Research Protocol

Version 1.2 24 June 2021

**Full/long title of the study**: 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.

### Short study title: Low back pain and A&E: understanding need and improving care

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| IRAS number: | 295242 |
| University of Southampton ERGO II number | 62611  |
| Protocol version number and date | Version 1.2 24 June 2021 |
| Sponsor | University of Southampton |
| Funder | HEE/NIHE Clinical Doctoral Research Fellowship, Round 4  |
| Study Coordination Centre | School of Health Sciences, University of Southampton  |
| Chief Investigator (Lead researcher/PhD student) | Clare Ryan Clinical Doctoral Research Fellow  |
| Academic supervisor | Professor Lisa Roberts, University of Southampton |

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| **IRAS number:** | 295242 |
| **University of Southampton ERGO II number**  | 62611 |

#### Research reference numbers

#### HRA protocol compliance declaration

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the declaration of Helsinki, the sponsor’s SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the sponsor.

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

#### Signatures and key study contacts

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| --- |
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#### Study summary

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| Study 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. |
| Internal ref. No. (or short title) | Low back pain and A&E: understanding need and improving care.  |
| Study design | Qualitative  |
| Study participants | Inclusion criteria: Adults (aged ≥18 years) Attended A&E for low back pain (all types and durations) within the past 6 weeks.Mental capacity to consent. Able to communicate in English (interpreters will be made available).Exclusion criteria: Family and close friends of the researcher and members of the research team Patients known to have been treated by the researcher in the past year. |
| Planned size of sample  | 40-50 |
| Data collection method | One individual semi-structured interview with each participant.Most interviews will be undertaken over the phone or via video software such as Microsoft Teams. Interviews will be audio or video recorded using an audio-recorder, Open Broadcasting Software or Microsoft Teams. |
| Planned study period | Anticipated end date: December 2023 |
| Research questions | 1. Why, from the patients’ perspective, do some people attend A&E for low back pain? 2. From the patients’ perspective, how might the needs of people who attend A&E for low back pain be best or alternatively met? |

#### Role of study sponsor and funder

**Sponsor**: The University of Southampton is the study sponsor and is responsible for:

* Monitoring and auditing the conduct of the study.
* Providing insurance and indemnity to meet the potential legal liability for harm to participants arising from the design, conduct or management of the research.

Alongside this role the University of Southampton provides academic supervision for the PhD which is being undertaken by the Chief Investigator, Clare Ryan.

**Funder:** The NIHR and HEE are the funders of the research. The study is funded as part of a PhD and Clinical Doctoral Research Fellowship being completed by the Chief Investigator Clare Ryan. The NIHR oversee the development of the research and contributed to initial ideas about study design. The study will be adopted onto the NIHR portfolio and the findings may be disseminated at NIHR events. The NIHR have no involvement in the conduct or management of the research.

**Key words**: Emergency Department; Emergency Medical Services; Low Back Pain; Patients’ Perspective.

#### Study timeline

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| --- | --- |
| Date | Activity  |
| February - May 2021 | Ethics approvals |
| June - Nov 2021 | Data collection and preliminary analysis |
| Nov 2021- Jan 2022 | Subsequent analysis and paper and presentation development |
| July 2022 - Nov 2022 | Integration of findings from this study with findings from a linked subsequent study (for which ethical approval is unlikely to be required).  |
| April- December 2023 | Dissemination of integrated findings  |

#### 1 Abstract

Low back pain is the leading cause of disability, both globally and in the UK. This condition occurs at 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?

This qualitative study will be informed by interpretative phenomenology, narrative inquiry and critical theory. Data will be collected using semi-structured individual interviews either remotely (using telephone and video technology) or face-to-face. The sample will comprise 40-50 adults presenting to A&E in the UK National Health Service for low back pain (all types/durations). Using purposive sampling to achieve maximum variation, interviews will explore why, from the patients’ perspective, people attend A&E, what is required to meet patients’ needs and if and how this need could be best or alternatively met. Interviews will be audio/video recorded and transcribed verbatim. Analysis will be thematic, managed using a framework approach and will be both inductive and theoretically informed. The end product will be a detailed account of patients’ perceptions supported by direct quotes. Dissemination will be through academic conferences and publications, presentations and social media. The anticipated impact is to inform policy makers, commissioners and providers about why people attend A&E for low back pain and potentially feasible strategies to best or alternatively manage this population.

#### 2 Background

Defined as pain arising between the 12th rib and the buttock crease, low back pain is a symptom rather than a disease and is often accompanied by leg pain and/or neurological signs/symptoms (Dionne et al 2008;Hill et al 2011). Low back pain is common (1-year prevalence: 38%), especially in high-income countries, and is slightly more prevalent in women and people over 40 years (Hoy et al 2012). For approximately 80% of episodes, no specific spinal cause can be identified. However, sometimes this condition has a non-spinal cause and serious conditions account for up to 2% of cases (Henschke et al 2009). Symptoms can be severe and/or disabling, particularly initially and mixed recovery patterns occur over the first year (Kongsted et al 2016). Whilst for approximately a third of cases, symptoms improve markedly within 3 months, for many symptoms can be long-lasting. Two-thirds have ongoing, often low-level, symptoms at 12 months (Itz et al 2010), persistent disabling symptoms affect 5-20% of all presentations (Kongsted et al 2016) and recurrences are common (1-year incidence:33%) (Machado et al 2017). In summary, low back pain is common, rarely has a serious cause and is often persistent.

In 2010 and 2015 low back pain was identified as the leading global (and UK) cause of years lost to disability (DALYs) (Global Burden of Disease 2015). With prevalence and disability increasing with age, the burden of this condition is growing; between 1990 and 2010, DALYs increased from 58million-83million (Hoy et al 2014). Low back pain is also costly to the health system and society; 58% of people seek care when experiencing this condition and approximately 78% of total costs are attributed to reduced productivity (Dagenais et al 2008). Low back pain is therefore a significant burden to the individual, healthcare and wider society.

It is imperative that people with low back pain receive the most appropriate care in the most appropriate setting at the optimal time. There are, however, currently few recommendations in UK National Institute of Health and Care Excellence (NICE) guidelines (2016) or NHS England’s National Low Back and Radicular Pain Pathway (2017) about how to alternatively/best manage those who attend A&E for low back pain. Low back pain accounts for around 4% of A&E attendances (Edwards et al 2017); this translates to approximately 650,000 attendances in the UK in 2019, or over 50,000 attendances each month (NHS Digital 2020), with visits lasting on average between 1.9-4.4 hours (Friedman et al 2010; Lovegrove et al 2011). Emerging evidence suggests that those who attend A&E for low back pain, rather than primary care, are more likely to have a non-spinal or serious cause, severe and/or disabling pain, and/or a high-risk of poor prognosis (Ferreira et al 2019a;Oliveira et al 2020). This population can, therefore, be complex to triage and manage; however, the vast majority are unlikely to require emergency care. Using emergency care well is imperative because demand for this service is rising at an unsustainable rate. A&E attendances have increased by 17% since 2010-11 and continue to rise annually by 1-3% (NHS Digital 2020). Addressing rising demand, particularly low-acuity (or clinically unnecessary) demand is a UK policy priority. Sustainability and Transformation Plans now require urgent and primary care to be more responsive to peoples' needs and to provide people with the support to self-manage (NHS England 2014,2019). There is, therefore, an urgent need to understand why some people attend A&E for low back pain and to develop strategies to alternatively/best manage this complex population.

This research aligns with Health Education England’s priorities of improving out of hospital care; creating the safest, highest quality health and care services; and improving the efficiency and productivity of the health and care system. It also aligns with the three global/national strategic healthcare priorities: the management of low back pain (World Health Organisation (2010); reducing demand for emergency care (NHS England 2014,19); and understanding the best ways to deliver services to meet patients’ needs and improve outcomes (Chartered Society of Physiotherapy 2018). This project will produce knowledge to inform service delivery thereby providing benefits to patients and the NHS, through informing policymakers, commissioners and healthcare providers about why patients choose A&E for low back pain and potentially feasible strategies to manage this population differently. If 25% of patients who currently attend A&E for low back pain could be managed alternatively, for example, through more responsive primary care, in Portsmouth alone, this would release at least 150 hours of A&E time each month[[1]](#footnote-1).

#### 3 Literature review

There is now a comprehensive, in-depth and theoretically informed literature about why, at population level, people attend A&E. There is, however, only limited understanding of why people attend for low back pain.

Current understanding about why people attend A&E at population level (for all/any conditions) is largely summarised by O’Cathain et al’s (2019) 10 programme theories, detailed in Figure 1. Developed from a realist synthesis of 32 qualitative studies (and tested using relevant behavioural theory, 29 quantitative papers and public and patient engagement), this review explains why people attend urgent and emergency care when it is not clinically necessary. The authors further identify that multiple and variable drivers impact on care seeking. These theories appear to be trustworthy and relevant. They are well grounded in the extant literature and the review has no significant methodological flaws. Whilst the theories relate to people who attend urgent as well as emergency care, they are relevant to those who attend A&E specifically, as twenty-three of the qualitative studies used this population, each individual theory was informed by these studies and all but 1 theory (inability to get on with daily life) was supported by at least 7 qualitative studies using this population. The theories are relevant to the UK as they are based on 28 papers from high-income countries, include samples with people of all ages and a wide range of conditions; diverse healthcare systems (with variable access to primary care (due to availability and cost); and various co-payment systems for emergency department care).

Figure 1: O’Cathain et al’s (2019) programme theories

1. Uncertainty about symptoms causing anxiety
2. Heightened awareness of risk as a result of experience or knowledge of traumatic health events leading to anxiety
3. Fear of consequences when responsible for others
4. Inability to get on with daily life
5. Need for immediate pain relief
6. Waited long enough for things to improve
7. Stressful lives/ can’t cope
8. Following the advice of trusted others
9. Perceptions or prior experiences of services
10. Poor access to a GP

O’Cathain et al’s (2019) theories align with the key findings of 16 additional primary studies that have explored why people attended A&E at population level (undertaken subsequent to O’Cathain et al’s (2019) review or in populations not specifying low-acuity demand) and this helps to confirm their validity. (Shipman et al 1997;Claver and Storms 2010;Kangovi et al 2013;Kua et al 2016;Schmiedhofer et al 2016;Siek et al 2016;Henson et al 2016;Kraaijvanger et al 2016;Hudelson 2017;Lee et al 2018;May et al 2018;Van Dyk et al 2019;Goodridge and Stempien 2019;Minderhout et al 2019;Bornais et al 2020;McLaughlan et al 2020). Three additional drivers, detailed in Figure 2, were identified in the primary studies. These drivers were also evident in the studies included in O’Cathain et al’s (2019) review. The most significant methodological concern about the primary studies was the unchecked influence of the research teams. Few authors identified their philosophical position, assumptions or values; around half used structured topic guides together with short interviews, often timed around the A&E attendance, with little opportunity for participants to reflect deeply about their reasons for attending. The homogeneity of the findings and their alignment with methodologically stronger studies somewhat mitigates this concern.

Figure 2: Additional drivers of A&E attendance

* Perceived severity or urgency of symptoms
* Convenience: no appointment required, out of hours availability and a ‘one-stop shop’ (including assessment, investigations and management in a single visit)
* Limited access to usual specialist care either routinely or urgently

No full text papers were identified about why people attend A&E for musculoskeletal conditions or low back pain. However, one related UK based qualitative study (Stafford et al 2014) (reviewed by O’Cathain et al 2019) population identified 7 key motivations for attending urgent care for back pain, detailed in in Figure 3. These findings align with 7 of O’Cathain et al’s (2019) drivers (1,4,5,7,8,9 & 10) and importantly identify drivers specific to the back-pain population. The sample size was however small (n=11) and the drivers are those of people attending urgent care (rather than A&E) and for ‘simple’ rather than all back-pain presentations.

Figure 3: Stafford et al’s (2014) motivations for attending urgent care for back pain

1. GP access
2. Pain
3. Function
4. Something being different
5. Something being wrong
6. Desire for investigation
7. Third party influence
8. Repeat visits

We did not identify any empirical work that explored patients’ perceptions of what is required to meet the needs of people who attend A&E for low back pain, or whether or how these needs could be met without attending A&E.

In summary, the extant qualitative literature provides an overarching understanding of why people attend A&E at population level, when not clinically necessary, in high-income countries. Further work is now required to explore why people attend A&E for all types of low back pain including complex presentations, the relative importance of different drivers, and what is required to meet patients’ need. The findings from the population level literature provide a useful theoretical framework in which to undertake this. Further research is also required to explore strategies to meet peoples’ needs including those that might minimise use of A&E.

#### 4 Aim, research questions and objectives

**Aim**: This study aims to inform understanding about why people attend A&E for low back pain and potential strategies to best or alternatively meet need.

**The research questions** to be addressed are:

1. Why, from the patients’ perspective, do some people attend A&E for low back pain?
2. From the patients’ perspective, how might the needs of people who attend A&E for low back pain be best or alternatively met?

**The Objectives** are to:

1. Identify, from the patients’ perspective, why people attend A&E for low back pain, how people make sense of this decision and how their needs could be best or alternatively met.
2. To compare the findings to relevant extant literature and behavioural theory.
3. To identify the implications for policy makers, commissioners and providers.

#### 5 Methodology

An exploratory, interpretative (qualitative) approach will be adopted as little is currently known about the questions being addressed. My methodological approach draws on narrative inquiry, interpretative phenomenology, and critical theory. I will use narrative inquiry to access patients’ stories, interpretative phenomenology to understand the concepts and ideas stakeholders use to make sense of the issues being explored in the context of their individual circumstances. I will draw on critical theory to ensure that the patients’ perspective is not oppressed at the expense of service priorities and as a counterbalance to the need to engage policy makers and providers and to develop feasible interventions.

#### 6 Theoretical framework

In this study, I aim to explore the stated phenomena on their own terms (inductively) whist using programme and midrange theory to facilitate comprehensive enquiry. To enable inductive enquiry in interviews, participants will be encouraged to tell their story and open, non-leading, questions and probes will be used. O’Cathain et al’s (2019) programme theories (explaining why, at population level, people attend A&E) will lightly inform the issues discussed. The initial analytical framework will be developed inductively. I will then reconsider the data using O’Cathain et al’s (2019) programme theories. Subsequent sampling decisions, interview questions and data interpretation will be informed by the inductively generated findings, the programme theories and midrange theory selected in response to the data. In addition to the midrange theory used by O’Cathain et al (2019) (to test their programme theories), I will consider Turnbull et al’s (2019) model of urgent care sense-making and health-seeking, Leppin et al’s (2015) minimally disruptive medicine and Rosenstock et al’s (1988) Health Belief Model. Finally, I will identify how my findings align with, differ from and build on current theoretical understanding of the phenomena explored and will use midrange theory to identify why this might be.

#### 7 Method

##### 7.1 Sample

The sample will include adults (aged ≥18 years) who have attended A&E in the past 6 weeks for low back pain, who have capacity to consent and can communicate in English (interpreters will be made available). 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. 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 strategy

Purposive sampling will be used to sample for ethnic and sociodemographic diversity and key characteristics of patients who present to A&E with low back pain. These include:

* Those who have previously sought help from usual care prior to attending A&E and those who did not.
* Those advised to attend A&E by a health care professional (or representative such as 111 call handler) and those who were not.
* Duration of low back pain (across the range of new to persistent and flare ups).
* Repeat A&E attenders and first-time attenders.
* Attendances likely to be clinically necessary and those likely to be clinically unnecessary.
* Those with leg pain and/or neurological symptoms.
* Those for who the cause is perceived to be non-spinal pathology; serious spinal pathology; non-specific low back pain or specific spinal pathology.

These characteristics will be determined based on participants’ interview accounts.

##### Sample size

Interviews will continue until no new significant 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 (Guest et al 2006;Baker and Edwards 2012).

##### 7.2 Setting and recruitment

##### Research sites

Research sites will be identified to include sites with regional spinal expertise; those with ethnically and/or socioeconomically diverse populations; those in rural as well as urban locations and sites managing A&E attendances and/or low back pain with a range of condition specific or demand management strategies. Expressions of interest at Portsmouth, Southampton, Salford and Bolton have been be sought. If necessary, further sites may be identified, using Wessex Clinical Research Network where required, and details of this would be submitted as a non-substantial amendment for University of Southampton ERGO II/ IRAS/HRA ethical approval.

##### Identifying potentially interested participants

Several strategies will be used.

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 or 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 interested 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 two 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.

##### 7.3 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 (Ritchie et al 2014). Due to the Covid-19 pandemic, interviews will be undertaken using telephone or via Microsoft Teams. Interviews are 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. Based on the extant literature and discussion with PPIE representatives, telephone and video interviews appear likely to be acceptable to participants and a feasible method to achieve the study’s aims (Hammersley et al 2019;Krouwel et al 2019). The key questions to be explored are why people choose A&E for low back pain and how peoples’ needs might be best or alternatively met. The proposed topic guide (informed by similar studies, patient and public involvement and engagement (PPIE) representatives and qualitative interview guidance) is detailed in Figure 4 (Ritchie et al 2014).

**Figure 4: Interview topic guide**

##### Background/context

* Nature of day-to-day life [home/family situation; work; co-morbidities]
* Nature and history of low back pain
* Impact of back pain on day-to-day life
* Experience of self-managing and treatment for low back pain

##### Attending A&E this time

* Situation
* Drivers/reasons for accessing healthcare and A&E specifically
* Sense-making: choosing between different healthcare services
* What happened
* Experience of attending A&E
* Outcomes/impact of attending
* Influence of Covid-19
* Thoughts about future management
* Whether and how needs were met and/or might have been met differently

##### Other examples of attending urgent or emergency care for low back pain

* Situation
* Drivers/reasons for accessing healthcare and service selected
* Sense-making: choosing between different healthcare services
* Experience of attending urgent emergency care
* Outcomes/impact of attending
* Whether and how needs were met and/or might have been met differently

##### Best or alternative ways to meet needs

* Necessary elements of care to meet need
* Potential strategies to meet needs including those that might reduce A&E attendances

**Key messages participant wishes the researcher to take away**

To enable the researcher to describe the sample and determine representation of ethnic and sociodemographic diversity, at the end of the interview I will ask questions about age; gender; employment status and nature of work; ethnicity and postcode.

Participants who undertake a face-to-face interview will be reimbursed for their travel and parking expenses. The form to claim for these expenses will be provided to participants at the time of the interview. All participants will be offered a £25 gift card for Amazon or Love 2shop as a gesture of thanks for their time. This gift card will be emailed or sent to participants after the interview. The cost of gift cards will be met by the researcher’s fellowship and has been approved by the funder.

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.

##### 7.4 Data analysis

Data analysis will be thematic, based on the framework approach (Gale et al 2013) 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. Using deductive strategies, I will then compare the data collected to existing programme theory, and 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 patient and public representatives at several time-points. Maintaining an audit trail, double data-coding, seeking disconfirming evidence and maintaining reflexivity will ensure rigour (Ritchie et al 2014). The findings will be reported in line with the consolidated criteria for reporting qualitative research (Tong et al 2007).

##### 7.5 Reflexivity

I will work to ensure the findings represent the views of participants rather than the researcher 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 my 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.

##### Ethical issues

From the time of receiving the Participant Information Sheet, participants will have at least 24hrs to decide whether or not to take part in the study before being contacted by the researcher.

Some people may feel sensitive about being asked to talk about why they attended A&E or about being managed for low back pain. However, it is thought to be unlikely that patients will find the interview upsetting. The researcher has experience in completing qualitative research interviews from two previous studies and has undergone recent training in this method. Also, the researcher is an experienced Clinical Specialist Physiotherapist with 24 years of experience in interviewing patients about sensitive issues. At the start of the interview the importance of gaining patients’ perspectives will be emphasised to participants, questions will be asked respectfully, and care taken to avoid any inference of judgement. Participants will be reminded at the start of the interview that they do not need to answer any questions that they prefer not to. Patients’ responses will be listened to respectfully and probes used to ensure understanding of their perspective.

In the highly unlikely event that participants require support following their interview, they will be encouraged to contact their usual care provider (e.g., their GP or physiotherapist).

Only adult participants with mental capacity will be recruited. If it becomes apparent whilst arranging or during the interview that the participant lacks or no longer has capacity, or the researcher feels it is not in the participant’s best interest to continue, the researcher will end the interview.

In the unlikely event that it becomes evident from the patient interviews that malpractice may have occurred, this situation will be discussed between the Chief Investigator and the Lead Academic Supervisor, who is also a Consultant Physiotherapist. When indicated, the appropriate authorities/services will be contacted. This duty of care will be made clear to clinicians during the research site briefing and to patients in the participant information sheet and on the consent form.

If participants are dissatisfied with their healthcare (as distinct from having likely experienced malpractice), they will be advised to discuss this with the relevant healthcare provider or their local Patient Advice and Liaison Service.

All study files that include patient identifiable data, special category and/or audio/video recordings will be stored only on the secure University of Southampton server, Filestore. Filestore is a secure server dedicated to research data storage. Only the researcher and the lead academic supervisor has access to the file space allocated to the researcher for the data collected in this study. If it is necessary to share these documents with the second academic supervisor, this will be completed using either the University of Southampton’s SharePoint or Safesend systems.

Participants will be advised of their right to withdraw from the study at any time, without reason and without affecting their clinical care, in the participant information sheet. They will be reminded of this during the introduction to the interview.

#### 9. Peer review

This study has been reviewed by the NIHR Academy, the University of Southampton and the Research Design Service (South Central) as part of the process of securing a NIHR CDRF. It was most recently reviewed by the University of Southampton in February 2021 as part of a progression review with an independent internal examiner.

#### 10. Patient & public involvement and engagement

My approach to patient & public involvement and engagement (PPIE) has been guided by and costed in line with INVOLVE (2012) and NIHR (2014) PPI guidelines. It has been designed to ensure that the patient/public perspective is inherent to the design, conduct and reporting of this project. Also, that patients’ views are accurately reflected, using a non-judgemental, accessible approach and that the findings reach the widest possible audience.

Twenty-two PPIE representatives and two PPIE leads were involved in designing this study, including people with low back pain who attended physiotherapy or A&E department, members of the public and committee members (n=4) of the Southampton branch of 'BackCare' (a national charity dedicated to helping people with back pain). They helped to prioritise and shape the research question, and to refine the methods and the issues to be explored at interview. Examples of their impact include the need to offer different formats of interview such as video and telephone; to explore the role of 111 in peoples’ decision to attend A&E and that interviewing patients on the day of their A&E visit might not always be appropriate due to pain/distress/medication side-effects.

Since starting the study, two PPIE representatives have helped to develop patient facing materials (study letter; participant information sheet; consent form) and to further refine the interview topic guide. The researcher is now working with two PPIE leads to develop a PPIE group with who she can discuss issues that may arise in the interviews; the interpretation of the findings; how the findings shape the subsequent phase of the research; how the findings will be integrated; and how findings should be disseminated.

#### 11. Research Ethics Committee and other regulatory review & reports

Before the start of the study, a favourable opinion will be sought from a Research Ethics Committee (REC) and the Health Research Authority. Substantial amendments that require review by NHS REC will not be implemented until that review is in place and other mechanisms are in place to implement at site. All correspondence with the REC will be retained. It is the researcher’s responsibility to produce the annual reports as required. The researcher will notify the REC of the end of the study. An annual progress report will be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the study is declared ended. If the study is ended prematurely, the researcher will notify the REC, including the reasons for the premature termination. Within one year after the end of the study, the researcher will submit a final report with the results, including any publications/abstracts, to the REC.

##### Regulatory review & compliance

Before any site can enrol patients into the study, the researcher will ensure that appropriate approvals from participating organisations are in place and will comply with the relevant guidance.

For any amendment to the study, the researcher, in agreement with the sponsor, will submit information to the appropriate body in order for them to issue approval for the amendment. The researcher will work with research sites so they can put the necessary arrangements in place to implement the amendment to confirm their support for the study as [amended](http://www.hra.nhs.uk/resources/after-you-apply/amendments/).

##### Amendments

The decision as to whether an amendment will be discussed between the researcher and her academic supervisors. Where indicated the sponsor will be referred to. If a substantial amendment is required, the researcher will submit this to the REC for consideration. The lead NHS R&D office and all research sites will be advised of the amendment. Non substantial amendments will be communicated to the lead NHS R&D office and all research sites as required following discussion between the Chief Investigator and her academic supervisors. Where indicated the sponsor will be referred to. All amendments will be documented and dated in the study protocol and an amendment log kept.

##### Protocol compliance

Accidental protocol deviations will be documented on adverse event forms and reported to the researcher and Sponsor immediately. Deviations from the protocol which are found to frequently recur will be investigated by the Chief Investigator and the Lead Academic Supervisor. Appropriate action will be taken, and the Sponsor will be informed.

#### 12. Data protection and patient confidentiality

The researcher, Clare Ryan, is the Data Custodian (and Chief Investigator). All members of the Research Team (the researcher and in exceptional circumstances, her Academic Supervisors) and staff involved in identifying potential participants, will comply with the requirements of the Data Protection Act 1998 (GDPR 2016) with regards to the collection, storage, processing and disclosure of personal information and will uphold the act’s core principles.

##### Data protection at research sites

Only members of the usual clinical team will identify potential participants or have access to patient records to determine patients’ eligibility for the study.

For most potential participants, clinical staff/delegated members of the research team at research sites will not be required to collect, store or transfer or disclose any patient details as patients will contact the researcher directly.

Where clinical staff ask patients, within their usual treatment consultation, if they are happy for their contact details to be passed to the researcher to contact them, these details will be transferred using a secure NHS email system such as NHS.net. Patients will be asked to verbally confirm their consent to the transfer of this information and confirmation of this will be indicated on the participant reply slip or the email sent by the clinician to the researcher.

##### Data protection by the Research Team

##### Maintaining patient confidentiality and/or anonymity

If potentially interested participants contact the researcher by email, the researcher will reply using the University of Southampton’s email system, with the encryption function enabled. All subsequent emails sent or received within this thread will be encrypted.

Participants will only be identifiable to the research team. Their data will be pseudonymised to ensure confidentiality is maintained in the analysis and any subsequent reporting of the data. To help preserve the anonymity of participants, following each interview, participants will be allocated a participant number. The participant number will be used to identify the interview recording and transcript. If the participants complete the questions about their sociodemographic details and comorbidities as a survey, this will use their participant number. Data identified by the participant’s name or participant number will each be stored in separate file locations on Filestore. Only the direct research team (the researcher, and in exceptional circumstances her academic supervisors) will have access to the code that links these identifiers.

Care will be taken to mitigate for the negligible risk that any participant could be identified from data made publicly accessible e.g., in published papers or at conferences/other dissemination events. This will include being mindful of the potentially identifying characteristics in verbatim quotes, in published demographic or clinical metadata. To help maintain participants’ anonymity, data will not be shared in a publicly accessible data repository. We aim to collected 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.

In the unlikely event that the information provided at interview results in a concern about malpractice, the issue will be discussed with the lead academic supervisor who is a Consultant Physiotherapist as well as a Clinical Professor. If indicated, relevant clinical and regulatory authorities will be contacted. This duty of care will be made clear to clinicians during the research site briefing and to participants in the participant information sheet and on the consent form.

##### Data storage

Where paper copies of consent forms etc are used, these will be scanned and saved electronically on the University of Southampton’s secure server Filestore. Paper copies will be disposed of in dedicated confidential waste facilities (e.g., at my clinical work site, Solent NHS Trust or at the University of Southampton) or shredded using a crosscut shredder. Interview recordings will also be uploaded onto the University of Southampton’s Filestore and then deleted from the recording device. Filestore is backed up every 30 minutes, and this is retained for 30 days. A Sync to replica is completed once a day (at 20:00hrs) and this is retained for 3 months.

A copy of transcripts, fieldnotes and audio recordings will also be stored on my personal password protected computer. This data will be backed up weekly onto a password protected, encrypted external hard drive. Video recordings will be stored only on the University of Southampton’s Filestore.

On completing data collection, data will be archived in the University of Southampton’s data repository ‘eprints’. Patient identifiable data, including consent forms, data sheets and the list linking participants’ names and participant numbers will not be available to anyone outside the immediate research team (or appropriate regulatory authorities). Personal data will be destroyed at the end of the study. In line with the University of Southampton’s data management policy, all significant research data will be retained for at least 10 years from the point of collection or publication of findings (whichever is later). After this time, unless this data has been controversial or is still in active use, it will be destroyed. The process for destroying data is managed by eprints in collaboration with the researcher. Significant data is likely to include interview transcripts and the sociodemographic data collected to describe the sample.

In line with NIHR requirements, where possible, research findings will be published in an open access format. Aligning with NIHR guidance this will be using a Creative Commons Attribution 4.0 Unported (CC BY 4.0) license, which permits others to copy, redistribute, remix, transform and build upon this work for any purpose, provided the original work is properly cited.

##### Indemnity

The University of Southampton’s insurance will cover indemnity to meet the legal liability to the sponsor of harm to participants arising from the design, management or conduct of the research. As the risk of harm to participants from participating in interviews is low, no arrangement for payment of compensation in the event of harm to the research participants where no legal liability arises has been made.

##### Access to the final study dataset

Only the Research Team (the Chief Investigator and her Academic Supervisors) will have access to the full data set. To help preserve participant confidentiality, research sites will not be able to request access to their individual data set. The final dataset may be used in teaching or future research overseen by the researcher, Clare Ryan. Participants’ explicit consent for this will be sought on the consent form.

To help maintain participants’ anonymity, data will not be shared in a publicly accessible data repository. We aim to collected 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.

#### 13. Dissemination policy

The University of Southampton owns the data arising from the study. On completion of the study, the data will be analysed, and a final study report prepared. The full report will be available to access from PURE, the University of Southampton’s repository, following the completion of the PhD. It is anticipated that this will be in late 2023. This report will be accessible to the public but may be subject to a period of embargo to enable publication of the findings in peer reviewed journals. It is intended that the findings will also be disseminated via academic papers and presentations and local presentations to research sites, patient groups or clinical groups. The funder will be acknowledged in any publications and presentations.

At the time of completing the consent form, participants will be asked if they would like to be sent a copy of the study results on completion of the study. Following the interview, participants will be emailed or sent a thank you gift card. At this time they will be reminded how to contact the researcher to obtain a copy of the results if they initially decline but subsequently change their mind.

**References**

Baker S and Edwards R (2012) How many qualitative interviews is enough? National Centre for Research Methods review paper. Available from: http://eprints.brighton.ac.uk/11632/ [Accessed 01/10/2020].

Bornais J, Crawley J and El-Masri M (2020) One stop: examining the reasons patients use

the emergency department for nonurgent care and the barriers they face. Journal of Emergency Nursing 46(2):163-70. https://doi.org/10.1016/j.jen.2019.08.007

Chartered Society of Physiotherapy (2018) James Lind Alliance Physiotherapy Priority Setting Partnership. Available from: <http://www.csp.org.uk/professional-union/research/james-lind-alliance-physiotherapy-priority-setting-partnership>. [Accessed on 08/04/20]

Claver M and Storms L (2010) The revolving door: high ER use among older Veterans Qualitative Health Research 20(3):365–374. https://doi.org/10.1177/1049732309350682

Dagenais S, Caro J and Halderman S (2008) A systematic review of low back pain cost of illness studies in the United States and internationally. Spine Journal 8: 8-20. https://doi.org/10.1016/j.spinee.2007.10.005

Dionne C, Dunn K, Croft P, Nachemson A, Buchbinder R, Walker B, Wyatt M, Cassidy D, Rossignol M, Leboeuf-Yde C, Hartvigsen J, Leino-Arjas P, Latza U, Reis S, Gil del Real M, Kovacs F, Öberg B, Cedraschi C, Bouter L, Koes B, Picavet S, van Tulder M, Burton K, Foster N, Macfarlane G, Thomas E, Underwood M, Waddell G, Shekelle P, Volinn E and Von Korff M (2008) A Consensus Approach Toward the Standardization of Back Pain Definitions for Use in Prevalence Studies. Spine 33(1):95–103. https://doi.org/10.1097/brs.0b013e31815e7f94

Edwards J, Hayden J, Ashbridge M, Gregoire B and Magee K (2017) Prevalence of low back pain in emergency settings: a systematic review and meta-analysis. BMC Musculoskeletal Disorders 18:143. https://doi.org/10.1186/s12891-017-1511-7

Ferreira G, Machado G, Abdel Shaheed C, Lin C, Needs C, Edwards J, Facer R, Rogan E, Richards B, Maher C (2019) Management of low back pain in Australian emergency departments British Medical Journal Quality and Safety 28:826-834. https://doi.org/10.1136/bmjqs-2019-009383

Friedman B, Chilstron M, Bijur P, and Gallagher J (2010) Diagnostic testing and treatment of low back pain in United States emergency departments. A national perspective. Spine 35(24):E1406-1411

Gale NK, Heath G, Cameron E, Rashid S and Rewood S (2013). Using the framework method for the analysis of qualitative data in multi-disciplinary health research. BMC Medical Research Methodology 13:117. <https://doi.org/10.1186/1471-2288-13-117>

General Data Protection Regulation (2016) Available from: <https://gdpr-info.eu/> [Accessed 7 July 2020]

Global Burden of Disease (2015) Disease and Injury Incidence and Prevalence Collaborators. Global, regional, and national incidence, prevalence, and years lived with disability for 310 diseases and injuries, 1990–2015: a systematic analysis for the Global Burden of Disease Study 2015. The Lancet 388:1545–602. [https://doi.org/10.1016/s0140-6736(16)31678-6](https://doi.org/10.1016/s0140-6736%2816%2931678-6)

Goodridge D and Stempien J (2019) Understanding why older adults choose to seek non-urgent care in the emergency department: the patient's perspective. Canadian Journal of Emergency Medicine 21(2):243-248. https://doi.org/10.1017/cem.2018.378

Guest G, Bunce A and Johnson L (2006) How many interviews are enough? An experiment with data saturation and variability. Field Methods 18:59-82. <https://doi.org/10.1177/1525822x05279903>

Hammersley, V, Donaghy E, Parker R, McNeilly H, Atherton H, Bikker A, Campbell J and McKinstry B (2019) Comparing the content and quality of video, telephone, and face-to-face consultations: a non-randomised, quasi-experimental, exploratory study in UK primary care. British Journal of General Practice September 2019: e595-604. https://doi.org/10.3399/bjgp19X704573

Henschke N, Maher C, Refshauge K, Robert D. Herbert R, Cumming R, Bleasel J, York J, Das A and McAuley J (2009) Prevalence of and screening for serious spinal pathology in patients presenting to primary care settings with acute low back pain. Arthritis & Rheumatism 60(10):3072–3080. https://doi.org/10.1002/art.24853

Henson L, Higginson I, Daveson B, Ellis-Smith C, Koffman J, Morgan M, Gao W, on behalf of BuildCARE (2016) ‘I’ll be in a safe place’: a qualitative study of the decisions taken by people with advanced cancer to seek emergency department care. British Medical Journal Open 6:e012134. https://doi.org/10.1136/bmjopen-2016-012134

Hill J, Konstantinou K, Egbewale B, Dunn K, Lewis M, van der Windt D (2011) Clinical outcomes among low back pain consulters with referred leg pain in primary care. Spine 36(25):2168-75. DOI: 10.1097/BRS.0b013e31820712bb. Avaiable from: <https://pubmed.ncbi.nlm.nih.gov/21358478/>

Hoy D, Bain C, Williams G, March L, Brooks P, Blyth F, Woolf A, Vos T and Buchbinder R (2012) A systematic review of the global prevalence of low back pain. Arthritis & Rheumatism 64(6):2028–2037. <https://doi.org/10.1002/art.34347>

Hoy D, March L, Brooks P, Blyth F, Woolf A, Bain C, Williams G, Smith E, Vod T, Barendregt J, Murray C, Burstein R, Buchbinder R (2014) The global burden of low back pain: estimates from the Global Burden of Disease 2010 study. Annals of the Rheumatic Diseases 73(6):968-74. https://doi.org/10.1136/annrheumdis-2013-204428

Hudelson C (2017) The use of patient narratives to understand high emergency department utilization among medicaid patients at a safety-net hospital: a quality improvement project. Doctoral dissertation, Harvard Medical School. Available from: http://nrs.harvard.edu/urn-3:HUL.InstRepos:40620635 [Accessed 1 April 2020]

INVOLVE (2012) Briefing notes for researchers: involving the public in NHS, public health and social care research. INVOLVE, Eastleigh. Available from: <http://www.invo.org.uk/wp-content/uploads/2012/04/INVOLVEBriefingNotesApr2012.pdf> [Accessed 1 April 2020]

Itz C, Geurts M, Kleef M and Nelemans P (2013) Clinical course of non-specific low back pain - A systematic review of prospective cohort studies set in primary care. European Journal of Pain 17:5-15. https://doi.org/10.1002/j.1532-2149.2012.00170.x

Kangovi S, Barg F, Carter T, Long J, Shannon R and Grande D (2013) Understanding why patients of low socioeconomic status prefer hospitals over ambulatory care. Health Affairs 32(7):1196–1203. <https://doi.org/10.1377/hlthaff.2012.0825>

Kongsted A, Kent P, Axen I, Downie A and Dunn K (2016) What have we learned from ten years of trajectory research in low back pain? BMC Musculoskeletal Disorders 17:220. https://doi.org/10.1186/s12891-016-1071-2

Kraaijvanger N, Rijpsma D, Willink L, Lucassen P, van Leeuwen H and Edwards M (2016) Why patients self‐refer to the Emergency Department: a qualitative interview study. Journal of Evaluation in Clinical Practice 23(3):593-598. https://doi.org/10.1111/jep.12680

Krouwel M, Jolly K and Greenfield S (2019) Comparing Skype (video calling) and in person qualitative interview modes in a study of people with irritable bowel syndrome – an exploratory comparative analysis. Medical Research Methodology 19:219. https://doi.org/10.1186/s12874-019-0867-9

Kua P, Wu L, Ong E, Lim Z, Luther J, Yiew L, Hui X, Thia M and Sung S (2016) Understanding decisions leading to nonurgent visits to the paediatric emergency department: caregivers’ perspectives. Singapore Medical Journal 57(6):314-319. https://doi.org/10.11622/smedj.2016023

Lee J, Lempp H, Srivastava V and Barley E (2018) Reasons for Accident and Emergency department attendance by people with chronic obstructive pulmonary disease or heart failure: recipients and providers’ perspectives. An exploratory study. British Medical Journal Open Respiratory Research 5:e000244. <https://doi.org/10.1136/bmjresp-2017-000244>

Leppin A, Montori V and Gionfriddo M (2015) Minimally disruptive medicine: A pragmatically comprehensive model for delivering care to patients with multiple chronic conditions. Healthcare 3:50-63. <https://doi.org/10.3390/healthcare3010050>

Lovegrove M, Jelinek G, Gibson N and Jacobs I (2011) Analysis of 22,655 presentations with back pain to Perth emergency departments over 5 years. International Journal of Emergency Medicine 4(59). https://doi:10.1186/1865-1380-4-59

Machado G, Maher C, Ferreira P, Latimer J, Koes B, Steffens D and Ferreira M (2017) Can recurrence after an acute episode of low back pain be predicted? Physical Therapy 97(9):889-895. <https://doi.org/10.1093/ptj/pzx067>

McLauchlan K, Ramlakhan S and Irving A (2020) Why do parents present to the Paediatric Emergency Department with conditions suitable for management in less acute settings? A qualitative study. European Journal of Emergency Medicine 27:40–45. https://doi.org/10.1097/MEJ.0000000000000611

May M, Brousseau D, Nelson D, Flynn K, Wolf M, Lepley B, Morrison A (2018) Why parents seek care for acute illness in the clinic or the ed: the role of health literacy. Academic Pediatrics 18(3):289-96. [https://dx.doi.org/10.1016%2Fj.acap.2017.06.010](https://dx.doi.org/10.1016/j.acap.2017.06.010)

Medical Research Council (2003) Personal information in medical research. Available from: <https://mrc.ukri.org/documents/pdf/personal-information-in-medical-research/> [Accessed 7 July 2020]

Minderhout R, Venema P, Vos H, Kant J, Bruijnzeels M, Numans M (2019) Understanding people who self-referred in an emergency department with primary care problems during office hours: a qualitative interview study at a Daytime General Practice Cooperative in two hospitals in The Hague, The Netherlands. British Medical Journal Open 9:e029853 https://doi.org/10.1136/bmjopen-2019-029853

Mishel M, Braden C (1987) Uncertainty. A mediator between support and adjustment. West J Nurse Researcher 9:43–57. <https://doi.org/10.1177/019394598700900106>

National Health Service Digital (2018) Code of practice on confidential information. Available from: <https://digital.nhs.uk/data-and-information/looking-after-information/data-security-and-information-governance/codes-of-practice-for-handling-information-in-health-and-care/code-of-practice-on-confidential-information> [Accessed July 7 2020]

National Health Service Digital (2020) Hospital Accident and Emergency Activity. Hospital Accident and Emergency Activity 2019-2020. Available from: <https://digital.nhs.uk/data-and-information/publications/statistical/hospital-accident--emergency-activity/2019-20> [Accessed 1 October 2020].

National Health Service England (2014) National Health Service England (2014) Five Year Forward View. Available from: <https://www.england.nhs.uk/wp-content/uploads/2014/10/5yfv-web.pdf>. [Accessed 08/04/2020]

National Health Service England (2017) National Low Back and Radicular Pain Pathway 2017. Available from: https://www.versusarthritis.org/media/3077/national-low-back-and-radicular-pain-pathway-2017.pdf [Accessed 08/04/2020]

National Health Service England (2019) NHS Long Term Plan. Available from: [www.longtermplan.nhs.uk](http://www.longtermplan.nhs.uk). [Accessed: 1 October 2020]

National Health Service England (2020) Transformation of urgent and emergency care: models of care and measurement. Available from: <https://www.england.nhs.uk/publication/transformation-of-urgent-and-emergency-care-models-of-care-and-measurement/> [Accessed 15 December 2020]

National Institute for Health and Care Excellence (2016) Low back pain and sciatica in over 16s: assessment and management (NG59). Available from: <https://www.nice.org.uk/guidance/ng59> [Accessed 08/04/2020]

National Institute for Health Research (2014) Patient and public involvement in health and social care research. A Handbook for researchers. Available from: <https://www.rds-yh.nihr.ac.uk/wp-content/uploads/2015/01/RDS_PPI-Handbook_2014-v8-FINAL-11.pdf> [Accessed 01 April 2020]

Nunn M, Hayden J and Magee L (2017) Current management practices for patients presenting with low back pain to a large emergency department in Canada. BMC Musculoskeletal Disorders 18(92). <https://doi.org/10.1186/s12891-017-1452-1>

O'Cathain A, Connell J, Jaqui Long J, Coster J (2019) ‘Clinically unnecessary’ use of emergency and urgent care: A realist review of patients' decision making. Health Expectations 23(10035). <https://doi.org/10.1111/hex.12995>

Oliveira I, Vanin A, Costa L; Medeiros F, R Oshima, Inácio A; Matos da Cunha T, Palomo A, Fukuda T, de Freitas D, Benvenuto F and Menezes Costa L (2020) Profile of patients with acute low back pain who sought emergency departments. Spine 45(5):E296-E303. https://doi.org/10.1097/BRS.0000000000003253

Ritchie J, Lewis J, Mcnaughton Nicholls C. and Ormston R (2014) Qualitative Research Practice. A Guide for Social Science Students and Researchers. Chapter 7 Indepth interviews 178-210 and Chapter 10: Analysis: principles and processes 269-90 London: Sage. ISBN: 978-1-4462-09110

Rizzardo A, Miceli L, Bednarova R, Guadagnin G, Sbrojavacca R and Rocca GD (2016). Low-back pain at the emergency department: still not being managed. Therapeutics and Clinical Risk Management 12:183-187. https://doi.org/10.2147/TCRM.S91898

Rosenstock I, Strecher V, Becker J (1988) Social learning theory and the health belief model. Health Education Quarterly 15:175–183. https//doi.org/10.1177/109019818801500203

Schmiedhofer M, Möckel M, Slagman A, Frick J, Ruhla S, Searle J (2016) Patient motives behind low-acuity visits to the emergency department in Germany: a qualitative study comparing urban and rural sites. British Medical Journal Open 6:e013323. https://doi.org/10.1136/bmjopen-2016-013323

Shipman C, Longhurst S, Hollenbach F and Dale J (1997) Using Out-of-hours general practice or A&E? Family Practice 14(6):503-9. https://doi.org/10.1093/fampra/14.6.503

Sieck C, Hefner J, Wexler R, Taylor C and McAlearney A (2016) Why do they do that? Looking beyond typical reasons for non-urgent ED use among Medicaid patients. Patient Experience Journal 3(2)5. Available from: https://pxjournal.org/journal/vol3/iss2/5

Stafford V, Greenhalgh S and Davidson I (2014) Why do patients with simple mechanical low back pain see urgent care? Physiotherapy 100:66-72. https://doi.org/10.1016/j.physio.2013.08.001

Tong A, Sainsbury P and Craig J (2007) Consolidated criteria for reporting qualitative research (COREQ): A 32-item checklist for interviews and focus groups. International Journal for Quality in Healthcare 19(6):349-357. https://doi.org/10.1093/intqhc/mzm042

Turnbull C, Pope C, Prichard J, McKenna G and Rogers A (2019) A conceptual model of urgent care sensemaking and help-seeking: a qualitative interview study of urgent care users in England. BMC Health Services Research 19:481. <https://doi.org/10.1186/s12913-019-4332-6>

Van Dyk A, Bentz A, Bissonette S and Cater C (2019) Why go to the emergency department? Perspectives from persons with borderline personality disorder. International Journal of Mental Health Disorders 28:757–765. <https://doi.org/10.1111/inm.12580>

World Health Organisation (2018) Priority Diseases and Reasons for Inclusion Chapter 6.24 Low Back Pain. Available from: <http://www.who.int/medicines/areas/priority_medicines/ch6-13_24/en/>. [Accessed 08/04/2020]

# Reply Slip

#### Version 1.0 31 March 2021

## **Study Title: Low back pain and A&E: understanding need and improving care**

#### Researcher: Clare Ryan Contact email: cr2e14@soton.ac.uk

I am interested in taking part in this study and am happy for the researcher to contact me about the study.

Name:…………………………………………………………………………………

Telephone number (mobile and/or landline):……………………………………….…………………...

Best time to be contacted:…………………………………..….………….

Email or postal address: ………………………………………………………………………………………………..…….

………………………………………………………………………………………………………………………………………………

If you would like an interpreter, please state your language: ……………………………………….………

Signed:……………………………………………. Date:…………….….

Location of A&E attended: ……………………………….………

If completed by the A&E clinician/delegated member of the research team:

I confirm that the above patient has provided their consent for the above details to be forwarded to the researcher.

Name …….………………….……………………………………….. Job role………………..……………………..

Signature……………………………………….

# Study Invitation Letter

#### Version 1.0 8 March 2021

## **Study title: Low back pain and A&E: understanding need and improving care**

#### Researcher: Clare Ryan Contact email: cr2e14@soton.ac.uk

Dear

I am writing to invite you to take part in a research study. The purpose of this study is to improve understanding around peoples’ decision to attend A&E for low back pain and about how to best meet peoples’ needs in this situation. This research is being undertaken at the University of Southampton as part of a PhD. We hope that this information can be used to improve the services that are available in the future.

I am contacting you as I understand that you have recently attended A&E for low back pain. This information will have been given or sent to you by the A&E you recently attended. We would like you to take part so that we can learn from your experiences to help make our services better.

If you decide to take part, you would be asked to take part in a ‘one-off’ individual interview or conversation. Most interviews will be held either over the ‘phone or via a Microsoft Teams video-call. We hope to interview 40-50 people who have recently attended A&E for low back pain. As a token of thanks for taking part in the study, you would be offered a gift card for £25 from either Amazon or Love2shop. During the study you will be asked if you would like to receive a copy of the findings and if so, this will be sent out to you once the study has been completed.

Further details about the study are provided in the enclosed participant information sheet. If you would be willing to take part, please complete and return the reply slip in the pre-paid envelope or email me at cr2e14@soton.ac.uk. I can then answer any questions and arrange a suitable method and date and time for the interview. At this point, I will arrange with you to sign and return the study consent form. Thank you for taking the time to read this information and for considering taking part.

Yours sincerely

Clare Ryan

PhD student, University of Southampton.

# CONSENT FORM

#### Version 1.1 1 June 2021

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

**Researcher: Clare Ryan Contact email:** **cr2e14@soton.ac.uk**

|  |  |
| --- | --- |
| I have read and understood the information sheet version 1.1, dated 01/06/2021 and have had the opportunity to ask questions about the study. |  |
| I agree to take part in the interview for the purposes set out in the participation information sheet.  |  |
| I understand that the interview will be recorded using audio or video and I agree to this.  |  |
| I understand that the personal information collected about me such as my name or where I live will not be shared beyond the study team. |  |
| I understand that special category information will be collected about me to achieve the objectives of the study. This will include providing information about my ethnicity, postcode and health issues. |  |
| I understand that I may be quoted directly in reports of the research but as my personal details will have been anonymised, I will not be directly identified (e.g., that my name/address etc will not be used). I also understand that Clare Ryan will ensure that I cannot be identified in papers or reports arising from this study. |  |
| I understand that in the unlikely event that the information I provide reveals a concern about malpractice, or presents a risk to you or others, the relevant clinical and regulatory authorities will be contacted.  |  |
| I agree that the information collected can be used, in an anonymised form, for teaching conducted or overseen by Clare Ryan. |  |
| I agree to allow the information collected to be used in further research that may be undertaken or overseen by Clare Ryan. |  |
| I understand that the University of Southampton will securely retain all information collected during the interview ten years in line with University policy. Personal data, such as your name and contact details, will be destroyed at the end of the study (likely late 2023). |  |
| I agree to take part in this research project and for my data to be used for the purpose of this study. |  |
| I understand my participation is voluntary and that I may withdraw at any time for any reason without my medical care or participation rights being affected.  |  |

**Please initial the box(es) if you agree with the statement(s):** **Initials**

**I would like to receive a copy of the study’s findings on completion of the study YES / NO**

Name of participant…………………………………………………………………...............................

Signature of participant………………………………………………..… Date……………..…

Name of researcher …………………………………………………………………………………………..

Signature of researcher ………………………………………….…….. Date………

# Participant Information Sheet

#### Version 1.1 1 June 2021

## **Study Title: Low back pain and A&E: understanding need and improving care**

#### Researcher: Clare Ryan Contact email: cr2e14@soton.ac.uk

You are being invited to take part in the above research study. This information sheet explains why the research is being done and what it will involve. We hope this information will help you to decide whether or not you would like to take part. If anything is not clear or you would like more information, please contact the researcher, Clare Ryan by email at cr2e14@soton.ac.uk. You may like to discuss whether or not to join the study with others, but this should be your choice. If you need an interpreter to take part, this can be arranged.

### What is the research about?

The purpose of this study is to improve understanding around peoples’ decision to attend A&E for low back pain and about how to best meet peoples’ needs in this situation. This research is being undertaken at the University of Southampton as part of a PhD. We hope that this information can be used to improve the services that are available, in this situation, in the future.

### Who is completing this research?

This project is being completed by Clare Ryan, a PhD student at the University of Southampton, and her academic supervisors. This work is being completed as part of a Clinical Doctoral Research Fellowship and Doctorate in Philosophy (PhD). The research is funded by the National Institute of Health Research and hosted by the University of Southampton.

### Why have I been asked to participate?

We are inviting you to take part as we think that you have recently attended A&E for low back pain. We would like to learn from your experience to help make our services better. We hope to interview 40-50 people who have recently attended A&E for low back pain. It might be that whilst you attended for low back pain, it later became clear that the cause was something else. No matter what you were diagnosed with, if you came to A&E for low back pain, we are interested in hearing from you.

**What would taking part in the study involve?**

If you choose to take part,you will be asked to take part in one interview with the researcher, Clare Ryan. The ‘interview’ will be a conversation between you and Clare about your recent 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.

With your permission, the interview will be recorded to make sure we have heard and understood you and to enable us to use your words to make sure our analysis is accurate. This will be either be an audio recording (using Open Broadcasting Software and/or a voice recorder) or video recording (using Teams). If you choose to complete the interview via Microsoft Teams, you will be sent instructions on how to do this and, if it would help, a trial run can be arranged. Microsoft Teams and Open Broadcasting Software have been recommended by the University of Southampton and approved by the ethics committee as safe and secure methods to host and record the interview.

Following the interview, the recording will be transcribed by either the researcher or a professional transcription service. Prior to being sent to the transcription service, the recording will be encrypted and labelled only with your study number and interview date. The transcription service is subject to a non-disclosure agreement and is therefore obliged to maintain the confidentiality of the information contained in the interview recording. Following returning the completed transcript to the researcher, the transcription company will (within 7 days) destroy the files received and the transcripts produced.

### Do I have to take part?

It is entirely up to you to decide whether or not to take part.

### Are there any benefits for me in taking part?

As a token of thanks for taking part in the study, you will be offered a gift card for £25 from either Amazon or Love2shop. If you travel to attend the interview in person, you will be able to claim for travel and parking expenses to help cover the costs of attending the interview. The researcher will provide the form to claim these expenses at the time of 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. We hope that this information can be used to inform how future care is provided and may therefore benefit others in the future.

### What data will be collected?

During the interview, you will be asked about your recent experience of attending A&E for low back pain. You will be asked about your experience of making the decision to attend A&E, of receiving care and about how to best meet your needs. At the end of the interview, you will be asked several questions about your ethnicity, gender, age, your level of education, postcode, other health problems and your work. This is to help us talk to a wide range of people so that our research is relevant to as many people as possible. You do not need to answer any questions that you would prefer not to.

Direct quotations from the interviews will be used when sharing the findings with others, such as at conference presentations or in publications. This is to help ensure that the findings accurately convey what participants have said. The researcher will ensure that it is not possible to identify you from any quotations used.

The findings of this study may be combined with the findings of a linked study, also lead by Clare Ryan. The linked study explores other stakeholders’ perceptions about how best to provide healthcare or support for people who attend A&E for low back pain. Stakeholders are likely to include healthcare professionals, managers and/or commissioners. Where data from the current study is used to inform the linked study, only the researcher and her direct academic supervisors will have access to the data collected from you.

In the unlikely event that the researcher, Clare Ryan, leaves the research team and the study continues, the lead academic supervisor will have access to and will oversee the use of the research data.

### How could taking part affect me?

As part of the interview, you may be asked about your experience of healthcare for low back pain. You might also be asked about any other health conditions and about the effect of your low back pain on family life. Some people might feel sensitive about talking about these issues. Please be reassured that the researcher will ask questions and listen to your replies respectfully. In the highly unlikely event that you require support following the interview, the researcher will be able to direct you to appropriate resources to access or you can contact your family doctor or any other health professional who usually helps you to manage your back pain.

### Will my taking part in the study be kept confidential?

Whether or not you take part in the study and any information that we collect about you during the study will be kept strictly confidential.

The only people who may be given access to your personal details will be:

1. The researcher (Clare Ryan) and in exceptional circumstances her academic supervisors.
2. Staff at the University of Southampton responsible for monitoring or auditing the study to ensure that the research complies with regulations.
3. Individuals from regulatory authorities who check that the researcher and University are carrying out the study correctly.

If you require an interpreter, your first name and contact details may be provided to the interpreter to help arrange and complete the interview. The interpreter will be from Language Line or Prestige, companies widely used by the NHS for interpretation services.

All of these people have a duty to keep your information strictly confidential.

Neither your personal details nor any of the information that we discuss during the interview will be shared with health professionals involved in your care.

To help protect your identity, following the interview, you will be allocated a participant number. This participant number will be used to identify all information you provide during the interview (our conversation and the information you provide about you at the end of the interview). This interview information will be stored separately from your personal data (name and contact details). Only the researcher Clare Ryan (or in exceptional circumstances, her University supervisors) will have access to the code that links your interview information to your personal data. This means that it will not be possible for anyone else to link the information we discuss during the interview to you. Any data that includes your personal information, and the interview audio/video recording, will be stored only on the secure University of Southampton research data storage system. If you complete any paper forms, these will be scanned and uploaded onto the secure University server, and the paper copies disposed of securely. If we need to electronically transfer information about you, this will be completed using secure University of Southampton systems that encrypt your data.

In line with current University policy, all interview data will be retained for at least ten years in a secure University of Southampton data repository. Your personal details will be kept only until the end of the study, so that we can contact you with any questions and send you a copy of the results if you would like to see them. At the end of the study and following preparing the results for publication, any data that contains your personal details will be destroyed.

It is possible that the data we collect from you may be looked at in further studies by the researcher or for teaching health professionals in future. In both cases, Clare Ryan would be involved, to safeguard the information. Your permission will be sought specifically for use in teaching and research on the consent form.

In the unlikely event that the information you provide reveals a concern about malpractice, or presents a risk to you or others, this situation would be discussed with the lead academic supervisor. If it is thought necessary to contact the relevant clinical and regulatory authorities, you will be alerted to this by the researcher either during or shortly following the interview. If it is necessary to disclose your identity to the relevant authorities as part of this process you will be informed.

### What happens if I change my mind?

You have the right to change your mind and withdraw from the study at any time. You do not need to tell us why you no longer wish to participate, and your care will not be affected. If you do wish to withdraw, you would be asked if any information you have given up to this point can be used. This is entirely up to you. Neither of these decisions will affect any aspect of your clinical care, now or in the future.

To withdraw from the study, please contact the researcher, Clare Ryan by email: cr2e14@soton.ac.uk. Alternatively, you can contact the research supervisor, Clinical Professor Lisa Roberts by email: L.C.Roberts@soton.ac.uk.

### Will I be able to access the results of the study?

Yes. When the study has been completed (Autumn 2023), a summary of the study findings will be available. If you would like a copy, please indicate this on the consent form or, if you decide later that you would like a copy please email Clare Ryan at cr2e14@soton.ac.uk before the end of December 2023.

### What will happen to the results of the research?

The results of the research will be published in journals of interest to health researchers and health professionals. Conference presentations will also be given. It will not be possible to identify you from any of the information we use in reporting the results.

### Where can I get more information?

If you have any further questions about participating in this study, please contact the researcher, Clare Ryan, on email cr2e14@soton.ac.uk.

### What happens if there is a problem?

If you are concerned about any aspect of this study, you should contact the researcher, Clare Ryan who will do her best to answer your questions. You can contact Clare by email: cr2e14@soton.ac.uk. Alternatively, you can contact the research supervisor, Clinical Professor Lisa Roberts by email: L.C.Roberts@soton.ac.uk.

If you remain unhappy or prefer to speak to someone independent to the study, please contact the Research Governance Office (Address: University of Southampton, Building 37, Highfield, Southampton, SO17 1BJ; Tel: +44 (0)23 8059 5058; Email: rgoinfo@soton.ac.uk.  You can also contact the Patient Advice and Liaison Service (PALS). The contact details for your local PALS team can be found at: <https://www.nhs.uk/nhs-services/hospitals/what-is-pals-patient-advice-and-liaison-service/>. Your GP surgery, local hospital or NHS 111 can also provide you with the number of your local PALS team.

### Who has reviewed this study?

All research in the NHS is independently reviewed to protect and promote the interests of participants. Therefore, this study has been reviewed and given favourable opinion by X Research Ethics Committee and the Health Research Authority.

## **How do I join the study?**

**To join the study, complete and return the reply slip in the pre-paid envelope or contact Clare by email at** cr2e14@soton.ac.uk**. Clare will then answer any questions and arrange a suitable method and date and time for the interview. She will also discuss with you how to complete and return the consent form.**

##### Data Protection Privacy Notice

The University of Southampton conducts research to the highest standards of research integrity. As a publicly funded organisation, the University has to ensure that it is in the public interest when we use personally identifiable information about people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use information about you in the ways needed, and for the purposes specified, to conduct and complete the research project.

Under data protection law, ‘Personal data’ means any information that relates to and is capable of identifying a living individual. The University’s data protection policy governing the use of personal data by the University can be found on its website (https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page).

This Participant Information Sheet tells you what data will be collected for this project and whether this includes any personal data. Please ask the research team if you have any questions or are unclear what data is being collected about you. Our privacy notice for research participants provides more information on how the University of Southampton collects and uses your personal data when you take part in one of our research projects and can be found at: <http://www.southampton.ac.uk/assets/sharepoint/intranet/ls/Public/Research%20and%20Integrity%20Privacy%20Notice/Privacy%20Notice%20for%20Research%20Participants.pdf>

Any personal data we collect in this study will be used only for the purposes of carrying out our research and will be handled according to the University’s policies in line with data protection law. If any personal data is used from which you can be identified directly, it will not be disclosed to anyone else without your consent unless the University of Southampton is required by law to disclose it.

Data protection law requires us to have a valid legal reason (‘lawful basis’) to process and use your Personal data. The lawful basis for processing personal information in this research study is for the performance of a task carried out in the public interest. Personal data collected for research will not be used for any other purpose.

For the purposes of data protection law, the University of Southampton is the ‘Data Controller’ for this study, which means that we are responsible for looking after your information and using it properly. The University of Southampton will keep identifiable information about you for 10 years after the study has finished after which time any link between you and your information will be removed.

To safeguard your rights, we will use the minimum personal data necessary to achieve our research study objectives. Your data protection rights – such as to access, change, or transfer such information - may be limited, however, in order for the research output to be reliable and accurate. The University will not do anything with your personal data that you would not reasonably expect.

If you have any questions about how your personal data is used, or wish to exercise any of your rights, please consult the University’s data protection webpage (https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page) where you can make a request using our online form. If you need further assistance, please contact the University’s Data Protection Officer (data.protection@soton.ac.uk).

**THANK YOU**

# Guide to using Microsoft Teams for a virtual/video call

#### Version 1.0 8 March 2021

## **Study Title: Low back pain and A&E: understanding need and improving care**

#### Researcher: Clare Ryan Contact email: cr2e14@soton.ac.uk

Research interviews completed using a video call will be via Microsoft Teams. You do not need a Microsoft Teams account to take part. To take part using Teams, please follow the instructions detailed below.

1. The researcher will send you an email inviting you to a ‘meeting’ on the date and time agreed. The email will come from Clare Ryan’s email address: cr2e14 soton.ac.uk. If you click yes on the invitation to accept the interview meeting, the meeting should appear on your calendar.



1. You can join the meeting from your smartphone, tablet, or computer. To improve the quality of the sound, you could use headphones, ideally ones with a built-in microphone.
2. To join the meeting, you can:
3. Click ‘join online’ on the meeting reminder that should pop up 15 mins or so before the meeting.



1. Click ‘join Microsoft Teams Meeting’ on the email invitation. Note that this email might have moved to your deleted emails folder.



1. You will then be asked how you wish to join the meeting. You can choose to download the app (program) called Microsoft Teams or join the meeting via the internet website. Alternatively, if you already have the Microsoft Teams app you can click on the link to join using your app.



1. You will then enter the ‘virtual lobby’, this is just a waiting space. The program will let the researcher know you have arrived and then she’ll then start the meeting. Please allow the program to use your microphone and camera as this allows the researcher to see and hear you. Please enter your name and wait for the researcher to start the ‘meeting’.



1. The researcher will confirm with you that you are happy for her to record the interview and whether this is an audio or video recording.
2. The researcher will then begin to ask you questions about your experience of attending A&E for low back pain.
3. You can ask to pause or stop the interview at anytime.
4. To end the call, click on ‘leave now’ or ‘hang up’.
1. Based on average monthly attendances of 400 patients with low back pain per month and a conservative estimate of 1.5 hours treatment time. [↑](#footnote-ref-1)