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A clinical study comparing two types of psychologically informed physiotherapy for people with long term non-specific neck pain

Submission date
27/03/2024

Recruitment status
No longer recruiting

Registration date
21/05/2024

Overall study status
Ongoing

Last Edited
10/04/2025

Condition category
Musculoskeletal Diseases

[X] 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
Chronic neck pain (CNP) is a common long-term condition resulting in pain, disability and reduced quality of life. It is the fourth leading musculoskeletal cause of disability in the UK, yet it receives less research attention compared to other common conditions like low back pain. Current management typically involves a combination of advice, pain relief, and physiotherapy. However, recent reviews suggest that while this approach may result in short-term improvements, long-term effects are limited, requiring more effective interventions.
Emerging research has highlighted increased levels of muscle tension and altered pain signalling mechanisms in CNP, leading to generalised pain sensitivity and altered pain tolerance. Emotional responses further contribute to pain experiences and affect participation in physical activity. Current mainstream physiotherapy approaches for CNP do not prioritise psychological aspects of the pain experience. However, early research suggests their significance, therefore these factors warrant further consideration.
Current physiotherapy mainly focuses on manual therapy (massage/ manipulation) and exercise (strength, stretches). This approach does not directly target muscle overactivity and psychological involvement in pain, possibly explaining limited success. Research has demonstrated that electromyography (EMG) biofeedback shows promise in reducing CNP. Therefore, interventions combining biofeedback and psychological elements may be important. A novel approach, Cognitive Muscular Therapy (CMT), combines psychologically informed practices with muscle biofeedback training to reduce muscle overactivity and alter pain-related beliefs. Initial application on five CNP patients demonstrated substantial improvement in pain and function with participants acknowledging newfound insights into their pain experiences. This study aims to conduct a feasibility study comparing CMT with psychologically informed physiotherapy (education, pacing, exercise and self-management) for CNP patients at risk of long-term disability.
In summary, CNP management requires new approaches that address its complex nature. CMT shows promise but further rigorous evaluation is required through comprehensive clinical trials. The aim of this study is to compare two new physiotherapy approaches for long-term neck pain. The two treatments both use psychological techniques and have either been shown to be effective for treating other chronic pain conditions or have some degree of proven benefit for

neck pain. The researchers aim to measure the change in pain and function after receiving each treatment.

Who can participate?
People aged 18- 100 years who have a 3-month history of neck pain and are able to stand for 10 minutes

What does the study involve?
Participants complete three types of questionnaires before they start the study, at 14 weeks after the start of the study and at 6 months after the start of the study.
1. Neck pain questionnaires: symptoms, daily life impact, and emotional aspects of neck pain.
2. Healthcare access questionnaires: about healthcare service use, such as GP visits.
3. Demographic information: information on age, ethnicity, socio-economic status, gender, disability, and religion.
After the questionnaires are completed, participants will be allocated randomly to one of two groups. Participants in treatment group 1 will receive the treatment over seven face-to-face physiotherapy sessions. The physiotherapist will first complete a physical assessment using muscle sensors. They will then explain how reacting and thinking differently about the condition has the potential to reduce pain. Participants will be taught how to consciously relax their neck, shoulder and stomach muscles and will learn how to maintain this relaxation in sitting, standing and during everyday movements. To help with the learning of new muscle patterns, the physiotherapist will use small sensors which visualise the patient's muscle patterns on a screen. Instructional videos are used to explain different parts of the treatment which are watched on a tablet or laptop computer. If patients don't have a tablet computer, they will be loaned one. If they are unable to use a tablet computer, they will be provided with written materials.
Participants in treatment group 2 will receive five face-to-face physiotherapy sessions and two online sessions. The physiotherapist will first assess the patient's movement and strength and then teach them gentle stretches for their neck, back, arms and legs. They will then be taught about pain and how lifestyle factors, such as sleep, diet and stress, may contribute to pain. Building on these ideas, they will be taught relaxation and mindfulness techniques and then provided with exercises designed to improve flexibility, strength, and balance. They will also be taught about the use of pacing to remain active and manage their pain and how to manage flare-ups. Again, instructional videos are used to explain different parts of the treatment which are watched on a tablet or laptop computer. If patients don't have a tablet computer, they will be loaned one. If they are unable to use a tablet computer, they will be provided with written materials.
After receiving the treatment, the researchers will select (through pain outcomes) a subset of 10 participants from each group, who together demonstrate a range of clinical responses. We will also select two participants who have withdrawn from the study. Each participant will be interviewed by an experienced independent qualitative researcher who did not take part in the intervention delivery to explore intervention acceptability. Interviews will be carried out over the phone or via video conference and will be guided by a topic guide.

What are the possible benefits and risks of participating?
Participants may benefit from improved pain, function and/or self-management of their condition. There is a slight risk of musculoskeletal pain in the form of delayed onset muscle soreness (DOMS). Patients will be advised about this by the physiotherapist who will explain the concept of delayed onset muscle soreness and how this should improve in 2-3 days and reduce following repeated completion of the exercise. Any discomfort that is prolonged will be noted as an adverse event and adaptations to the treatment will be agreed upon with the patient, for example reducing the weight or number of repetitions of exercise.

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

When is the study starting and how long is it expected to run for?
September 2022 to September 2025

Who is funding the study?
Chartered Society of Physiotherapy Charitable Trust (CSPCT) (UK)

Who is the main contact?
Mr Nathan Brookes, n.brookes1@salford.ac.uk

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
339104

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 339104, CPMS 61544

Study information

Scientific Title
COgnitive Muscular therapy versus psychologically informed Physiotherapy In non- specific chronic Neck pain: a feasibility study (COMPIN)

Acronym
COMPIN

Study objectives
This is a feasibility study so there will be no formal hypothesis testing. However, the study will provide data which will inform the design of a future trial which will test whether Cognitive Muscular Therapy reduces the pain associated with non-specific neck pain.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 14/05/2024, Riverside Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8150; riverside.rec@hra.nhs.uk), ref: 24/LO/0291

Study design
Multicentre feasibility study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
University/medical school/dental school, Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Non-specific neck pain

Interventions
Researchers have developed a new physiotherapy treatment (Cognitive Muscular Therapy) that may help people who do not experience benefit from exercise-based physiotherapy. This new treatment teaches patients how they can stop over-tightening the muscles in their neck during daily movements. It also teaches them to change the way they react to pain. Sensors are attached to the skin which enable patients to see their muscle patterns, both during movement and in response to pain. This muscle visualisation is supported with animated instructional videos to explain muscle and pain concepts. Researchers will compare this new physiotherapy

treatment with psychologically informed physiotherapy (PIP) which is a well-established management technique for patients with long-term pain.

Cognitive Muscular Therapy will be delivered by Nathan Brookes, a highly specialist physiotherapist who developed CMT as part of two National Institute of Health and Care Research (NIHR) grants.

The researchers plan to recruit a maximum of 4 band 7 (highly specialist) physiotherapists to deliver psychologically informed physiotherapy. Each physiotherapist who participates in the trial will receive training to deliver the control intervention via an online module followed by a face-to-face workshop. The physiotherapist will be expected to keep medical notes and to use an online platform to share experiences of the training and the intervention.

Once recruited the participants will be randomised using sealedenvelope.com into treatment group 1 and treatment group 2. Participants in treatment group 1 will receive CMT over seven face-to-face physiotherapy sessions. The physiotherapist will first complete a physical assessment using muscle sensors. They will then explain how reacting and thinking differently about the condition has the potential to reduce pain. The participants will be taught how to consciously relax their neck, shoulder and stomach muscles and will learn how to maintain this relaxation in sitting, standing and during everyday movements. To help with the learning of new muscle patterns, the physiotherapist will use small sensors which visualise the participant's muscle patterns on a screen. Instructional videos are used to explain different parts of the treatment which are watched on a tablet or laptop computer. If participants don’t have a tablet computer, they will be loaned one. If they are unable to use a tablet computer, they will be provided with written materials.

Participants in treatment group 2 will receive PIP over five face-to-face physiotherapy sessions and two online sessions. The physiotherapist will first assess the patient's movement and strength and then teach them gentle stretches for their neck, back, arms and legs. The participants will then be taught about pain and how lifestyle factors, such as sleep, diet and stress, may contribute to pain. Building on these ideas, they will be taught relaxation and mindfulness techniques and then provided with exercises designed to improve flexibility, strength, and balance. Participants will also be taught about the use of pacing to remain active and manage their pain and how to manage flare-ups. Again, instructional videos are used to explain different parts of the treatment which are watched on a tablet or laptop computer. If patients don’t have a tablet computer, they will be loaned one. If they are unable to use a tablet computer, they will be provided with written materials.

To assess the fidelity of the interventions the researchers will perform an audit of the clinical notes. This will involve reviewing a random selection of 10 sets of notes per site (40 in total). The researchers will use the treatment protocols as a checklist to assess treatment consistency across sites and physiotherapists.

Following the intervention, the researchers will purposively select (through pain outcomes) a subset of 10 participants from each group, who together demonstrate a range of clinical responses. The researchers will also select two participants who have withdrawn from the study. Each participant will be interviewed by an experienced independent qualitative researcher who did not take part in the intervention delivery to explore intervention acceptability. Interviews will be carried out over the phone or via video conference and will be guided by a topic guide.

Intervention Type
Behavioural

Primary outcome measure
As this is a feasibility study the primary outcome is related to establishing the feasibility of a future large-scale clinical trial:
1. The average number of participants screened, consented and randomised per month
2. Adherence and retention to the study determined by calculating the average number of sessions attended by participants
3. Optimal outcome measure questionnaires determined by calculating the percentage of participants providing 14-week and 6-month data
4. The acceptability of the intervention to patients determined via qualitative interviews at 14 weeks

The following stop-go criteria will be assessed prior to planning a future large-scale trial:
1. Recruitment: average participants recruited per month: red: <4 per month; amber: 4-6 per month; green >6 per month
2. Adherence/retention: participants attending >5 (of 7) clinical sessions: <60%; amber = 60-79%; green ≥80%
3. Outcomes: participants providing 14-week and 6-month data: red <60%; amber = 60-79%; green ≥80%. The appropriateness of outcomes is determined via qualitative evaluation
4. Acceptability to patients determined via the qualitative evaluation

Secondary outcome measures
1. Disability measured using the Neck Disability Index (NDI) at 14 weeks and 6 months
2. Pain measured using the Numerical rating scale of pain scale (0-10) at 14 weeks and 6 months
3. Kinesiophobia measured using the 13-item Tampa Scale of Kinesiophobia (TSK- 13) at 14 weeks and 6 months
4. Catastrophising measured using the Pain Catastrophising Scale (PCS) at 14 weeks and 6 months
5. Quality of life measured using the EQ-5D-5L (EuroQol) at 14 weeks and 6 months
6. Risk of chronic pain measured using the STarT MSK Screening Tool at 14 weeks and 6 months
7. Healthcare interactions measured using the Healthcare utilisation questionnaire at 14 weeks and 6 months

Overall study start date
01/09/2022

Completion date
01/09/2025

Eligibility

Key inclusion criteria
Patients:
1. Adults with CNP pain duration >3 months and considered at high risk of poor long-term outcome (identified with STarT MSK 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 (required to complete the intervention)
4. Speak and understand English sufficiently to read the information sheet and sign the consent form

Physiotherapist:
Band 7 physiotherapist (or above) with at least 3 years experience of managing patients with long-term pain.

Participant type(s)
Patient, Health professional

Age group
Adult

Lower age limit
18 Years

Upper age limit
100 Years

Sex
Both

Target number of participants
48

Key exclusion criteria
1. Diagnosis of inflammatory arthritis (e.g. rheumatoid arthritis, psoriatic arthritis)
2. Previous spinal surgery such as discectomy, anterior cervical discectomy and fusion, disc replacement, laminectomy and scoliosis fixation
3. Diagnosis of degenerative neurological disorders (e.g. multiple sclerosis/Parkinson's)
4. Vulnerable patients for example those who lack the mental capacity to make decisions, have dementia or are nearing the end of life
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. Unable to cancel or postpone other treatment that is being received for the condition, for example, physiotherapy, chiropractic or osteopathy

Date of first enrolment
03/06/2024

Date of final enrolment
30/04/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

University of Salford Frederick Road Campus
University of Salford
Allerton Building
Frederick Road Campus
Salford
United Kingdom
M6 6PU

Study participating centre
Northern Care Alliance NHS Foundation Trust
Stott Lane
Salford
Greater Manchester
Salford
United Kingdom
M6 8HD

Sponsor information

Organisation
University of Salford

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Sponsor type
University/education

Website
http://www.salford.ac.uk/

ROR
https://ror.org/01tmqtf75

Funder(s)

Funder type
Charity

Funder Name
Chartered Society of Physiotherapy Charitable Trust

Alternative Name(s)
CSP Charitable Trust, The Chartered Society of Physiotherapy Charitable Trust, The CSP Charitable Trust, Chartered Society of Physiotherapy, The Chartered Society of Physiotherapy, CSPCT

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The researchers will report the findings of the study through two papers, submitted to open access journals such as BMC Musculoskeletal Disorders. The first paper will report descriptive statistics on the clinical outcomes and on the feasibility of conducting a large-scale RCT. The second paper will describe the qualitative exploration of participant's experiences of the CMT and control interventions. These findings will be presented at the Chartered Society of Physiotherapy (CSP) Annual Conference. The researchers will also send each participant a written summary of the research findings on study completion and promote the findings by authoring an article in the CSP Frontline magazine.

Intention to publish date
01/07/2026

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?
Protocol file	version 5	17/04/2024	20/06/2024	No	No

Protocol file	version 6	16/10/2024	10/04/2025	No	No