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

Submission date
17/01/2023

Recruitment status
No longer recruiting

Registration date
25/01/2023

Overall study status
Ongoing

Last Edited
17/04/2025

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] 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)

Study website
https://www.ed.ac.uk/usher/edinburgh-clinical-trials/our-studies/all-current-studies/motion

Contact information

Type(s)
Principal Investigator

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Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
306571

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Home, Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

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

Secondary outcome measures
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

Overall study start date
01/08/2022

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
60 Years

Sex
Both

Target number of participants
224

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
England

Scotland

United Kingdom

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
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SR4 7TP

Sponsor information

Organisation
University of Edinburgh

Sponsor details
The Queens Medical Research Institute
47 Little France Crescent
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None available
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Sponsor type
University/education

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http://www.ed.ac.uk/home

ROR
https://ror.org/01nrxwf90

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NHS Lothian

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The Queens Medical Research Institute
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EH16 4TJ
None available
accord@nhslothian.scot.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.nhslothian.scot.nhs.uk/Pages/default.aspx

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

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.
The press will also be engaged through the University of Edinburgh press office. We may also use lay summaries and infographics which can be sent to trial participants, and trial hospitals, and published on our trial website, or in conjunction with the main publication, if journal policies allow. We will prepare articles for dissemination within magazines such as Arthritis Today and patient-focused websites such as https://www.patient.co.uk and https://www.versusarthritis.org.

Intention to publish date
31/07/2028

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?
Participant information sheet	version 3.0	10/01/2023	25/01/2023	No	Yes
Protocol file	version 2.0	06/12/2022	25/01/2023	No	No
HRA research summary			20/09/2023	No	No