A randomized trial to evaluate a home-based standardized exercise training program for preventing post-pulmonary embolism syndrome

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27136

Source
NTR

Brief title
PE@HOME

Health condition

Pulmonary embolism

Sponsors and support

Primary sponsor: LUMC
Source(s) of monetary or material Support: LUMC, trombose stichting, vriendenloterij

Intervention

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 an 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.
In this study we want to 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 objective

we aspect patient who are subjected to a 8-week exercise training program to have an improved endurance, functional performance, QoL and mental state compared to the control group

Study design

Visit 1 (phone):
- Check for in and exclusion criteria
- MRC and PVFS questionnaire

Vist 2:
- Obtain informed consent
- CPET
- Wearable

Visit 3:
- CWRT
- Randomization
- PROMS/questionnaires

Visit 4:
- CPET

Visit 5:
- CWRT

Contact physiotherapist before and at 1, 3 and 6 week(s) of the intervention
PROMS/questionnaires will be send (digitally) at 4 weeks, 6 weeks, 3 months and 6 months after randomization

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.

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following 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

A potential subject who meets any of the following criteria will be excluded from participation in this study:
 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 training program
 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
 If a patient has contra-indication for CPET as determined by the treating physician considering the ATS-guideline

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2022
Enrollment:	90
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL9615
Other	METC LDD : P21.103

Study results