



## **PARTICIPANT INFORMATION SHEET (BEPKO) – Intervention development**

**Title of Project:** The feasibility of using BioFeedback to reduce Pain in people with Knee Osteoarthritis (BEPKO) – Intervention development

**Name of researcher:** Nathan Brookes

You are being invited to take part in a research study to help us develop a new treatment for knee osteoarthritis. Before you decide, it is important for you to understand why the research is being done and what it will involve. This document gives you important information about the purpose, risks, and benefits of participating in the study. Please take time to read the following information carefully. If you have any questions, then feel free to contact the researcher whose details are given at the end of the document. Take time to decide whether or not you wish to take part.

### **What is the purpose of the study?**

Research has shown that people with knee osteoarthritis (OA) over-tighten the muscles of their knees (hamstrings and quadriceps) during day-to-day activities, such as walking. Although tensing muscles in response to pain is a very normal response, we believe that increased muscle tension can overstress the knee joint, increase pain and make knee OA worse. We therefore want to develop a new treatment which works by teaching people who suffer with knee OA how to move with less muscle tightness. This treatment will involve the use of state-of-the-art sensing technology which can measure how muscles activate as you perform everyday movements.

### **Why have I been invited to take part?**

You have been invited as you are affected by knee OA.

### **Do I have to take part?**

No, taking part is completely voluntary. If you are interested, contact the researcher (details at the end of this information sheet). If you are not interested, then just disregard this letter.

### **What will happen to me if I participate in this study?**

If you agree to take part in the study, you will be required to visit either the University of Salford, a local community site (such as a church hall) or a specific clinical facility (such as a GP practice) on between 1-10 occasions. At the start of the first visit, the study will be explained in full and, provided you are still happy to proceed, you will complete a consent form and a data access form if you have recently had a knee x-ray. This data access form will give us permission to access your knee x-ray data. You will then complete three short questionnaires, which allow

us to understand how much your knee arthritis interferes with your daily life. Unless you tell us not to, we will write to your GP to let them know you have taken part in this study and request your NHS number. At the start of the first visit, we will also measure your height and weight, after which you will watch an introductory video, which provides information about the treatment. We will also assess your capacity to complete the tasks during the session and will adapt the session dependent on your ability.

**What will the new treatment involve (first and subsequent sessions)?**

1. At the start of each treatment session we will ask you to change into a pair of shorts. This is necessary so that we can place sensors over your knee and calf muscles. However, if you wish, you can (loose fitting) trousers over the shorts once the sensors are in place.
2. The physiotherapist will then perform a clinical assessment to identify patterns of muscle tension in your body. This assessment will involve you standing and performing very simple movements, such as flexing forward, twisting to the side or balancing on one leg. The physiotherapist will also try to move some of your joints whilst you are lying down to identify which muscles are tight.
3. During the assessment we would like to take some digital images and videos of your posture. Note that we will use image modification software to remove an identifying facial features from each image as soon as you leave. We are unable to modify the videos, however, the videos will be kept on a password protected computer for a maximum of 2 weeks and then permanently deleted. However, if you aren't happy for us to take images and videos, then please let the physiotherapist know and we will omit this part. If you would like to keep a copy of your videos for your personal use we can provide a copy on a USB stick
4. After the assessment the physiotherapist will provide you with a "body map" of your patterns of muscle tension in the form of images and animations. You will be required to visualise these patterns later in the treatment (see below).
5. The physiotherapist will then attach the muscle sensors on the front and back of your thigh and on your calf. Before each of these sensors is positioned, the physiotherapist may need to shave a very small area of skin and will then clean this area with an exfoliating cream and an alcohol wipe.
6. Using a special computer programme (which communicates wirelessly with the sensors), the physiotherapists will show you how you knee muscles work during daily activities (such as walking). The physiotherapist will then work with you to teach you how to change these muscle patterns. In order to do this, you will be asked to develop a clear visual image of your "body map" of tension patterns. This will enable you to understand how to change the way your muscles work.
7. Our aim is to teach you to move with less muscle tension in your knee muscles. If we can do this successfully, your movement should feel easier and your pain could reduce.
8. We may give you some simple exercises to practice at home. These exercises will be aimed at developing your awareness of how much you over tense your knee muscles. As part of these exercises you will ask you to practice visualising your "body map."

9. At the end of the session we will ask for your opinion of the treatment. Specifically, we will ask what you thought of the exercises we are using, the computer software and the way we have drawn/animated your “body map”. We will also ask you about the home practice exercises and also what you thought about the introductory video.

If you get tired during any point, then we will give you sufficient time to rest. We anticipate that the total duration of this visit would be no longer than 1.5-2 hours. After the end of the session, we may give you the opportunity to attend again for another session if this is something you are interested in. However, we are only able to offer a maximum of 10 treatment sessions. It is recommended that you practice the exercises given during the session for 5 – 10 minutes per day.

#### **Expenses and payments?**

Although we are not able to pay you for taking part in this research, we will be able to cover any travel costs you might have incurred. If you can't travel independently, then we can arrange for a taxi to collect you and take you home.

#### **What are the possible disadvantages and risks of taking part?**

This is a very simple, straight forward study with negligible risks. The clinical physiotherapist will be using tests which are used in routine clinical practice and will be fully trained in the use of the muscle measurement equipment.

#### **What are the possible benefits of taking part?**

If, as a result of this treatment, you are able to successfully reduce change you muscle patterns during everyday moment you may experience reductions in your pain and knee joint stiffness. However, we can't promise that everyone will experience clear benefits. Nevertheless, the results of the study will help us develop a new treatment for people who suffer with knee OA.

#### **What if there is a problem?**

The university has insurance to cover against any harm to you which may occur whilst you are taking part in these tests. However, if you decide to take legal action, you may have to pay for this. If you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, you can contact the project supervisor Dr Stephen Preece on 0798 459 7046 or Nathan Brookes on 07927307563 or email [s.preece@salford.ac.uk](mailto:s.preece@salford.ac.uk) or [n.brookes1@salford.ac.uk](mailto:n.brookes1@salford.ac.uk) and if you are not happy you may then contact Professor Sue McAndrew, Ethics Chair, Mary Seacole Building, University of Salford, M5 4WT on 0161 295 2778 or email: [S.McAndrew@salford.ac.uk](mailto:S.McAndrew@salford.ac.uk).

#### **What will happen if I don't carry on with the study?**

You can withdraw from this study at any time without affecting your medical care before participating in the study. If you want to withdraw you may do so at any time by notifying the

study representative listed in the “Contact Information” section below. If you do decide to withdraw then all the data which has been collected up to that point will remain part of the study unless you specifically request that it is destroyed. Note that data can't be withdrawn after data analysis has been completed.

**Who is organizing and funding the research?**

This study is organised by the University of Salford and has been funded by the NHS.

**Will my taking part in the study be kept confidential?**

All information which is collected about you during the course of the research will be kept strictly confidential. Any information about you which leaves the University of Salford will have your name and address and any other identifying features removed so that you cannot be recognized from it. We are happy to send each participant in the study a summary of the results. Please indicate on the consent form if you would like to receive this summary and also confirm that you are happy for us to retain your contact information for 2-3 years to allow us to send this information to you. No identifiable data will be kept after the end of the study (apart from contact details if you would like a summary of the results). We hope to publish key findings from the study in medical journals.

**Further information and contact details:**

If you require more information about the study, want to participate, or if you are already participating and want to withdraw, please contact

Email: [n.brookes1@salford.ac.uk](mailto:n.brookes1@salford.ac.uk)

Phone: 07927307563

Address: PO34, Brian Blatchford Building, The university of Salford

**Thank you very much for taking time to read this document!**

**We appreciate your interest in this study and hope to welcome you at the School of Health Sciences, University of Salford.**