

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	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 02/12/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 27/12/2024	Condition category Signs and Symptoms	<input type="checkbox"/> 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

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

304751

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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 Committee (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

Study type(s)

Prevention

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(s)

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

Key secondary outcome(s)

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

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/carers
5. Able to complete surveys independently, or with support of a family member/carers or translator

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

16 years

Sex

All

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

United Kingdom

England

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**Morrison Hospital**

Heol Maes Eglwys

Morrison

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

ROR
<https://ror.org/04zet5t12>

Funder(s)

Funder type
Government

Funder Name
Health and Care Research Wales

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

Funding Body Type

Government organisation

Funding Body Subtype

Research institutes and centers

Location

United Kingdom

Results and Publications

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?
Results article		03/12/2024	27/12/2024	Yes	No
Protocol article		07/04/2022	09/01/2023	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes