



PARTICIPANT INFORMATION SHEET (BEPKO-2) – training course development (patient)

Title of Project: BEhaviour change to reduce Pain in Knee Osteoarthritis (BEPKO-2)

Name of researcher: Nathan Brookes

You are being invited to take part in a research study to help us test a new treatment for people who suffer with 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. Your decision whether to take part in the study or not will have no bearing on your medical care.

What is the purpose of the study?

We want to understand how to develop and refine a new training course for physiotherapists which will provide them with the skills to deliver a new treatment known as “Cognitive Muscular Therapy”. This technique has been developed to reduce pain in people who suffer with knee osteoarthritis and aims to teach patients how to stand and move with less muscle tension in their knees and throughout their body. It also teaches patients to change the way they think about and react to pain. Muscle biofeedback is used through the treatment to allow patients to directly observe, on a computer screen, when their muscles are tense or relaxed. The idea behind the new treatment is to reduce muscle tension, lower the pressure on the knee and so reduce knee pain. As part of this study, you will receive Cognitive Muscular Therapy from a physiotherapist, who has recently been trained to deliver this treatment, whilst members of the research team observe.

Why have I been invited to take part?

You have been invited as you have been diagnosed with knee osteoarthritis and may benefit from this new treatment.

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 first be asked to complete a set of questionnaires which allow us to understand your symptoms, how your knee pain interferes with your daily life

and how you think and feel about your pain. You will also complete a form which will give us permission to look at any previous x-ray data from your knee. You will be asked to complete these same questionnaires after you have finished the treatment.

You will be required to visit either the University of Salford or a specific clinical facility (such as physiotherapy department) on six separate occasions, each lasting approximately one hour. These visits will typically be 2 weeks apart. At the start of the first visit we will measure your weight and height and use a pinch test to assess the skin/fat over your quadriceps muscles. We will then take some simple measurement of your posture and breathing using a 3D measurement system. Note that it will not be possible to recognise you from these data. You will then receive the physiotherapy treatment.

To begin with, the physiotherapist will explain how reacting and thinking differently about your condition has the potential to reduce pain. You will then be taught how to consciously relax your knee muscles and how to relax your stomach muscles using diaphragmatic breathing. The next stage of the intervention is focused on teaching you to stand with less muscle tension. This is achieved using simple exercises which enable you to build awareness of patterns of muscle tension, particularly around your knees. Once you can stand with relaxed knees, the focus shifts to movement. Muscle feedback is used to visualise your muscle patterns on a screen. You are then guided through a process in which you learn to perform daily movements with less muscle tension.

At some points during the treatment, the physiotherapist will place small electrodes over your knee muscles which send data on muscle activity to a laptop computer. Note that it may be necessary to shave and use an exfoliating cream before the electrodes are attached to your skin. These electrodes are required to provide you with feedback on how your muscles are working. As you progress through the treatment, you will gain a new experience of standing and moving which may feel strange at first but which you will get used to. To help you understand many of the ideas which underlie the new treatment, animated instructional videos are used. These videos are watched on a tablet or laptop computer. If you don't have a tablet computer, we will loan you one. At the end of the treatment, we will repeat the posture and breathing measurements, described above.

We want to understand how good the physiotherapists are at delivering our new treatment. To do this, 2-3 members of the research team will watch the physiotherapist deliver the treatment to you. Note that this observation will not affect the treatment that you receive. We may also invite you to attend a one-day training course for physiotherapists, during which you will receive the treatment while the other people (approximately 6) observe. If you agree to attend the training course, we will pay you £15 per hour. However, attending the training course is not compulsory.

After you have received the treatment, we will offer you the opportunity to attend a workshop during which we will run a focus group with other people who have also received the new

treatment. During this focus group, we will ask you about your experience of receiving the treatment, both from the newly trained physiotherapist and from a more experienced physiotherapist. The discussion at the workshops will be recorded. However, all data will be completely anonymized and only the research team will have access to your anonymized opinions. We will ask you to keep focus group discussions confidential. If you are not able to make the workshop, then we will offer you the option of providing your opinion of the treatment via an individual interview, carried out over the phone or video conference. Again, this will be recorded but all data will be completely anonymized.

Expenses and payments?

Unfortunately, we are not able to pay you to receive the new treatment. However, if you agree to attend the one-day training course, then we will pay you £15 per hour. If you agree to attend the workshop, then you will also receive a payment of £15 per hour.

What are the possible disadvantages and risks of taking part?

This is a very simple, straight forward study with negligible risks. The physiotherapist will be using techniques which are used in routine clinical practice and these will be complemented with the muscle biofeedback which does not carry any risk.

What are the possible benefits of taking part?

You will receive six sessions of the new treatment and this may reduce your knee pain. However, we can't promise that everyone will experience clear benefits. The results of the study will help us to understand how to design a future training course for physiotherapists and therefore help people with knee osteoarthritis.

Who is organizing and funding the research?

This study is being led (and sponsored) by the University of Salford and has been funded by the NIHR (National Institute for Health Research). Other Universities will also be involved including York, Manchester and the University of the West of England.

How will we use information about you?

We will need to use information from you and may access information from your medical records for this research project. This information will include your name and contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly. If you provide us with consent (through the data access form) then we will look at previous x-rays, via your medical records, to understand your knee osteoarthritis. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure. Once we have finished the study, we will keep the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

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).

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you. If you do decide to withdraw, this will have no effect on your medical care before participating in the study. If you want to withdraw please notify the study representative listed in the "Contact Information" section below.

Where can you find out more about how your information is used?

You can find out more about how we use your information at <https://www.salford.ac.uk/privacy> and at www.hra.nhs.uk/information-about-patients or by asking one of the research team.

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 0161 295 2273 or email s.preece@salford.ac.uk and if you are not happy you may then contact Professor Andrew Clark, Ethics Chair, Mary Seacole Building, University of Salford, M5 4WT on 0161 295 5000 or email: A.Clark@salford.ac.uk. Alternatively, if you have any concerns that you feel should be dealt with by the NHS, then you can talk to the local Patient Advice and Liaison Service (PALS). The contact number for the Salford Royal PALS is 0161 206 2003.

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

Phone: 0161 295 2273

Address: Brian Blatchford Building, Frederick Rd Campus, The University of Salford, Manchester, M66PU

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 and Society, University of Salford.