



University of
Salford
MANCHESTER

PARTICIPANT INFORMATION SHEET (TKR Study – clinical trial)

Title of Project: Cognitive Muscular Therapy for patients awaiting knee joint replacement

Name of researcher: Nathan Brookes

Why am I being invited to take part?

We would like to invite you to take part in a research study. The study is being run by the Centre for Health Sciences Research, University of Salford. You are being invited to take part in this research study to help us test a new treatment that we are researching for people who suffer with knee osteoarthritis. You have been invited as you have been diagnosed with knee osteoarthritis and you are on an orthopedic waiting list. Your Consultant Orthopedic Surgeon or physiotherapist has identified this study as something which is relevant for you. We are asking up to 48 patients to help us with this study.

Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish. Ask us if there is anything that is not clear to you or if you would like more information. We can be contacted on the telephone numbers at the end of this sheet. Take time to decide whether you wish to take part. Your decision to take part in the study or not will not affect your medical care.

What is the purpose of the study?

This research has been designed to test a new physiotherapy treatment for knee osteoarthritis called “Cognitive Muscular Therapy”. Rather than focus on muscle strengthening, the aim of this treatment is to teach patients to move with less muscle tension, and therefore give injured areas a chance to heal. Research has shown that osteoarthritis pain doesn’t come from the cartilage because cartilage doesn’t contain pain receptors. Research has also shown that many older people have a complete loss of knee cartilage but feel no pain. Therefore, non-surgical treatments may offer pain relief to people who have been told that their knees are ‘bone on bone’ due to “wear and tear”.

Many people who are on a waiting list for a knee replacement will have tried standard physiotherapy for their knee pain and obtained little benefit. However, Cognitive Muscular Therapy is very different from standard physiotherapy. This is because the aim is to teach patients to reduce muscle tension by learning relaxation techniques and improving posture. It also aims to help people to recognise the link between pain, stress and muscle tension. This research has been designed to understand whether Cognitive Muscular Therapy can reduce pain in people whilst

they are waiting for a knee replacement and whether, for some people, it might remove the need for an operation.

Do I have to take part?

It is up to you to decide. Please read this information sheet and contact us if you have any queries. If you decide to take part, you will be free to withdraw at any time, without giving a reason. If you decide not to take part, this will not affect the standard of care you receive.

What will happen to me if I take part

We will ask you to sign a consent form to show you agree to take part in the study and that you are happy for us to contact your GP/surgeon to get confirmation that you are on the knee replacement waiting list. You will also need to complete a form which will give us permission to look the most recent x-ray of your knee.

We will then send you some questionnaires to complete in your own time, either online (via secure link) or on paper. If you fill out the questionnaires on paper, we will pay the return postage. The questionnaires will ask about, for example, your age, diagnosis and medication. They will also ask about 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 questionnaire which allow us to understand how often you access healthcare services (such as GP visits) and how your knee osteoarthritis affects your ability to work. The questionnaires typically take about 30 mins to complete. Note that you will be asked to complete the same questionnaires four months later.

Once we receive the first set of questionnaires, people taking part will be randomised and allocated by chance (by a computer) to one of two groups: the Cognitive Muscular Therapy (CMT) group or the usual treatment group. Only the Cognitive Muscular Therapy group will receive the treatment.

If you are in the Cognitive Muscular Therapy (CMT) group:

You will be required to visit a specific clinical facility (either the University of Salford or Stockport NHS Foundation Trust) on 7 separate occasions. The first session will last 90 minutes with each following session lasting 45-60 minutes. These visits will typically be 1 week apart. On the first visit the physiotherapist will measure your height and weight and use sensors to measure your muscle activity whilst you walk. The physiotherapist will then 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 movements 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 sessions, 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 Cognitive Muscular Therapy, animated instructional videos are used. These videos can also be watched at home on your phone, laptop or tablet via a web-based platform. The University of Salford will provide a tablet computer for those who don't have access to a device. At the end of the treatment, the University of Salford will pay for return postage, to include signed delivery. You will be responsible for any loss of, or damage to, this device, however, the university will insure against theft.

After you have received the CMT 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 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 usual treatment group:

You will be encouraged to continue with your current pain management. Taking part in the study won't affect your care or ability to access treatment for your knee osteoarthritis pain. This may include seeing your GP or other health practitioner.

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 to receive the CMT treatment. However, all participants will receive a £10 amazon voucher when they return (or submit electronically) the final set of questionnaires (which will take approximately 30 mins). We will cover the costs of car parking when attending appointments or public transport costs to and from appointments.

What are the possible advantages of me taking part?

If you are allocated to the CMT group, you will receive seven sessions of CMT and this may reduce your knee pain. However, we can't promise that everyone in the CMT group will experience clear benefits. If you are in the usual treatment group, you will not experience clinical benefit from the

research team but will continue to benefit from your normal NHS care. However, regardless of whether you are in the usual treatment group or CMT group, the results of the study will help us to understand whether CMT may be effective for people with knee osteoarthritis who are on waiting list for surgery. In future, this may help the NHS plan appropriate osteoarthritis-related services for people awaiting surgery.

What are the possible disadvantages and risks of taking part?

We do not anticipate any disadvantages or risks in taking part. The CMT treatment 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.

Who is organizing and funding the research?

This study is funded by and is being led by the University of Salford.

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 006 755, 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 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).

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

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

Finally

Thank you for considering taking part. Please keep this information sheet. We will ask you to sign a consent form if you agree to take part. We will give you a copy of this to keep.