Insert local contact details e.g. TRUST LOGO (for multi-centre studies can be done once approval is in place)

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PARTICIPANT INFORMATION SHEET

OsteoPorosis Tailored exercise adherence INtervention (Opt-In)

We would like to invite you to take part in our research study. Before you decide, it is important that you understand why we are doing this research and what it would involve for you. Please take time to read this information and discuss it with others if you wish. *If there is anything that is not clear, or if you would like more information, please ask us.*

What is the purpose of the study?

This study will test if physiotherapy exercise treatment plus a personalised programme of techniques to encourage people to do their exercises regularly is of more benefit to patients compared to physiotherapy exercises alone.

Why have I been invited?

You have been invited to take part in this study because you have osteoporosis and have had a spinal fracture. We are looking to recruit at least 116 people to participate in this study.

Do I have to take part?

No, 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.

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

You will first be contacted by a member of the research team by telephone to discuss the study further and to ask you questions to check that you would be eligible to participate. At that point, with your consent, a research team member will review relevant parts of your medical notes to make sure you are eligible. If you are eligible and you are happy to take part in the study, you will be asked to attend the hospital research site closest to you to take part in a physiotherapy assessment.

The research physiotherapist will ask you some questions about your osteoporosis and back pain and you will be asked to fill in questionnaires about how osteoporosis affects your daily life, about falls and your activity levels. The research physiotherapist will measure the curves of your spine, your back and hand strength, and your balance and walking ability. This will all take about an hour and we will allow you to rest as needed as we go along.

While most assessments will take place at a physiotherapy department, some assessments or parts of assessments may be conducted via video-call or home visit. If we visit your home, we will follow all COVID restrictions policies and NHS trust protocols, e.g. personal protective equipment requirements.

What will happen to me if I decide to take part (continued)?

When it is not known which treatment is best, the treatments need to be compared with each other. When participants join the study, they will be allocated to one of two treatments and this allocation will be decided entirely by chance (randomly) to ensure there is no bias in the comparison. A computer programme is used to ensure this. The two different treatments are:

- Usual care – Your first appointment will last about 60 minutes and include a physiotherapy assessment. The physiotherapist will prescribe you a personalised exercise programme. You will be invited to a further six 30 minute outpatient physiotherapy treatment sessions to review and progress your home programme. Your treatment will be carried out over 16 weeks either in person, over the telephone or video call as agreed with your physiotherapist.

- Opt-in intervention – We will ask you to complete a questionnaire about your exercise preferences and treatment goals before you come to your first appointment. Your first appointment will last about 90 minutes and include a physiotherapy assessment and a discussion with the physiotherapist about your exercise habits and preferences. The physiotherapist will prescribe for you a personalised exercise programme and techniques to help you with completing your exercises. You will be invited to a further six 30 minute outpatient physiotherapy treatment sessions to review and progress your home programme, plus given a further 60 minutes of support and advice (spread throughout your treatment, as needed) focused on ways that help you complete your home exercise. Your treatment will be carried out over 16 weeks either in person, over the telephone or video call as agreed with your physiotherapist.

To be able to compare the treatments we need to repeat the questionnaires and assessments after you have received your treatment. We will ask you to come back to the research clinic at approximately 4 and 8 months after you joined the study, and again at one year. At these visits you will be seen by a researcher who will not know which group you were allocated to and what treatment you received; you will be asked not to reveal your treatment allocation to them.

In addition, we will also ask you to fill in a diary to record any time that you fall and if you need any medical care through the duration (1 year) of your participation in the study.

You may also be invited to take part in a series of short interviews for this study to discuss your experience and views on exercise and the Opt-In study. These may occur via video call or in person. Participation in these interviews is voluntary and you will be given more information before deciding to take part at a later date.

What should I consider?

You may not be able to take part in the study if you have a severe heart, lung or brain condition that would limit your ability to carry out the physiotherapy assessments and exercises. Similarly, if your bone loss is due to another condition such as rheumatoid arthritis or cancer, or if you are less than 1 year post-menopause, then you will not be able to take part in this study. Furthermore, if you have recently had physiotherapy in the last 3 months or if your back pain spreads down your legs you may not be able to carry out the study at

this point in time. People who are younger than 55 years old are also unable to partake in the study.

If you are unsure you can contact the research team who will be able to provide you with further information and confirm whether you can take part in the study.

Are there any possible disadvantages or risks from taking part?

It is not anticipated there are any risks from taking part in the study as none of the treatments offered are "new" to patients with osteoporosis. While sensitive topics may be discussed, we will provide information for additional resources if needed.

What are the possible benefits of taking part?

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.

Will my General Practitioner/family doctor (GP) be informed of my participation?

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

Will my taking part in the 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 securely 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 and the relevant NHS Trust may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

Will I be reimbursed for taking part?

You will not receive any compensation for your time in taking part in the study. However, reasonable travel expenses (public transport, car mileage, car parking) will be reimbursed on production of receipts if you are coming to the hospital for a research assessment.

What will happen to my data?

Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest.' The University of Oxford is the data controller and is responsible for looking after your information and using it properly. We will be using information from you and your relevant medical records in order to undertake this study and will use the minimum personally-identifiable information possible.

We will be using information from you and your medical records in order to undertake this study and will use the minimum personally-identifiable information possible. We will keep

identifiable information about you for 6-12 months after the study has finished. This excludes any research documents with personal information, such as consent forms, which will be held securely at the University of Oxford for 5 years after the end of the study.

The local NHS Trust will use your name, NHS number, home address, and contact details to contact you about the research study and to oversee the quality of the study. They will keep identifiable information about you from this study for a time in keeping with retention of medical records.

Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at:

https://compliance.web.ox.ac.uk/individual-rights

You can find out more about how we use your information by contacting the study team on 01865 737526.

What will happen if I don't want to carry on 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 (however if data that has already been included in analysis it cannot be withdrawn). In addition, if you decide to halt treatment, you can choose to remain in the study to participate in some of the follow-up questionnaires and assessments. If you withdraw from the study this will not affect your future NHS care in any way.

What will happen to the results of this 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.

What if there is a problem?

The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study. NHS indemnity operates in respect of the clinical treatment which is provided.

If you wish to complain about any aspect of the way in which you have been approached or treated, or how your information is handled during the course of this study, you should contact Professor Karen Barker on 01865 737526 or karen.barker@ouh.nhs.uk or you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 616480, or the head of CTRG, email ctrg@admin.ox.ac.uk.

The Patient Advisory Liaison Service (PALS) is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. PALS is unable to provide information about this research study.

If you wish to contact the PALS team please contact them on 18865 738126 or PALS@ouh.nhs.uk.

How have patients and the public been involved in this study?

Service users helped develop the research topic and what research questions should be asked and one of them is a co-applicant who will continue to be involved in the study.

You may also be interested in the following links to general information about taking part in research:

- www.crn.nihr.ac.uk/can-help/patients-carers-public/how-to-take-part-in-a-study/
- www.nhs.uk/Conditions/Clinical-trials/Pages/Introduction.aspx

Who is organising and funding the study?

The Opt-In study funding has been awarded by the Chartered Society of Physiotherapy Charitable Trust.

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 participants' interests. This study has been reviewed and given favourable opinion by _____Research Ethics Committee.

Further information and contact details:

Please contact the study team on < ENTER LOCAL SITE DETAILS >

Thank you for considering taking part.