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Breathlessness relief at home

Submission date 31/10/2019	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 11/11/2019	**Overall study status** Completed	
Last Edited 24/11/2022	**Condition category** Respiratory	

Plain English summary of protocol

Background and study aims

Breathlessness is common in people with heart and lung conditions and can get very severe and frightening. When this happens patients or family members often call an ambulance, especially when their own doctor's surgery is closed. In a recent study, it was found that 1 in 5 of all people taken by ambulance to Accident and Emergency (A&E) called for help because of breathlessness. A third of these did not need to stay in hospital and went home. There are treatments to calm severe breathlessness that could be used in the patient's home. If paramedics can use this approach, breathlessness may be calmed more quickly and some people may not need to go to A&E. The aim is to see if it is possible to run a research study with people calling ambulances because of breathlessness. The study will test if paramedics trained in breathlessness techniques can ease breathlessness more quickly than usual care, and help more people stay at home. People with severe breathlessness have said this is important and have agreed to help run the study. At the end of this "test" study, it will be known whether i) such care can be used by paramedics, ii) a larger trial can be done and iii) the best way to run it. The researchers will let the participants, local support groups, charities, local clinicians and the funder know their findings and also publish them in a scientific journal. This study is a key first step to help people with severe breathlessness needing emergency help.

Who can participate?

Patients in their normal home environment experiencing a breathlessness crisis and receiving a 999 ambulance response from a participating paramedic

What does the study involve?

Eight paramedics in the Yorkshire area are chosen at random to use the breathing calming techniques in breathless patients or to give usual care. Patients are asked to provide consent for the use of routinely collected information from the call out and about whether there have been any further call-outs in the next 48 hours to be used in the study. They are also asked whether they are willing to be contacted about taking part in the follow-up of the study. Patients agreeing to further contact are contacted by a member of the research team about participating in the follow-up. If the patient agrees, a member of the research team visits them at a place suitable to them to gain written consent before completing an interview and/or three questionnaires. If the patient has a carer, they are invited to join the interview. The patient is contacted again at 1 month and 6 months after the original call-out about repeating the three questionnaires.

What are the possible benefits and risks of participating?
There is no specific benefit to the participants other than the potential to inform future research into the clinical practice of the ambulance service. The intervention is considered to be of low risk as it is based on best practice and optimisation of routine care.

Where is the study run from?
The study is being run by the University of Hull/Hull York Medical School and the Yorkshire Ambulance Service NHS Trust in the Yorkshire and Humber region (UK)

When is the study starting and how long is it expected to run for?
April 2019 to July 2021

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
1. Dr Ann Hutchinson
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2. Dr Matthew Northgraves
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Study website
https://www.hyms.ac.uk/research/research-centres-and-groups/wolfson/breathe

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
V3.0 17.12.2019; CPMS: 43288

Study information

Scientific Title
Breathlessness RElief AT HomE (BREATHE): a feasibility cluster randomised controlled trial (cRCT) to test if a definitive cRCT is possible to evaluate the effectiveness and cost-effectiveness of a paramedic-administered breathlessness crisis intervention for people with acute-on-chronic breathlessness compared with usual care

Acronym
BREATHE

Study objectives
To determine whether an adequately powered cluster randomised controlled trial (cRCT) of a breathlessness crisis intervention delivered by first responders (paramedics) is possible.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Current ethics approval as of 13/04/2021
Approved 22/11/2019, Substantial amendment 1 was approved 26/02/2020; Substantial Amendment 2 was approved 15/06/2020; Substantial Amendment 3 was approved 27/07/2020; Substantial Amendment 4 was approved 22/02/2021. NHS HRA Yorkshire & The Humber - Sheffield REC (NHS Blood and Transplant Blood Donor Centre, Holland Drive, Newcastle upon

Tyne, Tyne and Wear, NE2 4NQ; +44 (0)207 104 8086; nrescommittee.yorkandhumber-sheffield@nhs.net),
ref: 19/YH/0314

Previous ethics approval as of 24/08/2020:
Approved 22/11/2019, Substantial amendment 1 was approved 26/02/2020; Substantial Amendment 2 was approved 15/06/2020; Substantial Amendment 3 was approved 27/07/2020. NHS HRA Yorkshire & The Humber - Sheffield REC (NHS Blood and Transplant Blood Donor Centre, Holland Drive, Newcastle upon Tyne, Tyne and Wear, NE2 4NQ; +44 (0)207 104 8086; nrescommittee.yorkandhumber-sheffield@nhs.net), ref: 19/YH/0314

Previous ethics approval as of 19/06/2020:
Approved 22/11/2019, Substantial amendment 1 was approved 26/02/2020, NHS HRA Yorkshire & The Humber - Sheffield REC (NHS Blood and Transplant Blood Donor Centre, Holland Drive, Newcastle upon Tyne, Tyne and Wear, NE2 4NQ; +44 (0)207 104 8086; nrescommittee.yorkandhumber-sheffield@nhs.net), ref: 19/YH/0314

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Study design
6-month mixed-methods feasibility cluster randomised controlled trial (cRCT)

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Home

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Breathlessness as a result of either COPD, bronchitis, asthma, bronchiectasis, emphysema, heart disease or cancer in the lungs

Interventions
A group of paramedics (paramedic-participants) will be randomised to either deliver usual care or adopt the BREATHE intervention into routine practice for breathlessness patients. These paramedics will act as the cluster factor in a feasibility cluster randomised controlled trial:

Usual care:
The paramedic-participants in the control group will deliver usual care according to national guidelines including; initial history, baseline vital signs and tailored examination (chest auscultation, peak flow readings, 12-lead ECG).

BREATHE intervention:
In additional to usual care, patient-participants managed by paramedics-participants allocated to the intervention will receive a paramedic-administered short non-pharmacological complex intervention. This includes i) face-to-face advice (positioning, breathing techniques, panic management, fan) ii) a laminated leaflet and iii) a breathlessness management booklet to keep and refer to later. This booklet will have information to help the patient and carer self-manage breathlessness and information on local services they can turn to for support.

Intervention Type
Mixed

Primary outcome measure
Feasibility outcomes related to paramedics:
1. Paramedic recruitment rate recorded as the number of eligible paramedics who consent to participate in the study
2. Paramedic attrition rate recorded as the number of paramedics who consent to participate that remain in the study until the end of recruitment
3. Willingness of paramedics to be randomised recorded as number of paramedic declining participation for this reason
4. Patient recruitment per paramedic recorded as number of patients recruited by each paramedic

Feasibility outcomes related to patients:
1. Patient recruitment rate recorded as the number of eligible patients who consent to participate to Day 0 data use
2. Patient consent rate for follow-up data provision recorded as the number of patients who consent to Day 0 data use who also consent to follow-up
3. Patient attrition rate recorded as the number of patients who consent to participate in follow-up that remain in the study until the end of follow-up

Secondary outcome measures
Other feasibility outcomes:
1. Data quality of routinely collected and patient/proxy reported data recorded as completeness of data at Day 0 and 48-hour post-call-out data
2. Data quality of patient-reported outcomes recorded as completeness of questionnaire completion at 14 days, 1 month and 6 months
3. Intervention fidelity recorded as elements of BREATHE intervention used by the paramedic during Day 0 call-out
4. Patient adherence to the BREATHE intervention recorded as how they take part in the intervention in the call-out on Day 0
5. Acceptability of the BREATHE intervention to the patients is reported from qualitative analysis of interviews at 14 days post call out
6. Acceptability of the BREATHE intervention to the paramedics is recorded by Process evaluation and qualitative interviews at end of recruitment
7. Use of BREATHE intervention by patient since initial visit on Day 0 is reported from qualitative analysis of interviews at 14 days post call out and Health service utilisation questionnaires at 1

month and 6 months
8. Intracluster coefficient and sample size calculation for candidate primary outcomes

Potential definitive trial primary outcomes:
1. Improvement in breathlessness intensity at end of paramedic visit is measured by patient-participant report or paramedic-participant proxy report NRS intensity “now” every 2 minutes till decision to transfer to ED or decision to keep at home on Day 0
2. Conveyance to Accident & Emergency is being collected from routinely collected data at Day 0

Clinical measures:
1. Paramedic routinely collected clinical and service delivery data (pulse, respiratory rate, blood pressure (systolic and diastolic), capillary blood oxygen saturation level (SPO2) with air, SPO2 with oxygen) recorded at first and last assessments of call-out on Day 0
2. Working impression is recorded as paramedic impression on Day 0

Health service utilisation:
1. Duration of index call (Day 0) is collected from routine data
2. Future call-outs in 48 hrs (routinely collected) at 14 days
3. Health service utilisation relating to the 6 months prior to Day 0 is collected by Health service utilisation questionnaire at 14 days
4. Utilisation of primary and emergency services is collected by Health service utilisation questionnaire at 14 days, 1 month and 6 months

Health status:
This will be measured by the SF-6D which is derived from the SF-36. The SF-6D is a validated health status measurement tool widely used in health economic evaluations. For the purposes of this feasibility study data completion will be assessed and quality-adjusted life years will not be calculated

Chronic Respiratory Questionnaire dyspnoea domain:
This includes measurement of mastery of breathlessness and is recommended in addition to a unidimensional tool such as the NRS. This will be measured at 14 days, 1 month and 6 months

Overall study start date
01/04/2019

Completion date
31/07/2021

Eligibility

Key inclusion criteria
Paramedic-participants:
1. From a participating ambulance stations
2. Able to provide informed consent
3. Willing to undergo training and to deliver intervention if so randomised
4. Willing to undergo training to participate in study measures and processes

Patient-participants:
1. In their normal home environment experiencing a breathlessness crisis and receiving a 999 ambulance response from participating paramedics

2. Who do not require immediate life-saving intervention/transfer to ED in the opinion of the attending paramedic
3. Call-out due to breathlessness
4. Who experience chronic breathlessness (defined as short of breath most days in the last 3 months or longer)
5. With a self-reported diagnosis of a cardiorespiratory disease (including lung cancer [primary or secondary], COPD, bronchitis, asthma, bronchiectasis, emphysema, heart disease
6. Able to give retrospective consent at the end of the paramedic call-out to use collected data for researcher use

Carer-participants:
If any of the patient-participants who consent to the interview have a carer, the carer will be invited to be part of the interview

Participant type(s)
Mixed

Age group
Adult

Sex
Both

Target number of participants
68 (8 paramedic-participants, 60 patient-participants)

Total final enrolment
42

Key exclusion criteria
Paramedic-participants:
1. Failure of inclusion criteria

Patient-participants:
1. Patients requiring urgent disease-directed intervention and transfer to the ED for acute pathology in the opinion of the attending paramedic
2. Patient does not have capacity to provide retrospective consent
3. Patient is currently enrolled on the trial or has previously participated

Date of first enrolment
02/12/2019

Date of final enrolment
30/06/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Yorkshire Ambulance Service NHS Trust
Brindley Way
Wakefield 41 Business Park
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United Kingdom
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Sponsor information

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University of Hull

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Sponsor type
University/education

Website
https://www.hull.ac.uk/

ROR
https://ror.org/04nkhwh30

Funder(s)

Funder type
Government

Funder Name
National Institute for Health 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

Publication and dissemination plan
The study team plan to disseminate trial results to key stakeholders and patients in several ways:
1. Publication of study protocol in a peer-reviewed, open-access journal
2. Planned publication of findings in a peer-reviewed scientific journal
3. Conference presentations
4. Publication on website
5. Stakeholder group meeting
A full dissemination strategy will be produced for the trial

Intention to publish date
30/09/2022

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date

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?
Protocol article		29/03/2021	14/04/2021	Yes	No
Results article		21/11/2022	24/11/2022	Yes	No
HRA research summary			28/06/2023	No	No