pharmacists, researchers have developed a package of support to help doctors and pharmacists stop medicines that patients no longer need.

This hospital is taking part in a research study to test the support package to see whether it works and whether it improves the health and wellbeing of patients.

There are two parts to the study – part one where nothing is changed from a normal hospital stay, and part two where the doctors and pharmacists will have received our package of support to help them stop medicines patients no longer need.

You will only be approached to take part **once**, either before the doctors and pharmacists receive the research package or after. The person taking consent will tell you which part you are in.

To tell whether the new package of support works we would like to know about your health and wellbeing. We will do this by looking at information in your NHS medical records and giving you some questionnaires to answer now and then again in a few months after you've left hospital. If you have a medicine stopped when you are in hospital we might also telephone you after you leave hospital to find out about your experience.

To help you decide whether you want to take part, further information about the research study is on the following pages.

FUNDED BY NIHR | National Institute for Health and Care Research

What will happen if I take part?

All participants (in part one and part two) will be contacted as follows:

While you are in hospital

We will ask you to sign a consent form to confirm that you have read the information in this sheet. You will then answer some questions about your health and wellbeing. You can give consent:

- On paper
- Online
- By phone (we will ask you to sign a consent form on paper or online if and when you can)

About 3 months after you leave hospital

We will telephone* you for about 20 minutes to:

- Ask again the questions about your health and wellbeing.
- Ask if you have had any side effects from your medicines.
- Ask how often you have visited a healthcare professional

*This can also be sent via post for you to complete yourself if you prefer not to be called.

Information we will collect from your medical records

We will look at information held in your different NHS medical records. This is so that we can tell if any medicines that were stopped in hospital are restarted for example by your GP. This will also tell us if any people taking part in the study have used any hospital services or have died. We will look at information in your NHS medical record from 1 month before your hospital stay until the end of the research study. To make sure the health information we are collecting about you is correct NHS England will link information held in your different NHS medical records for us using your NHS number, date of birth and postcode.

If you take part in part two (once the doctors and pharmacists have received the research package) we will also contact you as follows:

About a week after you leave hospital

If you have had a medicine stopped while in hospital someone from the research team will telephone you to find out about your experience. The telephone call will take about 10 minutes.

Extra activities

If you have the time and are interested we might ask you to tell us in more detail about your experience of having a medicine stopped in hospital. We will do this about 1 week after you leave hospital and again about 3 months later. You can do this by either telling us over the telephone or through a video call (e.g., Zoom or Microsoft Teams) which would last 15–20-minutes, or we can send you a short survey to either complete online or fill out and post back to us in a free post envelope. If you do it over the telephone the researcher you talk to will record the discussion so that it can be typed up to make sure we don't miss anything important. Nothing that can identify you will be typed up and then the video and audio recording will be deleted.

Why have I been invited to take part?

You are on a ward where the doctors and pharmacists are taking part in a trial. The doctors and pharmacists are using a support package to help them to stop medicines that people on the ward no longer need. We would like to see if this support package works by seeing if it improves your health and how you feel.

What are the possible benefits of taking part?

You will be helping the NHS and policy makers to understand whether the package of support works and is good value for money. This will help them to decide whether it's a good idea to make the package of support available in all NHS hospitals.

What are the possible disadvantages of taking part?

We do not think that there are any major disadvantages to taking part. You will be giving up some of your time to answer questions.

What about confidentiality?

Your information will be treated in absolute confidence. It will only be shared with members of the research team at the University of Leicester, University of East Anglia, the Norfolk and Norwich University Hospital NHS Foundation Trust, NHS England, who need to see it to link your records, and regulatory authorities for auditing and monitoring purposes.

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 of a name. Information about you will be securely stored for 6 years after the study has ended.

The University of Leicester (lead research university) is the data controller for this study which means that they are responsible for looking after your information and using it properly. Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the study to be

reliable and accurate. This means that we won't be able to let you see the data we hold about you.

To safeguard your rights, we will use the minimum personally-identifiable information possible. You can find out more about how the University of Leicester manages Personal Data by visiting www.le.ac.uk/ias. Principles of the General Data Protection Regulations 2018 will be followed with respect to data storage, processing, and destruction.

What happens when the study ends?

We will publish what we learn from the study in scientific journals and news articles for the public. This way other people can learn from our study. We might use direct quotes from what you say but will remove any information that could identify you.

Who is organising and funding the study?

The study is funded by the National Institute for Health and Care Research [NIHR200874]. The study is being organised by researchers at the Universities of Leicester (the lead university or 'Sponsor'), East Anglia, Leeds, Newcastle and York, and the Norfolk and Norwich and Cambridge University Hospitals Foundation Trust.

Who has reviewed the research?

This research has been reviewed and approved by an independent group of people, called a Research Ethics Committee. They are committed to protect the rights, safety, dignity and wellbeing of research participants.

What if I change my mind?

You can stop being part of the research study at any time without giving a reason by contacting the lead researcher at this hospital (see further information section for contact details). If you choose to stop, we will keep the information that we have collected up to the point of withdrawal. We will not contact you again.

What if there is a problem

If you are worried about any aspect of the study you can speak to the lead researcher for the study at this hospital (see contact details below) who will do their best to answer your questions. If you have worries about how you have been approached or treated during the study or you would like to make a formal complaint you can contact the hospital's Patient Information and Liaison Service (PILS) by telephoning [PHONE NUMBER] or emailing [EMAIL ADDRESS].

In the unlikely event that you feel that you have been harmed during the study and that this is due to someone's negligence, then you may have grounds for a legal action for compensation against the University of Leicester. However, you may have to pay your legal costs as there are no special compensation arrangements for this study. The normal NHS complaints process will still be available to you.

For more information

The lead researcher for the study at this hospital is [Site Principal Investigator name] who may be contacted by emailing [Site Principal Investigator email address].

To find out more information about the CHARMER research programme, please visit www.CHARMERstudy.org, follow @CHARMERstudy on Twitter or email CHARMER.study@leicester.ac.uk.

You will be given a copy of this information sheet and the consent form to keep.