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Early View

Original research article

Mixed-methods feasibility cluster randomised controlled trial of a paramedic-administered breathlessness management intervention for acute-on-chronic breathlessness (BREATHE): Study findings

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Title: Mixed-methods feasibility cluster randomised controlled trial of a paramedic-administered breathlessness management intervention for acute-on-chronic breathlessness (BREATHE): Study findings

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Tweetable abstract/take home message

A paramedic-delivered BREATHE intervention for acute-on-chronic breathlessness, and study procedures were acceptable, but recruitment was low (pandemic related) and further work is necessary to answer remaining questions on sample size and best primary outcome.

ABSTRACT

Introduction: One-fifth of emergency department presentations by ambulance are due to acute-on-chronic breathlessness. We explored the feasibility of an evaluation-phase, cluster randomised controlled trial (cRCT) of the effectiveness and cost-effectiveness of a paramedic-administered, non-pharmacological breathlessness intervention for people with acute-on-chronic breathlessness at ambulance call-out (BREATHE) regarding breathlessness intensity and conveyance to hospital.

Methods: This mixed-methods, feasibility cRCT (ISRCTN80330546), randomised paramedics to usual care or intervention plus usual care. Retrospective patient consent to use call-out data (primary endpoint) and prospective patient/carer consent for follow-up was sought. Potential primary outcomes included breathlessness intensity (numerical rating scale) and conveyance. Follow-up included: interviews with patients/carers and questionnaires at 14 days, 1 and 6 months; paramedic focus groups and surveys.

Results: Recruitment was during COVID-19, with high demands on paramedics and fewer call-outs by eligible patients. We enrolled 29 paramedics; nine withdrew. Randomisation/trial procedures were acceptable.

Paramedics recruited thirteen patients, not meeting recruitment target (n=36); eight patients and three carers were followed up. Data quality was good but insufficient for future sample size estimation.

The intervention did not extend call-out time, was delivered with fidelity and was acceptable to patients, carers and paramedics. There were no repeat call-outs within 48 hours. All trained paramedics strongly recommended BREATHE as a highly relevant, simple intervention.

Conclusion: Patient recruitment to target was not feasible during the pandemic. Training and intervention were acceptable and delivered with fidelity. Results include valuable information on recruitment, consent, attrition, and data collection that will inform the design and delivery of a definitive trial.

INTRODUCTION

Chronic (persistent) breathlessness - disabling despite treatment of underlying causes[1] - is prevalent in cardiorespiratory disease(s) and acute exacerbations are frightening for patients and carers. It is more common in older adults[2] with widespread impacts for patients, family carers and health systems.[1-3] Acute worsening of chronic breathlessness (acute-on-chronic breathlessness[4]) is mostly triggered by physical and/or emotional exertion, but can relate to worsening of the underlying cause(s).[5] Non-pharmacological interventions can be effective[6] and include breathing retraining, anxiety management, activity pacing [7], and cool facial airflow.[8]

Severe episodes of acute-on-chronic breathlessness may be caused by a worsening of the underlying disease and/or when distress aggravates the symptom.[9] Acute-on-chronic breathlessness often triggers emergency use of health services.[10] However, one third of these emergency department (ED) attendees do not need hospital admission and some might be avoidable with adequate community support.[10] Estimates of breathlessness as a primary reason for adult ED presentations range between 2.7% and 9.0%[11-14]. In one UK study, acute-on-chronic breathlessness was a reason for 20% of attendances conveyed by ambulance.[10] The presence and intensity of breathlessness on ED arrival predicts hospital admission[15], and subsequent presentations.[16]

For many, the ED is necessary for best care. For others, the ED is less likely to be the optimal place if community-based care is working effectively.[17] Anxiety can play a significant role in people with recurrent acute-on-chronic breathlessness, and for whom targeted, community-based management plans may reduce the need for ED attendances.[18]

The American Thoracic Society (ATS) consensus, whilst recognising the evidence gap in the acute setting, recommends a dual approach to acute breathlessness management.[19] Initial management should be given by first responders, using evidence-based, non-pharmacological breathlessness interventions alongside management of any underlying condition. Patients and carers should receive education and training in self-management techniques[19]. For some, an acute worsening of breathlessness can become a “teachable moment”[20] and carers may also learn techniques by observing paramedics.[21] More people with acute-on-chronic breathlessness might thereby be managed safely in the community or, if hospital admission is needed, have their breathlessness reduced more quickly.

We aimed to explore the feasibility and acceptability of conducting a definitive, cluster randomised, controlled trial (cRCT) for people with acute-on-chronic breathlessness due to medical conditions to evaluate the effectiveness and cost-effectiveness of a paramedic-administered, non-pharmacological breathlessness intervention Breathlessness RElief AT HomE (BREATHE).

MATERIAL AND METHODS

Details of the planned methods for this mixed methods feasibility trial are documented elsewhere[22] and summarised here with protocol amendments due to COVID-19.

Study participants

Paramedic-participants willing to undergo training in study measures, processes and the BREATHE intervention (if allocated) were recruited from Yorkshire ambulance stations. Following consent, randomisation and training, paramedics then delivered usual care or BREATHE intervention plus usual care at appropriate call-outs. Usual care was defined by the Joint Royal College Ambulance Liaison Committee (JRCALC) guidelines.[23]

Eligible patients were in their usual home environment receiving an emergency response from participating paramedics because of acute-on-chronic breathlessness. They had self-reported cardiorespiratory disease, chronic breathlessness (breathless most days for ≥3 months) and gave retrospective consent for call-out data use at the end of the call-out. Patients needing immediate life-saving intervention in the paramedic's judgement were ineligible. Eligible carers were adults present at call-out to a patient-participant consenting to follow-up.

Study design

We explored the feasibility of a cRCT to evaluate the effectiveness and cost-effectiveness of a paramedic-administered non-pharmacological breathlessness intervention for people with acute-on-chronic breathlessness who have called an ambulance.

Objectives:

We addressed the following uncertainties for a definitive trial:

1. Paramedic-participants' and patient-participants' recruitment and attrition rates
2. Randomisation and consent process: acceptability, possibility within clinical priority time constraints.
3. Intervention: acceptability, adherence and fidelity, implementation issues (trial procedures and clinical practice), safety, contamination.
4. Feasibility of data collection and best primary outcome.
5. Sample size estimation using variability values for candidate primary outcomes.

The trial procedures for patient-participants are outlined in Figure 1 and Table 1.

Sample size

As a feasibility study, a formal sample size calculation was not required. We aimed to recruit 60 patient-participants over 6 months, 30 per group, to provide sufficient data to answer our research questions[24].

Recruitment, randomisation and consent

Paramedic-participants were recruited, consented and randomised as previously described [22], with an amendment allowing electronic consent. Paramedics were randomly allocated (paramedic being the unit of randomisation), at an intervention:control ratio of 1:1 by the HHTU (Hull Health Trials Unit) using a purpose built, web-based data capture system with integrated randomisation (REDCap cloud). An independent statistician prepared the randomisation schedule with random permuted blocks of size 2-4. All researchers involved in the analysis of the quantitative data were blinded to allocation.

Patient-participants were recruited and consented at call-out, with an amendment due to pandemic restrictions allowing those who consented at call-out for further contact to be phoned to discuss follow-up, gain verbal consent and arrange Day-14 data collection.

Training
All paramedic-participants received one-hour study training on consent and study procedures, with 30 minutes intervention training if randomised to BREATHE. The first group were trained in-person, with an amendment due to pandemic restrictions allowing online training, and refreshers provided on request.

Data Collection
Paramedics accessed REDCap cloud during call-outs via a Toughbook, their standard-issue tablet, and by researchers to input follow-up questionnaire data. A NoMAD (Normalisation Measure Development) survey was completed in REDCap by intervention paramedics. Qualitative data (online interviews and focus groups) were conducted by a researcher (AHu) using a semi-structured topic guide developed by the research team (see online supplement), recorded and transcribed verbatim. All study-active paramedics were invited to take part in the focus groups. Patients and carers consenting to further contact were invited to take part in an interview. No participants were asked their reason for declining to take part in focus groups or interviews.

Intervention
BREATHE is described in Table 2 (for evidence-based references see protocol paper)[22] and reported in accordance with the template for intervention, description and replication (TIDieR) checklist[25] (online supplement). Modifications to the intervention were in response to pandemic-related infection control procedures.

Outcomes and Assessments
Candidate primary outcomes were conveyance to hospital (transport of patient from their home to the hospital by ambulance) or change in breathlessness intensity measured at call-out (Numerical Rating Score (NRS) every 2 minutes). Follow-up data included the SF-36 and the CRQ. Participants recruited later in a funded extension (due to COVID-19), were only followed-up to 3 months. An additional paramedics' focus group and a free text survey was conducted to gain further insight about trial experiences.

Analysis
Quantitative data were described using STATA 17[26]. Intervention fidelity was assessed by component completion rates. Framework analysis was performed for interview, focus group and survey data informed by Normalisation Process Theory[27], managed with NVivo 12 software. Preliminary qualitative findings were discussed, then refined following open discussion with co-authors. This trial is reported consistent with relevant Consolidated Standards of Reporting Trials (CONSORT) statements[28].

Safety
At call-out paramedics were instructed to record any adverse events. A research paramedic accessed clinical records to check for repeat call-outs within 48 hours of the index visit.

Ethics approval
The trial was approved by the Yorkshire and Humber-Sheffield Research Ethics Committee (Reference: 19/YH/0314), institutional ethics committee and registered (ISRCTN80330546) prior to recruitment.

RESULTS

Paramedic recruitment was open between December 2019 and December 2021. Patient-participant recruitment was open for 12 months between February 2020 and June 2021 (includes five-month COVID-19 pause);follow-up ceased in July 2021. Figure 2 details the recruitment, consent and data collection for paramedics, patient-participants and carer-participants. Quantitative data were collected at call-out for 13 patient-participants (primary endpoint) and at follow-up for 8/13. Two paramedics completed the NoMAD survey[27]. Qualitative data were collected by interview for six patient-participants and two carer-participants and by two paramedic focus groups (n= 7; n = 8) and a free text survey.

Recruitment and retention

Paramedics (cluster) 29 paramedics were recruited (nine (31%) withdrew). Recruitment per cluster varied between zero and three.

Paramedic characteristics
Paramedics were: male (52%), white (100%), mean number of years' experience=5 [range 1-26].

Patient and carer recruitment
13 patient-participants were recruited: all agreed to be contacted by a research about follow-up and nine (69%) consented to follow-up (one withdrew before data collection). Three carer-participants were recruited for interview. Paramedics stated they saw far fewer of our target group during the pandemic (Table 4). The stop-go criterion for recruitment (≤60% target) was not met. The original recruitment period of 6 months was extended to 12 months with a funded extension of the study. Given the ongoing pandemic challenges at the end of the funded extension, the study oversight committees then agreed it was not feasible to pursue any further extension and the study closed.

Participant characteristics
All patients recruited met the eligibility criteria. Patient-participants were: male (61.5%), mean age 76.4 years (sd 10.7), from the four most deprived deciles of the Index of Multiple Deprivation (100%), lived alone (61.5%), white (100%). The most common diagnoses were COPD (n=10/13) and heart disease (n=7/13). Characteristics were similar between arms. Carer-participants were adult female family members.

Acceptability of randomisation and training to paramedics
All 29 paramedics approached consented. Withdrawal was balanced across the trial arms (reasons in Figure 2). Randomisation and training (trial processes; intervention) were acceptable to all responding (qualitative data).

Feasibility and acceptability of consent processes
Qualitative data found in-person and electronic consent processes feasible, quick and acceptable to paramedics and the two-stage consent process was acceptable and feasible to patients.

Intervention: fidelity and adherence
The intervention was delivered with fidelity and no contamination. During the pandemic, the handheld fan was discussed but not demonstrated, substituted by a damp tissue to face and/or opening a window (Table 3).

Intervention: acceptability
Qualitative and NoMAD survey data show acceptability to patients, carers and paramedics.

Intervention: patients' and carers' views
Patient-participants found the intervention provided them with useful techniques and resources. However, the intervention may not be acceptable to all patients; one paramedic stated she had seen a patient who engaged poorly with the intervention wishing for immediate hospital transfer (this patient was excluded because they did not give retrospective consent for data use) (See Table 4).The intervention was well received by patient-participants.

Two patients did not read the information booklet or leaflet, one patient and carer read and derived benefit from both and another patient and carer read the leaflet and then dealt with two further episodes without calling an ambulance.

Intervention: paramedics' views
NoMAD responses indicated paramedics saw potential in BREATHE. Qualitative data indicated that BREATHE was useful and easily incorporated into practice. Paramedics valued the intervention, especially improving airflow, resting positions, breathing exercises and distraction to help with anxiety. Components combined easily and helped engagement with patients (Table 4). The leaflet was a useful guide for them and for carers and patients for later use. Carers got involved with breathing exercises and reassurance.

All four intervention-arm paramedics would recommend training paramedics in BREATHE to improve their skills since they see many breathless patients and it is simple to learn and to do. They felt that BREATHE would enhance the part they play in community patient care.

Some had incorporated BREATHE into practice and noted that parts of the intervention were helpful with anxious patients in general. One suggested that a GP-referral post call-out would be useful for help with breathlessness management long-term.

Safety
There were no adverse events at call-out and no repeat call-outs within 48 hours.

Data quality
Data collection at call-out was complete for all items of routinely collected data, except for the second temperature and pulse measurements.

Call-out
Candidate primary outcome measures
Data completion of the potential primary outcome of conveyance was 100% and for the NRS breathlessness intensity score data completion was above 75% for the control group at 6 min intervals, whereas for the intervention arm it was between 20% and 60% complete. NRS intensity scores decreased in both arms (Table 5).
NRS score measurement every six, but not two, minutes was acceptable to patient-participants and paramedic-participants and they found clinical conveyance decisions acceptable. Paramedic-participants were confident in their conveyance clinical decisions. Patients interviewed found it acceptable to remain at home, where this occurred, preferring this to hospital conveyance unless necessary. This may not be the case for all in routine practice: the two (excluded because of lack of retrospective consent) reported via paramedic qualitative data insisted on conveyance.

A similar proportion in each arm were conveyed to hospital (1/5 intervention, 2/8 usual care). Though the sample size was small, our findings suggest that on-scene time for the intervention arm took no longer than controls (intervention mean: 87 minutes, control mean: 90 minutes), the intervention being incorporated into the paramedics routine.

Follow-up
Data collection was 100% at 14 days, 75% at 30 days and above 50% at 3 or 6 months (Table 6). All health service utilisation questionnaires were fully completed. Of the SF-36 questionnaires, 14/19 (74%) had data to calculate the SF6D score. CRQ mastery scores could be calculated from all 19 CRQs. All data were collected by phone taking 30-40 mins. The researchers found patients had difficulty with answering the CRQ questions which were time-consuming.

Implementation issues
From qualitative data, paramedics valued participation and found the intervention (as relevant) useful and acceptable. They were satisfied with intervention and trial procedure training and support. Suggestions for improvement included: providing a scenario to practice applying eligibility criteria; face-to-face and video with online training material should be provided; regular videocalls with participating paramedics for peer support and updates on trial progression. Accessing the study database by Toughbook was problematic for some: inability to log in, poor internet access and time constraints. This led to at least one patient not being recruited into the study (Table 4). Suggestions included paper CRFs at call-out with input to the database later, streamlining the online data entry process and database access via smart phone.

Stop-go criteria for recruitment and adherence
Recruitment stop-go criterion were not met. However, the intervention was delivered with fidelity and no contamination, and met the adherence criterion.

Sample size calculation and proposed primary outcome for a definitive trial
Although data completion was good, only 13 patients were recruited. A sample size calculation for a full trial, or clarification of the best primary outcome was not possible.

DISCUSSION

A definitive cRCT to evaluate the effectiveness and cost-effectiveness of a paramedic-administered, non-pharmacological breathlessness intervention for people with acute-on-chronic breathlessness due to medical conditions is feasible in terms of data quality, adherence, fidelity and acceptability of the intervention and acceptability of trial processes, but recruitment was not feasible to target during the pandemic. We have valuable information to inform a definitive trial, but we have insufficient data to determine a sample size, nor to identify the most appropriate primary outcome.

Most recruitment occurred under very difficult conditions (for both patients and for ambulance services) at the height of the various waves of the pandemic, with fewer call-outs to Yorkshire Ambulance Service by this particular patient population and increased demand on the service and individual paramedics.

Informing a definitive trial
It would not be possible to recruit to a definitive cRCT if patient call-out for acute-on-chronic breathlessness continued at COVID-19 pandemic rates. However, we demonstrated the acceptability of many study processes including: study and intervention training; randomisation and consent; intervention acceptability, adherence and safety; and patient-reported data collection which inform our proposed study design adaptations.

The BREATHE intervention was simple to learn and use and acceptable to recruited participants. A future study should note how the intervention is received by patients excluded from analysis due to lack of consent; those not consenting may be those less likely to find BREATHE acceptable. The intervention needs no modification at call-out, but further primary care contact post call-out to promote sustained breathlessness management may be helpful. There were no non-conveyance safety issues and paramedics were confident in their clinical decisions.

Implications for further research
The research question remains important with ongoing distress for patients with acute-on-chronic breathlessness, pressure on ambulance services and emergency departments; further research is needed to address this problem. Uncertainties remain about the feasibility of a future study.
We propose the following:

- Include an embedded pilot to address remaining uncertainties.
- Recruit from multiple NHS ambulance services.

- Deliver intervention as currently described at call-out, but consider triggered follow-up in primary care.
- Allow both face-to-face and remote solutions for intervention training delivery.
- Reduce the number of patient-reported outcomes, do not include CRQ.
- Refine methods of recording data and consent at call-out.
- Capture the experience of all otherwise eligible patients, e.g., Confidentiality Advisory Group approval to use call-out data without consent, or use a quality improvement paradigm [29].
- Given the small clusters (number of participants/paramedic), a cRCT sample size may be prohibitive. Other study designs will be considered e.g., quasi-experimental and/or RCT using the paramedic-participant first dyad as the unit of randomisation for effectiveness.

The ADePT process (*A process for Decision-making after Pilot and feasibility Trials* (https://doi.org/10.1186/1745-6215-14-353) will be used to inform a large-scale trial design.

Strengths and limitations
The study was delivered in the NHS by usual care practitioners and in the intended setting. The use of retrospective consent ensured immediate necessary treatment. Another strength was our use of mixed-methods. Qualitative findings helped identify problems and solutions to inform a future trial.

Study limitations: the patient/carer sample was white British, English speakers, unrepresentative of the general population. We did not recruit enough paramedics initially, adding to pandemic recruitment challenges and did not meet patient recruitment targets, nor collect sufficient data to meet all objectives. Due to COVID-19 we were unable to use the fan during call-out which has more supportive evidence than the cold facial wipe. We kept no record of reasons for declining to take part in any aspect of the study which may give an incomplete picture of the intervention (as well as study participation) acceptability; Suggested future study designs above would help address this.

Conclusion
Patient recruitment to target was not feasible during the COVID-19 pandemic. Training and intervention were acceptable and delivered with fidelity. Results include valuable information on recruitment, consent, attrition, and data collection that will inform adaptations for the design and delivery of a definitive trial.

Tables

Table 1: Schedule of Events for patient-participants and care-participants

Visit	**Call-out (Baseline)**	**48 hours**	**Day 14**	**Day 30**	**Month 6**
Day	**0**	**2 (± 0 days)**	**14 (±7 days)**	**30 (±7 days)**	**183 (±7 days)**
Procedure/Assessment					
Inclusion/exclusion criteria assessment	x				
Call-out Informed Consent	x				
Numerical Rating Scale (NRS) 0-10 breathlessness every 2 minutes (patient) 0 not breathless to 10 worst breathlessness	x				
Routinely collected paramedic data (pulse, respiratory rate, blood pressure, oxygen saturation measured by pulse oximetry (SpO2) with air, SpO2 with oxygen and working impression)	x				
Demographic measures (patient and carer)	x				
Index Ambulance Call-out outcome	x				
Further call-outs in 48 hours after index call-out		x			
Follow-up Informed Consent			x		
Interview (patient and carer)			x		
Health service utilisation questionnaire (patient)			x	x	x
SF-36 (patient)			x	x	x
CRQ-Dyspnoea questionnaire (patient)			x	x	x

CRQ: Chronic Respiratory Questionnaire; NRS: Numerical Rating Scale; SF-36: Short form 36

Table 2: BREATHE Intervention and Usual Care

INTERVENTION	**Examples of techniques**
Be reassured:	Reassure patient and carer; a reassuring and expert presence is sometimes sufficient to start “unwinding” escalating breathlessness
Resting position:	Check posture; find the most comfortable and efficient position to maximise ventilation
Exercises (breathing):	Use to slow breathing rate and encourage breathing out to prevent air trapping (e.g. pursed lip or “breathing rectangle”). Pursed lip breathing also provides increased end-expiratory pressure.
Airflow:	Airflow across lower face/nasal passages can reduce breathlessness and recovery time. The fan was not used at call-out, but recommended for future use* Use of damp cloth to cool the face* Windows opened*
Time:	“Take it easy, nice and slow”
Help with fears and worries:	Simple techniques to manage panic and fear
Education of patient/carer:	Information booklet and laminated single page leaflet about BREATHE intervention
USUAL CARE	
Immediate clinical assessment	History, baseline vital signs and targeted examination (e.g. 12 lead ECG).
Reassurance	Reassurance is a mainstay of high-quality patient care
Oxygen	Time critical feature: oxygen saturations of < 94% or less for those patients without chronic lung diseases Target range oxygen saturation in patients with chronic lung diseases: 88-92%. If SpO2 >92%, oxygen would not be administered.
Nebuliser	Depending on the initial assessment, the paramedic may ask the patient to use their own inhalers, or proceed to nebulisation

**indicates changes from the original protocol due to COVID-19*

Table 3: Intervention fidelity and adherence

Intervention used	**n=5**	**Reasons not doing intervention n (Reason)**
Positions to ease breathlessness	5	
Breathing exercises	5	
The fan	1	4 (COVID-19 restrictions)
Addressing fears and worries	5	
Go through the leaflet/action plan	3	2 (Not enough time for paramedic)
Introduce the information booklet	2	1 (Paper work damaged) 2 (Not enough time for paramedic)
Damp tissue on face	0	2 (Discussed) 1 (Not enough time for paramedic) 1 (Paramedic forgot) 1 (Missing data)
Opening a window	2	1 (Not enough time for paramedic) 1 (Patient already using) 1 (Missing data)

Table 4: Quotes from participants

	Patient recruitment
Q1	*"I agree that we normally see so many more COPD patients than we have, like when you came and gave us four packs, I was like this in't gonna be enough, I'll see four COPD patients in a week, and then COVID-19 hit.* *I think because we've seen so much less of them, clearly these people are managing in the community in some way, shape or form, and I don't know how that is." (ParamedicFG6)*
Q2	*"These last eighteen months, it's been really difficult; I've not seen those chronic patients that I would normally see." (ParamedicFG7)*
	Intervention: patients' and carers' views
Q3	*"But some patients are just so unreceptive to help from us, like some people just think they need to be in hospital. I did them all (parts of the intervention) and he was not cooperative with any of them, but also he didn't enter the study anyway*. I think a lot of COPD patients are like, 'I don't want to go to hospital', cos they spend their whole lives there, and so they are really receptive, but some people are just not." (ParamedicFG6)* **Did not provide retrospective consent*
Q4	*"And then they had a good talk to me and I was really distressed. All me family came, they was worried and I weren't quite all there, if you know what I mean. The paramedic, he was absolutely brilliant; he talked me through, pulled me round a bit and then after about an hour maybe I was a lot better." (Patient12)*
Q5	*"They did the right thing when they came, they sat me down and calmed the fears I had over it and gave us some good advice, yeah, it was good, thanks." (Patient11)*
Q6	*"They walked in, they were so friendly, they were very reassuring to me mum. They weren't patronising in any way, they just dealt with her but also included me, which I thought were really nice, they had time for me as well, and just chatted as well, which just reassured me mum a lot." (CarerofPatient4)*
Q7	*"Well I think it was good because they gave an immediate solution; they talked him right through what was needed to be done, but also with the written information for him to read when he felt better. Cos obviously being given lots of instructions and talking through alternative treatments, it's OK, but when you're unwell you don't absorb all the information, and to be left with really clear concise information was really good." (CarerofPatient12)*
Q8	*"I haven't used the Ventolin for two days because every time I feel like it I use that little fan and do what it says in the book, breathe in and hold it, you know, like a rectangle it is, and then breathe out." (Patient12)*
	Intervention: paramedics' views
Q9	*"Opening the window and using a window to visualise the breathing is easy and effective. It calms people down and once the patient is calmer the relatives seem to take over with the coaching." (ParamedicSurvey6)*
Q10	*"I really loved the idea behind this research." (ParamedicSurvey8)*
Q11	*"If we're gonna start this intervention, we're gonna give you an alternative, instead of relying on somebody else (another clinician) that doesn't do it and we still see that patient next week, then I'm all for it." (ParamedicFG7)*
Q12	*"There was the little laminated sheet, I think that was good and I think that that's really helpful for relatives to be able to use to coach people through, because I would notice that after sorta five minutes of me coaching them they would start to step in, because it's not hard, and so I think that was effective." (ParamedicFG6)*
Q13	*"I think that coaching it and the ease of access for it, for patients to be able to do it, it might*

	take a few minutes, but it's very doable if the patient is receptive to it." (ParamedicFG6)
Q14	*"We usually go to a lot of breathless patients and we are making a move as a profession to try and treat more people within the community so, yeah, I definitely think it's something that's worth incorporating." (ParamedicFG7)*
Q15	*"I feel like it's definitely a worthwhile thing, because it's gonna be better for the long-term care of patients and healthcare needs to change, it needed to change cos it's not managing. So, this is something that can help with that change and help people manage on their own and that can only be a good thing." (ParamedicFG6)*
Q16	*"I think it (the intervention) is necessary for people to know, I don't think it's a specialist thing because you don't need a specialist skill set to be able to do any of it, anybody could do it." (ParamedicFG6)*
	Implementation issues
Q17	*"She was probably the one that was like, yes, I can take this woman, I can do it with this woman, but that was the one time where I then ended up, couldna get any access to the database at all." (ParamedicFG6)* **Did not provide retrospective consent due to access issues but was prepared to join the study*

Table 5: NRS Scores summary statistics (Numerical rating scale of breathlessness intensity 0-10)

		Minutes from baseline															
		0	2	4	**6**	8	10	**12**	14	16	**18**	20	22	**24**	26	28	**30**
Control	Mean	6.3	5.0	5.7	**4.9**	4.0	4.3	**3.8**	4.3	3.5	**3.3**	3.5	3.5	**3.0**	3.0	3.0	**2.7**
	SD	2.5	1.4	2.5	**2.4**	2.8	2.1	**1.9**	2.1	2.1	**1.7**	2.1	2.1	**1.8**	1.4	1.4	**1.6**
	Median	**7**	**5**	**6**	**6**	**4**	**5**	**4**	**5**	**4**	**4**	**4**	**4**	**4**	**3**	**3**	**3**
	Percentile 25	5	4	3	**3**	2	2	**3**	2	2	**2**	2	2	**2**	2	2	**2**
	Percentile 75	8	6	8	**6**	6	6	**5**	6	5	**4**	5	5	**4**	4	4	**4**
	n	8	2	3	**8**	2	3	**8**	3	2	**7**	2	2	**6**	2	2	**6**
Intervention	Mean	3.0	7.3	*	**2.7**	7.0	2.0	**2.0**	2.7	4.0	**2.0**	2.0	3.0	**5.0**	*	2.0	**3.0**
	SD	0.0	2.1	*	**0.6**	1.4	1.4		1.2	2.0			2.8		*		**1.4**
	Median	**3**	**8**	*****	**3**	**7**	**2**	**2**	**2**	**4**	**2**	**2**	**3**	**5**	*****	**2**	**3**
	Percentile 25	3	5	*	**2**	6	1	**2**	2	2	**2**	2	1	**5**	*	2	**2**
	Percentile 75	3	9	*	**3**	8	3	**2**	4	6	**2**	2	5	**5**	*	2	**4**
	n	2	3	0	**3**	2	2	**1**	3	3	**1**	1	2	**1**	0	1	**2**

*missing data

Table 6: Follow-up data completion

	Intervention n=4	Control n=4
Day 14		
Interview	4 (2 with carer)	2
Health service utilisation	4	4
CRQ	4	4
SF 36	4	4
Day 30		
Health service utilisation	3	3
CRQ	3*	3
SF 36	3	3
3 months or 6 months		
Health service utilisation	2**	3
CRQ	2**	3
SF 36	2**	3

**one partially completed the CRQ but this still allows calculation of score*

***one patient was recruited in the last two months of the recruitment period and wasn't offered 3m follow-up*

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Authors contributions
AHu, VA, SH, AHo, MJ, SM, JR, SG and FS are co-applicants on the grant application. MN, JC, VA, DC, SH, KH, AHo, MJ, SM, FS, JR, SG and AHu assisted in development of the protocol and implementation of the study. AHu, MN and MJ drafted the manuscript. All authors read and approved the final manuscript.

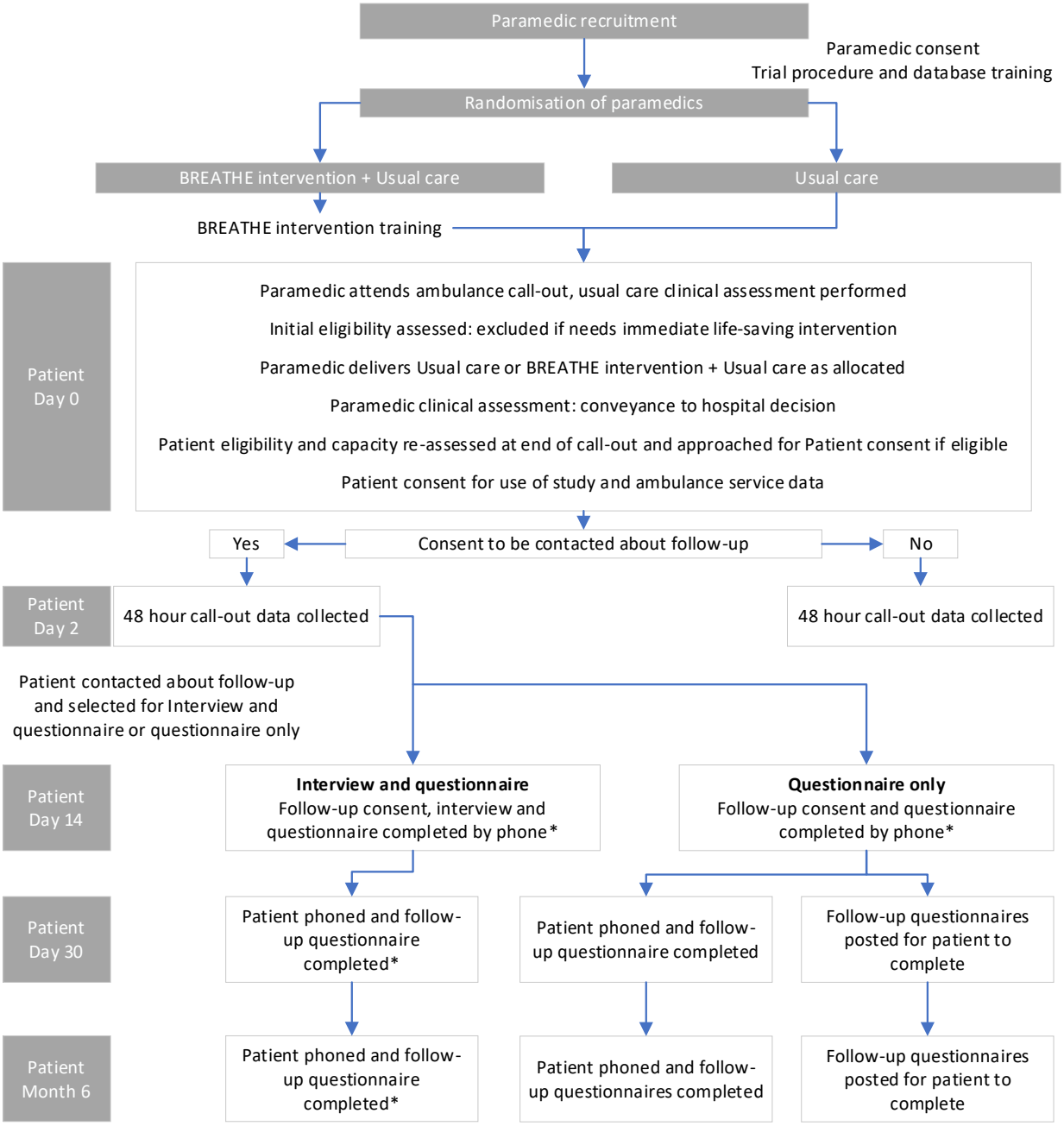

Figure 1: BREATHE Study flowchart

**indicates amendments to published protocol, trial procedures adapted due to delivery during COVID-19 pandemic*

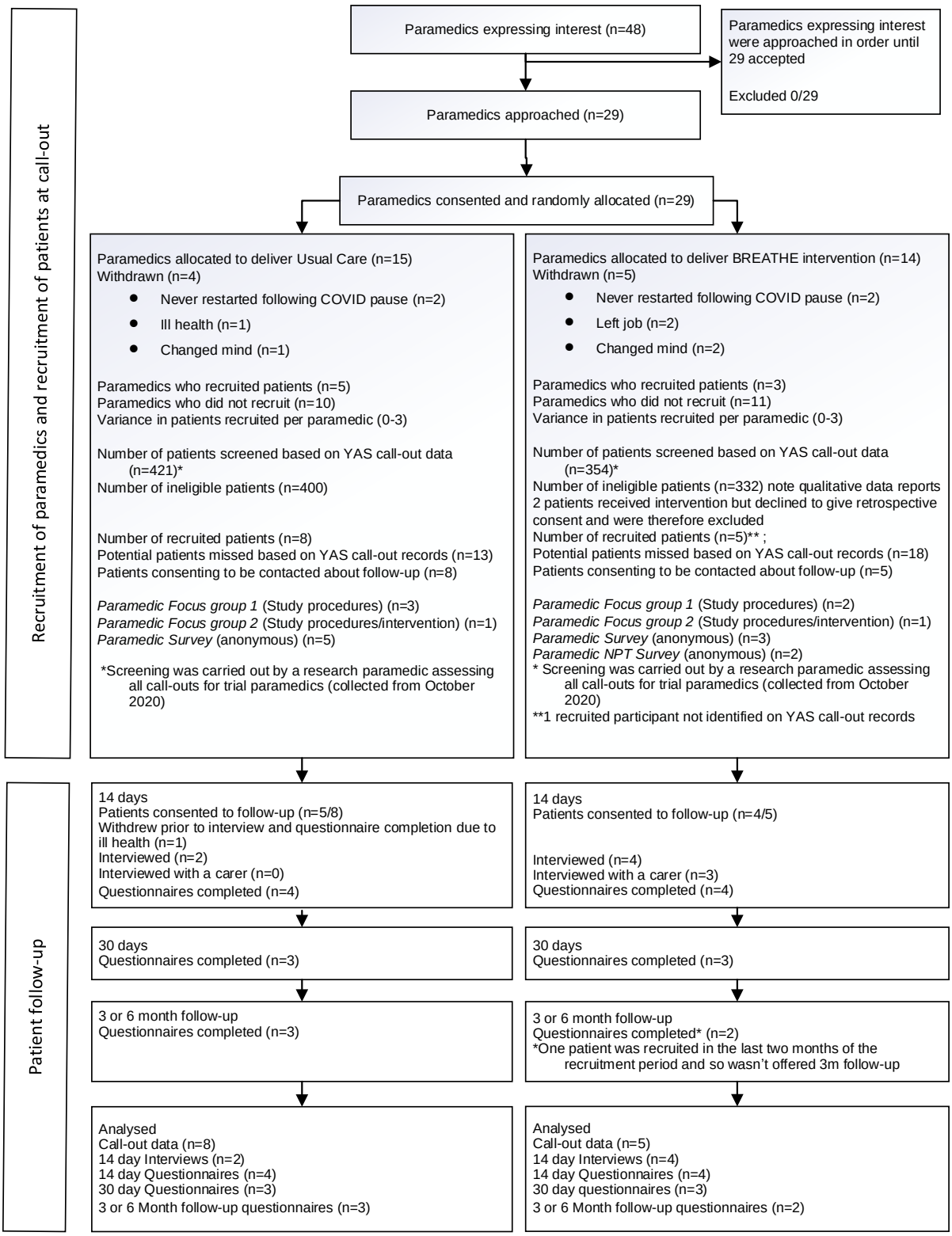

Figure 2: CONSORT diagram showing participant recruitment and retention throughout the trial

(Online supplement) TIDieR checklist to describe the BREATHE intervention

Item	Description	
1	Brief name: Provide the name or a phrase that describes the intervention	Breathlessness RElief AT Home (BREATHE)
2	Why: Describe any rationale, theory, or goal of the elements essential to the intervention	Each component was selected from components of evidence based chronic breathlessness management interventions if thought to be applicable in the emergency situation. The proposed intervention was then agreed on after feedback gained through interviews with a range of clinicians. The aim of the intervention is to provide paramedics with a structured set of breathlessness management strategies that they can incorporate into their practice. The combination of elements B, R, E, A and T are intended to settle the patient's breathlessness and then a decision on whether conveyance is now necessary or not can be made. The H and E elements are then added when the paramedic goes back over the BREATHE intervention on the leaflet and action plan to help the patient and carer know how they could act if there are future instances of acute-on-chronic breathlessness. Further information on managing every day breathlessness and where to find support is incorporated in the booklet that the paramedic leaves with them to read at their leisure.
3	What (materials): Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (for example, online appendix, URL)	The leaflet and action plan are on a laminated card for easy future reference when severely breathless. The information booklet is a 22-page booklet covering information on managing every day breathlessness and where to find support. (See online supplements)
4	What (procedures): Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities	
4i*	Be reassured that the breathlessness will ease and you will feel better	Paramedic provides a reassuring presence. Paramedic models all of the steps to the carer and encourages them to take part.
4ii*	Resting position: find the most comfortable position for you, flop and drop shoulders	Patient is helped to find a comfortable position to ease their breathlessness and to relax their shoulders.

4iii*	Exercises: use the breathing exercises to help control your breathing	Patient is encouraged to do a breathing exercise (e.g. rectangle breathing, pursed lip breathing).
4iv*	Airflow: use the fan as you've been shown	Paramedic introduces the fan, saying why and how it is used. Additionally, the patient was encouraged to put a damp cloth on their face and to open a window.
4v*	Time: take your time, nice and slow	Paramedic continues to help the patient take their time and relax.
4vi*	Help with fears and worries: use your action plan	Worries are addressed with reference to the action plan. Patient and carer are encouraged to try this process and follow the action plan in future times of increased breathlessness.
4vii*	Education: read the booklet for practical ways to help you manage your breathlessness	Paramedic recommends that the patient and carer read the information booklet at a later point in time.
5	Who provided: For each category of intervention provider (for example, psychologist, nursing assistant), describe their expertise, background and any specific training given	Paramedics are trained in the BREATHE intervention. The training is given in a group session by paramedics and a clinician experienced in breathlessness management.
6	How: Describe the modes of delivery (such as face to face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group	In person at call-out individually to the patient (and carer if present).
7	Where: Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features	In the patient's home.
8	When and how much: Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose	The intervention is provided once at call-out, the duration needed was determined by the paramedic in each case.
9	Tailoring: If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how	The intervention can be tailored to use specific breathing exercises or positions that the patient may already have a preference for.
10	Modifications: If the intervention was modified during the course of the study, describe the changes (what, why, when, and how)	The intervention was modified during the pandemic so that no direct contact was made with the patient and the fan was provided for their use later, rather than in the presence of the paramedic. This change was made due to

		the need for infection control.
11	How well (planned): If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them	Adherence and fidelity were assessed by paramedic self-report of which elements of the intervention were used with each patient.
12	How well (actual): If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned	The intervention was largely delivered as planned, but had to be adapted for infection control reasons. After each call-out in which the intervention was used paramedics recorded which parts of the intervention they had used. All parts were consistently used with the modifications described below. The intervention was planned to include the paramedics touching the patients to provide reassurance and aiding with relaxing the shoulders, but no touch was provided. Instead the paramedics relied on their voices to make a reassuring presence. Originally the intervention included the patient using the fan simultaneously with adopting a suitable position and doing breathing exercises, however these components were introduced without the fan at call-out and then the paramedic described how the fan should be used in future once their breathlessness had settled. Paramedics reported going over the leaflet and action plan with the patient and carer to reinforce learning. However, they reported having very little time to introduce the information booklet and so it was just left with the patient without a detailed introduction. The intervention was found to be acceptable in the modified form to paramedics, patients and carers.

Semi-structured interview (patient and carer if present)

- Introduction to researcher and project
- Information sheets for both patient and carer-any Qs?
- Consent forms to sign

1 Please tell me about your recent ambulance visit:

- Invite carer's perspective

2 From your recent ambulance visit can you suggest how they could improve the care of breathless people?

- Invite carer's perspective

3 What do you think of the information leaflet the ambulance staff left with you? (*For those who received the intervention)*

- Which parts have you used?
- Have you decided to seek any help because of what you read in the leaflet?
- Invite carer's perspective

Thank you, now let's think about your health in the future a little

4 What do you think you will do the next time you feel very breathless like when you called the ambulance last week?

- Use the BREATHE card? (For those who received the intervention)
- Remember anything the paramedics did with them/described to them?
- Invite carer's perspective

5 How do you see the next few weeks/months going?

- Plans to seek help/start new management?
- Invite carer's perspective

6 And finally is there anything else about your experience you'd like to share with me?

- Invite carer's perspective

Thank you for taking part!

- Thank you for helping us understand more about your situation and how to improve the services offered
- Remember we have told your GP you have been in a study (if consent given) and if you are upset/need advice/need to talk more, then your GP/specialist nurse will be able to discuss your health further…

Semi-structured interview/focus group with paramedics

Call-outs to patients with chronic breathlessness

1 **Can you tell me how you find call-outs to patients with acute-on-chronic breathlessness?**

2 **How did you find delivering the BREATHE intervention?** *(For those who were randomised to the intervention arm.)*

Thinking about deciding to convey or not

3 **Can you tell me how you feel about making decisions whether or not to convey breathless patients?**

Performing the BREATHE trial

4 **How did you find the trial processes?**

Finishing off

5 **Is there anything else from your field notes that you'd like to tell me about this intervention or the trial in general?**

Thank you for taking part!

- Thank you for helping us understand more about your experiences
- Payment form