A randomized controlled trial to evaluate the safety and efficacy of an 8-week home-based standardized exercise training program for preventing post-pulmonary embolism syndrome: the PE@HOME study

Published: 24-01-2022
Last updated: 30-01-2025

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Pulmonary vascular disorders
Study type	Interventional

Summary

ID

NL-OMON54292

Source
ToetsingOnline

Brief title
PE@HOME

Condition

- Pulmonary vascular disorders
- Embolism and thrombosis

Synonym
pulmonary embolism, venous thromboebolism

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Vriendenloterij en trombosestichting

Intervention

Keyword: Exercise training, Post PE-syndrome, Pulmonary embolism

Outcome measures

Primary outcome

The primary outcome is the relative increase in CWRT (%). Calculated as: (CWRT after intervention [seconds] - CWRT at baseline [seconds]) / CWRT at baseline [seconds].

Secondary outcome

Secondary outcomes include PROMS for functional status (post-VTE functional status scale), dyspnea (Medical Research Council [MRC] dyspnea scale), generic QoL (5-level EQ-5D), disease specific QoL (PEmbQoL), exhaustion fatigue (Checklist Individual Strength - fatigue domainseverity subscale), anxiety (Hospital Anxiety and Depression [HADS] scale), Work Productivity (Work Productivity and Activity Index), patient activation engagement in health care (Patient Activation Measure), exercise motivation (Behavioral Regulation and Exercise Questionnaire 2), at 4 weeks, 8 weeks, 3 months and 6 months following randomisation. In addition, we will evaluate and compare the proportion of patients achieving a relevant improvement of the CWRT (>100 seconds absolute improvement), metabolic

parameters and Borg scores of the cardiopulmonary exercise test (CPET), level of activity as measured with wearable during the intervention and after 6 months of follow-up, cost effectiveness, and lastly adherence to the exercise program. The main safety outcome involves overall survival, incidence of serious adverse events (SAE) and healthcare utilisation during the study period.

Study description

Background summary

After acute pulmonary embolism (PE), up to half of patients report persistent dyspnea and/or functional limitations despite adequate anticoagulant treatment. The so-called Post-PE Syndrome (PPES) is characterized by functional limitations and decreased quality of life in PE patients with or without abnormalities in cardiorespiratory function. Etiologies explaining PPES include chronic thromboembolic pulmonary hypertension (CTEPH), chronic thromboembolic pulmonary disease (CTEPD) and chronic right ventricular impairment, but mostly deconditioning. Depressive disorders, fear for complications or recurrences, and post-thrombotic panic syndrome further contribute to long-term functional impairment, which may lead to physical inactivity, subsequent deteriorating deconditioning and a downward spiral as result. Early exercise training likely has positive effects on exercise capacity and quality of life in both PE and CTEPH patients, although adequate quality trials investigating exercise training to prevent PPES are currently unavailble.

Study objective

The primary objective of the study is determine the effect of an 8-week standardized exercise training program in patients with persistent functional limitations 4 weeks after a diagnosis of acute PE, on physical performance (as assessed by the constant Work Rate cycle Test [CWRT]). Secondary objectives include the incidence of PPES (as assessed with patient reported outcome measures (PROMS) on quality of life (QoL), symptom severity, work productivity, activation, functional limitations and exercise motivation), the difference in physical activity, the cost-effectiveness of the 8-week intervention, and to

determine safety of the intervention

Study design

Randomized controlled, open label clinical trial with blinded endpoint assessment and 6-month follow-up.

Intervention

One group is subjected to a an 8-week, home-based standardized exercise training program using a cycle ergometer, supervised by a board certified physiotherapist, the other group receives a folder with general recommendation on a healthy lifestyle and physical activity.

Study burden and risks

All study patients will be subjected to CPET and CWRT before randomisation and after 8-weeks (4 clinical visits). No other study visits to the clinic will be necessary since all other outcomes are measured via a web based dashboard collecting all PROMS during the study, or via a wearable. The study will not interfere with routine patient care, including but not limited to anticoagulant treatment and both frequency and nature of follow-up visits to the outpatient clinic. Patients randomized to the active treatment arm will receive a cycle ergometer at home for the duration of the intervention and are asked to comply to the exercise program. The training will be remotely supervised by board certified physiotherapist and monitored by the study coordinator. Patients randomised to the control arm will be asked to consider the recommendations for a healthy life style (standard folder of the Dutch Heart Foundation; *Bewegen doet wonderen*) and to resume their usual physical activity. The study intervention will ask a considerable effort of the patient, but comes at the expected benefit of substantial improvement in physical fitness and quality of life. The risk of adverse events in this study is very low.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

-Provision of informed consent prior to any study specific procedures.
-Be diagnosed with a confirmed symptomatic acute PE <4 weeks before randomization
-Be aged 18 years or older
-Report dyspnoea (MRC 2 points or more) and functional limitations (PVFS scale 2 or higher)

Exclusion criteria

-Incapability to follow study procedures (including but not limited to participate in the exercise training program, have WiFi at the patients house to connect the cycle ergometer to the platform, or follow instructions of the research team and complete the web-based PROMS).
-Life expectancy shorter than 6 months
-Presence of settings (e.g. pregnancy) or comorbidities (e.g. planned surgery or cancer with systemic anticancer therapy) requiring intensive treatment that would interfere with the exercise program
- Chronic dyspnoea in the setting of known or suspected serious cardiopulmonary comorbidities: CTEPH, COPD >GOLD II, heart failure > New York Heart Association Classification (NYHA) 2 or interstitial lung diseases.

- Previous inclusion in the study
- COVID associated pulmonary embolism
- CWRT >15 minutes at baseline
- Contra-indication for Cardiopulmonary Exercise Testing (CPET) conform ATS-guideline (e.g. severe right ventricular strain with massive PE)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	14-02-2022
Enrollment:	156
Type:	Actual

Medical products/devices used

Generic name:	Advanced Ergometer Corival CPET
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	24-01-2022
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	24-06-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	17-05-2023
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	08-11-2024
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL78517.058.21
Other	NTR NL9615