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A home-based exercise intervention for individuals with high blood pressure in the lungs known as pulmonary hypertension

Submission date
22/06/2020

Recruitment status
No longer recruiting

Registration date
23/06/2020

Overall study status
Completed

Last Edited
22/07/2025

Condition category
Circulatory System

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Cuurent plain English summary as of 02/02/2021:

Background and study aims
Pulmonary Hypertension (PH) is a rare, severe lung condition characterised by elevated pressure along with narrowing and blockage within the blood vessels of the lungs. Substantial evidence exists to support the benefits of exercise training and physical activity (PA) as cost-effective treatment options for many chronic diseases. On the contrary, previously, patients with PH were advised to avoid exercise because of the associated risk of sudden death, related to right heart dysfunction.
However, in recent years, evidence has emerged that exercise, carefully prescribed, can be safely used in PH patients and can significantly enhance the quality of life and physical function.
There is currently a need to evaluate training modalities, individual preferences and outcomes of home-based exercise programmes for PH patients to increase accessibility for patients.
The aim of this study is to assess the feasibility, acceptability and utility of a novel home-based exercise training program for PH patients and to assess the effect it has on patient outcomes.

Who can participate?
Adults with Pulmonary hypertension

What does the study involve?
The study involves participants taking part in testing at baseline, 10 weeks and 20 weeks. Following baseline testing participants will undertake induction training to ensure they are confident to exercise at home safely and to educte them around PH and exercise training. Participants will then complete 10 weeks- home-based exercise training and will be provided with an exercise manual, logbook, Fitbit device, exercise bike, pulse oximeter and access to video material. During the 10 weeks, they will receive telephone support by researchers. After the 10 weeks, all baseline measures will be repeated followed by semi-structured exit interviews, followed by a follow up phase at 20 weeks.

What are the possible benefits and risk of participating?
Benefits: Participants will receive a copy of their results in a report format and have the opportunity to engage in an individualised tailored exercise programme
Risks: Exercise carries with it a very small risk of abnormal heart rhythms, heart attack, or death in less than one in 30,000 patients. However, all safety measures will be in place to ensure patient safety at all time and pre-screening assist will detect any abnormalities prior to exercise. The research team are appropriately qualified and experienced working with clinical populations in a safe and professional manner.

Where is the study run from?
Dublin City University (Ireland)

When is the study starting and how long is it expected to run for?
October 2018 to June 2021 (updated 23/10/2020, previously: December 2020)

Who is funding the study?
Actelion Pharmaceuticals (Switzerland)

Who is the main contact?
Miss Ciara McCormack
ciaramccormack250@gmail.com

Previous plain English summary:

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Pulmonary Hypertension (PH) is a rare, severe lung condition characterised by elevated pressure along with narrowing and blockage within the blood vessels of the lungs. Substantial evidence exists to support the benefits of exercise training and physical activity (PA) as cost-effective treatment options for many chronic diseases. On the contrary, previously, patients with PH were advised to avoid exercise because of the associated risk of sudden death, related to right heart dysfunction.
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Who can participate?
Adults with Pulmonary hypertension

What does the study involve?
The study involves participants taking part in testing at baseline, 6 weeks and 12 weeks. Following baseline testing participants will undertake induction training to ensure they are confident to exercise at home safely and to educte them around PH and exercise training. Participants will then complete 12 weeks- home-based exercise training and will be provided with an exercise manual, logbook, Fitbit device, exercise bike, pulse oximeter and access to video material. During the 12 weeks, they will receive telephone support by researchers. After the 12 weeks, all baseline measures will be repeated followed by semi-structured exit interviews.

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Who is the main contact?
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ciara.mccormack26@mail.dcu.ie

Contact information

Type(s)
Public

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Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Design deliver and evaluate the effect of a modified home-based pulmonary hypertension exercise programme for individuals with pulmonary hypertension

Acronym
PHAHB

Study objectives
The home-based exercise intervention will be feasible and acceptable and will improve functional capacity and quality of life in patients with Pulmonary Hypertension.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 28/11/2019, Mater Misericordiae, Institutional Review Board (Eccles Street Dublin 7, Ireland; +353 (01) 803 2971; soneill@mater.ie), ref: 1/378/2032
2. Approved 06/12/2019, Dublin City University Research Ethics Committee (Research and innovation support, Dublin City University, Dublin 9, Ireland; +35317008000; research@dcu.ie), ref: DCUREC/2018/246

Study design
Single group pre-post intervention design

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Home

Study type(s)
Quality of life

Participant information sheet
Not available in web format please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Pulmonary hypertension

Interventions
Current interventions as of 02/02/2021:

Participants will undertake baseline tests, selective testing at 6 weeks, and post-intervention testing at 10 weeks. Following baseline testing, participants will complete an induction followed by a 10-week home exercise program and post intervention testing at 10 weeks followed by a follow up phase at 20 weeks.

Testing will comprise of a series of physiological and psychometric assessments. Participants will wear an accelerometer for the 7 day period to assess physical activity and sedentary behaviour at baseline, 6 weeks and post-intervention.

All participants will complete a 10-week home-based exercise programme with weekly support via telecommunications technologies and health coaching sessions. They will be provided with an exercise manual, logbook, Fitbit device, exercise bike, pulse oximeter, blood pressure monitor and real time single lead ECG/HR/respiratory rate monitor and access to video support materials. The exercise programme will consist of aerobic, resistance and respiratory training and will be individually prescribed using the FITT principle. During the weekly phone call participants progress will be reviewed and programme targets for the following week will be set.

After the 10 weeks home-programme, all baseline measures will be repeated followed by semi-structured exit interviews to assess patients acceptability of the intervention. Following this, participants will be followed up 10 weeks post-intervention and all measures will be reassessed.

Previous interventions as of 23/10/2020:

Participants will undertake baseline tests, selective testing at 6 weeks, and post-intervention testing at 10 weeks. Following baseline testing, participants will complete an induction followed by a 10-week home exercise program.

Testing will comprise of a series of physiological and psychometric assessments. Participants will wear an accelerometer for the 7 day period to assess physical activity and sedentary behaviour at baseline, 6 weeks and post-intervention.

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After the 10 weeks home-programme, all baseline measures will be repeated followed by semi-structured exit interviews to assess patients acceptability of the intervention.

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Previous interventions:
Participants will undertake baseline tests, selective testing at 6 weeks, and post-intervention testing at 12 weeks. Following baseline testing, participants will complete an induction followed by a 12-week home exercise program.

Testing will comprise of a series of physiological and psychometric assessments. Participants will wear an accelerometer for the 7 day period to assess physical activity and sedentary behaviour at baseline, 6 weeks and post-intervention.

All participants will complete a 12-week home-based exercise programme with weekly telephone support. They will be provided with an exercise manual, logbook, Fitbit device, exercise bike, pulse oximeter, blood pressure monitor and access to video support materials. The exercise programme will consist of aerobic, resistance and respiratory training and will be individually prescribed using the FITT principle. During the weekly phone call participants progress will be reviewed and programme targets for the following week will be set.

After the 12 weeks home-programme, all baseline measures will be repeated followed by semi-structured exit interviews to assess patients acceptability of the intervention.

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measure as of 23/10/2020:

The feasibility, acceptability and utility of the program for PH patients assessed via semi-structured interviews, self-reported questionnaires (at 10 weeks, see secondary outcome measures for questionnaires), participant recruitment and retention (on-going during trial), intervention adherence (ongoing during trial), patient safety and researcher field notes (ongoing during trial).

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Previous primary outcome measure:

The feasibility, acceptability and utility of the program for PH patients assessed via semi-structured interviews, self-reported questionnaires (at 12 weeks, see secondary outcome measures for questionnaires), participant recruitment and retention (on-going during trial), intervention adherence (ongoing during trial), patient safety and researcher field notes (ongoing during trial).

Secondary outcome measures

Current secondary outcome measures as of 24/04/2023:

1. Exercise capacity assessed using 6MWT at baseline, 10 weeks and 20 weeks
2. Quality of Life using PH -specific questionnaire (CAMPHPOR) at 10 weeks and 20 weeks
3. Physical activity assessed using accelerometry (ActivPAL) at baseline, 10 weeks and 20 weeks
4. Fatigue assessed by The Fatigue Severity Scale (FSS) at baseline, 10 weeks and 20 weeks
5. Self-regulatory self-efficacy for exercise using modified 11-item scale at baseline, 10 weeks and 20 weeks
6. Outcome expectations assessed by 10-items at baseline, 10 weeks and 20 weeks
7. Intentions for exercise assessed using modified intentions for exercise scale at baseline, 10 weeks and 20 weeks
8. Social support assed using social support for exercise from family and friends scale at baseline, 10 weeks and 20 weeks
9. Lower body strength assessed by Sit-to-stand at baseline, 10 weeks and 20 weeks
10. WHO Functional class assessed at baseline, 10 weeks and 20 weeks

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Previous secondary outcome measures as of 02/02/2021:

1. Exercise capacity assessed using 6MWT at baseline, 10 weeks and 20 weeks
2. Quality of Life using PH -specific questionnaire (CAMHPOR & Emphasis-10) and General SF-36 at baseline, 10 weeks and 20 weeks
3. Physical activity assessed using accelerometry (ActivPAL) at baseline, 10 weeks and 20 weeks
4. Fatigue assed by The Fatigue Severity Scale (FSS) at baseline, 10 weeks and 20 weeks
5. Self-regulatory self-efficacy for exercise using modified 11-item scale at baseline, 10 weeks and 20 weeks
6. Outcome expectations assessed by 10-items at baseline, 10 weeks and 20 weeks
7. Intentions for exercise assessed using modified intentions for exercise scale at baseline, 10 weeks and 20 weeks
8. Social support assed using social support for exercise from family and friends scale at baseline, 10 weeks and 20 weeks
9. Lower body strength assessed by Sit-to-stand at baseline, 10 weeks and 20 weeks
10. WHO Functional class assessed at baseline, 10 weeks and 20 weeks

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Previous secondary outcome measures as of 23/10/2020:

1. Exercise capacity assed using 6MWT at baseline and 10 weeks
2. Quality of Life using PH -specific questionnaire (CAMHPOR & Emphasis-10) and General SF-36

at baseline and 10 weeks
3. Physical activity assessed using accelerometry (ActivPAL) at baseline and 10 weeks
4. Fatigue assed by The Fatigue Severity Scale (FSS) at baseline and 10 weeks
5. Self-regulatory self-efficacy for exercise using modified 11-item scale at baseline and 10 weeks
6. Outcome expectations assessed by 10-items at baseline and 10weeks
7. Intentions for exercise assessed using modified intentions for exercise scale at baseline and 10 weeks
8. Social support assed using social support for exercise from family and friends scale at baseline and 10 weeks
9. Lower body strength assessed by Sit-to-stand at baseline and 10 weeks
10. WHO Functional class assessed at baseline and 10 weeks

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Previous secondary outcome measures:

1. Exercise capacity assed using 6MWT at baseline, 6 weeks and 12 weeks
2. Quality of Life using PH -specific questionnaire (Emphasis-10) and General SF-12 at baseline , 6 weeks and 12 weeks
3. Physical activity assessed using accelerometry (ActivPAL) at baseline, 6 weeks & 12 weeks
4. Fatigue assed by The Fatigue Severity Scale (FSS) at baseline and 12 weeks
5. Exercise Self-Efficacy assed using the ESES scale at baseline and 12 weeks
6. Barriers to exercise assed using the BARSE scale at baseline and 12 weeks
7. Intentions for exercise assessed using modified intentions for exercise scale at baseline and 12 weeks
8. Social support assed using social support for exercise from family and friends scale
9. Lower body strength assessed by Sit-to-stand at baseline and 12 weeks
10. WHO Functional class assessed at baseline and 12 weeks

Overall study start date
01/10/2018

Completion date
01/06/2021

Eligibility

Key inclusion criteria
1. Age >18 years
2. PH diagnosed by right heart catheter showing baseline mean pulmonary arterial pressure ≥25 mm Hg
3. Pulmonary vascular resistance ≥240 dyn·s/cm5
4. Pulmonary capillary wedge pressure ≤15 mmHg
5. Receiving optimised conventional PH therapy including intensified treatment with diuretics and, who have been stable for the previous 3 months
6. Except for diuretics, medical treatment should not be expected to change during the study period
7. Negative pregnancy test (β-HCG) at the start of the trial and counselling on the need to avoid pregnancy during the study for women with child-bearing potential
8. Ablility to understand and willing to sign the Informed consent form

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
25

Key exclusion criteria
1. PH of any cause other than permitted in the entry criteria, (e.g., concomitantly to portal hypertension, complex congenital heart disease, reversed shunt and HIV infection)
2. Signs of right heart decompensation
3. Acute infection and pyrexia
4. Change in disease-targeted therapy within the last 2 months
5. Scheduled to receive an investigational drug during the course of the study
6. FEV1/FVC <0.5, total lung capacity <70% of the normal value
7. Active liver disease, porphyria
8. Elevations of serum transaminases >3 x upper limit of normal (ULN), bilirubin > 1.5 x ULN
9. Haemoglobin concentration <75% of the lower limit of normal
10. Systolic blood pressure <85 mmHg
11. Active myocarditis, unstable angina pectoris, exercise induced ventricular arrhythmias, decompensated heart failure, hypertrophic obstructive cardiomyopathy or highly impaired left ventricular function

Date of first enrolment
01/07/2020

Date of final enrolment
02/02/2021

Locations

Countries of recruitment
Ireland

Study participating centre
Dublin City University
Glasnevin
Dublin
Ireland
-

Study participating centre
Mater Misericordiae University Hospital
Eccles Street
Dublin
Ireland
-

Sponsor information

Organisation
Mater Misericordiae University Hospital

Sponsor details
Eccles Street
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+353 01 803 2000
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Sponsor type
Hospital/treatment centre

Website
https://www.mater.ie/

ROR
https://ror.org/040hqpc16

Funder(s)

Funder type
Industry

Funder Name
Actelion Pharmaceuticals

Alternative Name(s)
Actelion Pharmaceuticals Ltd

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Switzerland

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
06/06/2021

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		10/05/2021	12/05/2021	Yes	No
Other publications	The impact of gas transfer on responses to exercise training in patients with pulmonary hypertension	25/09/2024	22/07/2025	Yes	No
Results article		08/01/2024	22/07/2025	Yes	No