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What is the best treatment and the most cost effective treatment for patients with idiopathic pulmonary fibrosis (IPF): advice on breathlessness, or advice on breathlessness and oxygen to use whilst walking and doing other daily activities at home?

Submission date 19/02/2022	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 27/05/2022	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 16/01/2025	**Condition category** Respiratory	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
The OXYPuF trial is trying to find out what is the best treatment and the most cost-effective treatment for patients with idiopathic pulmonary fibrosis (IPF) by comparing the results from two groups of participants with IPF; one group will be given advice on breathlessness and the other group will be given advice on breathlessness AND oxygen to use whilst walking and doing other daily activities at home.
There is not currently an agreed best way to treat IPF patients with this condition who become breathless and whose blood oxygen levels fall when they exercise - exercise in this context means simple walking. Some hospitals provide advice on how to manage this breathlessness, whilst others arrange for portable oxygen cylinders to be delivered to the patient's home, which the patients can use if they feel breathless.

Who can participate?
This trial will recruit 260 patients with IPF

What does the study involve?
Participants will be randomly allocated to receive printed advice on breathlessness, or the same advice AND oxygen to use when they become breathless.
Factors such as the patient's physical activity, cough and severity of symptoms will be measured over 6 months to find which of these approaches is the best for the patient and the relative cost of providing it.

What are the possible benefits and risks of participating?
Benefits:

No identifiable benefits except contributing to a better understanding of the best treatment for future patients with this condition.
Risks:
There are no clinically identified risks of using oxygen cylinders at home with patients in this cohort. It is stated as part of the inclusion/exclusion criteria that a patient should only be approached to take part in this trial if the responsible clinician believes there are no known risks specific to that patient using oxygen. As the other arm in the trial does not provide oxygen and simply provides printed advice on breathlessness there are no associated risks with this intervention. To minimise any confounding variables, the breathlessness advice sheet will be standardised and the same for both groups. In the arm who receive home oxygen cylinders, a phone call will be made 1 week after randomisation to ensure they are able to use the cylinders and to escalate any issues the participants have with the clinical team. Participants will be given contact numbers of the clinical team looking after them as well as the trials office should they need to ask any questions or raise any concerns. Participants will be asked to attend three appointments in total to take part in the study: baseline; 3-month follow; and 6-month follow-up. Baseline and 6-month follow-up appointments will be conducted in the hospital setting as well as completion of the participant completed booklet. These booklets may be completed by the participant within the clinic setting and handed to the research nurse who will then return them to the trial office, however, participants will be provided with pre-paid envelopes to return the patient-completed booklets directly to the trial office should they complete them at home. If participants who are approached to take part in the qualitative study agree to take part will be asked to spend approximately 60 minutes with a qualitative researcher who will conduct an interview regarding their experience with their condition and using home oxygen.

Where is the study run from?
University of Birmingham (UK)

When is the study starting and how long is it expected to run for?
February 2022 to December 2024

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

Who is the main contact?
Dr Matthew Soden, oxypuf@trials.bham.ac.uk

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
2021-003535-29

Integrated Research Application System (IRAS)
1004392

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
RG_20-147, IRAS 1004392

Study information

Scientific Title
Ambulatory oxygen for idiopathic pulmonary fibrosis

Acronym
OXYPuF

Study objectives
The OXYPuF trial is trying to find out what is the best treatment and most cost-effective treatment for patients with idiopathic pulmonary fibrosis (IPF) by comparing two arms; arm one receives advice on breathlessness; arm two receives advice on breathlessness AND the use of oxygen

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 25/05/2022, Health and Social Care Research Ethics Committee B (HSC REC B) (-, Belfast, -, United Kingdom; +44 (0)28 9536 1400; RECB@hscni.net), ref: 2/NI/0053

Study design
Interventional randomized parallel group controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Idiopathic pulmonary fibrosis (IPF)

Interventions
2-armed unblinded RCT
Arm 1: Supply of ambulatory oxygen (home oxygen cylinders) and breathlessness advice
Arm 2: Breathlessness advice only. Follow up is 6 months (randomised intervention remains in place during this follow up period unless clinically indicated otherwise/withdrawal).
Randomisation is done via an online tool.

Intervention Type
Mixed

Primary outcome(s)
The King's Brief Interstitial Lung Disease (K-BILD) score at baseline and 6 months

Key secondary outcome(s))
Subscales within K-BILD (breathlessness, activity, chest symptoms) at baseline, 3 months and 6 months post randomisation:
1. Exercise capacity using the 6MWT or 1 minute sit to stand
2. MRC dyspnoea score
3. Physical activity using the IPAQ
4. Sleepiness using the Epworth Sleepiness Scale
5. Hospitalisations (all cause and IPF specific)
6. Cough using a 6 point Visual Analogue Scale (VAS)
7. Targeted adverse events
8. Mortality (6 months, and from medical record only at 12 months)
9. Medication use: benzodiazepines, antifibrotics; ACEis and opiates for breathlessness
10. Completion of pulmonary rehabilitation
11. Acceptability of AOT
12. Cost-effectiveness (using EQ-5D-5L, and scheduled and unscheduled health service use relating to IPF).

Completion date
29/12/2024

Eligibility

Key inclusion criteria
1. Aged 18 years or over
2. Clinically diagnosed IPF, confirmed by an ILD MDT linked to an NHS specialist commissioned IPF service
3. Breathlessness with MRC dyspnoea score ≥2
4. Willing and able to comply with completion of questionnaires out to 6 months post-randomisation
5. Able to complete a 6MWT or 1 minute sit to stand test
6. Able to use oxygen safely in the opinion of the local investigator

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
7

Key exclusion criteria
1. Unable to provide informed consent
2. Requires LTOT, defined by need for resting oxygen in the opinion of the local investigator
3. Life expectancy <6 months
4. On the active transplant list
5. Previous acidotic hypercapnic respiratory failure (AHRF) requiring non-invasive ventilation (NIV)

Date of first enrolment
01/10/2022

Date of final enrolment
30/03/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Queen Elizabeth Hospital
University Hospitals Birmingham NHS Foundation Trust
Mindelsohn Way
Edgbaston
Birmingham
United Kingdom
B15 2GW

Sponsor information

Organisation

University of Birmingham

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Via full execution of a data sharing agreement between the University of Birmingham and the organisation that requests the specific data to be shared.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Plain English results		18/12/2024	16/01/2025	No	Yes