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BMJ Open Early exercise in blunt chest wall trauma: protocol for a mixed-methods, multicentre, parallel randomised controlled trial (ELECT2 trial)

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ABSTRACT

Introduction Chronic pain and disability are now well-recognised long-term complications of blunt chest wall trauma. Limited research exists regarding therapeutic interventions that can be used to address these complications. A recent feasibility study was completed testing the methods of a definitive trial. This protocol describes the proposed definitive trial, the aim of which is to investigate the impact of an early exercise programme on chronic pain and disability in patients with blunt chest wall trauma.

Methods/analysis This mixed-methods, multicentre, parallel randomised controlled trial will run in four hospitals in Wales and one in England over 12-month recruitment period. Patients will be randomised to either the control group (routine physiotherapy input) or the intervention group (routine physiotherapy input plus a simple exercise programme completed individually by the patient). Baseline measurements including completion of two surveys (Brief Pain Inventory and EuroQol 5-dimensions, 5-Levels) will be obtained on initial assessment. These measures and a client services receipt inventory will be repeated at 3-month postinjury. Analysis of outcomes will focus on rate and severity of chronic pain and disability, cost-effectiveness and acceptability of the programme by patients and clinicians. Qualitative feedback regarding acceptability will be obtained through patient and clinician focus groups.

Ethics/dissemination London Riverside Research Ethics Committee (Reference number: 21/LO/0782) and the Health Research Authority granted approval for the trial in December 2021. Patient recruitment will commence in February 2022. Planned dissemination is through publication in a peer-reviewed Emergency Medicine Journal, presentation at appropriate conferences and to stakeholders at professional meetings.

Trial registration number ISRCTN65829737; Pre-results.

INTRODUCTION

Background

Longer-term complications such as chronic pain and disability are now well-recognised in patients with blunt chest wall trauma. In a recent prospective study of patients with

Strengths and limitations of this study

- To our knowledge, this is the first trial to investigate the impact of exercise on outcomes following blunt chest wall trauma.
- The inclusion of focus groups will help gain a full understanding of both patient and clinician perceptions of the exercise programme.
- Recruitment to the trial could be influenced by a reduction in trauma presentations to hospital, as reported during the current pandemic.

isolated rib fractures, a prevalence of chronic pain of 64% and disability of 67% were reported.¹ In a 2019 study, chronic pain and disability were reported in 62% and 57% of patients at 3 months postinjury, respectively.² It was reported by Baker *et al* in the RIOS study that despite a trend towards improving pain and physical functional at 6 months postinjury, outcomes did not return to participants perceived baseline level of function.³ In most hospitals in the UK, however, patients are simply discharged home with no follow-up care.⁴ Clinicians are traditionally taught that the pain and disability of rib fractures resolves in 6–8 weeks.¹ What remains unknown in blunt chest trauma literature, is the best management for addressing the longer-term complications, specifically chronic pain and disability.

Trial aims

The aim of this trial (protocol V.1.1, 5 November 2021) is to investigate whether early thoracic and shoulder girdle exercises improve chronic pain in patients with blunt chest wall trauma, when compared with normal care (where normal care traditionally involves chest physiotherapy techniques such

as breathing exercises and early mobilisation/walking and no thoracic/shoulder girdle exercises). To achieve this aim, these objectives will be addressed: (1) Investigate chronic pain prevalence and severity and physical disability at 3 months postinjury, using the Brief Pain Inventory⁵ (BPI) and EuroQol 5-dimensions, 5-Levels (EQ5D-5L)⁶ in patients with blunt chest wall trauma who present to hospital, receiving either usual care, or an early exercise programme and usual care.

1. Conduct focus groups to investigate the experiences of patients completing the intervention, and clinicians delivering the intervention.
2. Conduct an analysis of the cost-effectiveness of the exercise programme.

A feasibility study investigating the methods to be used in this main trial has been conducted, and a number of minor modifications made to the trial processes as a result.⁷

METHODS AND ANALYSIS

Trial design and randomisation

This is a mixed-methods, multicentre, parallel randomised controlled trial. The protocol was written following the Standard Protocol Items@ (SPIRIT) guidelines.⁸

Patients will be randomised (patient level) to the control or intervention arms of the trial using a 1:1 ratio, using 'Sealed Envelope' (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 specifically: Number of rib fractures: 0–2 vs 3 or more; Clinical Frailty Score (CFS) score: 1–3 vs 4–9

Population

Patients will be considered eligible if they present to one of the participating hospital with 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) and meet the following inclusion criteria: (1) aged 16 or more, (2) able to either give informed consent independently, or with support of a family member/carer or translator, (3) able to either complete the exercise programme independently, or with support of a family member/carer and (4) able to complete surveys independently, or with support of a family member/carer or translator. Exclusion criteria will include (1) any concurrent injury that precludes the completion of the exercise programme and (2) hospitalised prisoners.

Setting and recruitment

There are four hospital in Wales and one in England participating in the trial. Patients can be recruited from the emergency department or the hospital if admitted. The ward or critical care unit on which the patient will be

located will vary according to individual hospital policy. These will include general critical care areas, trauma units, cardiothoracic wards/critical care areas, general medical or surgical wards or emergency care wards. The physiotherapists or research nurses will screen, recruit and consent eligible patients to the trial.

Sample size

Four research sites in Wales and one in England have been selected in order to successfully achieve the required sample size, within the proposed recruitment period. All calculations have been completed using the findings of the feasibility study.⁷ We seek a sufficiently large sample size to be able to detect, with 80% power using 5% significance, which corresponds to a 15% reduction in chronic pain prevalence (as measured using a BPI median score of 3.5) from 37% to 22%.³ Such a change is judged to be of clinical significance. This will require 300 analysable outcomes; inflating this by 20% to accommodate attrition, our target sample size becomes 360 patients. Our feasibility work⁷ and Rib Injury Outcome Study (RIOS study)³ reported a recruitment rate of five and six patients per month respectively, so using a target of six per month (allowing for two of the participating sites, University Hospital Wales and Salford Royal Hospital being large major trauma centres), we will need five sites, recruiting for 12 months, with four further months follow-up.

Intervention

Following randomisation, if allocated to the intervention group, the physiotherapist will teach the patient 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 (see exercise programme in online supplemental file). Routine advice (including, but not exclusively, chest physiotherapy advice given as part of normal care) will also be provided to both arms of the trial. A written copy of the exercise programme and contact number for advice if needed will be provided to the patient, regardless of discharge disposition. The physiotherapy team in charge of the patient's management can decide whether further follow-up is required, as per routine/normal care, irrespective of the trial. The trial will be unblinded as the delivery of the trial is being completed by the clinical team, due to resource constraints during the current pandemic. [Figure 1](#) summarises the patients' journey through the trial.

Strategies to improve adherence to intervention

Full training (including a training manual) on the use of the programme and the trial design will be provided for each hospital's principal investigator (PI), who will then be responsible for training their teams. All documentation will be available in the Welsh language where applicable and translation services will be used as needed where available. Patients will be offered a number of methods for return of follow-up surveys including email, post or telephone.

ELECT2 Trial Flow Diagram

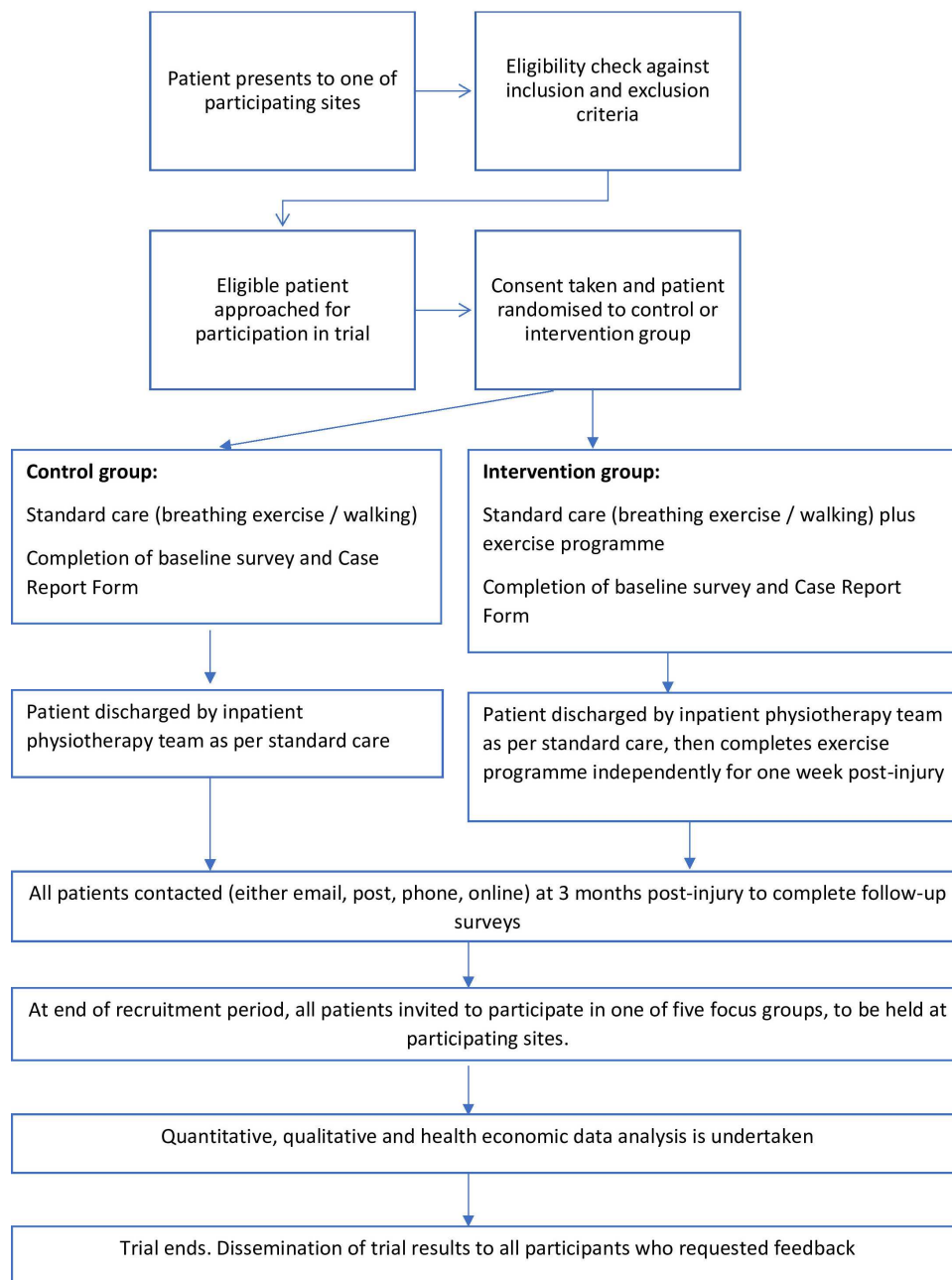


Figure 1 Summary of the patients' journey through trial.

Outcome measures

Primary outcome measures

To assess chronic pain prevalence and severity and physical disability, participants will complete two surveys: the BPI Short form⁵ and EQ5D-5L⁶ on initial presentation and at 3 months postinjury (by post, email or telephone).

Chronic pain is defined as pain that persists beyond the normal expected healing time and therefore lacks the acute warning function of physiological nociception. Pain is normally considered as chronic when it lasts or recurs for more than 3–6 months.³ For this study,

chronic pain was defined as having a BPI, Pain Severity Score of ≥ 3.5 at 3 months postinjury.³ It is short and easy to use.

Physical function is an individual's ability to undertake actions that involve physical activities, ranging from activities of daily living to more complex activities that involve a combination of skills, often within a social context. For the purposes of this study, physical disability was measured using the individual components of the EQ5D-5L at 3 months after discharge from hospital.

Secondary outcome measures

- ▶ Cost-effectiveness.
- ▶ Rate of adverse and serious adverse events (AEs and SAEs).
- ▶ Acceptability of programme by clinicians and patients (qualitative data collection using five focus groups, one per participating site, in intervention group only).

These outcomes were collected in our feasibility study (follow-up rate of 71% achieved). There were no SAEs reported.⁷

Data collection

Once the consent form has been signed, the baseline case report form (CRF), BPI and EQ5D-5L survey can be completed either independently by the patient, or with assistance from the family member, carer or translator if required. For patients who are admitted to hospital, the research team will be required to complete a second CRF, which will include outcomes and details of any complications, AEs and SAEs (see section 5 below). Each site will be required to keep a screening log, recruitment/allocation log and an AE/SAE log throughout the recruitment period.

At 3 months postinjury, the patient will be sent the questionnaires including an additional Client Services Receipt Inventory (CSRI) in the post, via telephone or via email (as requested by the patient on initial recruitment). If there is no reply to the postal survey after 1 month, the research nurse team, will contact that patient and administer the survey by telephone. At the end of the recruitment period, participants will be invited by the site research team to attend a focus group meeting, which will be held at their hospital/venue of close proximity to the hospital. This will be run by the trial team

A focus group meeting will be conducted (remotely via TEAMS or Zoom) with clinicians involved with delivery of the trial and intervention, in order to gain feedback regarding the exercise programme. Clinicians who have participated in the trial will be contacted once the recruitment period is completed. Clinician written informed consent will be gained before the focus group meeting.

Data management

Research Electronic Data Capture (REDCap) will be used for data capture at each participating site and for completion of the electronic CRF, hosted at Swansea University.⁹ REDCap is a secure, web-based application designed to support data capture for research studies, providing (1) an intuitive interface for validated data entry; (2) audit trails for tracking data manipulation and export procedures; (3) automated export procedures for seamless data downloads to common statistical packages and (4) procedures for importing data from external sources.⁹

Statistical methods

Quantitative analysis

Primary and secondary outcomes will be summarised, and analysed using generalised linear models. These models

will include potential confounders such as age, sex, frailty score, number of suspected rib fractures, study site (to account for geographical clustering); and whether the site is a major trauma centre. Analyses will be specified in advance as far as possible, in accordance with an approved and detailed statistical analysis plan. The plan will specify the use and selection of descriptive statistics; procedures for identifying covariates, and rules for their inclusion and exclusion in analyses; the level of statistical significance to be used; treatment of missing data (eg, multiple imputation procedures) and outliers; and presentation of results, including details of Consolidated Standards of Reporting Trials (CONSORT) diagrams, summary tables and figures. Analysis will be conducted using SPSS V.28.

Qualitative analysis

A random sample of trial patients and/or their carers where applicable (8–10 per group) will be asked to attend a focus group (one focus group at each of the participating hospitals) for the qualitative data collection (at a convenient location in which participants will be reimbursed travel expenses or using Zoom where necessary). In a qualitative research study, it is not possible to prespecify a required sample size. The aim is instead to reach data saturation where possible. The overall focus will be on exploring participants' experience and perception of completing the intervention. The focus group will last for up to 1 hour and will be audiorecorded, transcribed and anonymised. All of the qualitative data will be dealt with following the six stages: data familiarisation, generating initial coding, searching for themes, reviewing themes, defining and naming themes, producing a report. Focus group transcripts will be analysed thematically using NVivo V.12 (computer assisted qualitative data analysis software). Participants will be given the option of attend Welsh medium focus groups.

A remote e-focus group will also be undertaken with clinicians responsible for delivering the intervention (exercise programme) during the trial, in order to explore the impact of the intervention itself.

Health economic analysis

A health economics analysis plan will be developed alongside the statistical analysis plan. A UK National Health Service (NHS)/personal social services perspective will be adopted. A cost–utility (incremental cost per Quality Adjusted Life Year, QALY) analysis will be undertaken, based on the 3-month trial follow-up. We will determine the intervention costs associated with the exercise programme (which will be minimal as only one sheet of A4 paper), but more focused on the opportunity costs of staff time associated with training and delivery, through data collected during the trial and informant discussions with the project team. We will use the adapted Client Services Receipt Inventory (CSRI) developed from our previous STUMBL feasibility study in the same patient populations.¹⁰ Our clinicians and Patient and public involvement (PPI) will review the CSRI to ensure the

content and format (eg, time-frame) is accurate for use in the ELECT trial. We will collect participant level health and social resource use in both the intervention and control (usual care) groups using the adapted CSRI at 3 months. Published unit costs will be used to value resources in pound sterling. With a time horizon of less than 12 months, discounting will not be done.

Following current National Institute for Health and Care Excellence (NICE) guidance, we will map the EQ-5D 5L descriptive system data onto the 3L value set in order to derive utilities and QALYS for intervention and control groups, using area under the curve.¹¹ An incremental cost-effectiveness ratio will be produced, adjusted as needed to any baseline differences in costs or effects. Deterministic sensitivity analysis will assess the robustness of our findings to changes in varying parameters. Bootstrapping to explore joint uncertainty in costs and effectiveness, with cost-effectiveness acceptability curve to illustrate the probability of the exercise programme being cost effective at below or within NICE thresholds (£20–£30 000 per QALY gain). To capture the full extent of the trial outcomes, other primary and secondary outcomes will be presented in a cost–consequence analysis.

A recognised limitation is a short-trial horizon in providing information as to whether the exercise programme is cost-effective over the longer term. This also must be balanced by the feasibility and constraints in extrapolating the benefits of the trial (eg, maintaining post-injury function beyond 3 months), and research funding envelope available. Understanding the short-term costs of introducing an early exercise balance alongside the clinical benefits to reduce chronic pain and disability will provide complementary and comprehensive information to NHS decision-makers and commissioners. To consider whether the findings could be extended to capture likely longer term benefits and harms, we will assess the feasibility of conducting economic modelling to extrapolate the findings, including consideration of where the ‘information gaps’ are for populating a model.

Trial monitoring and management

An independent, joint trial steering/data monitoring committee has been formed that has no link to the trial team or sponsor and has no competing interests. Members of the committee include chair, two clinicians, patient representative and statistician. The role of the committee will be to monitor any AE and SAE and trial endpoint success criteria analysis. There will be no predefined stopping criteria as the intervention is considered low risk and no AEs were reported in the feasibility study.

Although there are a number of expected AEs for patients who have sustained blunt chest wall trauma, the PI may take appropriate urgent safety measures in order to protect research participants against any immediate hazard to their health or safety, without prior authorisation from a regulatory body. Any SAE and urgent safety measures will be reported to the CI immediately with details of the measure and a plan for further action. The

CI or Sponsor will notify the main REC and trial steering committee. SAEs will include; death, life-threatening complications, prolonged hospitalisation, persistent/significant disability or incapacity.

Patient and public involvement

Two patient representatives (JP and SD) have been involved from the outset in this phase of work, including in the design and management of our recent feasibility study related to this proposed full trial. They have been involved in the completion of this application, including the modifications made to study design in response to the feasibility work. They have advised us on aspects of the study design, including choice of surveys for the outcome measures, content of the exercise programme and best methods for follow-up of patients once discharged from hospital. Both representatives will continue to sit on the trial management group meeting for the duration of the trial. Two of our other PPI representatives will sit on the trial steering committee.

ETHICS AND DISSEMINATION

Ethical issues

This trial has received ethics approval by the London Riverside Research Ethics Committee (Ref: 21/LO/0782). Any necessary protocol modifications will be communicated to the investigators, regulatory authorities, trial participants and trial registries in a timely manner. Compliance with this will be monitored by the trial sponsor Swansea Bay University Health Board (SBUHB) R&D Department. PIs are all Good Clinical Practice GCP trained. Informed consent will be obtained by the clinicians or research nurses who will all have received ‘protocol and informed consent specific training’ in alignment with the principles of GCP and who have signed the trial delegation log. Consent will be sought, following a full introduction to the study and once the patient has had time to discuss the patient information sheet with a family member/carer or translator as required.

The trial’s chief investigator will assume overall responsibility to ensure that patient anonymity is protected and maintained. Trial patients’ data will be kept confidential and managed in accordance with the Data Protection Act, NHS Caldicott Guardian, The Research Governance Framework for Health and Social Care and Research Ethics Committee Approval. Once informed consent is obtained, all patients will be allocated a trial number. Personal data will only be identifiable by this trial number during data collection. All patient identifiable data will be removed and data anonymised once data collection is complete. The CI will act as the custodian of the data and the records will be kept securely for a further 5 years in the SBUHB archive facility. The Caldicott guidelines will be adhered to throughout the study.

The use of a focus group meetings using TEAMS brings about additional ethical issues that will be considered.¹² Personal data protection, software security and patient consent are the three most important parameters for telerehabilitation ethics that will be considered. Specific patient



consent shall be obtained prior to the start of the focus group meeting. Encrypted dictaphones will be used to audio-record the meeting and then transferred to an external professional business company that have standard operating procedures in place for the safe destruction of files, secure data transfer and completed confidentiality agreements with the clinical trials unit (who are part of the research team) in place. A confidentiality agreement has been set up between the trial sponsor and the clinical trials unit for data transfer.

Dissemination policy

Planned dissemination of the results from this trial is through publication in an appropriate emergency medicine (EM), physiotherapy or trauma journal and by presentation at relevant EM or trauma conferences. We will disseminate our findings to stakeholders via professional meetings, including the Association of Chartered Physiotherapists working in Respiratory Care and other relevant specialist interest groups. The Trauma and Audit Research Network (TARN) newsletter will be used to disseminate the results to the trauma leads in each ED participating in TARN in the UK.

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Contributors All authors of the paper have contributed to the design of the trial. CB wrote this protocol and all other authors edited and made revisions for intellectual content. CB, PAE, HAH, FEL, DF, SH, CO'N, AW, TD, HT and JP have been involved in the background development and validation work leading up to this trial. For the protocol development; PAE and FEL provided the Emergency Medicine expertise, SaD, HT, ThD, KJ and AC provided the physiotherapy expertise, JP and SD provided the PPI expertise, DF and SH provided the health economic expertise, AW and TD provided the statistical expertise and REDCap set-up, HAH provided patient reported outcomes expertise, HAH, AW and CB provided overall methodological expertise and CO'N developed and wrote the qualitative aspects of the protocol. All authors read and approved the final manuscript for publication.

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