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Developing a new treatment for knee osteoarthritis using feedback from muscle measurements

Submission date
07/02/2020

Recruitment status
No longer recruiting

Registration date
24/02/2020

Overall study status
Completed

Last Edited
13/08/2021

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Osteoarthritis is a condition that causes joints to become painful and stiff.
Research has demonstrated that individuals with knee osteoarthritis stand, walk and perform other activities with increased co-contraction (simultaneous activation) of the knee muscles: hamstrings and quadriceps. These muscle patterns will increase the stress on the knee joint and may speed up the progression of knee osteoarthritis. Importantly, despite the association between co-contraction and knee osteoarthritis, there are no physiotherapy approaches which aim to improve muscle coordination and reduce co-contraction in patients with this condition.
The aim of this study is to create a new biofeedback intervention using electromyography (EMG) technology. With EMG, small skin-mounted electrodes are used to measure electrical activity produced during muscle contraction. Although EMG technology has been used to develop biofeedback applications for conditions such as neck pain, a biofeedback application for knee osteoarthritis does not exist.
Following preliminary consultation with patients and physiotherapists, the researchers mapped out key components of a digital physiotherapy intervention for people with knee osteoarthritis. During this study, they aim to develop the different intervention components through an iterative approach, involving user consultation. The primary components of the intervention are:
1. Introductory video sequence – which explains key concepts and is watched before the first contact session
2. Physiotherapy assessment & patient report – used to map out and explain muscle tension patterns and abnormal muscle coordination
3. Tension release procedures – used to teach reorganisation of postural muscle activity in standing
4. Muscle coordination procedures – used to improve muscle coordination during functional tasks
5. Biofeedback software – used to assess muscle patterns and provide feedback to facilitate (3) and (4) above
By refining the intervention through continued consultation with people who have knee osteoarthritis, the aim is to develop a new intervention which can be delivered by physiotherapists. As part of this study, the researchers also plan to record reductions in pain so that they can develop an understanding of how effective the new treatment might be.

Who can participate?
Patients aged 40 - 80 years with knee osteoarthritis

What does the study involve?
All participants receive the intervention, typically attending for 6 face-to-face physiotherapy sessions with specific procedures to practice outside of contact sessions. After each session, participants are asked for their opinion of the treatment and for suggestions of how it could be improved.

What are the possible benefits and risks of participating?
The aim of the treatment is the reduce muscle tension and to improve knee pain. Participants may experience reductions in their knee pain after taking part. There should be no side effects from the treatment.

Where is the study run from?
The lead centre is the University of Salford, Manchester, UK. There will be four other local NHS trusts: Salford, Central Manchester, Stockport and Fairfield General Hospital Bury.

When is the study starting and how long is it expected to run for?
May 2018 to October 2020

Who is funding the study?
1. National Institute for Health Research (UK)
2. University of Salford (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
232749

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
v3, HLRB25, CPMS 38156, IRAS 232749

Study information

Scientific Title
The feasibility of using Biofeedback to rEduce Pain in people with Knee Osteoarthritis

Acronym
BEPKO

Study objectives
There was no formal hypothesis as this study aimed to develop a new intervention through successive testing and iteration.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/05/2018, North West - Greater Manchester East Research Ethics Committee (3rd Floor, Barlow House, 4 Minshull Street, Manchester, M1 3DZ, UK; Tel: +44 (0)207 104 8009; Email: nrescommittee.northwest-gmeast@nhs.net), REC ref: 18/NW/0282

Study design
Intervention development study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

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

Interventions
The intervention development study will involve a physiotherapist (employed on the project) delivering successive iterations of the intervention to individual patients with KOA. One of the key principles of the intervention is that patients will only be able to reduce muscle activity in their knee muscles if they become aware of, and are able to change, more general patterns of muscle tension throughout their whole body. By employing an artist/animator on the project, the researchers propose to develop a range of instructional animations which will convey the idea of whole-body patterns of muscle tension. During the intervention testing session, the physiotherapist will work with the patient to explain (using the animations) their individual patterns of muscle tension. Then, using the biofeedback software, the therapist will then teach the patient to downregulate the activation of their hamstrings, quadriceps and gastrocnemius across different tasks. These tasks will gradually increase in difficulty until full walking is achieved. The researchers refer to these tasks as the incremental training activities (ITAs). Following each intervention session, patients will be asked to provide feedback on their perception of the three main components of the intervention: the biofeedback software, the incremental training activities and the instructional animations. They will also be asked for their opinion on how these supervised sessions could be continued at home (home practice component) and also on an introductory video which the researchers will develop to explain the key ideas of the intervention.

The researchers anticipate each session would last 1-2 hours and envisage delivering between 1-10 sessions depending on
the stage of the project. In addition to obtaining patient feedback after each individual session, they propose to carry out focus groups and individual interviews at three timepoints (Month 4, Month 11 and Month 16) to fully explore patient's experiences and perceptions of the intervention. The data gathered from the focus groups/interviews, along with the individual feedback, will be used to improve the different components of the intervention. Specifically, the researchers will:
1. Improve the usability of the biofeedback software
2. Fully define an appropriate set of incremental training activities
3. Develop a library of easy-to-understand instructional animations which can be used with the different incremental training activities
4. Map out a home practice component
5. Develop an easy-to-understand introductory video which would be watched before the first intervention session

Through the procedures described above, the researchers will produce a fully defined intervention which will be formally evaluated in a follow-up study. Note that this project will not incorporate any formal evaluation of the intervention.

Intervention Type
Behavioural

Primary outcome measure

Pain measured using the knee injury and osteoarthritis outcome score (KOOS) at baseline and immediately after the end of the intervention (typically 6 sessions over 12 weeks)

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
05/05/2018

Completion date
02/10/2020

Eligibility

Key inclusion criteria
Knee OA participants will be included if they have a clinical diagnosis of knee OA, using the American College of Rheumatology (ACR) criteria. This is given as clinical presentation of pain in the knee and at least three of the following:
1. Age 40-80 years (note those under 50 must have a confirmed radiological diagnosis of knee OA)
2. Stiffness < 30 minutes per day
3. Crepitus
4. Bony tenderness
5. Bony enlargement
6. Palpable warmth

Full inclusion criteria are given below:
1. Age range of 18-80 (upper age limit to exclude people who may have limited mobility)
2. Ability to stand and walk independently
3. Speak and understand English to read the information sheet and sign consent form
4. Ability to walk without any assistive for at least 100 m (this is 100 m is not representative of the real demand of the testing, but we want to be sure participants will not get fatigued during the testing)
5. Clinical diagnosis of knee OA according to American College of Rheumatology (ACR) [37], see above, only for subjects with knee OA
6. Pain for at least 6 months' duration only for subjects with knee OA
7. Pain or difficulty in rising from sitting and/or climbing stairs, only for subjects with knee OA

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Upper age limit
80 Years

Sex
Both

Target number of participants
75

Total final enrolment
21

Key exclusion criteria
1. Complex pain conditions such as diabetic neuropathic pain, fibromyalgia
2. Dementia or other major cognitive impairment
3. Have had previous surgery to the lower limb
4. BMI >35 since it is not possible to obtain EMG muscle measurements on individuals with excess adipose tissue
5. Lower limb arthroplasty
6. Any systemic inflammatory disorders, such as rheumatoid arthritis
7. Any balance disorders which may increase the risk of a fall

Date of first enrolment
01/06/2018

Date of final enrolment
01/10/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Salford Royal NHS Foundation Trust
Stott Lane
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Study participating centre
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Sponsor type
University/education

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ROR
https://ror.org/01tmqtf75

Funder(s)

Funder type

Government

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

Funder Name
University of Salford Manchester

Alternative Name(s)
University of Salford, University of Salford, Manchester, USM

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
No additional documents will be made available as this is an intervention development study. The researchers aim to publish one intervention development paper in the journal BMC Musculoskeletal Disorders.

Intention to publish date
01/12/2020

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 v3	24/08/2018	24/02/2020	No	Yes
Results article		06/08/2021	13/08/2021	Yes	No
HRA research summary			28/06/2023	No	No