STUDY PROTOCOL

Randomised Evaluation of incentive Spirometry in OLder adults with rib fractures to preVEnt pulmonary complications: RESOLVE

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This protocol has regard for the HRA guidance

KEY TRIAL CONTACTS

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Table of Contents

1 FUNDING AND SUPPORT IN KIND

FUNDING AND SUPPORT IN KIND	**Financial and non-financial support given**
National Institute for Health and Care Research (NIHR) Research for Patient Benefit (RfPB) Programme Grange House 15 Church Street Twickenham TW1 3NL Telephone: 020 8843 8000 Email: urdrfpb@nihr.ac.uk	Grant funding
Bristol Trials Centre Population Health Sciences, Bristol Medical School, University of Bristol 1-5 Whiteladies Road Bristol, BS8 1NU Email: btc-mailbox@bristol.ac.uk	Methodological expertise and trial management
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2 GLOSSARY OF ABBREVIATIONS

AE	Adverse Event
AR	Adverse Reaction
BTC	Bristol Trials Centre
CI	Chief Investigator
CRF	Case Report Form
CTU	Clinical Trials Unit
DMC	Data Monitoring Committee
DSA	Data Sharing Agreement
DSUR	Development Safety Update Report
EC	European Commission
EPR	Electronic Patient Record
EU	European Union
GCP	Good Clinical Practice
GDPR	General Data Protection Regulation
HRA	Health Research Authority
HRQoL	Health Related Quality of Life
ISRCTN	International Standard Randomised Controlled Trials Number
ITT	Intention to Treat
MLTC	Multiple Long-term Conditions
NIHR CRN	National Institute of Health Research Clinical Research Networks
NICE	National Institute for Health and Care Excellence
PI	Principal Investigator
PIL	Participant Information Leaflet
PLR	Personal Legal Representative
PPI	Patient and Public Involvement
PPIE	Patient and Public Involvement and Engagement
QALY	Quality Adjusted Life Years
RCT	Randomised Control Trial
RDSF	Research Data Facility Storage
REC	Research Ethics Committee
RSI	Reference Safety Information
SAE	Serious Adverse Event
SAR	Serious Adverse Reaction
SOP	Standard Operating Procedure
SUSAR	Suspected Unexpected Serious Adverse Reaction
TMF	Trial Master File
TMG	Trial Management Group
TSC	Trial Steering Committee

3 TRIAL SUMMARY

Trial Title	Randomised Evaluation of incentive Spirometry in OLder adults with rib fractures to preVEnt pulmonary complications	
Short title	RESOLVE	
Chief Investigator	Kate Coates	
Joint Lead	Prof. Edd Carlton	
Sponsor	North Bristol NHS Trust (R&D)	
Funder	National Institute for Health and Care Research (NIHR) Research for Patient Benefit (RfPB) Programme	
Trial Design	Prospective multicentre parallel group randomised controlled superiority trial	
Trial Participants	Adults aged ≥65 years presenting to UK Emergency Departments with traumatic rib fracture(s)	
Target sample size	276	
Target number of study sites	12	
Intervention	Incentive spirometry (and usual care)	
Treatment duration	Minimum 72 hours	
Inclusion criteria	• Aged ≥65 years • Radiological evidence of acute rib fracture(s) • Planned for admission • Has capacity to provide informed consent or personal consultee/legal representative available and able to support use of incentive spirometer	
Exclusion criteria	• Co-existing injury or condition for which treating clinician deems patient unable to use incentive spirometer (e.g. facial injuries; burns to both hands; advanced dementia) • Patients who have Sp02 <92% on air at time of screening (<88% for known chronic lung disease) • Intubated • Haemodynamic instability (e.g severe hypo- or hypertension, significant atrial/ventricular arrhythmia) • History of eye, inner ear or brain surgery within previous four weeks (Contraindication to using incentive spirometry) •	
	Objectives	Outcome measures
Primary outcome	Onset of new pulmonary complications within 5 days of randomisation	Patient medical notes/EPR (see 6.6.1 for further detail) GP records*

Secondary outcomes	Patient reported breathlessness at 5 days (+2)	The Dyspnea-12 Questionnaire
	Patient reported pain at 5 days (+2)	Numeric Pain Rating Scale
	Length of stay up to 30 days post randomisation	Patient medical notes/EPR
	Admission to Critical Care/ICU up to 30 days post randomisation	Patient medical notes/EPR
	Mortality up to 30 days post randomisation	Patient medical notes/EPR
	Hospital readmission rates up to 30 days post randomisation	Patient medical notes/EPR
Internal pilot	Internal pilot progression criteria will be reviewed after 4 months of active recruitment. See section 6.3 for further detail.	
Study duration	Grant contract start date: 01 August 2025 Anticipated duration: 26 months Anticipated end date: 30th September 2027	

*For the small number of patients discharged within 5 days of randomisation, GP records will be checked for antibiotic prescription for pulmonary related events

3.1 Plain English Trial summary

Aim: To see whether a device that helps with breathing exercises can improve recovery for older people when they are taken to hospital with broken ribs.

Background: Thousands of older people are taken to hospital each year with broken ribs. They are painful and can make it harder to take a deep breath or cough. Over half of older people with broken ribs develop problems, like chest infections, because they can't take deep breaths. We think that a breathing exercise device called an 'incentive spirometer' may help to prevent these problems. The incentive spirometer helps people take a deeper breath. Incentive spirometers are already given to some patients who have had an operation. They aren't used everywhere for patients with broken ribs because we don't know yet whether they help with recovery.

Design: We will ask 276 older patients in hospital with broken ribs to take part in this project. We will split them into two groups by chance. Both groups will be treated in the normal way whilst in hospital, including being taught breathing exercises, but one group will also be given an incentive spirometer to use. We will ask this group to try and use the incentive spirometer regularly through the day for at least the first 3 days after they come into hospital. We will ask permission from patients (or their carers) to collect information from their hospital notes about their recovery. We will look to see whether people who use the device get fewer problems, like chest infections, in the first 5 days after they came into hospital. We will also ask everyone to complete questionnaires to see how well they are recovering.

Patient and public involvement: We have listened to the views of older patients who have had broken ribs and taken part in research. This has helped make sure our work is useful and easy for older people to take part in. We have tried the incentive spirometer with some older patients who enjoyed using it and tell us it doesn't make the pain from their broken ribs worse. We also have an active patient group who have agreed to continue helping with this project. They will work with us to make sure our research will benefit patients.

Dissemination: We will write up the results and publish them in journals that are read by hospital staff so that they can learn about our work. We will also share the results at healthcare conferences to help make more hospital staff aware of the results. We will also let patients know about the results and our patient group will help us to understand the best ways to do this.

4 BACKGROUND AND RATIONALE

Trauma in older patients presents a significant challenge to healthcare systems ([1]). Over 60,000 patients aged ≥65 years are admitted to UK hospitals each year having sustained injury after a fall ([2]). In those admitted to Major Trauma Centres over 20% have sustained a chest injury ([3]). Pain from rib fractures, and underlying lung injuries, impacts the mechanics of breathing. This results in ineffective ventilation, lung collapse, and impaired cough/secretion clearance all of which increase the risk of pulmonary complications ([4]). Coexisting injuries, common after falls, can also restrict mobility, potentially predisposing trauma patients to greater risk of pulmonary complications. In our recent feasibility trial in older people admitted to hospital with rib fractures (median age 83 years), we found that >50% of patients went on to develop pulmonary complications, such as pneumonia ([5]). Our systematic review of 73 observational studies demonstrated that the odds of mortality after rib fractures were significantly greater in adults aged ≥65 years ([6]).

Incentive spirometers are simple handheld devices that encourage patients to take sustained deep breaths to increase lung volume, optimise collateral ventilation and mobilise secretions. These are well recognised strategies aimed at reducing pulmonary complications. Whilst similar physiological effects can be achieved through breathing exercises alone, incentive spirometers incorporate visual volume and feedback markers (smiley face) and have been found to improve inhalation volumes, flow control and enthusiasm to undertake regular breathing exercises ([7]). Theoretically, this could lead to a greater reduction in pulmonary complications. Incentive spirometers are simple to use and have been well tolerated in the target population as part of our patient and public involvement (PPI) work.

We searched Medline, Embase and Emcare (all Ovid); CINAHL (EbscoHost) and Google for trials published from any time until 18th December 2023. We found one randomised controlled trial (RCT) comparing incentive spirometry and usual care in patients with rib fractures ([8]). They observed that incentive spirometry reduced pulmonary complication rates from 80% to 29% and led to a significant improvement in pre- and post-treatment lung function ($p<0.001$). However, generalisability is limited by a small sample (n=50) recruited at a single site in Taiwan and the mean age of participants was 55 years. A focus on older adults, who are more susceptible to pulmonary complications, is, therefore, lacking.

In a non-randomised interventional study ([9]) improved lung function and oxygen saturation levels were observed in patients with rib fractures treated with incentive spirometry. A small sample (n=25) and lack of randomisation increases susceptibility to selection bias and confounding. Dote et. al ([10]), investigating the effectiveness of incentive spirometry following trauma, found no significant difference in pulmonary complication rates between groups (n=299). As a retrospective observational study, findings are limited by an inherent risk of bias, with heterogeneity noted in the onset and frequency of intervention, and baseline characteristics of each group.

The use of incentive spirometers to prevent pulmonary complications has been evaluated extensively in the surgical population post-operatively ([11–16]). This literature has shown little to no benefit but is of poor methodological quality. It also lacks a focus on older adults who we believe could see greater benefit due to their higher risk of pulmonary complications.

We surveyed Major Trauma Physiotherapists across 22 UK sites (March 2024) on therapeutic incentive spirometry use with older adults and found variation in practice. 10 sites stated that incentive spirometry was listed in their chest trauma care guideline and routinely used. Five sites reported that incentive spirometry was not listed in their guidelines. Seven sites did not have a guideline but five of these stated that incentive spirometry is used sporadically in this population. Some advocated benefits ("very helpful for creating independence with chest care") whilst others cited a lack of evidence to support effectiveness for not using.

4.1 Evidence explaining why this research is needed now

In 2022, the National Institute for Health and Care Excellence (NICE) produced guidelines for rehabilitation after injury ([17]). They suggest consideration of incentive spirometry to aid rehabilitation following chest trauma. However, that recommendation was based on NICE committee member's experience rather than high quality evidence. A global expert consensus panel also recommends use of incentive spirometry for early intervention (within 24 hours of presentation to an Emergency Department (ED)) for patients with rib fractures ([18]). There is currently a paucity of robust evidence evaluating the effectiveness of incentive spirometry in the older trauma population but there is signal of efficacy that a reduction in pulmonary complications will be seen.

Prevention of complications in patients with broken ribs, early involvement of physiotherapy to improve patient outcomes following major trauma and improving the care of older major trauma patients were all 2023 Major Trauma James Lind Association (JLA) research priorities ([19]). Optimising the management, clinical outcomes, and patient experiences of older, frail patients with injury was a 2022 JLA priority for Emergency Medicine ([20]). In addition, our PPI group tell us that more work is needed to improve outcomes after chest injury and recognise the need to test interventions that move beyond pain control. They recognise the potential for incentive spirometers to improve outcomes, following rib fractures, in a way that is simple and acceptable to patients.

Therapeutic use of incentive spirometers continues to be taught to undergraduate physiotherapists. Despite a lack of evidence to support use in the surgical population, continuing extensive use and a reluctance to change practice has been observed amongst clinicians ([21]). A high-quality trial is needed to either demonstrate a positive effect in the older adult trauma population or provide strong evidence to stop NHS investment in training, equipment and patient treatment time for an ineffective therapy.

5 RESEARCH QUESTIONS, OBJECTIVES AND OUTCOMES

5.1 Research questions

For patients aged ≥ 65 years, does incentive spirometry used as an adjunct to usual care after rib fracture reduce the incidence of pulmonary complications compared to usual care (without incentive spirometry)?

5.2 Primary objective

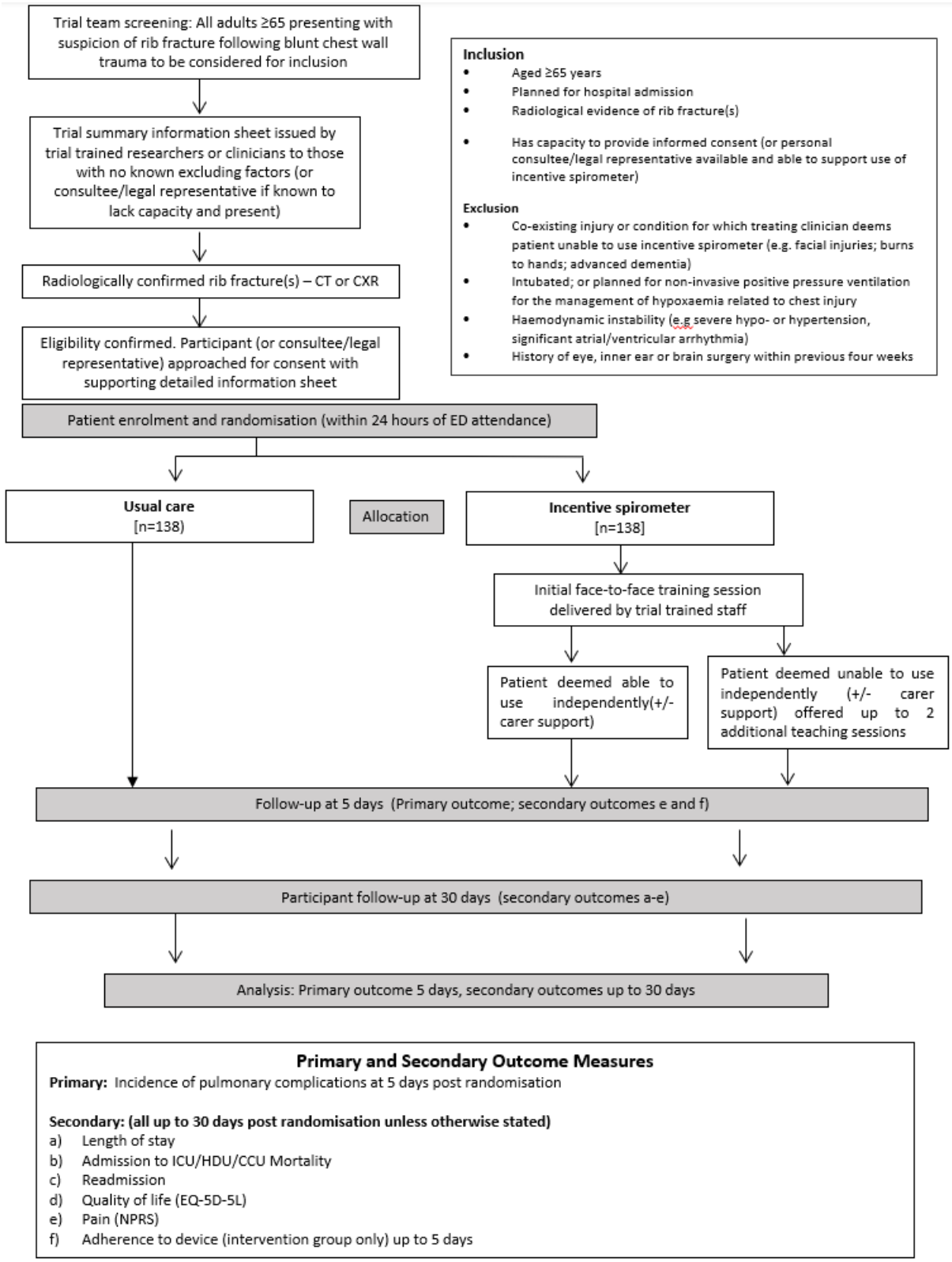
To compare the effect on pulmonary complications of usual care plus incentive spirometry compared with usual care without incentive spirometry, at 5 days post randomisation.

5.3 Secondary objectives

To compare the effect on patient reported outcome measures of breathlessness and pain 5 days post randomisation, and the length of initial hospital stay, the rate of admission to critical care, mortality and hospital readmission rates within 30 days of randomisation.

6 TRIAL DESIGN AND SETTING

6.1 Trial schema



6.2 Trial design

Pragmatic, multicentre, open-label, parallel two-group randomised controlled superiority trial. Older adults being admitted with traumatic rib fractures will be randomly assigned in a 1:1 ratio.

6.3 Internal pilot

The internal pilot progression criterion will be reviewed after the first four full months of active recruitment, with the criteria and thresholds for progression shown in Table 1.

Table 1: Internal pilot assessment criteria

Progression Criteria	Target	Green	Amber	Red
Site opening	100%	100% (n=4)	50-99% (n=2-3)	<50% (n=<2)
Total number of participants recruited	100%	100% (n=70)	50-99% (n=35-69)	<50% (n=<35)

If all criteria are Green, the trial will continue to the main recruitment phase as planned. If any of the criteria are in the Amber or Red zones, the Trial Management Group (TMG) will consider actions that could be taken to improve performance. If these steps are supported by the Data Monitoring and Trial Steering Committee (DMSC/TSC) and funder, the trial will proceed with regular monitoring. In the event of an issue arising that cannot be remedied, the funder may decide to terminate the trial.

6.4 Setting

The trial will recruit patients from 12 NHS hospitals across the UK (mix of Major Trauma Centres and Trauma Units).

6.5 Trial population

Adults ≥ 65 years being admitted to hospital with acute traumatic rib fracture(s).

6.5.1 Eligibility criteria

6.5.1.1 Inclusion criteria

Participants may enter the study if ALL of the following apply:

- Aged ≥65 years
- Radiological evidence of acute rib fracture(s)
- Planned for admission
- Has capacity to provide informed consent or personal consultee/legal representative available and able to support use of incentive spirometer

Exclusion criteria

Participants may not enter the study (i.e. may not be randomised) if ANY of the following apply:

- Co-existing injury or condition for which treating clinician deems patient unable to use incentive spirometer (e.g. facial injuries; burns to both hands; advanced dementia)
- Patients who have Sp02 <92% on air at time of screening (<88% for known chronic lung disease)
- Intubated

- Haemodynamic instability (e.g severe hypo- or hypertension, significant atrial/ventricular arrhythmia)
- History of eye, inner ear or brain surgery within previous four weeks (Contraindication to using incentive spirometry)

6.5.2 Co-enrolment in other research studies

Co-enrolment will be considered on a study-by-study basis; decisions around co-enrolment will consider participant burden and whether the randomised interventions are distinct from those in this trial. Where trials with overlapping inclusion criteria are identified, we will work with the Research Delivery Networks (RDNs) and CIs and/or Principal Investigators (PIs) to ensure co-enrolment is in the best interest of patients.

6.6 6.6 Intervention

6.6.1 General information

Patients randomised to the intervention arm will be issued with an incentive spirometer as soon as is practical and immediate care needs have been addressed. Each participating hospital will procure its own devices to ensure the generalisability of results across diverse clinical settings and to streamline logistical coordination. Restrictions will not be placed on brand or manufacturer but data on the type of incentive spirometer (volume or flow) will be collected.

6.6.2 Staff teaching

A site initiation visit (likely remote but in person where feasible if preferred) will be held with each site prior to opening to recruitment. At least one member of local site staff delegated for intervention teaching responsibilities will also receive an additional training session in use of incentive spirometry by the central study team. Training will be offered in person or remotely depending on local site preference and previous experience using incentive spirometry. Training will include a standardised Powerpoint presentation (which can be retained by sites) and physical demonstration of the incentive spirometer. Whilst central teaching for additional site staff will be offered, a train-the-trainer model will be adopted enabling site staff to cascade the training to relevant local personnel if preferred. This local site lead 'trainer' should be a registered health care professional. Due to the simplicity of the intervention, a formal trainer manual is not required; but providers can request refresher training or rely on the patient education materials to guide implementation. Central study staff will also provide guidance to site personnel regarding management of devices once primary outcome data have been collected.

6.6.3 Participant teaching

At the time of issue, a trained and delegated member of local site staff will instruct the participant in use of the incentive spirometer, in accordance with the manufacturer's instructions. Participants will be advised to use the incentive spirometer at least three times during the day and will be encouraged not to interrupt sleep for use. Participants will be advised to use the device for the first 5 days following injury.

The initial training session will be supplemented with an optional training video that participants will be able to access via their own personal devices, if they wish, and a paper education leaflet. The leaflet will be available in larger font if required. For patients who cannot speak English research teams will be encouraged to use local translation services to support training and device use where feasible. Competence in use of the incentive spirometer, judged as ability to use the device correctly without prompts (or with prompts for those supervised by a carer/staff member), will be assessed at the time

by the trainer. Up to two additional teaching sessions are permitted to promote independent use. Timescales for delivery of the initial and subsequent participant teaching sessions are shown in the schedule of assessments (section 7.8). Participants who do not achieve independent use (or supported use from carers/site staff where resources allow) after two teaching sessions will not receive any more teaching sessions but will remain in the trial.

The intervention is additive to standard clinical management which may include analgesic intervention, breathing exercises and mobilisation.

6.6.4 Fidelity

Patients in the control arm should not be issued with an incentive spirometer or receive any teaching on its use. Adherence to random allocation (provision of incentive spirometer and associated teaching for those randomised to the intervention; and no provision of incentive spirometer for those randomised to the control) will be captured on the baseline CRF.

6.6.5 Adherence

A paper diary will be provided to participants in the intervention arm to record adherence to intervention use during their inpatient admission. These will be collected by local site staff on or after day 5 post randomisation, or on discharge, whichever is sooner, and data entered to the study database.

A CRF will also be provided to record any observed adherence, where feasible, in recognition of variable participant adherence to diaries in previous clinical trials ([22]). This includes any use of a spirometer in the participants randomised to the control arm (usual care). In cases where both participant diaries and staff-collected adherence data are available, participant entries will take precedence in the event of discrepancies; however, if only staff-collected data are complete, those will be used.

Participants in the intervention arm will be classed as adherent if they undertake a minimum of two incentive spirometer sessions a day, for a minimum of three days, in the five days post randomisation.

6.7 Outcomes

6.7.1 Primary outcome

The primary outcome is a binary measure of the onset of one or more new pulmonary complications within five days of randomisation. This will be adapted from the outcome proposed by the European Society of Anaesthesiology and Intensive Care Medicine as a consensus definition (Table 2) ([23]). Patients with evidence of pulmonary complications prior to randomisation will not meet the primary outcome. Any deaths occurring within the first 5 days following randomisation will meet the criteria for the primary outcome.

Table 2: Pulmonary Complications

Complication	Definition
Respiratory Infection	Patient has received antibiotics for a suspected respiratory infection and met one or more of the following criteria: new or changed sputum, new or changed lung opacities, fever, white blood cell count >12 x 10^9l-1

Respiratory failure	$Pa0_2$ <8kPa (60mmHg) on room air, a $Pa0_2$:Fi02 ratio <40kPa (300mmHg) or arterial oxyhaemoglobin saturation measured with pulse oximetry <90% (or <88% for patients with known chronic respiratory disease) and requiring oxygen therapy
Pleural effusion	Chest radiograph demonstrating blunting of the costophrenic angle, loss of sharp silhouette of the ipsilateral hemidiaphragm in upright position, evidence of displacement of adjacent anatomical structures or (in supine position) a hazy opacity in one hemithorax with preserved vascular shadows
Atelectasis	Lung opacification with a shift of the mediastinum, hilum or hemidiaphragm toward the affected area, and compensatory over-inflation in the adjacent non-atelectatic lung
Pneumothorax	Air in the pleural space with no vascular bed surrounding the visceral pleura
Bronchospasm	Newly detected expiratory wheezing treated with bronchodilators
Aspiration pneumonitis	Acute lung injury after the inhalation of regurgitated gastric contents

Primary outcome data will be collected by research practitioners from inpatient hospital records at five days and reviewed/confirmed by the local Principal Investigator. For the small number of patients discharged in the interim, online GP records (routinely available at recruiting sites) will be checked for evidence of pulmonary related events (e.g., pneumonia).

6.7.2 Secondary outcomes

- Patient reported breathlessness at baseline and 5 (+2*) days (The Dyspnea-12 Questionnaire)
- Patient reported pain at baseline and 5 (+2*) days (Numeric Pain Rating Scale)
- Length of initial stay up to 30 days post randomisation
- Admission to Critical Care up to 30 days post randomisation
- Mortality up to 30 days post randomisation
- Hospital readmission within 30 days of randomisation

*Pain and breathlessness scores will be collected on day 5 where possible but a +2-day window will be accepted to accommodate lack of weekend staffing.

It is anticipated that the majority of patients will remain inpatients on day 5 and patient reported outcome measures can be collected in person by local site staff. For any patients discharged prior to day 5, follow-up can be completed remotely by telephone. The Dyspnea-12 questionnaire and Numeric Pain Rating Scale are both possible to complete by telephone. The researcher will make (up to) three contact attempts. If no response is received, the questionnaires will be marked as missing.

As the Dyspnea-12 Questionnaire includes a question pertaining to depressive symptoms, any participant identified as indicating severe levels of depression will be encouraged by local site staff to seek further evaluation or support from their treating clinician or General Practitioner.

The NPRS has been reported suitable to use with people with mild to moderate cognitive impairment ([24]). We are unable to find a breathlessness patient reported outcome, suitable for trauma, that has been validated for cognitive impairment in this population. It is recognised that some data for this secondary outcome may be missing for those with mild to moderate cognitive impairment. However, “here and now” symptom self-reporting tools have been shown to be valid and reliable in persons with mild cognitive impairment in previous literature ([25]) and use of the dyspnea-12 questionnaire in this

trial is supported by our patient and public involvement representatives. Secondary outcomes measured up to 30 days post randomisation will be collected by research staff from their hospital's electronic patient record.

6.7.3 Hospital transfers

Should a participant be transferred to another hospital prior to primary and secondary outcome data collection, their participation in the trial will be ongoing and the initial recruiting site will remain responsible for remote follow-up with participants and the receiving site (where necessary).

6.7.3 Estimands

Estimand component	**Definition**
Population	All participants meeting eligibility criteria and randomised to a treatment arm, with complete primary outcome data, and baseline data included in primary analysis model (i.e., complete case intention to treat population)
Treatment condition	Incentive spirometry in addition to usual care vs usual care without incentive spirometry, regardless of intervention compliance
Endpoint	Onset of new pulmonary complications within 5 days of randomisation (binary outcome)
Summary measure	Odds ratio
Handling of intercurrent events	Intercurrent events will be handled using a Treatment Policy approach (sensitivity analyses may be used to explore different approaches)

6.7.4 Target sample size (with calculation/justification)

276 patients recruited from 12 UK hospitals. The incidence of pulmonary complications in this population has been observed at 50% ([5]). In the only RCT of incentive spirometry for trauma identified, Sum and colleagues ([8]) observed a 50% absolute risk reduction in pulmonary complications, but this effect size was estimated with a large margin of error and may not be generalisable. A more conservative estimate of a 20% reduction in the intervention arm has, therefore, been proposed as a target effect size that is both achievable and meaningful to detect. Our PPI group agree this is a reasonable effect size to change practice. To detect a reduction in pulmonary complications from 50% in the control group to 30% in the intervention group with 90% power at a 5% alpha level, an analytical sample size of 248 is required. To allow for 10% attrition a total sample size of 276 is required. Most participants will remain inpatients at five days, and GP online records are routinely available for any that have been discharged. The only anticipated loss to primary outcome follow-up will be those who are admitted out of area and discharged within five days to another region where GP records may not be accessible. Sample size calculation was conducted using the '*power'* command in Stata (version 18).

6.8 End of trial

Participants end their involvement with the trial when their last planned interaction with the study is complete (or efforts to complete this have been unsuccessful), or they have discontinued their participation in the study.

The end of trial will be when the last participant has completed their involvement with the trial, all data collection is complete and any data queries have been resolved, the database has been locked, and subsequent planned data analyses have been completed.

7 TRIAL PROCEDURES

7.1 Onboarding of participating sites

To ensure representativeness and generalisability of findings across different healthcare settings, participating sites will be purposively onboarded to include a balanced mix of Major Trauma Centres (MTCs) and Trauma Units (TUs). This approach allows the study to capture variations in patient populations, care delivery models, and resource availability across the trauma system. In addition, sites will be selected to achieve broad geographical coverage across urban, suburban, and rural areas, thereby reflecting the diversity of clinical practice and patient demographics across regions. Site selection will also take into account anticipated patient volumes, local research infrastructure, and competing study recruitment to support timely recruitment and study delivery.

7.2 Trial advertising

The trial will be promoted through targeted dissemination at national and regional Emergency Medicine and Physiotherapy conferences to raise awareness and support site engagement.

7.3 Screening and identification of participants

Hospital staff will be asked to complete a trial-specific screening Case Report Form (CRF) for each patient aged ≥65 years admitted to that hospital with acute rib fracture(s) following blunt chest wall trauma.

Recruitment will be undertaken 24 hours a day, 7 days a week. Potentially eligible participants will be identified by clinical staff or research delivery staff (e.g. Research Nurses/Physiotherapists) at the time of arrival in ED or on/after transfer to inpatient settings (e.g. ward, acute medical/surgical assessment unit). Upon identifying a (potentially) eligible patient, a member of the clinical team or research practitioner will give the patient the written study Summary Participant Information Sheet (Summary PIS) and, where appropriate, the full Participant Information Sheet (Detailed PIS) (e.g. the patient has read the Summary PIS and requested further information and/or is suitably comfortable and able to read both documents at that time). We recognise that our target population is older adults. Patient information materials will therefore be available in a variety of formats, including paper (normal and large print) and video, as advised by our patient groups to maximise participation across all potentially eligible patients.

Patients will be given sufficient time to read/view the information material and ask any questions they may have about the trial. The length of time patients will have to consider participation will vary due to the nature of EDs and assessment pathways. If appropriate, consent can be received whilst the patient is still within the ED, however consent will not be taken until immediate care needs have been addressed. When considering participation in the emergency setting, patient consideration-time is estimated to be from one to four hours; this approach is considered acceptable by patients, as demonstrated by other ED-based research undertaken by our group ([5,26]). If required, the participant can be given longer to consider involvement even if transferred to a ward. However, due to the need for early intervention, a maximum of 24 hours from admission to randomisation will be set (and written consent must be received prior to randomisation).

In patients without capacity, we will seek approval from a patient's personal consultee/legal representative (see section 7.6)

Eligibility is required to be confirmed by a member of the team who has been delegated this role and is trained in the trial.

7.4 Inclusivity

The NIHR INCLUDE guidance ([27]) has been used to inform study design and assess potential barriers to inclusion, ensuring consideration of under-served groups throughout the research planning process. This study will recruit participants from a geographically diverse range of research sites across the UK, including urban, rural, and socioeconomically varied areas. This approach is designed to ensure that the study population reflects the broad demographic and health system contexts in which the intervention may ultimately be used.

All patients who meet the eligibility criteria will be offered the opportunity to participate, and no exclusions will be made on the basis of characteristics such as sex, gender identity, ethnicity, socioeconomic status, or frailty unless scientifically justified. Local recruitment teams will be supported with materials and strategies to enable inclusive recruitment, and screening logs will be used to monitor uptake and identify any barriers to participation.

Efforts will be made to identify and minimise barriers to participation among under-served or marginalised groups, including accessible study materials (e.g. large print font) and engagement with local community or patient groups where appropriate.

7.5 Consent

Written informed consent must be obtained before any trial related procedures or assessments can be undertaken. Patients who are willing and eligible to participate in the study will be asked to provide written informed consent and they will be allocated a unique study identification (I.D) number. Ideally patients will have read both the Summary PIS and Detailed PIS before providing written informed consent. We recognise, however, that it may not be appropriate or feasible for some patients to read both documents, or at least not the Detailed PIS in full, prior to providing written informed consent (e.g. due to being in pain, frailty, visual impairment). In these circumstances, patients who have read (or discussed) the Summary PIS, or watched the video PIS, and are willing and eligible to participate will be asked to provide full (written) informed consent and will be asked to read (or discuss) the Detailed PIS in full as soon as they are able.

The written informed consent process will be undertaken by an appropriately trained clinician or member of the research team. All members of the clinical and/or research team delegated by the PI to undertake the consent procedure must be listed on the study delegation log at the relevant site. These individuals should all understand the protocol and the potential implications it may have on the people to be involved; understand alternative treatments available to potential participants; have an ability to communicate effectively with potential participants, including explaining complex scientific/ medical concepts; and appreciate how to optimise the voluntary nature of decision making, avoiding undue influence.

Besides completing the consent form (which includes the study title and date of consent), sites should record key details of the informed consent process in the patient's medical notes. Copies of the consent form should be issued to the participant and stored in the medical notes. A scanned copy will also be uploaded to the study database. The original should be filed locally in the site's physical site working folder.

NB: When a patient has capacity but is unable to indicate their consent by signing/marking a Consent Form; then they may give their informed consent verbally in the presence of a witness (any clinician

on duty, nurse or doctor) *in addition to* the staff member taking consent. The witness will also be asked to countersign the consent form.

For patients lacking capacity to consent, recruitment can still be considered if a personal consultee/Personal Legal Representative (PLR) is available, and it is deemed that the patient will manage to use the incentive spirometer with their supervision/support (approach supported by PPI) (see section 7.6)

Where patients provide informed consent but endure a loss of capacity for ≥48 hours during the study, a personal consultee/PLR will be given the Summary Patient Information Sheet and/or equivalent video with the Detailed Information Sheet, and approached to provide approval for continued participation via a Consultee Declaration/PLR AWI Consent form. If a Consultee/PLR is not available, is unwilling or advises that the participant should no longer take part in the study after they have lost capacity, then their participation will stop; however, data already collected up to the point of loss of capacity will be retained and analysed. Advice from a Consultee/PLR about whether the individual would wish to be included in the study will be obtained in the same way as described above. Patients will be informed of this process at the outset via the participant study information materials. In all cases, we will consult with carers and take note of any signs of objection or distress from the participant, and we will withdraw a participant if they raise objections.

Informed consent/consultee approval will endure unless the individual requests to change permissions/withdraw, in which case the relevant procedures will be followed; see section 7.10.

It is possible that patients may regain capacity after a Consultee/PLR has agreed to them remaining in the study. In this case, we consider the original consent to remain valid. Staff will update the patient of any ongoing study procedures, and the patient will retain the right to withdraw at any time.

7.6 Patients with mild to moderate cognitive impairment lacking capacity to provide consent for themselves

Including patients with mild to moderate cognitive impairment is essential. It is widely agreed that such persons have a higher risk of falls, a common cause of rib fractures ([28]). Cognitive impairment in this population may stem from a chronic neurodegenerative condition, such as Alzheimer's disease, which is likely to persist for the duration of the trial. These individuals are frequently considered unsuitable for more invasive treatments due to frailty, multiple comorbidities, or impaired capacity to make informed decisions.

There is growing recognition that older adults tend to under-report pain; however, many studies have overlooked cognitive impairment as a confounding factor in pain assessment ([24]). In some cases, cognitive impairment may not be permanent — for example, when caused by an acute medical issue such as delirium. In these scenarios, cognitive function may improve over time, highlighting the importance of considering both chronic and temporary forms of impairment when evaluating this patient group

It is important to evaluate supportive interventions like the incentive spirometer in these vulnerable groups. The incentive spirometer is non-invasive, safe, and simple to use — qualities underscored by its routine application in paediatric populations. Its feasibility in older adults with cognitive impairment warrants further investigation, especially as they may benefit from interventions that are low risk and do not rely on complex instructions or decision-making capacity.

All senior ED clinicians and research practitioners have training in capacity assessment. Where, upon the initial capacity assessment, patients are judged to be unable to provide informed consent for themselves at the time a decision or action needs to be taken (under some circumstances, loss of capacity may be due to stress or pain related to their traumatic injuries) a personal consultee/Personal Legal Representative will be approached for approval.

In England, Wales and Northern Ireland a personal consultee will be presented with the Summary Participant Information Sheet or equivalent video and, where appropriate, the Detailed PIS. Based on the study information, the Consultee will provide advice about whether the individual would wish to be included in the study or not. A patient will only be enrolled via personal consultee approval if the consultee is available to provide approval within 24 hours of the patient's admission to hospital and reasonable support with IS training/use.

In Scotland a Personal Legal Representative (PLR) will be approached and presented with the Personal Legal Representative Summary PIS or equivalent video, and supporting Detailed PIS, and will provide advice about whether the individual would wish to be included in the study or not. A Personal Legal Representative can be a Welfare Guardian or Welfare Attorney, or the patient's nearest relative. If a PLR is not available, the participant will not be enrolled.

Patients where capacity is regained within 5 days of randomisation: patient's who have regained capacity (confirmed as ≥48 hours) will be approached by a member of the research team and provided with information about the study that will explain what has (likely) happened so far. If day 5 post-randomisation falls on a weekend, assessment will be completed on the following working day. Patients will be asked to provide consent to continue in the study; they may wish to continue active involvement in the study (e.g. will complete questionnaires) or passive involvement (e.g. no questionnaires but allow continued access to medical records only). If a patient decides that they do not wish to continue in the study, their ongoing participation will stop; however, data collected up to this point will be retained and analysed.

It is possible that patients may lose capacity again, after agreeing to remain in the study. In this case, we will consider the original consultee/PLR consent to remain valid. Staff will inform the consultee/PLR, who will retain the right to withdraw the person they provided consent for at any time.

A summary of the various study invitation and consent pathways and documentation are shown in Figure 1 below.

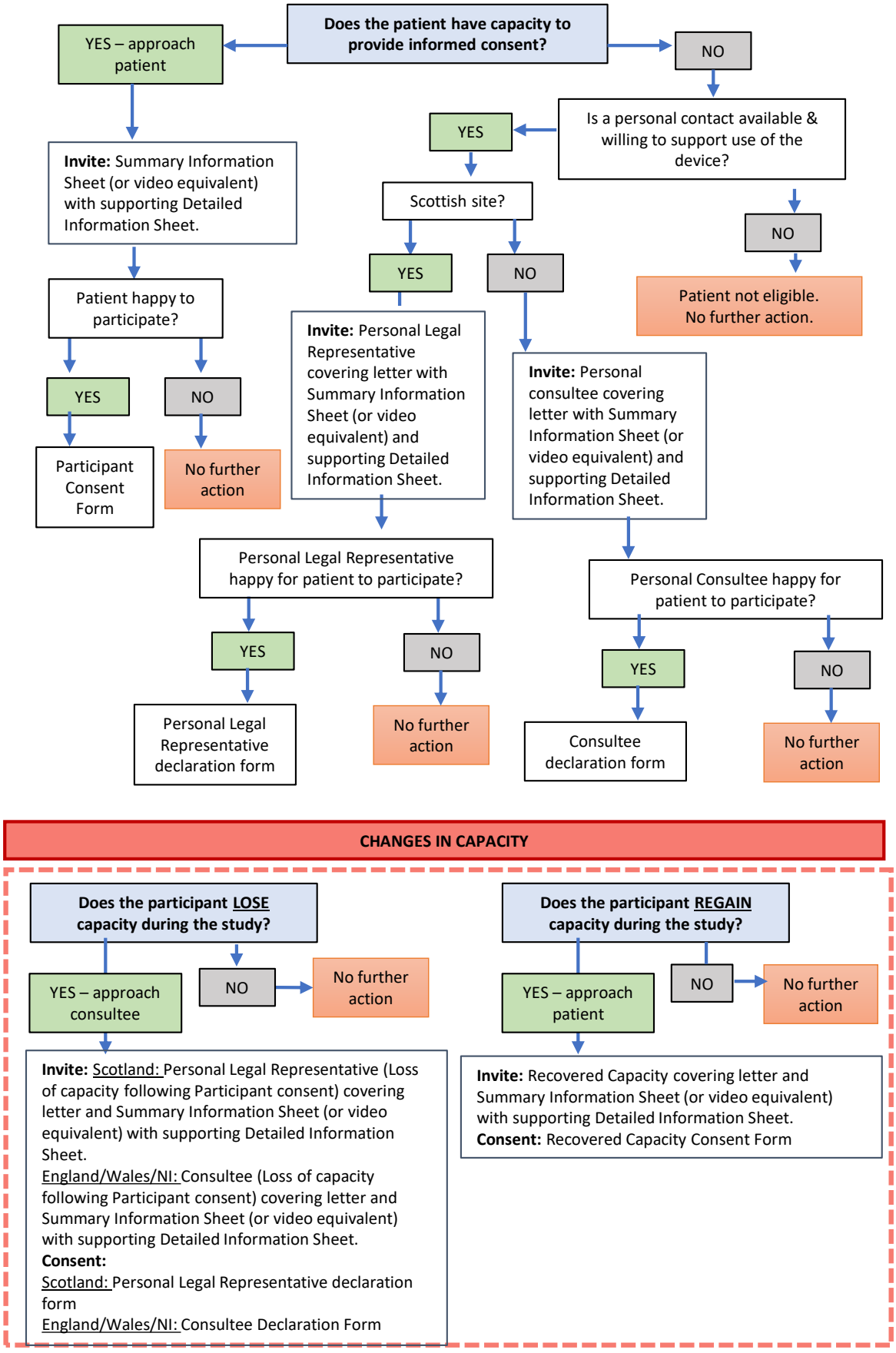


Figure 1: Approach and consent pathways

7.7 Randomisation

Randomisation should not take place until written informed consent (or consultee/Legal Representative approval for those lacking capacity) is obtained (see section 7.5). Allocation to intervention or control will be by concealed online randomisation. Participants will be randomised in a 1:1 ratio, to usual care without incentive spirometry (control) or usual care plus incentive spirometry (intervention) after consent. Randomisation will be undertaken by individuals trained and delegated for randomisation duties; this could be clinicians or research delivery staff. Randomisation will be stratified by site and minimised by consent status (self-consent or consultee/PLR approval) and co-existing injury status (isolated rib fracture(s) or rib fractures and ≥1 confirmed acute injury). Randomisation will be by means of a computer-generated code, with allocation concealed from the recruiter by use of a remote (web) randomisation service (Sealed Envelope). In the event of technical failure accessing the online randomisation system, recruiting staff will be encouraged to contact the Bristol Trials Centre (BTC) central coordination team to perform a manual randomisation.

The randomisation procedure will involve a delegated member of the research team signing into the trial database and adding a new participant, which will generate their unique Study ID. They will then enter information to confirm participant eligibility, and complete a form to confirm that valid consent has been received. They will then be required to enter relevant stratification and minimisation variables. Randomisation data will then be sent securely to Sealed Envelope and the allocation of intervention, (incentive spirometry and usual care) or control, (usual care without incentive spirometry), will be immediately returned in the study database. The online randomisation system will automatically send an email to relevant users with 'notifications enabled' confirming the randomisation. Appropriate site staff will place a record (electronic or print out) of the allocation generated by the randomisation system in the participant's medical notes.

Once a participant has been randomised, they are enrolled in the study and treatment can proceed. Hospital (site/equivalent research) staff should proceed to complete and send a study approved letter to the participant's GP (e.g. via post or secure email), including a copy of their patient's completed consent form (or declaration form where appropriate), informing the GP that their patient has entered the trial; a copy of this letter should also be filed in the ISF.

Medical case notes containing source data or other trial-related information should also be identified by a label (or equivalent for electronic notes, where feasible), e.g. "Keep until at least dd/mm/yyyy" where the date given is at least five years after the end of the trial.

7.8 Schedule of assessments and data collection

Activity/ Assessment	Enrolment	Randomisation/ Baseline	Initial teaching session †	Additional teaching†*	Follow-up			As required
Time point	Day 0 (-1)	Day 0	Day 0 (+2)	Day 0 (+≤5)	Day 5	Day 5(+2)	Day 30	Up to Day 30
Screening	**X**							
Consent	**X**							
Sociodemogr-aphic Details		**X**						
Injury Details		**X**						
Co-morbidities		**X**						
Clinical Frailty Scale (Rockwood)		**X**						
Initial incentive Spirometry Teaching Session †			**X**					
Up to 2 additional incentive spirometry teaching sessions†				**X***				
Adherence					**X**			
Primary outcome					**X**			
Secondary outcomes (PROMS)		**X**				**X**		
Length of stay (hospital and critical care/ HDU admission)							**X**	
Details of re-attendances to A&E or unplanned re-admissions							**X**	
Mortality						**X**	**X**	

Safety Reporting CRF								**X**
Change of Status CRF								**X**

† Intervention arm only

**only if required*

7.9 Screening and Baseline Data Collection

A screening CRF will be completed for each participant that presents, meeting the inclusion criteria. Data capture on this CRF will include (but is not limited to):

- Age
- Sex
- Preferred language
- Eligibility criteria and confirmation of eligibility status
- Approach details and outcome (e.g. decline reasons)

During online randomisation, data capture will include eligibility criteria, mental capacity status, co-existing injury status (binary). During screening, patients' initials and year of birth will be recorded to ensure correct identification of patients at site.

Patient Reported Outcomes (participants): Site staff should endeavour to conduct patient reported outcome measures (PROMS) at the time of enrolment (consent). However, it is acknowledged that this may not be feasible, or appropriate, if e.g. the patient is fatigued or breathless following the consent discussion. As such, PROMS can be delayed but, like randomisation, should be completed within 24hours of being admitted to hospital. Participants will be asked to complete the PROMs according to how they feel at the time of completion. They may be completed with the assistance of a researcher/member of the clinical team (or person with caring responsibility, e.g. family member, if/where feasible).

CRF (site staff): A delegated site staff member will complete the Baseline CRF. Data capture on this CRF will include (but is not limited to):

- Patient name and contact details
- Patient demographics, including (confirmed) date of birth, ethnicity and gender
- GP (Practice) contact details
- Details of Personal Consultee/PLR (if relevant)
- Admission details
- Injury Details
- History of any chronic lung disease
- Pre-injury anticoagulant use
- Clinical observations
- Rockwood clinical frailty scale

- Intervention fidelity (provision of incentive spirometers to intervention participants only)

7.10 Data Collection at Day 5

Participants who remain in hospital at 5-days post-randomisation (+2 days):

A member of the site research team will ask these participants to complete the 5-day PROMs. These can be entered directly into the database by site staff or completed on paper CRFs downloaded from the study database by site staff for participants.

For patients who have mild/moderate cognitive impairment (e.g. due to Alzheimer's disease), the PROMs may be completed with the assistance of a researcher/member of the clinical team (or person with caring responsibility if/where feasible); if in such participants it becomes unfeasible to complete the PROMS (or elements of it), site staff should record this in the 5-day CRF.

Participants who have transferred to a different hospital or who have been discharged from hospital at 5-days post-randomisation (+2 days):

Follow up will be completed remotely using a range of available methods to suit the participant's preferences and location (e.g. via telephone or site staff at receiving hospital if transferred to another trial site). If the participant does not have capacity, where possible, then a consultee (and/or person with caring responsibility) will be asked to assist the participant to complete the PROMS. If it is not feasible for the participant to complete (part of) the PROMs, site staff should record this in the 5-day CRF.

7.11 Follow up Data Collection at Day 30

CRF (site staff): A delegated site staff member will complete the 30-day CRF. Data capture on this CRF will include (but is not limited to):

- Hospital admission details, including discharge status and date (where applicable)
- Mortality data
- Resource use e.g. admission to critical care (including HDU) during index admission; any unplanned readmissions within 30 days

7.12 Blinding and unblinding

Given the nature of the intervention, it is not possible to blind participants or local research teams to treatment allocation. Self-reported outcomes will avoid observer bias. The lead statistician will be blinded to treatment allocation and the trial statistician, who is performing the analysis, will be unblinded to treatment allocation. Members of the TMG not involved in participant randomisation, intervention delivery, or performing disaggregated analyses will also be blinded to allocation.

7.13 Participant Payments

All participants will be offered a £20 voucher as a gesture of gratitude for completion of both Baseline and Day 5 Questionnaires. This will be offered to the participant upon completion of Day 5 questionnaires. The study centre will supply the vouchers in physical or digital format, to the site teams to disseminate to eligible participants.

We will also provide participating sites with trial branded pens. These will be given to participants who are allocated to the intervention, as an aid to completion of their adherence diary.

7.14 Change in participation status

Participants will remain in the trial unless they (or their Personal Consultee/PLR) choose to stop their participation, or they are unable to continue for a clinical reason. In the event that a clinician feels it is unsafe for a participant to continue in the study, agreement should first be sought from the PI. Any changes to a participant's continuation in the study should be recorded on the appropriate study document (e.g. Change of Permissions/Withdrawal Form). Trial specific guidance will be provided to participating sites on recording and reporting procedures.

The trial will retain any research data collected up to the point of stopping participation (or death) for analysis purposes. Furthermore, as advised in the trial participant information materials, the trial team will continue to collect relevant data about the patient's health from their electronic medical records unless they explicitly request otherwise.

It is of paramount importance to note that participants who do not wish to follow their randomised allocation , or where clinicians do not wish to adhere to the randomised allocation, should not stop their participation in the trial and they should continue to be followed up as per Protocol. Adherence to treatment allocation will be recorded and monitored via study data collection forms.

7.15 Communication with participants

An optional consent statement will be included to offer participants the opportunity to receive a summary of the trial results upon its completion. Updates on trial progress will be posted regularly on the study website, and all participants will be provided with the necessary access details to view this information.

8 SAFETY RECORDING AND REPORTING

8.1 Definitions

Adverse Event

An adverse event (AE) is any untoward or undesirable medical occurrence in a subject receiving treatment according to the protocol. This includes occurrences which are not necessarily caused by or related to administration of the research procedures.

Adverse Reaction

An adverse reaction (AR) is any undesirable experience that has happened to a subject that is suspected to be caused by the intervention.

Serious Adverse Event

A serious adverse event (SAE) is any adverse event which:

- results in death,
- is / was life threatening*,
- requires hospitalisation or prolongs an ongoing hospitalisation**,
- results in persistent or significant disability or incapacity,
- consists of a congenital anomaly or birth defect,

Other important medical events that may jeopardise the subject and may require medical or surgical intervention to prevent one of the outcomes listed above should also be classed as an SAE.

**"Life-threatening" in the definition of "serious" refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe.*

***"Hospitalisation" is defined as an unplanned overnight stay. Note, however, that the patient must be formally admitted – waiting in outpatients or an Emergency Department would not count as hospitalisation (even though this can sometimes be overnight). Planned hospital stays would not be counted as SAEs, nor would time in hospital for "social reasons" (e.g. respite care, the fact that there is no-one at home to care for the patient). Also, if patients had a day-case operation, this would not qualify as hospitalisation. However, if a planned operation was brought forward because of worsening symptoms, this would be considered as an SAE. Hospitalisations for the purpose of the intervention are an exception to SAE reporting unless complications occur.*

Suspected Serious Adverse Reaction

A suspected serious adverse reaction (SSAR) is any serious adverse event that is suspected to be related to the intervention.

Suspected Unexpected Serious Adverse Reaction

A suspected unexpected serious adverse reaction (SUSAR) is serious adverse event that is not consistent with the defined anticipated or expected events (below) and is assessed as being possibly, probably or definitely related to the intervention.

8.2 Approach – risk adaptive of following GCP

This study is following a risk-adaptive approach to safety reporting because the intervention being studied has already been proven to be safe and is already in use in standard medical care.

8.3 Reporting period

Local research teams are responsible for assessing all AEs that they become aware of for their participants from the time of enrolment until the 30 day follow-up.

8.4 Reporting overview

Adverse event (AE)	Non-serious adverse events do not need to be recorded or reported unless they are considered to be possibly, probably, or definitely related to the use of the intervention.
Adverse reaction (AR)	If a non-serious AE is considered to be possibly, probably, or definitely related to the intervention the AR should be recorded in the CRF and in the participant's clinical notes.
Serious adverse event (SAE)	Record in safety reporting CRF and participant's clinical notes. Record assessment of causality, severity and seriousness. Report to trial team within 24h of becoming aware (who will report on to Sponsor within 24h).
Suspected unexpected serious adverse reaction (SUSAR)	Record in safety reporting CRF and participant's clinical notes. Record assessment of causality, severity and seriousness Report to trial team within 24h of becoming aware (who will report on to Sponsor within 24h). CI will report to REC within 15 days of becoming aware of the event.

All safety information, including information relating to safety events that are not subject to expedited reporting but are captured as trial endpoints, will be closely monitored by the DMSC throughout the trial. The DMSC will be provided with a report at least annually (unless specified by the DMSC).

8.5 Anticipated events

Anticipated events are defined as safety events that are anticipated for this patient population. Although the investigational device poses minimal risk, adverse events are anticipated in this older, frailer population. The PI at each participating site (or appropriately delegated member of local site staff) is responsible for assessing all AEs and categorising whether they are serious, expected, and/or related.

The following events can be expected within trial participants:

- Pain
- Pulmonary complications
- Surgical emphysema
- Pneumothorax
- Delayed haemothorax
- Surgery for injuries present at enrolment
- Hospital admission complications, assessed by local PI as associated with frailty
- Prolonged hospitalisation due to social care needs

8.6 Expectedness of events

Expected events are clinical outcomes that routinely occur when delivering the intervention.

The following events can be expected for patients treated with incentive spirometry:

- Dizziness or light-headedness
- Temporary increase in shortness of breath
- Altered breathing pattern

8.7 Urgent safety measures

The Sponsor and investigator may take appropriate urgent safety measures (USM) to protect a research participant from an immediate hazard to their health and safety. This USM can be taken before seeking approval from the competent authorities and ethics committee.

The main research ethics committee must be notified by email within three days. Information should include that such measures have been taken and the reasons why. Where the USM requires an amendment to study documentation, this should be submitted as a substantial amendment as soon as possible and marked as being in response to USM. A copy of the USM notification should be submitted with the amendment.

If the Principal Investigator (and not the sponsor) has instigated the USM, the sponsor should be notified immediately so that they can assess and report the USM within the timelines required.

NHS R&D offices will require notification in accordance with local policies/procedures. Where applicable, oversight committees should review information relating to USM and report any recommendations to all relevant parties. The funder should be updated on all developments and actions as soon as possible.

9 DATA MANAGEMENT

9.1 Data protection

Data will be collected and retained in accordance with the UK Data Protection Act 2018.

9.2 Data handling

Full details will be provided in the data management plan, which will also define how personal identifiable and non-identifiable patient information is used in the study.

Data will be entered into a purpose-designed REDCap database hosted on the University of Bristol network. Database access will be password-controlled and restricted to trial staff at the participating site and the co-ordinating centre.

Any information capable of identifying individuals will be held on a secure University of Bristol server. Trial staff at the coordinating centre will have access to this identifiable information.

The processing of personal data of participants will be minimised by using a unique participant trial number on trial documents and the study database wherever possible.

All data management systems will be designed to protect participant information in line with data protection legislation. Trial staff will ensure that the participant's confidentiality is maintained through secure handling and storage of participant information at participating sites and in accordance with ethics approval. The Chief Investigator will preserve the confidentiality of participants taking part in the study and is the data custodian.

Data will be entered promptly with data validation and cleaning to be carried out throughout the trial. Training will be provided on data management, including using the trial database. Relevant training materials will be available for trial staff to access as required.

9.3 Data collection

9.3.1 Data Sources

A full list of source data and location will be maintained in the Data Management Plan (DMP). Hospital records and GP records will also form part of the source data for this trial.

Data will be collected using electronic/paper case report forms (CRFs). Direct data entry to eCRFs will be done using REDCap, if paper CRFs are used these will be entered into the database as soon as possible.

Participant questionnaires will either be completed on paper (with data entered into the REDCap database by trial staff) or through an email link sent to the participant (data saved directly to the REDCap database).

9.3.2 Data System

REDCap will be used to capture and store study data for the trial. REDCap is a web-based electronic central data management system which is built and supplied by Vanderbilt.

The BTC systems team have standard operating procedures (SOPs) to ensure there is a structured approach to designing, building, testing and validating the database prior to release.

Access to the trial REDCap database is managed at an individual level via delegation logs and requires a password that must meet the minimum format requirements.

Participant personal identifiers will be stored securely. Participants will be informed of data storage and security processes in the Participant Information Leaflet.

The database contains audit trails to record all changes to the data and who actioned the changes, user permissions and when access was granted and revoked. The database is held on UoB servers that are automatically backed up daily by UoB IT and stored securely.

In the event of a study amendment, updates to the study database will be coordinated through changes to the relevant specification documents. Specification updates will be discussed between the study team (including the statistician) and the CI.

9.4 Data quality

Throughout the trial, data integrity, accuracy and completeness of data collection will be monitored and reported in compliance with good clinical practice (GCP) guidelines. This may include source data verification, use of automated data validation rules, data cleaning, training and risk-based monitoring (further details of which can be found in section 10). Periodic data reviews will be carried out and audit trails will be maintained.

9.5 Essential document storage and security

Essential documentation, as specified by the sponsor, will be stored in an eTMF and eISF. Read only access to the relevant systems can be provided for inspection purposes.

Access to the eTMF and eISF will be restricted and access will be approved and monitored by the BTC trial team. All systems where essential documentation is held are automatically backed up daily by UoB IT teams and stored securely.

9.6 Essential document archiving

Essential documentation, as specified by the sponsor, and source data (including REDCap database) will be kept for at least 5years after the end of the trial. Documents will be kept at the University of Bristol and/or participating sites for this time. At the end of the archiving period, documents will be destroyed by confidential means. All non-essential documentation will be destroyed securely prior to archiving.

Where source data are documented in paper medical records, these records will be identified by a label bearing the name and duration of the trial and clearly stating the 'do not destroy before' date. Where electronic records are in use, local site policy will be followed.

Participant personal identifiers will be archived where they form part of the essential documentation and will be destroyed at the end of the archiving period.

A study archiving plan will be developed, to include the TMF and ISF, in accordance with the BTC archiving procedure which require sponsor and CI oversight. Sites will retain access to their ISF throughout the archiving period and the trial archive will be available for inspection purposes.

Data held at the University of Bristol will conform to the University of Bristol Data Security Policy and be held in compliance with the UK General Data Protection Regulation (GDPR), tailored by the Data Protection Act 2018.

9.7 Database lock and exports

At the point of data lock all user access to the database will be changed to read-only to prevent any changes to the data. A final data extract will be produced for analysis and a copy archived with

restricted access. At the end of the study all sites will be provided with a copy of their site data, or read-only access to their site data, for the archiving period.

9.8 Database archiving

The database export created at the point of database lock will be stored on secure UoB servers for the duration of the archive period. The REDCap database will then be archived following REDCap standard procedures. The BTC systems team have protocols in place to retrieve the database from archive for inspection purposes, if required.

9.9 Data sharing

Members of the TMG will develop a data sharing policy which will cover how final anonymised datasets will be shared at the end of the research.

All data sharing will comply with the consent provided by participants and adhere to data protection legislation.

10 RISK REVIEW AND MONITORING

The trial will be monitored and audited in accordance with the Sponsor's policy, which is consistent with the UK Policy Framework for Health and Social Care Research. All trial related documents will be made available on request for monitoring and audit by the Sponsor, the relevant REC and for inspection by regulatory authorities.

10.1 Risk Assessment

The risk assessment process is a careful examination of what could cause harm, who/what could be harmed and how, and risks to the study integrity. Reasonably foreseeable risks associated with a research study, and actions to control the risks so far as is reasonably practicable, will be identified and documented as soon as possible in a study specific risk assessment.

The risk assessment documentation and any subsequent revisions should be kept in the TMF. The risk assessment should be an ongoing process. Each time there are changes to the perceived risks and mitigating circumstances these must be agreed by the TMG and CI and documented.

10.2 Monitoring

Monitoring is defined as the act of overseeing the progress of a clinical trial, and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, SOPs, GCP, and the applicable regulatory requirements.

The purpose of monitoring is to verify that:

- The rights and well-being of the participants are protected;
- The reported study data are accurate, complete and verifiable from source documents;
- The conduct of the study complies with the currently approved protocol, GCP and the applicable regulatory requirements.

Study monitoring activities should be identified based on the study specific risk assessment and will be documented in a Quality Management Plan. This will be developed by the BTC based on the trial risk assessment.

10.3 Monitoring of study by Sponsor

The trial will be monitored and audited in accordance with the Sponsor's policy, which is consistent with the UK Policy Framework for Health and Social Care Research. All trial related documents will be made available on request for monitoring and audit by the Sponsor (or BTC if they have been delegated to monitor) and the relevant REC.

10.4 Monitoring of study by BTC

The Sponsor usually delegates some monitoring activities to the central trial team at BTC. Checks of the following would be typical:

- Informed Consent process and documentation
- Inclusion and Exclusion criteria verification
- Completed source documents and CRFs, data completeness and other types of data queries
- Study procedures and / or intervention compliance
- Safety documentation and adverse event reporting
- Protocol deviations

The BTC will carry out regular central monitoring and audit of compliance of sites with Good Clinical Practice (GCP) and trial-specific data collection procedures described in the protocol. The trial database will have in-built validation and the TMG will review the completeness of the data throughout the trial. The BTC will not check CRFs or other source data against the data entered to the trial database, unless there are good reasons to visit a site to complete a monitoring visit (e.g. the central monitoring highlights a problem).

The quality of the study data may be monitored through centralised database monitoring. Validation checks are documented in the database specification document. Data completeness and accuracy checks may be run through the study databases. Data queries are usually reported via the study database and may be supplemented by additional independent data checks carried out by the study statistical team.

Other study monitoring activities may also be carried out, e.g. remote site monitoring, on site monitoring.

10.5 Training of sites

Initiation training

Before the trial commences at each participating site, training will be organised by BTC. The provided training will ensure that site research personnel fully understand the protocol, CRFs and the practical procedures for the trial including using the data capture systems. These sessions may be provided virtually or on-site. They may include training videos and manuals as well as a site initiation meeting. Initial training and any subsequent training e.g. for new staff members will be documented.

Investigators' responsibilities

Investigators must ensure that local research approvals have been obtained and any required contractual agreements have been signed off by all parties before recruiting any participants. Investigators will be required to ensure compliance to the protocol and completion of the CRFs. Investigators will be required to allow access to trial documentation or source data on request for monitoring visits and audits performed by the Sponsor, BTC or any regulatory authorities.

Investigators will be required to read, acknowledge and inform their team of any amendments to the trial documents approved by the HRA/REC that they receive and ensure that the changes are complied with.

10.6 Protocol compliance

Prospective, planned deviations or waivers to the protocol are not allowed. Accidental protocol deviations will be documented and reported to the CI and Sponsor in line with the Sponsor's reporting requirements. They will also be reported to the DMSC. In the event of systematic protocol deviations, investigation and remedial action will be taken in liaison with the CI, DMSC and the TMG.

Sponsor specific procedures will be followed for the reporting of any breaches.

Sponsor will determine whether it constitutes a serious breach, requiring onward reporting to the REC.

10.7 Serious Breaches to GCP and/or the protocol

A "serious breach" is a breach which is likely to affect to a significant degree:

a. the safety or physical or mental integrity of the subjects of the trial; or

b. the scientific value of the trial.

In the event that a serious breach is suspected, the Sponsor will be notified as soon as possible and within 24 hours of becoming aware of the event. The serious breach will be reviewed by the Sponsor in collaboration with the CI. The Sponsor will determine whether it constitutes a serious breach, requiring onward reporting to the REC. If appropriate, the Sponsor will report it to the REC and the relevant NHS host organisation within seven calendar days of become aware of the serious breach.

11 ANALYSES

11.1 Statistical analysis

Analyses will be directed by a pre-specified Statistical Analysis Plan (SAP) and will be in line with CONSORT reporting guidelines for clinical trials. Participant flow will be reported in a CONSORT flow chart ([29]). Participant baseline characteristics will be reported, overall and by randomised allocation, using descriptive statistics.

Continuous data will be summarised as mean and SD or median and inter-quartile range (IQR) if distributions are skewed. Categorical data will be summarised as number and percentages. The primary analysis will be conducted under the intention-to-treat approach, consisting of logistic regression of presence vs absence of pulmonary complications on allocation, adjusted for site, capacity status, and co-existing injury status (design variables). Results will be reported as an odds ratio with associated 95% confidence interval and p-value. Result will also be presented as an absolute difference and Number Needed to Treat for completeness. Secondary outcome analysis will be consistent with that described for the primary outcome, using a form of regression appropriate to the nature of the outcome being analysed (linear regression for continuous outcome, logistic regression for binary outcome etc), plus additional adjustment for baseline value of outcome where relevant. A repeat analysis of the primary outcome using a Complier Average Causal Effect analysis, with reporting of treatment effect based on adherence, will be considered. Sensitivity of the primary analysis to the impact of missing data will be explored.

Model validity will be checked using standard methods; if a model is a poor fit, alternative models or transformations will be explored.

11.2 Subgroup analyses

Potential treatment effect heterogeneity will be explored by repeating the primary analysis model with the inclusion of allocation-by-moderator interaction terms (separately, different regression model for each moderator being evaluated). Potential treatment effect moderators to be explored include number of rib fractures, frailty, and smoking status.

11.3 Frequency of analyses

The primary analysis will take place when follow-up is complete for all recruited participants. Safety data will be reported to the TSC/DMSC at a frequency to be agreed, together with any additional analyses the committee requests. There are no planned formal efficacy/futility interim analyses.

11.4 Health economic evaluation

No formal health economic evaluation is planned. Resource use on length of hospital admission, admission to critical care, and readmission within 30 days of randomisation will be collected to inform clinical decision making.

12 TRIAL OVERSIGHT

12.1 Day-to-day management

The trial will be managed by the Bristol Trials Centre (BTC). The BTC is a fully registered UK Clinical Research Collaboration (UKCRC) Unit. North Bristol NHS Trust will act as Sponsor. Day-to-day management of the trial will be overseen by the Chief Investigator (CI) and BTC staff. The CI and BTC team will work with the co-applicants to prepare the final protocol and submissions for regulatory approvals; REC and HRA. The BTC will prepare all trial documentation and data collection forms, and design and implement the data management systems.

The Trial Manager will be the contact point to provide support and guidance to the participating sites throughout the trial.

12.2 Trial Management Group (TMG)

The trial will be managed by a trial management group (TMG), which will meet approximately monthly for the duration of the study. The TMG will comprise of all investigators, including the PPI co-applicant. Other members of the research team will be invited to attend as required. The TMG will have responsibility for the day-to-day management of the trial and will report to the combined Data Monitoring and Trial Steering Committee (DMSC/TSC).

12.3 Independent Data Monitoring and Trial Steering Committee

A single independent committee, combining the roles of the Data Monitoring and Safety Committee (DMSC) and the Trial Steering Committee (TSC), will be established to oversee trial conduct and review safety data during the course of the trial. This merged DMSC/TSC will also advise on any interim analyses, if appropriate, and make recommendations to the Trial Management Group (TMG) on key trial decisions. The committee will meet prior to the start of recruitment and approximately every six months thereafter.

Membership, responsibilities, and reporting mechanisms of the merged DMSC/TSC will be formalised in a committee charter. The committee will include independent members such as a Chairperson,

Statistician, experts in the clinical and/or academic field of this research, and a PPI representative. The Chief Investigator (CI), Trial Manager, Trial Portfolio Lead and Lead and study Statisticians will attend meetings as observers, and the attendance of any other TMG members will be at the discretion of the committee Chair. Individuals not directly involved in the study but from the same institution may attend as non-independent members with the agreement of the Chair.

The committee will usually hold both open and closed sessions. The observers will attend the open session only, while only the independent members and study statisticians will attend both open and closed sessions. The committee's recommendations will be provided to the CI and recorded in the minutes, which will be shared with the funder.

13 Trial stopping rules

The trial may be prematurely discontinued by the Sponsor, Chief Investigator (CI), Regulatory Authority, or Funder, based on new safety information or for other reasons provided by the DMSC/TSC, regulatory authority, or ethics committee.

The trial may also be prematurely discontinued due to lack of recruitment or upon advice from the DMSC/TSC, who will advise on whether to continue or discontinue the trial and make a recommendation to the Funder. If the trial is prematurely discontinued, no new participants will be recruited and a decision on data collection for active participants will be made in discussion with the Funder, DMSC/TSC and Sponsor.

14 PATIENT AND PUBLIC INVOLVEMENT (PPI)

Patient and Public Involvement (PPI) will be embedded throughout the project to ensure that the research remains patient-centred and relevant. PPI contributors will be actively involved in the review and refinement of all patient-facing materials to enhance clarity, accessibility, and appropriateness. Additionally, they will contribute to the planning and implementation of dissemination activities, helping to ensure that findings are shared in meaningful and accessible ways with patients, carers, and the wider public. We will offer reimbursement to all PPI members in accordance with NIHR guidelines.

15 ETHICAL AND REGULATORY CONSIDERATIONS

15.1 Governance and legislation

This trial will be conducted in accordance with:

- The principles of Good Clinical Practice, as set out in the International Conference for Harmonisation of Good Clinical Practice (ICH GCP) guidelines
- UK Policy Framework for Health and Social Care Research
- Data Protection Act 2018
- UK General Data Protection Regulation

Before any NHS site can enrol participants into the trial, the CI or designee will obtain confirmation of capacity and capability for each site in-line with HRA processes along with other documentation required for the sponsor or designee to grant sites with a greenlight letter.

Approved amendments will be submitted to participating NHS Trusts for information or approval, as required.

GCP training and trial specific training for research staff members will be at a level commensurate with their involvement within the trial. Informed consent to participate in the trial will be sought and obtained according to GCP guidelines.

15.2 Radiation Assurance

Please note Ionising Radiation (Medical Exposure) Regulation (IRMER) approval is not required for this trial. Any images used to confirm eligibility will be taken prior to receipt of consent or consultee/legal representative approval. These images are taken as part of standard care and consent will be sought for access to a participant's routine medical records, which includes these images.

15.3 Research Ethics Committee review and reports

Ethics review of the protocol and other trial related participant facing documents will be carried out by a NHS Research Ethics Committee (REC) and, where applicable, the Health Research Authority (HRA). It is the Sponsor's responsibility to decide whether an amendment is substantial or non-substantial for the purposes of submission REC, in accordance with the legislation and HRA processes. All amendments will be documented on the HRA amendment tool regardless of substantiality

All correspondence with the HRA/REC will be retained in the Trial Master File (TMF). The CI will notify the REC of the end of the trial and if the trial is ended prematurely (including the reasons for the premature termination). Within one year of the end of the trial, the CI will submit a final report with the results to the REC.

15.4 Amendments

Any amendments to the protocol or other trial related participant facing documents will be approved by the Sponsor (and where necessary the funder) before being submitted to the REC/HRA for approval prior to implementation.

It is the Sponsor's responsibility to decide whether an amendment is substantial or non-substantial for the purposes of submission to the REC, in accordance with the legislation and HRA processes. All amendments will be documented on the HRA amendment tool regardless of substantiality.

15.5 Financial and other competing interests

The research team must disclose any ownership interests that may be related to products, services, or interventions considered for use in the trial or that may be significantly affected by the trial. Competing interests will be reported in all publications and in the final report.

15.6 Indemnity

The necessary trial insurance is provided by the Sponsor. The PIS provides a statement regarding indemnity.

This is an NHS-sponsored research trial. For NHS-sponsored research if there is negligent harm during the clinical trial when the NHS body owes a duty of care to the person harmed, NHS Indemnity covers NHS staff, medical academic staff with honorary contracts and those conducting the trial. NHS indemnity does not offer no-fault compensation and is unable to agree in advance to pay compensation for non-negligent harm. Ex-gratia payments may be considered in the case of a claim.

16 DISSEMINATION POLICY

A publication policy will be developed following the BTC template, with authorship models agreed in advance with the TMG.

The findings will be disseminated by usual academic channels, i.e. presentation at international meetings, as well as by peer-reviewed publications and through patient organisations and newsletters to patients, where available.

Where possible, information will be disseminated to participating sites and participants in line with timelines for academic audiences (i.e. participant and sites being informed of the study results on or shortly after the date the academic paper is published). Before dissemination materials are drafted, PPI members should be consulted on the proposed methods for dissemination to non-academic audiences.

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18 AMENDMENT HISTORY

Amendment number (i.e. REC and/or HRA amendment number)	Previous version	Previous date	New version	New date	Brief summary of change	Date of ethical approval (or NA if non-substantial)