# A randomised study to compare the outcomes after realignment knee surgery versus nonsurgical treatment with bespoke knee physiotherapy, for patients under 60 years of age with osteoarthritis of the knee

Submission date 17/01/2023	<b>Recruitment status</b> No longer recruiting	[X] Prospectively registered		
		[X] Protocol		
Registration date 25/01/2023	Overall study status Ongoing	Statistical analysis plan		
		Results		
<b>Last Edited</b> 17/04/2025	<b>Condition category</b> Musculoskeletal Diseases	Individual participant data		
		[X] Record updated in last year		

#### Plain English summary of protocol

Background and study aims

Osteoarthritis (OA) is the leading cause of disability worldwide and most commonly affects the knee joint causing issues with mobility, quality of life, and ability to work. Treatment options include non-surgical management and surgery may also be considered. Knee replacement is successful in patients over 60 years but less so if under 60 as the implant wears out sooner, therefore alternative options are sought to delay knee replacement surgery as long as possible. High tibial osteotomy (HTO), is a surgical procedure where 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. This can decrease pain, improve function and delay or avoid the need for knee replacement. Personalised knee therapy (PKT) is a physiotherapist-delivered non-surgical focussed intervention consisting of a programme of exercise alongside exercise enabling pain relief (external braces if required) which aims to improve muscle control in the lower limb and knee joint, to shift weight away from the 'worn' part of the knee, help reduce pain and avoid the need for further surgery. In this study, the team want to find out if HTO is better at delaying or avoiding knee replacement surgery than PKT alone in patients under 60 years old by comparing these two interventions.

#### Who can participate?

Patients aged >18 and <60 years with old with symptomatic medial compartment knee OA who the treating orthopaedic surgeon considers a suitable candidate for medial opening wedge HTO

#### What does the study involve?

Patients will be enrolled at around 20 NHS hospitals in the UK to determine the clinical (pain relief, improvement in function, quality of life, return to work) and cost-effectiveness of both treatments at 24 months. A mixed method process evaluation in a subset of staff and patients will explore trial eligibility; recruitment and retention; acceptability of intervention

implementation including trial processes and collection of routine monitoring data; patient experience of taking part and the contextual factors that influence this.

For participants randomised to the surgical group:

- 1. They will be placed on a routine NHS waiting list to have the HTO surgery
- 2. They will have their surgery at their local hospital and follow the local process for having the surgery and recovering from the operation. After their operation, they will receive standard postoperative rehabilitation from their hospital

For participants randomised to the non-surgical group:

- 1. They will be referred to the local NHS Physiotherapy department at the hospital and receive the specialised PKT physiotherapy programme of rehabilitation for knee OA
- 2. PKT will be delivered at their 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 post or email) to assess whether these treatments have worked.

What are the possible benefits and risks of participating?

Both treatment options (non-surgical and surgical) have been proven in previous studies to improve 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 participants to attend at least six sessions with the physiotherapist and commit to the tailored exercise programme over this time. Participants may also be offered bracing and steroid injections. The treatment is directed at improving symptoms from osteoarthritis and does not alter the alignment of the lower leg.

Where is the study run from?

The lead study site is The Royal Infirmary of Edinburgh - NHS Lothian with the trial management team in Edinburgh Clinical Trials Unit - University of Edinburgh.

When is the study starting and how long is it expected to run for? August 2022 to July 2027

Who is funding the study? National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact for the study? Mr Anish Amin (Chief Investigator), Anish.K.Amin@ed.ac.uk (UK)

# Contact information

Type(s)

Principal investigator

Contact name

Mr Anish Amin

#### **ORCID ID**

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#### Type(s)

**Public** 

#### Contact name

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# Additional identifiers

## Clinical Trials Information System (CTIS)

Nil known

## Integrated Research Application System (IRAS)

306571

#### ClinicalTrials.gov (NCT)

Nil known

#### Protocol serial number

NIHR129820, CPMS 55238, IRAS 306571

# Study information

Scientific Title

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?

#### Acronym

MOTION Trial

#### **Study objectives**

Determine whether the intervention is superior to the comparator by answering the following two research questions:

- 1. For patients aged <60 years old with medial compartment knee OA, what is the relative clinical effectiveness (pain relief, improvement in function, quality of life, return to work) of HTO compared with non-surgical management at 24 months?
- 2. For patients aged <60 years old with medial compartment knee OA, what is the relative cost-effectiveness of HTO compared to non-surgical management at 24 months and as modelled over a lifetime horizon?

#### Ethics approval required

Ethics approval required

#### Ethics approval(s)

approved 16/01/2023, South Central - Hampshire B Research Ethics Committee (2 The Square, Temple Quay, Bristol, BS1 6PN, United Kingdom; +44 (0)207 104 8088; hampshireb.rec@hra.nhs.uk), ref: 22/SC/0446

#### Study design

Multi-centre prospective randomized open blinded endpoint (PROBE) parallel-group controlled trial

#### Primary study design

Interventional

#### Study type(s)

Treatment

#### Health condition(s) or problem(s) studied

Medial compartment knee osteoarthritis

#### **Interventions**

In this study, patients under 60 years old with knee OA who the treating orthopaedic surgeon considers a suitable candidate for medial opening wedge high tibial osteotomy (HTO) surgery will be selected to compare the two possible options (non-surgical versus HTO). Half of the participants will be randomised for surgery (HTO) and half will be randomised to undertake a personalised knee therapy (PKT) package. PKT consists of a core package of a progressive structured exercise programme and advice on pain management, lifestyle and if appropriate, weight management. If it falls within usual care, optional inclusion of additional manual therapy, steroid injection, insoles or bracing and treatment of any co-existing symptoms can be introduced. The package is delivered over a 12 – 16 week period and involves 6 face-to-face sessions of physiotherapy and a patient program of physiotherapy to complete at home. Patients will be asked to complete a diary to record their compliance with the programme and bring it along to each visit for the details to be recorded. 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 the interventions, we will ask patients about their pain, knee function, quality of life and ability to work before and after the treatment. The research will be carried out at the local hospital or institution where the patient would normally be seen and treated.

#### Intervention Type

Mixed

#### Primary outcome(s)

Patients' opinions about their knee and associated problems measured using the patient-reported Knee Injury and Osteoarthritis Outcome Score (KOOS) at 24 months

#### Key secondary outcome(s))

- 1. Fidelity of interventions measured using the minimum requirements/acceptable variation (MRAV) proforma completed between 6 -12 months post-intervention (note that this interval may be different from the same period post-randomisation due to NHS waiting lists)
- 2. Patients' opinions about their knee and associated problems measured using the patient-reported Knee Injury and Osteoarthritis Outcome Score (KOOS) at 12 months post-randomisation.
- 3. Symptoms, pain, ADLs, sports/recreation, and quality of life measured using five separate KOOS subscales at 12- and 24-months post-randomisation
- 4. Function and pain measured using the Oxford Knee score (OKS) at 12 and 24- months post-randomisation
- 5. Artificial prosthesis awareness during daily activities measured using the Forgotten Joint Score-12 (FJS-12) at 12- and 24- months post-randomisation
- 6. Health-related quality of life measured using the EuroQol EQ-5D-5L score (EQ-5D-5L EQ-5D) at 12- and 24- months post-randomisation
- 7. Sleep quality measure using the Pittsburgh Sleep Quality Index (PSQI) at 12- and 24-months post-randomisation
- 8. Employment status measured using a bespoke Return to Work/Employment Questionnaire developed at the lead centre at 12 and 24 months post-randomisation
- 9. Additional study-knee-related operative intervention measured using patient medical records at 12- and 24-months post-randomisation
- 10. Intraoperative and postoperative complications measured using patient medical records at 12 and 24 months post-randomisation
- 11. Health Economic Evaluation Outcomes derived from the EQ-5D score at 12- and 24- months post-randomisation
- 11.1. Health and social care resource utilisation and associated NHS and personal social services (PSS) cost and Quality Adjusted life years (QALY) at 24 months
- 11.2. Incremental Cost per QALY at 24 months
- 11.3. NHS and PSS cost, and QALYs as modelled over a lifetime horizon to account for future impacts on the need for TKR and associated revision surgery and their timing relative to retirement
- 11.4. Incremental Cost per QALY as modelled over a lifetime horizon to account for future impacts on the need for TKR and associated revision surgery and their timing relative to retirement

#### Completion date

31/07/2027

# **Eligibility**

#### Key inclusion criteria

1. Patient aged <60 years old with symptomatic medial compartment knee OA who the treating orthopaedic surgeon considers a suitable candidate for medial opening wedge HTO

#### Participant type(s)

**Patient** 

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Lower age limit

18 years

#### Upper age limit

60 years

#### Sex

All

#### Total final enrolment

91

#### Key exclusion criteria

- 1. Aged <18 or >60 years old
- 2. Body mass index (BMI) >40
- 3. Patients considered for HTO but who DO NOT have any knee OA including:
- 3.1. Offloading HTO for concomitant cartilage repair (No OA)
- 3.2. Offloading HTO solely to treat ligamentous instability (ACL/PCL)
- 3.3. Symptomatic avascular necrosis/osteonecrosis
- 3.4. Correction of intraarticular or extraarticular post-traumatic knee deformity
- 4. Patients requiring double-level knee osteotomy for correction of deformity
- 5. History of inflammatory arthropathy including rheumatoid arthritis, gout, psoriasis
- 6. Previous high tibial or distal femoral osteotomy in the same or contralateral knee
- 7. Previous knee replacement (partial or total) in the same or contralateral knee
- 8. Cognitive impairment or inability to consent.
- 9. Inability to comply with study procedures.
- 10. Previous history of septic arthritis in the knee

#### Date of first enrolment

01/02/2023

#### Date of final enrolment

01/04/2025

# **Locations**

#### Countries of recruitment

**United Kingdom** 

England

Scotland

Wales

# Study participating centre NHS Lothian

Waverley Gate 2-4 Waterloo Place Edinburgh United Kingdom EH1 3EG

## Study participating centre NHS Greater Glasgow and Clyde

J B Russell House Gartnavel Royal Hospital 1055 Great Western Road Glasgow Glasgow United Kingdom G12 0XH

# Study participating centre NHS Fife

Hayfield House Hayfield Road Kirkcaldy United Kingdom KY2 5AH

# Study participating centre

NHS Grampian Summerfield House 2 Eday Road Aberdeen United Kingdom AB15 6RE

#### Study participating centre University Hospitals Coventry and Warwickshire NHS Trust

Walsgrave General Hospital Clifford Bridge Road Coventry United Kingdom CV2 2DX

### Study participating centre Oxford University Hospitals

John Radcliffe Hospital Headley Way Headington Oxford United Kingdom OX3 9DU

#### Study participating centre Lewisham and Greenwich NHS Trust

University Hospital Lewisham Lewisham High Street London United Kingdom SE13 6LH

## Study participating centre

Warrington and Halton Teaching Hospitals NHS Foundation Trust

Warrington Hospital Lovely Lane Warrington United Kingdom WA5 1QG

# Study participating centre Guys and St Thomas' NHS Foundation Trust

St Homas' Hospital Westminster Bridge London United Kingdom SE1 7EH

# Study participating centre East Suffolk and North Essex NHS Foundation Trust

Colchester Dist General Hospital Turner Road Colchester United Kingdom CO4 5JL

# Study participating centre St George's University Hospital NHS Foundation Trust

St George's Hospital Blackshaw Road Tooting London United Kingdom SW17 0QT

#### Study participating centre Frimley Health NHS Foundation Trust

Portsmouth Road Frimley Camberley, United Kingdom GU16 7UJ

# Study participating centre Whiston Hospital (site)

Whiston Hospital Warrington Road Prescot United Kingdom L35 5DR

# Study participating centre University Hospitals Birmingham NHS Foundation Trust

Queen Elizabeth Hospital
Mindelsohn Way
Edgbaston
Birmingham
United Kingdom
B15 2GW

# Study participating centre NHS Lanarkshire

14 Beckford Street Hamilton United Kingdom ML3 0TA

## Study participating centre Kingston Hospital NHS Foundation Trust

Galsworthy Road Kingston upon Thames United Kingdom KT2 7QB

#### Study participating centre Salisbury District Hospital

Salisbury District Hospital Odstock Road Salisbury United Kingdom SP2 8BJ

#### Study participating centre The Maidstone Hospital

Hermitage Lane Maidstone United Kingdom ME16 9QQ

## Study participating centre Sunderland Royal Hospital

Kayll Road Sunderland United Kingdom SR4 7TP

# Sponsor information

#### Organisation

University of Edinburgh

#### **ROR**

https://ror.org/01nrxwf90

#### Organisation

NHS Lothian

#### **ROR**

https://ror.org/03q82t418

# Funder(s)

#### Funder type

Government

#### **Funder Name**

National Institute for Health and Care Research

#### Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

#### **Funding Body Type**

Government organisation

## **Funding Body Subtype**

National government

#### Location

**United Kingdom** 

# **Results and Publications**

## Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

## IPD sharing plan summary

Data sharing statement to be made available at a later date

# Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			20/09/2023	No	No
Participant information sheet	version 3.0	10/01/2023	25/01/2023	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 2.0	06/12/2022	25/01/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes