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Comparing two types of physiotherapy for chronic low back pain: a feasibility study

Submission date
02/09/2024

Recruitment status
Recruiting

Registration date
08/01/2025

Overall study status
Ongoing

Last Edited
10/04/2025

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
The current NHS treatment for people with low back pain (LBP) who are at high risk of long-term problematic symptoms involves a combination of physical exercises and psychological methods. However, the effectiveness of this combined approach is not very strong, partly because many patients prefer physical treatments and are hesitant to engage with the psychological aspects. Additionally, some musculoskeletal physiotherapists believe that current combined treatments lack sufficient "hands-on" guidance.
To address these issues, researchers have developed a new physiotherapy treatment for LBP called Cognitive Muscular Therapy (CMT). CMT integrates psychological techniques for pain management with training to improve postural control. Unlike traditional strength training, CMT focuses on improving postural control by reducing overactivity of the abdominal and low back muscles, using "hands-on" guidance during treatment. Small sensors are used to visualize muscle activity to facilitate this relearning process. In a small pilot study, 15 people with long-lasting back pain received 7 sessions of CMT and on average, their pain decreased by 77%.
This study aims to understand if CMT can be developed to form part of the NHS treatment for LBP. The study will compare CMT with best-practice NHS care to determine its potential clinical and cost-effectiveness.

Who can participate?
Adults with chronic low back pain lasting more than 3 months, scoring 4 or more on a pain scale, able to stand and walk for specified durations, and proficient in English.

What does the study involve?
The participants will be randomly assigned into two groups, treatment group 1 will receive CMT and treatment group 2 will receive psychologically informed physiotherapy. Both groups will receive seven weekly sessions, and outcomes will be measured at baseline, 14 weeks, and 8 months. The effectiveness of the treatments will be assessed using pain, function and quality of life questionnaires. Participants in each group will be interviewed about their experiences.

What are the possible benefits and risks of participating?
Participants may experience reduced pain and improved quality of life. Risks are minimal and include potential discomfort during physical assessments.

Where is the study run from?
The study is run from the University of Salford and three community or NHS sites in the Greater Manchester region (UK)

When is the study starting and how long is it expected to run for?
May 2024 to May 2026

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

Who is the main contact?
Dr Jennifer Parker, health-bepko@salford.ac.uk

Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
331773

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
NIHR206212, CPMS 57508

Study information

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

Acronym
BELOW

Study objectives
The study hypothesises that cognitive muscular therapy (CMT) will be a feasible and acceptable intervention for reducing chronic low back pain (LBP) and will show potential for clinical and cost-effectiveness compared to best practice NHS care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 26/06/2024, East of England - Cambridge East Research Ethics Committee (2 Redman Place, London, EC20 1JQ, UK; +44 (0)2071048181; cambridgeeast.rec@hra.nhs.uk), ref: 24/EE/0135

Study design
Randomized; Both; Design type: Treatment, Psychological & Behavioural, Physical, Rehabilitation, Qualitative

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)

Treatment

Participant information sheet
See study outputs table

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

Interventions
Participants will be randomly assigned to either the cognitive muscular therapy (CMT) group or the control group. Both groups will receive seven weekly sessions, and outcomes will be measured at baseline, 14 weeks, and 8 months. CMT integrates psychological techniques for pain management with training to improve postural control. Unlike traditional strength training, CMT focuses on improving postural control by reducing overactivity of the abdominal and low back muscles, using "hands-on" guidance during treatment. Small sensors are used to visualize muscle activity to facilitate this relearning process. The control intervention is a gold standard psychologically informed intervention for chronic pain, often delivered by physiotherapists in MSK physiotherapy spinal clinics or specialist pain services.

The participant receives an information sheet through the post or is prompted to contact the research team via text message. The participant gets in touch and discusses the study with the research coordinator who provides the participant information sheet as appropriate. The research coordinator completes screening questions to check eligibility.
If eligible, the research coordinator will send the consent form in the post.
Once the consent form has been returned to the trial coordinator, the participant will complete three types of questionnaires:
1. Back pain questionnaires: understand symptoms, daily life impact, and emotional aspects of back pain. There are
three of these types of questionnaires.
2. Healthcare access questionnaires: asks questions about healthcare service use, such as GP visits.
3. Demographic information: ask for information on age, ethnicity, socio-economic status, gender, disability, and religion.
The demographic questionnaire was checked by the PPIE group.

After the research coordinator receives the questionnaires, the participant is randomly assigned to treatment group 1 or treatment group 2. The participant will be provided an appointment schedule and attend seven face-to-face sessions if they are in treatment group 1 or five face-to-face sessions if they are in treatment group 2 (plus two self-directed online sessions). The sessions will take place every 1-2 weeks dependent on participant availability. After the final session the participant will be asked to complete the back pain questionnaires and healthcare access questionnaires at two more timepoints at 14 weeks and 8 months after randomisation. They will also be asked to complete a patient feedback questionnaire at 14 weeks.

Interviews will take place online via Microsoft Teams or telephone. This has been designed to enable most participants to attend. After receiving the treatment, 15 participants will be randomly selected from each group and offered the opportunity to be interviewed. All physiotherapists will be offered the opportunity to be interviewed. At this stage they will be provided with the Participant Information Sheet (physiotherapy interview) and given a minimum

of 24 hours to decide to take part. If the physiotherapist agrees to take part they will be sent a consent form by the trial coordinator. Once the consent form is returned to the trial coordinator, an interview date/time will be scheduled.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Current primary outcome measure as of 19/02/2025:
As this is a feasibility study the primary outcome is related to establishing the feasibility of a future large-scale clinical trial using the following criteria:
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-month 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%)

Previous primary outcome measure:
Pain is measured using the Numerical Rating Scale (NRS) at baseline, 14 weeks, and 8 months

Secondary outcome measures
Current secondary outcome measure as of 19/02/2025:
1. Pain is measured using the Numerical Rating Scale (NRS) at baseline, 14 weeks, and 8 months
2. Disability is measured using the Roland Morris Disability Questionnaire at baseline, 14 weeks, and 8 months
3. Pain catastrophizing is measured using the Pain Catastrophizing Scale at baseline, 14 weeks, and 8 months
4. Pain self-efficacy is measured using the Pain Self-Efficacy Questionnaire at baseline, 14 weeks, and 8 months
5. Quality of life is measured using the EQ-5D-5L at baseline, 14 weeks, and 8 months
6. Health resource utilisation is measured using a custom questionnaire at baseline, 14 weeks, and 8 months
7. Work productivity is measured using the Work Productivity and Activity Impairment (WPAI) questionnaire at baseline, 14 weeks, and 8 months

Previous secondary outcome measure:
1. Disability is measured using the Roland Morris Disability Questionnaire at baseline, 14 weeks, and 8 months
2. Pain catastrophizing is measured using the Pain Catastrophizing Scale at baseline, 14 weeks, and 8 months
3. Pain self-efficacy is measured using the Pain Self-Efficacy Questionnaire at baseline, 14 weeks, and 8 months

4. Quality of life is measured using the EQ-5D-5L at baseline, 14 weeks, and 8 months
5. Health resource utilisation is measured using a custom questionnaire at baseline, 14 weeks, and 8 months
6. Work productivity is measured using the Work Productivity and Activity Impairment (WPAI) questionnaire at baseline, 14 weeks, and 8 months

Overall study start date
01/05/2024

Completion date
01/05/2026

Eligibility

Key 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

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 90; UK Sample Size: 90

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
8. Unable to cancel or postpone other treatment for the condition, for example, physiotherapy, chiropractic or osteopathy

Date of first enrolment
01/12/2024

Date of final enrolment
31/10/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Salford
Room PO33
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Sponsor information

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Sponsor type
University/education

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ROR
https://ror.org/01tmqtf75

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The study results will be published in a high-impact peer-reviewed journal

Intention to publish date
01/05/2027

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 3	14/11/2024	07/01/2025	No	Yes

Protocol file	version 7	02/12/2024	07/01/2025	No	No
Participant information sheet	version 4	03/03/2025	10/04/2025	No	Yes
Protocol file	version 10	03/03/2025	10/04/2025	No	No