MOTION Study
Participant Information Sheet

Your local team is from:

Local research team's NHS institution logo goes here

What is the clinical-effectiveness and cost-effectiveness of surgery with medial opening wedge high tibial osteotomy (HTO) compared with non-surgical treatment in the management of osteoarthritis (OA) of the knee in patients younger than 60 years?

You are invited to take part in a research study. To help you decide whether or not to take part, 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. Contact us if there is anything that is not clear, or if you would like more information. Take time to decide whether or not you wish to take part.

Why have I been invited to take part?

You have osteoarthritis of the knee joint which is causing pain and disability, despite treatment that may have been prescribed previously. In your case the osteoarthritis only affects the inner half of the knee. Because you are also under the age of 60 years, a knee replacement may not be the most appropriate treatment for you. High tibial osteotomy (HTO) surgery or Personalised Knee Therapy (PKT) may help you avoid the need for a knee replacement in the future. There is more information about both these treatment options later in this information sheet which you should read carefully before you consider participating in this study. You have been invited to take part as you meet the criterion to be eligible for participation in this study.

What is the purpose of the study?

In a healthy knee joint, there is a smooth lining that covers the ends of the bones. In knee osteoarthritis, this smooth lining thins, roughens and is permanently damaged causing joint pain, swelling and stiffness. Patients have a reduced quality of life as they struggle with daily activities like walking, standing and sleeping and often cannot work due to the disability.

Initial treatment for knee osteoarthritis is non-surgical with general advice, painkillers, exercises and occasionally, steroid injections. If the knee is still painful, surgery may be considered. If patients are over 60 years of age, then knee replacement surgery is successful as the diseased part of the knee is physically removed and replaced with an artificial implant. However, in patients under the age of 60 years, knee replacement surgery is less successful because the metal/plastic knee implant wears out much sooner due to higher activity levels in these younger,

working age patients. The artificial joint has to be replaced again, sometimes several times, and patients have to go through complex, risky repeat operations. Most patients do not return to active work either. In patients under the age of 60 years, it is therefore preferable to delay knee replacement surgery as long as possible, and other treatments should be considered instead.

For example, there is an alternative surgical option whereby the knee can be realigned without the need for replacing it with an artificial implant. During this surgery called 'high tibial osteotomy', the bone is cut just below the knee joint and a small wedge is opened, to shift the person's weight away from the damaged part of the knee to a healthy part of the knee. By 'unloading' the damaged part of the knee, the surgery can decrease pain, improve function and delay the need for knee replacement or avoid it altogether. It may allow many more young patients to return to work. This surgical procedure is further explained in the figure below:

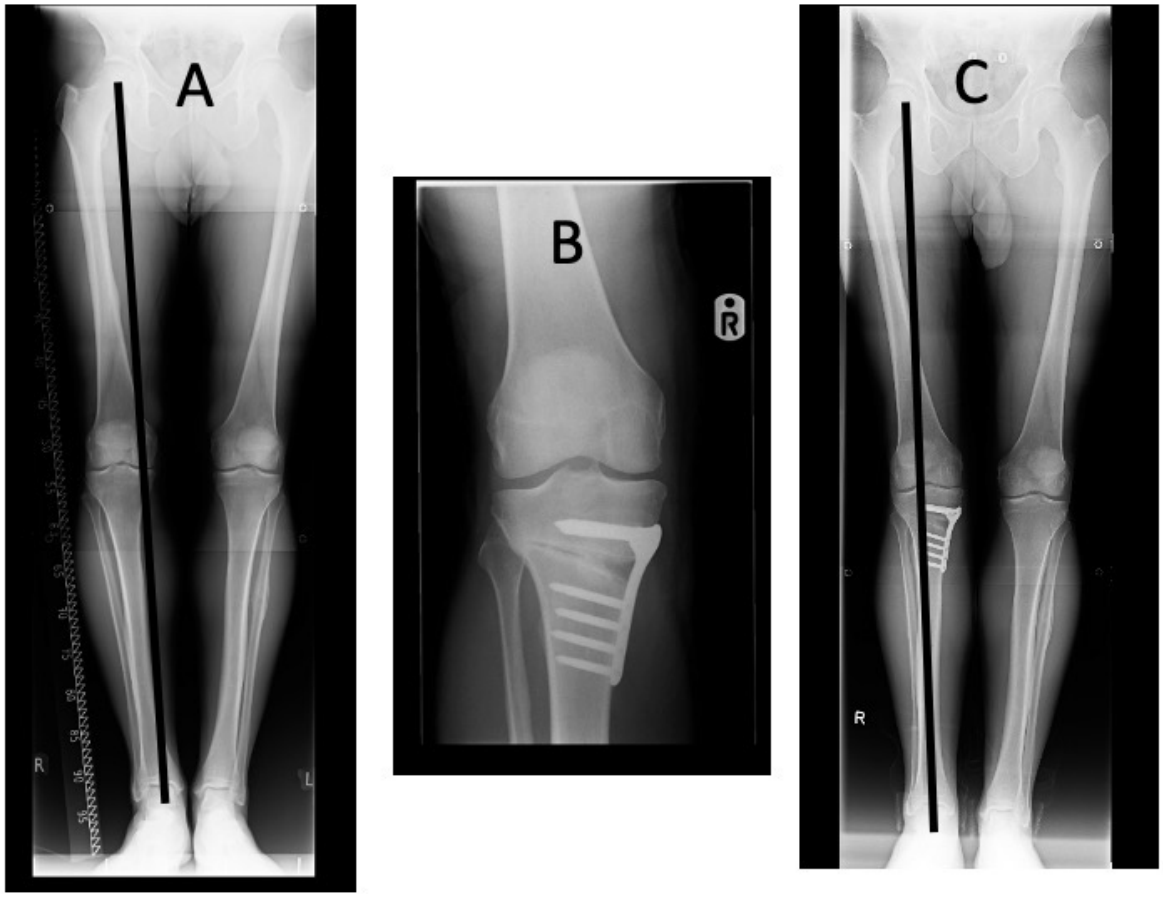

Figure 1: A. The black line (called the 'weight bearing axis') is drawn from the centre of the hip to the centre of the ankle and represents how the body weight passes through the leg. In most normal knees, this so called 'weight-bearing axis' passes through the centre of the knee. In this patient suffering from knee OA the weight-bearing axis is abnormal and passes through the inner diseased half of the knee instead of the centre of the knee **B:** A wedge has been opened just below the knee joint and stabilised with plates and screws in the operation called high tibial osteotomy (HTO). By opening this wedge of bone at the upper end of a long bone,

the overall alignment of the lower leg and its weight-bearing axis is altered as shown in **C.** The lower leg has been realigned so that the weight-bearing axis (black line) now passes through the middle of the knee, away from the diseased inner half of the knee. This shifting of the weight-bearing axis away from the arthritic inner part of the knee following high tibial osteotomy (HTO) surgery relives pain and reduces disability with preservation of the native knee joint.

Another option is to avoid surgery altogether and undergo a more focussed and personalised non-surgical treatment for the knee osteoarthritis, different from what you may have already received before your referral to hospital. These tailored non-surgical treatments aim to improve the muscle strength in the leg, mainly around the knee joint, through exercises and in some cases the temporary use of externally worn braces and other additional treatments including painkillers and steroid injections to allow you to undertake the exercise program. This can also help reduce the pain in the knee to the extent that some people do not need further surgery. We have called this approach Personalised Knee Therapy (PKT) in this study. This PKT is a 3-4 month program delivered by a physiotherapist in which you will have six separate sessions with the physiotherapist and be given a tailored 30 minute programme of exercises to do at home 3 times per week. A typical 30-minute program would incorporate a warm-up element (such as a stationary exercise bike), muscular control exercises followed by focussed strengthening of specific muscles. The aim of the PKT is the same as for the surgical option of realignment surgery with HTO – to relieve your pain from knee osteoarthritis and improve your function.

Why is the study being conducted and what are we trying to achieve?

We currently do not know if high tibial osteotomy (HTO) surgery is any better than non-surgical treatment alone with Personalised Knee Therapy (PKT) in patients under the age of 60 years in delaying or avoiding knee replacement surgery, as the two options have never been compared. The purpose of this study is therefore to find out whether treating a painful, arthritic knee joint in patients younger than 60 years with high tibial osteotomy (HTO) surgery is better than non-surgical treatment in terms of pain relief, improved quality of life and ability to return to work.

How many people will be involved?

In this study 224 patients under 60 years with knee osteoarthritis will be selected to compare the two possible options - non-surgical (Personalised Knee Therapy) vs surgical (High Tibial Osteotomy) using a type of study called a randomised study. Which of the two treatments patients will get will be decided by chance, using a computer - half the patients will get one treatment, and half will get the other. To compare, we will then ask patients about their pain, knee function, quality of life and ability to work using specific questionnaires after the treatment and follow them up at 12 and 24 months after randomisation.

What are the benefits and risks of the treatments offered in this study?

Both treatment options (non-surgical and surgical) have been proven in previous studies to improve your knee pain, reduce disability and delay or avoid the need for a knee replacement altogether.

Non-surgical treatment has the obvious advantage that it does not require an operation and all the risks that go with an operation. The non-surgical treatment takes around 3-4 months to deliver and requires you to attend at least six sessions with the physiotherapist and commit to the tailored exercise programme over this time. You may also be offered bracing and steroid injections. The treatment is directed at improving your symptoms from osteoarthritis and does not alter the alignment of your lower leg.

Surgery with high tibial osteotomy will alter the alignment of the lower leg (refer to Figure 1 again, if needed) to improve the symptoms from osteoarthritis of the knee. The surgery will avoid the need for a knee replacement in around 90% of patients for at least 5 years, and in 70% of patients for at least 10 years after the operation. The downside is that you are exposed to the risks of surgery such as infection, bleeding, clots, nerve/blood vessel injury, problems with healing of the bone and intra-operative fractures. It is always difficult to estimate the overall risk of complications with any surgery accurately. However, the approximate chance of any such complication with this operation is around 1 in 15. During the first 4-6 weeks after your operation you are likely to need crutches to get around and may also need painkillers. Depending on how the operation has gone, the surgeon may also decide to restrict weight-bearing on the operated leg for the first 4-6 weeks. You may also receive input from the local physiotherapist as part of the rehabilitation during your recovery. Most patients will make a good recovery within 3 months of the operation, but in some cases it may take you longer to fully recover from the operation.

Do I have to take part?

No, it is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form before any trial activities can take place. You will receive a copy of your signed consent form to keep. If you decide to take part you are still free to withdraw at any time, including post-surgery, and without giving a reason. Deciding not to take part or withdrawing from the study will not affect the healthcare that you receive, or your legal rights.

What will happen if I take part?

If you do decide to consent to take part, you will be asked complete some baseline questionnaires about your affected knee and how this affects your daily activities. The research team will record some personal and demographic information from you and from your health records. This information includes, your name, postal and email address, telephone number, age, sex, Body Mass Index, relevant medical/surgical history and treatments.

We will also collect your Community Health Index (CHI) or NHS number. CHI is a population register, which is used in Scotland for health care purposes. The CHI number uniquely identifies a person on the index.

These baseline details will ideally collected during a face-to-face consultation. However, if local circumstances prevent this, we may collect this information by telephone or video link.

To try to make sure the groups are the same to start with, each patient is put into a group by chance (randomly). You will therefore be "randomised" on a computer to either the non-surgical group or surgical group.

<u>If you are randomised to the surgical group:</u>

A. You will be placed on a routine NHS waiting list to have the High Tibial Osteotomy (HTO) surgery.
B. You will have your surgery at your local hospital and follow the local process for having the surgery and recovering from the operation. After your operation you will receive the standard postoperative rehabilitation from your hospital.

<u>If you are randomised to the non-surgical group:</u>

A. You will be referred to the local NHS Physiotherapy department at the hospital and receive a specialised physiotherapy programme of rehabilitation for the knee osteoarthritis that we refer to as Personalised Knee Therapy (PKT).
B. This Personalised Knee Therapy (PKT) will be delivered at your local NHS physiotherapy department over six sessions within a period of 3-4 months.

Participants in both arms of the study will get the same questionnaires at 12 and 24 months post randomisation (either via the post or email) to assess whether these treatments have worked. These questionnaires will be sent from the central research office in Edinburgh via the post or through an online portal. If a sent questionnaire is not received we will send two reminders or if information is missing we would call you.

What are the possible benefits of taking part?

Both treatments are accepted interventions for people with knee osteoarthritis and we expect both groups to benefit from the treatments, but at present we do not know which group will benefit more. As such there are no direct benefits to you taking part in this study, but the results from this study might help to improve the healthcare of patients in the future.

What are the possible disadvantages of taking part?

Apart for the usual treatment you would have received for your condition, you will be contacted after the treatment is completed for the purpose of this study. This will generally be by post or email to complete a questionnaire and hospital attendance is not required. We may telephone you if we have not received a completed questionnaire from you. Some people may find these extra questions tiring and they will take up about 30 minutes of your time.

What if there are any problems?

If you have a concern or questions about any aspect of this study, please speak to the study team, or you may also speak to a Consultant who is not involved in the study - details are at the end of this information sheet.

If you are unhappy about the study and wish to make a formal complaint, then you can use the normal NHS complaints procedure (details at end of this form).

In the unlikely event that something goes wrong, and you are harmed during the research, and this is due to someone's negligence, then you may have grounds for a legal action for compensation against NHS <<add local NHS>>, but you may have to pay your legal costs. The normal NHS complaint mechanisms will still be available to you (if appropriate).

What will happen if I don't want to carry on with the study

You can withdraw at any point from the study.

If you have were allocated to the non-surgical group and felt that the treatment had not worked for any reason, you can decide at any time to opt for the surgical treatment. You will see the consultant looking after you so that they can discuss the other treatment options that may be available to you.

If you were allocated to the surgical treatment, you can also withdraw at any point from the study. If you feel the high tibial osteotomy (HTO) surgery has not worked for any reason, you will need to arrange to see the consultant who performed your surgery so that they can discuss the other treatment options that may be available to you.

If you do decide to withdraw from your allocated treatment, with your consent, we would still contact you at 12 and 24 months to collect the follow up information planned for the study as it would still be useful for the purpose of analysing our study and the overall results. Again with your permission, we would like to include your data in our long-term follow-up plans to access registry data

However, you can request not to be contacted if you wish and you will be completely withdrawn from any further study participation. Any data collected up to the point of withdrawal will be kept.

What happens when the study is finished?

As part of this study we may retain your data within our system and you may be re-contacted for longer term follow up of the outcomes of your treatments. This is because we may wish to find out how whether you required any additional operations for your knee 5 and 10 years after your treatment. By linking your study data with the NHS database, we would be able to understand the long-term effectiveness of the treatments offered in this study. You can of course choose to not give your consent for this longer term retention of your data and this will be discussed with you as part of the consent process for the study.

Will my taking part be kept confidential?

All information that we record about you will be kept confidential and there are strict laws which safeguard your privacy at every stage.

How will we use information about you?

We will need to use information from you and your medical records for this research project. This information will include your full name, NHS/CHI number, contact details. With your permission we will inform your GP of your participation.

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 some of 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. If you choose to stop taking part in the study, with your permission we would like to continue collecting information about your health from [central NHS records/ your hospital/ your GP]. If you do not want this to happen, tell us and we will stop.

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

You can find out more about how we use your information

- At www.hra.nhs.uk/information-about-patients/
- Our leaflet available from www.hra.nhs.uk/patientdataandresearch
- By asking one of the research team
- By sending an email to motion.trial@ed.ac.uk
- By contacting a Data Protection Officer

University of Edinburgh
Data Protection Officer
Governance and Strategic Planning
University of Edinburgh

NHS Lothian
Data Protection Officer
NHS Lothian
Waverley Gate

Old College
Edinburgh
EH8 9YL
Tel: 0131 651 4114
dpo@ed.ac.uk

2-4 Waterloo Place
Edinburgh
EH1 3EG
Tel: 0131 465 5444
Lothian.DPO@nhs.net

What will happen to the results of the study?

This study will be written up as a publication and will also be presented at conferences. You may also be able to read about the results of the study from press releases and social media notifications. We will also make a summary of the study results available on the Edinburgh Clinical Trials Unit (ECTU website) at https://www.ed.ac.uk/usher/edinburgh-clinical-trials/our-studies/all-current-studies

You will not be identifiable from any published results.

Who is organising and funding the research?

This study has been organised/sponsored by the University of Edinburgh and NHS Lothian. Edinburgh Clinical Trials Unit provides the Trial Management, Database and Statistical Support for the study.

The study is being funded by the National Institute for Health Research (NIHR, Study reference NIHR129820

Who has reviewed the study?

Our Patient and Public Involvement (PPI) group have been involved with development of this study from the outset. We have patient representatives who are also an integral part our research team that oversees this study.

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee. A favourable ethical opinion has been obtained from <insert REC name>. NHS Management Approval has also been given.

Researcher Contact Details

If you have any further questions about the study please contact your local research team.
<<insert name>> on <<insert telephone number>> or email on <<insert email address>>

Independent Contact Details

If you would like to discuss this study with someone independent of the study please contact:
Professor John Keating,

Consultant Trauma and Orthopaedic Surgeon,
NHS Lothian,
Email: john.keating@ed.ac.uk
Phone: 0131 242 3436

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Complaints

If you wish to make a complaint about the study please contact:

<<insert local contact details>>.

PROCESS EVALUATION component of the MOTION trial (Optional)

In addition to collecting information about your general health and wellbeing we would also like to hear your thoughts on the trial itself and whether taking part was what you expected or not. We will do this by conducting telephone interviews with some of the participants taking part in the trial. This will be led by two researchers, also from the University of Edinburgh, called Dr Fiona Dobie and Dr Martine Miller. Not all patients will be invited to take part in a Process Evaluation interview but all patients are being asked if they are happy for their contact details to be passed to Martine so she can tell them a bit more about the interviews. For patients who are then invited to take part in an interview they will be given a separate information leaflet and consent form and asked to take part in three or four interviews. All interviews will be completely confidential and will not affect your participation in the trial in any way.

Participant ID: **Centre ID (if applicable)**

MOTION Study
CONSENT FORM

	Please **initial** box
1. I confirm that I have read and understand the information sheet (DD MMM YYYY and Version Number) for the above study. I have had the opportunity to consider the information, ask questions and have had these questions answered satisfactorily.	☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and without my medical care and/or legal rights being affected.	☐
3. I give permission for the research team to access my medical records for the purposes of this research study.	☐
4. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the Sponsor (University of Edinburgh and/or NHS Lothian), from regulatory authorities or from the NHS organisation where it is relevant to my taking part in this research. I give permission for these individuals to have access to my data and/or medical records.	☐
5. I give permission for my personal information (including name, address, date of birth, telephone number and consent form) to be passed to the University of Edinburgh Clinical Trials Unit (ECTU) for administration of the study.	☐
6. I give permission for my Community Health Index (CHI) number/NHS number to be collected and passed to the University of Edinburgh Clinical Trials Unit (ECTU).	☐
7. I agree to my General Practitioner being informed of my participation in the study.	☐
8. I understand that data collected about me during the study may be converted to anonymised data.	☐
9. I understand that the data generated and may be used for future commercial development of products/tests/treatments/biomarkers and I will not benefit financially from this.	☐

Participant ID: **Centre ID (if applicable)**

Please **initial** box

10. I understand that data collected about me during the study may be converted to anonymised data and linked to NHS digital data for later long term data linkage studies that require follow up information round 5 and 10 years after my treatment. I understand that I may be contacted after the trial is over about future studies to research the long term outcomes for the treatments I have had as part of this study.

Yes ☐ No ☐

11. I agree to take part in the above study. ☐

Please **initial** one box only below

12. OPT-IN for Process Evaluation

- **I agree** for my contact details to be passed to the Process Evaluation to be contacted by telephone or email to learn more about how I share my views about being part of the Motion trial. ☐
- **I do not agree** for my contact details to be passed to the Process Evaluation team to be contacted by telephone or email to learn more about how I share my views about being part of the Motion trial. ☐

Name of Person Giving Consent	Date	Signature
Name of Person Receiving Consent	Date	Signature

1x original – into Site File; 1x copy – to Participant; 1x copy – into medical record