ISRCTN25291958 https://doi.org/10.1186/ISRCTN25291958

A multi-centre feasibility study to understand the benefits of a new intervention designed to reduce muscle overactivity in people with knee osteoarthritis

Submission date
08/04/2022

Recruitment status
No longer recruiting

Registration date
27/04/2022

Overall study status
Completed

Last Edited
13/05/2025

Condition category
Musculoskeletal Diseases

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
People with knee osteoarthritis (KOA) often have physiotherapy which focuses on ways to strengthen the muscles in the leg. Unfortunately, for about 40% of people, this type of physiotherapy does not reduce their pain. This may be because people with KOA often over-tense their knee muscles during daily activities. In this situation, traditional exercise will not help to reduce their pain.
Researchers have developed a new physiotherapy treatment that may help people who do not experience benefit from muscle-strengthening physiotherapy. This new treatment teaches patients how they can stop over-tightening their muscles when they walk or do other daily movements. It also teaches them to change the way they react to pain. Sensors are attached to the skin which enable patients to see their muscle patterns, both during movement and in response to pain. This muscle visualisation is supported with animated instructional videos to explain muscle and pain concepts.
In a previous study, knee pain was reduced by an average of 69% following our treatment. It should therefore be possible to reduce pain in patients who do not respond to traditional muscle-strengthening. The researchers will ask 90 patients to take part who have previously received muscle strengthening for KOA but who have not experienced any improvement. They have already worked with patients and physiotherapists to develop the new treatment. The researchers will continue to do so in this study by asking their views on our training materials, how they experience the new treatment, and the best ways of letting people know about the results of the study. The information from this study will show whether the new treatment is acceptable for people who do not respond to muscle strengthening. If so, the researchers hope in the future to do a larger study which will show how helpful the intervention is at improving pain. This could change the way KOA is managed within the NHS, providing an alternative treatment for people who do not respond to muscle strengthening. This could help patients and also save the NHS money as it could stop patients needing to be referred for a knee replacement operation.

Who can participate?
1. Patients over 40 years old with a diagnosis of knee osteoarthritis
2. Physiotherapists working at the grade of a band 6 and above

What does the study involve?
Patients will be put into two groups by chance, like tossing a coin: half will get the new behavioural treatment, and the other half will get their usual care from their physiotherapist and other healthcare professionals. The researchers will ask participants to tell them about their pain, quality of life and how they manage their own pain before they start the study, at 20 weeks and at 8 months. They will also interview patients and physiotherapists to understand their experiences of receiving/delivering the new treatment. Physiotherapists who take part will receive both online and face to face training and will then deliver the new treatment with support from the research team. The physiotherapists will be invited to an interview to understand their experiences of delivering the new treatment.

What are the possible benefits and risks of participating?
Patients who get the new treatment may experience reductions in pain. The treatment is very low risk. Physiotherapists will develop new treatment skills. There is minimal risk involved in delivering the new treatment

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

When is the study starting and how long is it expected to run for?
December 2021 to April 2024

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

Who is the main contact?
Dr Stephen Preece
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Study website
https://hub.salford.ac.uk/cognitive-muscular-therapy/

Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
306258

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 51023, IRAS 306258

Study information

Scientific Title
BEhaviour change to reduce Pain in Knee Osteoarthritis (BEPKO-2) - a feasibility study

Acronym
BEPKO-2

Study objectives
This is a feasibility study so there will be no formal hypothesis testing. However, the study will provide data which will inform the design of a future trial which will test whether Cognitive Muscular Therapy reduces the pain associated with knee osteoarthritis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/01/2022, West Midlands - Solihull Research Ethics Committee (Equinox House, City Link, Nottingham, NG2 4LA, UK; +44 (0)207 104 8310; solihull.rec@hra.nhs.uk), ref: 21/WM/0255

Study design
Randomized; Both; Design type: Treatment, Rehabilitation, Validation of investigation /therapeutic procedures

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
See study outputs table

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

Interventions
Researchers have developed a new physiotherapy treatment that may help people who do not experience benefit from muscle-strengthening physiotherapy. This new treatment teaches patients how they can stop over-tightening their muscles when they walk or do other daily movements. It also teaches them to change the way they react to pain. Sensors are attached to the skin which enable patients to see their muscle patterns, both during movement and in response to pain. This muscle visualisation is supported with animated instructional videos to explain muscle and pain concepts. For more details on this new treatment see https://hub.salford.ac.uk/cognitive-muscular-therapy/.

Physiotherapists: The researchers plan to recruit six band 6 physiotherapists to deliver the CMT intervention. Each physiotherapist who participates in the trial will receive training to deliver the CMT intervention via an initial online module (approximately eight hours), followed by two face-to-face one-day workshops. The physiotherapist will be expected to keep a reflective diary and to use an online platform to share experiences of the training and the intervention. Further support from the lead physiotherapist or another suitably trained physiotherapist will be offered throughout the study if required.

Participants: The researchers will aim to recruit 90 participants to the study. Once recruited the participants will be randomised into one of two groups. Participants in the control arm will receive advice to continue exercise in line with the ESCAPE programme and to access usual care. Participants in the intervention arm will receive six sessions of cognitive muscular therapy by a

suitably trained physiotherapist, delivered over a period of 12 weeks. In addition to these intervention sessions, intervention arm participants will attend two Electromyography (EMG) data collection sessions. In these sessions, small sensors placed on the skin will be used to measure muscle activity during a variety of tasks. These will take place, the week prior to their first treatment and the week following their final treatment. The participants will be asked to perform a set of everyday activities, including walking, standing up from a chair, stepping down and balancing on one leg whilst EMG data is recorded. The researchers will also collect the same muscle outcome data, at the University of Salford, from a subset of 10 participants in the control arm. In addition, participants in the control group will be instructed to perform some maximal effort contractions, which involve standing on tiptoes, and flexing/extending the knee against a fixed resistance. The researchers will also assess hip flexibility, collect some simple balance measurements using a force platform and collect postural and breathing measurements using a 3D camera. It is possible that some patients who are included in the intervention arm will be continuing to practice ESCAPE strengthening exercises. Participants will therefore be advised to stop these exercises for the duration of the trial but to continue with low-intensity aerobic exercise.

To monitor intervention fidelity, the researchers will capture video recordings of approximately 15-20 of the physiotherapy sessions from all six NHS physiotherapists at different stages of the intervention cycle. These recordings will only be collected from participants who have consented and will not be shared outside the research teams. Once they have been analysed, they will be permanently deleted.

After completing the intervention the researchers will interview a subset of participants in the treatment arm and patients in the control arm to understand experiences of being involved in the trial. They will purposively select (through pain outcomes) 15 participants from the intervention arm who demonstrate a range of clinical responses. They will ensure that, with the sample of 15 participants, they include at least two to three who have decided to drop out before completing the full six intervention sessions, to gain insight into reasons for non-adherence. The researchers will interview all six NHS physiotherapists after intervention delivery is complete to understand their experience of delivering the intervention. These interviews will take place either face to face or over the phone/skype. The researchers will also ask each physiotherapist to complete the Normalisation Process Theory Survey.

Intervention Type
Behavioural

Primary outcome measure
Pain and function measured using the WOMAC questionnaire at baseline, 20 weeks and 8 months

Secondary outcome measures
1. Pain catastrophisation measured using the Pain catastrophizing scale at baseline, 20 weeks and 8 months
2. Kinesiophobia measured using the Tampa scale of kinesiophobia at baseline, 20 weeks and 8 months
3. Anxiety and depression measured using the Generalised Anxiety and Depression Scale at baseline, 20 weeks and 8 months
4. Health-related quality of life measured using the EQ-5D-5L at baseline, 20 weeks and 8 months
5. Health resource utilisation measured using a custom questionnaire at baseline, 20 weeks and

8 months
6. Work productivity and activity impairment measured using the work productivity and activity impairment (WPAI) questionnaire at baseline, 20 weeks and 8 months

Overall study start date
01/12/2021

Completion date
28/04/2024

Eligibility

Key inclusion criteria
1. Above 40 years old
2. Speak and understand English sufficient to read the information sheet and sign the consent form
3. Ability to walk without an assistive device for at least 100 m (to ensure patients have sufficient mobility to be able to complete the intervention)
4. Clinical diagnosis of KOA according to American College of Rheumatology (ACR) criteria
5. Pain for at least 6 months' duration
6. Attended a minimum of six (of 10/12) ESCAPE pain classes
7. Improvement in KOOS following ESCAPE <15% from their pre-ESCAPE condition

Participant type(s)
Patient

Age group
Adult

Lower age limit
40 Years

Sex
Both

Target number of participants
Planned Sample Size: 90; UK Sample Size: 90

Total final enrolment
84

Key exclusion criteria
1. Dementia or other major cognitive impairment
2. BMI >33 kg/m² (as increased subcutaneous fat prevents the collection of surface EMG signals)
3. Lower limb arthroplasty
4. Any systemic inflammatory disorders, such as rheumatoid arthritis
5. Any balance disorders which may increase the risk of a fall
6. Not fully vaccinated against COVID-19 (for the safety of the physiotherapist and research staff)

Date of first enrolment
16/05/2022

Date of final enrolment
11/08/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
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Study participating centre
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Study participating centre
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Study participating centre
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Sponsor type
University/education

Website
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ROR
https://ror.org/01tmqtf75

Funder(s)

Funder type
Government

Funder Name

NIHR Central Commissioning Facility (CCF); Grant Codes: NIHR202203

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
31/12/2024

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 Feasibility study interview (physiotherapist)	16/12/2021	26/04/2022	No	Yes
Participant information sheet	Collection of ESCAPE outcomes version 1	10/02/2022	26/04/2022	No	Yes
Participant information sheet	Feasibility study (patient) version 5	05/04/2022	26/04/2022	No	Yes
Participant information sheet	Feasibility study (physiotherapist) version 3	16/12/2021	26/04/2022	No	Yes
Protocol file	version 4	05/04/2022	26/04/2022	No	No
HRA research summary			28/06/2023	No	No
Basic results			13/05/2025	No	No