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Investigating the use of a breathing device in older people with broken ribs

Submission date
15/01/2026

Recruitment status
Recruiting

Registration date
06/02/2026

Overall study status
Ongoing

Last Edited
30/10/2026

Condition category
Injury, Occupational Diseases, Poisoning

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
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.

Who can participate?
Patients aged 65 years or older attending the Emergency Dept who have a chest injury such as broken ribs

What does the study involve?
Participants are split 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 throughout 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 come to hospital. We will also ask everyone to complete questionnaires to see how well they are recovering.

What are the possible benefits and risks of participating?
We cannot promise that the study will benefit patients directly, but it will help us decide on the best ways to care for people with broken ribs in the future. The benefit to patients, the NHS and society is that at the end of the study, it will be known if incentive spirometers reduce health complications in patients with broken ribs. In recognition of the patient's time, we will offer £20 vouchers on day 5 after the completion of all patient questionnaires.
Given that some NHS hospitals already safely use incentive spirometers and some do not, there are unlikely to be any risks. However, because we are using them in injured patients, the safety of all participants will be closely monitored by an independent group of experts.

Where is the study run from?
The study is being coordinated by Bristol Trials Centre on behalf of the study Sponsor organisation at North Bristol NHS Trust (UK)

When is the study starting and how long is it expected to run for?
April 2026 to March 2027

Who is funding the study?
National Institute for Health and Social Care (NIHR), Research for Patient Benefit (RfPB) (UK)

Who is the main contact?
Stephen Palmer, resolve-trial@bristol.ac.uk

Contact information

Type(s)
Scientific, Principal investigator, Public

Contact name
Dr Stephen Palmer

ORCID ID
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-
Resolve-trial@bristol.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)
349783

Central Portfolio Management System (CPMS)
64921

National Institute for Health and Care Research (NIHR)
208172

Study information

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

Acronym
RESOLVE

Study objectives
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.

Secondary Objective:
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.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 26/01/2026, Yorkshire & The Humber - Bradford Leeds Research Ethics Committee (NHSBT Newcastle Blood Donor Centre Holland Drive, Newcastle upon Tyne, NE2 4NQ, United Kingdom; +44 (0)2071048083; bradfordleeds.rec@hra.nhs.uk), ref: 26/YH/0013

Primary study design
Interventional

Study design
Randomized; Interventional; Design type: Treatment, Prevention, Process of Care, Education or Self-Management, Device, Management of Care, Rehabilitation

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Rib fractures

Interventions
In open, participating centres, staff will monitor admissions to the Emergency department to screen for suitable patients. Any patients who are 65 or older with suspicion of chest wall trauma will be considered, and those who go on to have a confirmed rib fracture will be given a summary information sheet and access to a patient video. The site staff will confirm eligibility and then approach the patient for consent. In any case where the patient is without capacity to consent, a consultee or personal legal representative (PLR) will be approached. A detailed information sheet can be provided if requested and there will be an opportunity to ask questions with the site staff member.

When consent is received via a signed paper form, the delegated ED staff member can access a REDCap database and add a new participant. They will need to complete the screening information, confirming eligibility, and confirm consent has been received. Before randomisation, they will need to add the minimisation factors; who consented (patient or consultee/PLR), and whether the patient has isolated rib fractures, or rib fractures plus other injuries. The details in REDCap will then be transmitted to Sealed Envelope and a randomisation allocation will be returned.

If usual care without the use of an incentive spirometer is returned, then the patient will be informed and treated according to usual care. This will include treatment for their injuries and any breathing instructions given as part of standard care.

If usual care plus use of an incentive spirometer is returned, they will be informed, and an initial face-to-face training session on use of the device will be delivered by the trained site staff. If the patient is deemed to be able to use the device independently (or in the case of patients lacking capacity, their consultee/PLR is deemed to be able to support the patient independently), they will continue to use the device, 3 times a day, for 5 days. However, the trained staff may feel that additional training sessions are needed for some patients and/or consultee/PLR's supporting patients. In those case, an additional two training sessions may be offered, up to a maximum of 3.

Patients receiving the intervention will be provided with an education leaflet and a diary. They will be asked to complete this over 5 days to document their adherence. This diary will be collected by site staff and entered into the REDCap database after 5 days, where a patient is still an inpatient. If the patient does get discharged within 5 days, the diary will be collected on discharge. Adherence data may be collected from observation by site staff, where feasible and where needed.

All trial patients will be asked to complete questionnaires on their pain and breathlessness at the point of consent. If this is not feasible, due to patient fatigue for example, this can be delayed but should still be completed within 24 hours of hospital admission. The forms may be completed with the support of a research/clinical staff member or a person with caring responsibility.

For patients who remain an inpatient at day 5 (+ 2 days tolerance given in case this falls on a weekend) post randomisation, follow-up questionnaires will be requested and entered into the database by the delegated trial staff.

For patients who have been transferred or discharged, the research staff will contact the patient or their consultee/PLR by telephone to complete these remotely.

Patients will be offered a £20 voucher upon completion of both of the above sets of questionnaires.

The REDCap database will need to be completed by a delegated staff member to add details of the patient's Baseline data, e.g. details of their injuries, standard care received or dates and times of training sessions.

A follow-up data collection will take place at 5 days after randomisation, where details comprising the primary and secondary outcomes will be captured in the REDCap database.

At 30 days post randomisation, research staff at the site will use hospital medical records to complete data collection on mortality and hospital readmissions. This will not involve contacting the patient or their consultee/PLR.

Any safety events that occur between randomisation and Day 30 will be captured on safety forms in the patient database and reported to the sponsor within 24 hours of the site staff becoming aware of the event.

Patients or their consultee/PLR will have the right to withdraw from any or all aspects of the trial at any time.

Intervention Type
Other

Primary outcome(s)
1. Respiratory infection measured using medical notes at Day 5

2. Respiratory failure measured using medical notes at Day 5

3. Plural effusion measured using medical notes at Day 5

4. Atelectasis measured using medical notes at Day 5

5. Pneumothorax measured using medical notes at Day 5

6. Death measured using medical notes at Day 5

7. Additional pulmonary related events measured using GP records at Day 5

Key secondary outcome(s)
1. Breathlessness measured using patient-reported outcomes in the Dyspnea-12 Questionnaire at Baseline and Day 5(+2)
2. Pain measured using patient-reported outcomes in a numerical pain scale at Baseline and Day 5(+2)
3. Patient length of hospital stay recorded in medical notes at Day 30
4. Admission to critical care recorded in medical notes at Day 30
5. Mortality in medical notes at Day 30
6. Hospital readmissions in medical notes at Day 30

Completion date
30/03/2027

Eligibility

Key inclusion criteria
1. Aged >=65 years
2. Radiological evidence of acute rib fracture(s)
3. Planned for admission
4. Has capacity to provide informed consent or personal consultee/legal representative available and able to support use of incentive spirometer

Healthy volunteers allowed
No

Age group
Senior

Lower age limit
65 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
Current key exclusion criteria as of 25/08/2026:
1. 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)
2. Evidence of established acute pulmonary complication developing after rib fracture injury requiring active treatment (e.g. pneumonia requiring antibiotic treatment, respiratory failure requiring ventilatory support)
3. Haemodynamic instability (e.g. severe hypo- or hypertension, significant atrial/ventricular arrhythmia)
4. History of eye, inner ear or brain surgery within previous four weeks (Contraindication to using incentive spirometry)

Previous key exclusion criteria:
1. Coexisting injury or condition for which treating clinician deems patient unable to use incentive spirometer (e.g. facial injuries; burns to both hands; advanced dementia)
2. Patients who have Sp02 <92% on air at time of screening (< 88% for known chronic lung disease)
3. Intubated
4. Haemodynamic instability (e.g severe hypo- or hypertension, significant atrial/ventricular arrhythmia)
5. History of eye, inner ear or brain surgery within previous 4 weeks (Contraindication to using incentive spirometry)

Date of first enrolment
27/04/2026

Date of final enrolment
28/02/2027

Locations

Countries of recruitment
United Kingdom

England

Scotland

Wales

Study participating centre
Swansea Bay University Local Health Board
Tonna Hospital
Tonna Uchaf
Tonna
Neath
Wales
SA11 3LX

Study participating centre
NHS Lothian
Waverley Gate
2-4 Waterloo Place
Edinburgh
Scotland
EH1 3EG

Study participating centre
North Bristol NHS Trust
Southmead Hospital
Southmead Road
Westbury-on-trym
Bristol
England
BS10 5NB

Study participating centre
Maidstone and Tunbridge Wells NHS Trust
The Maidstone Hospital
Hermitage Lane
Maidstone
England
ME16 9QQ

Study participating centre
West Suffolk NHS Foundation Trust
West Suffolk Hospital
Hardwick Lane
Bury St. Edmunds
England
IP33 2QZ

Study participating centre
Royal Infirmary of Edinburgh at Little France
51 Little France Crescent
Old Dalkeith Road
Edinburgh
Lothian
Scotland
EH16 4SA

Study participating centre
Cardiff & Vale University Lhb
Woodland House
Maes-y-coed Road
Cardiff
Wales
CF14 4HH

Study participating centre
Victoria Hospital
Hayfield Road
Kirkcaldy
Scotland
KY2 5AH

Study participating centre
Royal Berkshire Hospital
London Road
Reading
England
RG1 5AN

Study participating centre
Oxford University Hospitals
John Radcliffe Hospital
Headley Way
Headington
Oxford
England
OX3 9DU

Study participating centre
University Hospital Southampton
Southampton University Hospital
Tremona Road
Southampton
England
SO16 6YD

Study participating centre
St George's University Hospitals NHS Foundation Trust
St. Georges Hospital
Blackshaw Road
London
England
SW17 0QT

Study participating centre
Nottingham University Hospitals NHS Trust
Queens Medical Centre
Derby Road
Nottingham
England
NG7 2UH

Sponsor information

Organisation
Bristol NHS Foundation Trust

ROR
https://ror.org/054vvq170

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Detailed version 1.0	16/12/2025	30/01/2026	No	Yes
Participant information sheet	Summary version 1.0	16/12/2025	30/01/2026	No	Yes
Participant information sheet	Detailed version 2.0	11/02/2026	29/04/2026	No	Yes
Participant information sheet	Summary version 2.0	11/02/2026	29/04/2026	No	Yes
Participant information sheet	Detailed version 3.0	01/06/2026	19/06/2026	No	Yes
Participant information sheet	Detailed, Scotland Only version 1.0	02/04/2026	19/06/2026	No	Yes
Protocol file	version 1.0	16/12/2025	30/01/2026	No	No
Protocol file	version 2.0	11/02/2026	29/04/2026	No	No
Protocol file	version 3.0	01/06/2026	19/06/2026	No	No
Protocol file	version 4.0	19/08/2026	25/08/2026	No	No