

Rehabilitation to optimise major trauma recovery

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| Submission date 15/11/2023 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 11/12/2023 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 23/08/2024 | Condition category Musculoskeletal Diseases | <input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year |

Plain English summary of protocol

Background and study aims

Major trauma occurs when a person sustains serious injuries to one part of the body or injuries to several parts of the body at the same time. Many people experiencing major trauma have injuries to their legs. Pain immediately after a major injury is common and can last many months. Some people also experience pain after their injury has healed. Pain after a leg injury can lead to difficulties with recovery. The purpose of this study is to assess the feasibility of delivering a new treatment that aims to improve the management of pain after injury. The treatment involves supporting people after injury with advice from a health professional and the use of a special website that has been developed by clinical experts and patient representatives.

Who can participate?

People aged 16 years or older who have broken one or more bones in their leg and have had surgery for this injury in the last 7 days

What does the study involve?

After consenting to join the study, a researcher will assist participants in completing a series of short online questionnaires to assess how well they could perform certain activities before their injury and compare this to how well they can perform them currently. This should take about 20 minutes. The participants will then be randomised by a computer program which will then allocate them to one of two treatment groups. The two treatment groups are:

Group 1: Usual care: participants will be seen by the care team and be given their hospital's usual treatment.

Group 2: PROMOTE treatment: this includes usual hospital care with the addition of access to pain rehabilitation training materials via a study website. Participants will also have four intervention sessions delivered by one of the study-trained health professionals at their treating hospital.

What are the possible benefits and risks of participating?

By participating in the study, participants will benefit from having a chance of having access to a new treatment that could potentially help them manage their pain. As part of the study, participants will be asked how they are coping with their injury and their pain. Sometimes answering questions such as those about pain or confidence can bring back memories and

feelings which could be upsetting. It is not anticipated that any of the study procedures will be disadvantageous for the participants' well-being.

Where is the study run from?
University of Oxford (UK)

When is the study starting and how long is it expected to run for?
July 2022 to October 2024

Who is funding the study?
The NIHR Research for Patient Benefit (RfPB) Programme (UK)

Who is the main contact?
Kylea Draper, Trial Manager, promote@ndorms.ox.ac.uk

Study website
<https://www.promote-study.org>

Contact information

Type(s)
Scientific, Principal Investigator

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Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

318428

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

CPMS 58221, IRAS 318428

Study information

Scientific Title

Feasibility of a pain management intervention to improve recovery after major trauma: the PROMOTE study

Acronym

PROMOTE

Study objectives

Is it feasible to conduct a definitive multicentre randomised clinical trial of a novel intervention using psychological techniques that aim to help people self-manage their pain and reduce disability after a major lower limb injury?

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 04/10/2023, South Central - Oxford B Research Ethics Committee (Whitefriars. Level 3, Block B. Lewin's Mead, Bristol, BS1 2NT, United Kingdom; +44 (0)207 1048178, (0)207 1048386, (0)207 104 8019; oxfordb.rec@hra.nhs.uk), ref: 23/SC/0305

Study design

Randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital, Internet/virtual, Telephone

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Musculoskeletal trauma; self-managing pain and reducing disability after a major lower limb injury

Interventions

Once informed consent has been given and Baseline CRFs completed, the participant will be randomised by the local research team using a web-based service. Those participants randomised to the PROMOTE intervention will receive two face-to-face contact sessions within the first two weeks of in-patient care and two phone/video calls post-hospital discharge with a PROMOTE-trained healthcare professional. If the participant is still an inpatient at the recruiting centre when the follow-up sessions are due these may also be face-to-face. The two initial core contact sessions will introduce acknowledgement of the psychological consequences of a traumatic injury, the impact of these factors on future pain and disability, and engagement with the PROMOTE web-based support tools. Participants will be invited to use a mobile-friendly website, which includes brief video sessions and simple behavioural and cognitive exercises to aid recovery (including models of pain, relaxation techniques, and activity scheduling). The latter two phone/video call contacts will take place at approximately 2- and 6-weeks post-discharge (or if not discharged due to prolonged admission, 2 and 6 weeks after the second session) and aim to support engagement with the intervention. These will also be delivered by members of the PROMOTE rehabilitation team. Participants randomised to Usual Care will receive the normal treatment that they would have outside the trial.

Intervention Type

Behavioural

Primary outcome measure

Patient study engagement is measured using the screening and recruitment data at 0 days

Secondary outcome measures

1. Intervention adherence is measured using treatment records at baseline and each treatment session
2. Healthcare provider intervention delivery fidelity is measured using quality assurance audio recordings/site visits to assess the delivery of the PROMOTE intervention
3. Participant retention rate is measured using outcome data availability at the end of the study
4. Study and intervention acceptability, feasibility, barriers and facilitators are measured using patient and staff focus groups/interviews during the study period
5. Mobility and function are measured using Disability Rating Index (DRI) at baseline, 6 weeks and 3 months post-randomisation
6. Pain intensity is measured using the PROMIS Numeric Rating Scale at baseline, 6 weeks and 3 months post-randomisation
7. Pain interference is measured using PROMIS Pain Interference at baseline, 6 weeks and 3

months post-randomisation

8. Pain self-efficacy is measured using the Pain Self-Efficacy Questionnaire (PSEQ) at baseline, 6 weeks and 3 months post-randomisation

9. Pain catastrophising is measured using the Pain Catastrophizing Scale (PCS) at baseline, 6 weeks and 3 months post-randomisation

10. Depression and anxiety are measured using the Patient Health Questionnaire (PHQ4) at baseline, 6 weeks and 3 months post-randomisation

11. Pain medication use is measured using a bespoke pain medication questionnaire at baseline, 6 weeks and 3 months post-randomisation

12. Complications are measured using bespoke complications questionnaire at baseline, 6 weeks and 3 months post-randomisation

Overall study start date

31/07/2022

Completion date

31/10/2024

Eligibility

Key inclusion criteria

1. Aged 16 years or older
2. Surgically treated lower extremity fracture as part of a major trauma (classified as a lower limb fracture [pelvis and below] with an Injury Severity Score ≥ 16 as per Trauma Audit and Research Network (TARN) eligibility OR a single lower extremity complex fracture [pelvis and acetabular fractures or multiple/open/comminuted fractures]).
3. Able to provide informed consent
4. Initially operated for their lower limb injury within the last 7 days

Participant type(s)

Patient

Age group

Mixed

Lower age limit

16 Years

Sex

Both

Target number of participants

Planned Sample Size: 60; UK Sample Size: 60

Total final enrolment

57

Key exclusion criteria

1. Clinically significant brain or spinal cord injury (i.e., patients with a central nervous system injury sufficient to be on a dedicated neurological injury rehabilitation pathway)

2. Unable to adhere to the trial procedures or complete questionnaires
3. Unable to access the intervention materials (i.e., no internet access)

Date of first enrolment

16/02/2024

Date of final enrolment

31/07/2024

Locations

Countries of recruitment

England

United Kingdom

Study participating centre**John Radcliffe Hospital (Lead Centre)**

Headley Way

Headington

Oxford

United Kingdom

OX3 9DU

Study participating centre**Royal London Hospital**

Whitechapel road

London

United Kingdom

E1 1FR

Study participating centre**Queen Elizabeth Hospital**

Mindelsohn Way

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B15 2GW

Sponsor information

Organisation

University of Oxford

Sponsor details

Research Governance, Ethics and Assurance
Joint Research Office, 1st floor
Boundary Brook House
Churchill Drive
Oxford
England
United Kingdom
OX3 7GB
None provided
rgea.sponsor@admin.ox.ac.uk

Sponsor type

Hospital/treatment centre

Website

<https://www.ox.ac.uk/>

ROR

<https://ror.org/052gg0110>

Funder(s)**Funder type**

Government

Funder Name

Research for Patient Benefit Programme

Alternative Name(s)

NIHR Research for Patient Benefit Programme, RfPB

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

31/10/2025

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

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IPD sharing plan summary

Available on request