



Participant Information Sheet

What information will we collect?

You have been invited to take part in a research study called HERO, and have expressed an interest in taking part.

Before you decide if you want to take part, we would like to give you some further details about the information we plan to collect, how this information will be collected, by who, and what will happen to it.

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.

Contact Details

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

XXXXXXXXXXXXXXXXXX

What information will you collect about me?

As part of the HERO study we hope to;

1. Ask you to complete some questionnaires about you,
2. Ask your care team some questions about your current hospital stay,
3. Collect information about your care from electronic health records, for example visits to see your GP or attend hospital related to your rehabilitation.

We may also ask you some questions about your experience and care following agreeing to take part through discussions with a Researcher.

How will you collect this information?

Questionnaires

If you decide to take part we will ask you to complete 3 questionnaires over a total of 12 months.

The first will be completed with you once you have agreed to take part, with the support of your local researcher.

The other two questionnaires will be sent to you through the post at 6 and 12 months after you have been discharged from hospital.

If you would like any help to complete these postal questionnaires we can arrange for your local researcher to contact you to either complete them over the phone, or visit you at home. These questionnaires will ask you about your day-to-day activities, quality of life, and use of care services.

Care Team

If you agree to take part we may ask your care team to help your local researcher answer some questions about the care you have received. This will mean they will review your medical records.

Electronic Health Records (EHR)

Your medical records are held electronically by your GP practice and your hospital. There are different systems that can be used to hold data, dependent upon your care provider.

Therefore we are asking for your permission to access all these systems so we can ensure we are able to collect the information we require.

Systems that hold your medical data include;

Hospital records: NHS Digital holds records of all patients admitted to NHS hospitals in England – this data is known as ‘Hospital Episode Statistics’ or ‘HES’.

Office for National Statistics (ONS) holds information on date and cause of death.

GP records: Most GP practices hold electronic health records (in systems called SystemOne, EMIS Health or VISION) with information about your care provided by your GP and medications.

With your agreement we would like to access your data information held in these electronic records to avoid asking you more questions about your recent care. To do this we need to send your identifiable data (for example, your NHS number, date of birth, postcode, sex and initials) to each system provider to obtain the correct information from these records.

Discussions with you

If you agree a Researcher may contact you to discuss your experience of taking part in the study, and the care you have received at a convenient time and place for you. Your friends and family may be involved in

these discussions if they want to be. These discussions may be recorded using a voice recorder to help the Researcher so that they do not need to take lots of notes.

What happens if new information becomes available?

We will keep you updated regarding study progress and access to your data with regular newsletters. Additional information will also be available on the study website; <http://www.bradfordresearch.nhs.uk/research/HERO/86>. You can also contact the study team for updates at any time using the contact details on page 1.

Will my information be kept confidential?

Bradford Teaching Hospitals NHS Foundation Trust is the sponsor for this study based in the United Kingdom. We will be using information from you and/or your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Bradford Teaching Hospitals NHS Foundation Trust will keep identifiable information about you for 10 years after the study has finished.

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 research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

The Clinical Trials Research Unit, University of Leeds (CTRU) will collect information from you and/or your medical records for this research study in accordance with our instructions. Your data will be entered onto a secure database held at the CTRU. All access to data and databases will be restricted just to the staff who require access to process and analyse the data.

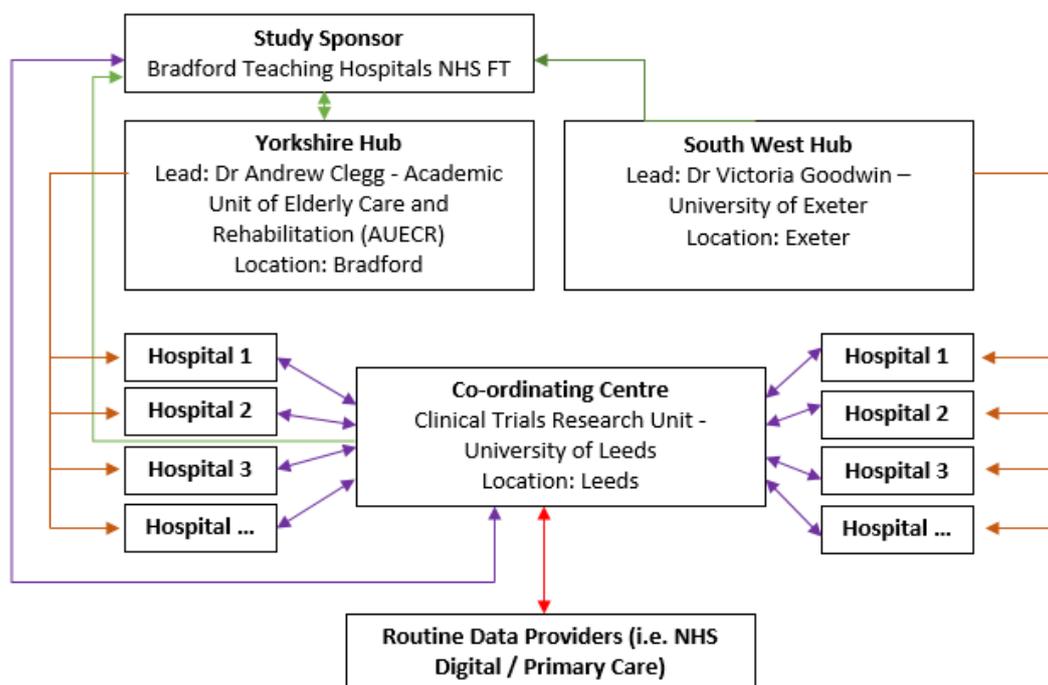
Most of the information needed for the study will be collected on paper forms and sent (usually using standard Royal Mail post but in some cases by email) to the study co-ordinator at the Clinical Trials Research Unit (CTRU). You will be allocated a study number, which will be used along with your date of birth and initials to identify you on each paper form instead of your name.

If you take part in discussions with a Researcher, audio recording of the discussion will be transported securely to the trial teams at the Academic Unit of Elderly Care and Rehabilitation (AUECR) and the University of Exeter - where the Researchers are based. It will be stored safely in the research office there, and only members of the research team will be able to access it. Recordings will be transcribed into a written format, with any personal identifiers removed – which means they would not identify you in anyway. If you agree, anonymous quotes from your discussions with the Researcher may be included when we share the findings of the study, in either written or spoken form.

The CTRU, AUECR, and the University of Exeter will be responsible for ensuring that information collected about you is kept safe and secure.

Your data may be used in future by the organisations involved in this research for evaluation, teaching and training purposes relating to the provision of NHS care and treatment, and for academic and non-commercial research purposes. If this happened, the information would be anonymised so that no-one would be able to identify you from it.

How will my information be stored?



Information collected about you will be processed by a study data manager and study statisticians at the CTRU and entered and stored on CTRU systems. Your information will only be accessed by the research team. Identifiable data will not be accessed by any third parties outside the research team unless in accordance with the consent given. All the data you give us, including personal details such as name and date of birth will be securely stored for up to 10 years after the end of the study and then destroyed.

Audio recordings will be securely stored where the Researcher is based (AUECR or University of Exeter). These recordings will be stored until the end of the study, and then securely destroyed.

Will you share any of my information?

The information collected about you may be shared with other research teams to answer new research questions in the future. Wherever possible, information will be anonymised – which means they would not identify you in any way.

We will share identifiable information when requesting information from Electronic Health Records to ensure we collect the correct information. Information will be securely shared, with these system providers also working in accordance with the Data Protection Act 2018.

Although the information we collect about you is confidential, should you disclose anything to us which we feel puts you or anyone else at risk, we may feel it necessary to report this to the appropriate persons.

Where can I find out more about how my information is used?

You can find out more about how we use your information

- at www.hra.uk/information-about-patients/
- a leaflet is available from www.hra.nhs.uk/patientdataandresearch
- by contacting the trial manager: Matthew Prescott Tel 01274 383424; email matthew.prescott@bthft.nhs.uk

- Bradford Teaching Hospitals NHS Foundation Trust Privacy Notice is available to read at <https://www.bradfordhospitals.nhs.uk/privacy-statement/>

What if I decide I no longer want to take part?

You are free to withdraw from taking part in the study at any time, without giving a reason. If you withdraw consent from further study treatment, information collected about you until that point will still be collected and included in final study analysis, unless you request otherwise. If you withdraw consent for further data collection, information collected about you until that point will remain on file and will be included in final study analysis. If you no longer wish to take part please contact your local researcher (contact details on page 1) and they will be able to process your request.

If you wish to stop completing questionnaires, we will stop asking you to complete them. You can still take part in the trial if you stop these and you can change your mind later and start completing them, if you want.

Unless you clearly tell us you don't want us to, we will continue collecting information about your health from routine visits, via your GP or through other contact between you and your hospital. This is to ensure the results of the study are valid.

Thank you for taking the time to read this information!