# Participant Information Sheet

#### Version 1.2 24 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 and/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 highly 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**