

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

## 1. Background and rationale

Knee osteoarthritis (KOA) is a chronic long-term condition which results in pain, disability and reduced quality of life [1]. Estimates suggest that one in three people over 40 will develop knee pain within 12 years [2] and that 10% of the UK population over the age of 55 will be diagnosed with KOA [3]. The NICE-recommended clinical pathway for people with KOA is an initial course of physiotherapist-delivered muscle strengthening [4]. If this fails, then patients proceed to orthopaedic referral for more invasive treatments, including total knee replacement. Before the Covid-19 crisis, approximately 80,000 knee replacements were carried out annually in the UK [5] at an estimated cost of over £500 million[6]. Such numbers, and associated healthcare costs, demonstrate that muscle strengthening does not provide sufficient pain relief for many people with KOA. Furthermore, with the recent cancellation of elective orthopaedic surgery, numbers on waiting lists for knee replacement are growing rapidly. Therefore, there is an urgent need to improve the conservative management of people with KOA who do not respond to muscle strengthening.

While current guidelines focus on the use of exercises to improve strength, there is clear evidence that people with knee OA over activate their muscles during functional tasks [7-9]. This overactivity is characterised by both increased amplitude [10] and prolonged duration [8] of the knee flexor and extensor muscles. Biomechanical research has demonstrated the potentially damaging effects of these patterns, showing that muscle overaction is linked to pain [11], elevated joint load [12] and a more rapid rate of cartilage loss [13]. It is therefore important to understand the potential of conservative management techniques which focus on reducing muscle overactivity.

Psychosocial factors have been linked with clinical pain/disability in knee OA. For example, catastrophising [14] and anxiety [15] have been associated with pain intensity and kinesiophobia linked to physical function [16]. Given these links, a number of physiotherapy interventions have been developed which integrate psychological techniques [17, 18] with muscle retraining. However, these interventions have focused primarily on muscle strength training. Therefore, it is unclear whether improved clinical outcomes would be obtained if psychological techniques were integrated with training to reduce muscle overactivity.

Through a previous NIHR project (BEPKO-1), we developed a new behavioural intervention for people with KOA. This intervention was developed from concepts to central sensitisation to generalised body pain, motor responses to knee pain and also focused on the idea that increased knee muscle overactivity could result from postural compensation. Building on these ideas, the final intervention comprises five components: making sense of pain; general relaxation; postural deconstruction; responding differently to pain; and functional muscle retraining. To facilitate delivery, the intervention incorporates a range of animated instructional videos to communicate concepts related to pain and biomechanical theory and also used EMG biofeedback to facilitate visualisation of muscle patterns. Given the integration of cognitive and muscular techniques, we refer to this new intervention as cognitive muscular therapy (CMT). Preliminary clinical data showed a 69% reduction in pain with very positive user feedback, following six individual sessions of CMT. Given these encouraging findings, further clinical research is required to investigate the clinical efficacy of the CMT intervention. However, before this research can be carried out, it is important to develop a robust training package which can be used to train NHS physiotherapists to

deliver the CMT intervention. The proposed project will address this objective, through two parallel studies. The first study has been designed to create materials required for the training course. The second will test a prototype version of the training course.

## 2. Overview of the component studies and the CMT intervention

An overview of each of the two separate studies is provided below. At the end of this section is a description of how the Cognitive Muscular Therapy (CMT) intervention is delivered to individual patients.

### 2.1 Video case studies

We have already created the background materials, clinical protocols and prototype clinical guidance to explain how to deliver each component of the CMT intervention. However, to ensure there is no ambiguity in our training materials, we propose to use a range of clinical case studies, incorporating videos of patients, to illustrate how to apply our clinical protocols for each intervention component. To create appropriate footage, we will video patients with KOA during clinical assessment and whilst receiving the intervention from a physiotherapist. Although this video material will not be released into the public domain, it will be central to our training course for the CMT intervention. A full description of the video case studies is provided in Section 3.

### 2.2 Training course development

To date, only our expert physiotherapist (Mr Brookes) has the required skills and knowledge to deliver the CMT intervention. Therefore, this study will allow us to test and make appropriate refinements to our prototype training course, designed to provide physiotherapists with the skills to deliver our intervention. For this study, we propose to recruit four NHS physiotherapists who have no previous experience with the CMT intervention along with 10 patients with KOA. The physiotherapists will be trained and will then deliver the intervention under observation from the research team. Following this delivery, appropriate modification will be mapped out via qualitative research. A full description of the training course development is provided in Section 4.

### 2.3 Overview of the Cognitive Muscular Therapy (CMT) intervention

The CMT intervention is delivered through six individual 45-60 minute physiotherapy sessions, each separated by a period of two weeks. There are five separate intervention components which the physiotherapist works through sequentially. A summary of each intervention component is provided below:

**Component 1: Making sense of pain:** This component focuses on patient education, challenging the idea that knee osteoarthritis pain is the inevitable result of “wear and tear”. Patients are introduced to the concept that muscle overactivity can increase pain and that brain processing and psychosocial factors can shape the pain experience.

**Component 2: General relaxation:** Patients are taught to become aware of inappropriate contraction of the quadriceps muscles and to learn a relaxed diaphragmatic breathing by minimising low-level contraction of the abdominal muscles. This component initiates the process of muscular re-education.

**Component 3: Postural deconstruction:** A set of clinical procedures are used that enable the physiotherapist to unpick (deconstruct) patterns of postural muscle activity and associated patterns of

hip/trunk muscle stiffness. Working through the procedures, the patient is provided with experiential learning of how to stand with reduced postural muscle activity and more relaxed knee muscles.

**Component 4: Responding differently to pain:** This component aims to raise awareness of inappropriate contraction of the knee muscles which can be triggered by pain expectations. Using biofeedback, the patient is taught to minimise anticipatory muscular contraction, which can occur before initiation of movement. Patients are also encouraged to reflect on emotional responses to anticipated pain.

**Component 5: Functional muscle retraining:** Muscle biofeedback software is used to visualise knee muscle activation during different functional tasks. This software contrasts the patient's muscle patterns with those collected from a healthy group. Using the biofeedback software to guide learning, patients use motor imagery to reduce muscle overactivity, gaining experience of how to perform everyday activities with improved muscle coordination. As part of this learning, the physiotherapist continues to challenge beliefs that certain movements should be avoided.

Delivery of the intervention is supported through the use of animated videos which explain intervention concepts, and which are watched prior to, during and following the clinical sessions. These videos are delivered through an online platform or via a tablet computer which we will provide to patients who do not have an appropriate device. EMG biofeedback is also used, in components 2-5, to visualise muscle patterns. This requires the physiotherapist to place small sensors on the skin overlying the patient's knee muscles. Muscle activation data is then visualised on a laptop computer.

Although novel, the CMT intervention integrates many standard physiotherapy techniques, such as training to encourage diaphragmatic breathing, muscle flexibility testing and postural assessment. It also integrates psychologically informed practice, which is now well-established across the profession. The key difference with conventional physiotherapy is that the CMT intervention aims to develop awareness of muscle tension, rather than use muscle strengthening. As such, there are negligible risks with this approach, and we did not observe any adverse effects in our intervention development study. Between the clinical sessions, patients are provided with exercises to practice, encouraged to integrate learning into everyday activities and to change the way they think about their knee pain. More information on the CMT intervention is provided in the publication of our intervention development study [19].

## 3 Procedures for the video case studies

### 3.1 Participants

We will recruit 10 patients with knee osteoarthritis to create our video case studies. We will include people if they have a clinical diagnosis of KOA using the American College of Rheumatology (ACR) criteria [20] and who are able to walk unaided for 100m. The ACR criteria are based on symptoms and clinical signs findings, including pain, stiffness and bone enlargement. See below for further details.

#### **Patient 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 [20]
5. Pain for at least six months' duration

### Patient exclusion criteria

1. Dementia or other major cognitive impairment
2. BMI >33 (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)

### 3.2 Recruitment

We will use the following approaches to identify patients with KOA both for this study and the training course development study (Section 4).

1. **Use of the Health Sciences volunteer database.** With this approach, we will write to/email people on a database that we hold at the University of Salford who have KOA and who have expressed an interest in taking part in research. This letter will include the participant information sheet as well as a letter of invitation (see Database letter of invitation).
2. **Via poster advert at physiotherapy outpatient clinics, local GP practices and community sites.** We propose to place posters in local GP practices, physiotherapy/musculoskeletal outpatient clinics along with community sites, such as gyms and in University buildings (see poster & social media advert). Patients who are interested in participating in our knee research will be required to text KNEE to a specific number e.g., 60006 or to send an email to our university generic volunteering email address i.e, [healthcare-volunteering@salford.ac.uk](mailto:healthcare-volunteering@salford.ac.uk). Note anyone who uses the text message service will have their mobile number forwarded to this email account. Potential participants, who contact the university via this route, will be contacted by the manager of our volunteer database who will send them the participant information sheet and pass their contact details to the lead researcher. The database manager will also ask them if they would like to join our volunteer database and if they agree, will send the appropriate documentation.
3. **Through visits to physiotherapy and musculoskeletal pain outpatient clinics.** The lead physiotherapist will visit clinics, for example, during knee OA classes to explain the project to both patients and physiotherapists. If patients are interested in participating, they will be given a copy of the participant information sheet. Following the visit, physiotherapists will be encouraged to talk to their patients about the study and then to direct anyone interested in taking part towards the poster advert, see above.
4. **Social media advert.** We will use social medial channels, such as Twitter, Facebook, Instagram to promote the study (see poster & social media advert). Similar to the poster, individuals who are interested in participating in our research will be required to text KNEE to a specific number and will follow the same procedure described above.

With the proposed avenues for recruitment, listed above, individuals who are interested in participating in the research will be required to contact the researcher directly after receiving a copy of the participant information sheet(s) or by responding to a study advert. On contacting the researcher, the participant will be asked a number of questions to ensure that they meet the inclusion/exclusion criteria. Those individuals deemed eligible will then be sent the appropriate participant information sheet(s) if required. Individuals will be given 2-3 days to read the information sheet(s) and then contacted again. On second contact, the researcher will talk to them about which studies they are happy to participate in. Note that we will provide

patients with the opportunity to participate in this study, the video case study or both studies together. A minimum period of 24 hours will be set between providing the information sheet(s) and determining their decision to take part in the study.

### 3.3 Setting and consent

Data for this study will be collected at either the University of Salford or a clinical facility e.g., physiotherapy outpatient clinic, during two visits. Upon arrival, participants will reread the information sheet (PIS – video case studies) and the study will be explained in full. If participants have no objections, they will complete the consent form (Consent form – video case studies). Consent will be taken by the researcher who collects the video data. Participants will also sign a University of Salford video release form which will provide the University with full rights to use the video data to create the training course materials. Each participant will receive a payment of £100 (£50 per visit) in recognition that they are providing data for a future training course.

### 3.4 Video recordings

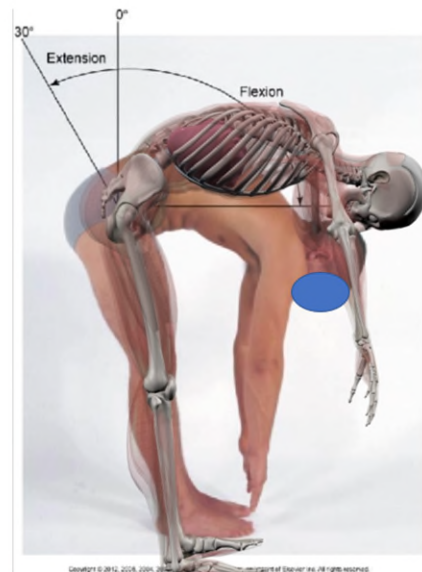
During the recording session patients will receive instruction on one or more components of the intervention. See Section 2.4 for a description of intervention procedures. For the video recordings, patients will wear clothing which they feel is acceptable for them to be recorded in. For females, this is likely to be a tight-fitting top and shorts and for males it may involve wearing just a pair of shorts or shorts and a tight-fitting top.

It is possible that some of the individuals who participate in the training course development study (Section 4) will also take part in this study. In this scenario, we will ask the physiotherapist who is delivering the intervention to pause for a few minutes while the researcher records video footage. If we do feel it necessary to include a physiotherapist in the video footage, then we will ensure this is Mr Brookes, our expert physiotherapist and not the novice physiotherapist.

Note that, in this protocol, we have not described the specific steps we will take to mitigate against the risk of Covid transmission. Instead, we have included a very detailed explanation of our Covid-related procedures in the attached document “AAA Local Covid19 Risk Assessment” This document details a plan of action based on current guidelines (June 2021). This constitutes a worst-case scenario. When the project starts, we propose to continually adjust (potentially relaxing) our Covid measures so that we are in line with appropriate government guidelines e.g., mask wearing, one-way systems). This statement applies to both studies described in this protocol.

### 3.5 Creation of video case studies

Each clinical case study will focus around the use of video footage which will be fused with custom animations to highlight specific biomechanical targets e.g., spinal flexion or muscle shortening, which are important for delivery of the intervention. We have provided an example of what this animation-video fusion will look like in the image on the right. Although this video material will not be released into the public domain, it will be central to our training course for the CMT intervention. We will ensure no visibility of facial features, using blurring to obscure appropriate parts of the image (as shown opposite). However, it is possible that this video material will contain recognisable data. This is because it is important that we capture a full representation of the body, including spinal posture and head alignment. Patients will be made aware of the use of this data and will receive a payment of £100 which will cover their time and recognise that they are providing this personal data for the training course. We will ensure that the use of all personal data is compliant with GDPR regulations.



## 4. Procedures for the training course development

### 4.1 Overview of the study

We propose to recruit four NHS physiotherapists who have no previous experience with the CMT intervention (referred to as novice physiotherapists) along with 10 patients with KOA. Each novice physiotherapist will undertake 8 hours of online training which will provide background information and an introduction on how to deliver each component of the CMT intervention. Following this online training, the physiotherapists will have 4-6 weeks to reflect on what they have learned within their own NHS clinical practice. At the end of this period, they will attend a one-day workshop at the University of Salford in which they will be able to observe and practice delivering the intervention to people with KOA. Each physiotherapist will then deliver the CMT to two patients with KOA over a 12-week period, under observation from the research team. Co-design workshops and individual interviews will then be used to map improvements for the training course.

### 4.2 Participants and recruitment

We will use the same inclusion/exclusion criteria as for the Video Case studies (see section 3.1) for the participants with KOA. We will also use the same recruitment approach as set out in the previous section (see Section 3.2). Any individual who is interested in participating will be sent the participant information sheet (PIS – training course development (patient)) and provided with a minimum of 24 hours to decide if they want to participate.

Our four Band 6 physiotherapists will be identified through contacts that we have with local NHS trusts. Specifically, we will identify four Band 6 physiotherapists who currently work in the NHS and have at least

three years' experience of treating patients with musculoskeletal pain. We will liaise with the department lead and ask them to send the information sheet (PIS – training course development (physiotherapist)) to eligible physiotherapists. The physiotherapist will then be required to contact us directly if they are interested in taking part.

#### 4.3 Setting and consent

*Patient consent:* This study will be carried out at either the University of Salford or a clinical facility e.g., physiotherapy outpatient clinic. Upon arrival, participants will reread the information sheet (PIS – training course development (patient)) and the study will be explained in full. If participants have no objections, they will complete the consent form (Participant consent form - training course development (patient)). Consent will be taken by the researcher not the physiotherapist. Once consent has been taken, measurements of height and mass will be taken along with a skinfold caliper measurement of fat thickness over the quadriceps muscle. Patients will also be asked to fill out a data access form (included in the application). This is to provide consent for the researchers to view any previous knee x-rays used to assess severity of KOA. Patients will not be paid to receive the new treatment. However, if they agree to attend the one-day training course (see below), they will be paid £15 per hour. If they attend the workshop (see below), they will also be paid £15 per hour.

*Physiotherapist consent:* We will obtain consent from the four physiotherapists via post. Specifically, once they have read and are happy with the information sheet and have talked to the research teams about the project, they will print, sign and return the consent form to the research team (Participant consent form - training course development (physiotherapist)). They will then be provided with access to the online training materials.

#### 4.4 Clinical and mechanistic outcomes

Before clinical instruction is provided, participants with KOA will complete the following questionnaires (included with the application). They will also complete the same questionnaires immediately after the end of the treatment.

1. WOMAC questionnaire
2. Pain catastrophizing scale
3. Tampa scale of kinesiophobia

In addition, we will measure hip flexibility and use a 3D camera to obtain a measurement of posture and to quantify movement of the abdomen during breathing (to give an indication of breathing pattern). Data from this camera will be in the form of a set of 3D coordinates, not a standard digital image. Therefore, it will not be possible to recognise the participant from these data. Instead, the data will be used to quantify specific aspects of postural alignment and breathing pattern. The primary aim of this study is not to quantify or estimate clinical efficacy or to understand mechanism of action. Nevertheless, we propose including these clinical and mechanistic outcomes as they may provide some insight into the proficiency of delivery. We may also report on these outcomes in a case study style journal paper.

## 4.5 Training workshop

Approximately 4-6 weeks after completing the online training course, the four novice physiotherapists will attend a one-day workshop at the University of Salford. In addition to the research team, this workshop will also be attended by two patients with KOA who will each have received at least one previous clinical session of CMT from our expert physiotherapist, Mr Brookes. During the workshop, the physiotherapists will receive further instruction on how to deliver the intervention and have the opportunity to practice their skills on the two patients with KOA. Participants with KOA who agree to attend a training workshop will be paid £15 per hour.

## 4.6 Intervention delivery by novice physiotherapists and observation of clinical sessions

Following the online training, each novice physiotherapist will deliver the CMT intervention (See Section 4.1) to two patients with KOA over a 12-week period (6 sessions, one every two weeks) at either the University of Salford or a clinical site (e.g. outpatient physiotherapy clinic). This intervention delivery will be observed by the expert physiotherapist (Mr Brookes) and other members of the research team, who will be able to reflect on how effective the training materials have been at conveying the subtleties involved with delivering the CMT intervention. To facilitate later comparison (see below) between expert and novice delivery of the intervention, one of the six intervention sessions will be delivered by Mr Brookes during which the novice physiotherapist will observe. During the 12-week period of intervention delivery, the NHS physiotherapists will be encouraged to practice specific components, and reflect on their experience, of the CMT intervention during their day-to-day NHS clinical practice. To encourage this reflection, the physiotherapists will be instructed to keep a reflective diary and to use an online forum to share experiences of delivering the intervention. Towards the end of intervention delivery, we will ask each physiotherapist to complete the Normalisation Process Theory Survey (see NoMAD survey) which will allow us to understand how easy it may be to implement the CMT intervention in any subsequent clinical trials.

## 4.7 Focus groups and Individual interviews

Following the 12-week period of intervention delivery, we will run a co-design workshop with both physiotherapists and patients at which we will map areas for improvement of the training course via two approaches. Firstly, we will use a focus group approach to understand differences in intervention delivery from the expert physiotherapist and from the novice physiotherapists. Secondly, we will run a focus group regarding the four physiotherapists' approach, drawing on thematic analysis and an acceptability framework, [21] to identify areas of the CMT intervention they found challenging to deliver. We anticipate inviting up to five patients to the co-design workshop, but we may also interview any patients who would like to contribute but who are unable to attend the focus group in person. Patients will be paid £15 per hour for taking part in focus group work.

### Focus groups:

Each focus group will last 1-2 hours and will be facilitated by an experienced qualitative researcher. A focus group method has been chosen as this will facilitate the sharing of opinion from multiple perspectives and hence create dialogue between participants. As we are not seeking insight into personal experiences, it is the most appropriate method for achieving the creation of specifications for the training course. Following an overview of the ground rules for conducting a focus group, an opening question will start the dialogue "would you tell us about your experience of delivering (physiotherapists)/receiving (patients) the CMT intervention".



Dependent on responses, further trigger questions will relate to the different intervention components. Responses will be transcribed, and thematic analysis used to identify areas for improvement of the training course. We have included a focus group topic guide to illustrate the topics which will be discussed (see Focus group topic guide - training course).

#### Individual interviews:

Interviews will be carried out by an experienced qualitative researcher over the phone or via video conference. Similar to the focus groups described above, we will start with an opening question relating to experiences of receiving the intervention, with further questions likely related to specific intervention components. All responses will be transcribed, and thematic analysis used to identify areas for improvement of the training course.

### 4.8 Modification of training materials

We will combine the findings from the focus groups/interviews with the learning derived from our observation of the novice physiotherapists delivering the intervention. From these findings, we will map a set of specific modifications for our training course (both online and face-to-face components). Once finalised, this training package will be used to train the physiotherapists who may deliver the CMT intervention as part of any future trials.

## 6. Project timetable

This project will be delivered over a 7-month period. During the two months, we will train the physiotherapists with the first iteration of the training course. We will then observe delivery of the intervention during months 3-5. At the end of month 5 we will run the co-design workshop to map improvements to the training package with subsequent modifications to the course made in months 6 and 7. The video case studies will be collected in parallel with the training course development study during the first 5 months. These videos will be integrated into the final training course during months 6 and 7.

## 7. Dissemination

The primary output from this study will be a training course. However, we will explore the possibility of developing some clinical case studies during the training course development study.

## 8. Participant and public involvement in the proposed research

We will form a user advisory group which will consist of four patient representatives who will advise on research design, participant information resources and dissemination. This groups will attend joint PPI/Steering group meetings at the start of the study, at 4 months and then at the end of the project. The user advisory group will be consulted on several different aspects of research design. These will include the appropriateness of specific trigger questions used in the focus groups designed to elicit user perspectives of our intervention. We will also consult the PPI group on how to timetable and run the workshops which will provide user perspectives on the physiotherapy training package.

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