ISRCTN81746901 https://doi.org/10.1186/ISRCTN81746901

Testing whether a new approach to exercise prescription for people with neck pain is acceptable and feasible to patients and physiotherapists in the NHS

Submission date
18/03/2024

Recruitment status
No longer recruiting

Registration date
20/03/2024

Overall study status
Ongoing

Last Edited
10/03/2025

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
Neck pain that has lasted for 3 months or longer (chronic neck pain) results in high levels of pain and limits daily function. Guidelines recommend physiotherapy-led exercise for people with chronic neck pain. Even though physiotherapists follow treatment guidelines, research shows current exercise programmes have limited short-term effects, poor engagement long-term, and provide insufficient long-term recovery. The EPIC-Neck exercise programme has been co-produced with people who experience neck pain and international neck pain experts to maximise short-term effects and increase long-term engagement and benefits. The aim of this small study is to see if it is possible, and acceptable, to deliver the EPIC-Neck exercise programme and whether a future bigger study can be conducted to test if the EPIC-Neck programme should be used in clinical practice, instead of the exercise currently prescribed.

Who can participate?
People aged 18 years or older with neck pain that does not involve nerves or bones and has lasted longer than 3 months

What does the study involve?
People with neck pain will be randomly allocated to one of two different groups.
1, EPIC-Neck exercise programme
2, Usual exercise care
People will receive exercise to help with their neck pain in BOTH groups. The difference is the people in the EPIC-Neck group will receive exercise using the approach and workbook developed by the researchers working with other people who have neck pain. The people in the usual exercise care group will get the exercise that is normally given in the NHS. All participants will be asked to complete a face-to-face baseline questionnaire and two follow-up postal questionnaires (3 and 6 months). Questionnaires will help understand the acceptability of the exercise programme and test data collection for future research. Participants in the EPIC-Neck group will also be interviewed at 4 months for their experiences of the exercise programme and

taking part in the study. Physiotherapy appointments in both groups will be audio-recorded to check the physiotherapist delivers the EPIC-Neck programme as intended or to describe usual NHS exercise care.

What are the possible benefits and risks of participating?
The information and exercises in either treatment group may help neck pain. It is hoped that the information from this study will help to further improve exercise for other people and decide how to complete a future bigger study. People who return the 3- and 6-month questionnaires will receive a £20 love2shop voucher as a thank you. People will need to attend an initial research appointment which would be additional to what would be required in normal care. People will have to find time to complete the 3- and 6-month questionnaires at home. Some people may find they experience some muscle soreness after completing the exercise. This is normal and the physiotherapist can give advice on how to manage this. Sometimes people are uncomfortable answering questions from the physiotherapist, researcher or questionnaire about their health, well-being, or relationships with others. You do not have to answer them if you do not want to. People in the EPIC-Neck group will have access to a paper and mobile application workbook. Access to the paper workbook will be forever. Unfortunately, access to the mobile application workbook will stop in January 2026.

Where is the study run from?
Birmingham Community Healthcare NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
July 2020 to July 2025

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

Who is the main contact?
Jonathan Price, Jonathan.price2@nhs.net

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
331102

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 59384, IRAS 331102

Study information

Scientific Title
Exercise Prescription Improved through Co-design for people with chronic non-specific Neck pain (EPIC-Neck): a randomized feasibility study with process evaluation

Acronym
EPIC-Neck

Study objectives
The EPIC-Neck programme is feasible and acceptable to deliver in NHS clinical practice and a full randomized controlled trial is warranted.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/02/2024, South Central - Oxford B Research Ethics Committee (Health Research Authority, 2 Redman Place, Stratford, E20 1JQ, UK; +44 (0)207 104 8178, +44 (0)207 104 8386, +44 (0)207 104 8019; oxfordb.rec@hra.nhs.uk), ref: 24/SC/0006

Study design
Randomized; Interventional; Design type: Treatment, Education or Self-Management, Psychological & Behavioural, Complex Intervention, Rehabilitation

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)

Treatment

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

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

Interventions
People with neck pain have been involved in designing this study, reviewing study documentation and co-producing the EPIC-Neck intervention.

People with neck pain will be recruited from NHS musculoskeletal physiotherapy departments using two methods:
1. Waiting list screening
2. Recruitment posters

Waiting list screening:
NHS physiotherapists at the local site will review current waiting lists and new referrals for people with neck pain. The NHS physiotherapists at the local site will call people with neck pain to introduce the study and send them a participant information leaflet and study invitation letter. The participant information leaflet and study invitation letter will be sent via post or email depending on preference. The participant information leaflet will be available via paper, . pdf or video. The video will be in English and Urdu.
NHS physiotherapists at the local site will conduct a follow-up call with people with neck pain to confirm their interest, perform a telephone screen and arrange a research assessment.

Recruitment posters:
Posters advertising the EPIC-Neck study will be in NHS musculoskeletal physiotherapy departments. Links to the participant information leaflet and contact details will be on the poster for the person with neck pain to know more about the study and express an interest in taking part. The contact details will be for the local site Principal Investigator (PI). The interested person will contact the PI at the local site to discuss the study, confirm their interest, undergo a telephone screen and arrange a research assessment. Follow-up calls will take place where the person with neck pain requires more time to read through any information before making a decision and to ask any follow-up questions.

Research assessment:
People with neck pain will attend a face-to-face research assessment at an NHS musculoskeletal physiotherapy department. The research assessment will be approximately 90 minutes and conducted by a local NHS physiotherapist trained in the study procedures and having undergone Good Clinical Practice training. The research assessment will include a brief history and physical examination to confirm they are suitable for the study.

Consent process:
Written informed consent will be received by the local Principal Investigator (PI), or other delegated person trained in Good Clinical Practice.
The PI will explain the study aims, interventions, potential benefits, and risks. They will explain that participation is voluntary and can withdraw at any time without giving reasons and without affecting further treatment. The PIL will be used to facilitate this process.

The person with neck pain will be given the opportunity to ask any questions before signing and dating the latest version of the Informed Consent Form (ICF). The PI or “delegate” will countersign the ICF.
The patient participant will be provided with a copy of their signed ICF either at the time or via post following the baseline visit. A letter will also be sent to the patient participants' GP informing them of their involvement in the study. Explicit consent will be obtained for appointments to be audio-recorded and for a member of the EPIC-Neck study team to observe any clinical appointments.

BCHC participants only - For those unable to read English, the PIL and ICF will be read aloud on their behalf, before signing. For those unable to speak, or understand spoken English, professional interpreters will be provided where possible, and the consent process will be audio-recorded. The patient participant will only be provided with a signed physical copy of the ICF and not the audio recording.

Baseline data collection:
Participants will then complete a questionnaire using pen and paper (approx. 40 mins).

Randomisation:
The local NHS physiotherapist trained in the study procedures will randomize the participants using a randomization website (https://www.sealedenvelope.com/help/redpill/). Participants will be randomly allocated to receive either the EPIC-Neck exercise programme or usual exercise care. Participants will be told which treatment they will get at the end of the research assessment. Participants will then have an initial physiotherapy appointment booked at a time and date of their choosing to start their treatment.

Treatment groups description:
The EPIC-Neck group is an approach to exercise for people with neck pain that is informed by current research and psychology and behaviour change strategies. It includes specific exercises for improving movement quality and building tolerance of the neck. It was co-produced with people who have neck pain and international experts in neck pain.
Usual exercise care is the current standard of practice in the NHS for which we want the EPIC-Neck programme to replace.
A key difference is that the physiotherapist in the EPIC-Neck group will conduct the history taking and examination using the EPIC-Neck principles, using psychological principles and behaviour change techniques. The EPIC-Neck group will be provided with a workbook (paper-based or mobile application), exercise sheets and a wall chart to support them with their exercise programme.
Participants may receive any other non-exercise-related treatment (e.g., postural advice, manual therapy, acupuncture) in either group.
To make sure enough data is obtained for the EPIC-Neck group, there is a 2:1 chance a participant will get the EPIC-Neck programme.

Treatment appointments:
Participants in both groups will attend an initial face-to-face physiotherapy appointment lasting 45-60 mins. These will be conducted in an NHS musculoskeletal physiotherapy department. Both groups will undergo a physiotherapy history and examination and be given an exercise programme. The exercise programme is to be completed at home.
The participant and physiotherapist will agree as to whether follow-up appointments are needed. There is no defined total amount of appointments in either group, and the decision is

made between the physiotherapist and the participant. It is estimated that participants in both groups will have 4-6 follow-up appointments, 20-30 mins each. In both groups, the decision to discharge from physiotherapy will be decided between the participant and the physiotherapist.

Data collection:
All participants will be asked to complete two follow-up postal questionnaires at 3 and 6 months. Questionnaires will be sent to the address participants provided when completing the informed consent procedures. Questionnaires will help understand the acceptability of the exercise programme and test data collection for future research.
Questionnaires will be returned to the EPIC-Neck study office at Birmingham Community Healthcare NHS Foundation Trust using a pre-paid envelope.

Participants in the EPIC-Neck group will also be interviewed at 4 months (n = 12-15) for their experiences of the exercise programme and taking part in the study. Interviews will be approximately 90 mins and conducted face-to-face, via telephone or through virtual meetings depending on the participant's preference. Face-to-face interviews will be conducted on Birmingham Community Healthcare NHS Foundation Trust premises in a private room. Interviews will be audio-recorded. Interviews will be conducted by the Chief Investigator, an employee of Birmingham Community Healthcare NHS Foundation Trust.

Physiotherapy appointments in both groups will be audio-recorded to check the physiotherapist delivers the EPIC-Neck programme as intended or to describe usual NHS exercise care. As some components of exercise cannot be checked via audio recording (e.g., accurate demonstration of exercise) the Chief Investigator will observe a sample of appointments. Audio recordings and observations will also be used to check for contamination i.e., important EPIC-Neck treatment components being found in the usual care group.

Physiotherapists delivering the EPIC-Neck programme will complete training before the study starts. A questionnaire will be used to understand the physiotherapist's confidence in delivering the intervention after the training and to get feedback. Physiotherapists delivering the EPIC-Neck programme will be interviewed at the end of the study for feedback on the training and the EPIC-Neck programme. Eight to ten physiotherapists delivering the EPIC-Neck programme will be interviewed. The training and interviews will be conducted by the Chief Investigator.

Physiotherapists (n = 8-15) delivering usual exercise care will be interviewed to further understand how, why, and what exercises are prescribed in usual exercise care in the NHS. Interviews will be conducted by the Chief Investigator.

Physiotherapist interviews will be approximately 90 mins and will take place using a mode that is preferred for the physiotherapist (phone or video). Informed consent will be taken at the time of the interview. Interviews will be audio-recorded.

Brief timetable:
Physiotherapist training is planned for March 2024
Participant recruitment is planned to start in March. Recruitment is anticipated to end in March 2025
Participant postal questionnaires will be sent at 3 and 6 months after randomization. The final 6-month questionnaire is anticipated to be in June 2025.
Participant interviews will take place 4 months after randomisation
Physiotherapy interviews will take place once the majority of treatment has been completed, approximately March 2025
Appointment audio recordings will be analysed throughout the study as they are received

The final analysis of questionnaire data will be completed in June 2025
Sharing of findings will be completed in July/August 2025

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The primary outcome aim of this study is to determine whether to continue to a large-scale definitive trial using pre-specified criteria. The researchers are primarily interested in whether
1. The EPIC-Neck intervention is delivered as intended (delivery fidelity), measured by EPIC-Neck appointment audio recordings and observations scored against a fidelity checklist at the study end
2. The EPIC-Neck programme and usual care exercise are sufficiently different (contamination), measured by usual exercise care appointment audio recordings and observations scored against a fidelity checklist and physiotherapist at the study end
3. The degree to which people delivering and receiving the EPIC-Neck programme consider it to be appropriate (acceptability), measured using an acceptability questionnaire at 3 and 6 months and EPIC-Neck participant interviews at 4 months, and interviews with physiotherapists delivering the EPIC-Neck programme after the majority of treatment has been completed.
4. The mean rate of recruitment per month (mean recruitment rate), measured using study monitoring data at treatment completion.

Secondary outcome measures
1. Safety of the intervention measured using an adverse event case report form during the study
2. The inclusivity of the recruitment procedures measured using the Participant Screening and Recruitment log at the study end
3. Usual exercise care defined using appointment audio recordings and interviews with physiotherapists at the study end
4. Completeness of the planned definitive trial outcome measures at 6-month follow-up

The planned definitive trial outcome measures collected as part of this feasibility study are:
1. Neck pain related disability measured using the Neck Disability Index at baseline, 3 and 6 months
2. Neck pain measured using the Visual analogue scale at baseline, 3 and 6 months
3. Health-related quality of life measured using the EQ-5D-5L at baseline, 3 and 6 months
4. Mental Well-being measured using the Hospital Anxiety and Depression at baseline, 3 and 6 months
5. Sleep quality measured using The sleep condition indicator at baseline, 3 and 6 months
6. Specific functional or activity limitations measured using the patient-specific functional scale at baseline, 3 and 6 months
7. Social and relationship impact measured using the relationship and self-worth domains of assessment of quality of life (AQoL 8D) at baseline, 3 and 6 months
8. Pain beliefs measured using the Single item survey of pain attitudes questionnaire at baseline, 3 and 6 months
9. Pain-related fear measured using the Tampa scale of kinesiophobia at baseline, 3 and 6 months
10. Pain self-efficacy measured using the pain self-efficacy questionnaire at baseline, 3 and 6 months

Overall study start date
14/07/2020

Completion date
31/07/2025

Eligibility

Key inclusion criteria
1. Chronic non-specific neck pain (>3 months)
2. Aged >=18 years old
3. Willing and able to give informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 61; UK Sample Size: 61

Key exclusion criteria
1. Received physiotherapy, chiropractic or osteopathic treatment (exercise, manual therapy, acupuncture etc) for neck pain in the past 6 months
2. Previous cervical spine surgery
3. Neck pain due to trauma (e.g., whiplash-associated disorders)
4. Neck pain due to a specific diagnosis (e.g., rheumatoid arthritis, osteoarthritis)
5. Presence or suspicion of neurological involvement (e.g., cervical radiculopathy or cervical myelopathy)
6. Presence or suspicion of serious pathology requiring onward referral
7. Headache as the primary complaint
8. Unable to understand or follow study procedures with support from family members or professional interpreters

Date of first enrolment
07/05/2024

Date of final enrolment
06/03/2025

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Birmingham Community Healthcare NHS Foundation Trust
3 Priestley Wharf
Holt Street
Birmingham Science Park, Aston
Birmingham
United Kingdom
B7 4BN

Sponsor information

Organisation
Birmingham Community Healthcare NHS Trust

Sponsor details
Unit 3, Priestley Wharf
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B7 4BN
+44 (0)7754748078
bchc.researchinnovation@nhs.net

Sponsor type
Hospital/treatment centre

Website
https://research.bhamcommunity.nhs.uk/

ROR
https://ror.org/04r10g051

Funder(s)

Funder type
Government

Funder Name

NIHR Academy; Grant Codes: NIHR302141

Results and Publications

Publication and dissemination plan

The EPIC-Neck study protocol will be published in an appropriate journal (Summer 2024). Outputs from the study will be disseminated via academic publication, conference presentation and BCHC social media around 1 year after the overall study end date.

The study participants and PPIE representatives will be informed of the findings via lay summary provided by post or email to the participants. Some PPIE representatives and participants may be involved in producing a video and/or attending conferences to disseminate the findings.

Intention to publish date

31/07/2026

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 article		08/03/2025	10/03/2025	Yes	No