Behaviour change to rEduce LOW back pain: a feasibility study (BELOW)

1. Background and rationale

Low back pain (LBP) causes more global disability than any another condition, with a global point prevalence estimated to be 9.4% [1]. As well as causing activity limitation and pain [2], LBP places an enormous economic burden on individuals, families, communities, and industry [3]. Current physiotherapy approaches for managing LBP focus on the use of exercise, combined with psychological techniques [4]. However, there is a growing body of research demonstrating that people with LBP have altered coordination and over activate their trunk muscles during functional tasks [5], [6]. For example, people with LBP exhibit increased activity of their spinal and abdominal muscles during walking [6] and reduced motion of the pelvis and thorax [5]. Similar muscle overactivity is observed in people with LBP during normal standing [7] and bending forwards [8]. These physical responses are thought to be the body's attempt to protect [9] injured structures, as it might initially after an acute injury. However, there is now growing support for the idea that muscle overactivity may play a key role in the aetiology of chronic LBP [10].

It has been suggested that elevated muscle activity can become a habitual maladaptive response to pain [8]. This is because it places an excessive demand on muscles [11], restricts movement [12] and generates increased loading of the spine [13]. Interestingly, research suggests there is a strong link between people's thoughts about their pain (such as catastrophising thoughts) and increased trunk muscle activity [14]. This link highlights the need for LBP interventions that incorporate a combined psychological and physical approach. However, it is not always easy for patients to understand or appreciate the link between their thoughts and their subconscious muscle responses and they can feel that clinicians are being dismissive of their pain. New treatments are therefore needed which engage patients and demonstrate and validate their pain whilst helping them to appreciate the link between physical and psychological responses.

Through two NIHR awards, we have created a completely new physiotherapist-led intervention for knee osteoarthritis [15], which we refer to as Cognitive Muscular Therapy (CMT). CMT is an integrated behavioural intervention that combines psychologically informed practice with a biomechanical framework which enables patients to understand the drivers of muscle activity and appreciate the link between physical (muscular) responses and psychological factors. We have already created a full implementation of CMT for chronic LBP and the proposed study will explore the feasibility of this treatment for people with chronic LBP. The project constitutes a first step towards the evidence needed for a new pathway for LBP pain. It could therefore change the way in which this condition is managed on the NHS.

This study will assess the feasibility of a future pragmatic two-arm RCT designed to compare clinical and cost-effectiveness of the CMT intervention with best practice NHS care for patients who are at high-risk of developing persistent, disabling LBP.

2. Study overview

This trial will deliver key parameters that are required to run a future, pragmatic, two-arm RCT we will work with local GP practices to recruit 90 patients with ongoing LBP who would be considered at high risk of a poor long-term outcome.

Once recruited, patients will be randomised into two groups: an intervention group who receive the CMT intervention (n=45) and a control group (n=45) who receive best practice psychologically informed physiotherapy. Each group will receive 7 weekly sessions and we will collect outcomes at baseline, 14 weeks and eight months post randomisation. Data will inform planning for a future trial. Full details are provided below:

3 Recruitment and inclusion

We will recruit 90 patients from general practice with ongoing LBP who would be considered at high risk of poor long-term outcome. Inclusion/exclusion criteria will align with previous studies in chronic LBP:

Inclusion criteria

1. Adults presenting with LBP pain duration >3 months and considered at high-risk of poor long-term outcome (identified with STarTBack 9item tool)
2. Currently scoring 4 or more on a numerical response scale for pain from 0-10 (0=no pain, 10=worst pain)
3. Ability to stand for 10 minutes and walk for 5 minutes (required to complete the intervention)
4. Speak and understand English sufficiently to be able to receive either of the two physiotherapy interventions. This will be assessed at the point of consent. If there is any doubt, a physiotherapist will call the participant to check whether their understanding of English is appropriate.

Exclusion criteria:

1. Diagnosis of inflammatory arthritis
2. LBP due to pregnancy and up to 12 months post pregnancy
3. Previous spinal surgery in the last 12 months such as discectomy, anterior cervical discectomy and fusion, disc replacement, laminectomy and scoliosis fixation
4. Diagnosis of degenerative neurological disorders (e.g. Multiple Sclerosis/ Parkinson's disease)
5. BMI of more than 33 (as increased subcutaneous fat prevents collection of surface EMG signals)
6. Pending litigation related to an injury, for example, at work or whilst driving
7. Vulnerable patients, for example, those who lack mental capacity to make decisions, have dementia or are nearing the end of life
8. Unable to cancel or postpone other treatment for the condition, for example, physiotherapy, chiropractic or osteopathy

Recruitment through local GP practices:

We will set up three sites around the Greater Manchester region at which we will deliver the CMT and control interventions. We will identify at least 2-3 GP practices within 5-7 miles of each delivery site. At each practice, a clinical research nurse will oversee a search to identify patients who attend primary care with a relevant diagnostic (SNOMED CT) code who have consulted their GP for LBP. Patients identified as eligible will be sent the participant information sheet and the invitation letter and asked to contact the research team directly if they are interested in taking part. Alternatively, eligible patients will be sent a text message (see "Text invitation"). This text message contains a contact telephone number and a link to a webpage which provides an overview of the study (https://hub.salford.ac.uk/volunteer-for-health-research/2024/11/11/below/) and a link to the participant information sheet. Embedded within this webpage is a link to an online form which volunteers will complete if they are interested in taking part. The questions from this form have been copied to the document "Screening webform". All data submitted via this form is strictly confidential and held on a secure server at the University of Salford. With this latter approach, volunteers are still free to contact the research team directly if they would prefer to be screened over the phone. If they do contact the research team in this way, they will be sent the participant information sheet and asked to contact the team again if they are still interested in taking part. Note that, with either of the approaches described above, the research team will not have access to patient records.

In addition to the search of electronic records, First Contact (physiotherapy) Practitioners (FCP's) will be prompted about the trial if they enter a relevant LBP symptom code into their computer system during a consultation. The system will independently check for eligibility against the inclusion/exclusion criteria. If eligible, the FCP will explain to the patient that they will receive an invitation to participate. Through searches carried out every two weeks, the GP practice will then send these eligible patients a text message and letter of invitation to participate or a text message with a link to the website, as described above.

Recruitment through musculoskeletal physiotherapy & pain team physiotherapy waiting lists

We will recruit patients through musculoskeletal and pain team physiotherapy waiting lists. At each site, a member of clinical or administrative staff will screen the waiting lists for patients with referrals for LBP. A clinical research nurse will then screen the referrals against the inclusion/exclusion criteria of the study. Letters of invitation (Letter of invitation – BELOW (FS) and a (participant information sheet- BELOW (FS) -(patient)) will be sent to all eligible patients with low back pain who are on the physiotherapy waiting list. Alternatively, patients will be sent a text message with a link to the website/phone number, as described above. Again, with either of these approaches, the research team will not have access to patient records.

With both GP recruitment and recruitment through musculoskeletal physiotherapy & pain team physiotherapy waiting lists, we may send reminder invitations about the opportunity to participate in this study. This will involve sending a repeat text message, explaining that this is a follow message and to disregard the message if they have already replied to first the invitation to participate.

Recruitment through social media

In response to PPIE feedback, we will also use posters in GP practices and community settings (e.g. University buildings) to reach patients who might have chronic LBP but who may not have consulted their GP recently. This poster (see "Poster (patient)") contains a QR to enable volunteers to view the website described above and a contact email and phone number. In addition to posters, we will

consider using social medial channels, such as Facebook, and Instagram, if other recruitment strategies fails to identify sufficient participants. The social media post (see "Social media advert (patient)") contains a link to the website described above and a contact email. note that Volunteers who respond to the poster or social media post via email will be send the participant information sheet for review and asked to contact the research team again if they are still interested in taking part.

Strategy to ensure representation across different social/demographic groups

We will take several steps to ensure that the sample of participants recruited is representative of the population the study in targeted at. Working with the CRN, we will assess the diversity of ethnicity and socioeconomic status across each GP practice. This information will then be used to guide choice of GP practices to maximise the likelihood that patients from underrepresented groups will volunteer to participate. Furthermore, as part of our baseline dataset, we will collect data on EDI characteristics, such as ethnicity, sexual orientation and religious beliefs (see below).

Recruitment of NHS physiotherapists

We plan to employ 12 NHS physiotherapists at band 6 or above to deliver the interventions. We need 12 physiotherapists to ensure that, at each of our three research sites, we have two physiotherapists who can deliver CMT and two physiotherapists who can deliver the control intervention. We will identify physiotherapists who are able to be seconded onto the project, work overtime or, if they work part time, to take part in this project on their day off. Specifically, we will liaise with the department lead and ask the physiotherapists to contact us directly if they are interested in taking part. We will also post an advert on the Chartered Society of Physiotherapy (CSP) website (see CSP advert- BELOW).

The research team will check the eligibility of the physiotherapists who wish to deliver the intervention according to the inclusion criteria: (band 6 or above and with >3 years' experience of managing patients with chronic low back pain). A competency checklist will be used to verify that the physiotherapists level of experience and knowledge is at an expected level to deliver the interventions before they are deemed eligible. Once deemed eligible, the physiotherapists will be consented (if they are happy to be interviewed), provided with the online training and attend training at the University of Salford. Further details are provided in the section below on physiotherapist training.

4 Consent and randomisation

Patient consent and randomisation

With the methods of recruitment described above, patients will either contact the research team directly (via phone or email) or will provided information on eligibility via the online screening form. In both situations, participants will have been instructed to read the PIS before either contacting the research team or completing the form. Patients who are deemed ineligible through the screening form will receive a text message or email (depending on preference) to explain that they are unable to take part. Those who appear potentially eligible (after completing the form) or who contact the team directly, will undergo telephone screening to confirm that all inclusion/exclusion criteria are met (see eligibility criteria above).

For those who are eligible, consent will be collected via post or email. Specifically, participants will be sent the consent form (Participant consent form- BELOW (FS)- (patient) and asked to return the signed copy via mail or scanned email attachment. All participants complete and sign the consent form (participant consent form – BELOW (FS)) to indicate they are giving valid consent. The Trial Manager / Research Administrator/CI completing consent countersigns this form indicating all available information has been given to the participant. All patients will be encouraged to take time to consider their participation.

Once the consent form has been received, the participant will be formally enrolled onto the study. Once enrolled, with the patients' permission, the research team will send a letter to the GP (Letter to GP- BELOW (FS)) informing them of the patients' participation in the study. Baseline outcomes will then be collected (see Section 7). Once baseline questionnaires are completed, patients will be randomised into either the intervention group (CMT- treatment group 1) or control group (psychologically informed physiotherapy- treatment group 2). Note that, in some cases, there will be a delay of 4-6 weeks between consent and collection of baseline outcomes. This delay will ensure that treatment commences within 6 weeks of randomisation and is necessary to coordinate the delivery of the intervention.

Randomisation will be stratified by site using variable block sizes, via a central, web-based randomisation system based at the York Trials Unit, University of York. The allocation sequence will be generated by a statistician from York Trials Unit not otherwise involved in the recruitment of participants. Once group allocation has been confirmed the intervention coordinator (member of the research team) will liaise with participants over the phone to schedule the intervention sessions. Once finalised, participants will be sent a participant appointment information letter and schedule (see "GROUP 1 BELOW FS participant appointment letter" and "GROUP 2 BELOW FS participant appointment letter")

Physiotherapists consent for interviews

We will ask the CMT physiotherapists if they are happy to be interviewed about their experiences of delivering the intervention. If interested, we will obtain consent from the physiotherapists during the face-to-face training sessions. Specifically, once they have read and are happy with the information sheet and have talked to the research team about the project, they will wait a minimum of 24 hours before signing and returning the consent form to the research team (Participant consent form- feasibility study interview (physiotherapist)). If they do not consent to be interviewed, they can still take part in the trial and deliver the intervention.

5 NHS Physiotherapist training

Training for Cognitive Muscular Therapy- treatment group 1

The physiotherapists who will deliver the CMT treatment group will receive training via a series of online modules (16 hours), followed by two face-to-face one-day workshops (each lasting 7.5 hours). The total training received by CMT physiotherapists will be 31 hours. The online module will provide background information and explain how to apply the CMT clinical protocols through illustration with video case studies.

There will be a period of at 1-2 weeks between completing the online modules and the first face-to-face workshop and a period of at least 4-6 weeks between the first and second face-to-face workshop. We will use a competency framework to ensure that physiotherapists are competent to deliver the CMT intervention without supervision of a more senior physio/researcher. Using this framework, the physiotherapists will be assessed at the end of the first half (morning) of the first workshop by a member of the research team. We will then directly observe the physiotherapists working with participants (recruited from training development study- IRAS: 339101) in the afternoon. A further assessment will be completed at the end of the session. The physiotherapists will then be signed off as competent to deliver the CMT intervention. They will then be encouraged to practice parts of the CMT treatment which are reflective of skills used in normal practice (such as diaphragmatic breathing or functional movement retraining) in their day-to-day NHS role so that they become familiar with the protocols. In addition, the physiotherapists will be encouraged to reflect on their learning and will be encouraged to keep a reflective diary and to use an online platform (Microsoft Teams group) to share experiences of delivering the intervention.

During the second one-day workshop, the research team will use this checklist to observe the delivery of the intervention to participants at different stages of the protocol. We will quantify how well each physiotherapist can deliver the intervention using an adapted intervention checklist developed for our knee OA intervention development study (IRAS: 339101). The checklist is scored from 0 (lowest) to 75 (highest). A score of over 60 will be deemed as competent to deliver CMT to participants on the trial. A score of below 60 will require the physiotherapist to undergo further learning as appropriate prior to sign off. However, based on previous experience we do not anticipate this being required. All physiotherapists were deemed competent after the second training session in our previous intervention development study (IRAS: 339101).

Training for the control intervention - psychologically informed physiotherapy

The control intervention has been designed to match best practice psychologically informed physiotherapy for patients with chronic musculoskeletal pain. While some NHS physiotherapist departments do deliver this care, there can be differences in practice across different NHS trusts. Therefore, to standardise this treatment, each physiotherapist who will be delivering psychologically informed physiotherapy, will complete six hours of online training and attend a four-hour workshop at the University of Salford. Through this training, they will learn to use the protocols we have developed for the control intervention and also undergo a competency assessment to ensure that they have the appropriate clinical skills to deliver the treatment.

6 Interventions, timing, and setting

6.1 Treatment group 1- CMT

Participants in the treatment group 1 will receive seven individual clinical sessions of CMT, each lasting 45-60 minutes. There are five separate intervention components which the physiotherapist works through sequentially. A summary of each intervention component is provided below:

Component 1/session 1 (Understanding back pain): Persuasive communication and imagery (through animated videos) are used to challenge the belief that LBP is the direct consequence or result of “wear and tear” on the spine or discs, and to convey the idea that increased muscle activation will increase spinal loads, potentially exacerbating pain.

Component 2/ sessions 1 and 2 (General relaxation): patients are taught to release specific patterns of muscular holding in the trunk muscles. A key focus is on the use of diaphragmatic breathing to train relaxation of the abdominal muscles and the use of EMG biofeedback (sensors placed over the lower back which provide feedback on a screen relating to the level of muscle activity) The aim of biofeedback is to raise awareness of overactivity of the spinal muscles in lying and sitting.

Component 3/ sessions 3,4 and 5 (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 spinal muscles. EMG biofeedback is used throughout component 3.

Component 4/ session 6 (Contextual triggers): This component aims to raise awareness of inappropriate contraction of the spinal 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. EMG biofeedback is used throughout component 4.

Component 5/ session 7 (Functional integration): This final component builds on the principles of component 4 (Contextual triggers). The physiotherapist works through a range of functional tasks which are known to provoke LBP. Using hands-on guidance, the physiotherapist first ensures that there is no muscular bracing or disturbance in postural muscle tone (component 3) triggered immediately prior to task performance. The focus then shifts to guiding smooth performance of the task, again without muscular bracing. EMG biofeedback is used throughout component 5.

Delivery of the intervention is supported with 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 low back 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 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 previous studies involving CMT. More information on the CMT intervention is provided in the publication of our intervention development study [15].

6.2 Treatment group 2- psychologically informed physiotherapy

Participants in treatment group 2 will receive psychologically informed physiotherapy which is a well-established treatment for patients with long term pain. The patients will receive five face-to-face sessions of 45-60 mins delivered at the University of Salford and complete two pre-recorded/prepared online sessions.

The sessions will include the following:

Session 1 will include a subjective and objective assessment. It will include a discussion about understanding pain, the chronic pain cycle and the benefits of exercise. The patients will be taught stretches and relaxation exercises. Goal setting will be completed at the end of the session.

Session 2 will include a review of the patients understanding of pain. Their goal and exercises will be reviewed. The session will include an introduction to unhelpful behaviours (boom/bust, avoidance, excessive persistence) and completing an activity diary. The session will end with stretches and relaxation exercises.

Session 3 (online) focuses on pacing theory and practice. It will include information on pacing such as planning/prioritising, reviewing activity diaries, and discovering/testing baselines. The session will end with setting a pacing goal.

Session 4 will include an activity diary review and goal setting related to pacing. Education will focus on pacing. The session will include a graded exercise circuit and relaxation exercises.

Session 5 will include a goal review. Education will focus on sleep hygiene and medication. The session will include a graded exercise circuit and relaxation exercises.

Session 6 will include a goal review. Education will focus on managing flare ups. The session will include a graded exercise circuit and relaxation exercises. The session will end with a future planning exercise.

Session 7 (online) will include education on employment, the role of healthy lifestyles (smoking, exercise, diet) and future goals.

Undergoing other interventions

Following completion of treatment 1 or 2, participants can opt to undergo other interventions e.g., private physiotherapy, without needing to withdraw from the study. However, if this occurs prior to the completion of the 8-month outcomes, these visits will need to be recorded in the healthcare resource questionnaire.

6.3 intervention delivery

We will use 3 community sites or NHS sites (depending on availability) to deliver the CMT and control interventions. We anticipate that the costs of paying for these sites would be covered through NHS treatment costs. We will train 6 physiotherapists to deliver the CMT intervention and identify 6 physiotherapists who will deliver the control intervention. This will provide us with one primary physiotherapist per intervention/site plus one extra physiotherapist as back up at each site. With this approach, 15 patients will receive the CMT intervention, and 15 patients will receive the control intervention per site. Delivery will be split into two separate waves (see project timetable-section 11). Appointments will be offered both during the day and at weekends/evenings to maximise participation for those who work or who have caring responsibilities during the day.

Non-attendance and withdrawals

Non-attendance will be recorded for those participants who do not attend (DNA) or are unable to attend (UTA) some or all of the BELOW interventions. Non-attending participants will remain in the

trial as this is an intention–to-treat study. The participant will still be asked to complete the follow-up outcome questionnaires and will not be withdrawn from the study unless they formally request this.

6.4 Fidelity assessment

We will use a quantitative approach to assess fidelity of the CMT intervention. This will involve capturing video recordings from the trial physiotherapists at different stages along the patient journey (among those patients who have consented to video recording). We will use the structure of our intervention fidelity checklists developed in our previous training development study for knee osteoarthritis.(IRAS: 339101). This includes 20 checklist items for each treatment component and will be adapted for LBP. Fidelity will be scored from the video recording by our two expert physiotherapists, Mr Brookes and Mr Smith. Recordings will not be shared outside the research teams and once they have been scored then they will be permanently deleted.

To assess the fidelity of the control intervention we will perform an audit of the clinical notes. This will involve reviewing a random sample of 10 sets of notes per site (30 in total) at different stages of the patient journey. We will use the control intervention protocol as a checklist to assess treatment consistency across sites and physiotherapists. This will be completed by co-applicant Dr Antcliff.

7 Clinical, QoL & health economic outcomes

Data will be collected using online questionnaires which will be managed using the REDCap system. For participants who are unable to complete online outcomes, we will send paper questionnaires. Clinical outcomes will be collected at

1. Baseline (prior to randomisation)
2. 14 weeks (1 week after the final intervention session)
3. 8 months post-randomisation

Will you send follow up reminders to maximise follow up data? Can patients still participate if they do not provide baseline data? If someone does not return the 14 weeks questionnaire, will you still send the 8 months questionnaire?

We will collect clinical data using the following questionnaires (included with the application):

1. Roland Morris Disability Questionnaire
2. Numerical rating scale of pain (0-10)
3. Pain catastrophizing scale
4. Pain self-efficacy questionnaire

We will collect the following health economic data (included with the application):

1. EQ-5D-5L
2. Health resource utilisation – custom questionnaire
3. Work productivity and activity impairment (WPAI) questionnaire

We will collect the following diversity and inclusion data at baseline only (included with the application):

1. Diversity and inclusion questionnaire

We will collect the following patient experience data at 14 weeks (included with the application):

1. Musculoskeletal Patient Reported Experience Measure- (MSK PREM)

Process and reminder schedule for the collection of outcome data

Baseline:

Once consented to the study, participants will be sent an email containing a weblink to the baseline outcome questionnaires. They will receive a maximum of three email reminders to complete these baseline data over a two-week period. If the outcomes are not completed within 2 days of the third reminder, they will be contacted once more by telephone to discuss options to remain in the study such as delaying the completion of baseline outcomes until the next recruitment wave.

Follow-up:

Following treatment, participants will be sent an information letter/email explaining next steps of the trial (see "BELOW FS post-treatment information letter"). This will inform them of the date that their first follow-up questionnaire will be sent out. It also reminds participants to delay any additional treatment for their back pain until after the 14-week outcome data has been completed.

The Trial Manager and administrator will monitor return of all outcome data and the quality of data. This monitoring will allow the research team to identify missing outcome data and send reminders as appropriate. Reminders for the 14-week and 8-month outcome data will follow the schedule below:

- **At 3 days after the initial invitation to complete outcomes is sent**, if outcome data not completed, a Trial Administrator (or the REDCap system) will e-mail the participant with a reminder to complete outcomes.

- **At 1 week after the initial invitation to complete outcomes is sent**, if outcome data not completed, a Trial Administrator (or the REDCap system) will e-mail the participant again with a reminder to complete outcomes.

- **At 2 after the initial invitation to complete outcomes is sent**, if outcome data not completed, a Trial Administrator (or the REDCap system) will e-mail the participant again with a reminder to complete outcomes. A text message will also be sent to the participant, and they will receive a follow-up call from a trial administrator.

- **At 3 weeks after the initial invitation to complete outcomes is sent**, if outcome data not completed, a trial administrator, will telephone the participant to obtain a minimal data set. This minimal dataset will include the Roland Morris Disability Questionnaire, the Numerical rating scale of pain (0-10) and the EQ-5D-5L.

If outcome data are unable to be collected post-intervention, this will be recorded in the Trial Database as missing (lost to follow-up). Participants that do not return the 14-week outcomes will still be contacted for their 8-month outcome data.

Patient newsletter:

In addition to the letter (described above) that patients will receive after their final intervention session, we will send a series of newsletters to each patient between the 14-week and 8-month outcomes. We anticipate sending one newsletter every 6-8 weeks, but this exact schedule will be determined through consultation with our PPIE group. These newsletters will be sent via email/letter (depending on participant preference) and will remind participants that they are still in the study, explain the importance of completing the 8-month outcomes and give some update on study progress, e.g. numbers of participants who have completed each intervention. The exact format of each newsletter will be developed through consultation with our PPIE group.

Incentives to complete 8-month outcome data

When contacted about the 8-month outcome data, participants will be offered a £10 payment. This payment will be made via bank transfer once we receive the full set of 8-month outcome questionnaires. This payment has been made clear in the participant information sheet.

8 Sample size and statistical analysis

This research is a feasibility trial and therefore does not have a primary clinical outcome measure to inform a power calculation. Sample sizes of between 24 and 70 have been recommended for feasibility trials to provide a reliable estimate of parameters required to calculate the sample size for a main trial, e.g. standard deviation of continuous outcomes, recruitment and attrition rates [16-18]. We propose to recruit 90 eligible patients (across nine GPs) to ensure we obtain at least 70 patients in the final analysis, allowing for a 20% attrition rate. If we identify at least 900 eligible participants, we will be able to estimate a participation rate of 10% to within a 95% confidence interval of ±2%. This sample size should also be sufficient to allow us to identify a subset of patients for qualitative evaluation who have varied clinical responses to the intervention.

To inform planning of a future trial, the number of participants screened, consenting and randomised will be presented by site and month. Reasons for non-participation or drop out (ineligible or non-consenting) will be summarised where available. Baseline and outcome data will be summarised descriptively by randomised group and overall using mean (SD) for continuous variables and number and percentage for categorical data. Trial follow-up rates and intervention session attendance will be summarised. Clinical outcome data analysis will be exploratory in nature and used to plan our future trial. We will plot line graphs to look at the trajectory of each outcome over time, looking at both individual participants and the mean values for each randomised group. However, if there is an unexpectedly large difference (>1 SD) in clinical outcomes between the two groups, we will undertake a formal statistical analysis using independent t-tests. This will allow us to test for differences in outcomes at the 14-weeks and 8-months follow-up points.

An intention-to-treat (ITT) analysis, along with a per-protocol analysis, will be conducted after the 8-months follow up point. In the per-protocol analysis, only participants who complete more than 5 out of 7 sessions will be included. Employing this dual methodology will allow us to determine the genuine impact of the CMT and control interventions while also providing data relevant to clinical allocation. This approach will help us refine the analysis plan for a future trial.

9 Health economic analysis

We will not perform statistical analysis on the health economic data. Instead, these data will be used to inform planning of a future RCT. Specifically, we will explore health outcomes (i.e. the EQ-5D-5L), healthcare resource use and costs of the intervention and control groups. Cost and outcome data will be collected at baseline, 14 weeks and 8 months using participant self-completed questionnaires. Health-related quality of life data will be obtained via the EQ-5D-5L to enable the measurement of participants' utility. Estimates of the raw EQ-5D-5L scores will be presented, both overall and by domain, with completion rates also summarised.

An NHS costing perspective will be taken for the analysis. Healthcare utilisation data will be collected and presented for relevant resources used by LBP patients in primary care and the community (i.e. appointments with a GP, nurse, physiotherapist, occupational therapist, and other primary/community care healthcare professionals) and the hospital setting (i.e., hospital outpatient attendances, accident and emergency admissions, day case attendances and inpatient admissions). Participants will be asked to record their resource use specifically in relation to LBP. Mean resource use by item will be summarised and completion rates will be presented. Unit costs for the healthcare resources will be sourced from established costing databases, such as NHS Reference Costs [19] and Personal Social Services Research Unit (PSSRU) Unit Costs of Health and Social Care [20]. Indicative costs of the intervention will be estimated, incorporating the cost of delivering the sessions, and the associated materials, versus the control intervention group.

10 Biomechanical Measurements

We will collect mechanistic data on all from a subset of 30 participants in the study, 15 from each arm. These measurements will take place during two additional face-to-face assessment sessions, one before the first treatment session and the second after the final treatment session. Attendance at these assessments will be optional, however, we will offer a £10 payment for each session.

This mechanistic data will consist of an EMG assessment (using surface electrodes) to quantify changes in muscle activation during a range of functional tasks (e.g. walking, forward bend). We will also quantify changes in flexibility and postural alignment using a portable 3D camera. Data from the 3D 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. In addition, we will collect data on muscle stiffness using the Myoton system (Myoton AS ®). This is a non-invasive measurement in which a small probe is placed in contact with the skin of the low back. We will also collect data on heart rate variability using a chest-worn heart rate monitor and on time to complete a set of simple movement tasks, such as standing up from a chair and walking 6 m.

11 Qualitative evaluation of the acceptability

There will be three qualitative components to the proposed study:

1. Exploration of physiotherapists' perceptions of the CMT intervention
2. Exploration of patients' perception of the CMT intervention
3. Exploration of patients' experience of being involved in the trial

Component 1: Physiotherapists' experience of intervention delivery: We will run a focus group with all physiotherapists who deliver the CMT intervention to understand their perceptions of CMT and to understand their experience of delivering the intervention. We will use an acceptability framework [21] to explore personal opinions of the intervention and to identify any aspects which were deemed difficult to deliver or which the physiotherapist believed to be challenging for the patient to understand. To guide discussion in the focus group, we will use a focus group topic guide (see "Focus group topic guide"), which contains a statement relating to confidentiality, safeguarding and professionalism at the start. Using this guide, we will explore how physiotherapists perceive the CMT intervention relative to existing combined psychological and physical therapies. We may use findings from this qualitative evaluation to map small modifications to the training package which may be required for a potential follow-on trial.

Component 2: Patients' perceptions of the intervention: We will purposively select 15 participants from each group (CMT and psych informed) who demonstrate a range of clinical responses (from pain outcomes: improvement, no change and worsened pain severity). To gain insight into the reasons for non-adherence, we will aim to include at least two patients who have decided to drop out before completing the full seven intervention sessions. With each patient, we will explore intervention acceptability through semi-structured interviews (see interview topic guide (feasibility study)). Using a conversational style of interviewing, with the questions to direct not to restrict the conversation, we will gain insight into the participants' personal experiences/opinions of the intervention (usability, adherence, effectiveness, and acceptability) and how it contrasts with their experience of previous physiotherapy. We will use an acceptability framework [21] to explore patient's perceptions of the CMT intervention after which will use thematic data analysis *[22]* to identify personal feelings and emotions in relation to patients' experience.

Component 3: Patients' experience of trial involvement: We will interview a subset of patients in both the treatment and control arms to understand their experiences of being involved in the trial (see interview topic guide (feasibility study)). This will allow us to identify any issues which would need to be considered for the follow-on trial, such as willingness to be randomised and appropriateness of outcomes used to capture pain, disability, health-related costs and other psychological factors related to pain. To capture a wide range of experiences and issues we will employ purposive sampling. It is anticipated that six patients from both groups would be sufficient to achieve this. However, we will continue to interview patients until we reach information power. In addition, we will contact any individuals who decide not to participate in the trial but who indicate that they are happy to be interviewed, to gain insight into the factors that motivated their decision and use this to inform participant information resources for the follow-on trial.

Interview data will be analysed using reflective Thematic Analysis [22] by two independent qualitative researchers to interpret the data and the resulting themes. This process will involve comparison of findings within and among transcripts, and use of memos to record decision points. The approach to analytical interpretation of the themes identified by the researchers will be collaborative and reflexive, aiming to achieve richer interpretations of meaning, rather than attempting to achieve consensus of meaning.

12 Stop-go criteria for the follow-on trial

To help decide whether to proceed to a full RCT we will use a stop-go criteria for each of our objectives using a traffic light signal where green indicates no issues, amber indicates changes required and red indicates issues that cannot be resolved:

We have defined the following criteria to assess whether it is feasible to proceed to a future large-scale trial.

1. Recruitment: Average number of participants per GP provider per 2 months: red<1; amber=1-2; green>2.
2. Adherence: Number of participants attending >5 (of 7) clinical sessions: red<60%; amber=60-79%; green>80%.
3. Trial retention: Participants providing 8-months outcome data: red<60%; amber=60-79%; green>80%.
4. Signal of effectiveness: 90% one-sided confidence interval of Roland Morris containing a standardised effect size: red<0.20; amber=0.20-0.29; green≥0.3.
5. Acceptability to patients (qualitative evaluation)
6. Feasibility of training NHS physiotherapists to deliver the intervention (qualitative evaluation & assessment of intervention fidelity>75%)

13. Project timetable

This project will be delivered over a 24-month period:

- Month 1: finalise ethical and research and development approvals
- Months 2-5: set up recruitment at GP sites and recruit physiotherapists
- Months 6-10: recruit 45 patients to wave 1 and train physiotherapists
- Month 10: patient consent and randomisation
- Months 10-13: wave 2 recruitment
- Months 11-14: wave 1 treatment delivery
- Month 14: patient consent and randomisation
- Months 15-18: wave 2 treatment delivery
- Months 14-21: post intervention, 14 weeks and 8-month outcomes
- Months 14-21: Qualitative evaluation
- Month 21-24: Data analysis and write up

14. Dissemination

The project will deliver a new training course for physiotherapists and the study findings will inform the planning of a future large-scale trial along with mechanistic/qualitative data on CMT. If our data supports further research, then we will submit a grant application for a definite RCT within 1-2 months of the project completing. The primary academic output for this study will be paper describing the feasibility trial. We will also report on the mechanistic data and qualitative analysis. In addition, we will present the research one relevant international conference e.g International Association for Pain (IASP).

We will communicate our findings with patients who experience LBP through articles for online magazines, such as Pain Concern (https://painconcern.org.uk/), and through charities, such as BackCare.org, who provide information/resources for people who live with back pain. To reach out to UK health professionals, we will present our findings at the Physiotherapy UK annual conference. Each participant in the trial will be sent a written summary of the research findings on study completion.

15. Participant and Public Involvement in Research

We will form a user advisory group which will consist of 4-6 patient representatives who will advise on research design, participant information resources and dissemination. This group will attend joint PPIE/Steering group meetings at the start of the study and every 4-6 months (6 over the course of the project). The user advisory group will be consulted on several different aspects of research design. For example, the appropriateness of specific trigger questions used in the interviews designed to elicit user perspectives of our intervention and on trial involvement.

16. References

1. Hoy D, March L, Brooks P, et al. 2014 The global burden of low back pain: estimates from the Global Burden of Disease 2010 study Ann Rheum Dis 73 968-74

2. Perrot S, Doane M J, Jaffe D H, et al. 2022 Burden of chronic low back pain: Association with pain severity and prescription medication use in five large European countries Pain Pract 22 359-71

3. Steenstra I A, Verbeek J H, Heymans M W, et al. 2005 Prognostic factors for duration of sick leave in patients sick listed with acute low back pain: a systematic review of the literature Occup Environ Med 62 851-60

4. George S Z, Fritz J M, Silfies S P, et al. 2021 Interventions for the Management of Acute and Chronic Low Back Pain: Revision 2021 Journal of Orthopaedic & Sports Physical Therapy 51 CPG1-CPG60

5. Koch C and Hansel F 2018 Chronic Non-specific Low Back Pain and Motor Control During Gait Frontiers in Psychology 9

6. Ghamkhar L and Kahlaee A H 2015 Trunk Muscles Activation Pattern During Walking in Subjects With and Without Chronic Low Back Pain: A Systematic Review Pm&R 7 519-26

7. Koch C and Hansel F 2019 Non-specific Low Back Pain and Postural Control During Quiet Standing-A Systematic Review Frontiers in Psychology 10

8. Geisser M E, Haig A J, Wallbom A S, et al. 2004 Pain-related fear, lumbar flexion, and dynamic EMG among persons with chronic musculoskeletal low back pain Clinical Journal of Pain 20 61-9

9. van Dieën J H, Selen L P and Cholewicki J 2003 Trunk muscle activation in low-back pain patients, an analysis of the literature J Electromyogr Kinesiol 13 333-51

10. Shigetoh H, Nishi Y, Osumi M, et al. 2020 Combined abnormal muscle activity and pain-related factors affect disability in patients with chronic low back pain: An association rule analysis Plos One 15

11. Sterling M, Jull G and Wright A 2001 The effect of musculoskeletal pain on motor activity and control J Pain 2 135-45

12. Hodges P W and Moseley G L 2003 Pain and motor control of the lumbopelvic region: effect and possible mechanisms J Electromyogr Kinesiol 13 361-70

13. Ershad N, Kahrizi S, Parnianpour M, et al. 2022 Trunk muscle activity during holding two types of dynamic loads in subjects with nonspecific low back pain J Bodyw Mov Ther 31 7-15

14. Pakzad M, Fung J and Preuss R 2016 Pain catastrophizing and trunk muscle activation during walking in patients with chronic low back pain Gait & Posture 49 73-7

15. Preece S J, Brookes N, Williams A E, et al. 2021 A new integrated behavioural intervention for knee osteoarthritis: development and pilot study Bmc

16. Julious S A 2005 Sample size of 12 per group rule of thumb for a pilot study *Pharmaceutical Statistics* 4 287-91

17 Teare M D, Dimairo M, Shephard N, et al. 2014 Sample size requirements to estimate key design parameters from external pilot randomised controlled trials: a simulation study *Trials* 15 264

18 Whitehead A L, Julious S A, Cooper C L, et al. 2016 Estimating the sample size for a pilot randomised trial to minimise the overall trial sample size for the external pilot and main trial for a continuous outcome variable *Stat Methods Med Res* 25 1057-73

19. Department of Health. NHS Reference Costs 2018/19:. 2019; Available from: https://improvement.nhs.uk/resources/national-cost-collection/.

20. *Curtis L, Burns A. Unit Costs of Health and Social Care 2019. University of Kent: Personal Social Services Research Unit; 2019.*; Available from: https://www.pssru.ac.uk/project-pages/unit-costs/unit-costs-2019/.

21. Sekhon M, Cartwright M and Francis J J 2017 Acceptability of healthcare interventions: an overview of reviews and development of a theoretical framework *BMC Health Serv Res* **17** 88

22. Braun V and Clarke V 2006 Using thematic analysis in psychology *Qualitative Research in Psychology* **3** 77-101