



Participant Information Sheet – What will happen if I take part?

You are being invited to take part in a research study called HERO, which is taking place in this hospital.

Before you decide if you want to take part, we would like to explain why the research is being done, how we will use the information we collect, and what the study would involve.

Please read this information carefully, and discuss it with your relatives and friends if you would like to. Ask us if anything is unclear, or if you would like more information. Take time to decide whether or not you wish to take part.

Once you have read this information, your Nurse, Physiotherapist or Researcher will talk to you about the study again and you can ask any questions you like.

What measures are we taking against COVID19?

We are following national and local guidance on COVID 19. This includes using personal protective equipment (PPE) and special considerations for vulnerable people:

- All staff coming to your home will be trained in infection prevention, will be wearing appropriate PPE, and will use hand gel when entering and leaving your home.
- If you have received a ‘Shielding’ letter from your GP or hospital at any time, please let us know so we can discuss study participation with you.
- If, at any time during the study, you receive new advice from your GP or other healthcare professional that you should be ‘shielding’ please let us know and we will speak with you about delaying or stopping home visits until national or local guidance advises us it is safe to continue. We will continue to contact you by telephone where appropriate and possible.

Your safety is extremely important to us at all times, if you have any questions about this please ask us.

Contact Details

If you have any questions about this study please ask; Principle Investigator: Professor Andy Clegg. Local Researchers: **XXXXXXXXXXXXXXXXXXXXXXXXXX**

What is the purpose of the study?

The purpose of our study is to assess whether a programme of exercises that can be undertaken at home is effective at improving quality of life, mobility and day to day living activities.

The programme of exercises is called the Home-based Older People's Exercise (HOPE) programme. It is provided by a physiotherapist in a person's home, with a total of 5 home visits and additional support available over the telephone.

To assess the effect of this programme we need to compare it to usual care after discharge, therefore we will put people into two groups, with only one group taking part in the exercise programme.

Why have I been chosen?

We are inviting people aged 65 years or over, who have been admitted to hospital following illness or injury to take part.

Do I have to take part?

No, your participation in this study is voluntary and you may withdraw your consent to take part at any time, without giving us a reason.

If after reading this information you decide to take part you will be given this information document to keep. You will be asked to sign a consent form to document your willingness to take part.

With your consent we will inform your GP that you are taking part in the study. If you decide not to take part, your treatment and care will not be affected in any way.

If I want to, will I definitely be able to take part?

Unfortunately, no. Although we think you might be suitable to take part, will still need to ask you some questions, and ask you to complete some tests. These questions are known as "eligibility screening tests" and are used to ensure that the study is appropriate for you.

These tests will include asking you to complete a short walking assessment, and answer some questionnaires about your current health status.

If the eligibility screening tests show that it is not appropriate for you to take part we will discuss this with you and will keep a record of why you were not able to take part.

Will my taking part be kept confidential?

If you decide to participate, the information collected about you will be handled strictly in accordance with the consent that you have given and also the 2018 Data Protection Act. However, if we have concerns that you, or someone else is at risk of harm then we may break confidentiality and tell the relevant healthcare services

What will happen to me if I agree to take part?

1. If you agree to take part we will ask you to complete some tests and answer some questions to ensure you are eligible to take part – these are the "eligibility screening tests".
2. If you are found to be eligible we will ask you a few more questions about your current quality of life, day to day activities, and use of care services, such as GP visits or district Nurse support.

This information will be completed with you whilst you are in hospital. We may also ask your care team some questions about your current hospital stay, and may review your medical records, with your permission.

3. When we have completed all the information, and you are ready to be discharged home, we will use a computer programme to randomly allocate you to either usual care only, or usual care plus the HOPE programme.

No-one will be able to pick which treatment you receive. In this way, a fair comparison can be made.

4. Following your discharge from hospital we will write to you to confirm which group you have been randomly allocated to.

Your local researcher will not know what you are allocated to, so please do not tell them if you speak to them once you have been discharged home.

If you are allocated to usual care plus the HOPE programme

4a. A therapist will contact you to arrange a home visit. During the home visit your therapist will teach you some exercises and answer any questions you may have. You will receive a total of 5 home visits over 12 weeks, with telephone support available for a total of 24 weeks.

You will also be asked to keep a record of the exercises you do every week in a diary that we will give you. The diary will be used to record the types of exercises completed, how many times those exercises were repeated, and on what days.

At the end of the 24 weeks we will ask you to complete a questionnaire to review your experience of the HOPE programme and ask you to return this to the study co-ordinator through the post with your exercise diary.

If you are allocated to usual care only

4b. Your care will continue as normal from your usual care team (i.e. GP).

5. We will contact you again 6 and 12 months after you agreed to take part to ask you some questions to see how you are getting on. With your permission we may also obtain information from your medical.

As a small token of our appreciation for your continued support of the study you will receive a gift voucher with each questionnaire.

What happens at the end of the study?

Once everyone has finished taking part in the study we will analyse the information we have obtained and will inform you of the outcome by writing to you. We will also publish study findings in medical papers. You will not be personally identified in any reports or publications. However, with your permission, we may use direct quotations from discussions.

If you were randomly allocated to the HOPE exercise programme you will be under no obligation to continue with the exercise programme. If you found the exercises beneficial we will leave you with the exercise manual so that you are free to continue. In line with Good Clinical Practice guidelines, at the end of the study, your data, including personal details such as name and date of birth will be securely archived for a minimum of 10 years. Arrangements for confidential destruction will then be made.

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

You are free to withdraw from taking part in the study at any time, without giving a reason. Information collected about you up to the point of withdrawal will still be included in the final study analysis, unless you request otherwise.

Who is organising and funding the research?

This study is collaboration between the Academic Unit for Ageing & Stroke Research (AUASR) at Bradford Teaching Hospitals Trust, the Clinical Trials Research Unit (CTRU) at the University of Leeds, and the University of Exeter. This study is funded by the Department of Health (National Institute for Health Research).

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given favourable opinion by the Bradford and Leeds Research Ethics Committee.

What if there is a problem?

We will take seriously any concerns you may have about the way you have been dealt with during involvement in this study, or if you think you may have suffered harm from the study. In the first instance, you should raise your concerns with the doctor, nurse, therapist, or researcher. If you remain unhappy and wish to complain formally, you can still do this through the normal NHS complaints procedures. Details can be obtained from your hospital, or your local Patient Advisory Liaison Office (PALS). There are no special compensation arrangements in place for this study.

Thank you for taking the time to read this information!

