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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

Registration date
24/02/2022

Overall study status
Completed

Last Edited
27/06/2023

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 osteoatrhritis

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 physiotherapists 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

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
298932

Protocol serial number
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

Study type(s)
Treatment

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

Key secondary outcome(s))
1. Pain catastrophizing scale at Baseline & 12 weeks
2. Tampa scale of kinesiophobia at Baseline & 12 weeks

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

England

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
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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
United Kingdom
SK2 7JE

Sponsor information

Organisation
University of Salford

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

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?
Abstract results		01/03/2023	27/06/2023	No	No
HRA research summary			28/06/2023	No	No
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
Study website	Study website	11/11/2025	11/11/2025	No	Yes