Behaviour change to rEduce LOW back pain: a training development 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. In a follow-on study, we created an implementation of CMT for people with chronic, longstanding LBP. This treatment was delivered to 15 LBP patients, and we observed a mean reduction in pain of 77% across the group. Given these promising results, we have been awarded 260K by the NIHR to deliver a project which will investigate the potential of delivering CMT for LBP on the NHS.

Our NIHR funded project will be delivered via two separate studies. This first study (IRAS ID: 339101) will focus on the testing and refinement of a physiotherapist training course for CMT for LBP. This course is currently being developed at the University of Salford and will be ready for the start of the proposed study. Once complete, we will use the training course to train the NHS physiotherapists in our feasibility study (IRAS ID: 331773).

2 Overview of the training development study

To test and refine our training course, we will recruit 4 NHS physiotherapists and 10 patients with LBP. Each of the physiotherapists will complete a first iteration of our training course, which includes both an online and a face-to-face component. They will then treat two patients with LBP under observation of the research team. The other two patients with LBP will be treated by a physiotherapist already experienced in delivering CMT for LBP. By observing delivery of the intervention, the research team will map out an appropriate set of changes to the training course. Through this testing of the intervention, the research team will also collect video footage to embed with successive versions of the training course.

2.1 Inclusion and exclusion criteria

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 read the information sheet and sign the consent form

Exclusion criteria:

1. Diagnosis of inflammatory arthritis
2. LBP due to pregnancy and up to 12 months post pregnancy
3. Previous spinal surgery 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

2.2 Recruitment of patients and identification of physiotherapists

Patient recruitment:

We will use the following approaches to identify patients with LBP for the study.

1. **Use of the School of Health & Society volunteer database**. With this approach, we will write to/email people on a database that we hold at the University of Salford who have LBP 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- BELOW- (TDS)).
2. **Social media advert**. We will use social medial channels, such as Twitter, Facebook, Instagram to promote the study (see poster & social media advert). Individuals who are interested in participating in our research will be required to text 'BACK' to a specific number and will follow the same procedure described below.

3. **Primary care searches.** We will identify at least 1 GP practice within 3 miles of the University of Salford. A clinical research nurse will oversee a search to identify primary care consulters with a relevant diagnostic (Snomed CT) code who has consulted their GP for LBP within the previous three months. Eligible participants will then be sent the participant invitation letter (Letter of invitation- BELOW- (TDS)) and participant information sheet (participant information sheet- BELOW- (TDS)- (patient)) to participate in the study by the GP practice or member of the direct care team. The patient will then independently contact the research team if interested in the study.

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 several questions to ensure that they meet the inclusion/exclusion criteria. Those individuals deemed eligible will then be sent the appropriate participant information sheet (participant information sheet- BELOW- (TDS)- (patient)) if required. Individuals will be given a minimum of 24 hours to read the information sheet(s) and then contacted again. On second contact, the researcher will talk to them about the study and discuss any further questions. 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.

Identification of Physiotherapists:

We will use the following approaches to identify NHS band 7 physiotherapists with at least 3 years' experience of managing patients with chronic LBP. We plan to recruit 4 Band 7 physiotherapists to the study. Following the same approach used in our knee osteoarthritis study, we will identify physiotherapists from local NHS trusts who are happy to be seconded onto the project 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 them to send the information sheet (participant information sheet- BELOW– (TDS)- (physiotherapist)) and ask them 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).

The research team will check the eligibility of the physiotherapists who wish to deliver the intervention according to the inclusion criteria: (band 7 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. Once deemed eligible, the physiotherapists will be consented (details below) and provided with the online training and attend training at the University of Salford. Further details are provided in the section below on physiotherapist training.

2.3 Setting and consent

Patient consent: This study will be carried out at the University of Salford. Upon arrival, participants will reread the information sheet (patient information sheet- BELOW- (TDS) (patient)) and the study will be explained in full. If participants have no objections, they will complete the consent form (Participant consent form- BELOW- (TDS)- (patient)). Consent will be taken by the researcher not the physiotherapist. Once consent has been taken, measurements of height and mass will be taken. Patients will not be paid to receive CMT but they will receive reasonable travel expenses. A letter will be sent to the patients registered GP to confirm their participation in the study (Letter to GP- BELOW (TDS)).

Physiotherapist consent: We will obtain consent from the 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 – BELOW- (TDS)- (physiotherapist)). They will then be provided with access to the online training materials.

2.4 Clinical and mechanistic outcomes

Before clinical instruction is provided, participants with LBP will complete the following questionnaires (included with the application). They will also complete the same questionnaires 2 weeks after the end of the treatment.

1. Roland Morris Disability questionnaire
2. Pain Catastrophizing Scale
3. Pain Self-Efficacy questionnaire
4. Numerical rating of pain scale

In addition to the clinical data, we will use a 3D camera to obtain a measurement of posture. 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. The primary aim of this study it 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.

2.5 Online course and training workshop

The physiotherapists will complete an online training course for CMT (16 hours over 4 weeks). Following completion of the online training course, the four 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 LBP who will each have received at least one previous clinical session of CMT from our expert physiotherapist, Mr Smith. Patients with LBP who agree to attend the training workshop will be paid £25.

2.6 The CMT intervention

There are five separate intervention components which the physiotherapist works through sequentially. A summary of each intervention component is provided below:

Component 1 (Understanding back pain): Persuasive communication and imagery (through animated videos) are used to challenge the belief that LBP is the direct consequence of 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 (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 to raise awareness of overactivity of the paraspinal muscles in lying and sitting.

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 back muscles.

Component 4 (Contextual triggers): This component aims to raise awareness of inappropriate contraction of the back 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 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.

The CMT intervention is delivered across seven individual clinical sessions, each lasting 45-60 minutes. Alongside the face-to-face sessions, patients are provided with access to an online learning platform which uses animated videos to convey intervention concepts and explain what should be practiced between clinical sessions.

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. if patients do not have access to a tablet or computer, then we will provide patients with 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 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].

2.7 Intervention delivery by physiotherapists and observation of clinical sessions

Following the training workshop, each physiotherapist will deliver the CMT intervention to two patients with LBP over an 8-week period (7 sessions, weekly with additional week as a backup) at the University of Salford. This intervention delivery will be observed by the expert physiotherapists (Mr Brookes and Mr Smith) 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 seven intervention sessions will be delivered by Mr Brookes or Mr Smith during which the novice physiotherapist will observe.

During the 8-week period of intervention delivery, the 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.

To develop the training course materials, videos will be taken during key parts of the intervention delivery. To avoid the physiotherapists being videoed, Mr Brookes or Mr Smith will step into the session to repeat the aspect of assessment or treatment of interest. Videos are optional and only taken if the patient has indicated on the consent form (Consent form- BELOW- (TDS)- (patient videos)) that they are happy to be videoed and also verbally agree to the video(s) during the session. The videos will be saved in a password protected folder accessible to the research team only.

After the final treatment session, the video(s) will be anonymised (face blurred using computer software) and sent to the patient(s) via a password protected video hosting platform for review. If the patient is happy for us to use the video in our training course, we will require a signed video release form which consents to use of the videos in future training materials (see Video release form). Once a signed video release form is received, the patient will be paid £100. If the video(s) are not acceptable to the patient, we will ask whether they would like the video(s) to be altered or deleted. If they want the video(s) deleting, they will be permanently deleted. If they would like the videos to be altered, we will ask for feedback which will be used to edit the videos to improve acceptability. We will ask the patient(s) to review the edited videos and if acceptable, the patient will follow the process stated above. If not acceptable, we will permanently delete the videos.

2.8 Individual interviews

Following intervention delivery, we will individually interview the 4 physiotherapists and patients who have consented to an interview. Interviews will be carried out by an experienced qualitative researcher over the phone or via video conference. We will start with an opening question relating to experiences of delivering/receiving the intervention, with further questions likely related to specific intervention components (see Interview topic guide- BELOW (TDS). All responses will be transcribed, and thematic analysis used to identify areas for improvement of the training course.

2.9 Modification of training materials

We will combine the findings from the interviews with the learning derived from our observation of the physiotherapists delivering the intervention. From these findings, we will map a set of specific modifications for our training course/protocols (both online and face-to-face components) and add in the anonymised video materials. Once finalised, this training package will be used to train the physiotherapists who may deliver the CMT intervention for LBP as part of the BELOW feasibility study or any future trials.

3. Project timetable

This project will take place over 10 months. In month 1 we will finalise the first prototype physiotherapist training course for the CMT intervention. In months 2-3 we will recruit and train 4 NHS physiotherapists. In months 4 and 5 we will observe the physiotherapists delivering the CMT intervention to 10 LBP patients. In month 6 we will interview the physiotherapists and patients. Following the final interview, the study will officially end. We will use the observations and the qualitative feedback to refine the training package in months 7 and 8. In months 9 and 10 we will train the feasibility study physiotherapists.

4. Dissemination

The primary output from this study will be a training course for physiotherapists. However, we will explore the possibility of publishing a paper in the journal of 'Musculoskeletal Care'. The paper would describe the experiences of the patients/physiotherapists in the training development study. We recently published a training development paper for patients with knee OA which describes this process (17).

5. 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 groups 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 have already 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.

7. References

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