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A feasibility, randomised controlled trial of a complex breathlessness intervention in idiopathic pulmonary fibrosis

Submission date
25/06/2018

Recruitment status
No longer recruiting

Registration date
05/07/2018

Overall study status
Completed

Last Edited
24/03/2025

Condition category
Respiratory

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Idiopathic pulmonary fibrosis (IPF) is a scarring lung disease that affects older adults. It usually progresses over time leading to disabling shortness of breath and cough. Unfortunately, although medications can slow down the rate of lung scarring, they do not improve patients' symptoms or quality of life. Shortness of breath is the most common symptom in IPF and the one which has the biggest impact on patients' lives. Treatments for breathlessness have been shown to be effective for people with other lung conditions but it is not known whether they work for people with IPF. It is important that treatments are properly tested in IPF to help patients, doctors and policy makers make correct treatment decisions. When designing a study to test a treatment's effectiveness we need to understand how many patients will be suitable and willing to take part and how many complete all study tests and measurements. We also need to identify the best measurements to use and ensure that they are meaningful to patients and their carers. The aim of this study is to answer these questions.

Who can participate?
Breathless IPF patients aged 50 and over

What does the study involve?
Participants are randomly allocated to either receive the breathlessness treatment straight away or to be placed on a waiting list to start the treatment 8 weeks later. The treatment involves training patients in techniques to help their breathing. It is delivered by a specialist therapist during 2 hour-long appointments and a telephone call over 3 weeks. Assessment of breathlessness and quality of life and measurement of daily activity are performed at the start of the study and repeated every 4 weeks for a total of 16 weeks.

What are the possible benefits and risks of participating?
This study will show whether a larger study is possible, whether it is potentially cost effective and how this study should be designed.

Where is the study run from?
1. Castle Hill Hospital (UK)
2. Scarborough General Hospital (UK)

When is the study starting and how long is it expected to run for?
June 2018 to May 2020

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

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
38299

Study information

Scientific Title

A feasibility, randomised controlled trial of a complex breathlessness intervention in idiopathic pulmonary fibrosis (BREEZE-IPF)

Acronym
BREEZE-IPF

Study objectives
Idiopathic pulmonary fibrosis (IPF) is a scarring lung disease that affects older adults. It usually progresses over time leading to disabling shortness of breath and cough. Unfortunately, although medications can slow down the rate of lung scarring, they do not improve patients' symptoms or quality of life. Shortness of breath is the most common symptom in IPF and the one which has the biggest impact on patients' lives. Treatments for breathlessness have been shown to be effective for people with other lung conditions but we do not know whether they work for people with IPF. It is important that treatments are properly tested in IPF to help patients, doctors and policy makers make correct treatment decisions.

When designing a study to test a treatment's effectiveness we need to understand how many patients will be suitable and willing to take part and how many complete all study tests and measurements. We also need to identify the best measurements to use and ensure that they are meaningful to patients and their carers. We will conduct a feasibility study to answer these questions. At the end of this study, we will know if a larger study is possible, whether it is potentially cost effective and how this study should be designed.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Yorkshire and the Humber - Bradford Leeds Research Ethics Committee, 17/04/2018, ref: 18/YH/0147

Study design
Randomised; Interventional; Design type: Treatment, Education or Self-Management, Psychological & Behavioural, Complex Intervention

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied

Idiopathic pulmonary fibrosis

Interventions
Participants will be randomised in a 1:1 ratio using random permuted blocks to receive the breathlessness treatment straight away or be placed on a waiting list to start the treatment 8 weeks later.

The complex breathlessness intervention consists of two, one hour sessions with a specialist respiratory therapist. The first session will occur within 1 week of randomisation (fast-track group) and the second session 1 week later. A final telephone consultation will be undertaken after a further week. During these sessions, participants will receive training in:
1. Breathing control techniques (e.g. pursed lip and diaphragmatic breathing)
2. Instructions on using a hand-held fan (fan will be provided)
3. Pacing and breathlessness management during everyday activities, including positions for recovery from exertional breathlessness and information on the importance of exercise
4. Techniques to promote relaxation and manage anxiety and panic

Participants will receive a standardised information leaflet detailing the breathlessness management techniques to take home. This has been adapted, with permission, from the Cambridge Breathlessness Intervention Service. Training in the intervention will be provided by AE and FS to ensure standardised delivery across study sites. As part of data collection, source data will be reviewed to ensure the intervention was delivered per protocol. Our team has experience of the scalability of this intervention in a 9 centred RCT delivered by a variety of clinicians. This experience will be valuable for the definitive trial.

Usual care will be received throughout to all participants. Details of usual care received by participants will be recorded during visits and includes any intervention that would ordinarily be offered out-with the trial setting. The sole exception is breathlessness clinic attendance. This constitutes the complex breathlessness intervention and is the trial's focus. Usual care includes, but is not limited to, any of the following if considered appropriate by the patient's clinician: outpatient clinic attendance; review and support by the specialist nursing team and/or primary care provider; antifibrotic drug treatment in accordance with NICE guidelines; and home oxygen therapy. Pharmacological or other non-pharmacological breathlessness treatments (e.g. opioids or hand held fan) will not be restricted if considered appropriate by the patient's clinician but will be documented.

Baseline measurements will be undertaken over a 7-day period following completion of consent. Consent procedures and baseline assessments will include 2 visits, 7 days apart. Physical activity monitoring during normal daily life will be undertaken between these visits. Randomisation will be undertaken following completion of baseline assessments. Following randomisation (wait-list group) and commencing the breathlessness intervention (fast-track group), assessments will be performed every 4 weeks to complete 16 weeks follow-up. The control group will undergo the intervention following their 8 week assessments and continue to complete assessments every 4 weeks for a further 8 weeks.

Intervention Type
Behavioural

Primary outcome measure
The primary aim of this trial is to establish the feasibility of a definitive trial. Specific study objectives will address uncertainties in the following 5 areas:

1. Recruitment: the eligibility:consent ratio, recruitment rate and participant retention rate to inform the number of sites needed to enrol sufficient participants within an acceptable timeline, and the acceptability of recruitment and randomisation processes from the patients' perspective
2. Intervention: the acceptability and fidelity of the intervention is assessed by measuring adherence in delivery and uptake, and via patient and carer interviews. This will include documenting aspects of breathlessness interventions used in the control arm provided ad hoc e. g. breathing techniques, use of the hand-held fan etc
3. Data quality: the amount and pattern of missing data for study measures. Data variability across the range of outcome measures will also be assessed. These findings will inform the choice of primary and secondary outcomes for a definitive trial
4. Outcome: assess the best primary outcome and agree other study measures for the definitive trial by identifying i) patient views about relevance, importance and acceptability of questionnaires or other measures (qualitative interview data), ii) data completion (objective 3), iii) data variability for potential primary outcome measures to inform sample size calculation for the definitive trial
5. Health economic assessment: the feasibility of undertaking a cost-effectiveness analysis in the definitive trial assessed by collecting data on health service utilisation (e.g. out-patient clinic attendance, emergency department attendance, hospital or hospice admission, appointment in primary care etc), health-related quality of life (EQ-5D-5L) and well-being (ICECAP-SCM)

Secondary outcome measures

The following study measures will be undertaken to assess acceptability and identify the most appropriate primary outcome measure for the substantive trial:

Clinical outcomes:
1. Breathlessness, assessed at baseline, 4, 8, 12 and 16 weeks using:
1.1. Breathlessness mastery assessed by the breathlessness mastery domain of the Chronic Respiratory Disease Questionnaire (CRQ)
1.2. Numerical rating scales (NRS, scored 0-10 where lower scores represent a lower symptom burden) to assess the following aspects of breathlessness over the past 24 hours: average breathlessness, worst breathlessness, distress caused by breathlessness, coping with breathlessness

2. Quality of life, assessed at baseline, 4, 8, 12 and 16 weeks using:
2.1. Disease specific: St George's Respiratory Questionnaire for patients with IPF (SGRQ-I)
2.2. Generic: EQ-5D-5L
2.3. Well-being: ICECAP-SCM

3. Mood, assessed at baseline, 4, 8, 12 and 16 weeks using:
3.1. The hospital anxiety and depression scale (HADS)

4. Physical activity, functional status and exercise capacity, assessed at at baseline, 4, 8, 12 and 16 weeks:
4.1. Functional status, assessed using the Australian-modified Karnofsky Performance Status
4.2. Exercise capacity, assessed using incremental shuttle walk tests (ISWT) performed in accordance with European Respiratory Society/American Thoracic Society technical standards. Two incremental shuttle walking tests will be undertaken at baseline (one when the activity monitor is fitted, and the second on its removal) with the second taken as the baseline value to eliminate the known learning effect
4.3. Physical activity, measured objectively during normal daily life by asking participants to wear an accelerometer for a period of 7 days. Data on step counts, physical activity duration and physical activity levels will be evaluated. The outcome measure will be average daily steps

Overall study start date
01/06/2018

Completion date
31/05/2020

Eligibility

Key inclusion criteria
1. Males and females aged ≥50 years. This age cut-off is chosen because IPF is very rare under 50 years of age making an alternative diagnosis likely
2. IPF diagnosed by multidisciplinary team (MDT) consensus in accordance with international guidelines
3. mMRC dyspnoea grades 3 or 4 despite optimal management
4. Oxygen saturation ≥90% on air/using usual oxygen prescription
5. Able to give informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 50; UK Sample Size: 50

Key exclusion criteria
1. Significant comorbid cardiorespiratory disease other than IPF considered by the principal investigator to be the primary cause of breathlessness
2. Pulmonary rehabilitation: completed < = 3 months previously
3. Breathlessness clinic attendance: completed < = 3 months previously
4. Unwilling or unable to consent or complete study measures

Date of first enrolment
16/07/2018

Date of final enrolment
16/01/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Castle Hill Hospital
Castle Road
Cottingham
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HU16 5JQ

Study participating centre
Scarborough General Hospital
Woodlands Drive
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Sponsor information

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01b11x021

Funder(s)

Funder type
Government

Funder Name

NIHR Central Commissioning Facility (CCF); Grant Codes: PB-PG-1216-20020

Results and Publications

Publication and dissemination plan

A manuscript will be prepared and submitted for publication in an appropriate peer-reviewed journal. The journal will be selected by the trial management group with input from patient and public representatives. Publication will be open access. If a substantive trial is found to be feasible, the design of this trial will be prepared for publication.

Intention to publish date

31/10/2021

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		21/10/2019	01/06/2021	Yes	No
HRA research summary			28/06/2023	No	No
Results article		22/03/2025	24/03/2025	Yes	No