

What are the treatments and outcomes of people with obesity and severe knee osteoarthritis?

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Registration date 29/10/2024	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 06/12/2024	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English Summary

Background and study aims

In the UK, nearly 18.5 million people live with obesity, making them almost five times more likely to develop knee arthritis compared to those with normal weight. Severe knee arthritis can be treated with a knee replacement, but many areas in the UK have rules that prevent obese people from having this surgery. This study aims to understand how best to help people with obesity and severe knee arthritis, whether they can have surgery or not. It will look at current treatments, how well they work for knee pain, and the relationship between weight, body image, and knee pain.

Who can participate?

Adults with severe knee arthritis of any weight who have good enough English language skills to respond to questionnaires can participate.

What does the study involve?

- 1. Interview study:** Participants will answer questions about their feelings regarding the care they receive for knee arthritis and their weight. The researcher will identify common themes from these interviews to understand what people think about NHS treatments for arthritis and obesity.
- 2. Cohort study:** 210 people with obesity will be asked to participate from three hospitals. They will answer questions about knee pain, disability, and body image at their appointment or at home. They will be contacted again 6 and 12 months later to update on their weight, treatments received, any surgeries, knee pain, and quality of life. This will help identify which factors most strongly impact knee pain.
- 3. Measurement of key patterns:** 190 more people of any weight with severe arthritis will fill in surveys at one time point. These surveys will measure knee pain, disability, and body image. The answers will be analyzed to find patterns and connections between knee pain, body image, and care experiences.

What are the possible benefits and risks of participating?

There are no specific benefits to taking part, but participants will help improve knowledge about

the links between psychosocial factors and knee pain, aiding future patient care and research. There are no additional physical risks as the study does not change or influence treatment pathways.

Where is the study run from?

The study is run from Warwick Clinical Trials Unit, Warwick Medical School, University of Warwick, Coventry, UK.

When is the study starting and how long is it expected to run for?

February 2024 to December 2027

Who is funding the study?

The study is funded by the National Institute for Health and Care Research (NIHR; UK)

Who is the main contact?

Dr Fatema Dhaif, Orthopaedic Registrar and Doctoral Research Fellow, University of Warwick (OAKS@warwick.ac.uk).

Contact information

Type(s)

Principal Investigator

Contact name

Prof Andrew Metcalfe

ORCID ID

<http://orcid.org/0000-0002-4515-8202>

Contact details

Warwick Clinical Trials Unit
Warwick Medical School
University of Warwick
Coventry
United Kingdom
CV4 7AL
+44 (0)24 76575288
a.metcalfe@warwick.ac.uk

Type(s)

Public, Scientific

Contact name

Dr Fatema Dhaif

ORCID ID

<http://orcid.org/0000-0001-8473-9045>

Contact details

Clinical Sciences Research Laboratory,
Clinical Sciences Building,

Clifford Bridge Road
Coventry
United Kingdom
CV2 2DX
+44 2476963587
fatema.dhaif@warwick.ac.uk

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

341128

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

CPMS 64836

Study information

Scientific Title

Obesity and arthritis of the knee study

Acronym

OAKS

Study hypothesis

A trial of an effective weight loss programme is needed for people with obesity and severe osteoarthritis (OA) but important preparatory work is required before this can be performed. The key questions that need to be addressed are a more detailed understanding of the baseline characteristics of people who present with this problem, the treatments that people who attend NHS clinics currently receive both for their weight and their knee problems, the factors that influence pain in this population and the relationship between psychosocial aspects and outcomes scores. Once we understand the answers to these questions, we will be able to select the best interventions and study design for a multi-centre randomised trial to determine the best management for this under-served population.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 10/10/2024, West of Scotland REC 5 (Ward 11, Dykebar Hospital, Grahamston Road, Paisley, PA2 7DE, United Kingdom; +44 (0)141 314 0213; ggc.wosrec5@nhs.sco), ref: 24/WS/0146

Study design

Observational study with combined cross-sectional and cohort design with a nested qualitative study

Primary study design

Observational

Secondary study design

Cohort, cross-sectional, and qualitative

Study setting(s)

Hospital

Study type(s)

Other

Participant information sheet

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

Condition

Knee osteoarthritis

Interventions

Qualitative interview study: We will recruit approximately 12 participants with obesity and severe knee arthritis using a purposive sampling technique. Attainment of data saturation will inform the exact sample size. We will perform semi-structured interviews revolving around experience of care and preferences in treatment modalities. Interviews will be recorded, transcribed, and analysed using thematic analysis. The interviews will take place over video teleconference or in person as per participant preference.

Prospective cohort study: We will recruit 210 participants with BMI ≥ 35 from UK secondary care centres. We will collect patient reported outcome measures (PROMs) questionnaire data and BMI from participants at 4 timepoints: baseline, 6, 12, and 24 months. We will also collect data on weight loss treatments delivered and whether participants underwent knee surgery. Follow up questionnaires will be administered over telephone, post or email as per participant preference.

Intervention Type

Other

Primary outcome measure

Oxford Knee Score at 12 months

Secondary outcome measures

Recorded at baseline, 12 months and 24 months:

1. Height and weight, which will be used to calculate BMI. This will be measured and recorded by a member of the research team.
2. OKS-APQ (activity participation score) a PROM which was developed as an adjunct to the OKS. The purpose of the APQ is to combat the issue with ceiling effect of the OKS when used alone.
3. Body-Q, a PROM which was developed for use by people with obesity undergoing weight loss interventions. It measures four domains (appearance, eating-related concerns, health-related quality of life and experience of care). An international multi-disciplinary consensus meeting identified which constructs were most important to measure and identified BODY-Q as the PROM instrument which best measured 6 out of 8 of the most important domains. Furthermore,

a systematic review of the most suitable instrument for bariatric surgery identified BODY-Q as the instrument with the strongest evidence for content validity.

4. Euro-Qol-5D-5L (EQ-5D-5L) as a measure of health-related quality of life. It is a score assessing mobility, self-care, usual activities, pain/discomfort, and anxiety/depression (5 dimensions).

5. Generalised self-efficacy (GSE) scale

6. Hospital Anxiety and Depression Scale (HADS)

Overall study start date

07/02/2024

Overall study end date

01/12/2027

Eligibility

Participant inclusion criteria

For the cohort study:

1. Referral from primary care to secondary or intermediate care services for their knee.
2. Severe arthritis as assessed by the treating clinician which can be defined as KL grade 4 primary knee arthritis (severe) in any knee compartment on a knee radiograph (x-ray) OR clinician deems arthritis severe enough to warrant a TKR.
3. BMI ≥ 35 kg/m²
4. Aged over 18 years
5. Has capacity to consent to being in a research study
6. Sufficient English language skills to understand study materials and respond to questionnaires

For the qualitative study with patients:

As above

For the cross-sectional study:

1. Any BMI
2. KL grade 4 primary knee arthritis (severe) in any knee compartment

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

400

Participant exclusion criteria

1. Presence of inflammatory arthritis
2. History of intra-articular fracture causing post-traumatic arthritis
3. Previous surgery on the ipsilateral knee only an exclusion criteria if implants were inserted
4. Unable or unwilling to comply with follow up procedure
5. Unable to provide informed consent (e.g does not have capacity to consent)
6. Insufficient English language skills to understand study materials and respond to questionnaires

Recruitment start date

01/12/2024

Recruitment end date

01/12/2025

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

University Hospitals Coventry and Warwickshire NHS Trust

Walsgrave General Hospital

Clifford Bridge Road

Coventry

United Kingdom

CV2 2DX

Study participating centre

Northumbria Healthcare NHS Foundation Trust

North Tyneside General Hospital

Rake Lane

North Shields

United Kingdom

NE29 8NH

Study participating centre

Nottingham University Hospitals NHS Trust - Queen's Medical Centre Campus

Nottingham University Hospital

Derby Road

Nottingham

United Kingdom

NG7 2UH

Study participating centre
Frimley Health NHS Foundation Trust
Portsmouth Road
Frimley
Camberley
United Kingdom
GU16 7UJ

Study participating centre
University Hospitals Birmingham NHS Foundation Trust
Queen Elizabeth Hospital
Mindelsohn Way
Edgbaston
Birmingham
United Kingdom
B15 2GW

Sponsor information

Organisation
University of Warwick

Sponsor details
University of Warwick, Coventry
Coventry
England
United Kingdom
CV4 7AL
+44 24 765 75732
sponsorship@warwick.ac.uk

Sponsor type
University/education

Website
<http://www2.warwick.ac.uk/>

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

Planned publication in a peer-reviewed journal and presentation at orthopaedic conferences.

Intention to publish date

01/08/2027

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study will be available upon request from OAKS@warwick.ac.uk

IPD sharing plan summary

Available on request