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Can exercise prevent long-lasting pain and disability following a blunt injury to the chest?

Submission date
01/12/2021

Recruitment status
No longer recruiting

Registration date
02/12/2021

Overall study status
Completed

Last Edited
27/12/2024

Condition category
Signs and Symptoms

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

Plain English summary of protocol

Background and study aims?
Injuries to the chest lead to a large number of admission to hospital every year in the UK and globally. It is now well-known that at least two thirds of patients with injuries to their chest, will go on to develop chronic pain and disability. Chronic pain is pain that lasts longer than 3 months after the original injury. Very little is yet known about how to reduce the risk of this chronic pain and disability, including the effectiveness of physiotherapy. The overall aim of this trial is to look at the impact of an early exercise programme, which includes simple upper back/chest and shoulder girdle movements, on the number of people experiencing chronic pain and physical disability, and the severity of the pain.

Who can participate?
The trial will run in five hospitals in Wales and England, where all adult patients who can complete the exercise programme, presenting to the Emergency Department with an injury to their chest, will be invited to participate.

What does the study involve?
The exercise programme consists of four simple exercises, which will be completed three times a day, for one week in total. Half of the patients taking part will complete the exercise programme and the other half will not. All patients will receive normal routine physiotherapy care and will be asked to complete questionnaires when they first come to hospital, and again at three months after their injury. The whole trial will take 2 years to complete, with patients being invited to participate over a one year period.

What are the possible benefits and risks of participating?
There are no known risks involved with participation in this trial. There were no adverse events reported by patients completing the intervention in the feasibility study. Patients will be asked to complete a number of chest and shoulder girdle exercises, which will be supervised by one of the physiotherapy team responsible for the patient's overall care. The potential benefit of the study is that the trial will demonstrate that the rate of chronic pain and disability is improved with the exercise programme, improving resource use in this patient group.

Where is the study run from?
Swansea Trials Unit, based at Swansea University Medical School (UK)

When is the study starting and how long is it expected to run for?
The study will start at the end of January 2022 and will run for one year.

Who is funding the study?
Health and Care Research Wales (UK), on behalf of the Welsh Government

Who is the main contact?
Dr Ceri Battle, ceri.battle@wales.nhs.uk

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
304751

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 304751, CPMS 51071

Study information

Scientific Title

EarLy Exercise in blunt Chest wall Trauma: a mixed methods, multi-centre, parallel randomised controlled trial

Acronym
ELECT2

Study objectives
An early exercise programme, consisting of simple thoracic and shoulder girdle movements, reduces chronic pain prevalence and severity and physical disability at 3 months post-injury, in adult patients with blunt chest wall trauma presenting to hospital, when compared with normal care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/12/2021, London Riverside Research Ethics Committtee (Ground Floor, Temple Quay House, 2 The Square, Bristol, BS1 6PN; +44 (0)207 104 8184; riverside.rec@hra.nhs.uk), ref: 21/LO/0782

Study design
Mixed methods multi-centre parallel randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Prevention of chronic pain and disability in patients with blunt chest wall trauma

Interventions
Patients will be randomised (patient level) to the trial using a 1:1 ratio, using Sealed Envelope (https://www.sealedenvelope.com), an independent company which is available 24 hours per day. Two stratification variables will be used for randomisation; the number of radiologically proven or clinically suspected rib fractures and the clinical frailty score, using the Clinical Frailty Scale (CFS) of the patient, specifically: Number of rib fractures: 0-2 versus 3 or more, CFS score: 1-3 versus 4-9.

Intervention: Routine care plus a simple exercise programme, consisting of four thoracic and shoulder girdle movements, that the patient completes for 1 week, three times per day as tolerated. The movements involve shoulder flexion, shoulder abduction, thoracic rotation and thoracic side-flexion.

Control: Routine care (including, but not exclusively, chest physiotherapy advice given as part of normal care).

Intervention Type
Behavioural

Primary outcome measure
1. Chronic pain is measured using the Brief Pain Inventory (short form) at baseline and 3 months follow-up
2. Disability is measured using the EQ5D-5L Survey at baseline and 3 months follow-up

Secondary outcome measures
1. Cost-effectiveness measured using a cost-utility (incremental cost per QALY) analysis at 3 month follow-up
2. Safety measured using rate of adverse events and serious adverse events at 3-month follow-up
3. Acceptability of programme measured using five focus groups, one per participating site, in intervention group only at end of 3-month follow-up

Overall study start date
01/10/2021

Completion date
30/09/2023

Eligibility

Key inclusion criteria
1. Presenting to hospital with a diagnosis of isolated blunt chest wall trauma (defined as any injury ranging from bruising to the chest wall to rib fractures with or without underlying injury to the lung, and no concurrent injuries that preclude completion of the exercise programme)
2. Aged 16 years or above
3. Able to either give informed consent independently, or with support of a family member /carer or translator
4. Able to either complete the exercise programme independently, or with support of a family member/carer
5. Able to complete surveys independently, or with support of a family member/carer or translator

Participant type(s)
Patient

Age group
Adult

Lower age limit
16 Years

Sex
Both

Target number of participants
360

Total final enrolment
360

Key exclusion criteria
1. Lacking sufficient capacity to provide informed consent or complete surveys. (Assistance from a family member/carer or translator is acceptable, if needed.)
2. Lacking sufficient capacity to complete the exercise programme either independently, or with the support of a family member/carer
3. Aged under 16 years
4. Presenting with immediately life-threatening injuries or any concurrent injury precluding participation in the intervention (patients with minor injuries not precluding participation, such as a concurrent knee ligament injury, will still be eligible)
5. Hospitalised prisoners

Date of first enrolment
31/01/2022

Date of final enrolment
24/02/2023

Locations

Countries of recruitment
England

United Kingdom

Wales

Study participating centre
Salford Royal Hospital
Stott Lane
Salford
United Kingdom
M6 8HD

Study participating centre

Wrexham Maelor Hospital
Croesnewydd Rd
Wrexham
United Kingdom
LL13 7TD

Study participating centre
Morriston Hospital
Heol Maes Eglwys
Morriston
Cwmrhydyceirw
Swansea
United Kingdom
SA6 6NL

Study participating centre
University Hospital Wales
Heath Park Way
Cardiff
United Kingdom
CF14 4XW

Study participating centre
The Grange University Hospital
Llanfrechfa Grange
Caerleon Road
Cwmbran
Newport
United Kingdom
NP44 8YN

Sponsor information

Organisation
Swansea Bay University Health Board

Sponsor details
Floor 1
ILS2 Building
Swansea University
Swansea

Wales
United Kingdom
SA2 8PP
+44 (0)1792 530889
anne-claire.owen@wales.nhs.uk

Sponsor type
Hospital/treatment centre

Website
https://www.abm.wales.nhs.uk/

ROR
https://ror.org/04zet5t12

Funder(s)

Funder type
Government

Funder Name
Health and Care Research Wales

Alternative Name(s)
Health & Care Research Wales, Ymchwil Iechyd a Gofal Cymru, Health Care Research Wales, HCRW

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The aim will be to publish the results of this study in an Emergency Medicine journal and present the results in a trauma/emergency medicine conference. The protocol will also be published.

Intention to publish date
31/12/2024

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study will be published as a supplement to the results publication

IPD sharing plan summary

Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		07/04/2022	09/01/2023	Yes	No
HRA research summary			28/06/2023	No	No
Results article		03/12/2024	27/12/2024	Yes	No