ISRCTN10290449 https://doi.org/10.1186/ISRCTN10290449

Rehabilitation to optimise major trauma recovery

Submission date
15/11/2023

Recruitment status
No longer recruiting

Registration date
11/12/2023

Overall study status
Completed

Last Edited
23/08/2024

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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

Contact information

Type(s)
Scientific, Principal investigator

Contact name
Dr David Keene

ORCID ID
https://orcid.org/0000-0001-7249-6496

Contact details
University of Exeter
St Luke's Campus
Heavitree Road
Exeter
United Kingdom
EX1 2LU
+44 (0)1865 223126
d.keene@exeter.ac.uk

Type(s)
Public

Contact name
Ms Kylea Draper

Contact details
PROMOTE Trial Manager
Oxford Trauma
Kadoorie Centre
John Radcliffe Hospital
Oxford
United Kingdom

OX3 9DU
+44 (0)1865 223126
promote@ndorms.ox.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
318428

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Treatment

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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
16 years

Sex
All

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
United Kingdom

England

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
Edgbaston
Birmingham
United Kingdom
B15 2GW

Sponsor information

Organisation
University of Oxford

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, Research for Patient Benefit (RfPB), The NIHR Research for Patient Benefit (RfPB), RfPB

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

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.
d.keene@exeter.ac.uk

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes