NIHR EXETER BIOMEDICAL RESEARCH CENTRE
UNIVERSITY OF EXETER

Bb544@exeter.ac.uk

Research Study Title:
Cardiopulmonary exercise testing for Pulmonary rehabilitation and Exercise Tailoring in Pulmonary Fibrosis (CPET-PF)

PARTICIPANT INFORMATION SHEET
Version number: 3.0 (15/04/2026)

You are being invited to take part in a research trial, which is part of a PhD study. Before you decide whether or not to be involved, it is important for you to understand why the research is being done and what it will involve. Please read the following information carefully and discuss it with friends, relatives and your clinician/GP if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

1. What is the purpose of the trial?

Pulmonary rehabilitation is a mix of exercise, advice and education that is used to support people with Pulmonary Fibrosis (PF) to help maintain their lung function, general function, and quality of life.

The James Lind Alliance – a group of researchers who directly ask patients what they want to have researched in their condition - stated that finding the 'best exercise program for people with Pulmonary Fibrosis' was a key research priority. This may be because a 'one size fits all' approach to exercise is not the best approach, due to the many challenges found for interstitial lung diseases as a condition.

To address these challenges, it is important to use a tool like Cardiopulmonary Exercise Testing (CPET) to help us understand how the heart, lungs and muscles work during exercise, for each person, so that we can tailor exercise better. This type of exercise is done on a stationary bike in a laboratory in the hospital.

The main aim of our research project is to explore the responses of people with PF to tailored exercise. Firstly, a CPET will be performed to see if our tailored methods are suitable. If appropriate, you will perform moderate intensity and heavy intensity exercise, which look to find out if tailored exercise is acceptable for people with PF.

2. Why have I been chosen?

We are recruiting people with PF, aged between 35-85 years old. We are hoping to recruit 15 people with PF to take part in this study. Your ILD clinical team will confirm that your lung function and overall health meet the study's inclusion criteria, before you are invited to participate.

3. Do I have to take part?

Taking part is entirely voluntary. It is up to you to decide whether or not you want to take part. If you do want to be involved, you will keep this information sheet, and be asked to sign a consent form giving your permission. Even if you say yes, you are free to withdraw from the trial at any time and there is no need to give a reason. Any decision to withdraw, or a decision not to take part in the first place will not affect the clinical care you receive in any way. If you would like to take part, please notify either someone in your care team (e.g. doctor, nurse, physiotherapist), or the researchers using the email address at the end. They will give you a consent form to complete.

4. What will happen to me if I decide to take part?

Participation in this research involves a number of steps, each with different measurements and requirements. The total time commitment is expected to be several weeks, depending on scheduling availability. Participation is expected to last approximately 3 months. If you take part in the trial, we will ask you to attend **three additional visits to the Royal Devon and Exeter hospital.**

During the CPET and exercise sessions, your heart rhythm, oxygen levels, and symptoms will be continuously monitored by trained clinicians. Exercise will be stopped if your oxygen levels fall below safe limits or if any concerning symptoms occur. If any abnormalities are detected (for example, changes in heart rhythm), the test will be stopped and your clinical team will be informed so they can arrange follow-up if needed.

Visit 1: Baseline assessments and CPET to determine exercise responses for tailored prescription methods in **Visit 2 and Visit 3.**

The order of Visits 2 and 3 will be randomised for each participant.
Visit 2 or 3: 10-minute moderate intensity exercise session.
Visit 2 or 3: 10-minute heavy intensity exercise session.

Each visit also includes: a 5-minute warm-up, 5-minute cool-down, patient-reported experience measures and health-related quality of life questionnaires to assess acceptability and perceived benefit. The questionnaires will take approximately 10 minutes to complete. All visits will be separated by a minimum of 72 hours to allow sufficient recovery between exercise bouts. Visits 2 and 3 will happen in a random order – you may do heavy exercise first, or you may do moderate exercise first.

You will also continue all your treatments as usual (such a therapies and medications), as directed by your care team. We may also ask you if we can take photographs during the project, for use in publicity materials or presentations. Permission for photographs will be obtained in writing prior to involvement in the trial.

5. What are the possible risks of taking part?

In this trial, there are some minor risks associated with exercise and activity. These are:

a) Increasing physical activity and exercise participation can lead to some breathlessness, and there is the risk of muscle or joint injury (e.g. sprains or strains). If you experience any muscular or joint injury, you should follow your usual routine, which may include application of ice and rest, seeking medical assistance as necessary, and advising the research team.
b) There is a risk of oxygen desaturation and/or cardiac rhythm changes; therefore, clinical supervision, monitoring procedures and stopping criteria will be performed.

6. What are the potential benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research, although possible benefits may include:
a) Improvement in your exercise capacity which may mean you find participation in exercise easier over the course of the trial.
b) Regular interaction with health professionals who can provide information about exercise and physical activity for people with PF.

7. Will I get reimbursement by taking part?

Participation in this study is entirely voluntary, and you will not be paid to take part. Reasonable travel costs will be met by the University of Exeter research team for this study. These can be claimed when you visit your hospital for your extra tests, and can take up to 28 days to be paid. Any expenses will be transferred electronically into a bank account of your choosing.

8. How will we use information about you?
We will need to use information from you for this research project.
This information will include your:

- Initials
- NHS number
- Name
- Contact details

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details; your data will have a code number instead.

The University of Exeter is the sponsor of this research.

The University of Exeter is responsible for looking after your information. We will share your information related to this research project with the following types of organisations:

- University researchers or research labs
- Hospital researchers or clinicians

We will keep all information about you safe and secure by:

- All data files will be under the control of the University of Exeter and your data will be stored on secure systems.
- Online databases will be created for research data collected by the research team.
- Password protection will be used to keep online data secure by controlling who does/does not have access.
- Direct access to patient identifiable information will only be available to members of the clinical care team and a member of the research team who will create a study code.
- After recruitment, your personal details are removed and a study code is used by the research team instead.
- Statistical analysis of reporting will be performed the research team.
- Archiving will be authorised by the Sponsor, University of Exeter, following submission of the end of study report.
- The database and study protocols will be archived by the University of Exeter; this will be archived for 10 years before being destroyed.
- At the conclusion of the study, some data may be retained for verification or future research purposes. Personal details will be removed in all published reports, so that no one can identify individual participants.

9. International Transfer of Data

We may share or provide access to data about you outside the UK for research related purposes to:

- Additional analysis of exercise or clinical data by scientific or clinical experts,
- Combining of data with other PF populations to create larger datasets

If this happens, we will only share the data that is needed. We will also make sure you can't be identified from the data that is shared where possible. This may not be possible under certain circumstances – for instance, if you have a rare illness, it may still be possible to identify you. If your data is shared outside the UK, it will be with the following sorts of organisations:

- University researchers or research labs
- Hospital researchers or clinicians

We will make sure your data is protected. Anyone who accesses your data outside the UK must do what we tell them so that your data has a similar level of protection as it does under UK law. We will make sure your data is safe outside the UK by doing the following:

- We use specific contracts approved for use in the UK which give personal data the same level of protection it has in the UK. For further details visit the Information Commissioner's Office (ICO) website: https://ico.org.uk/for-organisations/uk-gdpr-guidance-and-resources/international-transfers/,
- We do not allow those who access your data outside the UK to use it for anything other than what our written contract with them says

10. How will we use information about you after the study ends?

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

We will keep your study data for a maximum of 10 years. The study data will then be fully anonymised and securely archived.

11. What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. You have the right to ask us to access, remove, change or delete data we hold about you for the purposes of the study. You can also object to our processing of your data. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this

12. Where can you find out more about how your information is used?

You can find out more about how we use your information, including the specific mechanism used by us when transferring your personal data out of the UK:

- by asking one of the research team
- by sending an email to bb544@exeter.ac.uk or
- by ringing us on 01392 726842

ADDITIONAL LEGAL, CONFIDENTIAL, ETHICAL AND FINANCIAL INFORMATION

1. What if something goes wrong?

If taking part in this trial harms you, compensation arrangements are under the directive of the University of Exeter. Your rights are the same as any person undergoing research (i.e. if you are harmed due to someone's negligence, then you may have grounds for legal action, but you may have to pay for it). If you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this trial, the normal University complaints procedures will be available to you. If you have a complaint, you can contact RDUH PALS team by telephone on: 01392 402093 or 01271 314090 or via email: **rduh.pals@nhs.net**.

2. What will happen to the results of the trial?

Once the trial is completed, the results will be analysed and interpreted, and you will subsequently be sent a summary of our findings. It is the intention to submit the results of the research to relevant journals for publication, and to inform our colleagues of the findings at scientific meetings. In publishing and talking about the trial, you will not be identifiable.

3. Who is organising and funding the research?

The trial is being organised by the University of Exeter. The trial has been supported financially by Exeter NIHR Biomedical Research Centre. The research team includes people at the University of Exeter and at RDUH.