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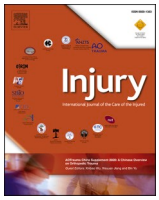

EarLy Exercise in blunt Chest wall Trauma: A multi-centre, parallel randomised controlled trial (ELECT2 Trial)

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ABSTRACT

Introduction: The aim of this trial was to investigate the impact of early thoracic and shoulder girdle exercises on chronic pain and Health-Related Quality of Life in patients with blunt chest wall trauma, when compared to normal care.

Methods: A multi-centre, parallel, randomised controlled trial, in which adult patients presenting to hospital with blunt chest wall trauma were allocated to either control or intervention group. The intervention was an exercise programme consisting of four simple thoracic and shoulder girdle exercises, completed for one week. Outcomes measures included prevalence and severity of chronic pain using the Brief Pain Inventory, health-related quality of life using EQ-5D-5 L, and cost effectiveness, measured at initial presentation and three months post-injury.

Results: 360 participants were recruited. Participants' mean age was 63.6 years (standard deviation (SD): 17.9 years) and 213 (59.8 %) were men. After loss-to-follow-up, the survey response rate at three months was 73.0 % (251/344 participants). The primary analysis, for chronic pain prevalence at three months post-injury, found no statistically significant differences between intervention and control groups, with lower rates in the control (intervention: 35/126 (27.8 %), control: 20/117 (17.1 %); adjusted odds ratio 1.862; 95 % CI: 0.892 to 3.893, $p = 0.098$). There were no statistically significant differences between intervention and control groups for pain severity at three months post-injury, (intervention mean (SD): 2.15 (2.49), control: 1.81 (2.10); adjusted difference 0.196, 95 % CI:0.340 to 0.731; $p = 0.473$); or Health-Related Quality of Life (intervention mean (SD): 0.715 (0.291), control: 0.704 (0.265); adjusted difference: 0.030; 95 % CI:0.033 to 0.094; $p = 0.350$). The health economic analysis found the intervention was associated with higher costs compared to normal care.

Conclusion: The results of this trial did not support a 'one-size fits all' simple, early exercise programme for patients with blunt chest wall trauma. Future research should consider the impact of a personalised exercise programme, commenced by the patient at least one week post-injury.

Introduction

Longer-term complications such as chronic pain and poor health-related quality of life are now well-recognised in patients with blunt chest wall trauma [1]. Baker et al. reported that despite a trend towards improving pain and physical function at six months post-injury, outcomes did not return to participants' perceived baseline level of function [2]. In patients with isolated rib fractures, a chronic pain prevalence of 64 % and disability prevalence of 67 % were reported at two months post-injury [3]. In a 2019 study, chronic pain and disability were

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reported in 62 % and 57 % of patients at three months post injury respectively [4].

Despite limited supporting evidence, inpatient physiotherapy is an important component of care pathways for blunt chest wall trauma. No previous research has been published investigating the impact of an early exercise programme on outcomes in patients with blunt chest trauma. In the UK, most patients are discharged with no follow-up care [5]. In a physiotherapy global survey, rehabilitation to address longer term sequelae following hospital discharge was reported by only 8 % of respondents [6]. Clinicians are traditionally taught that the pain and disability of rib fractures resolves in six to eight weeks [3]. What remains unknown, is the best management for addressing chronic pain and poor health related quality of life.

Research questions were:

1) In patients with blunt chest wall trauma, what is the impact of an early thoracic and shoulder girdle exercise programme on chronic pain prevalence and severity and health-related quality of life, when compared to normal care?
2) In patients with blunt chest wall trauma, what is the cost effectiveness of an early thoracic and shoulder girdle exercise programme, when compared to normal care?

Methods

Design

ELECT2 was a multi-centre, parallel randomised controlled trial. A feasibility study investigating the methods used in this main trial had been conducted, and a number of minor modifications made to trial processes as a result [7]. The ELECT2 protocol was written and published[8] following SPIRIT guidelines [9]. The trial was registered on the ISRCTN Trial Register, registration number: ISRCTN65829737

A sufficiently large sample size was sought to be able to detect, with 80 % power at 5 % significance, a 15 % reduction in chronic pain prevalence from 37 % to 22 % [2]. Such a change, with odds ratio of 0.48 and Cohen's h of 0.33, was judged to be of clinical significance. This required 300 analysable outcomes; inflating this by 20 % to accommodate attrition, our recruitment target was 360 participants.

Participants were randomised 1:1 to the control or intervention groups, using the independent randomisation service "Sealed Envelope" (www.sealedenvelope.com), with randomisation available 24 h per day. Randomisation was stratified by the estimated number of radiologically proven or clinically suspected rib fractures (0–2 versus 3 or more) and the estimated Clinical Frailty Scale (1–3 versus 4–9). The Clinical Frailty Scale (CFS) is a well-validated 9-point scale used to quantify the degree of disability from frailty [10].

Setting and participants

Participants were considered eligible if they presented to a participating hospital with 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 precluded completion of the exercise programme) and met the following inclusion criteria: 1) aged 16 or over, 2) able to give informed consent, 3) able to complete the exercise programme, and 4) able to complete follow-up surveys (where criteria 2–4 specified either "independently, or with support of a family member / carer or translator"). Exclusion criteria included 1) any concurrent injury that precluded the completion of the exercise programme, and 2) hospitalised prisoners.

Five hospitals (across four health boards) in Wales and one hospital in England participated in the trial. Participants could be recruited from the Emergency Department or the hospital ward if admitted. The type of ward or critical care unit on which the patient was located varied according to hospital policy. Trial physiotherapists or research nurses screened, recruited and consented eligible participants.

Data were collected at initial presentation and at three-months post-injury from patient-completed surveys by post, e-mail, or telephone, and were managed using REDCap electronic data capture tools hosted by Swansea University [11].

Intervention

Normal physiotherapy care (including, but not limited to; chest physiotherapy, early mobilisation and patient education) was provided to both arms of the trial. If allocated to the intervention group, the physiotherapist also taught the participant a simple exercise programme to be initiated within one week of injury. This programme consisted of four thoracic and shoulder girdle movements completed for one week, three times per day as tolerated (see supplementary file for exercise programme). Patients were asked to complete five repetitions of each exercise, as able. A diary to record adherence to the programme at each exercise session was kept by patients. A written copy of the exercise programme was provided to the patient regardless of the patient's destination on discharge. The physiotherapy team in charge of the patient's management could decide whether further follow-up was required, as per normal care, irrespective of the trial. The assessment of outcomes was not blinded as the delivery of the trial was being completed by the clinical team, due to resource constraints during the COVID-19 pandemic.

Data analysis: clinical effectiveness

Primary outcomes in this trial were chronic pain prevalence and severity measured using a Brief Pain Inventory survey[12] pain severity score $\geq$3.5. Secondary outcomes included health-related quality of life measured using EuroQol EQ-5D-5 L questionnaire, and cost-effectiveness measured using the validated mapping function to existing EQ-5D-3 L utility tariffs [13,14].

Primary and secondary outcome measures were summarised and analysed using generalised linear models. Models incorporated potential confounders such as age, sex, Townsend deprivation quintile (a measure of geographic deprivation)[15], CFS, number of suspected rib fractures, whether the patient took regular analgesia, relevant past medical history, trial site (to account for geographical clustering); baseline score; and whether the site was a major trauma centre. Chronic pain, pain severity and pain interference were also adjusted for baseline EQ-5D-5 L utility value to account for any correlation between outcome measures. Adherence was calculated as a percentage of the exercise sessions completed (three times per day for seven days).

Trial site intra-cluster correlations, seasonality, and the effect of missing data were assessed in sensitivity analyses based on multiple imputation. The imputation model included EQ-5D utility value, BPI pain severity and pain interference scores 3 months; covariates included age, sex, Townsend deprivation score quintile, study site, estimated clinical frailty score, estimated number of rib fractures, whether the participant took regular analgesia, relevant past medical history, mechanism of injury, whether the patient was admitted to hospital from ED, and baseline EQ-5D utility value, BPI pain severity and BPI pain interference scores

Tables 1–4

All analyses were specified in advance as far as possible, in accordance with an approved and detailed statistical analysis plan. Analyses were conducted using SPSS, version 29, except 95 % confidence intervals for small sample odds ratios (Table 3), which were calculated using the *PropsCI* package for R version 4.4.1.

Data analysis: cost effectiveness

The primary economic analysis was conducted from an UK National Health Service (NHS) and personal social services perspective, with a

Table 1
Participant baseline characteristics[a].

Characteristics	Intervention group ($n = 179$)	Control group ($n = 177$)
Site, n (%)		
A	84 (46.9)	81 (45.8)
B	31 (17.3)	34 (19.2)
C	27 (15.1)	37 (20.9)
D[b]	13 (7.3)	10 (5.6)
E	24 (13.4)	15 (8.5)
Estimated number of clinically suspected or radiologically reported rib fractures, n (%)		
0–2	73 (40.8)	67 (37.9)
3 or more	106 (59.2)	110 (62.1)
Actual number of rib fractures, n (%)		
0–2	68 (38.2)	64 (36.2)
3 or more	110 (61.8)	113 (63.8)
Mean (SD)	3.9 (3.3)	4.2 (3.8)
Estimated clinical frailty score, n (%)		
1–3	132 (73.7)	135 (76.3)
4–9	47 (26.3)	42 (23.7)
Actual Clinical Frailty Score, n (%)		
1–3	131 (73.6)	133 (75.6)
4–9	47 (26.4)	43 (24.4)
Mean (SD)	2.5 (1.6)	2.5 (1.6)
Age (yr), mean (SD)	63.5 (17.4)	63.7 (18.6)
Gender		
Male	104 (58.1)	109 (61.6)
Female	75 (41.9)	68 (38.4)
Townsend deprivation score of home postcode, n (%)		
1st quintile (least deprived)	27 (15.3)	33 (19.2)
2nd quintile	42 (23.9)	38 (22.1)
3rd quintile	43 (24.4)	49 (28.5)
4th quintile	39 (22.2)	32 (18.6)
5th quintile (most deprived)	25 (14.2)	20 (11.6)
Mechanism of injury, n (%)		
Fall <2 m (standing height)	91 (50.8)	82 (46.3)
High velocity fall >2m	34 (19)	37 (20.9)
Road traffic collision	23 (12.8)	30 (16.9)
Sporting injury	12 (6.7)	8 (4.5)
Assault	6 (3.4)	4 (2.3)
Crush	3 (1.7)	3 (1.7)
Other	10 (5.6)	13 (7.3)
Relevant injury descriptors present, n (%)		
Lateral rib fracture(s)	96 (54.2)	81 (46.0)
Anterior fracture(s)	45 (25.4)	40 (22.7)
Posterior fracture(s)	51 (28.8)	67 (38.1)
First rib fracture	6 (3.4)	6 (3.4)
Radiological flail	12 (6.8)	23 (13.1)
Bilateral fractures	0 (0)	4 (2.3)
Operative fixation	3 (1.7)	3 (1.7)
Sternum fracture	18 (10.2)	15 (8.5)
Clavicle fracture	9 (5.1)	8 (4.5)
Scapula fracture	5 (2.8)	7 (4.0)
Spinal fracture	8 (4.5)	9 (5.1)
Chest wall bruising only	24 (13.6)	21 (11.9)
Relevant past medical history, n (%)		
None recorded	39 (21.9)	45 (25.6)
Cardiac	62 (34.8)	64 (36.4)
Pulmonary	39 (21.9)	31 (17.6)
Rheumatological	16 (9.0)	17 (9.7)
Neurological	18 (10.1)	15 (8.5)
Mental health	16 (9.0)	20 (11.4)
Musculoskeletal	47 (26.4)	38 (21.6)
Other	45 (25.3)	50 (28.4)
Patient takes regular anticoagulants, n (%)	41 (22.9)	43 (24.3)
Patient takes regular analgesia, n (%)	43 (24)	41 (23.2)
ED disposition, n(%)		
Discharged	42 (23.5)	32 (18.1)
Admitted to ward	120 (67.0)	129 (72.9)
Admitted to HDU / ICU / other	17 (9.5)	16 (9.0)

n = number of participants; % = percentage; SD = standard deviation.
[a] ≤5 missing in any category.
[b] Site D includes two small hospitals that participated in the trial. These hospitals have been combined for reporting due to low counts.

secondary analysis from a partial societal perspective, which included costs associated with informal care. Resource use data relating to the intervention were estimated from discussions with clinicians. Data on health service, personal social services, and individual resource use were collected at three-months post-injury, including post-injury inpatient stays and outpatient visits, post-injury emergency department attendances, community based-health care use, prescribed medications, social service provision received, and informal care from friends or relatives. The resources used and the unit costs valued at 2021/22 prices and be found in the supplementary file.

Inpatient stays, day cases and outpatient procedures were allocated an appropriate Healthcare Resource Group code and valued using NHS national schedule costs [16]. Medication costs were obtained from the British National Formulary and were calculated based on dosage, dose frequency, and prescribed duration [17]. All other resources were allocated an appropriate unit cost, based on hourly cost from the Personal Social Services Resource Unit (PSSRU) [18].

The primary cost-effectiveness outcome was the quality-adjusted life year (QALY), as recommended by the National Institute for Health and Care Excellence (NICE)[19], derived from the EQ-5D-5 L completed at baseline and three-months. Utility values were estimated using the validated mapping function to existing EQ-5D-3 L UK utility tariffs [13]. Quality of life preference scores derived from the EQ-5D visual analogue scale (VAS) were converted to a 0–1 scale. QALYs from both the EQ-5D descriptive system and visual analogue scale were calculated by linear

Table 2
EQ-5D-5 L and Brief Pain Inventory scores.

	Intervention		Control		
Pain severity ≥ 3.5	n	count (%)	n	count (%)	Adjusted odds ratio[a] (95 % confidence interval)
Baseline	179	145 (81.0)	177	140 (79.1)	–
3 months	126	35 (27.8)	117	20 (17.1)	1.862 (0.892, 3.893) $p = 0.098$
EQ5D5 L utility value[b]	**n**	**Mean (SD)**	**n**	**Mean (SD)**	**Adjusted comparison**[a] (95 % confidence interval)
Baseline	179	0.256 (0.336)	177	0.262 (0.310)	–
3 months	130	0.715 (0.291)	119	0.704 (0.265)	0.030 (−0.033, 0.094) $p = 0.350$
Pain Severity[c]	**n**	**Mean (SD)**	**n**	**Mean (SD)**	**Adjusted comparison**[a] (95 % confidence interval)
Baseline	179	5.77 (2.28)	177	5.48 (2.10)	–
3 months	126	2.15 (2.49)	117	1.81 (2.10)	0.196 (−0.340, 0.731) $p = 0.473$
Pain Interference[d]	**n**	**Mean (SD)**	**n**	**Mean (SD)**	**Adjusted comparison**[a] (95 % confidence interval)
Baseline	179	6.69 (2.42)	177	6.53 (2.40)	–
3 months	125	2.10 (2.72)	114	1.82 (2.33)	0.236 (−0.366, 0.838) $p = 0.442$

[a] Adjusted for: trial site; age; sex; Townsend deprivation quintile; estimated clinical frailty score; estimated number of rib fractures; whether the patient takes regular analgesia; whether relevant past medical history was recorded; and baseline score. Chronic pain and pain severity were adjusted for baseline EQ-5D-5 L to account for any correlation between outcomes.
[b] 1 corresponds to perfect health, 0 corresponds to a state equivalent to dead, and negative values to a state considered worse than death.
[c] Scored from 0 (no pain) to 10 (worst pain).
[d] Scored from 0 (pain does not interfere with this activity) to 10 (pain completely interferes with this activity).

Table 3
Safety outcomes for admitted participants.

Outcome: n (%)[a]	Intervention(n = 137)		Control (n = 148)		Odds Ratio[b]	p-value[c]	95 % Confidence Interval[d]			
							Asymptotic		Agresti & Min	
Death or serious adverse event	4	(2.9)	4	(2.7)	1.083	1.000	0.223	5.268	0.290	4.044
Death	3	(2.2)	2	(1.4)	1.634	0.927	0.219	14.204	0.320	8.321
Other serious adverse event	2	(1.5)	4	(2.7)	0.533	0.758	0.067	3.449	0.112	2.545
Adverse event during admission	5	(3.6)	4	(2.7)	1.364	0.904	0.310	6.193	0.387	4.806
Delayed upgrade in care	1	(0.7)	1	(0.7)	1.081	1.000	0.029	39.943	0.111	10.486
Unplanned reattendance[e]	4	(2.9)	2	(1.4)	2.195	0.613	0.340	17.553	0.460	10.433

[a] Figures give the number of participants (percentage) recording each outcome at least once. Participants may record more than one category of event.
[b] Odds ratios are unadjusted, as 95 % confidence intervals were undefined when adjusting for factors included in the primary analysis.
[c] p-values determined by doubling the corresponding one-sided probability from Fisher's exact test, capped at 1.
[d] Asymptotic interval values use a continuity correction obtained from JavaStat (https://statpages.info/ctab2×2.html); Agresti & Min interval values are obtained via the R package PropCIs [23].
[e] Following discharge directly home from ED.

Table 4
Resources collected and corresponding valuations (2020–2021 prices).

Allocation arm	N	Mean Adjusted cost (£) (95 % CI)	Mean Adjusted QALY (95 % CI)	Incremental cost (£) (95 % CI)	Incremental QALY (95 % CI)	Net Monetary Benefit (£) at £20,000/QALY (95 % CI)	Net Monetary Benefit (£) at £30,000/QALY (95 % CI)
NHS and PSS Costs							
Intervention	179	856.92 (644.15, 1069.68)	0.12 (0.11, 0.13)				
Control	177	334.20 (154.21, 514.19)	0.12 (0.11, 0.12)	522.72 (240.89, 804.54)	0.00 (−0.01, 0.01)	−506.26 (−856.02, −156.49)	−501.66 (−905.15, −98.17)
Societal Costs							
Intervention	179	3957.78 (2531.00, 5383.99)	0.12 (0.11, 0.13)				
Control	177	1965.82 (538.70, 3392.94)	0.12 (0.11, 0.12)	1991.96 (−37.77, 4021.70)	0.00 (−0.01, 0.01)	−2003.16 (−4102.91, 96.59)	−2000.24 (−4123.83, 123.35)

Variables are adjusted for demographics, trial site, whether site is a major trauma centre, clinical frailty score and number of rib fractures. QALYs are also adjusted for baseline utility.

interpolation using the area-under-the curve approach, taking into account any deaths occurring during the trial period [20]. Net monetary benefits were calculated for willingness-to-pay thresholds between £0 to £100,000 per QALY. Adjusted mean costs and QALYs by trial group, differences in adjusted mean costs and QALYs, and incremental net monetary benefit were estimated using seemingly unrelated regression, accounting for the correlation between costs and QALYs [21]. Cost-effectiveness acceptability curves were constructed to explore sample uncertainty and estimate the probability that the intervention was more cost-effective than normal care across a range of willingness-to-pay thresholds.

Multiple imputation by arm using chained equations and predictive mean matching was used to address missing data for the health economic analysis. Missing values for baseline utility and EQ-5D visual analogue scale scores were imputed using the mean baseline utility value [22]. The covariates for the imputation model were age, sex, trial site, baseline utility, trial arm, number of clinically suspected rib fractures, and number of rib fractures from blunt chest trauma. Rubin's rules were used to combine the 55 individual imputations, and a randomisation seed was used to enable reproducible imputations.

The health economic analysis was conducted using Stata, version 17.

Role of the funding source

This work was supported by Health and Care Research Wales on behalf of Welsh Government (Grant number: RfPPB 20–1738). The funder played no role in the design, conduct, or reporting of this study.

Ethics approval

Ethics approval was obtained from the London Riverside Research Ethics Committee (Reference number: 21/LO/0782).

Results

Flow of participants through the trial

360 participants were recruited between February 2022 and February 2023. Fig. 1 summarises patient flow including reasons for attrition through the trial. Survey response rates were 75.9 % (132/174) in the intervention group and 70.0 % (119/170) in the control group.

Compliance with trial method

Baseline data were complete for all patients. The proportion of returned follow-up questionnaires with missing data was low: pain severity could be calculated for 96.8 % of participants (intervention: 126/132, control: 117/119), while EQ-5D utility values could be calculated for 99.2 % of participants (intervention: 130/132, control: 119/119).

Baseline characteristics

The participants' mean age was 63.5 years (standard deviation (SD) 17.4) in the intervention group and 63.7 years (standard deviation 18.6) in the control group. There were slightly fewer men in the intervention

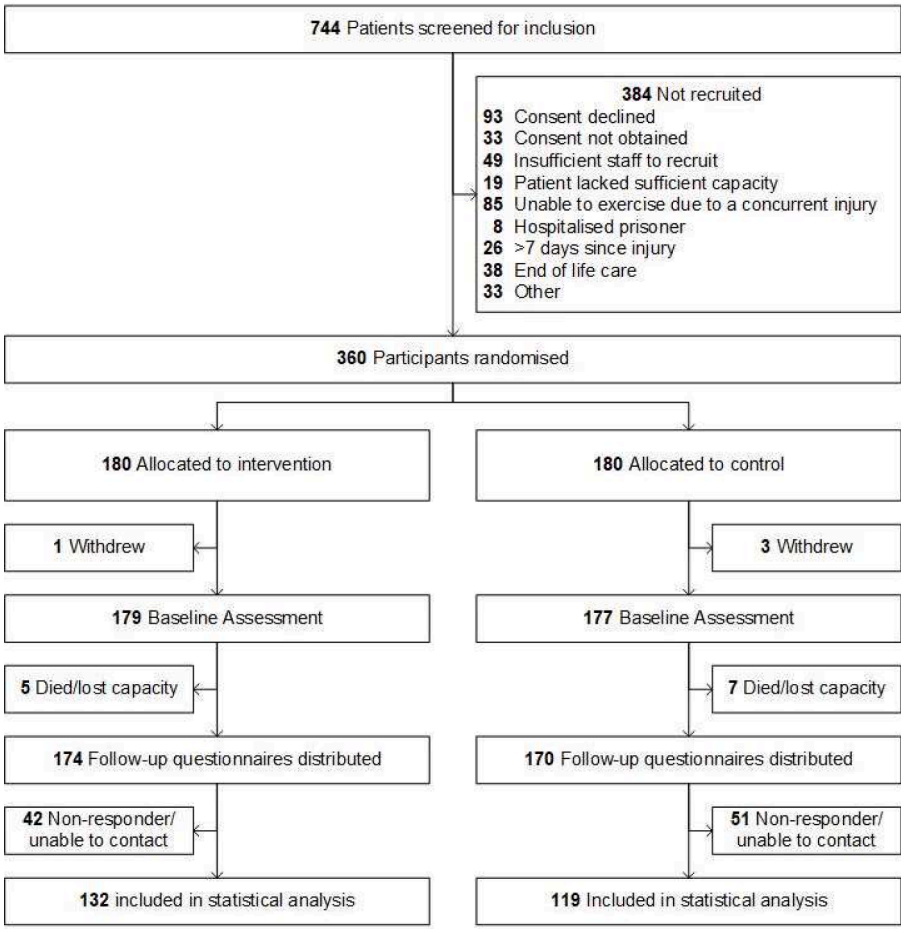

Fig. 1. ELECT2 Trial flow diagram.

group (104/179, 58.1 %) than the control group (109/177, 61.6 %). Nearly half of participants were recruited at a single site (intervention 84/179, 46.9 %; control 81/177, 45.8 %), with two other sites each accounting for between 15.1 % (Site C, intervention) and 20.9 % (Site C, control) of participants. The mean number of rib fractures sustained was 3.9 (SD 3.3) in the intervention group, and 4.2 (SD 3.8) in the control group. The mean CFS was 2.5 (standard deviation 1.6) in both groups. A fall from a standing height was the most frequent injury mechanism, reported by 96/179 (50.8 %) of patients in the intervention group and 82/177 patients (46.3 %) in the control group. For those patients admitted to hospital, there were no clinically meaningful differences between intervention and control groups in terms of analgesic management. Participants' baseline characteristics are summarised in Table 1.

Patients in the intervention and control groups reported similar pain and health related quality of life. The mean pain severity score was 5.77 (SD 2.28) in the intervention group and 5.48 (SD 2.10) in the control group. The mean EQ-5D-5 L utility value, was 0.257 (SD 0.336) in the intervention group and 0.262 (SD 0.310) in the control group. Four fifths of patients had a pain severity score of 3.5 or greater (intervention: 145/179 (81.0 %), control: 140/177 (79.1 %)). A full breakdown of baseline survey results can be found in the supplementary file.

Outcomes at three months

More patients in the intervention group reported chronic pain at three months (35/126, 27.8 %) than in the control group (20/117, 17.1 %); however the difference was not statistically significant (adjusted odds ratio: 1.862; 95 % CI: 0.892 to 3.893, $p = 0.098$).

The mean pain severity score was higher in the intervention group (2.15, SD 2.49) than the control group (1.81, SD 2.49), but this was not statistically significant (adjusted difference: 0.196; 95 % CI: −0.340 to 0.731; $p = 0.473$).

The mean health related quality of life was higher in the intervention group (0.715, SD 0.291) than the control group (0.704, SD 0.265), but this was not statistically significant (adjusted difference: 0.030; 95 % CI: −0.033 to 0.094, $p = 0.350$);

The baseline and three month BPI and EQ-5D-5 L survey results are summarised in Table 2. A full breakdown of survey results is in the supplementary file.

Sensitivity analyses

A sensitivity analysis using a mixed effects models incorporating both study site and study site by treatment effect as random effects found results broadly consistent with the primary analysis. Unadjusted results were largely similar, although the difference in the proportion of patients reporting chronic pain at three months post injury achieved borderline statistical significant in favour of the control group (odds ratio 1.865, 95 % confidence interval 1.004 – 3.466, $p = 0.049$).Multiple imputation data produced results consistent with those for the unimputed data.

Although a sensitivity analysis considering seasonality found that participants injured in December were more likely to report chronic pain at three months than those injured in January (January: 3/23 participants (13.0 %), December: 6/17 participants (35.3 %); adjusted odds ratio 15.636, 95 % confidence interval 1.790 to 136.576, $p = 0.013$), no other evidence of seasonality was found for either the chronic pain or

health related quality of life outcomes.

Analysis of intra-cluster correlations found some evidence of correlation for the prevalence of chronic pain (ICC = 0.073), but not for health-related quality of life (ICC = 0.00). Further inspection of the data suggests much of this correlation is associated with sites recruiting relatively few patients, which is consistent with the outputs from the generalised linear regression models used in the primary analysis.

Adherence to intervention

Data on adherence were available for 127/179 (70.9 %) intervention participants. The mean proportion of the exercise programme completed was 64.0 % (standard deviation 3.0 %). 29/127 (22.8 %) reported that they completed the entire intervention, which was the most frequent response. Only 11 respondents (8.7 %) reported that they did not complete any of the intervention.

Safety of intervention

There were very few reported adverse or serious adverse events in the trial, although these data were available for admitted participants only (n = 285). No statistically significant differences were observed between arms and there were no reported safety events related to the trial intervention. Table 3 summarises the safety data.

Health economic analysis

The primary economic analysis was conducted on 356 participants with 34 % having complete cost and utility data from an NHS/personal social services perspective. The proportion of missing data for each variable in the multiple imputation model can be found in the supplementary file. The intervention required a one-time instruction from an UK Agenda for Change Band 6 physiotherapist who was estimated to spend an additional 10 min per patient delivering the intervention. No additional training or consumables were required and there was no provision for supervision or administration. The cost of delivering the intervention was estimated at £8.83 per patient.

Higher levels of service usage were observed for those in the intervention group. These participants had more subsequent inpatient stays, outpatient visits, and ED attendances. Participants in the control group had more practice nurse visits and district nurse visits, whereas those in the intervention group had a greater number of GP visits, community-based nurse contacts, and other therapist contacts. Participants in the control group took fewer prescribed medications than those receiving the exercise programme. Participants in the intervention group required more informal care support with higher levels of personal care support, help in/around the home, and help outside the home.

The total adjusted mean costs from the NHS/personal social services perspective in the intervention group (£857) were higher than in the control group (£334), a cost difference of £523 (95 % CI: £241 to £805). More participants in the intervention group reported total costs greater than £2000, predominantly resulting from inpatient stays or having multiple social care attendances per day. Fig. 2 highlights the distribution of total NHS/personal social services costs and identifies a few individuals with high total costs in both arms.

Median total NHS/personal social services costs remained lower for the control group. Outliers did not therefore fundamentally change the interpretation of the results. From the partial societal perspective, the difference in costs increased to £1992 (95 % CI -£38, £4022) due to the higher level of informal care support received by individuals in the intervention group. The 95 % confidence interval was wide indicating substantial uncertainty in costs, but the difference between groups was not statistically significant.

There was no difference in the number of adjusted mean QALYs for participants in the intervention group compared to those in the control group (intervention: 0.12, control: 0.12; difference 0.00, 95 % CI −0.01 to 0.01). From the NHS/personal social services perspective, the incremental net monetary benefit of the intervention compared to normal care was -£506 (95 % CI -£856 to -£156) at a willingness to pay threshold of £20,000 per QALY and -£502 (95 % CI -£905 to -£98) at a willingness to pay threshold of £30,000 per QALY. Negative values indicate that the cost to derive the small QALY gain is greater than the willingness to pay threshold. The incremental net monetary benefit was larger from the societal perspective at -£2011 (95 % CI, -£4095 to £73) at the £20,000 per QALY gained threshold. Table 4 demonstrates the resources collected and corresponding valuations.

The cost-effective acceptability curves from both NHS/PSS and societal perspectives can be found in the supplementary material. This indicates that, at a willingness to pay threshold of £20,000 per QALY gained, the probability that the intervention was cost-effective compared to the control group is 2.6 % from the NHS/personal social services perspective and 3.0 % from the partial societal perspective. These small percentages were primarily driven by the lack of an observable difference in QALYs between the arms at three months.

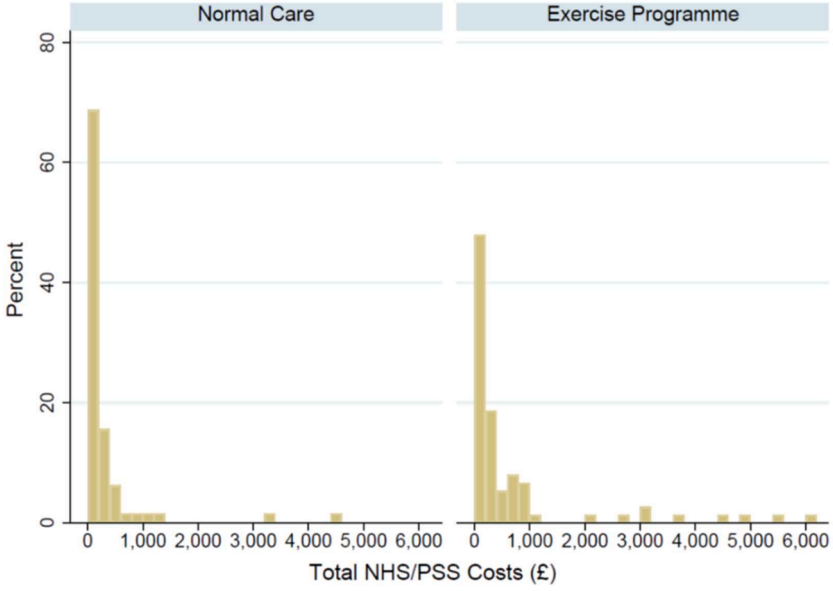

Fig. 2. Histogram of total NHS/PSS costs distribution.

A series of deterministic sensitivity analyses did not demonstrate any notable improvements in the probability that the intervention was cost-effective (data can be found in the supplementary file). A complete case analysis conducted on individuals with complete cost and QALY data showed little change to the base case results, with the intervention more expensive than normal care, and no statistically significant difference in QALYs between arms.

Discussion

No evidence was found supporting the use of an early exercise programme in patients presenting to EDs with blunt chest wall trauma. The proportion of participants reporting chronic pain at three months post injury was higher in the intervention group than the control group, as were the mean pain severity score, mean pain interference score, and mean health related quality of life. However, there were no statistically significant differences detected between the two groups, with the exception of the unadjusted sensitivity analysis for chronic pain ($p = 0.049$). There is also no evidence that the intervention was cost-effective when compared to usual care at standard willingness-to-pay thresholds. There is no previous physiotherapy research investigating the impact of an early exercise programme on chronic pain and health-related quality of life in patients with blunt chest trauma.

Compared to previous research, the results of the ELECT2 Trial demonstrated an overall lower prevalence and severity of chronic pain at three months post-injury [2]. The lower than expected prevalence and severity of chronic pain and health-related quality-of-life may have been due to the inclusion of participants being discharged directly home from the ED, hence having a lower injury severity. This could have been mitigated through the inclusion of participants only with radiologically proven fractures, however, this would have been difficult as not all participants undergo imaging and chest radiograph is well-recognised to miss at least 50 % of rib fractures [24].

The intervention was found to be safe, as there were no statistically significant differences in the number of adverse and serious adverse events between the two groups. It was not possible to conclude whether this was also true for the participants discharged home directly from the ED however, as safety events were only collected for participants admitted to hospital due to resource limitations. Participants were provided with a contact telephone number for any issues following discharge home, although no contacts were made throughout the trial.

It is well-recognised that pain from blunt chest trauma in the acute phase can be severe. It is possible that starting the intervention very early in the acute phase may have prolonged pain over the three month post-injury follow-up period. Future research could consider initiating the intervention later than seven days post-injury. It is also possible that the three month follow-up period was either too early or too late to demonstrate a difference, and future research may wish to consider alternative follow-up periods.

The 'one-size fits all' exercise programme may also have contributed to the trial's results. The differences in the severity, size and anatomic location of the participants' chest injuries could have impacted the pain and disability experienced with completion of the intervention. The results of this trial could suggest that a more personalised approach to rehabilitation is needed for this cohort, in which the exercises are tailored to the specific injuries sustained by the patient.

There were some limitations in this trial. We achieved the target sample size of 360 participants within the recruitment period. However, total attrition was higher than anticipated, resulting in 251 analysable outcomes rather than the 300 expected and consequently the trial was underpowered. This could have resulted in Type 2 error and this should be considered when interpreting the results of this trial. The trial was completed at the end of the COVID-19 pandemic and anecdotally, patients were experiencing survey fatigue and consequently response rates were lower than normal in many trauma trials in the UK at that time. The sample size calculation considered only the prevalence of pain and it may have been more accurate to take into account pain severity.

There was a long time period between completion of the intervention and follow-up in which confounders could have impacted the results of the trial. Whilst we modelled for confounders in our analysis, there may have been others which were not considered. Adherence is a well-recognised challenge in both physiotherapy research and clinical work, and may have impacted our results. Previous rates of non-adherence to physiotherapy exercise programmes were reported to range between 14 and 70 % [25]. We had attempted to address this during trial development stages, through the use of patient representatives, who helped to design the intervention and advise on issues including data collection methods, exercise after blunt chest wall trauma and adherence. Although there were no differences in the types of analgesic management used between the two groups, detailed data regarding quantities of analgesia delivered was not collected, which may have influenced the trial's results.

The quantity of missing data for the economic analysis was substantial. This was addressed using multiple imputation. The completion rate in the intervention group was slightly higher than the control group therefore, the data may not be missing at random. A complete case analysis produced results analogous to the base-case findings. It was not possible to identify whether the intervention had an impact on the primary admission including length of stay. Furthermore, the trial had a short follow-up period and it is unknown whether the cost differences observed would be observed in the longer term.

Despite the trial being underpowered to detect the anticipated reduction in chronic pain prevalence, there are still important conclusions for both service users and the healthcare community that should be considered. Based on our results, a simple, early exercise programme may not lead to an improvement in the prevalence and severity of chronic pain, or health related quality of life at three months following blunt chest wall trauma. There is also no evidence that the intervention was cost-effective at standard willingness-to-pay thresholds.

Ethics statement

Ethics approval was obtained from the London Riverside Research Ethics Committee (Reference number: 21/LO/0782).

CRediT authorship contribution statement

Ceri Battle: Writing – original draft, Supervision, Resources, Project administration, Methodology, Investigation, Funding acquisition, Data curation, Conceptualization. **Timothy Driscoll:** Writing – review & editing, Writing – original draft, Validation, Methodology, Formal analysis, Data curation, Conceptualization. **Deborah Fitzsimmons:** Writing – review & editing, Supervision, Methodology, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Shaun Harris:** Writing – review & editing, Writing – original draft, Validation, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Fiona Lecky:** Writing – review & editing, Supervision, Methodology, Conceptualization. **Claire O'Neill:** Writing – review & editing, Validation, Supervision, Project administration, Methodology, Investigation, Data curation, Conceptualization. **Alan Watkins:** Writing – review & editing, Validation, Supervision, Resources, Methodology, Formal analysis, Data curation, Conceptualization. **Jane Barnett:** Writing – review & editing, Validation, Project administration, Methodology, Conceptualization. **Susan Davies:** Writing – review & editing, Validation, Methodology, Conceptualization. **Hayley Anne Hutchings:** Writing – review & editing, Supervision, Project administration, Methodology, Conceptualization.

Declaration of competing interest

There are no conflicts to declare.

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Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.injury.2024.112075.

Appendix

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