Appendix D - Protocol

FULL STUDY TITLE

Evaluating the Efficacy of an mHealth Intervention to Support Pain Self-Management and Improve Analgesia in Patients with Rib Fractures

SHORT STYUDY TITLE

Pain Support for Rib Fractures

CONFIDENTIAL

STATEMENT OF COMPLIANCE

This document is a protocol for a clinical research study. The study will be conducted in compliance with all stipulations of this protocol, the conditions of ethics committee approval, the NHMRC National Statement on Ethical Conduct in Human Research (2007) and the Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95).

CONTENTS

PROTOCOL SYNOPSIS

Title	Evaluating the Efficacy of an mHealth Intervention to Support Pain Self-Management and Improve Analgesia in Patients with Rib Fractures
Objectives	*Primary objective*: To evaluate the efficacy of an mHealth intervention for reducing pain intensity during early recovery from rib fractures. *Secondary objectives*: To evaluate the efficacy of an mHealth intervention for reducing pain-related distress and opioid use during early recovery from rib fractures. To evaluate the feasibility and acceptability of the mHealth intervention in a diverse participant population with acute rib fracture pain. To explore mechanisms of action and predictors of response to the mHealth intervention.
Study Design	A double-blind randomised controlled trial with two parallel arms
Planned Sample Size	120 (60 per arm)
Selection Criteria	*Inclusion Criteria* - 18 years of age - Admitted to hospital with isolated rib fracture in last 24 hours - Capable of reading and understanding basic English - Capable of understanding study information and providing consent - Owns a mobile phone and able to use the phone during hospitalisation - Able and willing to complete survey measures on mobile phone device *Exclusion Criteria* - Inability to complete study procedures (lack of fluency in English, cognitive ability, mental health status, medical status) - Admission to hospital with other injuries or comorbidities (e.g., head, extremity, lung, or abdominal trauma) - NSAIDs contraindicated - Regional anaesthesia or blockade likely to be used for pain management
Study Procedures	Eligible patients will be identified by hospital staff (acute pain service) and invited to participate in a "study examining factors influencing pain and recovery from rib fractures. The study will involve receiving text messages from the research team". Patients who are interested in knowing more about the study will be given a QR code and will use their mobile phone to access study information, consent forms, and (if they consent to

	participate) baseline measures. After completing baseline measures, all participants will be provided with a brief pain self-management educational video (Day 0). After watching the video, participants will be randomised to either the intervention (video + SMS support) or active control group (video only). For 14 days after viewing the brief pain self-management video (Days 1-14), the intervention group will receive two SMS per day (mid-morning and mid-afternoon) providing them with ongoing support for engaging with pain self-management strategies to help them to manage pain (in addition to usual care). During this same period, the active control group will receive usual care only. For the first 7 days of the trial (Days 1-7), encompassing a period of hospitalisation, all participants will be sent measures of pain intensity on respiration (primary outcome) and pain-related distress via SMS (at the standardised time of 3pm). A measure of participant adherence to pain management strategies will be included in surveys received by all participants on Day 7. During hospitalisation, participants' daily opioid dose will be extracted from hospital records by investigators who are staff specialists on the acute pain team. On Day 14 of the trial, participants will receive an SMS with a link to a survey assessing their pain intensity, pain-related distress, self-reported opioid use, and adherence to behavioural pain management strategies. At the end of the study (Day 15) participants will be asked to complete a feedback survey about the acceptability of the pain support that they received (active control: video alone; intervention: video + SMS) and factors influencing their engagement with the pain self-management strategies provided (barriers and facilitators). Feasibility will be evaluated by recording the number of SMS sent and received.
Statistical Procedures Sample Size Calculation: Analysis Plan:	*Sample size calculation*: At alpha = .05 and beta .80, we estimate the need for 51 patients per group to detect a 1.3-point (out of 10) difference in pain intensity on respiration on average over 7 days. We will recruit 120 to account for an approximated 15% dropout rate. *Analysis plan*: A marginal mixed model analysis will be used, evaluating the main effect of the group (intervention vs. active control). Linear mixed models will be used to explore differences between outcome trends recorded over the trial. Per-protocol and intent-to-treat analyses will be conducted to minimise bias secondary to missing data or dropouts. Results will be reported with 95% confidence intervals, with an alpha of

	.05 used to establish statistical significance.
Duration of the study	12 months

GLOSSARY OF ABBREVIATIONS

ABBREVIATION	TERM
BPME	Behavioural pain management education
CAP-2	2-item Concerns about Pain Scale
HREC	Human Research Ethics Committee
NSLHD	Northern Sydney Local Health District
PISCF	Participant Information Sheet / Consent Form
RCT	Randomised Controlled Trial
RNSH	Royal North Shore Hospital
SMS	Short Message Service

1 STUDY MANAGEMENT

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Investigator-Initiated	
Royal North Shore Hospital	Sponsor: Northern Sydney Local Health District

1.5 Funding and resources

The study is supported by a Ramsay Research Grant awarded to Associate Professor Damien Finniss, Director, Acute and Transitional Pain Service, Royal North Shore Hospital. There is no conflict of interest either implied or actual with the funding body, person receiving funding (AI Finniss), or any member of the research team

1.6 Trial registration

This trial has been registered on the Australian New Zealand Clinical Trials Registry (registration number: ACTRN12623000006640p).

2. INTRODUCTION AND BACKGROUND

2.1 Background Information and Rationale for Current Study

Acute rib fractures are a common reason for hospitalisation and are associated with significant morbidity and mortality (Witt & Bulger, 2017). Effective pain relief is essential in patients with rib fractures to support their ability to breathe deeply, which can be painful, and to avoid complications associated with the avoidance of taking deep breaths, including pneumonia. Opioid medications play an essential role in the management of the moderate-severe pain associated with rib fractures. However, the Australian Commission on Safety and Quality in Health Care have recently raised concern about *over-reliance* on opioids for acute pain management, which (especially in this patient population) can become detrimental to patient outcomes, increasing risk of morbidity and mortality (Gupta et al., 2018; Hah et al., 2017). To help patients achieve the most effective analgesia with the lowest possible dose of opioids, there is an urgent focus on implementing adjuvant non-opioid analgesic strategies routinely into the acute pain management of patients with rib fractures.

Patients who engage with behavioural pain management strategies (e.g., relaxation, thought management, body awareness, social support) show improved analgesia, functioning (ability to perform activities of daily living) and reduced reliance on opioids after elective and emergency surgeries (Darnall et al., 2019; Szeverenyi et al., 2019; Tong et al., 2020). However, providing in-person support for pain self-management can be time consuming, may require more than a "single session" (i.e., ongoing support), and often requires additional training of clinicians, which is not always feasible, cost-effective, or accessible.

The Australia's National Digital Health Strategy (2017) emphasises the need to develop novel digital technologies to address challenges in healthcare delivery. Our research team previously co-designed a mobile health (mHealth) intervention (PainSupport) which combines a brief pain self-management educational video with ongoing SMS text message-delivered support for engaging with these strategies. Our previous research indicates that people with chronic pain found it helpful to receive this intervention while they were reducing their opioid dose (under the guidance of their primary care provider or pain specialist). Text messaging may also be a low-cost, scalable, accessible, and feasible solution to the challenges associated with providing patients with ongoing support for behavioural pain management strategies in the hospital (acute pain) setting. The current study aims to evaluate whether the PainSupport intervention has the potential to improve patient analgesia, increase engagement with behavioural pain self-management strategies, and reduce patient distress and opioid use during early recovery from rib fractures.

2.2 Research Question

Do adult patients with isolated rib fractures who receive an mHealth intervention (PainSupport, consisting of a brief pain self-management educational video and twice daily supportive SMS text messages for 14 days), in addition to usual care, report less pain intensity on respiration during their early recovery (measured Days 1-7 and Day 14; primary outcome), higher engagement with pain self-management strategies, and less distress and opioid use (secondary outcomes) compared with those who receive only the brief educational video in addition to usual care (active control)?

3 STUDY OBJECTIVES

3.1 Primary Objective

To evaluate the efficacy of the mHealth intervention (PainSupport) in reducing pain intensity on respiration during early recovery from rib fractures (Days 1-14).

3.2 Secondary Objectives

a) To evaluate the efficacy of the PainSupport (vs. active control) in reducing reliance on opioids during early recovery from rib fractures.
b) To evaluate the efficacy of PainSupport (vs. active control) in reducing pain-related distress during early recovery from rib fractures.
c) To evaluate the feasibility and acceptability of the educational video and SMS text messages
d) To explore mechanisms of action and predictors of response to the PainSupport

4 STUDY DESIGN

4.1 Type of Study

A double-blind randomised controlled trial with two parallel arms

4.2 Study Design

This is a double-blind randomised controlled trial with two parallel arms (ratio 1:1). The study is designed to test the primary hypothesis which is the superiority of receiving (in addition to usual care) an mHealth intervention consisting of an educational video and daily SMS vs. active control (video only in addition to usual care) in reducing pain intensity.

There is no gold-standard 'placebo' control for digital health interventions and designing a sham or placebo is challenging in this field. Using an active control condition in the current study will allow us to achieve blinding and investigate whether the observed effects can be attributed to a specific component of the digital support (i.e., daily text messages). Moreover, using an active control will reduce the chance of unblinding and will limit bias due to imbalanced co-intervention and bias in measuring the outcomes by the outcome assessors. Using an active control condition may also help to reduce the risk of dropouts and missing data. Importantly, the active control condition (i.e., the educational video) is likely to benefit participants. Educational videos have been shown to improve proximal outcomes including perceived tapering effectiveness and tapering self-efficacy (Feng et al., 2021) and can promote health behaviour change (Henry et al., 2021).

Mixed-method evaluations in this study will allow us to gather deep insight into the feasibility and acceptability of each component of the mHealth intervention, while repeated measures will provide the opportunity to better explore trajectories of change.

4.3 Number of Participants

120 adult patients with isolated rib fractures within one day of admission to the hospital will be recruited.

4.4 Expected Duration of Study

Expected time period for the recruitment of patients: 12 months.
Expected start date: as soon as the protocol is approved.
Expected stop date: 12 months after approval.

4.5 Primary and Secondary Outcome Measures

Please see Appendix A for full list of study questionnaires.

4.5.1 Primary outcome

Patient-reported pain intensity on respiration: Assessed daily for seven days after study enrolment (days 1-7) and again on Day 14 (end of the trial). Patients will be asked to take a deep breath report their pain using an 11-point numerical rating scale (0 = No pain, 10 = Worst pain imaginable) (Farrar er al., 2001). Assessment of pain intensity using a numerical rating scale has been supported in prior studies (Cook et al., 2013).

4.5.2 Secondary outcomes

Opioid use: Assessed daily during hospitalisation (extracted from health records) and again on Day 14 (self-reported use). Opioids used will be converted to an oral morphine equivalent daily dose using the ANZCA opioid converter (http://www.opioidcalculator.com.au). Opioids prescribed at discharge will be retrieved from medical records.

Pain-related distress: Assessed on days 1-7 and Day 14 after study enrolment using the 2-item Concerns about Pain Scale (CAP-2, short version; Amtmann et al., 2020) a new measure of pain catastrophising developed using modern psychometric methodology. Pain catastrophising is a term which captures patterns of negative cognition (worry, concern) and emotion (distress) in the context of actual or anticipated pain. Because the term “catastrophising” is considered stigmatising by people with chronic pain (Webster et al., 2022), we will use the phrase “pain-related distress”. We modified the instructions for this scale from “in the past 7 days” to “in the past 24 hours” to better fit with the acute pain context.

Patient-reported adherence to behavioural pain management strategies: Assessed on Day 7 and 14 after study enrolment using a single self-report item (6-point Likert scale): “How often are you using the strategies you learned in the video that you watched when you enrolled in the study to help you to manage your pain?” (1 = Not at all, 2 = A couple of times in the week, 3 = Every couple of days, 4 = Once a day, 5 = A couple of times a day, 6 = Several times a day).

Acceptability of intervention components: Assessed using a survey at the end of the study period. The survey design was based on previous studies conducted by our research team (Magee et al.,

2022a) and contains Likert scales and open-ended questions about the usefulness, readability, and acceptability of the digital support.

Feasibility of intervention components: Evaluated at the end of the study according to the number of messages delivered/not delivered which will be recorded automatically by the text message system. We will also report on (1) the number of candidate participants who were excluded and reasons for exclusion; (2) the number of eligible candidates who chose not to enter the trial; (3) all protocol deviations that may impact the interpretation of the trial results; (4) the number of withdrawals from each treatment group, including patients lost to follow up, and the reasons for withdrawals if known; and (5) the types, rates, and reasons for non-adherence with treatment in each treatment group (e.g., not watching the video). This information will either be recorded by the hospital staff handling recruitment or the Chief Investigator.

Other study measures

Engagement with the video: Assessed using a study-specific questionnaire shortly after participants receive the link to the video. Participants will asked to confirm they have watched the video by answering two questions about the content of the video.

Engagement with the text messages: On Day 15 Participants in the intervention group will be asked whether or not they read the text messages they were sent during the study.

Participant characteristics: Psychosocial characteristics including history of pain and medication use, cause of injury, context of injury, perceived fault of injury, history of rib fractures, and social support will be recorded at the beginning of the study (Day 0), as will baseline pain intensity and pain-related distress. Socioeconomic characteristics including education, language spoken at home, and place of usual residence (postcode) will be self-reported at the end of the study (Day 15) to reduce burden associated with the baseline survey. Clinical data (number of rib fractures, location of rib fractures, comorbidities, pain management plan, date and time of admission, age, and gender) will be extracted from hospital records by AI Finniss or AI Doane who are both staff specialists in the Department of Anaesthesia, Pain and Perioperative Medicine at the RNSH.

5 STUDY TREATMENTS

5.1 Treatment Arms

Pilot testing

The video and text messages used in this trial (see Appendix B) will be adapted from an intervention co-designed with people living with pain who were tapering off opioids as well as clinicians with expertise in pain management (Magee et al., 2022b). We will adapt a selection text messages that may be appropriate for people with rib fractures. A convenience sample (i.e., people known to the research team from social networks) of up to five people who have experienced rib fractures will be asked to rate a draft of the video script and text messages for appropriateness and usefulness on a scale from 0 to 10, and provide open-text feedback. The 24 texts with the highest ratings will be

included in the SMS library for this trial (provided they are evaluated as 8/10 or higher on average). If there are not enough text messages with ratings of 8 or higher, the process will be repeated with additional text messages.

Usual care

Participants in both groups will continue to receive usual care throughout the study period. Usual care in this context is multidisciplinary with a focus on maximising non-opioid analgesia while encouraging pulmonary hygiene. It may include incentive spirometry, high flow nasal prong oxygen, and/or multimodal analgesia (including patient-controlled analgesia).

Intervention group (video + text messaging)

The target intervention is composed of a brief pain self-management education video in combination with twice daily supportive text messaging, in addition to usual care.

Pain self-management education video. Participants will view a video resource containing brief, evidence-based pain self-management education. The video will be approximately 10 minutes in duration and will include narrated, animated PowerPoint slides with information on behavioural pain management strategies (e.g., relaxation techniques, thought management, distraction, and social support seeking) as well as education about rib fractures (e.g., reasons for pain, the importance of mobilising the lungs when breathing, timeline of recovery), and validation about the difficulty associated with breathing deeply with a rib fracture. Participants will receive the link to the educational video after randomisation (Day 0) via their mobile phone. The video will also contain instructions for how to perform the pain on respiration test (used throughout the study to measure pain intensity) correctly.

Supportive text messaging. Participants will receive supportive text messages daily to reinforce the information provided in the video described above. Starting from Day 1, participants will receive text messages (2/day, mid-morning and mid-afternoon) for 14 days. The text messages are designed to remind patients of behavioural pain management strategies and the value of using them (e.g., “Talking or texting with friend has been found to reduce pain and pain-related distress”), reinforce the importance of optimising inhalation to mobilise the lungs (e.g., “If you inhale deeply, your lungs will stay healthy and free from infection”), and provide patients with validation and reassurance (e.g., “Rib fractures are surprisingly common. We know they can be very painful in the short term, but we also know that this will pass. Hang in there.”).

The messages sent to the participants are standardised in their content and delivery (by day of study and by the time of day). All text messages are short and use simple language. Participants’ first names are used in a selection of messages to increase engagement (e.g., “Hi John,”). Messages will be sent over Australian telephone networks at no cost to individual participants. Messages will be sent between 9 AM and 5 PM (local time).

Participants will be informed that the text messages are designed to be one-way and that responses to the text messages will not be monitored by the research team in real time. However, they can cease receiving text messages by contacting the chief investigator (by email, as per the consent form and study information; See Appendix C), who will give participants the option of withdrawing from the study if they wish. If withdrawing from the study, no further assessment will be sent to the

participant. A sensitivity analysis will be conducted to account for adherence (i.e., excluding participants who stop receiving text messages).

Participants will be informed that they must not access their text messages whilst driving or walking near traffic or other hazards, to ensure their safety and abidance by the State Government laws.

Control group (video only)

Participants in the active control group will receive the same video delivered to participants in the intervention group. The active control group will not receive additional supportive text messages. However, they will receive text messages containing links to brief online surveys containing study outcome measures. Consequently, the intervention and active control groups will both expect and receive text messages (supporting double-blinding).

5.2 Measurement of participant compliance

Engagement with the video will be assessed using a study-specific questionnaire shortly after participants receive the link to the video (See Appendix A). Participants will be asked whether or not they watched the video, and if they can recall information from the video.

Engagement with the text messages will be assessed using a using a study-specific questionnaire at the end of the study (See Appendix A). Participants will be asked whether or not they read the text messages sent to them throughout the study.

Participants in both groups will receive all scheduled messages unless they choose to opt out of text messages or withdraw from the study. Delivery of messages will be recorded automatically on the text messaging system. If a message was not delivered, a second message will be sent.

6 PARTICIPANT ENROLLMENT AND RANDOMISATION

6.1 Recruitment

Eligible patients will be identified by daily assessment of emergency admission notes and referrals to the acute pain service for assistance in management. Patients who are eligible to participate will be invited to join a “study examining factors influencing pain and recovery from rib fractures” by a member of the acute and transitional pain service team (i.e., either a pain nurse, registrar, or consultant) within one day of admission. They will be told the study involves receiving text messages from the research team. Members of the acute and transitional pain service team will be responsible for checking eligibility either by consulting patient medical records or discussing with patients. Patients who express interest in the study will be provided with a QR code to scan with their mobile phone as well as a hard copy of the participant information sheet and consent form (PISCF) to take home. The QR code will link patients to online study information (PISCF), formatted to be read on a mobile phone device (using the Qualtrics online survey platform). Hospital staff will not be notified of whether eligible patients choose to participate or not.

6.2 Eligibility Criteria

6.2.1 Inclusion Criteria

- Over 18 years of age
- Admitted to hospital with isolated rib fracture in last 24 hours
- Capable of reading and understanding basic English
- Capable of understanding study information and providing consent
- Own a mobile phone and be able to use the phone during hospitalisation

Able to read text messages on mobile phone device

- Able and willing to complete survey measures on mobile phone device

6.2.2 Exclusion Criteria

- Inability to complete study procedures (lack of fluency in English, cognitive ability, mental health status, medical status)
- Admission to hospital with other injuries or comorbidities (head, extremity, lung and abdominal trauma)
- NSAIDs contraindicated
- Regional anaesthesia or blockade is likely to be used for pain management.

6.3 Informed Consent Process

Participants will be informed (via the PISCF, See Appendix C) that they will be randomly allocated (like tossing a coin) into two groups using computer-generated randomisation. They will be informed that both groups will receive digital support. They will be informed that the study aims to evaluate whether digital support can improve outcomes in patients with rib fractures.

Participants will be advised that their healthcare providers will not be aware of which intervention group they have been assigned to, and they will continue to receive usual care. As part of their participation in the study, patients will be advised that they will receive text messages. Participants can indicate their consent to participate in the trial online, by typing a statement of consent and checking off boxes to indicate that they have a) read and understood the study information, and b) understood that they can withdraw from the study at any time without implications for their healthcare by emailing the Chief Investigator Claire Ashton-James.

Participants will be informed that their consent includes permission for the researchers to keep identifiable information about them (name, mobile phone number, and email address) on the University of Sydney's secure server for the duration of the study because these identifiable data are required for sending emails and text messages. This data will only be accessible to the research team members. It will be emphasised that the identifying data will not be used for any purpose other than as stated for this study. Participants will be informed that the study involves daily surveys and the estimated time it takes to complete these surveys.

Consent to participate will only be accepted if the patient accesses the online consent form and completes all mandatory fields before submitting. The participant will be considered to have consented to participate in the trial once the consent form has been submitted correctly.

6.4 Enrolment and Randomisation Procedures

Participants who have provided informed consent, will automatically be enrolled in the study. Once they complete the consent form, they will be directed to the baseline survey and video (also hosted on Qualtrics). As part of the baseline survey, participants will be asked to provide their contact information (name, phone number, email). Participants will also be asked to create a unique identifier which they will use throughout the study (to link participant data). The unique identifier will be based on the first three letters of the street they currently live in and the day (dd) and month (mm) of their birthday (e.g., for a participant who lives in Columbia St, who is born 01/05/1980, their study ID would be COL0105). Participants will be asked to enter their seven-digit unique ID and reminded of the format at the beginning of every survey.

Once enrolled, participants will be randomised (1:1 allocation) to either the intervention (video plus supportive text messages) or active control (video alone) group in blocks of six. Block randomisation will be used to ensure the study groups are balanced. A research team member will be responsible for randomising patients and programming text messages for delivery. They will automatically be notified via Qualtrics when a new participant enrols in the study. They will randomly allocate participants to a study group based on a randomisation table provided by the Chief Investigator and generated using Research Randomizer (https://www.randomizer.org/). The randomisation table will include 20 sets of 6 randomly generated *unique* numbers between 1 and 6 (e.g., Set #1: 1, 2, 5, 4, 3, 6; Set #2: 6, 1, 5, 3, 4, 2; Set #3: 4, 5, 6, 1, 2, 3). Odd numbers will denote intervention group and even numbers will denote control group. Therefore, in the above example, the first six participants will be allocated as follows: intervention, control, intervention, control, intervention, control. The second six participants will be allocated as follows: control, intervention, intervention, intervention, control, control. The member who is aware of the group allocation will not be involved in recruitment, data collection or analysis after randomisation to prevent bias. Once the participant has been randomised, the member will then program the text messages accordingly with delivery starting the following morning.

6.5 Blinding Arrangements

Participants, their clinicians, research team members (except the member who manages text messaging and the Chief Investigator who will monitor data collection and manage withdrawal from the study), and statisticians are all blinded to the group allocation.

Participants in both the intervention and active control groups receive their treatments online, via their mobile phone device, and all participant-reported data are collected online. There is limited in-person contact clinicians involved in the study and participants will be asked not to talk about the content of the text messages with doctors or other staff at the hospital.

The statistician will be blinded to the group allocation. At the end of the study, a group variable will be added to the study database and each group will be labelled as A or B before it is sent to the statistician for statistical analyses. Groups will be unblinded after all analyses comparing groups are complete.

Participants will be informed by the PISCF (Appendix C) that they will be randomly allocated into two groups. They will be informed that both groups will receive digital health support. They will be informed that the study aims to evaluate whether digital supports can improve health outcomes in

patients with rib fractures. This "limited disclosure" of the between-group difference (i.e., study hypothesis) is required to maintain double-blinding and to achieve the main objective of the research in evaluating the efficacy of receiving daily text messages. To comply with the National Statement on Ethical Conduct in Human Research (2018), this limited disclosure does not involve deception. This method is recommended for "Improving Blinding Integrity and Reporting in Psychotherapy Trials" (Mataix-Cols & Andersson, 2021) and has previously been used in similar studies (TEXT4myBACK, NSLHD HREC ETH 13895, ANZCTR: 12618001263280; Fritsch et al., 2021; Magee et al., 2022a). The research involves no more than low risk to participants and limited disclosure does not increase the risk since after randomisation and before receiving the digital support, participants in both groups will become aware of the details of the digital support that they will receive.

6.6 Breaking of the Study Blind

6.6.1 On Study

This is a 'negligible risk' study and breaking the study blind is not expected to be required. However, patients are asked not to disclose the details of the digital support they are receiving unless it is directly requested by their doctor or a research team member or they decide to do so for safety reasons.

6.6.2 Following Completion of the Study

Once the final participant has completed the assessments, the Chief Investigator will divide the assessments into the two treatment arms (labelled as A/B) and provide them to the statistician for analysis. The statistician will remain blinded to the treatment arms until all the analyses comparing groups are finalised per the analysis plan.

6.7 Participant Withdrawal

6.7.1 Reasons for withdrawal

The possible circumstances that may lead to participant withdrawal include:

- Health and Safety
- Non-compliance
- Lost to follow-up
- Consent withdrawn

6.7.2 Handling of withdrawals and losses to follow-up

The Chief Investigator may remove a research participant from the study at any time in the event the participant's safety may be compromised such as the following:

- any unanticipated health problems
- the participant is non-compliant with the study protocol/procedures
- the Chief Investigator determines that it is in the best interest of the participant to be removed from the study.

Note: Criteria for participant removal by the Chief Investigator are outlined in the PISCF

Participants retain the right to withdraw from the study at any time and can choose whether the study will delete or retain the information it has collected up to the point that the de-identified data has been analysed and published. This can be done by informing the Chief Investigator, Claire Ashton-James, and completing the online withdrawal form. The reason for withdrawal (not mandatory to report), along with the time point at which they withdrew, will be recorded in the withdrawal form.

Participants can also withdraw from receiving the text messages at any time during the study emailing the Chief Investigator as outlined in the consent form and study information (Appendix C). The Chief Investigator will ascertain if the participant is fully withdrawing from the study or withdrawing from receiving text messages (i.e., will continue to complete follow-up data collection).

Strategies to maximise follow-up data collection adherence and prevent missing data will include email and text messages by study staff following the data collection due date if not completed. For participants who withdraw their consent or are lost to follow-up, available data will be included in an intention-to-treat analysis.

6.7.3 Replacements

We have estimated a 15% drop-out rate in the calculated sample size for recruitment. No replacement will be required if the drop-out rate is less than 15%. If the drop-out rate is greater than 15%, we will continue recruitment until we reach 102 study completers.

6.8 Trial Closure

No follow-up will be conducted after 14-days of participation in the study. The last data to be collected is the feedback survey at the end of the study (Day 15).

6.9 Continuation of therapy

Participants will not receive supportive text messages after 14 days but can access the video (via the link they were sent) and save the messages on their mobile phone. Participants will continue their usual care with their clinicians.

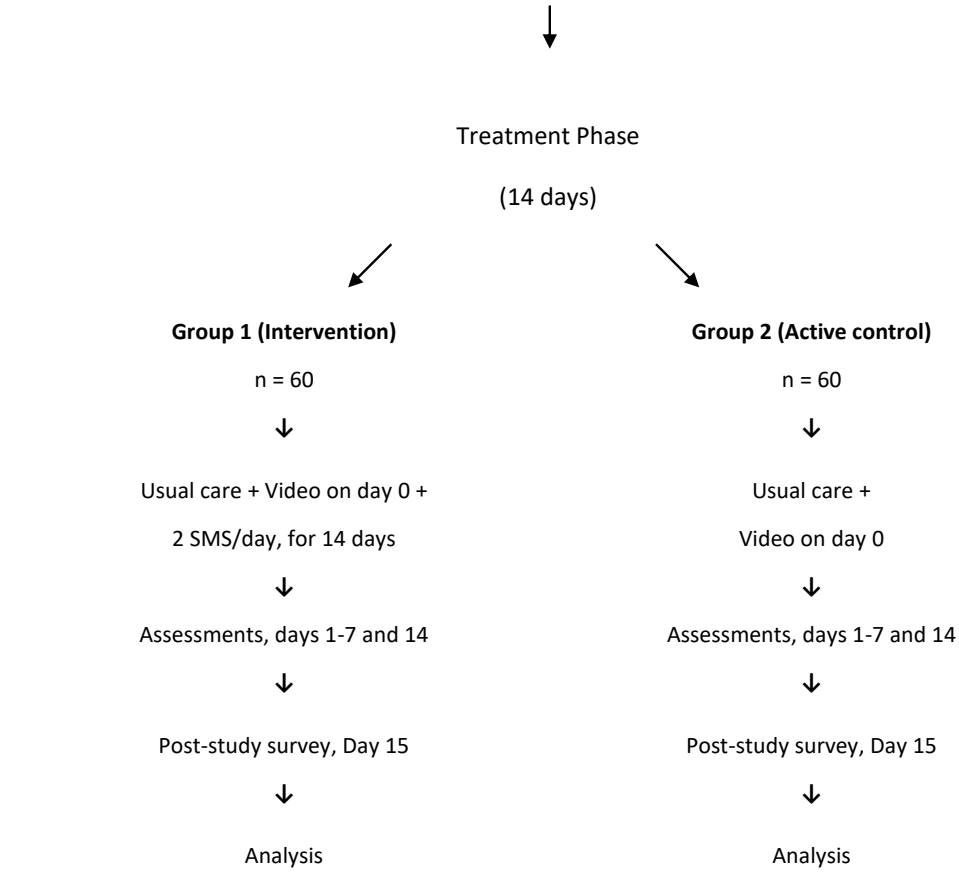
7 STUDY VISITS AND PROCEDURES SCHEDULE

Study Flow Chart

Enrolment

↓

Randomisation



	Day 0	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 14	Day 15
Eligibility screening	✓									
Informed Consent	✓									
Baseline survey	✓									
Video	✓									
Pain assessment (NRS)	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Opioid use from hospital records		✓	✓*	✓*	✓*	✓*	✓*	✓*		
Self-reported opioid use									✓	

Distress assessment (CAP-6)	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Adherence to strategies								✓	✓	
Engagement with video	✓									
Engagement with text messages										✓
Feedback survey										✓

* Opioid use will be extracted from hospital records until the date of discharge. The duration of hospitalisation may vary between participants.

8 CLINICAL AND LABORATORY ASSESSMENTS

All assessments are based on self-administered questionnaires and technical data collected from the SMS and data collection software.

9 SAFETY REPORTING

The research described in this protocol is 'negligible risk research', with no foreseeable risk of causing harm or discomfort; the only foreseeable risk is the inconvenience of completing the study questionnaires. In particular, the digitally delivered support (educational video and supportive text messages) is not expected to cause any physical harm, anxiety, pain, psychological disturbance, devaluation of personal worth, or social disadvantage to participants.

Participants in both arms will continue to work with their physicians and other health practitioners on "usual care". Participants are advised if they experience any medical concern, they should contact their treating doctor/clinician as part of their usual care component.

10 STATISTICAL METHODS

10.1 Sample Size Estimation

Sample size was calculated using the online app GLIMMPSE (General Linear Mixed Model Power and Sample Size v 3.0) for testing the overall main effect (i.e., group) with 7 days repeated measures post-intervention (day 1 to 7). The study was powered to test for mean differences in pain intensity on respiration (primary outcome). We set a power threshold of 0.8, a two-tailed alpha of 0.05, standard deviation (SD) of pain at 2.5, and SD ratio at 1.5 over 7 days. Accordingly, we estimate the

need for 51 patients per group to detect a 1.3 (out of 10) difference, in overall, in pain intensity. This is the minimum clinically important difference (MCID) for average pain levels (4 to 7 out of 10) in acute pain (Olsen et al., 2017). With 15% estimated dropouts, we will recruit 120 patients.

10.2 Population to be analysed

The participants in the two treatment arms will be compared.

10.3 Statistical Analysis Plan

All analyses will be blinded to the group status. Descriptive statistics of demographics and other baseline variables will be reported. To address the study primary hypothesis, which is an overall lower pain intensity 7 days after randomisation, a marginal mixed model analysis will be used, evaluating the main effect of the group (intervention vs. active control). Model statement (e.g., whether to include Day 0 pain as a covariate in the model) and parameters (e.g., covariance structure) will be determined based on the fit statistics and distribution of residuals. Marginal model will also be used for comparing opioid use and distress (measured over 7 days) and adherence (measured at days 7 and 14) between the two groups. Data will be transformed to approximate residuals to normality if required. Analysis of covariance (ANCOVA) will be used for comparing pain at Day 14 between the groups while including pain at Day 0 a covariate in the model. Linear mixed models will be used to explore the differences in outcome trends recorded over the 7 days after randomisation. Other outcomes will be compared between the two groups using independent t-Test (or Mann-Whitney Test). All analyses will be conducted using SAS software (v 9.4), and a per-protocol and intent-to-treat analyses (all randomised participants will be included in the analyses) will both be conducted, to minimise bias secondary to missing data or dropouts. Where applicable, results will be reported with 95% confidence intervals, with an alpha of 0.05 used to establish statistical significance.

10.4 Interim Analyses

There will be no interim analyses.

11 DATA MANAGEMENT

11.1 Data Collection

Outcome measures will be completed online via Qualtrics software. The links to the Qualtrics surveys will be sent to participant's mobile phones. If participants do not respond to measures sent by SMS on days 14 and 15, they will be sent a reminder text message.

11.2 Data Storage

For data collected online via Qualtrics, all data will be automatically saved in the Qualtrics database on the University of Sydney (multifactor authentication) secure cloud storage. Only the Chief Investigator and the team member who manage text messaging have access to the Qualtrics database. Access to Qualtrics is through their University of Sydney password-protected user account

and they will access Qualtrics via their University of Sydney owned password-protected computer. To ensure participants' privacy is protected, when exporting data from Qualtrics for analysis, no identifiable data will be exported. Also, no participants IDs will be stored in exported data, therefore the stored data cannot be re-identified out of Qualtrics. Any exported data will be in password-protected spreadsheet stored on a computer owned by the University of Sydney to ensure data security.

Data within the SMS software (name, phone numbers, messages) will be deleted after being exported at the study closure. Exported data will be stored in password-protected spreadsheet on a computer owned by the University of Sydney to ensure data security.

11.3 Data Confidentiality

Patients' privacy will be protected for archiving, storage, and publication. We are recording their name, mobile phone number, and email address but no other identifying data such as the exact dates of birth, addresses, country of birth or other sensitive information such as medical diagnoses (beyond what is required for the participation in this study), Aboriginality or sexual orientation. While the data are being collected via Qualtrics, the participants would be identifiable in the Qualtrics database as this is required during the study. When exporting data from Qualtrics for analysis, identifiable data including unique IDs will be deleted so that the exported data cannot be linked to identifiable data out of the Qualtrics database. No identifiable information will be used in publications and dissemination of the results.

11.4 Study Record Retention

The data will be retained for a minimum of 15 years from the publication of the project's final report.

12 ADMINISTRATIVE ASPECTS

12.1 Independent HREC approval

This study will be submitted to the NSLHD HREC.

12.2 Amendments to the protocol

Any amendments will be submitted to the HREC for review prior to implementation as per HREC guidelines.

12.3 Serious Breach Reporting

Serious Breaches will be submitted to the HREC for review.

Serious Breach definition; A breach of Good Clinical Practice or the protocol that is likely to affect to a significant degree;
a) The safety or rights of a trial participant, or
b) The reliability and robustness of the data generated in the clinical trial.

Serious breaches will be reported by the sponsor through the principal investigator within 7 calendar days of the breach. The breach will be submitted as a general amendment via Regis.

12.4 Participant reimbursement

There is no reimbursement for participation in this study as indicated in the PISCF (Appendix C).

12.5 Financial disclosure and conflicts of interest

The study is supported by a Ramsay Research Grant. There are no conflicts of interest.

13 USE OF DATA AND PUBLICATIONS POLICY

The results of this study will be presented at scientific meetings and submitted to peer-reviewed scientific journals for publication. There will also be dissemination of results back to the participants (if they request), in the media, and to the policy makers where relevant (e.g., for implementation of the digital support program).

Authorship of scientific publications from this study will be according to the target journals' 'Information For Authors' guidelines. The Ramsey Research Foundation, University of Sydney, Kolling Institute and NSLHD and their roles will be acknowledged in the publications.

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