ISRCTN42984928 https://doi.org/10.1186/ISRCTN42984928

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

Submission date
07/10/2024

Recruitment status
No longer recruiting

Registration date
29/10/2024

Overall study status
Ongoing

Last Edited
10/07/2025

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

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

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Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
341128

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 64836

Study information

Scientific Title
Obesity and arthritis of the knee study

Acronym
OAKS

Study objectives
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

Study type(s)
Other

Health condition(s) or problem(s) studied
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(s)
Oxford Knee Score at 12 months

Key secondary outcome(s))
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)

Completion date
31/12/2027

Eligibility

Key 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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key 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

Date of first enrolment
01/12/2024

Date of final enrolment
31/12/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University Hospitals Coventry and Warwickshire NHS Trust
Walsgrave General Hospital
Clifford Bridge Road
Coventry
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CV2 2DX

Study participating centre
Northumbria Healthcare NHS Foundation Trust
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Study participating centre
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Study participating centre
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Study participating centre
South Tees Hospitals NHS Foundation Trust
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Study participating centre
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Sponsor information

Organisation
University of Warwick

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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes