

Early Exercise in blunt Chest wall Trauma: a feasibility trial (ELECT Trial)

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Abstract

Background For patients with blunt chest wall trauma, no evidence exists regarding the optimal physiotherapy treatment aimed at 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 patients with blunt chest wall trauma, when compared to normal care.

Methods A single centre, parallel, feasibility randomised controlled trial was completed at a University Teaching Hospital in Wales. Adult patients with blunt chest wall trauma, admitted to hospital for greater than 24 hours, with no concurrent, immediately life-threatening injuries, were included. The intervention was a simple physiotherapy programme comprising thoracic and shoulder girdle exercises. Feasibility outcome measures included: Primary: 1) adherence to the protocol by the physiotherapy team (more than 80% of eligible patients randomised), and 2) acceptability of the intervention by the patients (less than 30% of patients dissented to participation). Secondary: 1) ability to retrieve follow up data (response rate of more than 70% of participants) and, 2) safety of the intervention compared to routine care (no more than 10% increase in serious adverse events).

Results 14 patients were recruited to the trial. Clinicians randomised 100% of eligible patients during the trial period. All feasibility criteria were fully met. The intervention was safe the number of serious adverse events was comparable between the control and intervention periods.

Discussion We have demonstrated that a fully powered randomised clinical trial of the ELECT Trial is feasible. Minor methodological modifications will be made for the full trial. ISRCTN Trial registration number ISRCTN 16197429

Background

Blunt chest wall trauma accounts for over 15% of all trauma admissions worldwide, with reported mortality ranging between 4 and 60%.^[1] The most common injury mechanisms include low velocity falls (> 2 m), high velocity falls (> 2 m), road traffic accidents, assaults and sporting injuries. Over 1800 patients presented to the Emergency Department (ED) in Morriston Hospital in 2018 with blunt chest wall trauma. Difficulties in the management of blunt chest wall trauma patients in the ED are becoming increasingly well recognised in the literature.^[2] Historically, analgesia and chest physiotherapy have been 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 fatal pulmonary complications.^[3]

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 a median pain severity score of 6 out of 10 (IQR: 3–7).^[4] 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.^[5] In a 2019 study, chronic pain and disability were reported in 62% and 57% of patients at 3 months post injury respectively.^[6] 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 post injury, this highlights a major healthcare problem which is not currently being addressed in clinical practice.

Patients are generally 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.[5] What remains unknown in blunt chest trauma literature, is the best management for addressing the longer-term complications, specifically chronic pain and disability. The aim of this trial was to establish the feasibility and acceptability of a future definitive trial, which will determine whether the exercise programme can be used safely and effectively in clinical practice in the UK.

Methods

This study adheres to the CONSORT extension guidelines for pilot and feasibility trials.

Trial design

This was a single-centre, parallel feasibility randomised controlled trial. Patients were allocated to the trial on a 1:1 ratio to control or intervention arms.

Participants

Patients admitted to the hospital for 24 hours or more, with isolated blunt chest wall trauma, were included in the trial if they were capable of giving consent to participation and aged 18 and over. Exclusion criteria included: patients lacking capacity to provide informed consent, aged under 18, or presenting with immediately life-threatening injuries including any concurrent injury precluding participation in the intervention.

Setting

This feasibility trial ran in a University Teaching Hospital in Wales, which is also a Trauma Unit. The critical care physiotherapy team were responsible for screening, recruiting and consenting eligible patients to the trial.

Intervention

Patients allocated to the intervention group, received standard care (where standard care traditionally involves chest physiotherapy techniques such as breathing exercises and early mobilisation), 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 was continued by the patient, three times per day, for seven days post-assessment. The exercise programme consisted 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). Participants were instructed to complete each exercise five times, per session. (See Additional file 1 for exercise programme). The control group received

standard care only. All participants were asked to complete one survey (EQ5D-5L)[9] on initial presentation and two more surveys at three months (EQ5D-5L and the Brief Pain Inventory).[10]

Criteria for establishing feasibility

In order to evaluate the feasibility of a full definitive trial, the trial results were assessed against predetermined success outcome criteria (Table 1) using a traffic light system.[17]

Primary: 1) adherence to the protocol by the physiotherapy team, and 2) acceptability of the intervention to the patients. Secondary: 3) ability to retrieve follow up data and, 4) safety of the intervention compared to routine care.

Table 1
Trial feasibility criteria

Primary outcomes
1) 80% or more of identified eligible patients were approached for potential recruitment to the trial
2) 30% or less of approached, eligible patients dissented to participate in the trial
Secondary outcomes
3) Follow up data for patient secondary outcomes can be collected for 80% or more of patients
4) There should be no greater than 10% increase in serious adverse events in the intervention group compared to the control group
Traffic light assessment: 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.[17]

Outcome measures

The EQ5D-5L is a generic, patient-reported, health-related quality of life measure.[9] The descriptive system comprises five dimensions; (mobility, self-care, usual activities, pain/discomfort and anxiety/depression), all of which have five levels; (no problems, slight problems, moderate problems, severe problems and extreme problems). The EQ Visual Analogue Scale (VAS) records the patient's self-rated health on a vertical visual analogue scale, where the endpoints are labelled 'The best health you can imagine' and 'The worst health you can imagine'. The VAS can be used as a quantitative measure of health outcome that reflect the patient's own judgement.

The Brief Pain Inventory (BPI) measures pain intensity (severity) and the impact of pain on functioning (interference) and it has been recommended that both domains should be included as outcomes in all chronic-pain clinical trials).[10] The BPI assesses pain at its "worst," "least," "average," (in the last 24-hours) and "now" (current pain), and the participant is required to give a score of between 0–10, where 0 = no pain and 10 = pain as bad as you can imagine. Each pain severity time-point should be reported separately, as the models for validation of the BPI included all four items.[10] The BPI measures how

much pain has interfered with seven daily activities, (general activity, walking, work, mood, enjoyment of life, relations with others, and sleep) and is typically scored as the mean of the seven interference items. The authors recommend that the mean can be used if more than 50%, or four of seven, of the total items have been completed on a given administration.

Sample size

The trial had a three month recruitment period. The aim was to recruit 20–30 patients, the minimum number considered necessary to test data collection processes based on existing recommendations.[8] This recruitment period was chosen to allow for low response rates for surveys, attrition, and potential inability to recruit out of office hours. At the start of this feasibility trial we did not know our main outcome measure would be. In this feasibility trial, we planned to collect data on quality of life and pain outcomes, using the EQ5D-5L[9] and Brief Pain Inventory[10] surveys. We will use this information to determine whether these data can be collected and what the most appropriate outcome for the main study will be. We will use data collected from patients in the feasibility study to inform the fully powered study in terms of: a) specifying the most important outcome measure; b) deciding what the smallest clinically significant difference for that outcome which we plan to detect in the main trial; and

c) selecting the power which we wish to detect that difference (at a reasonable level of statistical significance).

Randomisation

Patients were randomised (patient level) to the trial using a 1:1 ratio, using “Sealed Envelope”, an independent company which is available 24 hours per day.[7] We considered appropriate confounders which will be included as possible stratification variables for randomisation (such as age, sex and injury severity), moving forward to the full trial. Blinding was not possible due to the nature of the intervention in this trial.

Data analysis

Quantitative analyses were performed on SPSS (Version 23; IBM, Armonk, NY, USA) using the intention-to-treat principle. Analysis was not powered to detect clinically important effects, due to this being a feasibility trial. Results were presented as numbers (percentages), means (standard deviations), and medians (interquartile ranges) where non-normally distributed. Results of the EQ5D-5L survey were reported as medians, calculated using the Chartered Society of Physiotherapists EQ5D-5L Calculator (developed by Sheffield Hallam University.[11] Statistical differences between baseline characteristics and follow-up survey data between groups were not reported.

Patient and public involvement

Two patients recovering from recent blunt chest trauma were members of the ELECT Trial Development Group (TDG) that developed the protocol and designed the study. They continued to sit on the Trial

Management Group (TMG), attending trial meetings and contributing to the overall running of ELECT trial.

This trial received ethics approval by the Wales Research Ethics Committee 6 (Ref: 19-WA-0144) and was funded by a Pathway to Portfolio Grant from Health and Care Research Wales, on behalf of Welsh Government.

Results

Patients were recruited over the three month period (June to Sept 2019) and there were no difficulties implementing the protocol. A total of 14 patients were recruited (Fig. 1). A screening log was maintained accurately throughout the trial. In the intervention group, patients reported completing a mean of 79% (range 62%-100%) of the exercise programme. No issues were reported by patients completing the exercises.

Feasibility criteria

All pre-set feasibility criteria achieved a green status (Table 2). A mixture of postal and telephone follow up contacts were required for survey completion at three months.

Table 2
Feasibility outcomes

Feasibility Criteria	Result	Feasibility assessment
Primary outcomes		
1) 80% or more of identified eligible patients were approached for potential recruitment to the trial	n = 19/19 (100%) patients were deemed eligible for the trial and were approached for participation	GREEN
2) 30% or less of approached, eligible patients dissented to participate in the trial	n = 5/19 (26%) eligible patients declined to participate in the trial	GREEN
Secondary outcomes		
3) Follow up data for patient secondary outcomes can be collected for 80% or more of patients	Follow-up data collected for n = 10/14 (71%) of patients	GREEN
4) There should be no greater than 10% increase in serious adverse events in the intervention group compared to the control group	There were no serious adverse events reported in either group	GREEN
number of cases (percent). Feasibility criteria traffic light system: GREEN: feasibility criteria achieved, AMBER: feasibility criteria not achieved, but progression is possible with some minor protocol modifications, RED: Feasibility criteria not achieved and progression to a full trial is not possible		

The intervention and control groups were comparable at baseline. The median age of patients recruited to the trial was 75 years, with a low velocity fall the most frequent injury mechanism. No patients required admission to critical care or mechanical ventilation. The intervention group had a longer median hospital length of stay than the control group, but no statistical inference can be made with the small sample size.

Table 3
Baseline Characteristics

	Total (n = 14)	Control (n = 7)	Intervention (n = 7)
Age (years)	75 (70–80)	75 (71–86)	72 (60–80)
Male	10 (71%)	4 (29%)	6 (43%)
Female	4 (29%)	3 (21%)	1 (7%)
Number of rib fractures (median/IQR)	4 (3–7)	4 (3–8)	4 (3–6)
Flail chest (yes / no)	4 (29%)	2 (14%)	2 (14%)
Injury mechanism:			
• Fall < 2 metres	6 (43%)	4 (29%)	2 (14%)
• Fall > 2 metres	4 (29%)	1 (7%)	3 (21%)
• Road traffic accident	4 (29%)	2 (14%)	2 (14%)
Underlying lung injury:			
• Pulmonary contusion	1 (7%)	1 (7%)	0 (0%)
• Haemothorax	3 (21%)	1 (7%)	2 (14%)
• Pneumothorax	4 (29%)	2 (14%)	2 (14%)
Intercostal chest drain	2 (14%)	0 (0%)	2 (14%)
Highest level of care:			
• Intensive Care	2 (14%)	2 (14%)	0 (%)
• High dependency	4 (29%)	2 (14%)	2 (14%)
• Ward	8 (57%)	3 (21%)	5 (36%)
Complications			
• Type 1 respiratory failure	2 (14%)	0 (0%)	2 (14%)
• Type 2 respiratory failure	1 (7%)	0 (0%)	1 (7%)
Mechanical ventilation	0 (0%)	0 (0%)	0 (0%)
ICU length of stay	0 (0–1)	0 (0–1)	0 (0–1)
Total hospital length of stay	8 (4–15)	4 (2–10)	10 (7–17)
Discharged home	14 (100%)	7 (100%)	7 (100%)
Number (%), median (IQR)			

Table 3 highlights comparable results for the EQ5D-5L at baseline and at follow-up, in the intervention and control groups. Improvements in patient-reported health-related quality of life was seen in all but one patient, at three months post-injury.

Table 4

EQ5D-5L results at baseline and three month follow-up, for control and intervention groups.

	Total	Control	Intervention
Baseline median EQ5D-5L	0.21	0.23	0.18
3 month median EQ5D-5L	0.69	0.70	0.67
Patients improved by 3 months (n %)	9 / 10 (90%)	5 / 5 (100%)	4 / 5 (80%)
Baseline median patient reported health-score	48	48	48
3 month median patient reported health-score	68.6	72.5	65.4
Baseline n = 14, with n = 7 in each group. Surveys were not completed by two patients in each group at three months, so follow-up data is presented for n = 5 in control and intervention arms. Median EQ5D-5L results calculated using the CSP-EQ5D-5L calculator.			

Table 4 reports the results from the Brief Pain Inventory, completed by patients at the three month follow-up. The intervention group had a higher mean pain interference than the control group, but no statistical inference can be made with the small sample size.

Table 5

Brief Pain Inventory results at baseline and three month follow-up, for control and intervention groups.

	Total	Control	Intervention
Pain severity			
Median 'Worst'	3.0	2.4	3.6
Median 'Least'	1.8	1.4	2.2
Median 'Average'	2.4	1.8	3.0
Median 'Now'	2.3	2.4	2.2
Pain interference	1.9	1.2	2.7
Baseline n = 14, with n = 7 in each group. Surveys were not completed by two patients in each group at three months, so follow-up data is presented for n = 5 in control and intervention arms			
BPI Pain severity scoring: "worst", "least" and "average" in the past 24-hours, and "now," where 0 = no pain and 10 = pain as bad as you can imagine			

Discussion

This is the first trial to test the feasibility of conducting a parallel-randomised controlled trial into the effectiveness of an early exercise programme for the management of blunt chest wall trauma patients presenting. All feasibility criteria were met and there were no serious adverse events throughout the trial period, suggesting that progression to a full trial is possible.

The median age of this patient cohort was greater than that of some of our previous chest trauma trials with the same cohort.[12,13] The five eligible patients who were approached by the physiotherapy team, but declined to participate in the trial, were all younger than 30 years. This would have influenced the median age of participants. The main reason cited by patients who declined to participate was a lack of time and is potentially something that should be considered in the main trial.

This trial has highlighted some minor modifications that need to be made to the methods prior to moving forward to the full trial. The recruitment rate was lower than expected as the trial ran over a three month period in the summer. In our previous blunt chest trauma studies, recruitment rates were markedly higher, in all other seasons of the year. In the full trial, we would aim to recruit throughout the year, which should overcome this issue.

The exercise programme was reported to be straightforward to complete and not burdensome by a number of the patients in the intervention group. There were no serious adverse events or reported issues, such as unexpected increases in acute pain or complications, as a result of the exercise programme. Moving forward to the main trial, this programme could be used without modification. The outcome measures used in the trial were straightforward to complete and follow-up response rates were reasonable for this type of intervention and patient cohort. Use of postal surveys was not sufficient to achieve a good response rate, and follow-up telephone calls were needed. This will be considered moving forward to the full trial.

Conclusion

The intervention used in this trial, appeared acceptable to the patients. In conclusion, this work has demonstrated that with some minor modifications, progression to the full definitive impact trial is feasible.

Abbreviations

BPI
Brief Pain Inventory
EQ5D-5L
Euro-Qol 5 Dimension survey
ICU
Intensive Care Unit
IQR

Interquartile range

N

number

VAS

Visual analogue scale

Declarations

Ethics approval and consent to participate: Wales Research Ethics Committee 6, Health and Care Research Wales. (16/WA/0290). Written consent was obtained from study participants.

Consent for publication: Not applicable

Availability of data: The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests: The authors declare that they have no competing interests

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Authors' contributions: (CB,CO'N,HT,LN,HH) contributed to the conception and design of the trial. CB,HT,LN contributed to the running of the trial. CB,CO'N and HH completed the data analysis. CB wrote the initial draft and all authors (CB,HH,CO'N,HT,LN) contributed to its revision. All authors approved the final submission.

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Figures

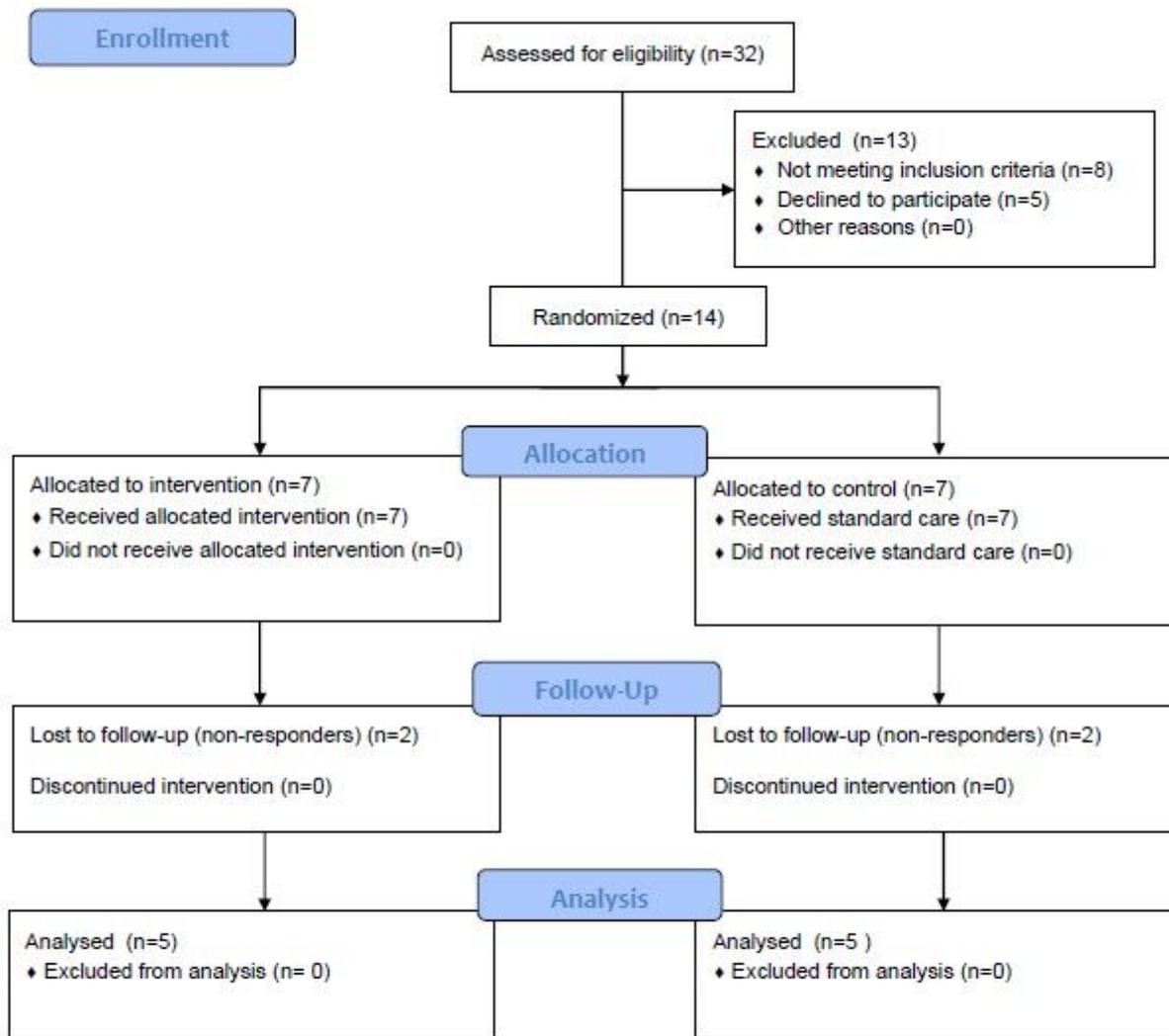


Figure 1

STUMBL CONSORT diagram

Supplementary Files

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- [Additionalfile1ELECTstudyexerciseprogramme.pdf](#)