■ TRAUMA

Pain Rehabilitation to Optimize Major Orthopaedic Trauma REcovery (PROMOTE) compared with routine care

A MULTICENTRE, PARALLEL-GROUP, RANDOMIZED FEASIBILITY TRIAL WITH AN EMBEDDED QUALITATIVE STUDY

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Aims

The aim of this study was to assess the feasibility of conducting a randomized controlled trial (RCT) to test the effectiveness of an online, biopsychosocial intervention for the management of recovery in patients with complex lower-limb orthopaedic trauma.

Methods

This was a multicentre, parallel-group, randomized feasibility trial with an embedded qualitative study. Patients were recruited from four UK NHS major trauma centres if they were aged ≥ 16 years and had undergone surgery for complex lower-limb orthopaedic trauma. They were randomized to gain access to a biopsychosocial support website to target psychological predictive factors of poor outcomes for three months in addition to routine care, plus four one-to-one sessions with healthcare professionals to increase adherence, compared with routine care only. The primary outcome was patient acceptance, and secondary outcomes were the patients' adherence and intervention delivery fidelity.

Results

A total of 57 of 112 eligible patients (51%) participated (≥ 50% study feasibility criterion) and a mean of 2.7 were recruited per centre per month (≥ 2 criterion). They attended a median of three out of four sessions (3 to 4 criterion). However, the intervention delivery fidelity criterion (≥ 90% of intervention providers deliver the intervention as per manual) was not met (58% observed). The retention criterion (< 20% loss to follow-up at three months) was also not met (49% observed).

Conclusion

The intervention was feasible in terms of patient acceptance; however, it needs to be modified to increase patient adherence and delivery fidelity.

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Introduction

The global, age-standardized annual incidence of lower-limb fractures is 440 per 100,000 population (95% CI 360 to 528).[1] The prevalence of chronic pain within these patients is 63%.[2] The National Institute for Health and Care Excellence (NICE) defines a complex fracture as: a pelvic fracture, an open fracture and/or severe ankle fracture, and one which will probably require surgery.[3] Living with chronic pain following trauma is associated with disability, poor mental health,[4] reduced quality of life,[5,6] delayed return to work,[7] and problematic opioid use.[8]

Several factors have been identified which predict poor outcomes following complex lower-limb trauma, independent of the severity of the injury.[9] These include sociodemographic variables: older age, being female, being from an ethnic-minority group (based on studies in Europe and USA where the largest groups are white), lower economic status, fewer years of education, and low levels of social support;[10-12] cognitive variables: low pain

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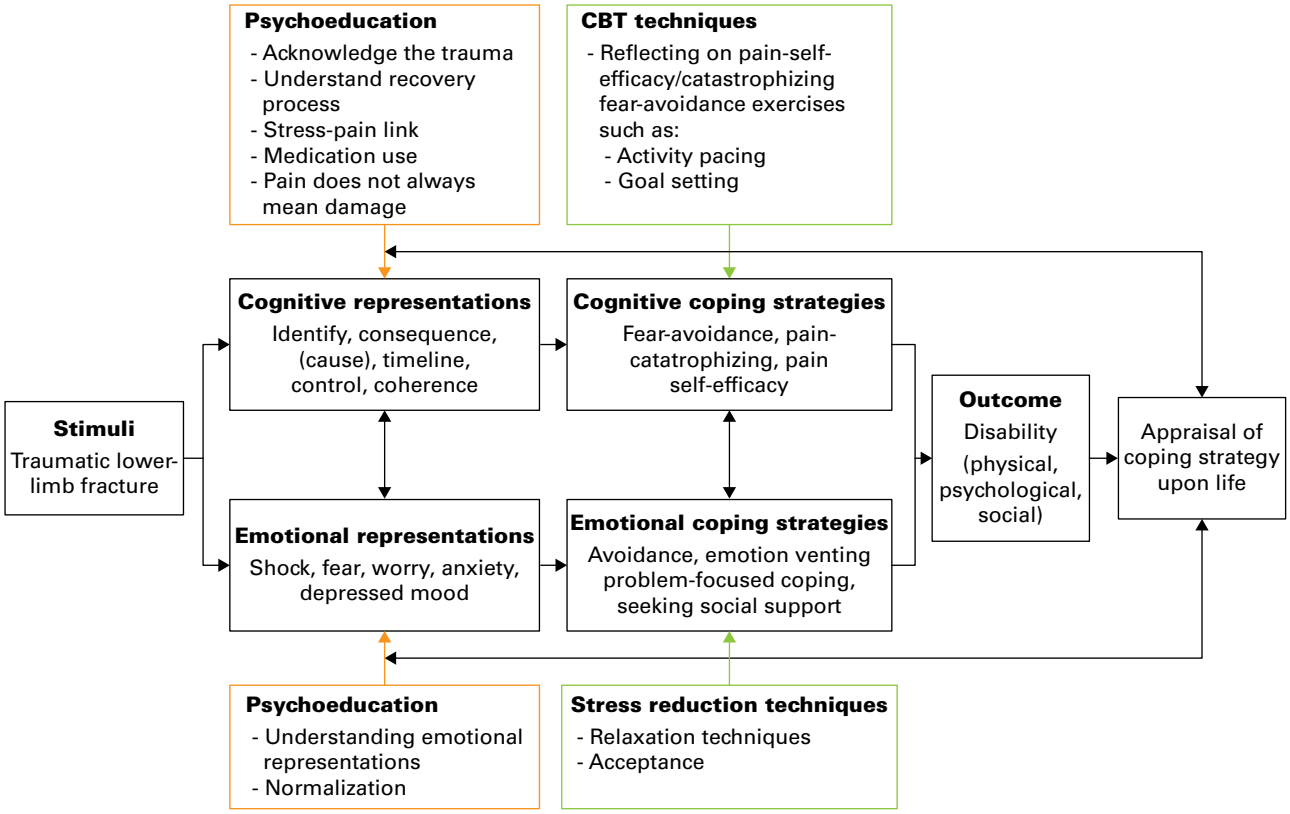

Fig. 1

Pain Rehabilitation to Optimize Major Orthopaedic Trauma REcovery (PROMOTE) intervention model. CBT, cognitive behavioural therapy.

self-efficacy, high pain catastrophizing, high fear avoidance, and low resilience;[13-16] and emotional variables: pre- and post-injury anxiety, depression, and post-traumatic stress disorder.[17] While it may not be possible to address sociodemographic variables, the negative cognitive variables are an obvious area for intervention.

The Common-Sense Model of Self-Regulation (CSM-SR)[18] is a psychological model used to understand how people respond to injury and illness, cognitively and emotionally. We used this as the basic model for the development of our interventions, during which time we conducted several rounds of stakeholder review with patient and clinical staff representatives. This enabled us to identify core cognitive representations of injury and pain which could be helpful, or unhelpful, in recovery following complex orthopaedic trauma. For example, a lack of injury/pain coherence ("I do not understand why my leg is hurting now, then it stops, it is a mystery") and emotional representations ("I was scared, confused and very alone on the ward"). The injury/pain cognitive and emotional representations are individual to each patient, and they evolve and reform in response to new information and experience. The tools and messages throughout Pain Rehabilitation to Optimize Major Orthopaedic Trauma REcovery (PROMOTE) aim to suggest alternative ways of representing the same threats of pain and stress, giving voice to many views to demonstrate the core message that there is not one way of rehabilitating after trauma, but many different paths to recovery. The website aims to empower patients to explore thoughts and behaviours which can help them recover as well as possible.[18]

In collaboration with expert clinical psychologists, this model was mapped onto the cognitive behavioural therapy (CBT) treatment model, which has shown effectiveness at targeting modifiable cognitive factors and improving outcomes in patients with established chronic pain.[19] However, there is less evidence about whether these techniques can be used prophylactically to prevent patients experiencing poor outcomes following orthopaedic trauma.[20,21] In planning to address this gap in the evidence, we were conscious that due to the high incidence of lower-limb trauma in UK major trauma centres, the intervention needed to be predominantly self-management in order to be measurable. CBT interventions have been found to be effective in other groups of patients when delivered via low-intensity web-based methods with clinical support.[19]

The PROMOTE intervention model is shown in Figure 1.

The rationale for enhancing biopsychosocial support for these patients has been recognized by the James Lind priority setting partnership,[22] who are now asking, 'What psychological support would be useful for patients with complex fractures and when?' and 'What are the options for preventing and treating chronic pain after complex fractures?'.

The aim of this study, therefore, was to test the feasibility of conducting a definitive randomized controlled trial (RCT) com-

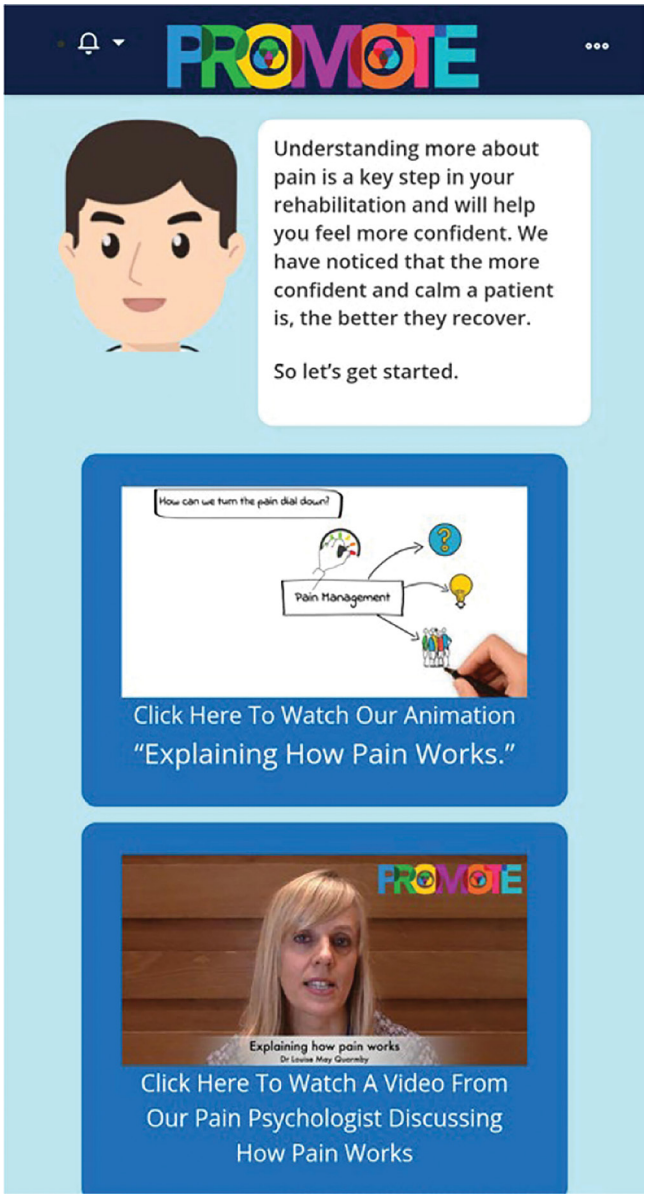

Fig. 2

Screenshot from the 'What is happening to me?' section of Pain Rehabilitation to Optimize Major Orthopaedic Trauma Recovery (PROMOTE).

paring this intervention in addition to routine care, with routine care alone, to reduce the impact of chronic pain and disability after a complex lower-limb trauma.

Methods

The PROMOTE study was a multicentre, parallel-group, feasibility RCT with an embedded qualitative study assessing the acceptability and feasibility of a mixed format biopsychosocial intervention delivered in the early post-surgical phase compared with routine care.

Patients were recruited from four NHS major trauma centres (MTCs). Clinical teams identified potentially eligible patients, who were screened and given information about the study within the first seven days after orthopaedic surgery for a lower-limb fracture, in order specifically to test the feasibility of introducing a biopsychosocial intervention early to allow satisfactory rehabilitation. Eligible patients who were keen to participate were approached for their informed consent.

The target population were patients who were: aged ≥ 16 years; had been treated surgically for a lower-limb fracture as part of major trauma (Injury Severity Score ≥ 16,[23] or with a single complex periarticular fracture or several open long-bone fractures); had been operated on within the last seven days; and were willing and able to provide informed consent. Patients were excluded if they had a significant brain or spinal cord injury, or were unable to adhere to the study procedures or complete questionnaires.

We used 1:1 allocation stratified by NHS centre and used permuted blocks of varying sizes. Randomization lists were generated using Stata v. 14 (StataCorp, USA) and administered with Research Electronic Data Capture (REDCap) to ensure concealed allocation. It was not possible to blind the patients or those delivering the intervention. The local research team reviewed the medical records and were not blinded to the allocation of treatment. The data were collected and managed using REDCap hosted at the University of Oxford.[24]

The PROMOTE intervention is a CBT-based, web-delivered programme designed to improve pain outcomes following major lower-limb orthopaedic trauma by targeting maladaptive cognitive factors. Introduced by trained healthcare professionals (physiotherapists or nurses) in major trauma settings, the intervention combines a structured, interactive website with four brief, clinician-supported sessions delivered face-to-face or remotely over approximately eight weeks. The website, accessible for up to three months after surgery, provides education on injury and treatment, strategies to address unhelpful thoughts, techniques to support recovery (e.g. stress and sleep management), and tools for self-monitoring and communication with clinicians. Healthcare professionals receive training and guidance to facilitate patient engagement, while intervention fidelity is monitored through logs, recordings, and usage data. The programme allows flexible, self-directed use with minor modifications (e.g. simplified login) made to enhance accessibility and adherence. Descriptions of the interventions based on Template for Intervention Description and Replication (TIDieR) guidance can be found in Supplementary Table i.[17]

The website used different methods such as infographics and 'talking head' videos to communicate adaptive health information. Figure 2 is a screenshot from the 'What is happening to me?' section. One aim was to help a patient's understanding of their injury through education about how pain is a biopsychosocial experience and not simply a message of damage.

The patients who were allocated to routine care received the normal treatment which they would have recieved outside the study. They were discharged from hospital when their acute medical needs had been met, and were supported on discharge by local community health and social care services. A routine prescription for their rehabilitation was completed before they were discharged.

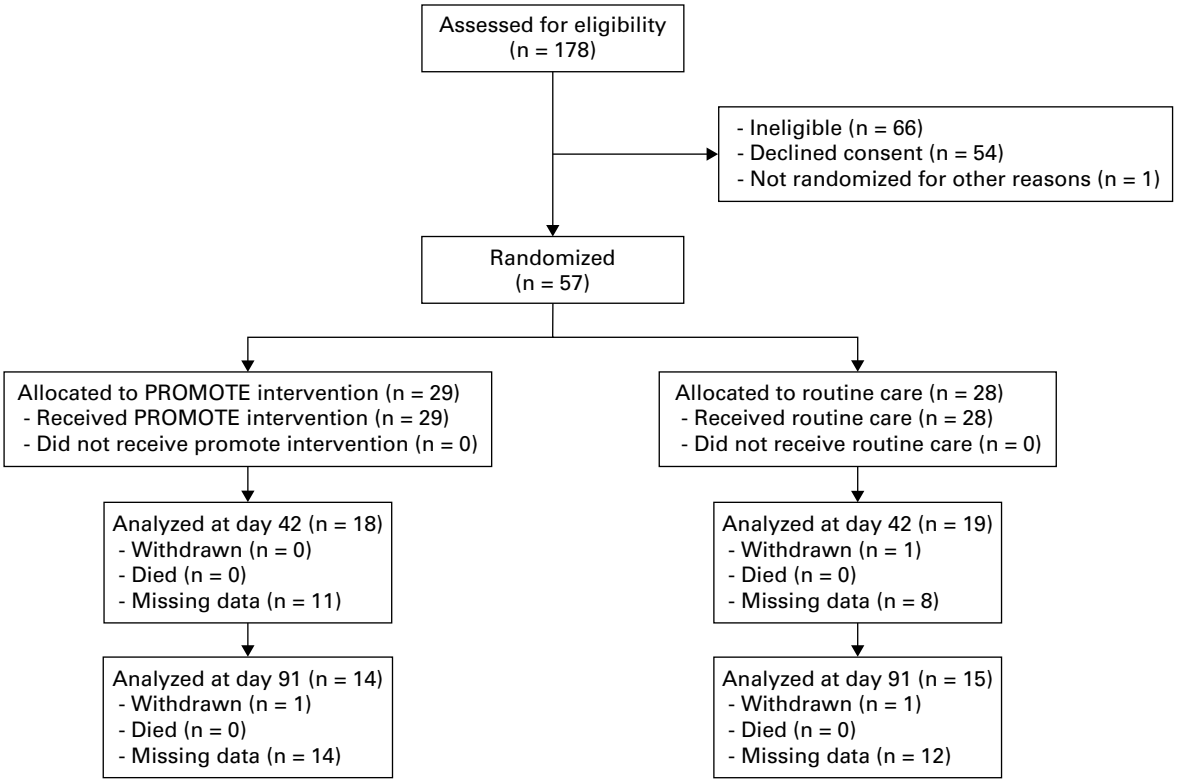

Fig. 3

CONSORT flowchart.[27]

The healthcare professionals delivering the PROMOTE intervention were trained in a two-hour, face-to-face session and given some written material. They were trained by an experienced health psychologist (BF) who codeveloped the PROMOTE intervention. The central study team monitored the treatment logs for the delivery of the interventions. All other aspects of their health and social care continued as usual.

The testing of the feasibility of conducting a RCT in the future is a novel type of intervention for these patients, and our primary aim was to understand if the study would be acceptable to them.[25] A priori feasibility success criteria were developed and assessed using a traffic light system as shown in Supplementary Table ii.[26] 'Green' indicates feasible, 'Amber' indicates that modification is required, and 'Red' indicates that a definitive trial would not be considered feasible.

The patients were recruited between February and July 2024. Of the 178 who were assessed for eligibility, 112 were found to be eligible and 57 were recruited and randomized (Figure 3).

The main reason why patients were found to be ineligible was because they were unable to adhere to the trial procedures, such as completing questionnaires (29/66; 44%). The remaining reasons for ineligibility are shown in Supplementary Table iii.

The main reason for eligible patients declining to participate was because they did not want to be part of a research project (28/54; 52%). Of the 29 who were allocated to receive PROMOTE, ten (35%) agreed to participate in the qualitative interviews. All 16 of the healthcare providers involved in delivering PROMOTE participated in the four focus groups.

The baseline characteristics of the patients are summarized in Table I.

The patients were reviewed at six weeks and three months after randomization. They received a text and/or email invitation to complete patient-reported outcomes, reminder texts, emails, and phone calls were used to optimize the number of responses. The patient-reported outcomes were the Disability Rating Index,[28] PROMIS Pain Intensity,[29] PROMIS Pain Interference,[30] Pain Self-Efficacy Questionnaire,[31] Pain Catastrophizing Scale,[32] Patient Health Questionnaire,[33] and the use of pain medication.

The adverse events and complications which were recorded were: wound infection, further surgery, thromboembolic events, complex regional pain syndrome, chest infection, urinary tract infection, stroke, heart attack and other cardiac issues, pressure sores, dislocation, neurological injury, and tendon injury. Serious adverse events were unexpected complications, possibly related to the intervention.

The trial management group included a patient and public involvement and engagement (PPIE) representative (JG), who oversaw the trial and the intervention from the initial concept through to the interpretation of the results.

The mixed-methods design was informed by the Medical Research Council (MRC) guidance for evaluating complex

Table I. Patient characteristics.

Variable	PROMOTE intervention	Usual care	Declined consent	Qualitative participants
Total patients, n	29	28	54	10
Median age, yrs (IQR)	45 (32 to 62)	30.5 (25.5 to 45.5)	38 (22 to 52)	56 (45 to 66)
Sex, n (%)				
Male	19 (65.5)	20 (71.4)	39 (72.2)	5 (50.0)
Female	10 (34.5)	8 (28.6)	15 (27.8)	5 (50.0)
IMD, n (%)				
1 to 5	18 (62.1)	20 (71.4)	31 (57.4)	5 (50.0)
6 to 10	9 (31.0)	7 (25.0)	21 (38.9)	5 (50.0)
Unable to produce score	2 (6.9)	1 (3.6)	2 (3.7)	
Ethnicity, n (%)				
White	19 (65.5)	17 (60.7)	36 (66.7)	9 (90.0)
Mixed or multiple	1 (3.4)	0 (0)	2 (3.7)	1 (10.0)
Asian/Asian British	4 (13.8)	2 (7.1)	3 (5.6)	0 (0)
Black African, Caribbean, or Black British	4 (13.8)	4 (14.3)	0 (0)	0 (0)
Other	1 (3.4)	4 (14.3)	12 (22.2)	0 (0)
Does not wish to state	0 (0.0)	1 (3.6)	1 (1.9)	0 (0)
ISS				
Available, n	3	6	15	
Median (IQR)	9 (9 to 9)	9 (9 to 14)	9 (9 to 16)	N/A

IMD, Index of Multiple Deprivation; ISS, Injury Severity Score.

interventions,[34] and involved any patient who was randomized into the PROMOTE arm of the study and all the staff who delivered the intervention. All interviews were video interviews and the audio data were recorded with consent. Audio data were downloaded, anonymized, and transcribed. Data were managed using NVivo v. 14 (Lumivero, USA) with framework analysis using the feasibility criteria.[35]

Statistical analysis. No formal sample size calculation was done for the feasibility trial. We had a target rate of recruitment per centre per month, but the main research question was about the acceptability of the intervention rather than the rate of recruitment.

Baseline characteristics were reported with descriptive statistics, separately per group and overall, using mean and SD (or median and IQR if not normally distributed) for continuous variables, and the number and percentage of patients in each group for binary or categorical variables.

Feasibility outcomes, clinical outcome measures, records of treatment sessions, quality assurance checks, complications, and adverse events were reported using descriptive statistics. No comparative statistical testing was undertaken. Complications were collected during follow-up at six weeks and three-months, and serious adverse events were reported as and when the staff from recruiting sites became aware of them.

Results

A higher proportion of patients had a high energy fall in the PROMOTE arm (9/29; 31%) compared with the routine care arm (2/28; 7%), and a higher proportion had road traffic collisions in the routine care arm (16/28; 57%) compared with the PROMOTE arm (10/29; 35%). The details of the injuries are shown in the Supplementary Table iv. The clinical outcomes are summarized in Table II.

The feasibility outcomes were assessed by triangulating the quantitative and qualitative data as shown in Supplementary Table v.

The mean rate of recruitment per month per site was 2.7, exceeding the feasibility study progression criterion. The proportion of eligible patients screened who were recruited between February and July 2024 was 57/112 (51%), achieving feasibility.

Of the patients who declined to participate, 28 (52%) gave their reason as "Does not want to be part of a research project". The screening data capture allowed free-text answers for why they did not want to participate. Each of the four sites found that the approach was at the wrong time, "Patient declined to take part as he feels "too out of it" to engage" (Site 1), "Thinks his head is not in the right place right now to take part" (Site 3); "In too much pain and discomfort does not want to take part in research as cannot focus on anything at the moment"; (Site 2) and "Feels overwhelming" (Site 4). And, staff in the focus groups suggested that many eligible patients declined the study because it was offered to them too soon after their injury.

Patients attended a median of three of the four sessions (achieving feasibility). They found that the face-to-face sessions helped them 'join-the-dots' of the PROMOTE intervention.

> *"There's so much information on the PROMOTE… it was helpful to talk through what it was all about… joining the dots really."* (Site 4: Patient 03)

The qualitative interviews explained that while the staff adhered, they were concerned that in a full trial, the administration surrounding the four face-to-face sessions could be become burdensome.

> *"I think if it went to a full trial we'd have to think about how we organize that because if it was on a bigger scale and for longer it could be a problem."* (Site 3: Staff)

Table II. Continuous outcomes.

Outcome	PROMOTE Intervention		Routine care	
	n	Median (IQR)	n	Median (IQR)
DRI*				
Pre-injury	29	2 (0 to 7)	28	0 (0 to 3)
Baseline	29	93 (77 to 95)	28	95 (87 to 99)
Day 42	18	71 (47 to 79)	19	75 (50 to 86)
Day 91	14	60 (53 to 71)	15	46 (27 to 72)
PROMIS Pain Intensity†				
Baseline	29	72 (68 to 74)	27	72 (67 to 74)
Day 42	18	60 (53 to 70)	19	66 (59 to 72)
Day 91	14	61 (50 to 66)	14	61 (56 to 65)
PROMIS Pain Interference‡				
Baseline	29	64 (60 to 73)	27	69 (64 to 73)
Day 42	18	54 (48 to 59)	19	59 (50 to 67)
Day 91	14	57 (48 to 64)	14	56 (50 to 63)
PSEQ§				
Baseline	29	12 (5 to 23)	28	9 (3.5 to 18)
Day 42	18	20.5 (12 to 37)	19	17 (11 to 40)
Day 91	14	25.5 (20 to 53)	14	36.5 (15 to 48)
PCS¶				
Baseline	29	16 (7 to 26)	28	21.5 (7 to 29.5)
Day 42	18	8 (1 to 18)	19	17 (13 to 25)
Day 91	18	8 (0 to 22)	14	9.5 (3 to 16)
PHQ4**				
Baseline	29	4 (1 to 7)	28	4.5 (1 to 7.5)
Day 42	18	3.5 (0 to 9)	19	5 (4 to 9)
Day 91	14	2 (0 to 11)	14	3.5 (2 to 6)

*Scores range from 0 to 100 with higher scores indicating more disability.
†Scores range from 0 to 10 with higher scores indicating more pain.
‡Scores range from 0 to 100 with higher scores indicating pain has a bigger impact on daily life.
§Scores range from 0 to 60 with higher scores indicating better self-efficacy.
¶Scores range from 0 to 52 with higher scores indicating more pain catastrophizing.
**Scores range from 0 to 12 with higher scores indicating a greater likelihood of underlying depressive or anxiety disorder.
DRI, Disability Rating Index; PCS, Pain Catastrophizing Scale; PHQ4, patient health questionnaire; PROMIS, Patient-Reported Outcome Measurement Information System; PSEQ, Pain Self-Efficacy Questionnaire.

When reflecting on the content of PROMOTE, patients felt that the content was empowering and useful for them when recovering from their injury.

> *"PROMOTE has actually empowered me to be able to manage it."* (Site 1: Patient 16)

> *"I had to go for an MRI on my leg and it ended up being very painful… and I used that box breathing and I think that probably got me through most of it."* (Site 3: Patient 03)

The treatment logs documented that staff delivered 58% of session 1s, 55% of session 2s, 50% of session 3s, and 44% of session 4s as per manual, which does not meet the feasibility criteria. The staff recorded reasons for why the contents of the sessions were not delivered. Most often it was because "Patient has not engaged with the website" (16/32 sessions). Of the 29 patients allocated to PROMOTE, 23 (79%) accessed the website at least once and six did not access the website at all. Patients accessed a median of 88 (IQR 56 to 208) of the website pages out of 275 pages (thus accessing some pages many times). A detailed exploration of the engagement of patients with the website is explored separately.[36]

The two quality assurance audio recordings demonstrated satisfactory quality with no concerns.

At three months after randomization, 28/57 patients (49%) were lost to follow-up, which is not feasible. Patients and staff said that once they returned home, they were busy managing the challenges of daily life and lost the motivation to engage with the study.

> *"Since I also lost my job … I prioritize other things – aka find a job."* (Site 1: Patient 11)

> *"I was really surprised that they didn't adhere… I think life gets in the way it's such a major injury that everything else will maybe be prioritized."* (Site 3: Staff FG)

There were no serious adverse events. Five patients in the PROMOTE group and nine in the routine care group reported complications. Sites reported one complication in the PROMOTE group and two in the routine care group. The details are reported in Supplementary Table vi.

Discussion

Our findings indicate that the PROMOTE intervention in its current form is not feasible for testing in a definitive RCT. The study was acceptable to patients as measured by the rates of recruitment and the approach to the intervention was well received, as reflected by the patients' engagement with the face-to-face sessions. However, the fidelity rates were lower than expected because patients were not engaging with the website. The rates of retention were also lower than expected, possibly because patients had not engaged with the website. In the qualitative study, we explore the reasons why they did not engage well with the website using the Capability-Opportunity-Motivation model of Behaviour (COM-B).[37] The model has helped us identify a set of recommendations for optimizing the intervention which we propose to test in a second feasibility study, and funding for this has been applied for. For example, patients explained how they felt that PROMOTE was primarily to help with their pain, and many did not feel that their pain was the problem. They were managing it well with medication. Therefore, they suggested that the focus and the branding of the intervention should be about supporting recovery more broadly, as this would increase their motivation to engage. The COM-B model also identified more practical changes. Some patients explained that the internet connection was too poor for them to use the website when they were in hospital. The next iteration of PROMOTE will be hosted on a mobile application which can be accessed offline to overcome this barrier.

There were no discernible differences in sociodemographics between those patients who were eligible and declined to participate, and those who agreed, nor between those assigned to PROMOTE or routine care. The sample was younger, with a median age of 39 years, compared with a mean age of 62.3 years in a UK epidemiological study of lower-limb trauma cases.[38] Additionally, there was a lower proportion of females in this study (32% compared with 56%).

Several patients who might have found PROMOTE helpful did not participate because the time when they were approached was not right. Although all patients were invited to join within the first week after their surgery, there was some variation in the number of days, and some patients reported that they did not have the "bandwidth" to engage with the research at this stage. During the staff focus groups we learnt that staff would like more autonomy in deciding when they offered PROMOTE to patients, as they felt they would know when someone was ready or not. This advice has been integrated into the next version of PROMOTE.

The staff delivered the face-to-face support sessions with fidelity. However, in the qualitative study, staff identified that delivering the face-to-face sessions could become onerous in a full-scale RCT or if implemented into routine care. This could suggest the need for more support for staff who are delivering an intervention which is outside their usual clinical remit. Moreover, it is important to be mindful of limiting the amount of time demanded of the staff. The qualitative data also suggested that the content of PROMOTE was helpful to those who engaged with the website. However, many patients did not engage with the website well.

Two research groups in North America have also produced CBT-informed interventions for orthopaedic trauma patients and tested their feasibility. One was delivered using four 45-minute live video sessions with a CBT therapist and reached feasibility.[39] The other delivered the intervention using a commercial app with asynchronous support from a therapist and did not reach feasibility.[21] When we compare the content of the three interventions, it is clear that, although developed in different countries and healthcare systems, the core structures of the interventions are the same, adding weight to the assertion that the content is useful but the method of delivery is problematic.

The feasibility study was conducted as per protocol and clearly answered the individual feasibility progression criteria. However, the overall feasibility of a definitive trial is unclear. The intervention is novel and the research is being run in a complicated and highly heterogeneous group of patients, and we believe that further preliminary work is needed before we can run a definitive RCT.

In conclusion, patients with complex lower-limb orthopaedic trauma have unmet psychosocial needs. The content of PROMOTE is suitable to meet these needs. While the content is useful, the method of delivery is not suitable in its current form. The content needs to be streamlined, according feedback from patients, and a new method is needed to engage them early on without overwhelming them.

Take home message

- This study demonstrates that a low-intensity, cognitive behavioural therapy-informed digital intervention for patients with complex lower-limb trauma is acceptable and feasible to deliver within major trauma pathways, addressing an important gap in early psychosocial support.
- However, challenges with patient engagement, intervention fidelity, and follow-up highlight that modifications to delivery are required before large-scale implementation.
- Optimizing how and when such interventions are introduced could improve recovery outcomes, and help prevent chronic pain and disability, in this high-risk population.

Social media

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Supplementary material

Further details on data collection methodology, and tables displaying further details on outcome measures and participant injury details, TIDieR intervention reporting, feasibility success criteria traffic light system, reasons for participant ineligibility for the study, trial feasibility assessment, and reported complications.

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