Core outcomes for research on Postoperative Periprosthetic Femoral Fractures (PoPFF COS study)

Participant Information Leaflet: Healthcare Professionals and Researchers

We would like to invite you to take part in a research study which is being conducted by the Musculoskeletal Research Unit at the University of Bristol. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. You may want to talk to others about the study before taking part.

What is the purpose of the study?

We are looking for people who have experience working with or researching Post-operative Periprosthetic Femoral Fractures (PoPFF) to share their opinions on how we should measure the success of treatment.

Who do we want to take part and why?

We want to make research and treatment more effective. Ideally, we would like to involve people from a wide range professions, researchers and clinicians.

Before you decide to take part, it is important that you understand why we are doing this research and what it will involve. Please take time to read the following information and talk to others about the study if you wish.

If anything is unclear or if you would like more information, please contact Rebecca Fox on behalf of the research team:

Email: pv24764@bristol.ac.uk | Phone: 01271 314077.

Why are we doing this study?

Unfortunately, we don't yet know the best way of measuring the results (outcomes) after treatment of these injuries. Until now, studies have been done in many different ways. This makes it difficult to compare them. We need to be able to compare studies so we can find the best way of treating a periprosthetic fracture.

We aim to develop a list of key outcomes of treatment (known as a 'Core Outcome Set' or COS) so that all future research on periprosthetic fractures can be measured in the same way. It is important that the opinions of all professionals who work with patients with periprosthetic fractures on which outcomes are important are strongly represented, alongside the opinions of patients and caregivers themselves.

What does taking part in the study involve?

There are two stages to get involved in this study. You can choose to be involved in only the first stage or both. The stages include:

- **Stage One: an online or paper survey** (we need a minimum of 60 people for this). We will invite you to do an online survey online. We will ask you to rate on a scale of 1-9 how important you feel different outcomes are when recovering from a periprosthetic fracture based on your own experience. You will also have a chance to suggest other outcomes you feel have been missed.

  There will then be a second survey which will feedback the results from the first round of the survey and ask you to rate how important you feel the outcomes in the revised list.

  Each survey will take a maximum of 20 minutes to complete.

- **Stage Two: Two consensus meetings** (we need a minimum of 10 professionals from a range of backgrounds for this). The meetings are likely to last 5-6 hours with a long break for lunch. The meetings will be held at an accessible location, with lunch provided, and travel expenses for car mileage, standard class rail travel, and parking charges may be supported. We are unable to recompense for your time. We aim for a varied group of patients, caregivers, healthcare professionals including surgeons, doctors, nurses, physiotherapists and researchers, to be there. If necessary, we will also have facilities for people to attend virtually over video conferencing.

At the first meeting, we will discuss the outcomes people have told us are important in the online survey. After discussion, we will decide what outcomes we think should be used in future research studies. We will vote on these.

At the second meeting, we will explain and discuss the possible options to measure these outcomes. We will then invite you to help us choose how we should measure the outcomes that we decided are important (at meeting 1).

We will ask your permission to make an audio-visual recording of these meetings using the record function on the videoconferencing software. This will provide an autogenerated transcript of the meeting to support recall of the discussion for the researcher when reporting the study. The recording will be deleted as soon as the transcript has been checked for accuracy by the research team .

What are the possible benefits of taking part?

There are no direct benefits of agreeing to take part in this study. Your contribution will help us do future research and make it more effective and efficient.

What are the possible disadvantages and risks of taking part?

Agreeing to help will take some of your time. For the survey, this will be approximately 20 mins each time. For the consensus meetings, we will send you documents to read before you come. These documents may take up to 30 minutes to read. Each meeting will be a day with lunch and payment for travel.

If you agree to take part, we will need to record some basic personal information. This is so that we can contact you to invite you to join in with different parts of the study and give feedback about the study results. Data protection laws will guide the handling of all personal data (see below for further information).

Do I have to take part?

No. You decide whether or not you want to take part in this study. You are welcome to keep this leaflet and use it to help you decide.

If you participate in the surveys, the first page of the survey will ask you to confirm your agreement to participate. If you wish to take part in the consensus meetings, we will ask you to sign a consent form on the day you attend the meeting. Additionally, if you would like to attend the consensus meeting, we kindly ask that you complete both the survey rounds beforehand.

You are free to leave the study at any point without giving a reason and without any adverse consequences. If you decide to take part and then withdraw, the data you have provided up to that point will continue to be included in the study.

Who is organising and funding this study?

This study is a collaboration between the Musculoskeletal Research Unit, University of Bristol, Southmead Hospital https://www.bristol.ac.uk/translational-health-sciences/research/musculoskeletal/ and the NIHR Exeter Biomedical Research Centre https://www.exeter.ac.uk/research/biomedicalresearchcentre/

The research team includes researchers and clinicians, such as orthopaedic surgeons and physiotherapists. This study is being funded by The Academy of Medical Sciences and Orthopaedic Research UK (ORUK)

What will happen to the results of this study?

The results of this study will be used to develop a 'Core Outcome Set' for use in research studying different treatment options for periprosthetic femoral fractures. This will be shared with the health research community and is intended to be published and presented at conferences. Participants will not be identifiable in any publications, reports or presentations from this work. Anonymous direct quotations may be published.

All participants will be provided with a summary of the findings of this research study at the end of this project.

Who has approved this study?

A group of expert researchers and patient representatives has approved this study.

All research in the NHS is looked at by an independent group of people, called a Health Research Authority Research Ethics Committee, to protect participants' interests. This study has been reviewed and given a favourable opinion by Yorkshire & The Humber – Leeds West Research Ethics Committee (REC Reference 26/YH/0034).

How will we use information about you?

We will need to use the information from you for this research project.
This information will include your name, preferred contact details, age, gender, ethnicity, job role and the capacity in which you have experience of PoPFF. 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.

The University of Bristol is the sponsor of this research. This means the University of Bristol is responsible for looking after your information. We will share your information related with this research project with the University of Exeter collaborators in the study.

We will keep all information about you safe and secure by:

- Keeping your personal identifiable information separately from your survey responses.
- Using a 'study ID' or "code number" in place of your name when storing your survey responses.
- Storing all study information secure University of Bristol servers.

Your contact details such as your name and contact details will be kept for one year after the study has ended. We will ask if you agree for us to contact you for future research. If you agree for us to contact you for future research, we will keep your personal information for 5 years from the end of the study. This will be held securely at the University of Bristol and will only be used to contact you with information about research to improve care for people who have a fracture after joint replacement.

International transfers

Your data will not be shared outside the UK

How will we use information about you after the study ends?

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study. We will keep your study data for a maximum of 10 years. The study data will then be fully anonymised and securely archived or destroyed.

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.

You have the right to ask us to access, remove, change or delete data we hold about you for the purposes of the study. You can also object to our processing of your data. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- From the Health Research Authority leaflet: www.hra.nhs.uk/patientdataandresearch
- By asking one of the research team

- By sending an email to pv24764@bristol.ac.uk
- By ringing the University of Bristol Data Protection Officer on 0117 39 41824

What if I have concerns?

If you have any concerns or complaints about any aspect of the study, please contact the University of Bristol Research Governance office at:

research-governance@bristol.ac.uk

THANK YOU FOR READING THIS INFORMATION LEAFLET

AND THINKING ABOUT TAKING PART