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Low back pain and A&E: understanding need and improving care

Submission date
09/07/2021

Recruitment status
No longer recruiting

Registration date
05/08/2021

Overall study status
Completed

Last Edited
12/05/2025

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Low back pain is the leading cause of disability, both globally and in the UK. This condition occurs at a significant cost to those who experience it, to the healthcare system and the wider economy; it is therefore crucial to manage well. Clinical guidelines recommend that low back pain should, for most, be managed in primary care. However, in the UK, each month, more than 50,000 people attend the Emergency Department (A&E) for this condition. This is despite emergency care being clinically unnecessary for the vast majority. Both in the UK and internationally, demand for A&E is rising at an unsustainable rate and reducing this is a UK policy priority. This study aims to inform understanding about why people attend A&E for low back pain. The research questions to be addressed are: why, from the patients' perspective, do some people attend A&E for low back pain and how might this need be best or alternatively met?

Who can participate?
Adults (aged 18 years and over) with mental capacity, who have presented to A&E in the UK NHS for low back pain (all types/durations) within the previous 6 weeks

What does the study involve?
Participating in the study involves completing a 'one-off' individual interview with a member of the research team, about the participant's experience of attending A&E for low back pain. Most interviews will be held either over the phone or via a video call using Microsoft Teams. If COVID-19 rules allow and it is feasible, a face-to-face interview might be possible. Most interviews will take less than an hour.

What are the possible benefits and risks of participating?
As a token of thanks for taking part in the study, participants will be offered a gift card for £25 from either Amazon or Love2shop. Participants who travel to attend the interview in person will be able to claim for travel and parking expenses to help cover the costs of attending the interview. The information gained will help us to better understand what people who attend A&E for low back pain need and how they prefer healthcare to be provided. It is hoped that this information can be used to inform how future care is provided and may therefore benefit others in the future. As part of the interview, participants may be asked about their experience of healthcare for low back pain. Participants might also be asked about any other health conditions

and about the effect of their low back pain on family life. Some people might feel sensitive about talking about these issues.

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

When is the study starting and how long is it expected to run for?
April 2019 to April 2022

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

Who is the main contact?
Mrs Clare Ryan
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Contact information

Type(s)
Scientific

Contact name
Mrs Clare Ryan

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
295242

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number

CPMS 49486, IRAS 295242

Study information

Scientific Title
A qualitative interpretative study exploring why, from the patients' perspective, people attend A&E for low back pain and how this need might be best or alternatively met.

Study objectives
This study aims to inform understanding about why people attend A&E for low back pain. The research questions are, from the patients' perspective, why do some people attend A&E for low back pain and how might this need be best or alternatively met?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 09/06/2021, West of Scotland REC 3 (Research Ethics, Clinical Research and Development, Dykebar Hospital, Grahamston Road, Paisley PA2 7DE, UK; +44 (0)141 314 0211; WestofScotland.ResearchEthicsCommittee3@ggc.scot.nhs.uk), REC ref: 21/WS/0068

Study design
Observational; Design type: Qualitative

Primary study design
Observational

Study type(s)
Treatment

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

Interventions
This is a qualitative interview study. A qualitative method is required as little is currently known about the specific research questions being addressed.

The study will be informed by interpretative phenomenology, narrative inquiry and critical theory. This approach will put emphasis on exploring how participants present and shape their story; how they make sense of their situation and how their individual circumstances affect health-seeking expectations, decisions and experiences.

Sample: The sample will include adults (aged ≥18 years) who have recently presented to A&E for low back pain (within 6 weeks). Aligning with the population presenting to A&E (as identified in the literature and during site visits), all types and durations of low back pain will be included. Participants will be required to have the mental capacity to consent and to be able to communicate in English. Interpreters will be made available through Language Line, a telephone-based interpreting company used widely in NHS clinical practice. Exclusions include people in an

existing relationship with the researcher, including those currently being treated by the researcher (who is a Clinical Specialist Physiotherapist) and the researcher's family, close friends and members of the research team.

Sampling method: Purposive sampling will be used to help enable ethnic and sociodemographic diversity and key characteristics of patients who present to A&E with low back pain. Characteristics to be included are as follows.
1. Those who have previously sought help from usual care prior to attending A&E and those who did not.
2. Those advised to attend A&E by a health care professional (or representative such as 111 call handler) and those who were not.
3. Duration of low back pain (across the range of new to persistent and flare-ups).
4. Repeat A&E attenders and first-time attenders.
5. Those whose presentation was likely to have been clinically necessary and those whose presentation was likely to have been clinically unnecessary.
6. Those with leg pain and/or neurological symptoms.
7. Those with a musculoskeletal spinal cause for low back pain and those who do not.
These characteristics will be determined based on participants' interview accounts.

Sample size: Interviews will continue until no new themes have arisen in two interviews. Based on existing literature, it is anticipated that 40-50 participants will be interviewed to enable a rich detailed qualitative analysis, sufficient information to answer the research question and sufficient variation within the sample to enhance transferability.
Participant identification centres will be identified via the Clinical Research Network and purposively selected to include locations that are socioeconomically and ethnically diverse; urban, suburban and rural areas and sites known to offer different ways of managing people with low back pain or clinically unnecessary presentations. Recruitment is proposed from 4 participant identification centres, Salford, Portsmouth, Southampton and Bolton.

Recruitment:
At each participant identification centres, one/several recruitment strategies will be employed.
1. In A&E, A&E clinicians (any healthcare professional) and/or a delegated member of the research site's A&E research team will be asked to identify potential participants, briefly explain the nature of the study and provide potential participants with the study information pack (consisting of the study letter, the participant information sheet, the reply slip and the consent form). The study information will be available in paper and electronic formats. Patients will be able to elect to join the study by, (i) completing and returning the reply slip in the pre-paid envelope, (ii) emailing the researcher directly or (iii) providing verbal consent for their clinician /the delegated member of the research team to forward their contact details to the researcher. Clinicians will record in patients' notes if they have been asked about their interest in participating in the study. If participants agree for their clinician/the delegated member of the research team to forward their contact details to the researcher, confirmation of patients' verbal consent for this will be indicated in their email to the researcher on the participant reply slip.
2. In A&E, members of the usual clinical team and/or a delegated member of the research site's A&E research team may be asked to screen records for eligible participants and to send those identified the study information pack. The clinician/delegated member of the research team will record in a patient's notes if they have been sent the study information pack. Potential participants will be able to elect to join the study by (i) completing and returning the reply slip in the pre-paid envelope or (ii) emailing the researcher directly. Clinicians will record in patients' notes if they have been sent a study information pack.

Once a participant has expressed an interest in participating in the study and has provided their contact details, the researcher will contact them by telephone/email, provide further information about the study and arrange an interview date. If contact cannot be made by 'phone, the researcher will leave a message or send a text to advise who she is and what she is calling about. If after 4 attempts contact has not been made, the researcher will assume the person is no longer interested in participating and no further contact will be made.

Research sites will receive a donation of £5 per participant they recruit to the study. This donation will be to their staff refreshment fund and has been approved by the funder. The cost of this will be met by the researcher's fellowship.

For the interviews, written consent will be obtained from participants. The consent form will be included in the study information pack (provided to participants at the point of being approached) and, at the participant's request, the consent form will be emailed to them in an electronic format. For telephone/video interviews, participants will be asked to email or post the consent form back to the researcher (in a pre-paid envelope), before the interview. Electronic signatures will be accepted. For those participants completing the interview face-to-face, written consent will be gained immediately prior to the interview.

Data collection: Data will be collected using individual semi-structured interviews. This method was considered to provide the best opportunity for the researcher to develop rapport, for participants to each have the time and safe environment to tell their story and for the researcher to explore and probe participants' perspectives. Due to the COVID-19 pandemic, interviews will be mainly or exclusively undertaken using telephone or Microsoft Teams video technology. Each participant will complete one interview which is expected to last around 60 minutes. Interviews will be undertaken by the researcher Clare Ryan who has experience in this method from two previous qualitative interview studies and 24 years of experience as a Spinal Clinical Specialist Physiotherapist. The key questions to be explored are: why do people choose A&E for low back pain, what is required for care to meet patient needs and how might it be feasible to best or alternatively meet patients' needs. The proposed topic guide (informed by similar studies, patient and public involvement and engagement (PPIE) representatives and qualitative interview guidance (Ritchie et al 2014) is detailed in the Research Protocol on page 14. Interviews will be audio/video recorded via Open Broadcasting Software or Microsoft Teams, and transcribed verbatim. A professional transcriber will be used. Field notes will be used to capture the researcher's reflections of the interview, key emergent issues and how the data fits within/varies from existing theory and literature. Based on the extant literature, and discussion with patient representatives, telephone and video interviews appear likely to be acceptable to participants and a feasible method to achieve the aims of the study.

At the start of the data collection period, an internal pilot of 2-3 interviews will be completed with participants who meet the inclusion criteria. If the content of the topic guide or key wording of questions are not altered significantly, the findings from these interviews will be included in the main study.

Data analysis will be thematic, based on the framework approach using NVivo software. The Framework method comprises seven stages: (1) transcription; (2) familiarisation with the interview; (3) coding; (4) developing a working analytical framework; (5) applying the analytical framework; (6) charting data into the matrix; (7) interpreting the data (Gale et al 2013). The structured, transparent approach of Framework analysis will produce a matrix output where rows (cases), columns (codes) and 'cells' of summarised data provide a structure into which the data are reduced in order to enable analysis by case or by code. Initial analysis will be inductive. This involves identifying the key issues raised by participants, on their own terms, without

reference to previous theory or literature. Using deductive strategies, I will then compare the data collected to existing programme theory, relevant literature and behavioural theory to identify how it is similar/different. If appropriate, potential explanations for variation will be sought, informed by midrange theory. Analysis will be ongoing. To inform how data is interpreted, emergent findings will be discussed with the patient and public representatives at several time points. To ensure the process of developing the findings is transparent and rigorous, I will maintain an audit trail (detailing the process of analysis and examples of how the key findings were developed). Also, components of the analysis will be undertaken by at least two members of the research team and all findings will be discussed and interrogated by all members of the research team. Finally, I will proactively seek evidence that does not align with my findings.

Reflexivity: The researcher will work to ensure the findings represent the views of participants rather than her own perspective through keeping a reflexive diary; including a narrative approach to data collection and analysis; asking open questions; providing the opportunity and encouragement for participants to raise those issues that are important to them; discussing her approach and findings with PPIE representatives; and regularly discussing the issue of reflexivity in academic supervision and through having members of the research team with different professional backgrounds.

The research findings will be reported in line with the consolidated criteria for reporting qualitative research.

Intervention Type
Other

Primary outcome(s)
Why people choose to attend the emergency department for low back pain and how peoples' needs might be best or alternatively met, assessed using interviews at a single timepoint. Data analysis will be thematic, based on the framework approach using NVivo software.

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

Completion date
10/01/2022

Eligibility

Key inclusion criteria
1. Adults (aged ≥18 years) who have attended A&E for low back pain in the past 6 weeks
2. Mental capacity to consent
3. Able to communicate in English (interpreters will be made available)
4. All types and durations of low back pain will be included

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
48

Key exclusion criteria
1. People currently being treated by the researcher (who is a Clinical Specialist Physiotherapist)
2. Family or close friends of the researcher
3. Members of the research team

Date of first enrolment
09/08/2021

Date of final enrolment
10/01/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Queen Alexandra Hospital
Portsmouth Hospitals University National Health Service Trust
Southwick Hill Road
Cosham
Portsmouth
United Kingdom
PO6 3LY

Study participating centre
Southampton General Hospital
University Hospital Southampton NHS Foundation Trust
Tremona Road
Southampton
United Kingdom
SO16 6YD

Study participating centre
Salford Royal
Salford Royal NHS Foundation Trust
Stott Lane
Salford
United Kingdom
M6 8HD

Study participating centre
The Royal Bolton Hospital
Bolton NHS Foundation Trust
Minerva Road
Farnworth
Bolton
United Kingdom
BL4 0JR

Study participating centre
Royal Bournemouth Hospital
Royal Bournemouth And Christchurch Hospitals NHS Foundation Trust
Castle Lane East
Bournemouth
United Kingdom
BH7 7DW

Sponsor information

Organisation
University of Southampton

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
Government

Funder Name
NIHR Academy; Grant Codes: ICA-CDRF-2018-04-ST2-040

Results and Publications

Individual participant data (IPD) sharing plan

To help maintain participants' anonymity, data will not be shared in a publicly accessible data repository. The researchers aim to collect rich, detailed and sensitive data. It is unlikely to be possible to remove all details from which participants could be identified whilst also retaining the essence of the data.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		11/05/2025	12/05/2025	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	version 1.2	24/06/2021	05/08/2021	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 1.2	24/06/2021	05/08/2021	No	No