The Randomised Evaluation of early topical Lidocaine patches In Elderly patients admitted to hospital with rib Fractures (RELIEF): feasibility trial.

INTERVIEWS WITH PATIENTS AND PEOPLE WITH CARER RESPONSIBILITIES

PARTICIPANT INFORMATION SHEET

Chief Investigator: Dr Edward Carlton

You are being invited to take part in an interview as part of the RELIEF feasibility trial (study). Before you decide, it is important for you to understand why the research is being done and what it will involve. You are welcome to ask us any questions you may have. Thank you for taking the time to read this information. Please keep a copy of this information sheet for your records.

Please note: *for the purpose of this information sheet, any reference to 'we' means the study Sponsor (North Bristol NHS Trust).*

1. Purpose of the interviews

In the RELIEF study, **we want to find out if it is feasible to conduct a study exploring the use of lidocaine patches as a means of pain control for broken ribs. Results from this study will aid the design and development of a larger research study (trial) to explore whether patients who have patches put over their broken ribs may have improved pain.** This may influence the treatment of patients in the future.

Qualitative research (interviews) with patients, and people with carer responsibilities, is a vital component of the RELIEF. The purpose of these interviews is to explore their experience of being involved in the trial. For example, we may explore details of the study design, acceptability of proposed outcome measures, and understand recruitment processes.

2. Why have I been invited?

You have been invited to take part because you, or the person who care for, are participating in the RELIEF study, and we would like to hear your opinions and perspective.

3. Do I have to take part? If I do take part, can I change my mind?

No. It is entirely up to you to decide whether to take part in this (interview) part of the RELIEF study. You (or the person you care for) can still take part in the main study if you do not want to take part in an interview.

If you are interested in taking part in an interview, you should indicate this on the main study RELIEF Consent/Declaration Form (where applicable). Alternatively, you can also contact a member of the qualitative research team, whose contact details are provided at the end of this information sheet.

If you agree to take part, you are free to refuse to answer any specific interview question(s), and/or withdraw at any time, without giving a reason. Your medical care (or that of the person you care for) and legal rights will not be affected. **If you change your mind and withdraw**, any information collected before you withdraw will be retained and used for this research study.

4. What will happen to me if I take part?

If you are willing to take part, a member of the research team will contact you to arrange a suitable time (and place if meeting in person). The interview will take place via telephone (or alternative method if requested and where it is appropriate and feasible, e.g. Sponsor/NHS-approved video/tele-conference platforms, or face-to-face), and with your permission we will audio-record your conversation. The interview is estimated to last between 30-60 minutes.

5. What will I have to do?

At the beginning of the audio-recording you will be asked to provide verbal informed consent to confirm that you understand what is involved and agree to take part. The researcher will also make a written record of your agreement.

During the interview you can ask the interviewer to pause the recording at any time and you are also free to stop taking part should you wish to do so. The audio-recording will be transcribed and anonymised ahead of being analysed. The information you provide will be kept confidential. Upon request we can send you a copy of the anonymised transcript for your information.

6. What are the benefits, and possible disadvantages and risks, of taking part?

Benefits. The results of this qualitative research will feed into the main RELIEF study. These findings will allow the RELIEF team to interpret the overall results of this feasibility study in a more complete manner, and also make improvements to the study processes if possible. If this feasibility study is successful, we will use the information we collect to design and carry out a larger study.

Some people find that taking part in an interview helps them talk through their situation and their views, and that this is comforting. Face-to-face interviews will be held at a location convenient to you; reasonable travel expenses will be reimbursed, where applicable.

Disadvantages or risks. There are no disadvantages or physical risks to taking part. If you do experience any difficulties, please feel free to discuss this with the lead researcher, whose contact details are provided at the bottom of this information sheet.

7. Will my taking part in this study be kept confidential? What will happen to my data?

Yes, we will follow ethical and legal practice and all information about you will be handled in confidence. We will abide by the UK Policy Framework for Health and Social Care Research and follow the research sponsor, North Bristol NHS Trust's, Research Governance guidelines.

As also specified in the Detailed Information Pack for the study, we will be using information from you in order to undertake this study and North Bristol NHS Trust and the University of Bristol will act as joint data controllers for this study. This means that we are both responsible for looking after your information and using it properly. Personal information such as your name, email address and phone number will be stored on a secure database with the central research team (University of Bristol). The University of Bristol, on behalf of North Bristol NHS Trust (Sponsor) will keep identifiable information about you for at least 5 years after the study has finished.

Audio-recordings will be made using an encrypted device and uploaded to a password protected, secure University of Bristol server as soon as possible after each focus group. Audio-recordings will be labelled with a unique reference number (not with your name) to hide your identity and will be transcribed by

either a University of Bristol employee or by a University of Bristol approved transcribing service. These transcripts will also be anonymised so that you cannot be recognised from any of the information we collect from you. We *may* use anonymised quotations and parts of voice modified audio-recordings for training, teaching, research, and publication purposes for this and future studies, but we will ensure that you cannot be identified.

All recordings and electronic and paper copies of the transcripts will be stored securely during the conduct of the trial and for at least 5 years after the end of the trial. After this period, data will be destroyed by confidential means with the exception of a final trial dataset which will be made available for data-sharing purposes. Anonymised research data, including audio-recordings and associated data, will be stored in a secure research data storage facility, alongside the other study data. The data is only accessible to authorised users ('controlled access'), and you cannot be identified by any information held. We anticipate that data will be made available to researchers to use in other related research, but they will only be allowed to access it if their research has been approved by a Research Ethics Committee and suitable data sharing agreements are in place. Sharing the study data helps to maximise the impact of the money invested into this study and can encourage new avenues of research.

You can find out more about how we use your information:

- You can find out more about how we use your information at: www.hra.nhs.uk/information-about-patients/
- our leaflet "How we use information from patients" available from: relief.blogs.bristol.ac.uk
- at the University of Bristol website: www.bristol.ac.uk/secretary/data-protection/policy/research-participant-fair-processing-notice/
- at North Bristol NHS Trust website: www.nbt.nhs.uk/research-innovation/our-research/patient-information-health-care-research
- by contacting North Bristol NHS Trust's Head of Information Governance: helen.williamson@nbt.nhs.uk
- by asking one of the research team: see details on final page
- by sending an email to: relief-trial@bristol.ac.uk, or by ringing us on 0117 331 3907.

8. What if there is a problem?

As this study only involves the audio recording of an interview (conversation), it is extremely unlikely that you will be harmed by taking part. However, any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. If you have a concern about any aspect of this study, you should ask to speak to the lead researcher, who will do their best to answer your questions (contact details can be found on the final page).

9. What will happen to the results of the research study?

After a thorough review by independent experts, our report will be published in respected journals but most importantly it will inform the researchers who are working on the RELIEF trial to optimise trial design. **You will not be identified in any way whatsoever, in any report or publication.**

Please continue to the final page.

10. Who is organising and funding the research?

The trial is led by a team of experienced doctors and researchers and is sponsored by North Bristol NHS Trust. Dr Edward Carlton (RELIEF Chief Investigator) is funded by a National Institute for Health Research (NIHR), Advanced Fellowship (NIHR300068) for this research project. This trial was designed and delivered in collaboration with the Bristol Randomised Trials Collaboration (BRTC), a UKCRC registered clinical trials unit which, as part of the Bristol Trials Centre (BTC), is in receipt of National Institute for Health Research CTU support funding. The BRTC, as part of the BTC, are responsible for managing the trial.

11. Who has reviewed the study?

This study has been reviewed and approved by North Bristol NHS Trust, the Health Research Authority, 'South Central – Oxford C' Research Ethics Committee (reference 21/SC/0019) and 'Scotland A Research Ethics Committee' (reference 21/SS/0043). An independent Trial Steering Committee will monitor the study to ensure it is conducted according to good research practice.

12. Further information and contact details

If you want to talk to someone about this element of the RELIEF trial, please contact:

- **RELIEF Chief Investigator:** Dr Edward Carlton | Email: relief-trial@bristol.ac.uk
- **RELIEF Qualitative Researcher:** *[Insert name – to be confirmed]* | Email: *[insert – to be confirmed]*
- **RELIEF Trial Team (Study Office):** Dr Amanda Lewis, Trial Manager | Email: relief-trial@bristol.ac.uk

THANK YOU FOR TAKING THE TIME TO READ THIS INFORMATION LEAFLET.
PLEASE RETAIN A COPY FOR YOUR RECORDS.

Dr Edward Carlton is funded by a National Institute for Health Research (NIHR), Advanced Fellowship (NIHR300068) for this research project. The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care. This study was designed and delivered in collaboration with the Bristol Randomised Trials Collaboration (BRTC), a UKCRC registered clinical trials unit which, as part of the Bristol Trials Centre, is in receipt of National Institute for Health Research CTU support funding. This study is sponsored by North Bristol NHS Trust.

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