University of Salford MANCHESTER

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

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.

What is the purpose of the study?

We want to understand whether a new form a physiotherapy could be effective for people with knee osteoarthritis. This new form of physiotherapy is known as "Cognitive Muscular Therapy" 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. This study has been designed to test and obtain feedback on a training course we have developed for physiotherapists to enable them to deliver the new treatment.

Why have I been invited to take part?

You have been invited as you are an NHS physiotherapist with experience of working with people with knee osteoarthritis.

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 undertake an online training course which will explain how to deliver the new treatment. You will then be expected to reflect on this training material during your own clinical practice. After this reflection, will attend a one-day workshop

during which you will have the opportunity to practice delivering the intervention to people with knee osteoarthritis. Following the training course, you will treat two patients with knee osteoarthritis while you are observed by 2-3 members of the research team. Each patient will receive six individual physiotherapy sessions which last approximately one hour. As part of the new treatment, you will need to use EMG (electromyography) to capture muscle patterns, however, we will provide full instruction on how to collect these EMG data during the training course. Note that although members of the research team will observe you as you deliver the new treatment, your competence will not be tested in any way. Instead, the research team will use this opportunity to reflect on whether the material in the training course was sufficiently well communicated. Be assured that confidentiality will be maintained at all times

Cognitive Muscular Therapy comprises five separate components. To begin with, patients are taught how to react and think differently about their knee pain. They are then taught how to consciously relax their knee muscles and how to relax their stomach muscles using diaphragmatic breathing. The next stage of the intervention is focused on teaching patients to stand with less muscle tension. This is achieved using simple exercises which enable patients to build awareness of patterns of muscle tension, particularly around their knees. The focus then shifts to movement retraining. Using EMG biofeedback, patients are provided with a visualization of their muscle patterns on a screen. They are then guided through a process in which they learn to perform daily movements with less muscle tension.

After the treatment has finished, you will be asked to attend a workshop with the other physiotherapists involved in the study and the patients who have received the new treatment. At this workshop, we will run a focus group to ask you and the other physiotherapists about your experiences of delivering the intervention and how you think that our training course could be improved. 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.

Expenses and payments?
You will receive your normal salary when you deliver this treatment to patients. If you undertake the treatment, or attend the workshop, outside your normal hours, then we will pay you at your normal rate.

What are the possible disadvantages and risks of taking part?
This is a very simple, straight forward study with negligible risks. The clinical technique which you will deliver, and which are part of Cognitive Muscular Therapy, are very low risk for both the patient and physiotherapist.

What are the possible benefits of taking part?

You may learn new clinical skills as part of taking part in the study. Other than that, there will be no direct benefit to you. However, by taking part in this study, you will be helping us to understand the best way of training physiotherapists to deliver the new treatment.

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 for this research project. This information will include your name and contact details. People will use this information to contact you. 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 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.

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.