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Minimal versus specialist equipment in the delivery of pulmonary rehabilitation

Submission date 12/03/2018	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [X] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 15/03/2018	**Overall study status** Completed	
Last Edited 13/08/2025	**Condition category** 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 (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 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
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CPMS 37582

Study information

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

Acronym
MISTER

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
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 measure
Exercise capacity measured by the incremental shuttle walk test distance at baseline and 8 weeks

Secondary outcome measures
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.

Overall study start date
01/11/2017

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 ≥5 metres, functional impairment related to breathlessness, typically MRC dyspnoea score ≥2)
5. Able to communicate verbally and respond to questions in written English

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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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
432

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
England

United Kingdom

Study participating centre
Harefield Hospital
Hill End Road
Harefield
United Kingdom
UB9 6JH

Sponsor information

Organisation
Royal Brompton & Harefield NHS Foundation Trust

Sponsor details
Royal Brompton Hospital
Sydney Street
London
England
United Kingdom
SW3 6NP

Sponsor type
Hospital/treatment centre

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

Publication and dissemination plan

1. The results of this study will be published in a high-impact peer reviewed journal
2. All participants will be offered feedback on the study results (when they are published) via a letter, as specified in the consent form. They will also be invited to a research open day showcasing the latest research projects at Royal Brompton and Harefield Hospital.
3. Dissemination to charities with an interest in IPF e.g. British Lung Foundation, Asthma UK Action for Pulmonary Fibrosis.
4. Dissemination via Patient and Public Involvement routes: electronic newsletters of the collaborating local patient groups (Breathe Support Group, Breathe Easy Clubs, Singing for Breathing group) and at NIHR CLAHRC Collaborative Learning Delivery events.
5. Dissemination via social media: Twitter (accounts held by the Chief Investigator, the Royal Brompton and Harefield NHS Foundation Trust and the NIHR).

Intention to publish date

30/06/2025

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?
HRA research summary			28/06/2023	No	No
Protocol article	version 2.0	18/10/2021	06/07/2023	Yes	No
Statistical Analysis Plan		26/04/2023	13/11/2023	No	No
Results article		01/08/2025	13/08/2025	Yes	No