USING CARDIOPULMONARY EXERCISE TESTING (CPET) TO TAILOR EXERCISE FOR PATIENTS WITH PULMONARY FIBROSIS

CPET-PF

- **This protocol has regard for the HRA guidance and order of content**

USING CARDIOPULMONARY EXERCISE TESTING (CPET) TO TAILOR EXERCISE FOR PATIENTS WITH PULMONARY FIBROSIS (PF)

The aim of the study is to identify the responses to exercise at above- and below-ventilatory thresholds in patients with PF. The impact on engagement and the acceptability for this tailored method of exercise will also be tested. It is hoped that, if patients with PF find this acceptable, it would lay ground for a training study that uses exercise intensities derived from CPET. This study could expand into a post-doctoral series of research and ultimately a full trial, which could help inform development of PF exercise guidelines.

CPET-PF

The aim is to use CPET so that we can explore the responses that patients with PF have to aerobic exercise at above, or below ventilatory thresholds. We will also determine if these methods are acceptable by using questionnaires and patient reported experience measures.

PROTOCOL VERSION NUMBER AND DATE
Version 2.0: 20/02/2026

SPONSOR:
University of Exeter

RESEARCH REFERENCE NUMBERS
IRAS Number: 354740
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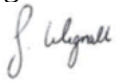
SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the trial in compliance with the approved protocol and will adhere to the principles outlined in the Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031), amended regulations (SI 2006/1928) and any subsequent amendments of the clinical trial regulations, GCP guidelines, the Sponsor's (and any other relevant) SOPs, and other regulatory requirements as amended.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the clinical investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the trial publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the trial will be given; and that any discrepancies and serious breaches of GCP from the trial as planned in this protocol will be explained.

For and on behalf of the Trial Sponsor:

Signature: 

Date: 30/06/2025

Name (please print):
Suzy Wignall
Position: Senior Clinical Research Governance Manager

Chief Investigator:

Signature: ..... Date: ...../...../.....

Name: (please print):
.....

KEY TRIAL CONTACTS

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Joint sponsor(s)/co-sponsor(s)	N/A
Funder(s)	NIHR Exeter Biomedical Research Centre
Clinical Trials Unit	N/A
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ii. LIST OF ABBREVIATIONS

ANOVA Analysis of variance
ARTP Association for Respiratory Technology & Physiology
ATS American Thoracic Society
BMI Body mass index
BRC Biomedical Research Centre
BTS British Thoracic Society
CI Chief Investigator
CO-I Co-Investigator
CPET Cardiopulmonary Exercise Test
DL_{CO} Diffusing capacity of the lungs for carbon monoxide
ECG Electrocardiogram
EPIC-PF Exeter Patients in Collaboration for Pulmonary Fibrosis Research
ERS European Respiratory Society
FEV_1 Forced expiratory volume in 1 second
FVC Forced Vital Capacity
GCP Good clinical practice
GDPR General Data Protection Regulation
GET Gaseous Exchange Threshold
GP General practitioner (GP)
HR Heart Rate
HR_{max} Maximum heart rate
HRQoL Health related quality of life
Hz Hertz
ILD Interstitial Lung Disease
K-BILD Kings Brief Interstitial Lung Disease health status questionnaire
mMRC Modified Medical Research Council
NHS National Health Service
NIHR National Institute for Healthcare Research
PAG Patient Advisory Group
PET-O_2 End-tidal oxygen tension
PF Pulmonary Fibrosis
PF-ILD Progressive Fibrosing Interstitial Lung Disease
PFT Pulmonary function testing
PPI Patient and Public Involvement
PR Pulmonary rehabilitation
PREM Patient-reported experience measures
pwPF patients with Pulmonary Fibrosis
pwILD patients with Interstitial Lung Disease
QoL Quality of life
R&D Research and development
RDUH Royal Devon University Healthcare
REC Research Ethics Committee
RER Respiratory exchange ratio
RPB Rate of perceived breathlessness
RPE Rate of perceived exertion
R5 Resistance at 5 Hz
R20 Resistance at 20 Hz
R5-R20 Difference between R5 and R20
SOC Standard of care

SOP(s) Standard Operating Procedure(s)
SpO_2 peripheral oxygen saturation
TFA Theoretical Framework of Acceptability
VE_{peak} Peak minute ventilation
VO_2 Volume of oxygen
VO_{2peak} Peak volume of oxygen
W Watts
WR_{peak} Peak work rate (expressed in watts, W)
X5 Reactance at 5 Hz
%Δ % difference between GET and VO_{2peak}

iii. TRIAL SUMMARY

Trial Title	**USING CARDIOPULMONARY EXERCISE TESTING (CPET) TO TAILOR EXERCISE FOR PATIENTS WITH PULMONARY FIBROSIS (CPET-PF)**	
Internal ref. no. (or short title)	CPET-PF	
Clinical Phase	Observational	
Trial Design	Prospective observational laboratory-based study of patients with pulmonary fibrosis	
Trial Participants	Adult patients with pulmonary fibrosis under the care of Royal Devon University Healthcare NHS Foundation Trust	
Planned Sample Size	15 participants with PF	
Treatment duration	N/A	
Follow up duration	N/A	
Planned Trial Period	3 years	
	Objectives	Outcome Measures
Primary	To evaluate physiological responses to exercise at 'moderate' and 'heavy' intensities in patients with PF.	CPET variables - this will include, but will not be limited to: • Peak volume of oxygen consumption (VO_{2peak}), the gold-standard measure of cardiorespiratory fitness, expressed as $mL \cdot kg^{-1} \cdot min^{-1}$ and $L \cdot min^{-1}$; • Peak work rate (WR_{peak}), expressed in watts (W), the maximum achieved work rate during an incremental CPET; • Volume of oxygen consumption at the gas exchange threshold (GET), expressed as $\%VO_{2peak}$; • Peak minute ventilation (VEpeak •), expressed as $L \cdot min^{-1}$;

		• Electrocardiogram (ECG) recordings: Heart Rate, expressed as the number of times the heart beats per minute (beats·min^{-1}); • Rate of perceived breathlessness (RPB); • Rate of perceived exertion (RPE); • Feeling of effectiveness scale; • Oxygen saturations; • Blood pressure; • Lung function: Diffusing capacity of the lungs for carbon monoxide (DL_{CO}), Forced expiratory volume in 1 second (FEV_1), Forced Vital Capacity (FVC); • Grip strength
Secondary	Assess the acceptability and feasibility of a CPET-guided, tailored exercise approach.	• Anthropometric measures; • Patient acceptability/feasibility questionnaire (via customised form), • Health status measure (K-BILD) • Health-related quality of life measure (Living with PF)
Investigational Medicinal Product(s)	N/A	
Formulation, Dose, Route of Administration	N/A	

iv. FUNDING AND SUPPORT IN KIND

FUNDER(S)	**FINANCIAL AND NON FINANCIALSUPPORT GIVEN**
NIHR Exeter Biomedical Research Centre PhD Studentship	£15,000 research/equipment fund

v. ROLE OF TRIAL SPONSOR AND FUNDER

The University of Exeter will have overall responsibility for the initiation and management of the study. Trial design, conduct, data analysis, interpretation, manuscript writing and results dissemination will be completed by Mr Ben Bowhay as part of a PhD studentship with the support of the University of Exeter and the supervisory team outlined in “Key Protocol Contributors.”

Funder: NIHR Exeter Biometrical Research Centre (BRC)

vi. ROLES AND RESPONSIBILITIES OF TRIAL MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

Study Management Group

The study management will include:

- Mr Ben Bowhay –Trial Co-ordinator and PhD student
- Dr Owen Tomlinson – Chief investigator
- Professor Chris Scotton – Supervisor
- Professor Craig Williams - Supervisor
- Professor Michael Gibbons – Supervisor and Clinical Lead (RDUH)
- Dr Pilar Rivera Ortega – Clinician (RDUH)
- Dr Stefan Stanel – Clinician (RDUH)
- Dr Sophie Goodrum – Clinician (RDUH)
- Ian Martin – Head of Clinical Physiology (RDUH)

Members of the Study Management Group will ensure all practical aspects of the study are functioning and be available to address key issues arising over the duration of the study.

Sponsor Representative

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vii. Protocol contributors

Person	Role	Protocol input/expertise
Mr Ben Bowhay	Trial Co-ordinator and PhD student	Conceptualisation and development
Dr Owen Tomlinson	Chief investigator	Conceptualization, development and overall oversight
Professor Chris Scotton	Supervisor	Scientific
Professor Craig Williams	Supervisor	Scientific
Professor Michael Gibbons	Supervisor and Clinical Lead (RDUH)	Clinical and scientific
Dr Pilar Rivera Ortega	Clinician (RDUH)	Clinical and scientific
Dr Stefan Stanel	Clinician (RDUH)	Clinical and scientific
Dr Sophie Goodrum	Clinician (RDUH)	Patient reported outcomes
Mr Ian Martin	Head of Clinical Physiology (RDUH)	Clinical and scientific

viii. KEY WORDS: Pulmonary Fibrosis; Interstitial Lung Disease; Cardiopulmonary Exercise Testing; Exercise Pulmonary Rehabilitation; Prescription

ix. TRIAL FLOW CHART

Please see **Section 16. Appendix A titled CPET-PF Participant Pathway.**

1 BACKGROUND

Interstitial lung diseases (ILD) are a heterogeneous group of approximately 200 chronic lung conditions which are associated with lung parenchymal fibrosis and/or interstitial inflammation (Saketkoo et al., 2022). Of which, Pulmonary Fibrosis (PF) is one of the most common ILDs, which result in rapidly progressive lung function decline that cannot be cured (Gupta et al., 2024) and is therefore a condition that is managed. The exact aetiology of PF development is unclear; at present, patients with fibrosing ILD phenotypes such as PF have a median survival rate of between 2-3 years from diagnosis (Ley, Collard and King, 2011).

As part of ILD management, pulmonary rehabilitation (PR) regimens are recommended; these incorporate exercise, advice and education into a structured programmes that help patients manage their lung conditions (Mendes et al., 2021). A joint statement produced by the American Thoracic Society (ATS) and European Respiratory Society (ERS) recommends regular exercise training and PR to maintain cardiorespiratory health (Spruit et al., 2013). The recent 2023 British Thoracic Society (BTS) 'Clinical Statement on Pulmonary Rehabilitation' states that validated exercise tests should be conducted, as a core component for pulmonary rehabilitation (PR), to inform individualised exercise prescription (Man et al., 2023).

Cardiopulmonary exercise testing (CPET) offers a robust, valid method for assessing disease severity and exercise capacity in individuals with ILD, providing detailed physiological data that can inform tailored exercise prescription (Tomlinson et al., 2022). By using CPET it is possible to use submaximal markers such as the Gaseous Exchange Threshold (GET), anecdotally called the 'anaerobic threshold' for lay audiences (Visschers et al., 2015), to prescribe tailored exercise into either 'easy' or 'heavy' physiological domains. This method has demonstrated utility in cardiology (Fabre et al., 1997; Mezzani et al., 2012; Milani et al., 2023), however, this approach remains insufficiently investigated within ILD and PF research.

1.1 Aims

- To evaluate physiological responses to exercise at intensities above and below the GET in patients with PF(pwPF).
- To assess the patient acceptability and feasibility of a CPET-guided, tailored exercise approach.

1.2 Methods

This is a prospective, observational study involving 15 adults (aged 35–85 years) with PF, recruited from the Royal Devon University Healthcare (RDUH) National Health Service (NHS) Foundation Trust and the Exeter Patients in Collaboration for Pulmonary Fibrosis (EPIC-PF) research group.

All participants will undergo three study visits (detailed below), all performed on an exercise bike to collate physiological data in response to differing intensities.

- Visit 1: Baseline assessments and CPET to determine GET and $VO_{2peak.}$
- Visit 2 or 3: 10-minute exercise session below GET ('moderate' exercise).
- Visit 2 or 3: 10-minute exercise session above GET ('heavy' exercise).

Each session includes a 5-minute warm-up and 5-minute cool-down. Patient-reported experience measures (PREMs) and health-related quality of life (HRQoL) questionnaires will assess acceptability and perceived benefit. Visits 2 and 3 will be

randomised in order, and separated by a minimum of 72 hours to allow sufficient recovery between exercise bouts.

1.3 Study Design
This is a prospective, observational only study, consisting of the aforementioned three study visits.

1.4 Research Questions
1. What are the physiological responses of pwPF to exercise at intensities above, and below, the gas exchange threshold
2. Are these tailored exercise methods acceptable and feasible for pwPF?

1.5 Ethical Considerations
Regarding the purpose and design of this study, predominant risks are those relating to a) patient safety during exercise, and b) time commitment. The exercise is deliberately tailored to each individual and all tests will be undertaken in the presence of supervising clinicians to monitor patient safety during exercise. All tests will be coordinated with patients to find mutually convenient times for them, and travel costs will be reimbursed to minimise participant burden.

2 RATIONALE
Pulmonary fibrosis (PF) is one of the most common ILDs, typically occurring in middle aged to elderly males (70-80% male predominance) (Neely et al., 2023; Wallis et al., 2023) and results in lung function decline that cannot be cured (Neely et al., 2023). In addition, patients often report progressive breathlessness and exercise limitation, which also detrimentally impacts quality of life (QoL) (Agrawal et al., 2016). Therefore, it is of paramount importance to slow disease progression, maintain lung function and improve QoL for pwPF (Nakazawa, Cox and Holland, 2017).

Exercise has been highlighted as key component of PR programmes for patients with ILD (pwILD) (Dowman et al., 2021a; Dowman and Holland, 2024). A joint statement produced by the ATS and ERS recommends regular exercise training to improve and/or maintain cardiorespiratory health and exercise capacity (Spruit et al., 2013). The BTS recommends that exercise should be offered to symptomatic individuals with chronic respiratory disease, including pwPF, to reduce the severity of symptoms and benefit their QoL (Man et al., 2023).

A recent systematic review by Bondarenko et al., (2024) found that performing PR resulted in 34% of pwILD achieving clinically important differences in exercise capacity; however, only 15% of control participants, who received standard care without PR, had clinically important differences in exercise capacity. This evidence highlights the current clinical utility of PR (Bondarenko et al., 2024), however, as only two studies were included and approximately two-thirds of pwILD did not achieve clinically important differences, more work is needed to refine PR regimens in ILD.

There is a lack of UK dedicated PR services for pwPF (ILD-IN, 2023), whilst PR is often low quality and infrequently meets the core exercise prescription components of the BTS Clinical Statement (Man et al., 2023). Furthermore, the widespread use of COPD (Holland et al., 2008; Dale et al., 2014; Essam et al., 2022), respiratory disease (Vainshelboim et al., 2014) and cancer (Wallis et al., 2023) exercise prescription

guidelines may not be beneficial for the PF population, given differing disease mechanisms. Therefore, the specificity of exercise prescription for pwPF is lacking and needs to be addressed.

To aid exercise prescription, CPET may be of help. The CPET has been shown to be a safe, valid and reliable method for evaluating disease severity (Barratt et al., 2020; Gille and Laveneziana, 2021; Tomlinson et al., 2021; Stubbe et al., 2022; Tomlinson et al., 2022) and exercise capacity (Tran, 2018; Barratt et al., 2020; Tomlinson et al., 2021; Tomlinson et al., 2022), and importantly, for the purposes of the proposed study, inform precise exercise prescription in pwPF (Vonbank et al., 2022). A recent systematic review showed that objective CPET measures utilised for pwPF detected physiological changes, but also determined prognosis and mortality (Barratt et al., 2020).

A concern is the lack of PF-specific exercise guidelines. This has led to variation in application, design and success of exercise and clinical practice (Dale et al., 2014; Vainshelboim et al., 2014; Herrera-Olivares et al., 2020; Essam et al., 2022; Wallis et al., 2023). Currently, CPET-based exercise prescription for pwPF is heterogenous (Bowhay et al., 2025) and often based on 'anchor' cardiopulmonary outcome measures achieved at maximal exercise i.e., maximum HR (HR_{max}) (Essam et al., 2022; Nikoletou et al., 2023), peak volume of oxygen (VO_{2peak}) (Wallis et al., 2023) or peak work rate (WR_{peak}) (Dale et al., 2014; Dowman et al., 2021b).

Evidence shows that using fixed percentages does not appropriately normalise exercise intensity between individuals (Milani et al., 2023); resulting in under- or over-training (Guida et al., 2024), particularly if they have impaired cardiac function and chronotropic incompetence (Vonbank et al., 2022; Vaddoriya et al., 2024). This could result in inappropriate tailoring of exercise in pwPF; therefore, to improve current exercise prescription, this study examines principles of exercise prescription based upon the GET – a metabolically consistent, submaximal threshold - which are not yet fully established in pwPF.

Despite promising results in cardiology (Pymer et al.,2020; Anselmi et al., 2021; Milani et al., 2023), using submaximal prescription outcomes to determine the GET; it is yet to be fully investigated within literature for pwPF. However, we have limited evidence for using above GET (McNarry et al., 2017) and below GET (Baidats et al., 2024) to prescribe exercise. Previously, McNarry et al., (2017) used 40% of the difference between the GET and VO_{2peak} to 'standardise' exercise at a 'heavy' intensity, and Baidats et al., (2024) used 80%GET to 'standardise' exercise at a 'moderate' intensity, yet no studies have compared the two. Utilising CPET and subsequent threshold-based prescription methods, it is possible to identify physiological domains which someone can exercise in, and thus possible to investigate exercise prescription above and below the GET. This would normalise exercise prescription relative to individual metabolic thresholds and potentially be an acceptable process of varying PR sessions for the benefit of pwPF – one this study aims to determine.

2.1 Public and patient consultation

The study has been directly aligned to the James Lind Alliance Top Ten priorities for progressive PF research (Tikellis et al., 2021; Fabbri et al., 2022); this was based on

a research prioritisation questionnaire completed by 261 respondents who indicated that finding the best exercise programme was a ‘top ten’ priority.

The premise of the clinical study was further discussed with the Exeter Patients in Collaboration for Pulmonary Fibrosis (EPIC-PF) (https://blogs.exeter.ac.uk/eri/research-opportunities/epic/) and patient representatives from RDUH. Patients unanimously supported this as area key area for research. In a recent meeting with the EPIC-PF group, members indicated that it would have been beneficial to have tailored exercise prescription based on these individualised values and were very enthusiastic about the prospect of such a study being designed and delivered.

2.2 Assessment and management of risk

Risk	**Compared to standard practice**	**Frequency**	**Mitigating factors**
Patient safety during exercise	All exercise caries a risk whether this is serious adverse events during exercise and/or minor injuries. This can include desaturation during exercise, musculoskeletal discomfort, and cardiac changes.	3 study days (1.5 hours duration per study visit)	All participants will have clearance from their consultant to participate in the study, in line with inclusion/exclusion criteria, and all exercise will be supervised by a medical practitioner with experience working with this patient population. A previous study by Tomlinson et al. (2022) showed safety in using CPET with ILD participants across the disease severity spectrum. All CPETs were conducted under the supervision of an exercise physiologist and a medical doctor to ensure clinical oversight. Each test was terminated if safety concerns arose based on either electrocardiographic (e.g., arrhythmia) or peripheral oxygen saturation (SpO_2) responses. In the initial CPET series, the SpO_2 threshold for cessation was set at <88%. In subsequent rounds, this limit was lowered to <80%, informed by evidence from the first round demonstrating that moderate hypoxemia was well tolerated in the monitored ILD population. Therefore, these

			aspects will be replicated in this study. There were few cardiac issues detected, and were all minor in presentation. All exercise was terminated as a precaution, and this process will be followed in the present study. The participant will be referred to general practitioner (GP)/cardiologist for further investigations, if abnormalities in cardiopulmonary function are found.
Inconvenience and changes to lifestyle	The participants will be required to attend 3 times for study investigations.	3 study days (1.5 hours duration)	The participants will be made aware of this time commitment at study outset and travel expenses will be provided.
Time commitments	Participation in the study may cause an added burden on top of daily treatments and appointments.	3 study days (1.5 hours duration)	Any testing carried out within the hospital will endeavour be arranged around clinic appointments and at a convenient time for patients.

3 OBJECTIVES AND OUTCOME MEASURES/ENDPOINTS

The aim is to use CPET so that we can explore the physiological and perceptual responses that pwPF have to aerobic exercise at above, or below the GET, which could inform tailored exercise prescription in this population. We will also determine if these methods are acceptable by using questionnaires and patient reported experience measures.

The objective is to perform an acute, laboratory-based trial with a sample of 15 pwPF, derived from the EPIC-PF group and outpatient clinics at RDUH, to evaluate the responses that pwPF have whilst performing and recovering from aerobic exercise at different intensities; above- and below- GET.

3.1 Primary objectives

Assess the responses that patients with PF have whilst performing and recovering from 10-minutes aerobic exercise at different intensities; at above (% difference between GET and VO_{2peak}: %Δ) or below (%GET) ventilatory thresholds. This will include measurement of VO_2, heart rate (HR), ventilation, feeling effectiveness scale, perception of effort and breathlessness.

3.2 Secondary objectives

Following exercise, to collate perspectives from the patients with PF via a questionnaire and patient reported outcome measures; to indicate the acceptability of exercising above/below thresholds.

3.3 Outcome measures/endpoints

3.3.1 Primary:

Variable derived from CPET values, including:

- VO_{2peak}, the gold-standard measure of cardiorespiratory fitness, expressed as $mL \cdot kg^{-1} \cdot min^{-1}$ and $L \cdot min^{-1}$
- WR_{peak}, expressed in (W), the maximum achieved work rate during an incremental CPET
- Volume of oxygen consumption at GET, expressed as a percentage of VO_{2peak}
- Peak minute ventilation (VE_{peak}), expressed as $L \cdot min^{-1}$
- ECG recordings: HR, expressed as the number of times the heart beats per minute ($beats \cdot min^{-1}$)

Non-CPET variables:

- mMRC (Modified Medical Research Council) Breathlessness scale (0-10)
- Borg (0-10) RPE
- The Affective Response to Exercise scale (-5 to +5)
- Oxygen saturations
- Blood pressure
- Lung function (DL_{CO}, FEV_1, FVC)
- Oscillometry (R5 (resistance at 5 Hz), X5 (reactance at 5 Hz), R20 (resistance at 20 Hz), and the difference between R5 and R20 (R5-R20)
- Lung sounds (digital stethoscope)
- Grip strength
- Spironose

3.3.2 Secondary:

- Anthropometric measures
- Health status measurement: King's Brief Interstitial Lung Disease (K-BILD)
- Health related quality of life (Living with PF)
- Theoretical Framework of Acceptability (TFA) questionnaire (customised)

4 TRIAL DESIGN

A single-centre prospective observational laboratory-based study of patients with PF.

5 TRIAL SETTING

The acute, laboratory-based study will be performed at the RDUH NHS Foundation Trust Hospital.

6 PARTICIPANT ELIGIBILITY CRITERIA

6.1 Inclusion criteria

The following inclusion and exclusion criteria will be applied:
Identification criteria for researcher

- Male or female ≥ 35–85 years of age
- PF diagnosis based on clinical features; determined by the Royal Devon and Exeter ILD Team

- FVC >40%;
- DL_{CO} >25%
- Willing and able to provide informed consent.
- Patient can understand and co-operate with the study protocol
- Clinically stable

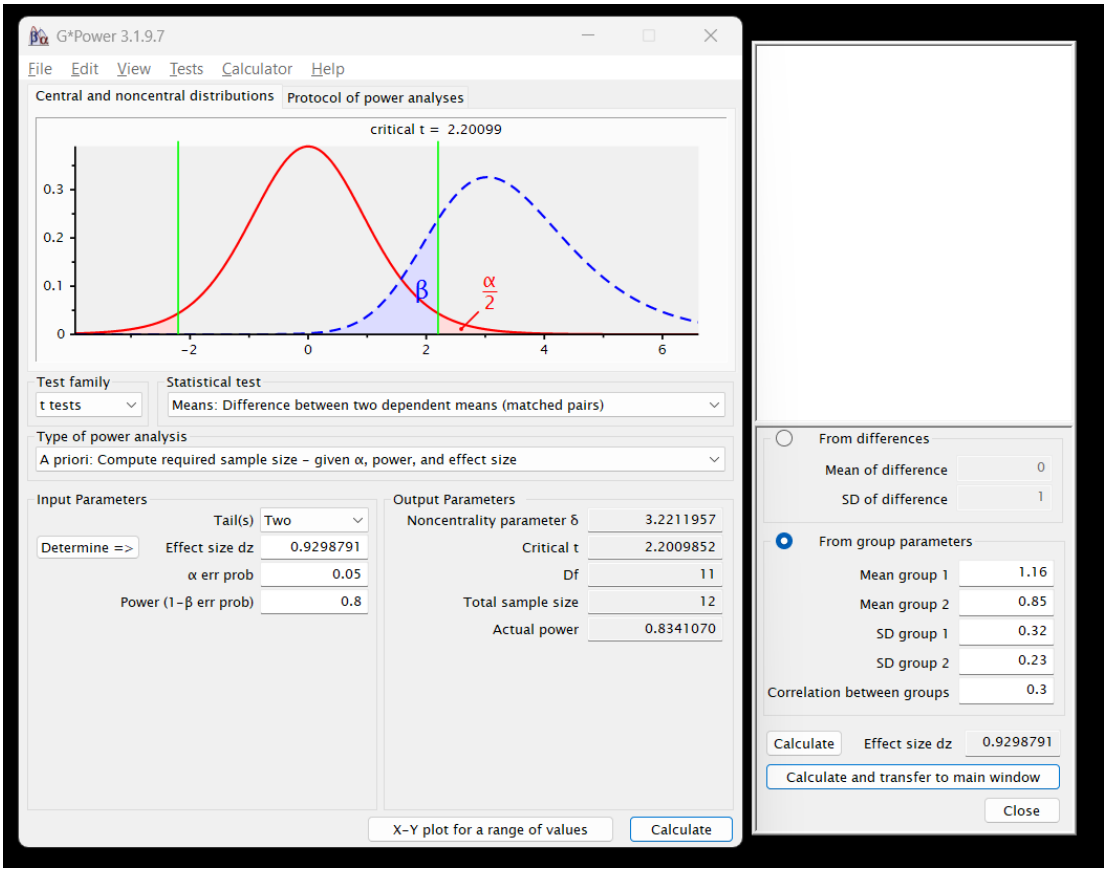
6.2 Exclusion criteria

Identification criteria for researcher

- Unable/unwilling to provide informed consent
- Known severe cardiovascular comorbidity or other medical conditions that could contribute to dyspnoea
- Daytime oxygen therapy
- Any other contraindications to exercise testing as determined by clinical team

6.3 Sample Size

It is calculated that this study will necessitate 15 participants. This is derived from data from McNarry et al., (2017) and Baidats et al., (2024). The former identified a mean VO_2 during heavy intensity steady state exercise of 1.16±0.32 $L \cdot min^{-1}$, and the former identified a mean VO_2 during moderate intensity steady state exercise of 0.85±0.23 $L \cdot min^{-1}$. Therefore, in anticipation of detecting the same mean responses, and to compare this effect size (ES = 0.93) via an independent sample t-test, with a power of 0.8 and statistical significance of 0.05, a minimum of n = 12 is needed; assuming a conservative correlation (r = 0.3). To account for withdrawal, or failure to complete all three visits, a 25% buffer is included and therefore n = 15 will be recruited. A screenshot from the GPower software is provided below.



7 TRIAL PROCEDURES

7.1 Recruitment

The participants will be recruited via two pathways. Firstly, from the outpatient ILD clinics at the RDUH NHS Foundation Trust, and secondly, via the Exeter EPIC-PF patient and Public Involvement and Engagement group (of which many are under the care of the aforementioned RDUH clinical service).

Within outpatient clinics at the RDUH, the recruitment process will initially involve RDUH ILD clinical staff collaborating to identify potentially eligible PF study participants during routine outpatient clinics. Screening for study eligibility, against the inclusion and exclusion criteria, will be performed by the RDUH ILD clinical team, with oversight from Professor Michael Gibbons.

If patients are eligible, a patient invitation letter and study information document will be provided the clinical team to the patient with PF in advance of their next clinical appointment. At the subsequent appointment, eligible patients will meet the study lead (BB) to discuss the study. No consenting will take place at this outpatient clinic. BB will follow up, via telephone or email (patient choice)after 48-hours to go through further questions if they are applicable. This call/email serves to finalise interest in the study and BB will arrange an appointment for the first study day with the participant, at which a written consent form will be provided.

Furthermore, the study will be advertised by BB via presentation and discussion at regular EPIC-PF patient and public involvement (PPI) meetings, with information packs left for potential participants. If interested, phone numbers will be taken from individuals and a phone call/email after 48 hours will be performed to answer questions, verify matching of inclusion/exclusion criteria, and obtain initial interest. If interest is verbally provided, an appointment for the first study day will be arranged with the participant, at which a written consent form will be provided.

7.2 Screening

Patients under the care of the clinical teams at RDUH will be screened for study inclusion by the RDUH ILD Team.

7.3 Payment

Reasonable travel expenses (e.g. train tickets, fuel, parking) will be paid to participants for any study visits. Fuel will be covered at the standard University of Exeter rate (£0.45/mile for 100 miles; £0.25/mile thereafter). Participation in the study is voluntary, reasonable expenses reimbursement is not considered payment.

7.4 Consent

A study pack will be provided (by BB) to the person with PF at their clinic appointment, or at the PPI meeting and will include: an Invitation Letter (Section 16: Appendix. C) Patient Information Document (Section 16: Appendix. D), Study Information Leaflet (Section 16. Appendix. E), A phone call (from BB) will be performed after 48-hours to go through the details and serves to finalise consent. If informed consent is verbally provided, BB will arrange an appointment for the first study day with the participant. Written consent will be obtained from participants at their baseline visit by BB using a

Consent Form (Section 16. Appendix. F) and Photo Consent Form (Section 16: Appendix. G) Consent may be delegated to an appropriately co-investigator according to the research protocol, Good Clinical Practice (GCP) principles and the Declaration of Helsinki. Capacity to consent will be assessed by the consenting healthcare professional. The right of a participant to refuse participation without giving reasons will be respected and participants will be able to withdraw at any time from the study. There will be no exclusion criteria defined by sex or ethnic origin. During analysis patients may be stratified by age, sex, or other demographics however this will be clearly reported in the analysis. Potential participants with any audio/visual impairment will be considered on a case-by-case basis as adherence to the exercise protocol requires ability to read a screen which displays pedalling speed. The consent forms will be completed using paper copies. Copies will be made available to participants. Once written consent is provided a GP Letter (Section 16: Appendix. H) will be sent to the participants GP.

7.5 Additional consent provisions for collection and use of participant data

Participants will be invited to provide consent to being contacted regarding future studies that may be of interest, and which may require further study procedures. Participants will also be asked to provide consent to anonymised data being shared with further, legitimate researchers as part of study analysis, or after study completion (e.g. sharing of data for secondary analyses, or systematic reviews).

7.6 Baseline data

Primary participant details will be collected via an Identifying Details Form (Section 16. Appendix I). All baseline measurements will be taken at the RDUH by BB, or a supervising clinician using a Baseline Medical and Demographic Information Form (Section 16: Appendix. J). These baseline demographics will be stored within a secure password protected database, using Microsoft Office, provided by the University of Exeter.

Baseline demographics to be collected and stored at each participating site:

- Name
- Date of Birth
- NHS Number
- Local hospital number

This database will also include:

- Co-morbidities
- Family history of respiratory disease
- Medication history
- Smoking status (Current, Ex (>100 lifetime cigarettes), Never)
- Ethnicity

Anthropometric measures will also be recorded and include height, body mass, body mass index (BMI) and grip strength; these measures are already routinely measured in clinical settings and therefore participants will be accustomed to these procedures.

Careful consideration will be given to achieving an acceptable and appropriate balance between relevant data collection and participant experience to ensure that participants are not overloaded by data collection measures.

Baseline CPET also conducted for determination of GET for visit 2 and 3.

7.7 Trial assessments

Participants will undergo the following assessments on all study visits (1,2 and 3). The trial assessments are displayed in **Section 16. Appendix B. Study Timings Table.**

7.7.1 Pulmonary function testing

Routine Pulmonary Function Testing (PFT) is standard of care (SOC) for patients with ILD. Currently patients under the care of the ILD services receive PFTs at 4-6 monthly intervals as SOC. Pulmonary function testing will be carried out by the NHS services at the relevant site and will be undertaken according to Association for Respiratory Technology & Physiology (ARTP) standards (https://www.artp.org.uk/Spirometry-Standards).

Pulmonary function tests

- Date of procedure
- FVC (predicted, actual and %predicted)
- DL_{CO} (predicted, actual and %predicted)
- FEV_1 (predicted, actual and %predicted)
- Oscillometry (R5 (resistance at 5 Hz), X5 (reactance at 5 Hz), R20 (resistance at 20 Hz), and the difference between R5 and R20 (R5-R20).
- Lung sounds (digital stethoscope)

BB will be responsible for liaison with the clinical physiology department, on the day of the CPET, to facilitate the booking of individual PFTs. A Lung Function Information Form (Section 16: Appendix. K) will be used to document recordings for each test.

7.7.2 Exercise outcomes

- Variable derived from CPET values, including:
    - VO_{2peak}, the gold-standard measure of cardiorespiratory fitness, expressed as $mL \cdot kg^{-1} \cdot min^{-1}$ and $L \cdot min^{-1}$
    - WR_{peak}, expressed in (W), the maximum achieved work rate during an incremental CPET
    - Volume of oxygen consumption at GET, expressed as a percentage of VO_{2peak}
    - Peak minute ventilation (VE_{peak}), expressed as $L \cdot min^{-1}$
    - ECG recordings: HR, expressed as the number of times the heart beats per minute ($beats \cdot min^{-1}$)

Non-CPET variables:

- Borg (0-10) RPE (Section 16: Appendix. L)
- mMRC (Modified Medical Research Council) Breathlessness scale (0-10) (Section 16: Appendix M)
- The Affective Response to Exercise scale (-5 to +5) (Section 16: Appendix. N)
- Oxygen saturations
- Blood pressure
- Lung function (DL_{CO}, FEV_1, FVC)
- Oscillometry (R5 (resistance at 5 Hz), X5 (reactance at 5 Hz), R20 (resistance at 20 Hz), and the difference between R5 and R20 (R5-R20)

- Lung sounds (digital stethoscope)
- Grip strength
- Spironose

7.8 Qualitative assessments

7.8.1 Patient reported outcome measures

Patient reported outcome measures will be collected using electronic device via an MS Office database. Participants will be able to access direct assistance to complete the measures should this be required. BB will be responsible for facilitating the collection of patient reported outcome measures. The measures to be recorded are:

- The K-BILD questionnaire (Section 16: Appendix O) will be used to measure HRQoL; this questionnaire is a brief, valid and self-completed health status measure for ILD (Sinha et al., 2019).
- The Living with PF questionnaire (Section 16: Appendix. P) to further assess health related quality of life, specifically for patients with PF.
- A customised Theoretical Framework of Acceptability (TFA) questionnaire to evaluate acceptability for CPET (Section 16: Appendix. Q), Moderate Intensity Exercise (Section 16: Appendix. R) and Heavy Intensity Exercise (Section 16: Appendix. S).

8 RESPONSIBILITIES

8.1 Adverse events

This is a low-risk study, and it is not anticipated that participants involved in this project will be subject to adverse effects. The sponsor and study sites will be informed of any adverse effects within 24 hours, and they will be reported following local NHS Research and Development (R&D) SOPs with a copy of any adverse event form stored in the project site file.

8.2 Withdrawal criteria

Participants have the right withdraw from the study, at any point, at their discretion. Any withdrawals will be respected and not affect participants' subsequent clinical care.

9 STATISTICS AND DATA ANALYSIS

The aim of this pilot study is to obtain preliminary data and assess the feasibility of a more detailed study to assist in the clinical management of patients with PF.

A repeated measures analysis of variance (ANOVA) will be performed for the statistical analysis of the primary outcome measures. The repeated measures ANOVA has been selected because the same sample population will be used, but under different conditions (moderate and heavy intensity exercise) and different time points (e.g. start of exercise, mid-exercise, end-exercise). Descriptive and frequential statistics will also be used.

10 DATA MANAGEMENT

10.1 Data collection tools and source document identification

This study will be conducted in accordance with GCP, the research governance framework for health and social care, local information governance protocols and according to the principles as outlined in the Declaration of Helsinki. The study will be carried out in accordance with the Declaration of Helsinki (2024), the UK Policy

Framework for Health and Social Care Research (2020) and the general principles of GCP.

Following analysis, the fully anonymised data will be published in accordance with the University of Exeter Open Access Research and Research Data Management Policy and good practice guidance (https://ore.exeter.ac.uk/repository/handle/10871/26168). Once complete data will be stored in the Open Research Exeter data depository (https://ore.exeter.ac.uk/repository). All data will be inputted using a secure University of Exeter computer. All research records will be destroyed after 10 years.

10.3 Data handling and record keeping

All data files will be under the control of the University of Exeter. All hard copies of data will be stored in the patients' notes, which will be stored in locked filing cabinets again in agreement with the NHS trust policy. A database will be created by BB for statistical analysis, which the research team can access. Statistical analysis of reporting will be performed by the research team.

10.4 Access to Data

Direct access to patient identifiable information will only be available to members of the clinical care team. Pseudonymised data will be available to all members of the research group via the partition of data within the database.

10.5 Archiving

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.

11 MONITORING, AUDIT & INSPECTION

The sponsors standard monitoring and audit practices will be followed.

12 ETHICAL AND REGULATORY CONSIDERATIONS

12.1 Research Ethics Committee (REC) review & reports

Prior to commencing study there will be approval of the trial protocol, participant information sheet, and consent forms by an appropriate Research Ethics Committee.

12.2 Public and Patient Involvement

The premise of the clinical study was discussed with the Exeter Patients in Collaboration PF (https://blogs.exeter.ac.uk/eri/research-opportunities/epic/) and patient representatives from RDUH. Patients unanimously supported this as a key area for research.

Meetings with the EPIC-PF group have discussed:

- Review of the study protocol
- Refining the patient and public facing materials
- Activities to support participant engagement and connectedness to the study
- Development of the dissemination via social media

12.3 Regulatory Compliance

Prior to commencing the study will receive:

- Appropriate REC approval

- Health Research Authority approval
- Local site permissions/capacity and capability confirmation

12.4 Notification of Serious Breaches to GCP and/or the protocol
Serious breaches to GCP or the protocol will be reported directly to the sponsor. The sponsor will then notify the licensing authoring in writing of any serious breach within 7 days of becoming aware of the breach.

12.5 Data protection and patient confidentiality
The study will be carried out according to the requirements of the General Data Protection Regulation (GDPR), Data Protection Act 2018. Access to study databases will be limited to the minimum number of individuals necessary for quality control, audit, and analysis.

12.6 Financial and other competing interests for the chief investigator, PIs at each site and committee members for the overall trial management
No members of the Study Management group have financial or other competing interests in relation to the study design, conduct or reporting.

12.7 Indemnity
As sponsor the University of Exeter will provide indemnity for the study and has insurance in place to cover legal liabilities arising from the conduct, design, and management of the research.

13 AMENDMENTS
Substantial amendments to the documents submitted in the original REC application will be submitted using a valid notice of amendment to REC and to the trial sponsor. Non-substantial amendments will be made throughout the trial as needed. The CI and sponsor will be responsible for determining whether an amendment is substantial. Substantial amendments will be highlighted in an updated version of the document.

13.1 End of study
The end of the study will be 5 years after the last participant has undergone the final group of investigations.

13.2 Post study care
The data acquired from CPET will not be reviewed by the clinical care team for clinical decision making. The study report will be circulated to participants in a lay findings summary at the time of publication in peer reviewed literature upon completion of the study.

13.3 Access to the final trial dataset
All members of the study management group will have access to the complete pseudonymised dataset.

14 DISSEMINATION POLICY
14.1 Authorship eligibility guidelines and any intended use of professional writers

Research outputs will be published in peer reviewed open access publications. These will also be disseminated as conference abstracts.

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Appendix A. CPET-PF Participant Pathway



Appendix B. Study Timings Table

Stage	Visit 1	Visit 2 or 3	Visit 2 or 3
Initial Procedures	Consent, Eligibility	—	—
Assessments	Baseline anthropometric data, Lung function	—	—
Warm-Up	Cycling – No resistance (5 mins)	Cycling – No resistance (5 mins)	Cycling – No resistance (5 mins)
Main CPET/Exercise	CPET (10–12 mins), Incremental workload cycling	Below GET – Moderate Intensity Cycling (10 mins)	Above GET – Heavy Intensity Cycling (10 mins)
Cool-Down	Cycling – No resistance (5 mins)	Cycling – Without resistance (5 mins)	Cycling – No resistance (5 mins)
Follow-Up	Questionnaires (×3)	Questionnaires (×3)	Questionnaires (×3)
Total time	90 minutes	1 hour	1 hour

Appendix C. Invitation letter

NIHR EXETER BIOMEDICAL RESEARCH CENTRE
UNIVERSITY OF EXETER

Bb544@exeter.ac.uk

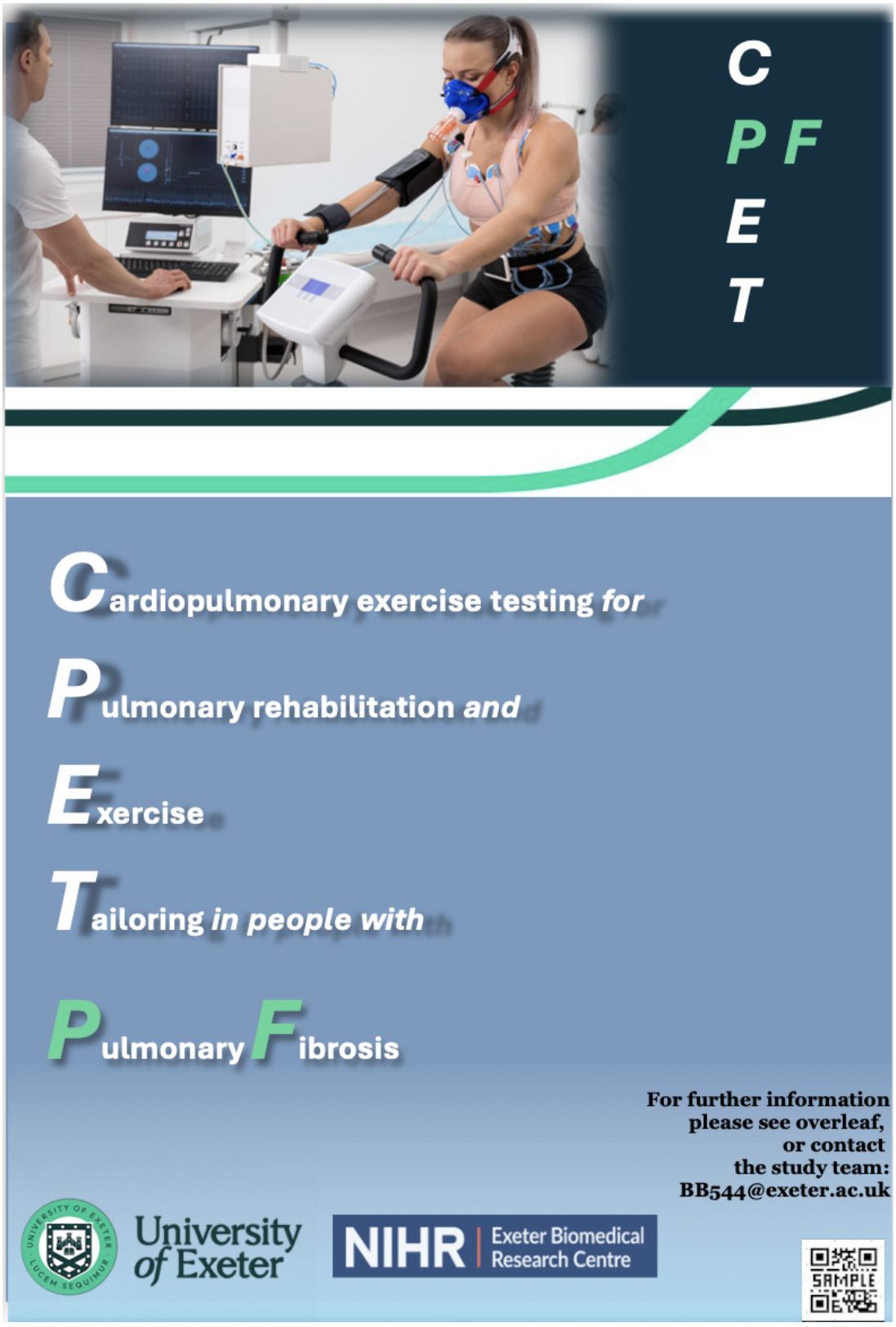
Research Study Title:
CardioPulmonary exercise testing for Exercise Tailoring in Pulmonary Fibrosis (CPET-PF)

Invitation Letter
Version number: v2 (20/02/2026)

Dear [insert patient name]
We are currently looking for a number of patients with Pulmonary Fibrosis who would be interested in taking part in our new research study. The aim is to explore if Cardiopulmonary Exercise Testing (CPET) can support tailored exercise prescription, to hopefully add more health and quality of life benefits for patients with PF. This is being undertaken by the University of Exeter, in conjunction with the NIHR Exeter Biomedical Research Centre and Royal Devon and Exeter University Hospitals Trust.
An information sheet has been included for you to read and help you decide whether you would like to take part. If this research project is something which you feel you may be interested in, do let either your immediate PF care team (e.g. doctor, nurse, physiotherapist) know, or you can contact us using the details at the top of this letter.
Your participation in this research project would be much appreciated. However, you do not have to if you do not wish to. Your medical care and individual rights are not affected by a decision not to take part, or drop out in the future if you do take part.
Many thanks for reading this,
Kind Regards,

Mr Ben Bowhay
Ph.D. candidate
NIHR Exeter Biomedical Research Centre
University of Exeter

Appendix D. Study information leaflet



Appendix D. Study information leaflet

University of Exeter
NIHR | Exeter Biomedical Research Centre
C P F E T

How does exercise personalised to you sound…?

We are looking for people with **PF**

WHY? A '**One size fits all' approach** to exercise may not the best approach, due to the many challenges found for PF as a condition.

CPET Helps us understand how the heart, lungs and muscles work during exercise.

AIM Improve pulmonary rehabilitation practice for people with PF by using a tailored approach.

Baseline data



- Patient details
- Screening
- Height/Weight
- Lung function

Warm up



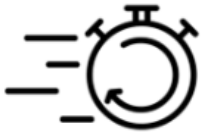
- 5-minutes
- Cycling
- Without resistance

Exercise



Visit 1:
CPET
10-12 minutes

Recovery



- 5-minutes
- Cycling
- Without resistance

Final observations

- Questionnaires

If acceptable… **Visit 2:** Moderate intensity exercise (10 minutes) **and** **Visit 3:** Heavy intensity exercise (10 minutes)

If you are interested in this study, please contact for further information:
Ben Bowhay
Bb544@exeter.ac.uk

Appendix E. Participant Information Sheet

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: 2.0 (20/02/2026)

You are being invited to take part in a research trial. 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 patients 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 patients with PF to tailored exercise. Firstly, a CPET will be performed to see if our tailored methods are suitable. After that, we will ask you to complete two exercise sessions at different intensities that have been tailored to your own ability.

2. Why have I been chosen?

We are recruiting patients with PF, aged between 35-85 years old. We are hoping to recruit 15 patients with PF to take part in this study. Three study visits will be required; these are additional to your standard care. We aim to complete the overall study within a 3-year timeframe.

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. If you take part in the trial, we will ask you to attend **three additional visits to the Royal Devon and Exeter hospital.**

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: 10-minute moderate intensity exercise session.
Visit 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. 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. 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.

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 patients 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. All 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 and your medical records for this research project. During the screening stage, this will include your initials, NHS number, name, and contact details. Your ILD clinical team already has access to this information. After screening, Mr Ben Bowhay will use these details to generate a unique study code for you. Once this code is created, your personal information will not be accessible to any other member of the research team.

The University of Exeter is the sponsor for this study and is responsible for ensuring that your information is handled securely and in accordance with data-protection regulations.

We will share your information related to this research project with the following types of organisations: Royal Devon University Healthcare Trust. We will share anonymised results and findings in form of presentations with Asthma and Lung UK, and Exeter Patients In Collaboration for Pulmonary Fibrosis Research (EPIC-PF) group; all results data will be analysed as a whole study participant group, which would prevent identification of individual participants.

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

- All data files will be under the control of the University of Exeter.
- 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.
- Anonymised data will be available to all members of the research group via the partition of data within the online database.
- Direct access to patient identifiable information will only be available to members of the clinical care team.
- All hard copies of data will be stored in the patients' notes, which will be stored in locked filing cabinets again in agreement with the NHS trust policy.
- Statistical analysis of reporting will be performed by 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. All published reports will be anonymised so that no one can identify individual participants.

9. 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 or destroyed.

10. 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.

- If you choose to stop taking part in the study, we would like to continue collecting information about your health from central NHS records/your hospital/your GP. If you do not want this to happen, tell us and we will stop
- 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
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

11. Where can you find out more about how your information is used?
You can find out more about how we use your information:

- Our research participant privacy notice - https://www.exeter.ac.uk/about/oursite/privacy/research/
- By asking one of the research team
- By sending an email to: bb544@exeter.ac.uk or informationgovernance@exeter.ac.uk
- By ringing us on 01392 727049

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. In any such case, complaints should be directed to Dr Owen Tomlinson. 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**.

Will my involvement in this trial be kept confidential?

We have a responsibility to inform you of how we will collect, store and use your information gathered during this trial. Due to recent regulatory changes in the way that data is processed (General Data Protection Regulation 2018 and the Data Protection Act 2018) the University of Exeter's lawful basis to process personal data for the purposes of carrying out research is termed as a 'task in the public interest'. The University will endeavour to be transparent about its processing of your personal data and this information sheet should provide a clear explanation of this. If you do have any queries about the University's processing of your personal data that cannot be resolved by the research team, further information may be obtained from the University's Data Protection Officer by emailing dataprotection@exeter.ac.uk or at www.exeter.ac.uk/dataprotection. If you have any concerns about how the data is controlled and managed for this trial then you can also contact the Sponsor (University of Exeter) Representative, Suzy Wignall, Senior Clincal Research Governance Manager at the University of Exeter , res-sponsor@exeter.ac.uk].

For the purposes of this study, we will also use consent to protect your confidentiality and provide you with choice in your participation. All information collected in this study will be kept strictly confidential and stored either on an encrypted password protected computer, or in a locked cabinet at the University of Exeter, which can only be accessed by researchers. You will be allocated a unique participant number, which will ensure the clinical information you provide (e.g. lung function, questionnaires) will be protected and cannot be identified by anyone else.

Clinical data generated by the trial will be entered into a secure database. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, or in compliance with the law. When the study ends, all paper and computer files in the UK containing clinical information generated by the trial will be stored for no more than 10 years. After this period, paper files will be destroyed, and computer files erased.
Any personally identifiable information (e.g. email addresses, phone numbers) will be stored separately and securely from clinical information obtained from the research and will be securely destroyed within three months following the end of your involvement in the study.

Information about you will be obtained from your health records held at your hospital for the purpose of this research. By signing the consent form you agree to the trial team accessing health records if they are relevant to your participation in this research project. Information about your participation in this research project will be recorded in your health records, and your GP will be informed. You have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. If you would like to access your information, please contact Dr Owen Tomlinson (o.w.tomlinson@exeter.ac.uk).Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

3. 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.

4. 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 (names…) and at RDUH (names…).

5. Who has reviewed the trial?

All research within the NHS is looked at by an independent group of people, called a Research Ethics Committee, who safeguard the rights, safety, dignity and well-being of people participating in NHS research. They review applications for research, give an opinion about the proposed participant involvement and whether the research is ethical.

Appendix F. Consent

NIHR EXETER BIOMEDICAL RESEARCH CENTRE
Bb544@exeter.ac.uk

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

CONSENT FORM

Version number: v2 (20/02/2026).

		Please initial box
1	I have read and understand the information sheet [Version v2, 20/02/2026] for the above study and have had the opportunity to ask questions.	
2	I understand that my taking part is voluntary, with travel expenses paid for by the University of Exeter research team. I am free to withdraw at any time, without giving any reason and without my medical care or legal rights being affected.	
3	I understand that sections of any of my medical records may be looked at by the researchers (who are outside my usual direct clinical care team at the hospital) in the study where it is relevant to my participation, and that this information will be kept secure.	
5	I am aware that my results will be kept anonymous by a unique study code and participant number. I give consent for my medical records to be used as indicated in the participant information sheet [Version 2.0, 20/02/2026].	
6	I understand that my GP will be informed of my participation in this trial, and that the research team will communicate this information on my behalf.	
7	I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from regulatory authorities, the University of Exeter or from the NHS Trust where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records and data.	
8	I am aware my research data could be used in future ethically approved research studies.	
9	I consent to anonymised research data generated in this study being shared with legitimate researchers, outside the initial research team for further analysis, including within ethically approved research.	
10	I give my consent to take part in the above study.	
11	Optional: I wish to receive a copy of the study results, and I understand that my contact details will be kept for this purpose.	

Name of participant _____ Date _____ Signature _____

Researcher _____ Date _____ Signature _____

☐ Tick to confirm three copies have been signed – Participant, research file and medical notes

Appendix G. Photo Consent

NIHR EXETER BIOMEDICAL RESEARCH CENTRE
UNIVERSITY OF EXETER

Bb544@exeter.ac.uk

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

Photo Permission
Version number: 2.0 (20/02/2026)

Please note that you do not have to give photo permission – you are still invited to take part in this study whether or not you are happy to have your photo taken.

I, , give permission for photographs of me to be taken during my participation in the study. I understand that the photographs might be used in publicity materials by the University of Exeter; and in conference presentations/lectures, such as posters and PowerPoint presentations

I understand that my face will not be identifiable from any photographs used in any future publicity and/or presentation materials.

Signed (participant)

Signed (researcher)

Date

Appendix H. GP Letter

NIHR EXETER BIOMEDICAL RESEARCH CENTRE
UNIVERSITY OF EXETER

Bb544@exeter.ac.uk

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

GP Letter
Version number: 1.0 (26/11/2025)

[Insert date here]

Dear [insert GPs name here]

We are writing to inform you that [insert patient's name] has with the approval of his/her lead consultant agreed to participate in the study. This project has been reviewed and given favourable opinion by the Health Research Authority and relevant research ethics committees. A participant information sheet has been included with this letter for your reference.

[Insert patient name] will be under the care of his/her lead clinician and there is no need to do anything further.

If you would like any further information, please do not hesitate to contact me using the details above.

Yours sincerely

Mr Ben Bowhay
Ph.D. candidate
NIHR Exeter Biomedical Research Centre
University of Exeter

Appendix I. Identifying Details

IDENTIFYING DETAILS
Version number: 2.0 (20/02/2026)

PARTICIPANT NAME			
DOB	BIOLOGICAL SEX	Male / Female	
NHS No/HOSPITAL No.			
PREFERRED CONTACT NUMBERS			
ADDRESS			
EMAIL			
EMERGENCY CONTACT (NAME & CONTACT)			
INCLUSION CRITERIA		**EXCLUSION CRITERA**	
Confirmed diagnosis of PF		Presence of severe co-morbidity limiting mobilisation or physical activity participation	
Aged 35 – 85 years		Previous lung transplantation	
Able to provide informed consent		Pregnancy	
NHS SITE			
DATABASE PATIENT CODE			

COMPLETED BY: _____DATE:_____

Appendix J. Baseline Medical & Demographic Information

Baseline Medical and Demographic Information

Version number: 2.0 (20/02/2026)

Age: _____ years

Height: _____ cm

Gender: ☐ Male ☐ Female

Weight: _____ kg

BMI: _____

Ethnicity: _____

PF diagnosis: _____

Age at diagnosis: _____ years

Smoking status: (Current, Ex (>100 lifetime cigarettes), Never)

_____
_____

Coexisting conditions:

_____
_____
_____
_____

Medications:

_____
_____
_____
_____

Appendix K. Lung Function Information

Lung Function Testing

Version number: 2.0 (20/02/2026)

Lung function conducted Date: ____ /____ /____ Time: ____ : ____

FEV_1: _____L _____% predicted

FVC: _____L _____% predicted

DL_{CO}:_____% predicted

Oscillometry

R5: _____

X5: _____

R20: _____

R5-R20: _____

Lung sounds (digital stethoscope)
_____

Spironose:
_____

Appendix L. Rate of Perceived Exertion (RPE) scale

0	Rest
1	Really easy
2	Easy
3	Moderate
4	Sort of Hard
5	Hard
6	
7	Really Hard
8	
9	Really, Really Hard
10	Maximal

Appendix M. Rate of Perceived Breathlessness (RPB) scale

Shortness of Breath Modified Borg Dyspnea Scale	
0	Nothing at all
0.5	Extremely slight (just noticeable)
1	Very slight
2	Slight
3	Moderate
4	Somewhat Severe
5	Severe
6	
7	Very Severe
8	
9	Extremely Severe (almost maximal)
10	Maximal

Appendix N. Affective Response to Exercise Scale

Affective Response to Exercise Scale	
+5	Very Good
+4	
+3	Good
+2	
+1	Fairly good
0	Neutral
-1	Fairly Bad
-2	
-3	Bad
-4	
-5	Very Bad

Appendix O. Quality of Life Questionnaire – K-BILD

Quality of Life Questionnaire – K-BILD

The King's Brief Interstitial Lung Disease Questionnaire (K-BILD)©2011

This questionnaire is designed to assess the impact of your lung disease on various aspects of your life. Please circle the response that best applies to you for each question

1. In the last 2 weeks, I have been breathless climbing stairs or walking up an incline or hill.

1. Every time 2. Most times 3. Several Times 4. Some times 5. Occasionally 6. Rarely 7. Never

2. In the last 2 weeks, because of my lung condition, my chest has felt tight.

1. All of the time 2. Most of the time 3. A good bit of the time 4. Some of the time 5. A little of the time 6. Hardly any of the time 7. None of the time

3. In the last 2 weeks have you worried about the seriousness of your lung complaint?

1. All of the time 2. Most of the time 3. A good bit of the time 4. Some of the time 5. A little of the time 6. Hardly any of the time 7. None of the time

4. In the last 2 weeks have you avoided doing things that make you breathless?

1. All of the time 2. Most of the time 3. A good bit of the time 4. Some of the time 5. A little of the time 6. Hardly any of the time 7. None of the time

5. In the last 2 weeks have you felt in control of your lung condition?

1. None of the time 2. Hardly any of the time 3. A little of the time 4. Some of the time 5. A good bit of the time 6. Most of the time 7. All of the time

6. In the last 2 weeks, has your lung complaint made you feel fed up or down in the dumps?

1. All of the time 2. Most of the time 3. A good bit of the time 4. Some of the time 5. A little of the time 6. Hardly any of the time 7. None of the time

7. In the last 2 weeks, I have felt the urge to breathe, also known as 'air hunger'.

1. All of the time 2. Most of the time 3. A good bit of the time 4. Some of the time 5. A little of the time 6. Hardly any of the time 7. None of the time

8. In the last 2 weeks, my lung condition has made me feel anxious.

1. All of the time 2. Most of the time 3. A good bit of the time 4. Some of the time 5. A little of the time 6. Hardly any of the time 7. None of the time

9. In the last 2 weeks, how often have you experienced 'wheeze' or whistling sounds from your chest?

1. All of the time 2. Most of the time 3. A good bit of the time 4. Some of the time 5. A little of the time 6. Hardly any of the time 7. None of the time

10. In the last 2 weeks, how much of the time have you felt your lung disease is getting worse?

1. All of the time 2. Most of the time 3. A good bit of the time 4. Some of the time 5. A little of the time 6. Hardly any of the time 7. None of the time

11. In the last 2 weeks has your lung condition interfered with your job or other daily tasks?

1. All of the time 2. Most of the time 3. A good bit of the time 4. Some of the time 5. A little of the time 6. Hardly any of the time 7. None of the time

12. In the last 2 weeks have you expected your lung complaint to get worse?

1. All of the time 2. Most of the time 3. A good bit of the time 4. Some of the time 5. A little of the time 6. Hardly any of the time 7. None of the time

13. In the last 2 weeks, how much has your lung condition limited you carrying things, for example, groceries?

1. All of the time 2. Most of the time 3. A good bit of the time 4. Some of the time 5. A little of the time 6. Hardly any of the time 7. None of the time

14. In the last 2 weeks, has your lung condition made you think more about the end of your life?

1. All of the time 2. Most of the time 3. A good bit of the time 4. Some of the time 5. A little of the time 6. Hardly any of the time 7. None of the time

15. Are you financially worse off because of your lung condition?

1. A significant amount 2. A large amount 3. A considerable amount 4.A reasonable amount 5. A small amount 6. Hardly at all 7. Not at all

Appendix P. Quality of Life Questionnaire – L-IPF

Instructions for Completing the Living with L-IPF Symptoms Questionnaire

Complete this questionnaire every evening, to assess the symptoms you may have experienced from Idiopathic Pulmonary Fibrosis (IPF) over the last 24 hours.

Keep in mind:

- you are not being asked to compare yourself to anyone else
- you are not being asked to compare how you are now with any time in the past

---

Items 1-6: The first 6 items ask about your symptoms in relation to physical activities, some of which you may not have done in the **last 24 hours**. If you did not perform an activity, we would like to know whether it was because you did not have the opportunity to do it (for example, maybe your home doesn't have stairs, so you did not walk up a flight of stairs), or whether you avoided the activity because it was too difficult.

If you did the stated activity, then reflect on the last 24 hours, and consider whether, on average, doing the activity at your usual pace or intensity level made you short of breath—and if so, how much.

If you normally use oxygen when you perform a given activity, then consider your response as if you were using supplemental oxygen.

Please select the box that best describes your experience.

1. Did you walk up one flight of stairs in the last 24 hours?

Yes — How short of breath did walking up one flight of stairs make you?

Not at all 0 1 2 3 4 **Extremely**

No — I did not walk up one flight of stairs in the last 24 hours because:

A I avoided this activity because it was too difficult to perform

B Not applicable, because I did not want or have the opportunity to do it

2. Over the last 24 hours, how short of breath have you been while sitting down, relaxing, reading, or watching TV?

Not at all 0 1 2 3 4 **Extremely**

3. Did you perform a grooming activity (e.g., brush teeth, shave, fix hair) in the last 24 hours?

Yes How short of breath did grooming make you?

Not at all 0 1 2 3 4 **Extremely**

No I did not perform a grooming activity in the last 24 hours because:

A I avoided this activity because it was too difficult to perform

B Not applicable, because I did not want or have the opportunity to do it

4. Did you walk outside on a level surface (approximately 150 feet/45 meters, or the distance of half a typical city block) in the last 24 hours?

Yes How short of breath did walking outside on a level surface make you?

Not at all 0 1 2 3 4 **Extremely**

No I did not walk outside on a level surface in the last 24 hours because:

A I avoided this activity because it was too difficult to perform

B Not applicable, because I did not want or have the opportunity to do it

5. Did you bathe or shower in the last 24 hours?

Yes How short of breath did bathing or showering make you?

Not at all 0 1 2 3 4 **Extremely**

No I did not bathe or shower in the last 24 hours because:

A I avoided this activity because it was too difficult to perform

B Not applicable, because I did not want or have the opportunity to do it

6. Did you lift and carry a light load (e.g., less than 10 lbs) a short distance (e.g., from one room to another) in the last 24 hours?

Yes How short of breath did lifting and carrying a light load make you?

Not at all 0 1 2 3 4 **Extremely**

No I did not lift or carry a light load a short distance in the last 24 hours because:

A I avoided this activity because it was too difficult to perform

B Not applicable, because I did not want or have the opportunity to do it

Items 7-9: Each item focuses on cough. Again, reflect on the last 24 hours as you consider where you are on the scale between the two statements.

7. Over the last 24 hours, how often did you cough?

Not at all 0 1 2 3 4 **Constantly**

If you chose "0", please skip to item 10.

8. Over the last 24 hours, how often did you cough when you took a deep breath?

Not at all 0 1 2 3 4 **Constantly**

9. Over the last 24 hours, how often did you cough when you over-exerted yourself?

Not at all 0 1 2 3 4 **Constantly**

10. Over the last 24 hours, how often did you feel an annoying tickle in your throat?

Not at all 0 1 2 3 4 **Constantly**

Living with L-IPF Symptoms Questionnaire

Items 11-15: These items primarily focus on your energy level. Again, reflect on the last 24 hours as you consider where you are on the scale between the two statements.

11. Over the last 24 hours, how was your energy level?

Extremely low 0 1 2 3 4 **Excellent**

12. Over the last 24 hours, of all that you wanted to get done, how much did you actually get done?

Nothing 0 1 2 3 4 **Everything**

13. Over the last 24 hours, how much energy did you have to do all the things you like to do?

No energy 0 1 2 3 4 **A lot**

14. Over the last 24 hours, how much did coughing have a negative effect on your energy?

No energy 0 1 2 3 4 **A lot**

15. Did you become short of breath in the last 24 hours?

Yes How long did it take you to recover when you became short of breath?

No time at all 0 1 2 3 4 **An extremely long time**

No Please continue to the next page

Living with L-IPF Symptoms Questionnaire

Finally, we would like to ask you 5 questions about your supplemental oxygen use.

Oxygen Question 1. Do you ever use supplemental oxygen?
(Place an "X" in one box)

Yes	→→	proceed to Oxygen Question #2.
No	→→	skip Oxygen Questions 2-5

Oxygen Question 2. I use supplemental oxygen…
(Place an "X" in one box)

1	→→	only when I sleep (answer Oxygen Question #3)
2	→→	only when I perform a physical activity (such as getting dressed or walking) (answer Oxygen Question #4)
3	→→	when I sleep or perform a physical activity (such as getting dressed or walking) but not at rest (answer Oxygen Questions #3 and #4)
4	→→	all the time (answer Oxygen Questions #3-5)

Oxygen Question 3. When I sleep, I most often use an oxygen flow rate of ___ L/min.
(Place an "X" in one box)

0.5	1.0	1.5	2.0	2.5	3.0	3.5	4.0	4.5	5	6	7	8	9	10	11	12	>12

Oxygen Question 4. When I perform a physical activity (such as getting dressed or walking), I most often use an oxygen flow rate of L/min.
(Place an "X" in one box)

0.5	1.0	1.5	2.0	2.5	3.0	3.5	4.0	4.5	5	6	7	8	9	10	11	12	>12

Oxygen Question 5. At rest, I most often use an oxygen flow rate of ___ L/min.
(Place an "X" in one box)

0.5	1.0	1.5	2.0	2.5	3.0	3.5	4.0	4.5	5	6	7	8	9	10	11	12	>12

Thank you for taking the time to complete the L-IPF Symptoms Questionnaire.

Acceptability Questionnaire – CPET

Question	1	2	3	4	5
Did you like or dislike CPET?	Strongly dislike	Dislike	No opinion	Like	Strongly like
How much effort did it take to engage with CPET?	No effort at all	A little effort	No opinion	A lot of effort	Huge effort
How fair is CPET for patients with PF	Very unfair	Unfair	No opinion	Fair	Very fair
The CPET has improved my behaviour towards exercising	Strongly disagree	Disagree	No opinion	Agree	Strongly agree
It is clear to me how CPET will help manage my PF	Strongly disagree	Disagree	No opinion	Agree	Strongly agree
How confident did you feel about engaging with CPET?	Very unconfident	Unconfident	No opinion	Confident	Very confident
CPET interfered with my other priorities	Strongly disagree	Disagree	No opinion	Agree	Strongly agree
How acceptable was the CPET to you?	Completely unacceptable	Unacceptable	No opinion	Acceptable	Completely acceptable

Acceptability Questionnaire – Moderate Intensity Exercise

Question	1	2	3	4	5
Did you like or dislike Moderate Intensity Exercise?	Strongly dislike	Dislike	No opinion	Like	Strongly like
How much effort did it take to engage with Moderate Intensity Exercise?	No effort at all	A little effort	No opinion	A lot of effort	Huge effort
How fair is Moderate Intensity Exercise for patients with PF	Very unfair	Unfair	No opinion	Fair	Very fair
The Moderate Intensity Exercise has improved my behaviour towards exercising	Strongly disagree	Disagree	No opinion	Agree	Strongly agree
It is clear to me how Moderate Intensity Exercise will help manage my PF	Strongly disagree	Disagree	No opinion	Agree	Strongly agree
How confident did you feel about engaging with Moderate Intensity Exercise?	Very unconfident	Unconfident	No opinion	Confident	Very confident
Moderate Intensity Exercise interfered with my other priorities	Strongly disagree	Disagree	No opinion	Agree	Strongly agree
How acceptable was the Moderate Intensity Exercise to you?	Completely unacceptable	Unacceptable	No opinion	Acceptable	Completely acceptable

Acceptability Questionnaire – Heavy Intensity Exercise

Question	1	2	3	4	5
Did you like or dislike Heavy Intensity Exercise?	Strongly dislike	Dislike	No opinion	Like	Strongly like
How much effort did it take to engage with Heavy Intensity Exercise?	No effort at all	A little effort	No opinion	A lot of effort	Huge effort
How fair is Heavy Intensity Exercise for patients with PF	Very unfair	Unfair	No opinion	Fair	Very fair
The Heavy Intensity Exercise has improved my behaviour towards exercising	Strongly disagree	Disagree	No opinion	Agree	Strongly agree
It is clear to me how Heavy Intensity Exercise will help manage my PF	Strongly disagree	Disagree	No opinion	Agree	Strongly agree
How confident did you feel about engaging with Heavy Intensity Exercise?	Very unconfident	Unconfident	No opinion	Confident	Very confident
Heavy Intensity Exercise interfered with my other priorities	Strongly disagree	Disagree	No opinion	Agree	Strongly agree
How acceptable was the Heavy Intensity Exercise to you?	Completely unacceptable	Unacceptable	No opinion	Acceptable	Completely acceptable

Appendix T. Study Documentation Log

STUDY SPECIFIC DOCUMENTATION LOG

Study Title	**CardioPulmonary exercise testing for Exercise Tailoring in Pulmonary Fibrosis (CPET-PF)**		
IRAS ID:	354740	**Study Coordinator:**	MR BEN BOWHAY

Participant ID No.	Initials	Date of consent (DD/MM/YY)	Participant Information Sheet		Signed Informed Consent Form			GP Letter	
			Copy to participant	Copy to medical records	Original to site file	Copy to participant	Copy to medical records	Sent to GP	Copy to medical records

Appendix U. Participant Recruitment Log

PARTICIPANT RECRUITMENT LOG

Study Title	**CardioPulmonary exercise testing for Exercise Tailoring in Pulmonary Fibrosis (CPET-PF)**		
IRAS ID:	354740	**Study Coordinator:**	MR BEN BOWHAY

Participant ID No	Initials	Pt. Hospital/ NHS no.	Date of Birth (DD/MM/YY)	Version of PIS/Consent form used	Date of consent (DD/MM/YY)	Comments

Appendix V. Participant Screening Log

PARTICIPANT SCREENINIG LOG

Study Title	**Cardiopulmonary exercise testing for Exercise Tailoring in Pulmonary Fibrosis (CPET-PF)**		
IRAS ID:	354740	**Study Coordinator:**	MR BEN BOWHAY

Initials	Gender		Screening date (DD/MM/YY)	Pt. Hospital/ NHS no.	Outcome (please tick)		Reason for failure (e.g. no interest, no time, competing trial)
	Male	Female					
					Recruited		[redacted]
					Screening Failure		
					Recruited		[redacted]
					Screening Failure		
					Recruited		[redacted]
					Screening Failure		
					Recruited		[redacted]
					Screening Failure		
					Recruited		[redacted]
					Screening Failure		
					Recruited		[redacted]
					Screening Failure		
					Recruited		[redacted]
					Screening Failure		
					Recruited		[redacted]
					Screening Failure		
					Recruited		[redacted]
					Screening Failure		

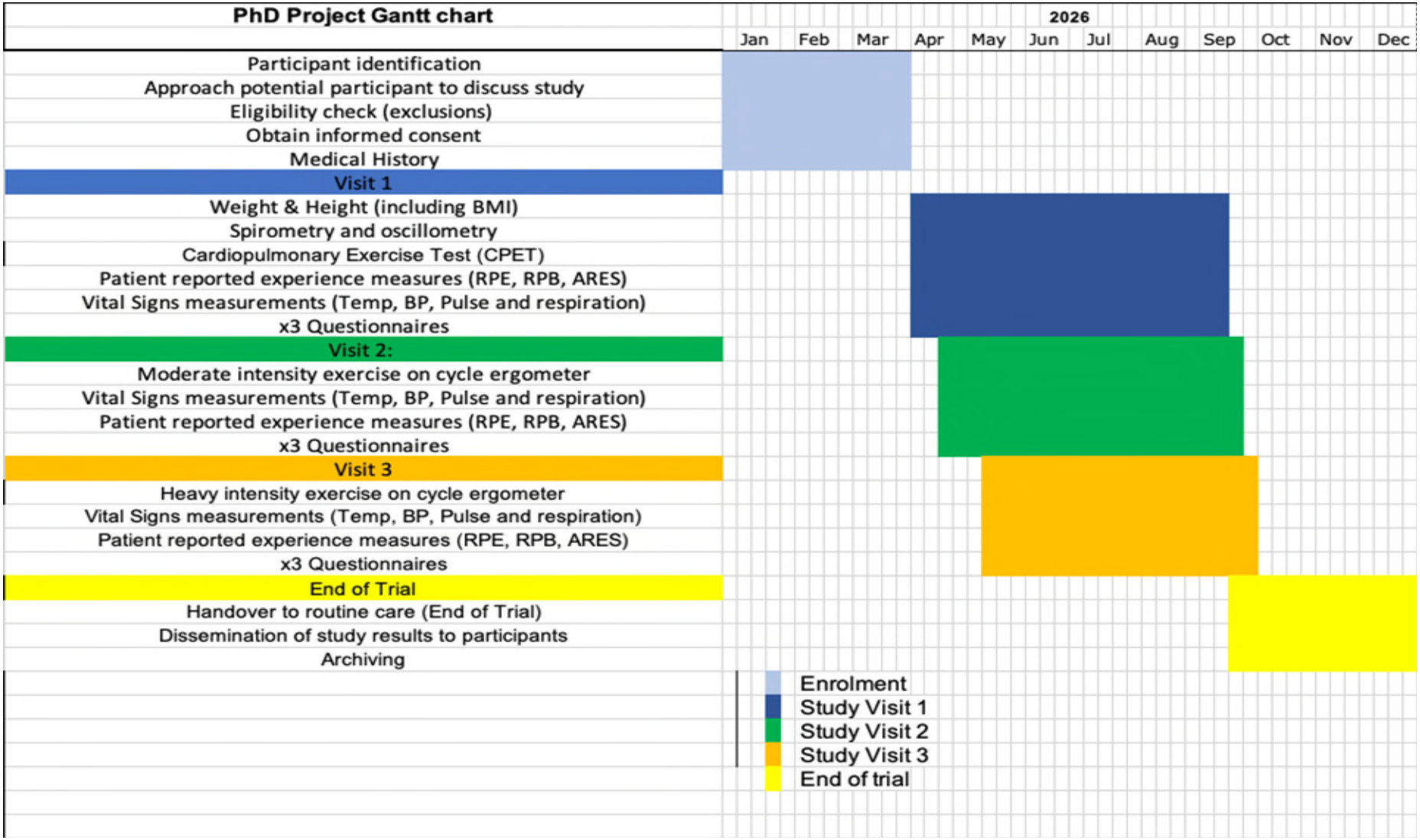
Appendix W. Participant Withdrawal Log

PARTICIPANT WITHDRAWAL LOG

Study Title	**Cardiopulmonary exercise testing for Exercise Tailoring in Pulmonary Fibrosis (CPET-PF)**		
IRAS ID:	354740	**Study Coordinator:**	MR BEN BOWHAY

Participant ID No.	Initials	Date of withdrawal (DD/MM/YY)	Reason for withdrawing	Stage of study (e.g. mid-intervention, follow up)	Data collected to date (e.g. clinical data, questionnaires)	Signature of staff

Appendix X. Project Gantt Chart



Appendix Y. Letter of Support 1

University of Bath, Department for Health
Centre for Nutrition, Exercise and Metabolism
University of Bath
Claverton Down
Bath, BA2 7AY

Ref: Letter of support – CPET PF

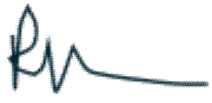
To whom it may concern,

I have been requested to review the above protocol based on my expertise in clinical exercise for people with chronic lung disease. I am a physiotherapist with a background in exercise prescription and pulmonary rehabilitation, having worked in tertiary care centres in this field since 2018. I am currently completing a PhD investigating exercise in people with Cystic Fibrosis, and have presented my research internationally on cardiopulmonary exercise testing (CPET) and exercise prescription in chronic lung disease. I also serve as the Wales representative for the Association of Chartered Physiotherapists in Cystic Fibrosis. I am therefore well positioned to comment on the validity of this proposal from a patient-centered perspective.

This proposed study, led by Owen Tomlinson and Ben Bowhay and sponsored by the University of Exeter, represents a timely and relevant investigation into the feasibility and acceptability of prescribing moderate- and heavy-intensity exercise in people living with pulmonary fibrosis using CPET. Using CPET to identify individual exercise thresholds allows for truly personalised exercise prescription. In my clinical experience, such tailored approaches result in more suitable and sustainable exercise plans, increasing patients' likelihood of long-term adherence. Personalised exercise prescription is an effective way to engage patients in self-management and can be highly empowering for those living with chronic conditions. Furthermore, education around breathlessness within the context of exercise prescription can help to reduce fear and build confidence, enabling patients to train effectively and safely.

In my opinion, this study has the potential to make an invaluable contribution to pulmonary rehabilitation practice. If shown to be feasible and acceptable, CPET-guided exercise prescription could provide detailed physiological insights and support longitudinal disease monitoring in people with pulmonary fibrosis. In summary, I fully support this study.

Yours faithfully,



Appendix Z. Letter of Support 2

NHS
Hampshire and
Isle of Wight Healthcare
NHS Foundation Trust
Research and Improvement
Tom Rudd Unit
Moorgreen Hospital
West End
Southampton
SO30 3JB
Tel: 02382 318790
www.hiowhealthcare.nhs.uk

30th of October 2025

Re. Letter of Support – Feasibility & Acceptability of Personalised Exercise in Pulmonary Fibrosis

To Whom It May Concern,

I am writing in support of the proposed study evaluating the feasibility and acceptability of prescribing moderate- and heavy-intensity exercise in individuals living with pulmonary fibrosis. This project is timely and highly relevant given the growing emphasis on personalised rehabilitation strategies in chronic respiratory disease. Importantly, this research aligns with the current shift in healthcare from a sickness-based model to one focused on prevention. By enabling appropriate, personalised exercise prescriptions for this population, the study has the potential to prevent further decline in health, reducing future healthcare burden, and support long-term wellbeing.

From a practical standpoint, the design is both clinically meaningful and operationally realistic. Personalisation through using cardiopulmonary exercise testing to determine objective thresholds ensures that exercise prescriptions are tailored to an individual's physiological capacity, which aligns with best practice in exercise science. Furthermore, the physiological monitoring using real-time oxygen uptake and heart rate data will provide insights into the mechanisms of exercise intolerance and physiological burden of exercise, supporting evidence-based refinement of pulmonary rehabilitation programmes.

This study will impose minimal burden on NHS resources. The protocol leverages existing infrastructure and staff expertise, making it imminently deliverable within current service models. Furthermore, the findings could inform pulmonary rehabilitation service development for pulmonary fibrosis, enhancing patient-centred care and improving functional outcomes without significant additional cost or complexity.

Given my experience in research delivery and exercise physiology in chronic diseases, I believe this study is well-conceived and will generate valuable data to guide future research and clinical practice.

Please do not hesitate to contact me if further clarification is required.

Yours sincerely,

Dr Curtis Wadey PhD, MSc, BA (Hons), AFHEA
Research Business Development Manager and Project Manager
Hampshire and Isle of Wight Healthcare NHS Foundation Trust

Hampshire and Isle of Wight Healthcare NHS Foundation Trust Headquarters,
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