ISRCTN31860277 https://doi.org/10.1186/ISRCTN31860277

Cognitive Muscular Therapy - developing a training programme for physiotherapists

Submission date
19/06/2024

Recruitment status
No longer recruiting

Registration date
21/06/2024

Overall study status
Completed

Last Edited
08/11/2024

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Low back pain (LBP) affects many people globally and causes more disability than any other condition. It limits daily activities and causes pain. Additionally, it puts a heavy financial burden on individuals, families, communities, and industry.
People with LBP tend to use their trunk muscles differently during everyday tasks. For example, they might overuse certain muscles during walking or standing. This altered muscle activity might be the body's way of protecting injured structures after injury, however, it becomes problematic when maintained long term.
Interestingly, research has demonstrated a link between how people think about their pain and their muscle activity. Negative thoughts such as being concerned about pain means your body is damaged can lead to increased muscle tension. As such, we need treatments that address both physical and psychological aspects of LBP.
As such, researchers at the University of Salford have developed a new physiotherapy approach called Cognitive Muscular Therapy (CMT). CMT helps patients understand how their thoughts affect their muscular responses. In a pilot study, CMT reduced disability by 77% in patients with long-term persistent low back pain.
The University of Salford has received further funding to test CMT for LBP in the NHS. The aim of the first part of the study is to produce a training course suitable for NHS physiotherapists. This training course will be used to train physiotherapists up for a larger study.

Who can participate?
People aged 18-100 years who have had low back pain for more than 3 months

What does the study involve?
If participants agree to take part, the research team will need their personal information (name, date of birth, address, email, height, and weight) for eligibility and contact purposes. Only the lead researcher and research coordinator will have access to this information, stored securely. Participants will then complete questionnaires about their symptoms, daily life impact, and thoughts about pain. At this stage, they'll be offered the opportunity to take part in a training course for physiotherapists where they'll be paid £25/hour (this is an optional part of the study). All participants will visit the University of Salford seven times (one week apart). The research team will measure their weight, height, and posture in the first session. Then, they'll receive

Cognitive Muscular Therapy (CMT) over seven face-to-face sessions. Their physiotherapist will explain how changing muscular reactions and thoughts can reduce tension and improve pain. They'll learn to consciously relax stomach and low back muscles during daily activities. Videos and instructional materials will guide them in the sessions and at home.
At each session, researchers will watch the physiotherapist deliver treatment. Videos of treatment sessions may be taken (participants can opt out). If taken, they can be reviewed and participants can request edits or deletion. If participants consent to the use of the videos, they will be paid £100. The videos will then be anonymised and used in a future training course for physiotherapists.

What are the possible benefits and risks of participating?
Participants will receive seven sessions of CMT and this may reduce their back pain. However, we can't promise that everyone will experience clear benefits. The results of the study will help us to understand how to design a future training course for physiotherapists and therefore help people with low back pain.
This is a very simple, straightforward study with minimal risks. The physiotherapist will be using techniques which are used in routine NHS practice, and these will be complemented with muscle biofeedback sensors. There is a small risk of an allergic reaction to the adhesive stickers used during muscle biofeedback. If this occurs, treatment with the muscle biofeedback will be discontinued. Participants may continue in the study, but the physiotherapist will stop using the muscle biofeedback.

Where is the study run from?
University of Salford (UK)

When is the study starting and how long is it expected to run for?
August 2023 to March 2025

Who is funding the study?
National Institute of Health Research (NIHR) (UK)

Who is the main contact?
Prof. Stephen Preece, S.Preece@salford.ac.uk

Contact information

Type(s)
Scientific

Contact name
Mr Nathan Brookes

Contact details
Room PO34
The Brian Blatchford Building
The University of Salford
Manchester
United Kingdom
M6 6PU
-
n.brookes1@salford.ac.uk

Type(s)
Principal investigator

Contact name
Prof Stephen Preece

ORCID ID
https://orcid.org/0000-0002-2434-732X

Contact details
PO33 Blatchford Building
University of Salford
Stratham Street
Manchester
United Kingdom
M6 6PU
-
S.Preece@salford.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
339101

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 61590, IRAS 339101

Study information

Scientific Title
Behaviour change to rEduce LOW back pain: a training development study (BELOW)

Acronym
BELOW

Study objectives
Following the completion of an online and face-to-face training course NHS physiotherapists will be competent to deliver Cognitive Muscular Therapy to NHS patients with persistent low back pain. This process will be acceptable to physiotherapists and patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 30/05/2024, HRA and Health and Care Research Wales (15-19 Cowbridge Road East, Cardiff, CF11 9AB, UK; +44 (0)2920 230457; healthandcareresearch@wales.nhs.uk), ref: 24/WA/0115

Study design
Non-randomized; Both; Design type: Treatment, Psychological & Behavioural, Physical, Rehabilitation, Qualitative

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Low back pain

Interventions
Patient participant flow through the study:
1. Participant receives the participant information sheet through the post.
2. Participant gets in touch and discusses the study with the research coordinator.
3. Research coordinator completes screening questions to check eligibility
4. If eligible, participants are invited to attend seven treatment sessions OR invited to attend and receive some sessions from expert physiotherapist Mr Smith prior to attending the physiotherapist training sessions (see below). They will then receive the remaining session after the training course.
5. On attendance at the first session, participants will complete a consent form and complete the following questionnaires:
5.1. The Roland Morris Disability questionnaire
5.2. The Pain Catastrophizing Scale
5.3. The Pain Self-Efficacy questionnaire
5.4. Numerical rating of pain scale
6. If given consent, participants will undergo a postural assessment using a 3D camera at the start of the first session.
7. Participants will receive seven weekly sessions of CMT lasting for 45 minutes to 1 hour.
8. If given consent, participants will undergo a postural assessment using a 3D camera at the end of the final session.
9. Two weeks after the final session, the participant will be asked to complete the four questionnaires again.
10. After receiving the treatment, the participants will be offered the chance to be interviewed.
11. If participants consented to videos, relevant videos will be shared with the participant/s who will decide if they consent to the videos being used as part of the future training course for physiotherapists. If participants consent, they will be paid £100. If they do not consent, the videos will be deleted.

Physiotherapist participant flow through the study:
1. The physiotherapist receives the participant information sheet through the post.
2. The physiotherapist gets in touch and discusses the study with the research coordinator.
3. The research coordinator completes screening questions to check eligibility.
4. If eligible, physiotherapists consented onto the study and provided with online training

materials.
5. Physiotherapists attend a one-day workshop at the University of Salford.
6. Physiotherapists deliver 7 observed sessions of CMT to 2 participants with LBP.
7. Physiotherapists complete a reflective diary during this time.
8. At the end of the final session, physiotherapists will complete a Normalisation Process Theory Survey (NoMAD survey).
9. After delivering the sessions, the physiotherapists will be offered the chance to be interviewed.

Interviews:
Interviews will be completed by an experienced qualitative researcher and take place online via Microsoft Teams or via telephone. This has been designed to enable most participants to attend.

Bias:
This is a non-randomised, unblinded study aimed at developing a training course for CMT. As such researcher and participant bias is inherent. However, certain measures can be taken to mitigate this.
1. Screening of participants will be completed by the research coordinator, not the physiotherapists.
2. Outcome measures will be collected and analysed by research staff, not physiotherapists.
3. Analysis will be completed using a computer program and not by hand.
4. Interviews will be completed and analysed by an independent qualitative researcher, not by the direct research team.

Sample size:
There is no set sample size recommendation for a case series of this type. However, the sample size of 10 patient participants and 4 physiotherapist participants matches our previous training development study for knee osteoarthritis (IRAS ID: 298932).

Project timetable:
This project will take place over 10 months. In month 1 the researchers will finalise the first prototype physiotherapist training course for the CMT intervention. In months 2-3 the researchers will recruit and train four NHS physiotherapists. In months 4 and 5 they will observe the physiotherapists delivering the CMT intervention to 10 LBP patients. In month 6 they will interview the physiotherapists and patients. The researchers will use the observations and the qualitative feedback to refine the training package in months 7 and 8. In months 9 and 10 they will train the BELOW feasibility study physiotherapists (IRAS ID: 331773).

Intervention Type
Behavioural

Primary outcome(s)
1. Pain measured using the Numerical Rating of Pain Scale at baseline and 10 weeks
2. Disability measured using the Roland Morris Disability Questionnaire at baseline and 10 weeks
3. Catastrophising measured using the Pain Catastrophising Scale (PCS) at baseline and 10 weeks
4. Risk of chronic pain measured using the STarT Back Screening Tool at baseline and 10 weeks

Key secondary outcome(s))
There are no secondary outcome measures

Completion date

28/03/2025

Eligibility

Key inclusion criteria
1. Adults presenting with low back pain (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

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
15

Key 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 the 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 the mental capacity to make decisions, have dementia or are nearing the end of life

Date of first enrolment
01/07/2024

Date of final enrolment

01/11/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The University of Salford
Room PO34
The Brian Blatchford Building
Manchester
United Kingdom
M6 6PU

Study participating centre
Salford Royal Hospital
Stott Lane
Eccles
Salford
United Kingdom
M6 8HD

Sponsor information

Organisation
University of Salford

ROR
https://ror.org/01tmqtf75

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: NIHR206212

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study will be published as a supplement to the results publication

IPD sharing plan summary

Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet version 2	11/11/2025	11/11/2025	No	Yes
Protocol file		26/04/2024	19/06/2024	No	No