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

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EarLy Exercise in blunt Chest wall Trauma: a mixed methods, multi-centre, 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, multi-centre, 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). Baseline measurements including completion of two surveys (Brief Pain Inventory and EQ5D-5L) will be obtained on initial assessment. These measures and a Client Services Receipt Inventory will be repeated at 3 month post-injury. 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.

ISRCTN Trial registration number: ISRCTN65829737

Strengths and limitations of trial:

1) This established research team has published a substantial amount of background work supports this trial protocol

2) The trial has full funding, research ethics and HRA approval in place, with the required number of sites already recruited for commencement of patient recruitment

3) Recruitment to the trial could be influenced by a reduction in trauma presentations to hospital, as reported during the current pandemic.

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 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 three months post injury respectively.[2] It was reported by Baker et al (2021) in the RIOS study that despite a trend towards improving pain and physical functional at six months post-injury,

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 six to eight 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 version 1.1, 5th November 2021) 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 (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:

a) Investigate chronic pain prevalence and severity and physical disability at three months post-injury, using the Brief Pain Inventory (BPI) and EQ5D-5L in patients with blunt chest wall trauma who present to hospital, receiving either usual care, or an early exercise programme and usual care.

b) Conduct focus groups to investigate the experiences of patients completing the intervention, and clinicians delivering the intervention.

c) 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.[5]

METHODS AND ANALYSIS

Trial design and randomisation

This is a mixed methods, multi-centre, parallel randomised controlled trial.

Patients will be randomised (patient level) to the to 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 versus 3 or more; CFS score: 1-3 versus 4-9

Population

All adult patients (aged ≥16) presenting to hospital diagnosed 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) will be screened for eligibility to the trial. Patients will be considered eligible if they meet the following inclusion criteria; able to either give informed consent independently, or with support of a family member / carer or translator, able to either complete the exercise programme independently, or with support of a family member / carer, able to complete surveys independently, or with support of a family member / carer or translator.

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.[5] 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 work[5] and 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, UHW and Salford 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 one week, three times per day as tolerated (see exercise programme in supplementary 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.

Figure 1: Summary of the patients' journey through 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, 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.

Outcome measures

Primary outcome measures:

To assess chronic pain prevalence and severity and physical disability, participants will complete two surveys; the Brief Pain Inventory Short form (BPI), and the EuroQol 5-dimensions, 5-Levels (EQ5D-5L) on initial presentation and at 3 months post-injury (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 three to six months (30 Ed). For this study, chronic pain was defined as having a Brief Pain Inventory (BPI), Pain Severity Score (PSS) of ≥3.5 at three-months post-injury. 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 (ADL's) 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 EuroQol 5-dimensions, 5-Levels (EQ5D-5L) at three months after discharge from hospital.

Secondary outcome measures:

- Cost-effectiveness
- Rate of adverse events and serious adverse events
- 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 serious adverse events reported.[5]

Data collection

Once the consent form has been signed, the baseline Case Report Form (CRF), Brief Pain Inventory (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, adverse events and serious adverse events (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 three months post-injury, 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 one 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

REDCap (Research Electronic Data Capture) will be used for data capture at each participating site and for completion of the electronic case report forms, hosted at Swansea University.[6] 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.[6]

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 CONSORT diagrams, summary tables, and figures. Analysis will be conducted using SPSS version 28.

Qualitative analysis:

A 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 pre-specify 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 one hour and will be audio-recorded, 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 NVivo12 (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 delivering the intervention, in order to explore the impact of the new intervention.

Health economic analysis:

A health economics analysis plan will be developed alongside the statistical analysis plan. A UK NHS/Personal Social Services Perspective will be adopted. A cost-utility (incremental cost per 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 CSRI developed from our previous STUMBL feasibility study in the same patient populations.[7] Our clinicians and PPI will review the CSRI to ensure the content and format (e.g. 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 three 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 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.[8] An incremental cost-effectiveness ratio (ICER) 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 (e.g. 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 adverse and serious adverse events and trial endpoint success criteria analysis. There will be no pre-defined stopping criteria as the intervention is considered low risk and no adverse events were reported in the feasibility study.

Although there are a number of expected adverse events 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 serious adverse event 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. Serious adverse events will include; death, life-threatening complications, prolonged hospitalization, persistent / significant disability or incapacity.

Patient and Public Involvement

Two patient representatives (Joanne Prosser and Susan Davies) 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 DISSMINATION

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. Principal Investigators are all 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 (CI) 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.

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.

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, PE, HH, FL, DF, SH, CON, AW, TD, HT and JP have been involved in the background development and validation work leading up to this trial. For the protocol development; PE and FL provided the Emergency Medicine 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, HH provided patient reported outcomes expertise, HH, AW and CB provided overall methodological expertise and CO'N developed and wrote the qualitative aspects of the protocol. All authors have read and approved the final manuscript for publication.

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Competing interests: None declared

Ethics approval: London Riverside Research Ethics Committee (21/LO/0782)

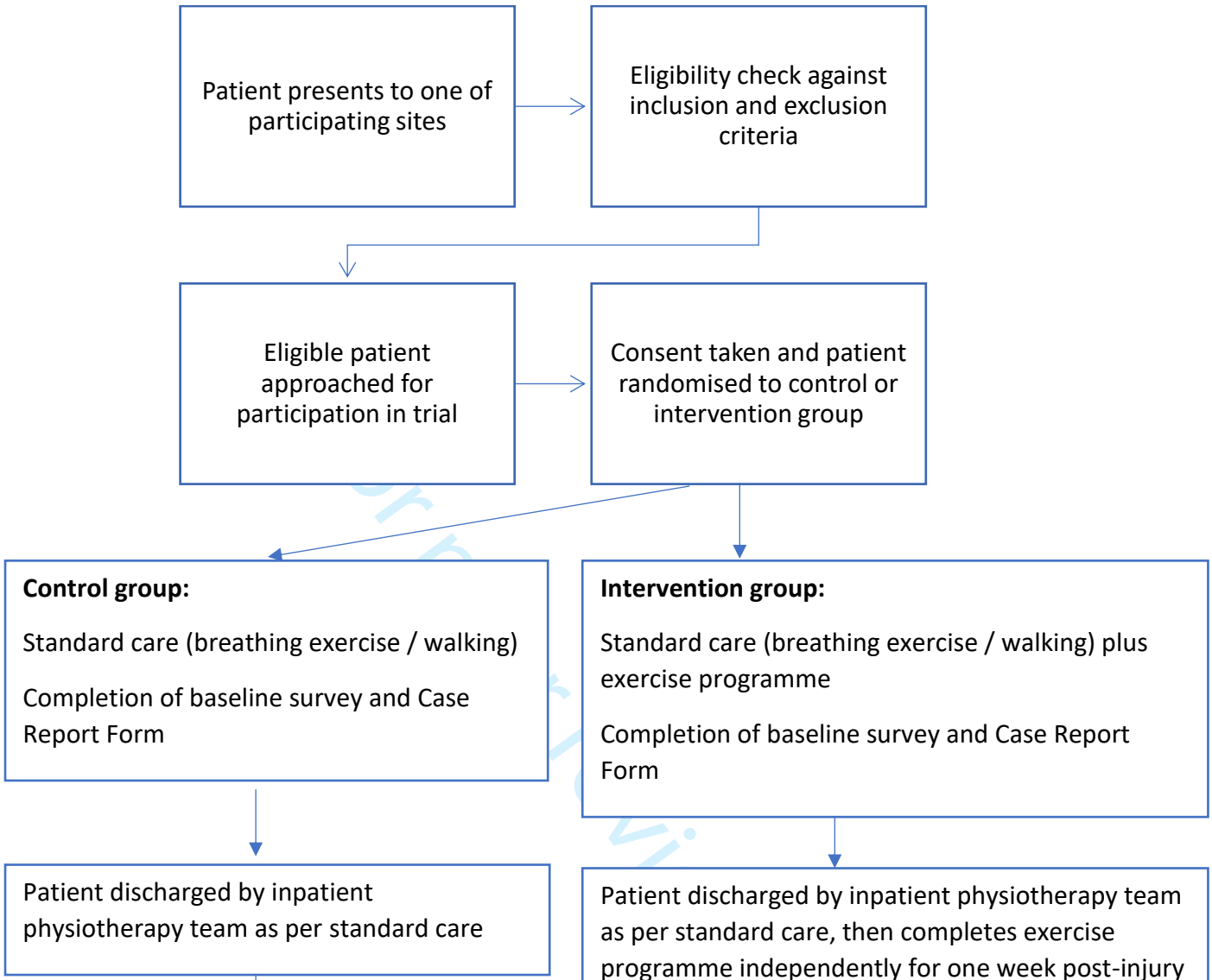
Provenance and peer review: Not commissioned; externally peer reviewed

Data sharing statement: Data from the trial (once completed) will be available from the corresponding, on reasonable request.

REFERENCES

1. Fabricant L, Ham B, Mullins R, et al. Prolonged pain and disability are common after rib fractures. *Am J Surg* 2013; 205: 511-515; discusssion 515-516. 2013/04/18. DOI: 10.1016/j.amjsurg.2012.12.007.
2. Carrie C, Guemmar Y, Cottenceau V, et al. Long-term disability after blunt chest trauma: Don't miss chronic neuropathic pain! *Injury* 2019; 50: 113-118. 2018/11/06. DOI: 10.1016/j.injury.2018.10.023.
3. Baker E, Battle C, Banjeri A, et al. Prospective observational study to examine health-related quality of life and develop models to predict long-term patient-reported outcomes 6 months after hospital discharge with blunt thoracic injuries. *BMJ Open* 2021; 11: e049292. DOI: 10.1136/bmjopen-2021-049292.
4. Battle C, O'Neill C, Newey L, et al. A survey of current practice in UK emergency department management of patients with blunt chest wall trauma not requiring admission to hospital. *Injury* 2021; 52: 2565-2570. DOI: 10.1016/j.injury.2021.06.013.
5. Battle C, O'Neill C, Toghill H, et al. EarLy Exercise in blunt Chest wall Trauma: a feasibility trial (ELECT Trial). *Emergency Medicine Journal* 2021; 38: 501-503. DOI: 10.1136/emermed-2020-209608.
6. Harris PA, Taylor R, Thielke R, et al. Research electronic data capture (REDCap)--a metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform* 2009; 42: 377-381. 2008/10/22. DOI: 10.1016/j.jbi.2008.08.010.
7. Battle C, Hutchings HA, Driscoll T, et al. A multicentre randomised feasibility STUdy evaluating the impact of a prognostic model for Management of BLunt chest wall trauma patients: STUMBL Trial. *BMJ Open* 2019; 9: e029187. DOI: 10.1136/bmjopen-2019-029187.
8. NICE. Position statement on use of the EQ-5D-5L value set for England, (2019, accessed 1st March 2021).

ELECT2 Trial Flow Diagram



Physiotherapy exercises following blunt chest wall trauma

These exercises have been given to you to help speed up your recovery and as part of the ELECT study. The exercises should help to reduce any problems with long-term pain and stiffness. If you have any questions about these exercises, please speak to your physiotherapist.

Some of the exercises may cause discomfort, and a stretching feeling, but it is important to remember that they will get easier with time. These exercises should not cause severe pain. If it is too painful to do the exercises, please ask your nurse for more pain relief or if you are at home, make sure you are taking the painkillers that have been recommended to you.

Try to complete 5 repetitions of each exercise. The exercises should be done 3 times a day, for the next 7 days. Record in the diary whether you have been able to complete each exercise.

Exercise 1:

In standing or sitting. Starting with your arms by your sides, try to keep your arms straight and slowly lift them forwards and upwards above your head, as far as you can without causing pain. Then slowly lower until your arms are back by your sides. Repeat 5 times

Exercise 2:

In standing or sitting. Starting with your arms by your sides, try to keep your arms straight and slowly lift them sideways and upwards above your head, as far as you can without causing pain. Then slowly lower until your arms are back by your sides. Repeat 5 times

Exercise 3:

In standing or sitting. Put your hands on your shoulders or across your chest. Slowly bend towards one side as shown. Then straighten back to the middle. Then slowly bend towards the other side. Repeat 5 times

Exercise 4:

In standing or sitting. Fold your arms gently across your chest. Slowly turn your body as if you are trying to look behind you, without uncrossing your arms. Then straighten back to the middle. Then slowly turn towards the other side. Repeat 5 times

DIARY:

Please write how many repetitions of each exercise you completed. If necessary, please record in the comments box why you couldn't complete all the exercises. NB: Day 1 is the day you were shown the exercises by the physiotherapist. Day 1 is <insert date and day>

DAY 1	Morning	Afternoon	Evening
Exercise 1	/5	/5	/5
Exercise 2	/5	/5	/5
Exercise 3	/5	/5	/5
Exercise 4	/5	/5	/5
Comments			

DAY 2	Morning	Afternoon	Evening
Exercise 1	/5	/5	/5
Exercise 2	/5	/5	/5
Exercise 3	/5	/5	/5
Exercise 4	/5	/5	/5
Comments			

DAY 3	Morning	Afternoon	Evening
Exercise 1	/5	/5	/5
Exercise 2	/5	/5	/5
Exercise 3	/5	/5	/5
Exercise 4	/5	/5	/5
Comments			

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DAY 4	Morning	Afternoon	Evening
Exercise 1	/5	/5	/5
Exercise 2	/5	/5	/5
Exercise 3	/5	/5	/5
Exercise 4	/5	/5	/5
Comments			

DAY 5	Morning	Afternoon	Evening
Exercise 1	/5	/5	/5
Exercise 2	/5	/5	/5
Exercise 3	/5	/5	/5
Exercise 4	/5	/5	/5
Comments			

DAY 3	Morning	Afternoon	Evening
Exercise 1	/5	/5	/5
Exercise 2	/5	/5	/5
Exercise 3	/5	/5	/5
Exercise 4	/5	/5	/5
Comments			

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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, multi-centre, 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 EQ5D-5L) will be obtained on initial assessment. These measures and a Client Services Receipt Inventory will be repeated at 3 month post-injury. 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.

ISRCTN Trial registration number: ISRCTN65829737

Strengths and limitations of trial:

1) To our knowledge, this is the first trial to investigate the impact of exercise on outcomes following blunt chest wall trauma

2) The inclusion of focus groups will help gain a full understanding of both patient and clinician perceptions of the exercise programme.

3) Recruitment to the trial could be influenced by a reduction in trauma presentations to hospital, as reported during the current pandemic.

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 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 three months post injury respectively.[2] It was reported by Baker et al (2021) in the RIOS study that despite a trend towards improving pain and physical functional at six months post-injury, 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 six to eight 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 version 1.1, 5th November 2021) 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 (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:

a) Investigate chronic pain prevalence and severity and physical disability at three months post-injury, using the Brief Pain Inventory[5] (BPI) and 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.

b) Conduct focus groups to investigate the experiences of patients completing the intervention, and clinicians delivering the intervention.

c) 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, multi-centre, parallel randomised controlled trial. The protocol was written following the SPIRIT guidelines.[8]

Patients will be randomised (patient level) to the to 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 versus 3 or more; CFS score: 1-3 versus 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 work[7] and 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, UHW and Salford 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 one week, three times per day as tolerated (see exercise programme in supplementary 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.

Figure 1: Summary of the patients' journey through 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, 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.

Outcome measures

Primary outcome measures:

To assess chronic pain prevalence and severity and physical disability, participants will complete two surveys; the Brief Pain Inventory Short form (BPI)[5], and the EuroQol 5-dimensions[6], 5-Levels (EQ5D-5L) on initial presentation and at 3 months post-injury (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 three to six months.[3] For this study, chronic pain was defined as having a Brief Pain Inventory (BPI), Pain Severity Score (PSS) of ≥3.5 at three-months post-injury.[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 (ADL's) 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 EuroQol 5-dimensions, 5-Levels (EQ5D-5L) at three months after discharge from hospital.

Secondary outcome measures:

- Cost-effectiveness
- Rate of adverse events and serious adverse events
- 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 serious adverse events reported.[7]

Data collection

Once the consent form has been signed, the baseline Case Report Form (CRF), Brief Pain Inventory (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, adverse events and serious adverse events (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 three months post-injury, 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 one 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

REDCap (Research Electronic Data Capture) will be used for data capture at each participating site and for completion of the electronic case report forms, 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 CONSORT diagrams, summary tables, and figures. Analysis will be conducted using SPSS version 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 pre-specify 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 one hour and will be audio-recorded, 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 NVivo12 (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 NHS/Personal Social Services Perspective will be adopted. A cost-utility (incremental cost per 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 CSRI developed from our previous STUMBL feasibility study in the same patient populations.[10] Our clinicians and PPI will review the CSRI to ensure the content and format (e.g. 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 three 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 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 (ICER) 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 (e.g. 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 adverse and serious adverse events and trial endpoint success criteria analysis. There will be no pre-defined stopping criteria as the intervention is considered low risk and no adverse events were reported in the feasibility study.

Although there are a number of expected adverse events 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 serious adverse event 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. Serious adverse events will include; death, life-threatening complications, prolonged hospitalization, persistent / significant disability or incapacity.

Patient and Public Involvement

Two patient representatives (Joanne Prosser and Susan Davies) 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 DISSMINATION

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. Principal Investigators are all 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 (CI) 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

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, PE, HH, FL, DF, SH, CON, AW, TD, HT and JP have been involved in the background development and validation work leading up to this trial. For the protocol development; PE and FL 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, HH provided patient reported outcomes expertise, HH, AW and CB provided overall

methodological expertise and CO'N developed and wrote the qualitative aspects of the protocol. All authors have read and approved the final manuscript for publication.

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Disclaimer: The funding sources have no role in the design of this trial. The views expressed are those of the author(s) and not necessarily those of the NHS, Health and Care Research Wales, the NIHR or the Department of Health.

Competing interests: None declared

Ethics approval: London Riverside Research Ethics Committee (21/LO/0782)

Provenance and peer review: Not commissioned; externally peer reviewed

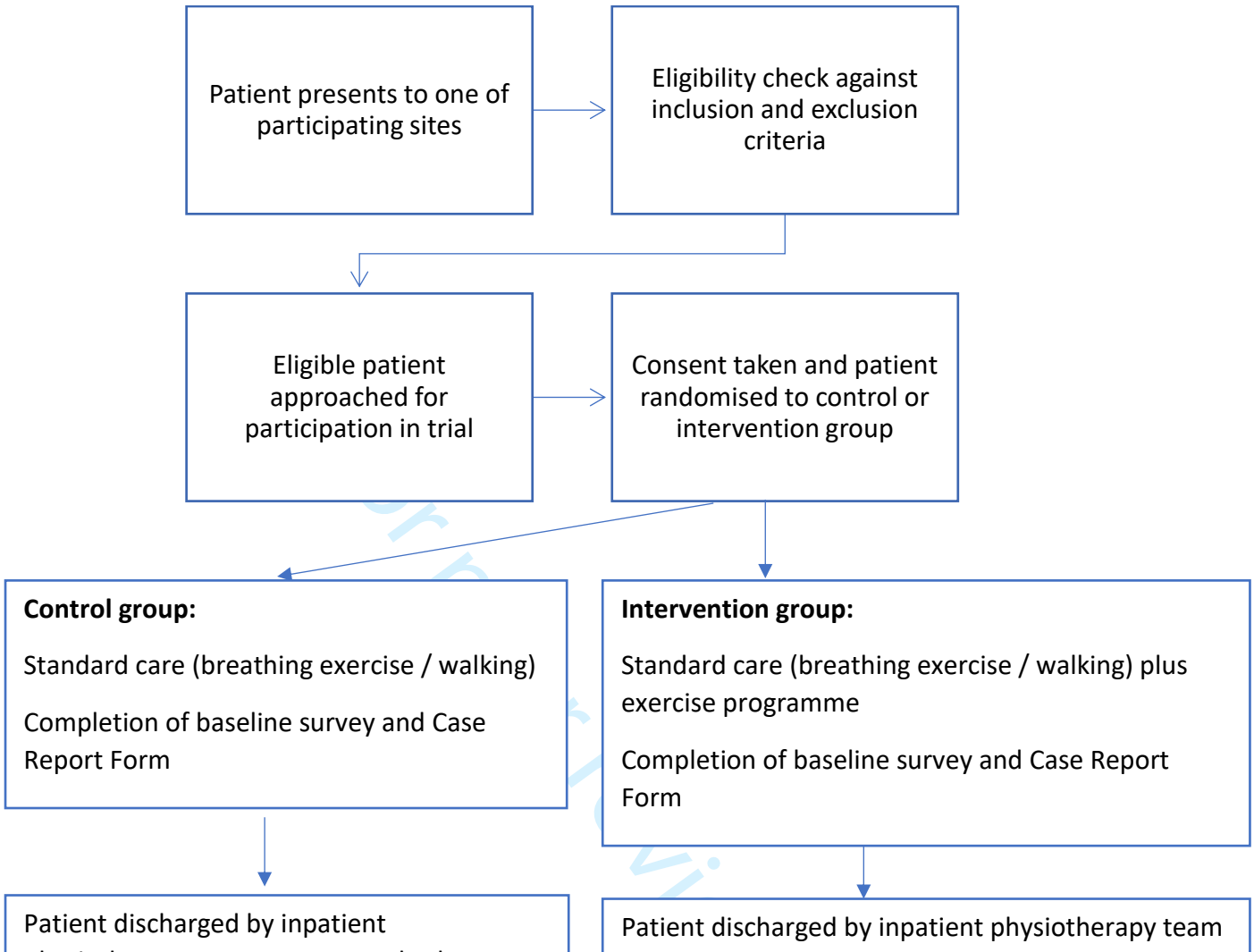
Data sharing statement: Data from the trial (once completed) will be available from the corresponding, on reasonable request.

REFERENCES

1. Fabricant L, Ham B, Mullins R, et al. Prolonged pain and disability are common after rib fractures. *Am J Surg* 2013; 205: 511-515; discusssion 515-516. 2013/04/18. DOI: 10.1016/j.amjsurg.2012.12.007.
2. Carrie C, Guemmar Y, Cottenceau V, et al. Long-term disability after blunt chest trauma: Don't miss chronic neuropathic pain! *Injury* 2019; 50: 113-118. 2018/11/06. DOI: 10.1016/j.injury.2018.10.023.
3. Baker E, Battle C, Banjeri A, et al. Prospective observational study to examine health-related quality of life and develop models to predict long-term patient-reported outcomes 6 months after hospital discharge with blunt thoracic injuries. *BMJ Open* 2021; 11: e049292. DOI: 10.1136/bmjopen-2021-049292.
4. Battle C, O'Neill C, Newey L, et al. A survey of current practice in UK emergency department management of patients with blunt chest wall trauma not requiring admission to hospital. *Injury* 2021; 52: 2565-2570. DOI: 10.1016/j.injury.2021.06.013.
5. Poquet N and Lin C. The Brief Pain Inventory (BPI). *Journal of Physiotherapy* 2016; 62: 52. DOI: https://doi.org/10.1016/j.jphys.2015.07.001.
6. Garratt A, Schmidt L, Mackintosh A, et al. Quality of life measurement: bibliographic study of patient assessed health outcome measures. *BMJ* 2002; 324: 1417. DOI: 10.1136/bmj.324.7351.1417.
7. Battle C, O'Neill C, Toghill H, et al. EarLy Exercise in blunt Chest wall Trauma: a feasibility trial (ELECT Trial). *Emergency Medicine Journal* 2021; 38: 501-503. DOI: 10.1136/emermed-2020-209608.
8. Chan AW, Tetzlaff JM, Gøtzsche PC, et al. SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials. *Bmj* 2013; 346: e7586. 2013/01/11. DOI: 10.1136/bmj.e7586.

9. Harris PA, Taylor R, Thielke R, et al. Research electronic data capture (REDCap)--a metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform* 2009; 42: 377-381. 2008/10/22. DOI: 10.1016/j.jbi.2008.08.010.
10. Battle C, Hutchings HA, Driscoll T, et al. A multicentre randomised feasibility STUdy evaluating the impact of a prognostic model for Management of BLunt chest wall trauma patients: STUMBL Trial. *BMJ Open* 2019; 9: e029187. DOI: 10.1136/bmjopen-2019-029187.
11. NICE. Position statement on use of the EQ-5D-5L value set for England, (2019, accessed 1st March 2021).
12. Lembarkİ FÖ and Yassine. The Ethical Necessities and Principles in Telerehabilitation. *3* 2022. Derleme. DOI: https://dergipark.org.tr/tr/pub/jhse/issue/52989/701013.

ELECT2 Trial Flow Diagram



Physiotherapy exercises following blunt chest wall trauma

These exercises have been given to you to help speed up your recovery and as part of the ELECT study. The exercises should help to reduce any problems with long-term pain and stiffness. If you have any questions about these exercises, please speak to your physiotherapist.

Some of the exercises may cause discomfort, and a stretching feeling, but it is important to remember that they will get easier with time. These exercises should not cause severe pain. If it is too painful to do the exercises, please ask your nurse for more pain relief or if you are at home, make sure you are taking the painkillers that have been recommended to you.

Try to complete 5 repetitions of each exercise. The exercises should be done 3 times a day, for the next 7 days. Record in the diary whether you have been able to complete each exercise.

Exercise 1:

In standing or sitting. Starting with your arms by your sides, try to keep your arms straight and slowly lift them forwards and upwards above your head, as far as you can without causing pain. Then slowly lower until your arms are back by your sides. Repeat 5 times

Exercise 2:

In standing or sitting. Starting with your arms by your sides, try to keep your arms straight and slowly lift them sideways and upwards above your head, as far as you can without causing pain. Then slowly lower until your arms are back by your sides. Repeat 5 times

Exercise 3:

In standing or sitting. Put your hands on your shoulders or across your chest. Slowly bend towards one side as shown. Then straighten back to the middle. Then slowly bend towards the other side. Repeat 5 times

Exercise 4:

In standing or sitting. Fold your arms gently across your chest. Slowly turn your body as if you are trying to look behind you, without uncrossing your arms. Then straighten back to the middle. Then slowly turn towards the other side. Repeat 5 times

DIARY:

Please write how many repetitions of each exercise you completed. If necessary, please record in the comments box why you couldn't complete all the exercises. NB: Day 1 is the day you were shown the exercises by the physiotherapist. Day 1 is <insert date and day>

DAY 1	Morning	Afternoon	Evening
Exercise 1	/5	/5	/5
Exercise 2	/5	/5	/5
Exercise 3	/5	/5	/5
Exercise 4	/5	/5	/5
Comments			

DAY 2	Morning	Afternoon	Evening
Exercise 1	/5	/5	/5
Exercise 2	/5	/5	/5
Exercise 3	/5	/5	/5
Exercise 4	/5	/5	/5
Comments			

DAY 3	Morning	Afternoon	Evening
Exercise 1	/5	/5	/5
Exercise 2	/5	/5	/5
Exercise 3	/5	/5	/5
Exercise 4	/5	/5	/5
Comments			

DAY 4	Morning	Afternoon	Evening
Exercise 1	/5	/5	/5
Exercise 2	/5	/5	/5
Exercise 3	/5	/5	/5
Exercise 4	/5	/5	/5
Comments			

DAY 5	Morning	Afternoon	Evening
Exercise 1	/5	/5	/5
Exercise 2	/5	/5	/5
Exercise 3	/5	/5	/5
Exercise 4	/5	/5	/5
Comments			

DAY 3	Morning	Afternoon	Evening
Exercise 1	/5	/5	/5
Exercise 2	/5	/5	/5
Exercise 3	/5	/5	/5
Exercise 4	/5	/5	/5
Comments			

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	3
	2b	All items from the World Health Organization Trial Registration Data Set	
Protocol version	3	Date and version identifier	4
Funding	4	Sources and types of financial, material, and other support	15
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	14
	5b	Name and contact information for the trial sponsor	13
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	13
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	12

Introduction

Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	3,4
	6b	Explanation for choice of comparators	4
Objectives	7	Specific objectives or hypotheses	4
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	5

Methods: Participants, interventions, and outcomes

Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	5
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	5
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	6
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	6
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	7
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	7
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	7,8
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	7

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	6
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	7
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	5
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	5
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	5
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	7
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n/a
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	8
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	8

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	9
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	10
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	9-11
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	9
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	12
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	12
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	12
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	12
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	13
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	13

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	13
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	13
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	15
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	15
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	n/a
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	14
	31b	Authorship eligibility guidelines and any intended use of professional writers	14
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	15
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	n/a
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.