ISRCTN17829217 https://doi.org/10.1186/ISRCTN17829217

A randomised trial to understand the benefits of a new intervention designed to reduce muscle overactivity in people with knee osteoarthritis

Submission date
30/01/2026

Recruitment status
Recruiting

Registration date
09/02/2026

Overall study status
Ongoing

Last Edited
09/02/2026

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
People with knee osteoarthritis tighten their knee muscles too much when they perform daily activities. These muscle patterns will increase pressure on the knee joint, making pain worse. However, current physiotherapy management of knee osteoarthritis focuses on strengthening exercises and does not teach patients to change habitual muscle patterns.
We have developed a new treatment called “Cognitive Muscular Therapy (CMT)”, which can be delivered by physiotherapists. The therapy teaches patients to change the way they respond to pain and to improve the way they use their knee muscles during different activities. The treatment uses skin-mounted sensors to provide patients with visual feedback, and this helps patients to re-learn muscle patterns during standing and daily movements.
We want to understand whether this new form of physiotherapy could be effective for people with knee osteoarthritis who have not benefited from current physiotherapy treatment.

Who can participate?
Adults older than 45 that have knee osteoarthritis and who are not satisfied with the results of previous physiotherapy.

What does the study involve?
All participants will be asked to complete a set of questionnaires which allow the research team to understand their symptoms and how knee osteoarthritis interferes with their daily life. They will be required to complete these same questionnaires again at 6 months and again at 12 months after enrolling on the study.
After completing the first set of questionnaires, participants will be randomly allocated (like flipping a coin) to either receive the new treatment (group 1) or to be in the control group (group 2). Participants in the treatment group will receive the new physiotherapy treatment across seven weekly session and will also be asked to continue to access NHS care for their knee

osteoarthritis as they would normally. Participants in the control group will simply be asked to continue to access NHS care for their knee osteoarthritis as they would if they were not in the trial.

What are the possible benefits and risks of participating?
Participants who are allocated to the treatment group may experience reductions in knee pain and improvements in physical function. There are minimal risks to participating as this is a very simple, straight forward study. The treating physiotherapists will be using techniques which are used in routine clinical practice, which do not carry risk.

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

When is the study starting and how long is it expected to run for?
The study started in November 2025. Recruitment will begin in February 2026 and end in September 2027. Participants will be followed for one year and we anticipate the results to be ready in October 2028.

Who is funding the study?
The National Institute for Health and Care research (UK), Research for Patient Benefit funding scheme.

Who is the main contact?
Dr Jennifer Parker: J.Parker17@salford.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Central Portfolio Management System (CPMS)
65380

National Institute for Health and Care Research (NIHR)

208766

Integrated Research Application System (IRAS)
350962

Study information

Scientific Title
BEhaviour change for People with clinically diagnosed Knee Osteoarthritis: A pragmatic trial (BEPKO-3)

Acronym
BEPKO-3

Study objectives
The primary aim is to assess whether Cognitive Muscular Therapy (CMT) + usual care results in less knee pain and disability at 1-year post-randomisation compared to usual care alone. We hypothesise that CMT + usual care will be associated with lower composite WOMAC scores at 1 year in comparison to usual care alone for people with a clinical diagnosis of knee OA (OA), who are dissatisfied with the outcome of therapeutic exercise.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 21/11/2025, - (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; -; a@a), ref: 25/WA/0329

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Knee osteoarthritis

Interventions
Participants will then be randomly assigned to one of two groups. This assignment is done using a process called randomisation, which is similar to flipping a coin. It ensures that each participant has an equal chance of being placed in either group. This helps make the results fair and unbiased. The randomisation is done by a computer programme, not by the researchers, so no one can influence which group a participant goes into. The process also considers which hospital or clinic the participant is attending, to make sure both groups are balanced across different locations. Participants will be told which group they are in, after the randomisation is complete. The researchers collecting follow-up data will not know which group each participant is in, to help keep the results as objective as possible.

Group 1 will receive CMT which involves seven one-hour sessions with a trained physiotherapist over 7–9 weeks. The treatment includes education about pain, relaxation techniques, and exercises to reduce muscle overactivity. Participants will also be given online or paper materials (dependent on preference) to support home practice. Group 2will be advised to continue with their current NHS care as if there were not in the trial.

All participants, regardless of group, will be asked to complete follow-up questionnaires at 6 months and 12 months, after starting the study. These questionnaires will measure pain, function, quality of life, and healthcare use. Participants may complete these online, by post, or over the phone. Researchers will follow a reminder schedule when contacting participants about questionnaire completion.

Some participants and physiotherapists will also be invited to take part in interviews or focus groups to share their experiences of the treatment and the study.
Participants can withdraw at any time. If they stop the treatment, they will still be invited to complete the follow-up questionnaires.

Intervention Type
Behavioural

Primary outcome(s)
1. Knee pain, stiffness and physical function measured using Composite WOMAC (validated questionnaire) at Baseline, 12 months

Key secondary outcome(s))
1. Knee pain, stiffness and physical function measured using Composite WOMAC (validated questionnaire) at Baseline, 6 months

2. Knee pain measured using pain subscore on WOMAC scale (validated questionnaire) at Baseline, 6 months, 12 months

3. Knee stiffness measured using stiiffness subscore on WOMAC scale (validated questionnaire) at Baseline, 6 months, 12 months

4. Physical function measured using function subscore on WOMAC scale (validated questionnaire) at Baseline, 6 months, 12 months

5. Pain Catastrophizing measured using Pain Catastrophizing Scale Validated Questionnaire at Baseline, 6 months, 12 months

6. Work productivity and acvity impairment measured using WPAI:OA validated questionnaire at Baseline, 6 months, 12 months

7. Quality of life measured using EQ-5D-5L Validated Questionnaire at Baseline, 6 months, 12 months

8. Pain Self-Efficacy measured using PSEQ Validated Questionnaire at Baseline, 6 months, 12 months

9. Healthcare Resource use measured using Healthcare Resource Utilisation questionnaire (custom questionnaire) at Baseline, 6 months, 12 months

10. Global assessment of knee symptoms measured using Global Assessment of knee symptoms question (custom questionnaire) at 6 months and 12 months

11. Adverse events measured using Question (custom questionnaire) at 6 months

Completion date
31/10/2028

Eligibility

Key inclusion criteria
1. Aged 45 years or older. (KOA is most common in people over 45 and used in NICE criteria for knee osteoarthritis)
2. Activity-related joint pain (These are typical clinical signs of knee osteoarthritis and help confirm the diagnosis without needing an X-ray)
3. Morning stiffness lasting less than 30 minutes. (These are typical clinical signs of knee osteoarthritis and help confirm the diagnosis without needing an X-ray)
4. Score 4 or more (out of 20) on the WOMAC pain scale. (This ensures participants have a minimum level of pain, making it possible to detect meaningful improvements from the intervention)
5. Knee pain lasting more than 6 months. (This ensures participants have a long-term condition and are not experiencing temporary or acute symptoms)
6. Have tried therapeutic exercise and are dissatisfied with the outcome. (CMT is designed as a second-line treatment for people who have not responded well to exercise therapy, which is the first recommended treatment for knee OA)
7. Able to stand for 5 minutes and walk independently with no more than one walking stick or elbow crutch. (The intervention involves physical tasks such as standing, walking, and stair climbing. Participants need a basic level of mobility to safely take part)
8. Able to attend for seven hour-long intervention sessions with a physiotherapist (to receive the intervention)

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
45 years

Upper age limit
120 years

Sex
All

Total final enrolment
0

Key exclusion criteria

1. Body Mass Index (BMI) over 33 kg/m². (Excess body fat can interfere with the equipment used to measure muscle activity (electromyography), which is essential for the treatment)
2. Systemic inflammatory arthritis (e.g. rheumatoid arthritis). (This is a different type of joint condition that requires other forms of treatment and may respond differently to the intervention)
3. Diagnosis of a widespread pain condition (e.g. fibromyalgia). (These conditions involve pain throughout the body and may not benefit from a treatment focused specifically on the knee)
4. Neurological disorders. (These conditions may affect movement and safety during the physical parts of the treatment)
5. Diagnosis of dementia and score > 17 on the Telephone-Mini mental state examination (T-MMSE). (Participants need be able to understand intervention materials to benefit. If dementia is diagnosed, we will assess severity using the T-MMSE and include those with mild impairment)
6. Unable to speak English well enough to understand the treatment and complete study tasks (The treatment involves detailed explanations and guided exercises. Participants need to understand instructions clearly to benefit and stay safe. We have no budget to translate intervention materials or pay translators)

Date of first enrolment
09/02/2026

Date of final enrolment
30/09/2027

Locations

Countries of recruitment
United Kingdom

Study participating centre
University of Salford Frederick Road Campus
Health and Society
Brian Blatchford Building
Statham Street
Salford
England
M6 6PU

Sponsor information

Organisation
University of Salford

ROR
https://ror.org/01tmqtf75

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
- Data will be stored in FigShare and link provided in the final publication
- We will share raw anonymised, questionnaire data). This dataset will include only summary (group-level) descriptors of comorbidities, religion, socio-economic status and ethnicity to ensure there is no possibility of participants being identified from published data.
- Data will be uploaded once the main journal paper is accepted for publication and will be available for 10 years. Anyone will be able to access the data (we have consent for this)
- Researcher will be free to use any type of analysis of the data.

IPD sharing plan summary
Published as a supplement to the results publication, Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 3	20/11/2025	05/02/2026	No	Yes
Protocol file	version 5	23/01/2026	05/02/2026	No	No