Appendix C - Consent form

PARTICIPANT INFORMATION SHEET AND CONSENT FORM

CLINICAL TRIAL

Digital Support for People with Rib Fractures

Project Sponsor:	Northern Sydney Local Health District
Chief Investigator:	Associate Professor Claire Ashton-James
Associate Investigators:	Associate Professor Damien Finniss
	Dr Matt Doane
	Professor Paul Glare
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Location: Department of Anaesthesia, Pain and Perioperative Medicine, Royal North Shore Hospital, Reserve Rd, St Leonards, NSW, Australia 2065

Invitation

You are invited to participate in a study evaluating two forms of digitally-delivered support for pain management in people with rib fractures. Before you decide whether or not you wish to participate, please take the time to read the following information carefully and discuss it with others if you wish.

1. 'What is the purpose of this study?'

The purpose of this study is to investigate whether patients with rib fractures benefit from digitally-delivered education about pain and strategies to manage pain.

2. 'Why have I been invited to participate in this study?'

You are eligible to participate in this study if you have been admitted to hospital with a rib fracture.

3. 'What if I don't want to take part in this study, or if I want to withdraw later?'

Participation in this study is voluntary. It is completely up to you whether or not you participate. If you decide not to participate, it will not affect the treatment you receive now or in the future. Whatever your decision, it will not affect your relationship with the staff caring for you.

If you wish to withdraw from the study once it has started, you can do so at any time without having to give a reason. If you choose to withdraw, you can inform the research team by sending an email to Claire Ashton-James (claire.ashton-james@sydney.edu.au). They will send you the 'Participant Withdrawal of Consent Form' to sign.

If you withdraw from the study, your data and information will be deleted from study records and will not be used in future research, unless you agree to your de-identified (anonymised) data being used.

Note: The Chief Investigator may remove a participant from the study at any time if they feel it is in their best interest or that their safety may be at risk due to unanticipated health issues or not following study procedures.

4. 'What does this study involve?'

Your participation in the study will last for 15 days starting from the day you sign the consent form.

If you agree to participate in this study, the following will happen:

1. You will be provided with a consent form to read and sign on the next page of this online survey
2. If you provide your consent, you will be asked to complete some questions about your pain, injury, and personal information (e.g., gender, marital status). You will also be asked to provide your name, phone number, and email address so that we can contact you throughout the study. These initial questions will take around 10 minutes to complete.
3. As part of this study, you will be randomly assigned to receive one of two forms of support. The randomisation is done by a computer and is similar to flipping a coin. Both forms of support are delivered by mobile phone and were designed by a team of researchers, patients, and clinicians who are experts in pain and recovery from injury.
4. Your doctors will not be aware of the form of support you are receiving, and it is important that you do not tell them unless it is directly requested by your doctor or a research team member or you decide to do so for safety reasons.
5. Participation in this research will involve completing short online questionnaires about your pain, mood, and medication, which will be sent to your mobile phone via text message every day for seven days and then again on Day 14. These questionnaires will take around 5 minutes to complete.
6. On Day 15, you will be sent a final feedback survey, which will take around 15 minutes to complete.

In addition, the researchers would like to have access to your medical records to obtain information relevant to the study. The information collected will include:

- Date of hospital admission
- Date of hospital discharge
- Medication during hospitalisation
- Rib fracture details
- Other health diagnoses
- Gender
- Age

Please note, the support provided to you while participating in this study is not a crisis service. If you are in crisis or it is a health emergency, you should contact your nearest hospital (if you have been discharged). If you experience a flare-up of pain or have any other pain-related concerns, you should contact your doctor or clinician as you would normally.

5. 'How is this study being paid for?'

The study is being sponsored by a grant to the Northern Sydney Local Health District from the Ramsey Research Foundation.

6. 'What are the alternatives to participating in this study?'

The digitally-delivered support you will receive while participating in this study will not replace or change the care that you are receiving from your doctor and other healthcare professionals. If you decide not to participate, your treatment will continue as usual.

7. 'Are there risks to me in taking part in this study?'

We do not expect you to experience any harm as a result of participating in this study. If any unexpected consequences occur during your participation or you feel distressed by an aspect of your participation, please contact Claire Ashton-James (claire.ashton-james@sydney.edu.au) or speak to your doctor. We also encourage you to call Lifeline (13 11 14) for mental health support if needed.

8. 'What happens if I suffer injury or complications as a result of the study?'

If you suffer any injuries or complications related to your participation in this study, you should contact the research team (claire.ashton-james@sydney.edu.au). They will assist you in arranging appropriate medical treatment as soon as possible.

You may have a right to take legal action to obtain compensation for injuries or complications relating to this study. Compensation may be available if your injury or complication is caused by the interventions in this study, or by the negligence of any of the parties involved in the study. If you receive compensation that

includes an amount for medical expenses, you will be required to pay for your medical treatment from those compensation payments.

If you are not eligible for compensation for your injury or complication under the law but are eligible for Medicare, you can receive medical treatment free of charge in any Australian public hospital.

9. 'Will I benefit from the study?'

The digital support provided as part of your participation in this study may help you to manage pain associated with rib fractures. However, we cannot guarantee this, and you may not benefit from participating in study.

10. 'Will taking part in this study cost me anything, and will I be paid?

The digital support will be provided to you for free. However, your participation in this study will cost you some time and energy including the time it takes to complete the study surveys which, in total, will be approximately 60 minutes over the 15-day study period. You will not receive payment to participate in this study.

11. 'How will my confidentiality be protected?'

Hospital staff will not know whether or not you are participating in this study unless you tell them. Any identifiable information that is collected about you will remain confidential and will be disclosed only with your permission, or except as required by law. Only the researchers named above and, if required for monitoring purposes, The Northern Sydney Local Health District Human Research Ethics Committee and regulatory bodies will have access to your information and data, which will be held securely on password-protected University of Sydney servers.

We will send text messages to your phone over Australian telephone networks at no cost. We will use Qualtrics software for online surveys which will be saved on The University of Sydney server. These are automated and secure systems with protocols for encryption and authentication.

Data within the SMS software will be deleted after being exported at the end of the study. Exported data from the database will be de-identified and stored in a password-protected computer owned by the University of Sydney to ensure data security and confidentiality. Data gathered in this study may be used by the research group of this study in future research approved by an ethics committee and such data will not contain your name or any identifiable information about you. All data will be stored for 15 years after the publication of the project's final report and then will be securely destroyed per requirements for clinical research.

12. 'What happens with the results?'

We hope that the results of this research project will be published in scientific journals and presented at conferences and other meetings. All data that is collected in this study, including data collected by the online eligibility form from all applicants, will be saved and de-identified to remove personal information before

analysis and reporting. In any publication, report, or presentation, information will be provided in such a way that you cannot be identified, except with your permission. The overall results of the study will be provided to you if you wish.

13. 'What happens to my treatment when the study is finished?'

After the study is finished, your care will continue as usual. You can save and access the information sent to your phone and email for as long as you wish.

14. 'What should I do if I want to discuss this study further before I decide?'

If you would like to know more or have questions about this study, you can contact us by email at claire.ashton-james@sydney.edu.au or by phone [0410 365 816] during office hours.

15. 'Who should I contact if I have concerns about the conduct of this study?'

This study has been approved by the Northern Sydney Local Health District HREC. Any person with concerns or complaints about the conduct of this study should contact 02 9926 4590 or email NSLHD-Research@health.nsw.gov.au and quote HREC reference [2023/ETHXXXXX].

Thank you for taking the time to consider this study.

If you wish to take part in it, please sign the attached consent form.

This information sheet is for you to keep.

CONSENT FORM

CLINICAL TRIAL

Digital Support for People with Rib Fractures

1. I agree to participate as a participant in the study described in the Participant Information Sheet set out above.

Please provide your full name _____

2. I have read the Participant Information Sheet explaining why I have been selected, the aims of the study, and the possible risks, and the study has been explained to me to my satisfaction.

◯ YES / ◯ NO

3. Before signing this consent form, I have been given the opportunity to ask any questions relating to possible physical and mental harm I might suffer as a result of my participation, and I have received satisfactory answers.

◯ YES / ◯ NO

4. I understand that I can withdraw from the study at any time without affecting my relationships with the research team or my treating clinicians.

◯ YES / ◯ NO

5. I agree that research data gathered from the study may be published and that publications will not contain my name or any identifiable information about me.

◯ YES / ◯ NO

6. I agree that data gathered in this study may be used by the research group of this study in future research approved by an ethics committee and that such data will not contain my name or any identifiable information about me.

◯ YES / ◯ NO

7. I understand that if I have any questions relating to my participation in this research, I may contact the research team by email at claire.ashton-james@sydney.edu.au or by phone [0410 365 816] during office hours who will be happy to answer them.

◯ YES / ◯ NO

8. I acknowledge receipt of a copy of this Consent Form and the Participant Information Sheet.

◯ YES / ◯ NO

'I understand that by submitting this consent form I consent to participate in the study as outlined in the Participant Information Statement.'

◯ YES / ◯ NO

Please indicate below if you would like to be informed about the overall results of this study when available. This will be sent to your email address.

I would like to be informed about the overall results of this study when available.

◯ YES / ◯ NO

SUBMIT

CLINICAL TRIAL

Digital Support for People with Rib Fractures

REVOCATION OF CONSENT

I hereby wish to **WITHDRAW** my consent to participate in the study described above and understand that such withdrawal **WILL NOT** jeopardise any treatment or my relationships with my doctors or my medical attendants or with the researchers.

Please provide your full name

'I understand that by submitting this withdrawal form I am withdrawing my consent to participate in the study as stated in the information statement.'

◯ YES / ◯ NO

'I agree to my de-identified (anonymised) information and data being used in this study and/or future research.'

◯ YES / ◯ NO

SUBMIT

Ashton-James CE, *et al. BMJ Open* 2024; 14:e086202. doi: 10.1136/bmjopen-2024-086202