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For people with pain after a meniscectomy, but without established OA, does a treatment strategy of undertaking MAT surgery or personalised knee therapy result in better clinical and/or cost effectiveness outcomes?

Submission date
01/09/2022

Recruitment status
No longer recruiting

Registration date
02/09/2022

Overall study status
Ongoing

Last Edited
02/01/2025

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
Background and study aims
The meniscus is an important structure within the knee. One of its key roles is to cushion impact and protect the gliding surface of the joint from wear. Patients that have damaged their meniscus, and had a removal of the meniscus (a total meniscectomy), are more likely to develop persistent pain after this resulting in years of disability.
At present, there are several treatment options ranging from knee therapy (physiotherapy) to a replacement meniscus also known as a 'meniscal transplant'. Meniscal transplant is thought to provide cushioning to the joint surfaces and improve symptoms but it has a long recovery period and the operation carries risk of surgery as well as not helping with symptoms. At present, there is no direct evidence that meniscal transplant is better or worse than a specific targeted rehabilitation and therapy program.
In this study, we will compare two treatments for patients with a total meniscectomy.

Who can participate?
Adults with knee pain and/or functional limitation following meniscectomy but without large areas of articular cartilage loss or established OA.

What does the study involve?
One group of patients will have a course of personalised knee therapy and the other group will have a meniscal transplant. In total 144 participants will be recruited from 12 NHS Trust and 3 International sites and followed-up for 24 months post randomisation.

What are the possible benefits and risks of participating?
There are no specific benefits to taking part. Both treatments are designed to help reduce the symptoms you currently feel in your knee. By taking part in the trial, you are helping to decide about the best treatment for people in the future.

There are no special risks over and above what your doctor would normally inform you about. There are risks with meniscal transplant surgery, including surgical risks of tearing the new meniscus, persistent knee pain, infection, and blood clots, but these are the same risks for patients that do not take part in the study. The risks of the operation will be discussed in more detail with you by the clinical team who are looking after you in hospital, as part of your consent to treatment.
The risks associated with personalised knee therapy are also the same for patient that do not take part in the study. These may include temporary muscle soreness from exercise. A knee brace may be offered as part of both personalised therapy, and they are routinely used in recovery from surgery. They may provide good pain relief and are important after surgery to protect the recovering tissues. They may be uncomfortable or inconvenient. The personalised knee therapy programme is likely to be a shorter wait compared with surgery. We do not know which treatment would give a better improvement in the long-term that is what this study is trying to find out.

Where is the study run from?
University of Warwick (UK)

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

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

Who is the main contact?
Miss Natalie Hammonds, meteor2@warwick.ac.uk

Study website
https://warwick.ac.uk/fac/sci/med/research/ctu/trials/meteor2/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number
307686

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 307686, NIHR131629, CPMS 54157

Study information

Scientific Title
The Meniscal Transplant Surgery or Optimised Rehabilitation - Full Randomised Controlled Trial

Acronym
METEOR2

Study hypothesis
For people with pain after a meniscectomy, but without established OA, does a treatment strategy of undertaking MAT surgery or personalised knee therapy result in better clinical and /or cost effectiveness outcomes?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 19/08/2022, London - Bloomsbury Research Ethics Committee (HRA RES Centre Manchester, 3rd Floor Barlow House, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 2071048272; bloomsbury.rec@hra.nhs.uk), ref: 22/LO/0327

Study design
Two-arm multi-centred pragmatic randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See study outputs table

Condition
Adults with knee pain and/or functional limitation following meniscectomy but without large areas of articular cartilage loss or established OA.

Interventions
Participants are randomised to personalised knee therapy or meniscal transplant surgery. Participants will be randomly allocated (1:1) to the two treatment groups via a central computer-based randomised system provided by the Warwick Clinical Trials Unit's programming team. Randomisation will be 1:1 allocation by minimisation with a random factor with a 70% weighting towards balance across the whole study, stratified by age (greater or equal to 30, or less than 30), centre and knee compartment (lateral or medial).

Personalised Knee Therapy: The PKT programme is an optimised non-surgical intervention (i.e. optimised rehabilitation) to improve the outcomes of people with knee pain and/or functional limitation following meniscectomy. The programme is outlined below:
PKT Aim: To reduce pain, restore full knee range of motion, improve function, and optimise overall social participation through a goal-setting approach personalised to the participant.
Delivered by: A senior physiotherapist trained in the principles of PKT
Mode of delivery: The intervention will be personalised to the participant. Through this there is flexibility, as determined by clinical judgement and service provision at the time, for PKT to be delivered face-to-face, through virtual consultation or a hybrid of the two.
Duration: Minimum of 3 months from first assessment and a minimum of four sessions in total, but would be as many as clinically required, reflecting normal clinical practice.
Treatment starting point from randomisation: When an appointment with a physiotherapy appointment is available according to normal clinical waiting times. Typical waiting times for physiotherapy appointments at the lead site are approximately 2-3 months, but this may vary depending on individuals' sites' usual processes.
Time of consultations: The interval between consultants will be personalised to the needs of the participant based on the progress, presentation, and treatment goals. This will be a shared decision between physiotherapist and participant.
Content of consultants: Assessment: All participant will be reviewed in an initial assessment by a physiotherapist. In this, the participant's history (subjective assessment) and physical examination (objective assessment) will be taken. This will follow a routine musculoskeletal physiotherapy assessment made to the participant's rehabilitation, optimising their outcome. Through this, the physiotherapist and participant, through discussion and clinical reasoning, select intervention in a menu-approach, to personalise the rehabilitation to the participant. The specific exercises, interventions, dosage, intensity, and frequency of exercise will be determined by the presenting participant and prescribed accordingly by their physiotherapist. This ensures a personalised programme is offered as part of PKT (and is consistent with good quality physiotherapy care in routine practice).

MAT Surgery:
MAT surgery will be done will done once an allograft becomes available and will follow a trial-specific surgical manual. All care including the choice of anaesthetic, the surgical procedure and post-operative analgesia, will be in accordance with usual procedures and care at participating sites. Fidelity and process measures will be assessed using a surgical care report form which will include details of surgery (surgical findings, theatre time, tourniquet time, graft size, fixation of graft, an other procedures) and the anaesthetic on a case report form (CRF).
Rehabilitation for the surgery group will be according to a standardised programme specific to MAT. We will use the lead centre's established programme for this and, in discussion with participating centres, adapt it to ensure it is delivered across multiple NHS and international

sites in a multi-centre trial. This will be led by the physiotherapy co-applicants in paraellel to the refinement of the PKT intervention. A formal PKT programme will not be used prior to surgery in the MAT arm, although we will not discount people having prior or current physiotherapy.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Participant-reported knee function at 24 months, post randomisation, using the four-domain version of the Knee Injury and Osteoarthritis Outcome score (KOOS4).
2. To assess the cost effectiveness of MAT compared to PKT from an NHS and Personal, Social Service (PSS) perspective measured using health utility, occupational status, sports participant, mental wellbeing, further surgery (treatment switching or secondary knee surgery), satisfaction with the outcome of treatment, participant global impression of change and adverse events at three (EQ-5D 5L only), 6, 12, 18 and 24 months after randomisation

Secondary outcome measures
1. KOOS4 at baseline, pre-intervention, 6, 12, 18 and 24 months post randomisation.
2. EQ-5D 5L at baseline, pre-intervention, 6, 12, 18 and 24 months post randomisation.
3. The five individual KOOS domain at baseline, 6, 12, 18 and 24 months post randomisation.
4. International Knee Documentation Committee subjective score (IKDC) at baseline and 24 months post randomisation.
5. Short Warwick-Edinburgh Mental Wellbeing Scale at baseline, 6, 12, 18 and 24 months post randomisation.
6. Tegner activity/sport scale at baseline, 6, 12, 18 and 24 months post randomisation.
7. Satisfaction with the outcome of treatment at 6, 12, 18 and 24 months post randomisation.
8. Patient global impression of change at 6, 12, 18 and 24 months post randomisation.
9. Adverse events at 6, 12, 18 and 24 months post randomisation.
10. Further knee surgery at 6, 12, 18 and 24 months post randomisation.
11. Health resource use at baseline, 6, 12, 18 and 24 months post randomisation.
12. Analgesia use at baseline, 6, 12, 18 and 24 months post randomisation.

Overall study start date
01/06/2022

Overall study end date
30/11/2027

Eligibility

Participant inclusion criteria
1.Pain and/or functional restrictions from the knee, severe enough to warrant potential MAT in the judgement of the treating clinician
2. Previous meniscectomy more than 6 months ago

Participant type(s)
Patient

Age group
Adult

Lower age limit
16 Years

Sex
Both

Target number of participants
144

Participant exclusion criteria
1. Symptomatic ligament instability, not previously corrected, as determined by the assessing clinician
2. Coronal limb alignment which requires surgical correction, (previous correction, performed at least 6 months before entry to the trial, is not an exclusion criteria), as determined by the assessing clinician
3. Age under 16 years, or if ≥16, open growth plate at the proximal tibia as judged by the clinical team on imaging taken as part of standard care
4. Full thickness cartilage loss (exposed bone) >1 cm2 on routine clinical MRI, prior surgery, or any other form of clinical imaging or evaluation. This will be determined by the assessing clinician (it could be based on an assessment by a clinician or a radiologist, although the final decision rests with the treating clinician)
5. Inflammatory arthritis affecting the study knee as determined by the assessing clinician (i.e., a prior inflammatory event not considered to be related to the current clinical condition would not require exclusion)
6. Unable or unwilling to engage with rehabilitation
7. Unable to adhere to trial processes
8. Previous randomisation in the present trial (i.e., other knee). Where a previous randomisation has occurred in error, a participant may be withdrawn and this criterion will not apply

Recruitment start date
01/11/2022

Recruitment end date
31/03/2025

Locations

Countries of recruitment
Australia

Belgium

Canada

England

Northern Ireland

Scotland

United Kingdom

Study participating centre
University Hospitals Coventry and Warwickshire NHS Trust
Clifford Bridge Road
Coventry
United Kingdom
CV2 2DX

Study participating centre
Belfast Health and Social Care Trust
Trust Headquarters
A Floor - Belfast City Hospital
Lisburn Road
Belfast
United Kingdom
BT9 7AB

Study participating centre
University College London Hospitals NHS Foundation Trust
250 Euston Road
London
United Kingdom
NW1 2PG

Study participating centre
Cambridge University Hospitals NHS Foundation Trust
Cambridge Biomedical Campus
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
North Bristol NHS Trust
Southmead Hospital
Southmead Road
Westbury-on-trym
Bristol
United Kingdom
BS10 5NB

Study participating centre
The Rotherham NHS Foundation Trust
Moorgate Road
Rotherham
United Kingdom
S60 2UD

Study participating centre
NHS Lanarkshire Health Board
University Hospital Monklands
Monkscourt Avenue
Airdrie
United Kingdom
ML6 0JS

Study participating centre
Gloucestershire Hospitals NHS Foundation Trust
Sandford Rd
Cheltenham
United Kingdom
GL53 7AN

Study participating centre
Royal National Orthopaedic Hospital NHS Trust
Brockley Hill
Stanmore
United Kingdom
HA7 4LP

Study participating centre
The Royal Orthopaedic Hospital
Bristol Road South
Northfield
Birmingham
United Kingdom
B31 2AP

Study participating centre
Nuffield Orthopaedic Centre
Windmill Road

Headington
Oxford
United Kingdom
OX3 7HE

Study participating centre
Royal Devon University Healthcare NHS Foundation Trust
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Barrack Road
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EX2 5DW

Study participating centre
Wrightington Hospital
Hall Lane
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United Kingdom
WN6 9EP

Study participating centre
Queen Elizabeth University Hospital
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1345 Govan Road
Glasgow
United Kingdom
G51 4TF

Study participating centre
Golden Jubilee National Hospital
Agamemnon Street
Clydebank
United Kingdom
G81 4DY

Study participating centre
The Royal Wolverhampton NHS Trust
New Cross Hospital
Wolverhampton Road
Heath Town

Wolverhampton
United Kingdom
WV10 0QP

Study participating centre
Royal North Shore Hospital
Reserve Rd
St Leonards
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NSW 2065

Study participating centre
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3 Westbourne St
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NSW 2065

Study participating centre
Brisbane Private Hospital
259 Wickham Terrace
Brisbane City
Brisbane
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QLD 4000

Study participating centre
Cleveland Clinic London
33 Grosvenor Place
London
United Kingdom
SW1X 7HY

Sponsor information

Organisation
University of Warwick

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Sponsor type
University/education

Website
https://warwick.ac.uk/fac/sci/med/research/ctu/

ROR
https://ror.org/01a77tt86

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
Dissemination to patients and the public will be led in conjunction with our patient partners, who have been closely involved throughout the study development.

Dissemination to trial participants will follow current HRA guidelines and Warwick SOP 22 on publication & dissemination (https://www.hra.nhs.uk/planning-and-improvingresearch/best-practice/publication-and-dissemination-research-findings/).
We will use lay summaries and infographics which will be sent to trial participants (participants permission for this will be obtained at baseline), trial hospitals, and published on our trial website, or in conjunction with the main publication, if journal policies allow.
Trial participants will be informed of the results using lay summaries and infographics on publication of the primary outcome results, we will follow current Health Research Authority guidelines in delivering this. We will prepare articles in magazines such as Arthritis Today, patient focused websites such as patient.co.uk and utilise social media to report our findings. We will use press releases to alert the popular press in conjunction with our press officer. A trial website will be hosted by WCTU and used to promote study progress and trial publications.

Intention to publish date
01/12/2027

Individual participant data (IPD) sharing plan
De-identified data that underlie the results reported in the study will be available for non-commercial use, up to one year after publication of the primary outcome trial findings, or from metadata stored in a university repository up to 10 years without investigator support. To access trial data, third parties must complete a data-sharing agreement with the sponsors, have an ethically approved protocol in place for use of the data, and agree the approved protocol with the MeTeOR2 TMG. Data may be used for commercial purposes, according to the conditions above, but will need specific agreements in place prior to access being agreed, this may include a license fee. Analyses may include individual patient data meta-analyses or other purposes as agreed with the MeTeOR2 TMG. Available data will include (but is not exclusive to) de-identified individual participant data that underlies the results reported in trial publications, the study protocol, statistical analysis plan, master copy of the informed consent sheets and analytic codes used. After a year following the publication of the final report, the data will be stored in an appropriate repository, it may still be available according to the conditions laid out above but may not receive investigator support.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1	03/08/2022	02/09/2022	No	Yes
Participant information sheet	version 2	10/11/2022	25/05/2023	No	Yes
HRA research summary			28/06/2023	No	No
Participant information sheet	version 3	14/11/2023	06/02/2024	No	Yes
Protocol file	version 2	01/08/2023	06/02/2024	No	No
Protocol article		03/06/2024	04/06/2024	Yes	No