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Emotional awareness and expression therapy (EAET) for chronic pain following traumatic orthopaedic injury and surgery: study protocol for a single-arm feasibility clinical trial

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ABSTRACT

Background Nearly half of individuals who sustain orthopaedic trauma develop chronic pain and experience significant levels of depression and anxiety. Emotional awareness and expression therapy (EAET) is a newly developed psychological intervention designed to treat chronic pain by helping patients process psychological trauma and conflict to reduce pain. The purpose of this study is to examine the feasibility of delivering EAET to individuals who sustained traumatic orthopaedic injuries requiring surgery and who have chronic pain 6 months after hospital discharge.

Methods and analysis The study will consist of a single-arm design. Thirty individuals who sustained traumatic orthopaedic injuries requiring surgery and who reported chronic pain 6 months after hospital discharge will be recruited. Participants will receive eight sessions of individually administered EAET delivered via telehealth and complete self-report questionnaires at three timepoints (pretreatment, post-treatment and 3-month follow-up). Quantitative sensory testing will also be done before and after treatment. The primary outcome of the study is feasibility (eg, per cent of eligible patients recruited and per cent of study completers) and acceptability as reported by responses to a self-report questionnaire.

Ethics and dissemination This study has been approved by the Johns Hopkins Institutional Review Board. All data are expected to be collected by 2026, with results of this study to be disseminated via relevant peer-reviewed journals and scientific conferences.

Trial registration number ClinicalTrials.gov NCT05989230. Registered on 14 August 2023.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Delivering emotional awareness and expression therapy (EAET) via telehealth will increase access to this intervention among individuals who sustained traumatic orthopaedic injuries requiring surgery.
⇒ An advisory board of adults with lived experience of orthopaedic trauma will be engaged throughout the duration of this study in order to enhance the relevance and acceptability of EAET in this clinical population.
⇒ The study will use both patient-reported outcomes of pain and quantitative sensory testing.
⇒ As a feasibility study, this trial will not be sufficiently powered to detect the efficacy of EAET in individuals with orthopaedic trauma.

INTRODUCTION

Orthopaedic trauma occurs in around 3 million people annually in the USA,[1] resulting in injuries that require surgical intervention and hospitalisation, such as the repair of multiple fractures. At the time of discharge, pain and distress are common, as is an opioid prescription for acute pain.[2 3] For many people, however, pain and psychological distress persist. In fact, in the year following trauma, nearly half of the patients experience chronic post-traumatic or postsurgical pain,[4 5 6] around half of the people experience significant symptoms of depression or anxiety[4] and a fifth meet criteria for post-traumatic stress disorder (PTSD).[5 7 8] Psychological distress relates to greater opioid use, and a third of patients will rely on prescription opioids 2 months post-trauma.[2 9] In the first year after trauma, pain and distress relate to and exacerbate one another,[10] contributing to long-term disability.[7 11–13] At 7 years post-trauma, nearly half of the patients continue to report significant pain and disability.[13 14]

Psychological interventions are needed to effectively treat chronic pain and psychological distress following orthopaedic trauma. Although low-intensity interventions (e.g., provision of an education handbook and coaching calls) can be widely disseminated and result in small improvements in pain and distress following orthopaedic trauma,[15–17] people with clinically significant symptoms

of pain and distress likely require intensive psychological intervention.[12] Our recent systematic review and meta-analysis showed that only a few psychological interventions are available to treat pain following orthopaedic trauma and those that are available have limited efficacy for improving pain outcomes.[18]

Emotional awareness and expression therapy (EAET) is a psychological intervention recently developed to treat chronic pain. EAET is explicit in assessing psychological trauma, which can lead to and exacerbate chronic pain,[19 20] with the goal of increasing awareness of avoided yet adaptive emotions that are often linked to stressful past experiences and developing adaptive ways to process—experience, express and release—those emotions in a therapeutic environment.[21] This approach may be ideal for people with chronic pain following orthopaedic trauma and surgery. First, exposure to stressful and life-threatening events—such as major injury, hospitalisation and surgery—is ubiquitous and likely to result in psychological distress. Moreover, people who sustain orthopaedic trauma tend to be characterised by elevated psychosocial complexity, such as high rates of substance use,[22] which can confer risk for injury (eg, driving under the influence) and stem from previous lifetime stress or trauma. Compared with other available psychological treatments for pain [e.g., cognitive behavioural therapy (CBT)], EAET is unique in targeting both current and past stressful life events. Three recent trials have shown that compared with CBT, EAET resulted in greater improvements in pain intensity[23–25] among people with chronic musculoskeletal pain or fibromyalgia. One trial found that the effects of EAET versus CBT were stronger among people with greater symptoms of depression, anxiety and PTSD,[25] further highlighting its relevance for the orthopaedic trauma population, for whom these symptoms are common. However, EAET has not yet been tested in adults who have chronic pain after traumatic orthopaedic injuries requiring surgery. Significant documented barriers may prevent the orthopaedic trauma population from engaging in psychological intervention, including fear of stigma and shame,[26] low utilisation of available mental health resources[16 17] and limited integration of mental healthcare into orthopaedic care.[27] Thus, establishing the feasibility of EAET in this population is a first step in determining its efficacy for improving pain-related outcomes in people with chronic pain after traumatic orthopaedic injuries requiring surgery.

The present study

The current paper presents the protocol for a study evaluating the feasibility and acceptability of an 8-week telehealth-delivered course of EAET for individuals who sustained traumatic orthopaedic injuries requiring surgery and have chronic pain 6 months after hospital discharge. We will assess the feasibility of recruiting eligible patients from an orthopaedic trauma clinic and retaining patients through the trial (to 3-month follow-up assessment). Patient adherence and therapist fidelity will also be assessed to determine feasibility, and treatment satisfaction will be used to assess treatment acceptability.

METHODS

Overview

This study will use a single-arm within-group study design. Thirty total participants with chronic pain 6 months after hospital discharge will be recruited from an orthopaedic trauma clinic during a routine postoperative clinic appointment. Participation in this study will involve completing 8 weekly sessions of EAET within a 12-week window and completing assessments at pretreatment, immediately post-treatment, and at a 3-month follow-up. Pretreatment and post-treatment assessments will be comprised of a combination of online self-report questionnaires and in-person quantitative sensory testing (QST). The 3-month follow-up assessment will be comprised of online self-report questionnaires only. Five participants will be used to pilot the initial study protocol and treatment manual in order to identify opportunities to improve study materials. The remaining 25 participants will receive the finalised EAET intervention and related assessments. Participants will receive payment for completing study assessments and EAET sessions.

Patient and public involvement statement

We have assembled an advisory board of adults with lived experience of orthopaedic trauma who will be engaged throughout the duration of this study, from study planning to dissemination.

Screening and recruitment

Screening for eligibility will occur in two phases. In the first phase, screening and recruitment will take place at routine postoperative appointments in the weeks and months following injury. In the second phase, screening will take place approximately 6 months after hospital discharge, with the goal of assessing for the presence of chronic pain.

To determine phase 1 eligibility, a member of the research team will complete a prescreening review of the medical records of patients scheduled to be seen in an orthopaedic trauma clinic. Eligibility will be confirmed with the treating surgeon, who will introduce the study to the patient and obtain permission to meet with a member of the research team for additional information. After their clinic appointment, interested participants will then be approached by a member of the research team for recruitment and to obtain informed consent. Participants can be screened for Stage 1 eligibility up to 6 months post-trauma. In phase 1, inclusion criteria will include (1) a history of one or more orthopaedic injuries, (2) having undergone an operative fixation for at least one acute orthopaedic injury, (3) initial admission to the recruiting trauma or orthopaedic centre and (4) aged 18 years or older. Exclusion criteria will include (1) injury managed non-operatively, (2) moderate to severe traumatic brain

injury, (3) major amputations of lower extremities, (4) history of dementia or Alzheimer's disease, (5) history of neurological disorder resulting in cognitive and/or physical impairment (eg, prior stroke), (6) pregnant, due to concerns about QST testing, (7) non-English speaking and (8) expected problems maintaining follow-up (eg, relocating outside of the hospital catchment area).

To determine phase 2 eligibility, a member of the research team will contact previously enrolled patients to determine continued eligibility via interview. Patients who meet full eligibility criteria will be invited to enrol in the EAET treatment. Inclusion criteria include (1) the presence of pain most days (>3 days/week) for the past 3 months and (2) an average of ≥4/10 past week pain severity as assessed by the Brief Pain Inventory (BPI).

The goal of the two-phase screening process is to recruit patients early in the course of their routine postoperative care to minimise the bias associated with recruiting only patients who are compliant with routine care (ie, patients who attend the 6-month follow-up clinic visit). This is particularly important in this population, in which adherence to routine clinical care declines significantly over time.[28] In addition to the above strategies, we will also contact previous research participants who agreed to be contacted for future research.

Procedures

EAET intervention

The EAET intervention will be delivered via 8 weekly visits by doctoral-level clinical psychologists with specialisation in chronic pain. Study therapists will complete a 15-hour EAET training, attend monthly case consultation meetings and will have access to additional case consultation when necessary. The first session will be 90 min in length, and each subsequent session will be 60 min in length. Sessions will be delivered in a one-on-one format using Health Insurance Portability and Accountability Act-compliant videoconferencing software.

Consistent with previous EAET interventions among other chronic pain populations,[23 24] the planned EAET intervention incorporates: (1) psychoeducation about the role of the brain in generating and amplifying pain; (2) assisting participants in identifying connections between stress, interpersonal conflicts and their current pain symptoms; (3) helping participants face emotion-laden situations by having them recognise, experience and express core emotions; (4) encouraging participants to face and express emotions associated with existing interpersonal conflicts; and (5) having participants express needs and feelings in their existing relationships outside of session.

Table 1 Weekly emotional awareness and expression therapy session content

Week	Topic	Content
Introduce the treatment model and identify targets of intervention		
1	Introduction to Treatment; Pain Neuroscience Education Part I	Introduce treatment format, assess pain history, introduce pain neuroscience model for chronic pain postinjury and surgery
2	Pain Neuroscience Education Part II; Identifying Stressors	Learn how stress can impede recovery from pain after injury, Identify sources of stress in your life, draw associations between pain, stress and emotions.
Skill in Action: Practice Emotional Awareness and Expression through Structured Activity		
3	Core emotional needs and defenses that maintain and intensify pain in the brain	Learn how emotional avoidance can lead to sensitised neural pain processing. Promote positive feelings towards oneself and discuss need for agency/power and connection/vulnerability.
4	Experiencing, expressing and releasing emotion related to *present* stressors	Learn how current stress can maintain pain; engage in experiential emotional expression related to a current conflictual relationship.
6	Experiencing, expressing and releasing related to *past* stressors	Learn how lifetime stressors can enhance the brain's threat response and intensify pain and engage in experiential emotional expression related to early life adversity or injury.
5	Experiencing, expressing and releasing related to *past* stressors	Learn how positive relationships and intimacy can protect against pain and structured experiential exercises to express intimacy and/or grant forgiveness.
7	Healthy communication in relationships	Introduce and practice healthy communication strategies and structured exercises to increase gratitude.
Wrapping up Treatment and Planning for the Future		
8	Planning for the future	Review lessons learnt in treatment, identify progress made, discuss barriers to recovery moving forward and develop a positive plan for the future.

The main content and skills covered in each session are outlined in table 1.

Baseline characteristics

Participants will report demographic information, including race, ethnicity, education, household income and marital status at T1. They will also provide information about substance use and a history of chronic pain prior to injury. Injury characteristics will be extracted from the medical record, including injury type(s), primary mechanism of injury, opioid prescriptions at the time of hospital discharge and length of hospitalisation. We will also assess the Injury Severity Score for all participants in order to obtain a standardised metric of the severity of traumatic injuries.

Primary outcomes

Feasibility

Recruitment feasibility will partially be determined by the level of participation throughout the study, including study enrolment rate and assessment completion rate at post-treatment and 3-month follow-up. Rates and reasons for ineligibility and attrition will also be collected. Target recruitment feasibility will be defined as enrolling 50% of eligible patients and having less than 20% study dropout from enrolment to 3-month follow-up. Treatment fidelity, as determined by the treatment component checklist, will also be used to confirm that the therapy is being delivered as intended. Study therapists will complete a treatment component checklist after each session of EAET. Sessions will be audio-recorded, and 20% of sessions will be randomly selected and reviewed by a non-study therapist who will complete an additional checklist. Target treatment fidelity will be defined as delivering an average of 80% of treatment components as assessed by the treatment component checklist.

Acceptability

Treatment acceptability will be assessed via the following outcomes: participant retention rate across study time points and EAET session attendance rate. Target attendance will be defined as 75% of participants completing at least 6/8 EAET sessions. Treatment satisfaction will be measured by participants' responses to an adapted four-item treatment credibility measure. Specifically, items are rated on an 11-point Likert scale ranging from 0 (*not at all*) to 10 (*completely*) and inquire about how successful participants thought the treatment was in reducing the impact of their pain, the likelihood of participants recommending the treatment to someone with orthopaedic chronic pain, how interesting and engaging they considered the treatment to be and their overall satisfaction with the treatment.[29] Acceptable levels of treatment satisfaction will be defined as at least 75% of participants reporting a seven or higher on the aforementioned treatment satisfaction questions.

Adherence to completing assessments (questionnaires, QST)

Self-report questionnaires

Although this pilot study will not be sufficiently powered to detect changes in patient-reported outcomes, we will determine the feasibility of obtaining data pertaining to key outcome measures defined by the Initiative on Methods, Measurement and Pain Assessment in Clinical Trials.[30] These domains include pain, physical functioning, emotional functioning and participants' ratings of global improvement. Pain severity over the past week will be assessed by the BPI.[31] Patients will also complete the Widespread Pain Index.[32] Physical function will be assessed using patient-reported outcomes measurement information system (PROMIS) physical function and pain interference computer adaptive testing (CAT) measures. Emotional functioning will be measured using the PROMIS anxiety and depression CATS.[33] Participant ratings of global improvement will be assessed via the patient's global impression of change.[34] Participants will also complete measures related to coping, including the Pain Catastrophising Scale,[35] Chronic Pain Acceptance Questionnaire[36] and the Toronto Alexithymia Scale.[37] Given the inherent traumatic nature of orthopaedic trauma and the high rates of substance use in this clinical population,[22] the following measures will be used to assess for trauma exposure/symptoms and substance abuse: the Life Events Checklist-5,[38] PTSD checklist for the Diagnostic and Statistical Manual of Mental Disorders, Fifth edition,[39] PROMIS Prescription Pain Medication Misuse V.1.0-Short Form 7a[40] and the tobacco, alcohol, prescription medication and other substance use tool.[41] Finally, participants will also provide information about their demographic background and social determinants of health using the accountable health communities health-related social needs screening tool.[42]

Quantitative sensory testing

We will describe the feasibility of using QST, a method of testing individual pain responses across a battery of psychophysiologically mediated, experimentally induced measures of pain perception at baseline and post-treatment. The QST battery consists of tests of pain threshold and tolerance, temporal summation and conditioned pain modulation tasks. Participation in the clinical trial is not contingent on QST, and participants will have the option to opt out. In order to inform the design of future trials, we will describe the percentage of participants who decline QST.

Data analyses

Sample size determination

This study will enroll 30 participants who sustained traumatic orthopaedic injuries requiring surgery and with chronic pain 6 months after hospital discharge (five individuals receiving the pilot intervention and 25 receiving the final standardised intervention). This sample size is based on formal recommendations for feasibility studies[43 44] and corresponds with recent feasibility trials

of behavioural interventions for adults following orthopaedic trauma.[27 45]

Primary analyses

Descriptive statistics will be computed to examine the study's primary aims related to feasibility and acceptability.

Ethics and dissemination

Ethics

This study has been approved by the Johns Hopkins Institutional Review Board (IRB#: 00277255; date of approval: 15 February 2022). The trial began participant recruitment on 28 August 2024. The study was registered with ClinicalTrials.gov on 3 August 2023 (NCT05989230). Adverse events will be assessed informally and formally over the course of the trial. Study interventionists will be trained to use the Unwanted Event to Adverse Treatment Reaction Checklist to identify adverse events that may arise during treatment.[46] Adverse events will also be formally assessed using the Patient Global Impression of Change[34] administered immediately post-treatment and during the 3-month follow-up assessment. All adverse events will be reported to the IRB as required.

Dissemination

The primary results of this clinical trial will be disseminated in a peer-reviewed scientific journal and presented at national/international conferences.

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Contributors SGR: study design, adaptation of treatment manual and draft manuscript. NC: adaptation of treatment manual and critical revision of manuscript for important intellectual content. CMC, RCC, STW and FSR: study design and critical revision of manuscript for important intellectual content. MAL: study design, adaptation of treatment manual and critical revision of manuscript for important intellectual content. RVA: study design, adaptation of treatment manual and draft manuscript. RVA is responsible for the overall content as guarantor.

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Competing interests ML is a paid research consultant for CognifSense and he collects fees for training professionals in the therapy tested here. Other authors have no competing interest to declare.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

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