Evaluation of a personalized home-based exercise program for patients with combined chronic cardiac and pulmonary disease: a feasibility study

Published: 06-11-2018
Last updated: 11-04-2024

The primary objective is to determine feasibility of a home-based exercise program in a pilot study with patients with combined chronic pulmonary and cardiac disease.Secondary objectives are to evaluate patient satisfaction and changes in functional…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Heart failures
Study type	Interventional

Summary

ID

NL-OMON46005

Source
ToetsingOnline

Brief title
-

Condition

- Heart failures
- Bronchial disorders (excl neoplasms)

Synonym
combination of different chronic pulmonary and cardiac diseases, not applicable

Research involving
Human

Sponsors and support

Primary sponsor: Maxima Medisch Centrum
Source(s) of monetary or material Support: Sponsorbijdrage remote monitoring Bayer en Novartis

Intervention

Keyword: Combined cardiac and pulmonary disease, Exercise program, Feasibility, Home-based

Outcome measures

Primary outcome

The primary endpoint is feasibility of a home-based exercise program (i.e. the

ability to complete the exercise program and a qualitative exploration of

barriers for adherence).

Secondary outcome

Secondary endpoints include patient satisfaction, functional capacity and

quality of life.

Study description

Background summary

Chronic cardiac and pulmonary diseases often co-exist and both diseases are associated with high morbidity and mortality. Exercise is a proven effective strategy in these patients to reduce the risk of rehospitalization and improve functional capacity. However, due to breathlessness, muscle atrophy and anxiety, patients with combined cardiac and pulmonary disease generally have low activity levels and have low motivation to participate in centre-based rehabilitation programs. To improve exercise behaviour in the home environment we aim to conduct a pilot-study to evaluate the feasibility of a telemonitored home-based exercise program.

Study objective

The primary objective is to determine feasibility of a home-based exercise

program in a pilot study with patients with combined chronic pulmonary and cardiac disease.
Secondary objectives are to evaluate patient satisfaction and changes in functional capacity and quality of life. Data generated from this pilot study will be used to design a larger randomized controlled trial.

Study design

This is a prospective, non-randomized, single-center pilot study evaluating feasibility.

Intervention

Patients included will receive a two-month home-based exercise program and are coached by a physiotherapist and/or ergo therapist via video calls. The content of this exercise program will be based on personal goals set at the baseline intake.

Study burden and risks

Exercise training, both in a centre-based and a home-based setting, has been proven to improve quality of life and functional capacity and to reduce risk of rehospitalization in both patients with chronic heart failure and COPD. Several studies showed that telerehabilitation can be safely performed and is not associated with additional risks. To further minimize the risk of adverse events, the exercise program consists of low-to-moderate intensity exercises. Despite the potential benefits of exercise training, the training sessions and uploading results afterwards may be experienced as a burden for patients.

Contacts

Public
Maxima Medisch Centrum

De Run 4600
Veldhoven 5504 DB
NL
Scientific
Maxima Medisch Centrum

De Run 4600
Veldhoven 5504 DB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Patients with combined chronic pulmonary and cardiac disease already participating in remote patient care.
2. Motivated to participate in an exercise program.
3. Age * 18 years.
4. Speaking, writing and reading the Dutch language.

Exclusion criteria

1. Neurological, orthopaedic of peripheral vascular conditions preventing the patient from performing exercise.
2. Hemodynamic significant valvular disease.
3. Proven cardiac ischemia or heart rhythm disturbances at a low-intensity exercise level.
4. Already participating in the IN-TOuCH trial (telemonitoring for patients with COPD and chronic heart failure)
5. Already receiving physio- and/or occupational therapy.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-10-2019
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO Date:	06-11-2018
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	27-02-2019
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	18-06-2019
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	30-09-2019
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	08-06-2020
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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	NL67504.015.18