# Minimal versus specialist equipment in the delivery of pulmonary rehabilitation

Submission date Recruitment status [X] Prospectively registered

12/03/2018 No longer recruiting [X] Protocol

Registration date Overall study status [X] Statistical analysis plan

15/03/2018 Completed [X] Results

Last Edited Condition category [ ] Individual participant data

13/08/2025 Respiratory

#### Plain English summary of protocol

Background and study aims

Pulmonary rehabilitation (PR) is an exercise and education programme for people with chronic lung disease that aims to improve fitness levels, breathlessness and quality of life. Most of the evidence to support PR has come from studies conducted in centres that use specialist exercise equipment such as treadmills, cycle ergometers, and specialist resistance equipment (PRspecialist). However, in clinical practice routine access to this equipment may not be feasible. In the 2015 Royal College of Physicians National Audit, it was identified that 81% of PR programmes in England and Wales were hosted in community sites and 59% of these probably did not have access to specialist equipment. Accordingly, exercise training at these sites was completed with minimal exercise equipment (PR-min), typically using simple, portable equipment such as free weights, walking programmes, and bodyweight resistance exercises. Apart from improving accessibility, it has been argued that PR-min may have other advantages over PR-specialist. Exercise training using minimal equipment may better reflect activities of daily living than training using specialist equipment, and therefore be easier to replicate and maintain at home following discharge from PR. However, there is a lack of studies examining the effectiveness of centre-based PR completed with minimal exercise equipment. The aim of this study is to determine whether an eight-week supervised PR programme using minimal exercise equipment (PR-min) is as effective as a standard eight-week supervised PR programme delivered using specialist exercise equipment (PR-specialist) in terms of health benefits for patients with chronic lung disease.

Who can participate?

Patients aged 18 and over with chronic lung disease

What does the study involve?

Participants are randomly allocated to either PR-min or PR-specialist for two supervised sessions per week for 8 weeks. Exercise capacity, breathlessness, quality of life, leg muscle strength and costs are measured at the start of the study, at 8 weeks and at 12 months.

What are the possible benefits and risks of participating?

It is hoped that minimal and specialist equipment pulmonary rehabilitation will improve walking ability, breathlessness and quality of life. However, it is not known whether minimal equipment

pulmonary rehabilitation will provide as much benefit as specialist equipment pulmonary rehabilitation. The results of this study may provide the information to decide whether pulmonary rehabilitation using minimal equipment is as good as using specialist equipment. Therefore the research may benefit patients directly and provide more information in order to potentially help other people in the long term. This is a very low risk study. There is a very small risk of a sports-related injury but this will be minimised by performing warm-up exercises before the exercise part of the pulmonary rehabilitation programme.

Where is the study run from? Harefield Hospital (UK)

When is the study starting and how long is it expected to run for? November 2017 to March 2023

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

Who is the main contact? Dr Claire Nolan

# Contact information

#### Type(s)

Scientific

#### Contact name

Dr Claire Nolan

#### **ORCID ID**

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#### Contact details

Harefield Hospital Hill End Road Harefield United Kingdom UB9 6JH

# Additional identifiers

# Protocol serial number

**CPMS 37582** 

# Study information

#### Scientific Title

MInimal versus SpecialisT Equipment in the delivery of pulmonary Rehabilitation (MISTER): a randomised controlled trial

#### Acronym

#### **Study objectives**

Pulmonary rehabilitation (PR) is an exercise and education programme for people with chronic lung disease that aims to improve fitness levels, breathlessness and quality of life. The majority of evidence to support PR has come from trials conducted in centres that utilise specialist exercise equipment such as treadmills, cycle ergometers, and specialist resistance equipment (PR-specialist). However, in clinical practice routine access to this equipment may not be feasible. In the 2015 Royal College of Physicians National Audit, it was identified that 81% of PR programmes in England and Wales were hosted in community sites and 59% of these probably did not have access to specialist equipment. Accordingly, exercise training at these sites was completed with minimal exercise equipment (PR-min), typically using simple, portable equipment such as free weights, walking programmes, and bodyweight resistance exercises.

Apart from improving accessibility, it has been argued that PR-min may have other advantages over PR-specialist. Exercise-training using minimal equipment may better reflect activities of daily-living than training using specialist equipment, and therefore be easier to replicate and maintain at home following discharge from PR. However, there is a paucity of robust literature examining the efficacy of centre-based PR completed with minimal exercise equipment. The aim of this research is to determine whether an eight-week supervised PR programme using minimal exercise equipment (PR-min) is non-inferior to a standard eight-week supervised PR programme delivered using specialist exercise equipment (PR-specialist) in terms of health benefits for patients with chronic lung disease.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

London – Camden and Kings Cross Research Ethics Committee, 12/03/2018, ref: 18/LO/0315

# Study design

Randomized; Interventional; Design type: Treatment, Rehabilitation

# Primary study design

Interventional

# Study type(s)

Treatment

# Health condition(s) or problem(s) studied

Chronic respiratory disease

#### Interventions

This study is a parallel, two-group, assessor- and statistician-blinded, randomised trial. The method of randomisation is minimisation. Consenting participants will be randomised at the individual level with a 1:1 allocation, using an independent web-based system provided by the United Kingdom Clinical Research Collaboration registered King's Clinical Trials Unit (CTU) to either an eight-week supervised PR programme using minimal exercise equipment (PR-min) or a standard eight-week supervised PR programme delivered using specialist exercise equipment

(PR-specialist). Both interventions will comprise two supervised sessions per week for eight weeks delivered by the same team. Outcome measures will be recorded at initial assessment for PR, following PR at 8 weeks and at 12 months.

#### Intervention Type

Behavioural

#### Primary outcome(s)

Exercise capacity measured by the incremental shuttle walk test distance at baseline and 8 weeks

#### Key secondary outcome(s))

- 1. Breathlessness measured using the Chronic Respiratory Questionnaire (CRQ) dyspnoea domain at baseline, 8 weeks and 12 months
- 2. Disease-specific health-related quality of life measured using the CRQ at baseline, 8 weeks and 12 months
- 3. Lower limb muscle strength measured using isometric quadriceps maximum voluntary contraction at baseline, 8 weeks and 12 months
- 4. Trial process details: number of patients recruited to the trial; proportion of patients that uptake, adhere to and complete PR; reasons for PR non-completion and proportions of patients satisfaction levels on the GROC. This information will be collected in each arm of the study, at the appropriate stage of the trial e.g. baseline, 8 weeks and 12 months
- 5. The cost and cost-effectiveness of the intervention from the perspective of the NHS using the Modified Service Receipt Inventory, quality-adjusted life years using the Euro-Qol 5 Dimensions 5 Levels questionnaire utility index and healthcare resource usage data obtained from NHS Digital at baseline and 12 months

Amended 06/07/2018: last timepoint corrected from 14 months to 12 months.

# Completion date

14/12/2022

# **Eligibility**

#### Key inclusion criteria

Current inclusion criteria as of 27/03/2019:

- 1. Age range: 18 years and over (updated 02/08/2018)
- 2. Gender: male and female
- 3. Physician diagnosis of stable chronic respiratory disease, typically COPD, interstitial lung disease, bronchiectasis, chronic asthma or chest wall disease (updated 27/03/2019)
- 4. Referred for PR in line with British Thoracic Society guidelines (i.e. ambulatory can walk  $\geq$ 5 metres, functional impairment related to breathlessness, typically MRC dyspnoea score  $\geq$ 2)
- 5. Able to communicate verbally and respond to questions in written English

Previous inclusion criteria:

1. Age range: 18 to 100 years 2. Gender: male and female

- 3. Physician diagnosis of stable chronic respiratory disease, typically COPD, interstitial lung disease, bronchiectasis, chronic asthma or chest wall disease with no change in medication in past 6 weeks
- 4. Referred for PR in line with British Thoracic Society guidelines (i.e. ambulatory can walk ≥5 metres, functional impairment related to breathlessness, typically MRC dyspnoea score ≥2) 5. Able to communicate verbally and respond to questions in written English

#### Participant type(s)

Patient

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Lower age limit

18 years

#### Sex

All

#### Total final enrolment

436

#### Key exclusion criteria

- 1. Contra-indication to moderate intensity physical exercise e.g. unstable cardiovascular disease
- 2. Progressive cancer or neurological disorder with expected life expectancy less than 12 months
- 3. Completed PR within previous 12 months
- 4. Unable to provide informed consent

#### Date of first enrolment

15/10/2018

#### Date of final enrolment

21/12/2021

# Locations

#### Countries of recruitment

**United Kingdom** 

England

# Study participating centre Harefield Hospital

Hill End Road

# Sponsor information

## Organisation

Royal Brompton & Harefield NHS Foundation Trust

#### **ROR**

https://ror.org/02218z997

# Funder(s)

## Funder type

Government

#### **Funder Name**

NIHR Central Commissioning Facility (CCF); Grant Codes: PB-PG-0816-20022

# **Results and Publications**

#### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available as consent was not sought from participants to share their data in this manner

# IPD sharing plan summary

Not expected to be made available

# **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/08/2025	13/08/2025	Yes	No
Protocol article		18/10/2021	06/07/2023	Yes	No
HRA research summary			28/06/2023		No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Statistical Analysis Plan	version 2.0	26/04/2023	13/11/2023	No	No