ISRCTN36893888 https://doi.org/10.1186/ISRCTN36893888

The FANFirst Study: Feasibility of a trial of a handheld-fan based breathlessness treatment in COPD.

Submission date 21/09/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 25/10/2023	**Overall study status** Ongoing	
Last Edited 03/06/2026	**Condition category** Respiratory	

Plain English summary of protocol

Background and study aims
Chronic obstructive pulmonary disease (COPD) is a lung disease that tends to affect older adults. Breathlessness is the most common symptom which greatly impairs quality of life. COPD is mainly treated using inhalers taken once-or-twice every day, but another type of inhaler, called a short-acting beta agonist (SABA), is only meant to be used when needed to provide short-term symptom relief.
People with COPD often don't know how best to manage their breathlessness and can become reliant on their SABA, using it too often, risking side effects. Those with COPD that use their SABA frequently have worse breathlessness and are more likely to have COPD 'flare-ups'. We believe that teaching COPD patients how to use a hand-held-fan (HHF), and other techniques to manage their breathlessness (the FanFIRST intervention), may improve their breathlessness and reduce how often they need their SABA. SABA inhalers contain a strong greenhouse gas that contributes to global warming. Therefore, reducing how many SABA inhalers are used each year has potential dual-benefits to both COPD patients and the environment.

The FanFIRST intervention takes about 10-minutes and includes providing a fan and teaching people how to use it, alongside guidance on positions and breathing techniques to help manage breathlessness. Written information about breathlessness and anxiety and how to manage this will also be provided.

A large trial is needed to tell if the FanFIRST intervention can help people manage their breathlessness and reduce SABA inhaler use. But, before we start, there are a number of questions which need to be answered. For example:

- Can we recruit enough people to a trial?
- What sort of health services are best to recruit people from?
- Do people like the FanFIRST intervention; and What do people with COPD (and their carers) think about the trial design, and the questions that it is designed to answer?

To answer these questions and more, we will first undertake a smaller study called a feasibility trial. The results of the feasibility study will tell us two important things. First, whether a larger trial is possible, and if so, how best to run it. Second, if provisional results are deemed effective, how best to roll-out the FanFIRST intervention across the NHS.

Who can participate?
Adults aged 30 years or over, with a medical diagnosis of chronic obstructive pulmonary disorder (COPD). There are other criteria which are detailed in the participant information sheet.

What does the study involve? (for participants)
We will invite 80 people with COPD that use their SABA inhaler frequently. Eligible participants will be chosen at random to receive either the FanFIRST intervention, or usual care. Regardless of study condition, all participants will be given devices that attach to their SABA inhaler to count how often they are used. We will measure usage throughout the study and compare use at the start of the study with usage at the end of the study. People will take part for 4 months in total, with breathlessness questionnaires and other measures completed every 28 days during the study. A total of 40 participants (and their carers) will also be invited to take part in an interview with a researcher.

What are the possible benefits and risks of participating?
We do not anticipate that you will experience any significant disadvantages from taking part in this study. However, you should be aware that the study will involve commitment in terms of time and travel.
Benefits: If you are selected at random to be in the intervention group, you will be able to start the breathlessness treatment straight away. The treatment you will receive is not currently available as part of your usual care. Those not randomised to receive the FanFIRST intervention will be able to receive it at the end of the study, after all other aspects of your participation have concluded. By participating in this study, you will be helping us to design a large trial of the FanFIRST intervention for treatment of breathlessness in COPD patients. This has the potential to benefit you and others with COPD in the future and has potential benefits for the environment.

Where is the study run from?
Hull University Teaching Hospitals NHS Trust (UK)

When is the study starting and how long is it expected to run for?
April 2023 to April 2027

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

Who is the main contact?
Bronwen Williams, Bronwen.Williams@hyms.ac.uk

Contact information

Type(s)
Scientific

Contact name
Ms Bronwen Williams

Contact details
Hull Health Trials Unit
3rd Floor Allam Medical Building
University of Hull
Cottingham Road
Hull
United Kingdom
HU6 7RX
+44 1482 463621
Bronwen.Williams@hyms.ac.uk

Type(s)
Principal investigator

Contact name
Dr Mike Crooks

ORCID ID
https://orcid.org/0000-0001-6876-0258

Contact details
Hull York Medical School
University of Hull
1st Floor Daisy Building
Castle Hill Hospital
Castle Road
Cottingham
Hull
United Kingdom
HU16 5JQ
+44 1482624067
michael.crooks@nhs.net

Type(s)
Scientific

Contact name
Dr Amy Wilkinson

Contact details
Hull Health Trials Unit
3rd Floor Allam Medical Building
University of Hull
Cottingham Road
Hull
United Kingdom
HU6 7RX
+44 (0)1482 464897
amy.wilkinson@hyms.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)
318320

Central Portfolio Management System (CPMS)
53460

National Institute for Health and Care Research (NIHR)
204349

Study information

Scientific Title
Fan Feasibility Randomised Controlled Trial (RCT) for people living with COPD and high SABA intake (FanFIRST)

Acronym
FanFIRST

Study objectives
A phase-3 trial of handheld fan based breathlessness management, for people with COPD and high SABA-use, will be both feasible and acceptable.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 12/09/2023, Yorkshire & The Humber - Bradford Leeds Research Ethics Committee (Holland Drive, Newcastle-upon-Tyne, NE2 4NQ, United Kingdom; +44 207 104 8243; bradfordleeds.rec@hra.nhs.uk), ref: 23/YH/0180

Primary study design
Interventional

Study design
Interventional randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic Obstructive Pulmonary Disease

Interventions
Design: The study is a 16-week (112 day) randomised controlled trial (RCT) which will be operated over four centres.
An RCT is a rigorously monitored study which attempts, as far as is possible, to reduce all aspects that might interfere with a study's outcome, apart from the intervention/treatment being studied. In an RCT like this one, where there are two study groups, one group is chosen at

random to receive the intervention while the other group does not. At the end of the RCT, the outcomes are compared between the two groups. There will be two study arms: 1) those selected randomly to receive the FanFIRST intervention* and 2) a control group who will receive treatment as usual, without the FanFIRST intervention. It is important that we include both those randomised to the intervention, and those that are not, in order to understand if any observed or reported benefits can be understood as a direct result of the intervention. The study is a feasibility study and is therefore being run in order to inform whether a larger trial involving a greater number of participants and study sites would be justified. Those that are not initially randomised to the intervention arm will be
able to receive the FanFIRST intervention after they complete the study. In designing the study, patient and public participation has been incorporated. For example, breathlessness management was highlighted by PPI representatives as critical in COPD and they supported the use of hand-held fans (HHFs) to reduce SABA overreliance.
PPI is embedded throughout the trial with representatives having reviewed and commented on patient facing documents and contributing to oversight groups.
*The FanFIRST Intervention includes: hand-held fan (HHF) provision; verbal and written instruction in HHF-use, breathing positions/techniques and exercises to relieve breathlessness; and written information about managing anxiety to improve breathlessness. The intervention has been designed to be deliverable within 10-minutes, making it practical for delivery within current clinical practice if proven effective.

For successfully enrolled participants, the day of consent will also mark the day of the baseline period, a 28 day period to record usage of SABA. In order to record the number of times that SABA inhalers are used over the baseline period, participants will be provided with either one or two sensors which attach to the top of their inhalers. Each time participants press on their inhaler, this will be recorded. Participants will be able to participate in the study in either one of two ways: 1) By downloading a mobile app which will sync with their inhaler via Bluetooth, or 2) by syncing with a web-app at their study site which will download data from their inhaler when brought to site every 28 days. For the former way of participation, visits to site will be reduced from 5 down to 3. At the end of baseline, all participants will return to site to mark the end of baseline monitoring and undertake further measures/tests (Day 0). Randomisation will be performed at this visit and those randomised to the intervention will receive it during this visit. At the end of each subsequent 28 days (days 28 and 56), participants will complete a number of questionnaires. For those that are using the mobile app, they will be able to complete these remotely, while those not using the mobile app will need to attend their study site in order to have their usage data downloaded from the inhaler sensor(s). Day 84 will mark the end of the study and all participants will be required to visit their study site for this visit.

Embedded Qualitative Study
A qualitative interview sub-study will be conducted involving two groups of participants. Group 1: Adult COPD patients (n=5) who completed, withdrew, or did not start the main RCT, and, optionally, their nominated carer(s). Group 2: Clinicians (n=3), and service managers (n=2) who were involved in the main RCT. In total, 40 participants will be invited across the two groups, and from across the four study sites. In order to ensure that the sample are representative, a sampling grid will be constructed inclusive of profession, gender, and ethnicity, and those who did not start, withdrew, or completed. By exploring differences in the acceptability of trial processes and how the intervention is implemented at each centre, we shall identify:
1. Key feasibility issues for the design and delivery of a future trial.
2. Factors that would impact NHS implementation at-scale, if the intervention is in future found to be effective.

Using a theory-based approach to explore how mechanisms and context interact and therefore how the intervention brings about change, we will undertake semi-structured interviews with a purposive sample at each site.
Interviews will be conducted using an interview guide, structured using the Theoretical Framework of Acceptability (TFA). This theory, developed following a systematic review and consensus group exercise, breaks down the 'acceptability' of delivering or receiving a healthcare intervention into seven component constructs for investigation as listed below:
1. Affective attitude - How an individual feels about the intervention
2. Burden - The perceived amount of effort that is required to participate in an intervention
3. Ethicality - The extent to which an intervention fits with an individual's value system
4. Intervention coherence - The extent to which an individual understands an intervention and how it works
5. Opportunity costs - The extent to which benefits, profits or values must be given up to engage in an intervention
6. Perceived effectiveness - The extent to which an intervention is perceived as likely to achieve its purpose
7. Self-efficacy - The extent to which a person is confident that they can perform the behaviour (s) required to participate in an intervention

Intervention Type
Behavioural

Primary outcome(s)
Mean daily SABA use from baseline (days -28-0) at days 56 - 84. Daily SABA use will be recorded throughout the trial

Key secondary outcome(s)
1. COPD Assessment Test (CAT) score at Day -28, 0, 28, 56, and 84
2. Breathlessness numerical rating scales for 'worst', 'distress caused by' and 'coping with' breathlessness within the past 24 hours at Day -28, 0, 28, 56, and 84
3. Modelled annual SABA inhaler/cannister pick-up rate will be reported (based on number of actuations at baseline (days -28 – 0) and between days 56 and 84
4. Health-related quality-of-life: EQ-5D-5L and VAS at Day -28, 0 and 84
5. Healthcare-resource-utilisation measured using self-reported usage and medical records at Day 0, 28, 56 and 84
6. Modelled CO2e (for COPD treatments alone and combined for COPD treatments, study intervention and healthcare-resource-utilisation) using calculated carbon footprint of fan, calculated carbon footprint of inhalers, as well as calculated carbon footprint of healthcare utilisation while in the study at Day -28 – Day 84

Feasibility outcome measures:
1. Recruitment and retention: recruitment rate (per site and aggregated), eligibility to consent ratio, screen failures and participant retention measured using completed consent forms, screening and enrolment logs, and number of participants completing the study at Day -28 and end of study
2. Data quality and integrity: Amount and pattern of missing data (SABA inhaler use) measured through sensor recorded data collected perpetually throughout participant duration e.g., Day -28 – Day 112
3. Intervention: feasibility, acceptability and fidelity of the intervention will be measured through adherence in delivery and uptake of the intervention (as a whole and individual

intervention components) as documented in the eCRF. Overall intervention acceptability will be assessed via qualitative interviews conducted at the end of participants participation in the RCT e.g., post-Day 112. For those participants that withdrew from the study, interviews may be held at any time post-withdrawal.

Completion date
02/04/2027

Eligibility

Key inclusion criteria
1. Adults aged > = 30 years
2. Clinician diagnosed COPD with airflow obstruction, confirmed on spirometry (FEV-1/FVC ratio < 0.7)
3. Current or ex-smokers with > = 10 pack-year smoking history
4. Modified Medical Research Council Dyspnoea Scale (mMRC) breathlessness score > = 2
5. Patients receiving optimal guideline recommended inhaled treatment for COPD, including a minimum of dual-acting bronchodilator therapy (long-acting beta-agonist and long-acting muscarinic antagonist) with or without an inhaled corticosteroid.
6. Patients prescribed > = 12 SABA inhalers/canisters within the past year with self-reported SABA use most days. Only those prescribed a pressurised metered dose inhaler (pMDI) SABA are eligible for inclusion.
7. Provision of written informed consent
8. Willing and able to comply with all required study activities

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
30 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Those with significant cardiorespiratory disease, other than COPD, considered the primary cause of their breathlessness/high SABA use.
2. Those with a COPD exacerbation requiring oral corticosteroids and/or antibiotics and/or

hospitalisation within 4-weeks before recruitment (taken from last day of exacerbation treatment).
3. Those with a planned pulmonary rehabilitation attendance during the study (pulmonary rehabilitation referral will be offered one on completing trial participation if appropriate).

Date of first enrolment
17/05/2024

Date of final enrolment
31/07/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Bradford Royal Infirmary
Duckworth Lane
Bradford
England
BD9 6RJ

Study participating centre
Holderness Health
Queen Street
Withernsea
England
HU19 2PZ

Study participating centre
Hull University Teaching Hospitals NHS Trust
Castle Hill Hospital
Castle Road
Cottingham
England
HU16 5JQ

Sponsor information

Organisation
Hull University Teaching Hospitals NHS Trust

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF)

Results and Publications

Individual participant data (IPD) sharing plan
Participants of the FanFIRST study will be asked if they agree to the sharing of their anonymised data as part of the informed and written consent process. Those participants not agreeing to this will not have their data shared. Requests should be made to: The Data Manager at Hull Health Trials Unit HHTUenquiries@hull.ac.uk. All requests for anonymised data will be considered and discussed. If request is approved, a Data Sharing Agreement would need to be put in place and signed by respective parties.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1.1	29/08/2023	05/10/2023	No	No