

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

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<b>Registration date</b> 02/12/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 27/12/2024	<b>Condition category</b> 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](mailto:ceri.battle@wales.nhs.uk)

## Contact information

### Type(s)

Scientific

### Contact name

Dr Ceri Battle

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Integrated Research Application System (IRAS)

304751

### 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/carers 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/carers
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?
<a href="#">Results article</a>		03/12/2024	27/12/2024	Yes	No
<a href="#">Protocol article</a>		07/04/2022	09/01/2023	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No