

Physiotherapy Rehabilitation for Osteoporotic Vertebral Fracture (PROVE)

What is the purpose of the study?

This is a study about how best way to treat patients with osteoporosis. The PROVE team have been funded to investigate different types of physiotherapy treatments comparing exercise, 'hands on' manual therapy and advice to find out which type of physiotherapy is the most beneficial to offer people with osteoporosis who have a vertebral fracture.

Why have I been asked to participate?

You have been invited to take part in this study because you have osteoporosis.

Do I have to take part in the study?

It is up to you whether or not to take part. If you decide not to take part then your future medical care will not be affected in any way. You are also free to ask the researchers any questions you may have at any time during the study. If you decide to take part you would be given this information sheet to keep and be asked to sign a consent form.

Who can take part in the study?

Men and women with one or more vertebral fractures and osteoporosis can take part in the study if they:

- Have had their diagnosis of osteoporosis confirmed by an X-ray or bone (DEXA) scan
- May have had a vertebral fracture and/or back pain associated with osteoporosis lasting for more than 24 hours in the last 12 months
- Can walk at least 10 metres (with or without a walking aid)
- Have not had physical therapy (physiotherapy, osteopathy, chiropractic treatment) for back pain in the previous 12 weeks

What will happen if I take part in this study?

You will be asked to go to your local clinic and take part in a physiotherapy assessment. The physiotherapist will ask some questions about your osteoporosis and back pain and you would be asked to fill in questionnaires about how osteoporosis affects your daily life, about falls and activity levels. We would look at the curves of your spine, back strength, balance, walking, getting up from a chair and standing posture. This should all take about an hour.

When it is not known which treatment is best, the treatments need to be compared to each other. When participants join the study they will be allocated to one of three treatments and the allocation will be decided entirely by chance. A computer programme is used to ensure this.

The three treatments are:

- Best current practice. An advice session lasting up to one and a half hours with a physiotherapist who will provide advice about osteoporosis and discuss lifestyle choices and living with osteoporosis.
- Manual therapy. This includes gentle (pain free) "hands on" treatments, tape being used to help people maintain a better posture and a home stretching

programme. Up to 7 individual sessions with a physiotherapist will be offered over a twelve week period.

- Exercise. This includes balance, strengthening and stretches exercises. Up to 7 individual sessions with a physiotherapist will be offered over a twelve week period.

To be able to compare the three treatments we need to repeat the questionnaires and assessments after you have received your treatment. We will ask you to come back to clinic at approximately 16 weeks after you have joined the study, and again at one year. Also, we will ask you to complete the questionnaires again at 6 and 9 months and post them back to us (in a prepaid postage envelope).

Will I have to do anything at home as part of the study?

Depending on the group you are allocated you will be asked to carry out a home exercise program and fill in patient diaries to log the exercise program as well as fill in a calendar provided to you to log any falls and medical attention needed through the duration of your participation in the study.

Expenses and payments

Travel expenses (public transport, car mileage, car parking) will be reimbursed when coming to clinic for a research assessment.

What are the benefits of taking part in the study?

We do not expect any particular benefits from taking part. The information we get from this study will help us to treat future patients with vertebral fractures due to osteoporosis.

Is there any risk of taking part in this study?

There are no "new" treatments included in this study. The treatments are those already used with patients with osteoporosis.

Will anything change during the study?

We will be monitoring the participants carefully during the course of this study. An analysis will be performed after 70 patients are recruited into each treatment arm. If it is shown that one of the treatment arms is considerably less effective than the others we will stop recruiting any further participants into this treatment arm. Any existing participants will continue in this treatment arm until their participation finishes.

What happens when the study ends?

We will inform your hospital /GP of the treatment that you have received and they will continue to treat your osteoporosis if / as appropriate.

What if I have any concerns?

If you have a concern or problem about any aspect of the study please speak to any one of the researchers who will do their best to answer your questions. Their contact details at the Physiotherapy Research Unit are at the top of this patient information sheet. You may also contact the hospital's Patient Advice and Liaison Service [REDACTED] or email [REDACTED].

What if there is a problem?

The University has a specialist insurance policy in place which would operate in the event of any participant suffering harm as a result of their involvement in the research (Newline Underwriting Management Ltd, at Lloyd's of London, policy numbered :WD1200463). NHS indemnity operates in respect of the clinical treatment which is provided.

Complaints statement

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 Karen Barker at [REDACTED] or at [REDACTED] you may contact the

University of Oxford Clinical Trials and Research Governance (CTRG) office on [REDACTED] or the head of CTRG, email [REDACTED]

Will my taking part in this study be kept confidential?

All information that is collected about you for the study will be kept strictly confidential. We will ask you for your permission to look at your medical notes (so that we can check details such as bone scan findings). Information will be held in a secure place and questionnaire and assessment information sent from your local clinical site to the trial team will have your name and address removed first

All information will be securely stored for five years after the study has ended and then be destroyed.

Responsible members of the University of Oxford or the NHS Trust may be given access to data for monitoring and/or audit of the study to ensure we are complying with regulations.

What if new relevant information becomes available?

If new relevant information about physiotherapy treatments for vertebral fracture becomes available then your physiotherapist clinician or a member of the study team will tell you about it and discuss with you whether you want to continue in the study. If the study team believed it would be in your best interest for a person to withdraw from the study they would also discuss this with you. Your hospital/GP would be informed. If you decided to continue with receiving a study treatment you would be asked to sign an updated consent form.

What would happen if I don't want to continue with the study?

You can withdraw from the study at any point. You would be asked which type of withdrawal you would prefer – you can choose between leaving the study and allowing the information already given to be used by the study team OR leaving the study and asking for the information already given by you to be destroyed. If you withdraw from the study this will not affect your future NHS care in any way.

Would anyone else know if I was taking part?

We would ask for your permission to write to your GP to tell them you are taking part in this study.

What happens to the results of the study?

The results will be used to write a report and health journal articles so that health care professionals can use the results to help other patients in the future. In any report or publication we will not use your name or give any information that could identify you. We will send out a summary of the results to people who take part in the study when the study is complete.

Who is organizing and funding the research?

The main person responsible for the research is Dr Karen Barker from the Nuffield Orthopaedic Centre in Oxford. It is sponsored by the University of Oxford and is being paid for by the National Institute of Health Research's Health Technology Assessment Programme who identified this as an important research question.

Who has reviewed this study?

The study was reviewed by independent experts when the study was being considered for funding. All research in the NHS is also 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 NRES Committee South Central - Portsmouth REC Number 12/SC/0411.

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 local PROVE team. For further information you can contact the Varsha Gandhi the study co-ordinator at [REDACTED] or on [REDACTED] email [REDACTED] or Tamsin Hughes on [REDACTED] email [REDACTED]

What do I do now?

REC 12/SC/0411

Patient Information Sheet
Version 6 27/03/2014

ISRCTN49117867



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If you would like to take part in this study then please fill in the reply consent slip and post it to us in the pre-paid envelope provided. If you have received this invitation in the post and we do not hear from you we will send you one further invitation.

Thank you for taking the time to read this Patient Information Sheet.