

## PARTICIPANT INFORMATION SHEET (BEPKO-2) - Collection of ESCAPE outcomes

**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 understand the effectiveness of physiotherapy treatments for knee osteoarthritis. You have been invited as you have been diagnosed with knee osteoarthritis and are about start an ESCAPE pain programme.

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 effective the ESCAPE pain is at reducing pain in knee osteoarthritis. By collecting data on pain before and after the ESCAPE treatment, we will be able to identify people who do not have a large change in pain following the ESCAPE programme.

#### 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 asked to complete a pain questionnaire before and after your ESCAPE pain treatment. These data will then be checked to understand whether you have had a large change in pain following the treatment. If you do not have a large reduction in your pain, then we will contact you to understand if you would like to try another form of physiotherapy. Note that you will only be offered this further treatment if you attend at least 8 out of 12 (or 6 out of 10) ESCAPE classes.

Note that you will also be asked to provide pain data directly to the ESCAPE programme organizers. However, as we can't access these data, then you will have to provide us with the

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same information. All our data will be collected via online form (or telephone) to make it as easy as possible for you.

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

We are not able to pay participants for taking part in this trial.

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

There are no risks associated with this study as we are simply collecting pain data.

## What are the possible benefits of taking part?

There is no immediate benefit to taking part in this study.

### 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. 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.

## 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 <a href="https://www.salford.ac.uk/privacy">https://www.salford.ac.uk/privacy</a> or by asking one of the research team.

#### What if there is a problem?

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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 006 755, 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.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: healthcare-volunteering@salford.ac.uk/ health-bepko@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.