LOCAL TRUST LOGO

Local Principal Investigator:

Contact details:

PATIENT PARTICIPANT INFORMATION SHEET

Tailored Exercise Management for People aged 80 years or older with hip/knee Osteoarthritis: a feasibility randomised trial.

We are working with researchers from the Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences at the University of Oxford. We would like to tell you about a study called TEMPO and ask if you would like to take part. The TEMPO study will try to find out if it is possible to do a large trial investigating a tailored exercise programme for people aged 80 years and older with hip and/or knee joint pain caused by osteoarthritis.

Before you decide, it is important that you understand why the research is being done and what it involves. Please take time to read this information carefully and discuss it with others if you want to. If anything is unclear, or you would like more information, please ask a member of the local study team, call the TEMPO team on 01865 737927, or email them on tempo@ndorms.ox.ac.uk. This leaflet explains why we are doing this research, what the study involves and exactly what being in the

study would mean for you. We hope it helps you decide whether you would like to take part or not.

What is the purpose of the study?

Exercise is recommended for all people with hip and/or knee osteoarthritis. However, these recommendations are based on clinical trials including people with an average age between 60 and 70 years, and we do not know if we can apply the results to people aged 80 or older. Having more than one health condition is common as we get older and can impact on your ability to exercise. We have developed an exercise programme called TEMPO for people aged 80 years and older with hip/knee osteoarthritis that is tailored to other common health conditions. In this small study we want to see if it is possible, and acceptable, to deliver this exercise programme.

Why have I been invited?

You have been invited to take part because you are aged 80 years or older and have hip or knee osteoarthritis and at least one other health condition. We are hoping to recruit 50 people to take part in the study. After the main study we will also interview up to 20 people who take part, and the physiotherapists who deliver the TEMPO programme, to understand more about people's experiences of being involved in this study.

Do I have to take part?

No. It is your choice you would like to take part. If you decide to take part you can change your mind and leave the study at any time without giving a reason. Leaving the study will not affect any care that you receive from the NHS or any other healthcare provider, or your participation in any other studies.

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

If you do decide to take part in the study, you will be invited to attend an assessment appointment at < Insert HOSPITAL NAME >. This appointment will take up to 1 ½ hours. A researcher will carry out some simple assessments to check whether you are eligible for the study. If you are eligible and you decide that you would like to take part, you will be asked to sign and date a consent form. You will then complete a questionnaire which asks about your symptoms, health and well-being, and to do some simple physical tasks.

You will be allocated to one of two treatments. A researcher will enter your details into a computer and a computer program will decide which group you will be in for the study. This allocation is made by chance. This is important because it ensures that the treatments are tested fairly, and no one can influence which group the computer puts you in. You will be told which treatment you are to receive at the end of your assessment appointment.

<u>TEMPO Treatment Group</u>

If you are allocated into the TEMPO Treatment Group, you will receive 4 to 8 sessions of outpatient physiotherapy. The first 4 sessions will be delivered by a physiotherapist at <Insert HOSPITAL NAME>, additional sessions may also be delivered at the hospital or they may be delivered remotely at your home via video or telephone. You and your physiotherapist will be able to discuss this closer to the time. The first session will be 60 minutes long and each following session will last for 30 minutes. Sessions will include exercises and a walking programme tailored to your individual needs. You will also be given a home exercise programme and any

equipment such as ankle weights that you may need to safely perform these exercises at home.

A researcher from the TEMPO team based in Oxford may attend some of your TEMPO physiotherapy sessions either in person or via video or audio recording so that we can check how the treatment is being delivered. This is only to ensure that the sessions are being run correctly.

Usual NHS Care Group

If you are allocated into the Usual NHS Care Group, you will continue to receive care as recommended by your GP. If you have already been referred to Physiotherapy you will have sessions as they think is appropriate for you. You will also be given a booklet about managing your hip or knee joint pain and suggested exercises.

Follow-up

Regardless of which group you were allocated to, you will be invited back to <Insert HOSPITAL NAME> to attend a follow-up appointment with the researcher, so that we can find out if the treatment has helped or not. We will ask you to complete a questionnaire that is similar to the one you completed at the beginning of the study. We will also ask you about any appointments you have had at the hospital or GP practice since joining the study and to do a physical assessment. This appointment will take approximately 1 ½ hours.

Optional Interviews

We would like to understand more about people's experiences of being involved in this study. To help us with this, we will invite some participants to have an interview with a researcher. This would involve a face-to-face or telephone chat with one of the

TEMPO researchers to ask about how you got on with the study, including the assessments and treatments, so we can use your opinions and experiences to make improvements for a bigger study. This interview would last a maximum of 1 hour and would be in a location which is convenient to you or completed over the telephone. These will be digitally audio recorded. Only 20 participants are required for these optional interviews so you may not be required for this part, however we may offer this opportunity to you once you have completed your treatment.

The interviews will be typed up by a professional transcription service so that they can be analysed. Recordings of the interviews will be destroyed following transcription. Quotes from the interviews may be used in the reporting of this part of the study. Any quotes used will be anonymised so it will not be possible to identify you. Copies of the anonymised typed transcripts will be kept in a secure place for a maximum of 5 years and then destroyed.

Taking part in these interviews at the end of the study is entirely optional. You will be asked to indicate if you are happy to be contacted about taking part in the interviews on the consent form you will sign before taking part in the study.

What are the possible benefits and risks of taking part in the study?

The information and exercises that you receive from either intervention may help your hip or knee joint pain. We hope the information we get from this trial will help in the treatment of future patients.

You are unlikely to be harmed by this treatment. If you attend physiotherapy they will assess you to make sure that the exercises are at the right level for you. However, you may find that you experience muscle soreness after completing some of the

exercises. This is normal and the physiotherapist will give you advice on how to manage this.

Sometimes people feel uncomfortable answering certain questions about their health. If there are any questions, from the Researcher, Physiotherapist or in the questionnaire that you are uncomfortable with then you do not have to answer them.

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

Yes. With your permission we will send a letter to your GP notifying them that you are taking part in the study. We will also notify your GP if there are any findings during assessment or your participation in the study that require follow up.

Will my taking part in the study be kept confidential?

All information collected will be kept strictly confidential by the research team.

With the exception of your consent form and your contact details all other study information will be identified by a study number only. All information will be stored securely and only accessible by study staff and authorised personnel. The only people in the University of Oxford who will have access to the information that identifies you will be people who need to contact you to see how you are at 14 weeks, to provide you with the follow-up questionnaire, to send you a copy of the study results or to audit the data collection process.

Responsible members of the University of Oxford [and the relevant NHS Trust(s)] may access your data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

If you have agreed to take part in the optional interviews, the audio of these interviews will be typed up by a transcription service approved by University of Oxford and bound by a confidentiality agreement. The audio recording will be sent via secure encrypted data transfer. Your contact details will not be shared with this company. Their copy of the interview recording, and the original copy held by the Tempo Study Team, will be destroyed once the typed copy of the interview has been received and checked by the Tempo Study Team.

Will I be reimbursed for taking part?

It should not cost you to take part in the study and you will not be paid to take part. You will be reimbursed for any travel costs you incur in attending the baseline and follow-up assessments. All postage costs for the questionnaires will be pre-paid.

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, the sponsor for this study, 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 medical records in order to undertake this study and we will use the minimum personally-identifiable information possible.
The University of Oxford will delete identifiable information about you when no longer required as part of the study (following posting of the summary of study results). This will be within 1 year 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.

[Name of NHS Trust] will collect information from you and your medical records for this research study in accordance with our instructions. [Name of NHS Trust] will use your name, NHS number, and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. [Name of NHS Trust] will keep all research-related documents, including those with personal information, such as consent forms, securely at [Name of NHS Trust] for 5 years after the end of the study.

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 TEMPO Team on 01865 737927 or at tempo@ndorms.ox.ac.uk .

What will happen if I don't want to carry on with the study?

You can leave the study at any time. Leaving the study will not affect any care that you receive from the NHS or any other healthcare provider.

If you withdraw from the study, we will keep the information about you that we have already obtained. If you leave before the 14 week review we will ask whether you are still happy to be sent the questionnaire in the post. You can decide whether you want to do this or not.

What will happen to the results of this study?

The results of this study may help us decide if it is possible to do a large trial testing the programme. We plan to share the results from the research in medical journals, at conferences and online. You will not be identified in any report or publication. At the end of the study you will be posted a summary of the study findings.

What if we find something unexpected?

If during the clinical assessment, physiotherapy sessions or from your responses to the questionnaire something is indicated that requires clinical follow up, we will notify your GP who will contact you.

What if there is a problem?

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 Dr Philippa Nicolson, University of Oxford (01865 737927; philippa.nicolson@ndorms.ox.ac.uk) or you may contact the University of Oxford Research Governance Ethics and Assurance office on 01865 616480, or 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 <insert relevant NHS site phone number and email from the PALS website http://www.ouh.nhs.uk/patient-guide/pals.aspx>.

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.

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

Potential participants have been involved throughout the concept and design of this study, and one is a co-applicant who will continue to be involved in overseeing the running of the study. Potential participants were involved in deciding on the content and structure of the exercise programme, how to recruit participants to the study, which outcomes to measure and the study logo. Potential participants were involved in reviewing this Patient Information Sheet, and all participant materials included in the study.

Who is organising and funding the study?

This study is sponsored by the University of Oxford and funded by Versus Arthritis. This research is led by Dr Philippa Nicolson (University of Oxford) and organised in conjunction with the Oxford Clinical Trials Unit. If you were invited to join the study via your GP practice they will receive a nominal fee to compensate them for their time in mailing the invitation letters on our behalf. The [Name of NHS Trust] will also be compensated for the care they provide on the study's behalf.

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:

Dr Philippa Nicolson:

Telephone: 01865 737927 Email: tempo@ndorms.ox.ac.uk

Address: Botnar Research Centre, University of Oxford, Windmill Road, Headington, Oxford, OX3 7LD

Thank you for reading this information and considering taking part.