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

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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

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27136

Bron
Nationaal Trial Register

Verkorte titel
PE@HOME

Aandoening

Pulmonary embolism

Ondersteuning

Primaire sponsor: LUMC
Overige ondersteuning: LUMC, trombose stichting, vriendenloterij

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel

Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2022
Aantal proefpersonen:	90
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9615
Ander register	METC LDD : P21.103

Resultaten