

Development of a physiotherapist training course for a new intervention designed to reduce muscle overactivity in people with knee osteoarthritis

Submission date 16/02/2022	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 24/02/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 27/06/2023	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims:

We 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/>.

Before we can run a trial to understand the effectiveness of this new treatment, it is important that we test a training course, which has been designed to provide NHS physiotherapists with the skills they need to deliver the new treatment. To do this we will train 4 NHS physiotherapists and then observe them while they deliver the new treatment to patients with knee osteoarthritis. Both physiotherapists and patients will then attend a focus group workshop at will map appropriate modifications to the training course via qualitative research. Once we are happy with the training course, we will use it to train physiotherapists in a follow-on clinical trial.

Who can participate?

Patients over 40 years old, with knee osteoarthritis

What does the study involve?

Patient with knee osteoarthritis who take part in the study will receive 6 sessions of the new treatment from an experienced NHS physiotherapist who has been recently trained to deliver the new treatment. They will then attend a focus group to discuss their experiences.

Physiotherapists who take part will receive both online and face to face training and will then deliver the new treatment under the observation of the research team. They will then attend a focus group to discuss their experiences.

What are the possible benefits and risks of participating?

Patient with knee osteoarthritis may experience clinical benefit from receiving the new treatment, such as reductions in pain. The treatment is very low risk.

Physiotherapists will develop new skills and become proficient at delivering the new treatment. 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?

November 2021 to October 2022

Who is funding the study?

National Institute for Health Research (NIHR) (UK).

Who is the main contact?

Dr Stephen Preece, s.preece@salford.ac.uk

Study website

<https://hub.salford.ac.uk/cognitive-muscular-therapy/>

Contact information

Type(s)

Scientific

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Type(s)

Principal Investigator

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Additional identifiers**EudraCT/CTIS number**

Nil known

IRAS number

298932

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

CPMS 50613, NIHR202203, IRAS 298932

Study information**Scientific Title**

BEhaviour change to reduce Pain in Knee Osteoarthritis (BEPKO-2) - Training course development

Acronym

BEPKO-2

Study objectives

This is primarily a qualitative study to explore physiotherapists experiences of being trained and then delivering the new intervention. Although we will also collect and report clinical data from the patients who receive the intervention, we will not undertake any hypothesis testing.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 12/10/2021, Leicester Central NHS REC (2 Redman Place, Stratford, London, E20 1JQ, UK; +44 207 104 8070; leicestercentral.rec@hra.nhs.uk), ref: 21/EM/0225

Study design

Interventional non randomized

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Knee osteoarthritis

Interventions

This is aimed at testing and refining a training package for the new intervention that we have recently developed. More details on this intervention can be found at <https://hub.salford.ac.uk/cognitive-muscular-therapy/>. To test and refine the training package, we will recruit four NHS physiotherapists who have no previous experience with the new intervention along with 10 patients with KOA. The physiotherapists will be trained and will then deliver the intervention under observation from the research team. Each patients will receive 6 sessions of the new intervention, typically lasting 1 hour from one of the four NHS physiotherapists or from an expert physiotherapist. They will then be asked to attend a focus group workshop. Physiotherapists will also attend this workshop, during which we will map appropriate modifications to the training via qualitative research.

Intervention Type

Other

Primary outcome measure

Osteoarthritis condition measured using the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) at Baseline & 12 weeks

Secondary outcome measures

1. Pain catastrophizing scale at Baseline & 12 weeks
2. Tampa scale of kinesiophobia at Baseline & 12 weeks

Overall study start date

04/11/2021

Completion date

01/10/2022

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 100m (to ensure patients have sufficient mobility to be able to complete the intervention)
4. Clinical diagnosis of KOA according to ACR criteria
5. Pain for at least six months' duration

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

Planned Sample Size: 10; UK Sample Size: 10

Total final enrolment

20

Key exclusion criteria

1. Dementia or other major cognitive impairment
2. BMI >33 kg/m² (as increased subcutaneous fat prevents 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

23/02/2022

Date of final enrolment

01/07/2022

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

The University of Salford

Room PO34

The Brian Blatchford Building

Manchester
United Kingdom
M66PU

Study participating centre

Salford Royal Hospital

Stott Lane
Eccles
Salford
United Kingdom
M6 8HD

Study participating centre

Manchester Royal Royal Infirmary

Cobbett House
Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre

Stepping Hill Hospital

Stockport NHS Foundation Trust
Stockport
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SK2 7JE

Sponsor information

Organisation

University of Salford

Sponsor details

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Sponsor type

University/education

Website

<http://hub.salford.ac.uk/health-and-society-research/>

ROR

<https://ror.org/01tmqtf75>

Funder(s)

Funder type

Government

Funder Name

NIHR Central Commissioning Facility (CCF)

Funder Name

National Institute for Health 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 high-impact peer-reviewed journal

Intention to publish date

31/12/2022

Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be 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	Patient version 4	14/10/2021	17/02/2022	No	Yes
Participant information sheet	Physio version 4	14/10/2021	17/02/2022	No	Yes
Protocol file	version 1	24/08/2021	17/02/2022	No	No
Abstract results		01/03/2023	27/06/2023	No	No
HRA research summary			28/06/2023	No	No