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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24873

Source
NTR

Brief title
TBA

Health condition

Combined chronic cardiac and pulmonary disease

Sponsors and support

Primary sponsor: Máxima Medical Centre, Eindhoven/Veldhoven, The Netherlands
Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

To determine the feasibility (i.e. the ability to complete the exercise program and a

qualitative exploration of barriers for adherence) of a home-based exercise program in a pilot study with patients with combined chronic pulmonary and cardiac disease.

Secondary outcome

- Patient satisfaction with the program.
- Safety of the program.
- Changes in 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 center based rehabilitation programs. To improve exercise behavior in the home environment we aim to conduct a pilot-study to evaluate the feasibility of a telemonitored home-based exercise program. The results of this study will be used to design a larger randomized trial.

Study objective

A novel, home-based, goal-orientated exercise program for patients with combined chronic cardiac and pulmonary disease is feasible and safe.

Study design

At baseline / intake the following questionnaires and functional tests will be obtained:
- EQ-5D-5L (quality of life) questionnaire
- mMRC dyspnea scale
- One-minute sit-to-stand test
- Handgrip test
- Patient Specific Complaints (PSC) questionnaire

At final evaluation the following questionnaires and functional tests will be obtained:
- EQ-5D-5L (quality of life) questionnaire
- mMRC dyspnea scale
- One-minute sit-to-stand test
- Handgrip test
- Patient Specific Complaints (PSC) questionnaire
- CSQ-8 (patient satisfaction) questionnaire
- Purpose-designed patients satisfaction questionnaire

Intervention

Eligible patients participate in an 8 week home-based, goal-orientated exercise program. The program begins with in an intake at the outpatient physical therapy clinic of Máxima MC. This intake is performed with both a physical therapist and an occupational therapist. Based on this intake, the patient receives a personalized, goal-orientated exercise program using a digital platform to report training sessions and a smartwatch. Weekly video consultations take place to discuss progress and to adjust the training scheme if needed. Also, the digital platform is equipped with an activity diary to be filled in by the patient for evaluation with the occupational therapist. After 8 weeks a final evaluation takes place at the outpatient physical therapy clinic.

Contacts

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Eligibility criteria

Inclusion criteria

- Patients with combined chronic pulmonary and cardiac disease already participating in remote patient care.
- Motivated to participate in an exercise program.
- Age ≥ 16 years.
- Speaking, writing and reading the Dutch language.

Exclusion criteria

- Neurological, orthopedic or peripheral vascular conditions preventing the patient from performing exercise.
- Hemodynamic significant valvular disease.

- Proven cardiac ischemia or heart rhythm disturbances at a low-intensity exercise level.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-12-2019
Enrollment:	10
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Plan description
N/A

Ethics review

Positive opinion

Date:	08-01-2021
Application type:	First submission

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	NL9182
Other	METC MMC : W18.116

Study results