University of Salford MANCHESTER

PARTICIPANT INFORMATION SHEET (BEPKO-2) – Feasibility study (patient)

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

Name of researcher: Nathan Brookes

Why am I being invited to take part?
You are being invited to take part in a research study to help us test a new research treatment for people who suffer with knee osteoarthritis. You have been invited as you have been diagnosed with knee osteoarthritis and have had minimal benefit from the ESCAPE- pain programme or another form of physiotherapy or you are on an orthopedic waiting list.

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 whether a new form a physiotherapy could be effective for people with knee osteoarthritis who have not benefited from current physiotherapy treatment. 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 treatment is to reduce muscle tension, lower the pressure on the knee and so reduce knee pain.

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?
We are aiming to recruit a total of 90 participants to the 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 osteoarthritis interferes with your daily life and how you think

and feel about your pain. You will also be asked to complete a set of questionnaires which allow us to understand how often you access healthcare services (e.g. GP visits) and how your condition affects your capacity to work. 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 required to complete these same questionnaires on two other occasions: 20 weeks and again at 8 months after you enroll on the study. Once we receive the first set of questionnaires, you will be randomly allocated to either the treatment or control group.

If you are in the treatment group:
You will be required to visit a specific clinical facility (such as physiotherapy department) on 9 separate occasions, with each visit lasting 45-60 minutes. These visits will typically be 2 weeks apart. During the first visit you will not receive any physiotherapy treatment. Instead, the physiotherapist will measure your weight and height and will then place small electrodes over your knee and calf muscles. Note that it may be necessary to shave and use an exfoliating cream before the electrodes are attached to your skin. You will then be asked to perform some everyday activities, such as walking, standing up from a chair and stepping down, whilst we measure your muscle patterns. After you have completed these movements, the physiotherapist may ask you to perform some maximal exertion tests which involve standing on tip toes, and flexing/extending the knee against a fixed resistance. The physiotherapist will also measure your hip flexibility and use a 3D camera to measure your posture and the movement of your stomach as you breathe. These data will not contain recognizable features.

You will receive the physiotherapy treatment in sessions 2-8. Initially, 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 a special breathing technique. The next stage of the treatment 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 biofeedback 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.

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 research 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.

We want to understand how good the physiotherapists are at delivering the new research treatment. To do this, we need to video one session of the research treatment. The video footage will be stored in a secure folder on the University of Salford network. The video footage will only be accessible to the research team and will be permanently deleted after it has been reviewed (typically within two weeks). However, if you don't want to be videoed, then you can

refuse this. In session 8, we will repeat the muscle measurements (explained above) but you will not receive additional physiotherapy.

After you have received the treatment, we will offer you the opportunity to be interviewed about your experiences of being involved in the study and to understand what you think about the new research treatment. These interviews will be carried out over the phone or via video conference and will be an informal way of you expressing your opinions. We will record these interviews, but all data will be completely anonymized and only the research team (not the physiotherapist) will have access to your anonymized opinions. The interview recordings will be stored in a secure folder on the University of Salford network. The interviews will be transcribed (typed onto a computer) by the research team. After this transcription, the recording will be permanently deleted, this will typically be within two weeks of the recording.

If you are in the control group:
You will be advised to continue with your ESCAPE- pain exercise programme or physiotherapy exercises or remain on the orthopedic waiting list as appropriate. At the end of the study, we will offer you the chance to be interviewed about your experiences of being involved in the trial. These interviews will be carried out via phone call or video conference and as explained above, all information will be kept strictly confidential.

In addition, 10 participants from the control group will undergo additional testing at our laboratory. We will ask you if you would be willing to visit our laboratory on two separate occasions, separated by 6-12 weeks. Note that these laboratory visits are not compulsory and so you can still be involved in the study if you don't want to attend for this testing. If you do agree to come into the laboratory, then we will collect muscle activation data, following the same procedure described above during each of the two visits. The researcher may also measure your hip flexibility and use a 3D camera to measure your posture and the movement of your stomach as you breathe. These data will not contain recognizable features. If you do agree to come into the laboratory, then you will be paid £20 for each visit.

Will participation affect my current NHS treatment?
Participation in this study will not affect any treatment that you are currently receiving or are due to receive. If you are on an orthopedic waiting list, then you will receive your offer of surgery at the same point in time, whether you take part in this study or not.

Expenses and payments?
We are not able to pay participants for taking part in this trial. However, if you are allocated to the control group, and agree to come to the University for laboratory testing, you will receive £20 for each visit, along with reasonable travel expenses (please note- only 10 participants from the control group will undergo additional testing at our laboratory).

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?

If you are allocated to the treatment group, you will receive seven sessions of the new research treatment and this may reduce your knee pain. However, we can't promise that everyone in the treatment group will experience clear benefits. If you are in the control group, you are unlikely to experience any direct clinical benefit. However, regardless of whether you are in the control group or treatment group, the results of the study will help us to understand whether our new research treatment may be effective for people with knee osteoarthritis.

Who is organizing and funding the research?

This study is being led 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 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 Chief Investigator Dr Stephen Preece on 07498 006 755email 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.If you have concerns with regards to how your data is collected and stored then contact Andrew Hartley, Data Protection Officer, Legal and Governance Directorate, Maxwell 6th floor, University of Salford, M5 4WT on 0161 295 6428 or email: a.hartley2@salford.ac.uk. Alternatively, if you 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).

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:	07498 006 755
Address:	The School of Health and Society, The University of Salford, Brian Blatchford Building, Salford, M6 6PU

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.