OXFORD



NHS logo

A study comparing two different ways of looking after older people in hospitals to see if we can improve how quickly they go home

INFORMATION SHEET FOR PATIENTS

We would like to invite you to take part in a research study. It is important for you to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Please take time to decide whether you wish to take part.

What is the purpose of the research?

It is common for older people to feel worried, down or confused when they are in hospital. These problems can lead to longer hospital stays. We are doing research to compare two ways of looking after older people who have been admitted to hospital to see if we can improve how quickly they go home.

Why have I been invited to take part?

We are inviting you to take part because you are aged 65 or over and you have recently been admitted to hospital. We will recruit 3,300 patients to take part in this study.

Do I have to take part?

It is up to you to decide if you want to take part. If you do decide to take part, we will ask you to sign a consent form. You are free to withdraw from the study at any time, without giving a reason, by calling 01865 618226 or emailing pmr@psych.ox.ac.uk. Withdrawal will not affect your treatment from the NHS in any way.

Patient PIL
The HOME Study
Chief Investigator: Prof Michael Sharpe

Version 2.0 17/10/2017 IRAS ref: 205376 REC ref: 17/SC/0497

What are the two types of care in this study?

Half of the study participants will get usual NHS care. This means that you will be looked after by doctors, nurses and other staff in the usual way during your hospital stay. The other half will get usual NHS care and they will also see a doctor or nurse who specialises in psychological problems – they will talk to you to find out if you have problems such as worries or confusion that might delay your discharge from hospital and will make a plan to help you with these. The type of care that each patient gets is chosen randomly (by chance, using a computer) to make the comparison fair.

What else will I be asked to do?

A member of the research team will contact you in one month's time and three months' time to complete a brief questionnaire, either over the telephone or face-to-face. It will take about 15 minutes to complete and will ask you about how you are feeling and the things you are able to do. A relative or friend can help you do this if needed. We will ask your permission to collect information from your medical records. We will also ask your permission to send your details to NHS Digital so that they can give us information about your health and healthcare use. If you do see a doctor or nurse who specialises in psychological problems, we may also ask you later to talk to one of our researchers about how you found this. This separate interview (a call or home visit) will last about 30 minutes - it is entirely optional and you can take part in the study without agreeing to an interview. We will ask about 80 people to do this part of the study.

How will taking part affect me and others (possible benefits and disadvantages)?

Taking part will involve talking with our research team and allowing them access to your information. You may see an additional doctor or nurse who specialises in psychological problems. However, we do not know if this will help you get home more quickly; that is why we are doing the study. The aim of the study is to find out how best to care for patients like you in the future.

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What if something goes wrong?

In the unlikely event that you suffer any harm as a direct consequence of your participation in this study, the University of Oxford, as Sponsor, has appropriate insurance in place. NHS indemnity operates in respect of the clinical treatment which is provided. If you wish to complain about any aspect of the way in which you have been approached or treated during the course of this study, you should contact Dr Jane Walker (jane.walker@psych.ox.ac.uk, 01865 618226) or you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 572224, or the head of CTRG, email ctrg@admin.ox.ac.uk. The Patient Advisory Liaison Service (PALS) is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. PALS is unable to provide information about this research. If you wish to contact the PALS team please contact <local PALS number to be inserted>.

Is the information collected about me confidential?

All the information that we collect will be sent to our central study office in the University of Oxford where it will be securely stored. Responsible members of the University of Oxford and your hospital trust may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations. If this does happen they would also keep your information confidential. NHS Digital will be sent basic details about you (such as your name, date of birth, NHS number) so that they can send us the information they hold about your health and healthcare use. They will also send us information about any study participants who have died. NHS Digital exists to improve health and care by providing national information, data and IT services for patients, clinicians, commissioners and researchers. It also obtains mortality data on NHS patients from the civil registration data held by the Office for National Statistics. NHS Digital has a legal responsibility to securely look after all the data it collects and maintains. The study analyses will be done by members of the research team who are based at the London School of Hygiene and Tropical Medicine and the University of York – they will be sent participants' information in a secure way to enable them to do this. In addition, if you take part in an interview the researcher will audio-record this and delete the recording after the study has been analysed. We will give talks about the study results and publish them in medical journals, and we will put a summary of the results on the study website – we will only use your information, including any

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quotes from interviews, in a way that means you will not be individually recognisable. We will keep your information for 5 years from the end of the study then delete it.

Who are the researchers?

The doctor in charge of the study is Professor Michael Sharpe at the University of Oxford. The research is funded by the NIHR HS&DR (National Institute for Health Research Health Services and Delivery Research) programme. Your local doctors and healthcare professionals will continue to look after you if you take part in the study.

Who else will be told I am taking part?

We will inform your GP you are taking part and about any relevant clinical information.

Will I be paid?

You will not be paid for taking part.

Who has reviewed the study?

All research in the NHS is looked at by independent groups of people, called Research Ethics Committees in order to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given a favourable opinion by the Oxford C Research Ethics Committee.

Can I get an independent opinion about this study?

If you wish to speak to a doctor who is independent of the research you may discuss the study with your own hospital doctor.

How have patients and public been involved so far?

Patients and carers have been involved in designing this study. We have a panel of patients, carers and members of the public who will continue to be involved in the study.

Who do I contact?

If you would like more information or if you are already taking part and need to speak to us, please contact us on 01865 612284 during office hours or email us at pmr@psych.ox.ac.uk. If you need urgent medical advice please contact your doctor in the usual way.

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Thank you very much for your help.

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