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# Early exercise in blunt chest wall trauma: a feasibility trial

**Submission date**
29/05/2019

**Recruitment status**
No longer recruiting

**Registration date**
29/05/2019

**Overall study status**
Completed

**Last Edited**
07/09/2020

**Condition category**
Injury, Occupational Diseases, Poisoning

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

## Plain English summary of protocol

Background and study aims
Blunt chest wall trauma, such as bruising or broken ribs, makes up 15% of all trauma admissions to Emergency Departments (ED) worldwide, with reported mortality ranging between 4 and 60%. The most common injury mechanisms include low velocity falls (>2m), high velocity falls (>2m), road traffic accidents, assaults and sporting injuries. Over 1800 patients presented to the Emergency Department of a South Wales Hospital in 2017 with blunt chest wall trauma. Difficulties in the management of blunt chest wall trauma patients in the ED are becoming increasingly well recognised. Historically, pain relief and chest physiotherapy have been advocated as the primary methods of managing a patient with blunt chest wall trauma, with the main aim of reducing the acute risk of the development of potentially life-threatening chest complications.
Longer-term complications have also been investigated and in a small study conducted by this research team, chronic pain was reported in 35% patients with an average pain severity score of 6 out of 10. In a similar recent prospective study of 111 patients with isolated rib fractures, a prevalence of chronic pain of 64% and disability of 67% were reported. In a 2019 study, chronic pain and disability were reported in 62% and 57% of patients at 3 months after injury respectively. If over 1800 patients are presenting to one ED in Wales per year with blunt chest wall trauma, with a prevalence of 57-67% disability at two to three months after injury, this highlights a major healthcare problem which is not currently being addressed in clinical practice. Patients are simply discharged home with no follow-up care. Clinicians are traditionally taught that the pain and disability of rib fractures resolves in six to eight weeks.
What remains unknown in blunt chest trauma literature is the best management for addressing the longer-term complications, specifically chronic pain and disability. The overall aim of this phase of work is to investigate whether early thoracic and shoulder girdle exercises improve chronic pain in blunt chest wall trauma patients, when compared to normal care (where normal care traditionally involves chest physiotherapy techniques such as breathing exercises and early mobilisation/walking and no thoracic/shoulder girdle exercises). If the trial is successful and early exercise is shown to be beneficial in reducing chronic pain in this large patient cohort, then the programme can be shared throughout Wales and the UK.
The aim of this study is to test the feasibility and methods of a future trial that compares the use of early thoracic and shoulder exercises for the management of blunt chest wall trauma patients versus normal standard care. This study will have two main aims:

1. To assess the number of patients needed for the full randomised control trial and recruitment period needed to achieve this target
2. To test the feasibility and acceptability of the proposed trial methods; including the parallel randomised controlled design, the patient recruitment and consent processes, and collection of the proposed outcome measures at certain timepoints.

Who can participate?
Any adult patient who is admitted to Morriston Hospital for 24 hours or more, with isolated blunt chest wall trauma. The patient will be approached to participate in the trial if they have the capacity to follow instructions to complete the exercise programme and complete the surveys.

What does the study involve?
Participants are randomly allocated to the intervention group or the control group. Patients chosen for the intervention group receive standard care, in addition to a programme of thoracic /shoulder girdle exercises (delivered by the physiotherapist who would routinely manage the patient as part of standard care). This programme is continued by the patient, three times per day, for seven days after assessment. The exercise programme consists of shoulder active range of movement exercises, trunk active side-flexion, rotation, forward flexion and extension range of movement exercises (all within limits of pain). The control group receive standard care only. At the start of the study and three months later, participants complete two surveys about quality of life and pain, in order to test the usefulness of the surveys and potential difficulties in collecting the surveys after the patient has been discharged home from hospital. Participants in the intervention group record compliance with the exercise programme.
Pre-set trial feasibility criteria are assessed using a traffic light system (in which green means the target was achieved, amber means the target was not achieved but progression is possible with some minor protocol modifications, and red means progression to a full trial is not possible). The survey responses are entered onto a paper case report form. Any survey with missing information is still included in the study and the remaining responses included in the analysis. Response rates are recorded and non-responder (participants who don't return the surveys) analysis is completed to compare the characteristics of the non-responders and the responders. Patients are identified only by their hospital numbers once completed surveys are received.

What are the possible benefits and risks of participating?
The potential benefit of the study is that the feasibility study will achieve the progression criteria and the future full trial can be developed in which the exercise programme improves blunt chest wall trauma patients' longer-term outcomes. There are no known risks involved with participation in this study. Patients are asked to complete a number of thoracic and shoulder girdle exercises, supervised by a qualified physiotherapist responsible for the patient's overall care.

Where is the study run from?
Morriston Hospital, Swansea with support from Swansea Trials Unit, Swansea University Medical School (UK)

When is the study starting and how long is it expected to run?
August 2018 to March 2020

Who is funding the study?
The study is funded by a Pathway to Portfolio grant from Health and Care Research Wales, on behalf of the Welsh Government

Who is the study contact?
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# Contact information

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Scientific

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# Additional identifiers

### Protocol serial number
Version 1.1_10th March 2019

# Study information

### Scientific Title
Early exercise in blunt chest wall trauma: a feasibility randomised controlled trial

### Acronym
ELECT

## Study objectives
This feasibility trial will have two primary objectives:
1. To assess the sample size requirements and attrition rates for a full randomised control trial and recruitment period needed to achieve this target.
2. To test the feasibility and acceptability of the proposed trial methods; including the parallel randomised controlled design, the recruitment and consent processes, and collection of the proposed outcome measures at pre-specified timepoints.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Approved 23/05/2019, Wales REC 6 (Floor 4, ILS2, Swansea University, Swansea, SA2 8PP; Tel: +44 (0)29 2023 0457; Email: Wales.REC6@wales.nhs.uk), REC ref: 19/WA/0144

## Study design
Single-centre feasibility interventional randomised controlled trial

## Primary study design
Interventional

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Isolated blunt chest wall trauma

## Interventions
Patients will be randomised using "sealed envelope" programme, on a 1:1 basis, with no stratification, due to the feasibility design:

Control group: Standard care: analgesia, respiratory physiotherapy and mobilisation

Treatment group: Standard care (as above) plus: Three times daily, simple thoracic and shoulder girdle exercises from first assessment to end of day 7 (delivered by the physiotherapist who would routinely manage the patient as part of standard care). The exercise programme will consist of shoulder active range of movement exercises, trunk active side-flexion, rotation, forward flexion and extension range of movement exercises (all within limits of pain).

At baseline and at three months post recruitment, participants will be asked to complete two surveys about quality of life and pain, in order to test the usefulness of the surveys and potential difficulties in collecting the surveys after the patient has been discharged home from the hospital. Participants in the intervention group will be asked to record compliance with the exercise programme.

## Intervention Type
Behavioural

## Primary outcome(s)
1. Recruitment rate recorded as the number of eligible participant who consent to participate in the study by the end of three months

2. Attrition rate recorded as the number of participants who consent to participate that remain in the study until the end of follow up at three months

### Key secondary outcome(s)
1. Pain measured using the Brief Pain Inventory at baseline and at 3 months post-injury
2. Quality of life measured using the EQ5D-5L at baseline and at 3 months post-injury

### Completion date
31/03/2020

## Eligibility

### Key inclusion criteria
1. Isolated BCWT patient
2. Aged 18 years or more
3. Capacity to consent to participation
4. Capacity to complete survey
5. Length of stay of 24 hours or more

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
All

### Total final enrolment
14

### Key exclusion criteria
1. Aged less than 18 years
2. No capacity to consent to participation
3. No capacity to complete survey
4. Length of stay of less than 24 hours

### Date of first enrolment
10/06/2019

### Date of final enrolment
09/09/2019

## Locations

**Countries of recruitment**
United Kingdom

Wales

**Study participating centre**
**Morriston Hospital**
Swansea Bay University Health Board
Morriston
Swansea
United Kingdom
SA6 6NL

# 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 during and/or analysed during the current study are/will be available upon request from Ceri Battle (ceri.battle@wales.nhs.uk).

## IPD sharing plan summary

Available on request

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 02/09/2020 | 07/09/2020 | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |
| Protocol file | version v1.1 | 10/03/2019 | 30/05/2019 | No | No |