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PARTICIPANT INFORMATION LEAFLET



Neck

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

For an electronic copy or video of this leaflet (English or Urdu) please scan the QR code below.

[INSERT QR CODES]



My name is Jon, and I am a physiotherapy researcher in Birmingham. I would like you to be involved in my PhD research aiming to improve exercise for people with neck pain. This information leaflet explains the research and what you would need to do if you were to take part.

Please take the time to read it carefully and contact me if you have any questions.

WHAT IS THE PURPOSE OF THE RESEARCH?



Exercise is the top recommended treatment for people with neck pain. However, even with exercise treatments, lots of people continue to have neck problems that affect their lives and they struggle to look after their neck pain long-term.

I think this is because

1. There is no consistent approach to exercise
2. People struggle to do their exercises
3. Exercise could be more effective
4. Researchers don't include people with neck pain when designing and developing exercises for research

To solve these problems, I have spent the past few years working with people who have neck pain to develop a new approach to neck exercise called EPIC-Neck. I hope that this approach will be used by researchers and healthcare professionals when treating people who have neck pain so that people engage with the treatment more and it is more effective.

Before healthcare professionals use the new approach to neck exercise, I am doing this small study to see if it is acceptable to use, get feedback to make it even better and test whether it is possible to do a bigger piece of research.

In this study, you will be put into one of two exercise treatment groups. Group 1 will have treatment for their neck pain using the EPIC-Neck programme. Group 2 will have treatment for their neck pain using exercise that is usually given in the NHS.

WHY HAVE I BEEN INVITED?

You have been invited because you have neck pain that does **not involve** nerves or bones and has lasted longer than 3 months. I am hoping to include 45 people in this study. After the study I will also interview 12-15 people who took part in the EPIC-Neck programme to understand their experience of the exercise and taking part in the study.



WHAT IF I HAVE ALREADY HAD TREATMENT FOR MY NECK PAIN?

If you have seen your GP and been given medication, advice, or a leaflet about neck pain you are still suitable to take part. You are still able to take part if the GP has already given you exercises to do.

You are not eligible to take part in this study if you have had treatment for your neck pain in the past 6 months from a physiotherapist, chiropractor, or osteopath. These treatments may include massage, hands on treatment, acupuncture, or an exercise programme for your neck.

Although you are not suitable for this study, you may still be able to have routine treatment in the NHS as per normal practice. Speak to your local physiotherapy department for more information.

ARE THERE ANY REASONS WHY I CAN'T TAKE PART?

There are a few reasons why you may not be able to take part in the study.

1. You are younger than 18
2. You have had physiotherapy, chiropractic or osteopathic treatment for neck pain in the past 6 months
3. You have previously had surgery on your neck
4. Your neck pain is due to a fall, trauma or car accident
5. You have a type of neck pain that has been given a specific diagnosis such as rheumatoid arthritis or osteoarthritis
6. Your neck pain involves the nerves in the neck or arm
7. You have a type of neck pain that is not suitable for physiotherapy and needs to be seen by a doctor
8. Your main problem is a headache
9. You are unable to understand or follow study procedures with support from family members or a professional interpreter

DO I HAVE TO TAKE PART?

No. It is up to you. If you decide you don't want to take part, it will not affect any treatment you receive from the NHS or any other healthcare provider.



WHAT WILL HAPPEN TO ME IF I DECIDE TO TAKE PART?

Research assessment

If you do decide to take part in the study, you will first attend a face-to-face research assessment with a physiotherapist researcher. **This is not part of your treatment.**

At this appointment we will first ask you to sign and date a consent form saying you are happy to take part.

We will then ask you some questions about your neck pain and perform a few neck movements to make sure you are suitable to take part. This should take approximately 15 minutes.

If you are not suitable for the research, you will not be able to take part in the study. However, you will still be able to have treatment which the physiotherapist will arrange for you.

If you are suitable for the research, you will then need to complete the research paperwork. This should take approximately 75 minutes. You will complete a questionnaire about your neck pain, general health, mental well-being, sleep, and relationships with other people.

A researcher will then enter your details into a computer and a computer program will decide which treatment you will get for your neck pain. There are two treatment groups:

- 1) EPIC-Neck programme
- 2) Usual exercise care

The decision as to which treatment you get is made by the computer. It is **random** and neither the researcher nor you can control which group you end up in. Unfortunately, you cannot choose. This is because it is important to ensure treatments are tested fairly. There is a 2:1 chance you will get the EPIC-Neck programme. You will be told which treatment you will get at the end of the research appointment.



Group 1 - EPIC-Neck programme treatment group

If you are allocated to the EPIC-Neck programme treatment group, the following will happen:

- You will need to attend an initial physiotherapy assessment for 45-60 mins.
- At this appointment, the physiotherapist will ask you some questions and do some movements with you to prescribe the EPIC-Neck exercise programme to complete at home.
- You will be provided with a workbook to help you with the EPIC-Neck exercise programme. There are paper and mobile application versions of the workbook depending on your preference.
- The physiotherapist will decide how many more appointments you may need. There is no limit on how many appointments you can have.
- Follow-up appointments will be 20-30 minutes long and will be used to help you with your exercise programme.
- Your physiotherapist can also give you other treatments for your neck pain alongside exercise if they think it will help.
- When the appointments are, and how long between appointments will be decided between you and your physiotherapist.
- All appointments will be one-to-one with a physiotherapist.
- All appointments will be audio-recorded. This is so I can check the EPIC-Neck approach to exercise was followed by the physiotherapist as it should be. I may also observe one of your appointments for the same reason.

Group 2 - Usual exercise care

If you are allocated to the usual exercise care treatment group, the following will happen:

- You will need to attend an initial physiotherapy assessment for 45-60 mins.
- At this appointment, the physiotherapist will give you exercises to do at home that are usually given in the NHS.
- The physiotherapist will decide how many more appointments you may need. There is no limit on how many appointments you can have.



- Follow-up appointments will be 20-30 minutes long and will be used to help you with your exercise programme.
- Your physiotherapist can also give you other treatments for your neck pain alongside exercise if they think it will help.
- When the appointments are, and how long between appointments will be decided between you and your physiotherapist.
- All appointments will be one-to-one with a physiotherapist.
- All appointments will be audio-recorded. This is so I can check what exercises have been given. I may also observe one of your appointments for the same reason.

What's the difference between the two groups?

You will receive exercise to help with your neck pain in BOTH groups. The difference is the people in the EPIC-Neck group will receive exercise using the approach and workbook I have developed through my PhD research and 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.

Follow-up research questionnaires

Regardless of which treatment group you are in, you will be asked to complete a questionnaire after 3 months and 6 months. The questionnaire will be like the one you completed at the initial research appointment. You will be sent the questionnaire in the post so you can complete it at home. You will be asked to return the questionnaire to the study team using a pre-paid envelope. This questionnaire should take around 40 minutes to complete.

Interviews

I will invite some people who received the EPIC-Neck treatment to take part in interviews to help me understand more about your experience of taking part in the study and exercise. I will invite people after they have been in the study for 4 months. The interview would be a face-to-face, telephone or virtual meeting with a



member of the study team to talk about your experiences. The interview will be a maximum of 90 minutes. Interviews will be digitally audio-recorded.

Only 12-15 people will be required for these interviews so you may not be required for this part. Taking part in the interviews is entirely optional. You will be asked if you are happy to be contacted about the interviews on the consent form you will sign before taking part in the study.

People who receive usual exercise care will not be invited to interviews.

WHAT IF I CHANGE MY MIND ABOUT TAKING PART?

You can change your mind about taking part at any time without giving a reason. Leaving the study will not affect any care you receive from the NHS. If you want to leave the study, speak to your physiotherapist, or contact me.

WHAT ARE THE BENEFITS OF TAKING PART?

The information and exercises you receive in either treatment group may help your neck pain. I hope that the information I get from this study helps me 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.

WHAT ARE THE DISADVANTAGES OF TAKING PART?

You will need to attend an initial research appointment which would be additional to what you would have to do if you didn't take part in the study. You would also have to find time to complete the 3- and 6-month questionnaires at home.

The physiotherapists will make sure the exercises are right for you. However, you may find that you experience some muscle soreness after completing the exercise. This is normal and the physiotherapist can give you 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.



If you are randomly selected to the EPIC-Neck group you will have access to a paper and mobile application workbook. You will have access to the paper workbook forever. Unfortunately, access to the mobile application workbook will stop in January 2026.

WILL MY GENERAL PRACTITIONER (GP) KNOW I AM TAKING PART IN THE STUDY?

Yes. With your permission, a letter will be sent to your GP letting them know you are taking part in the study.

WILL I BE REIMBURSED FOR TAKING PART?

We will reimburse you for your travel expenses when attending the research assessment, even if you don't take part in the study because you are not suitable. Mileage will be covered at 45p per mile.

Travel expenses will not be provided for the physiotherapy appointments.

People who return the 3- and 6-month questionnaires will receive a £20 love2shop voucher as a thank you. All postage costs for the questionnaires will be pre-paid.

WHAT WILL HAPPEN TO THE RESULTS OF THIS STUDY?

The plan is to share the results from the study in medical journals, conferences and online. You will not be identified in any report or publication. At the end of the study, you will be posted a summary of the study findings.

HOW HAVE PATIENTS AND THE PUBLIC BEEN INVOLVED IN THIS STUDY?

A diverse group of 20 people with neck pain have been involved in developing this study and the EPIC-Neck programme. The group helped develop this participant information leaflet and protocol for the study.

WHO IS ORGANISING AND FUNDING THE STUDY?

Birmingham Community Healthcare NHS Foundation Trusts are responsible for running the study in accordance with existing research legislation and guidelines. The study is funded by the National Institute for Health and Care Research.



WHO HAS REVIEWED THIS STUDY?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given a favourable ethical opinion by a research ethics committee.

WHAT IF THERE IS A PROBLEM?

Please speak to the research team initially if you are worried about the study (tel: 07927551262; email: bchc.epic-neck@nhs.net). If you wish to formally complain, you can contact the patient advice and liaison service (PALS) at Birmingham Community Healthcare NHS Foundation Trust using the details below:

Anne Pemberton (Patient Experience Manager) or Zarina Mansuri (Advise and liaison officer),

Birmingham Community Healthcare NHS Trust,

PALS,

Moseley Hall Hospital,

Alcester Road,

Moseley,

Birmingham,

B13 8JL

Tel: 0800 917 2855 or 0121 466 6502 (Anne), 0121 466 6507 (Zarina)

E-mail: contact.bchc@nhs.net

Birmingham Community Healthcare NHS Foundation Trust, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study.

NHS indemnity operates in respect of the clinical treatment which is provided.



HOW WILL WE USE INFORMATION ABOUT YOU?

Birmingham Community Healthcare NHS Foundation Trust is the sponsor for this study based in the United Kingdom.

We will need to use information from you for this research project.

This information will include your

- initials
- NHS number
- name
- gender
- date of birth
- ethnic background
- contact details (address, phone number, email address)
- bank details (if making a travel expenses claim)

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

More technical information can be found at <https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/template-wording-for-generic-information-document/>

Audio-recording data



Password-protected dictaphones will be used for all audio recordings. Once audio recordings have been transferred onto a secure Birmingham Community Healthcare NHS Foundation Trust laptop, they will be deleted from the dictaphones.

Audio recordings may be transcribed by a commercial company outside of the NHS that will have a confidentiality agreement in place with Birmingham Community Healthcare NHS Foundation Trust. The commercial company will remove and destroy all personal identifiable data from the transcripts and participants will be coded and referred to in study documents using a unique identification number.

EPIC-Neck app data

If you are randomised to the EPIC-Neck group and you choose to use the EPIC-Neck mobile app, the app will require some data about you.

This information will include your

- name
- email address

The app will also store any images you chose to upload to assist with your exercises. The app will keep your data secure on servers based in the UK and in keeping with GDPR guidelines. Your data will be kept secure using a username and password access and two factor authentication logins.

Circumstance where confidentiality maybe breached.

The researchers would need to break confidentiality and share identifiable information with external agencies if they think there is a risk of harm to you or others at any point in the study, or if disclosures of criminal activity are made. In this case, the researchers will follow the Trust's Safeguarding Policies and inform appropriate staff or agencies.

WHAT ARE YOUR CHOICES ABOUT HOW YOUR INFORMATION IS USED?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.



We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

WHERE CAN YOU FIND OUT MORE ABOUT HOW YOUR INFORMATION IS USED?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team
- by sending an email to bchc.epic-neck@nhs.net

WHERE CAN I GET MORE INFORMATION

Please contact me

Mr Jonathan Price

Tel: 07927551262

Email: bchc.epic-neck@nhs.net

Address: Research and Innovation, Birmingham Community Healthcare NHS Foundation Trust, Trust Headquarters, 3 Priestley Wharf, 20 Holt Street, Birmingham, B7 4BN.

Thank you for reading this information and considering taking part