



Physiotherapy Rehabilitation for Osteoporotic
Vertebral Fracture

Participant Information Sheet for Research Study

Qualitative Section



National
Osteoporosis
Society



NHS
National Institute for
Health Research

Physiotherapy Rehabilitation for Osteoporotic Vertebral Fracture (PROVE)

What is the purpose of this study?

The PROVE team would like to find out more about why people decided to take part in the PROVE study and what they thought about taking part and the physiotherapy treatment they received. We would like to invite you to tell us your views about taking part in PROVE, and about living with osteoporosis and having a vertebral fracture/s to help the study team to explain the results of the study more fully, and to give other people in the same position as yourself information to help them decide whether to have physiotherapy treatment.

Why have I been asked to take part in this study?

You are being invited to take part in this project because you are taking part in the PROVE study, which is studying which type of physiotherapy treatment is most helpful to people who have osteoporosis. We would like to invite you to tell us your views on this subject to help the study team to explain the results of the study more fully and to give other people in the same position as yourself, information to help them decide whether to have surgery or not. There are no right or wrong answers to this – we are keen to hear a wide variety of opinions.

What will I have to do if I take part in this study?

If you decide to take part in the study you will be asked to discuss your views and experiences. A researcher would ask you for a one-off discussion about your views about the research study, the treatment you have received and about your experience of having

osteoporosis and a vertebral fracture/s. This discussion would last for 45-60 minutes and could either take place in your home or a local venue convenient to you as you prefer. If you choose to travel to a local venue then your travel expenses would be reimbursed.

The researcher would ask for your permission to audio record this discussion and to jot down some notes during this discussion to help them remember the discussion accurately (you can choose not to have the discussion recorded if you prefer).

Following the discussion the researcher will send you the discussion written out as a letter. This means that you can check what is written down and to add or comment upon any other things you wish to say. If you would like to discuss this with the researcher on the telephone then you can let her know and she will telephone you at a convenient time for you.

What are the benefits of taking part in the study?

There is no direct benefit to you in taking part in this study; although we have found in similar studies that people like to give us their opinions about their treatment to help people in a similar position.

Is there any risk of taking part in this study?

We do not anticipate any risks from your participation in this study and from you telling us about your experiences.

What if there is a problem?

If you have a concern about any aspect of this study, please speak to the researchers who will do their best to

answer your questions [REDACTED]
If you would prefer to speak to someone not involved in the study then you could contact the Patient Advice and Liaison Service [REDACTED] If you remain unhappy and wish to complain formally, you can do this by contacting The Chief Executive, Oxford University Hospitals NHS Trust, Headley Way, Headington, Oxford, OX3 9DU. [REDACTED] In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against Oxford University Hospitals NHS Trust, but you may have to pay your legal costs.

Would anyone else know if I was taking part?

We will follow ethical and legal practice and all information about you will be handled in confidence. We remove any personal information from the audio recording and we give each discussion file a number (rather than using your name). We will keep this information (on a password protected computer) until one year after we have published the results (so we can help anyone contacting us with any questions) and then we will destroy your file. We keep your personal contact details in a separate place (in a locked filing cabinet in a locked office) so that we can send you a letter telling you about the results of this study. We will then destroy these paper files after we have posted you this letter. Your continued involvement in the PROVE study and your future NHS care will not be influenced in any way by your taking part in this part of the project.

Do I have to take part in this study?

It is up to you to decide to join the study. We will describe the study and go through this information sheet. If you

agree to take part, we will then ask you to sign a consent form. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive.

What will happen to the results of the study?

We plan to publish the results of the study in a medical journal to help other patients in the future. Although there is a possibility that you may recognize your own quotes if you read the final paper, we take the greatest care to ensure that no one else reading the results would ever know your identity. We would also present the results of the study to a scientific conference for doctors and physiotherapists to make sure that health professionals know your thoughts.

Who approves this study and who is funding the research?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by South Central Research Ethics Committee (12/SC / 0411) and by the Research and Development Committee at the Oxford University Hospitals NHS Trust. This research has been funded by the National Institute of Health Research's Health Technology Assessment Programme.

Who do I contact for further information?

If you would like any further details about this study or would like to ask us any questions then please do not hesitate to contact us. You may speak to the research team on [REDACTED] between 8 am and 5 pm on weekdays or email [REDACTED]

What do I do now?

If you are interested in taking part in this study then please fill in the reply consent slip and post it to us in the pre-paid envelope provided. You will then be contacted by a member of the research team who will discuss the study with you and arrange to meet you.

Thank you for taking the time to read this information