The feasibility of a home-based remotely supervised maintenance exercise training program in patients with COPD

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To evaluate the safety, feasibility and efficacy of an 8-week remotely supervised home-based maintenance exercise training program following pulmonary rehabilitation in patients with COPD.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Observational non invasive

Summary

ID

NL-OMON51560

Source
ToetsingOnline

Brief title
The feasibility of a home-based maintenance exercise program in COPD

Condition

- Bronchial disorders (excl neoplasms)

Synonym
Chronic bronchitis, pulmonary emphysema

Research involving
Human

Sponsors and support

Primary sponsor: Ciro

Source(s) of monetary or material Support: Ciro

Intervention

Keyword: COPD, home-based exercise training

Outcome measures

Primary outcome

- Feasibility will be assessed by the adherence to home-based maintenance exercise training sessions (i.e. the number of completed training sessions uploaded in the web-portal and training variables of these sessions (duration, intensity)).

- Safety will be assessed by the number of (S)AEs.

- Efficacy will be assessed by the change in exercise capacity on constant work rate cycle test (endurance time, Borg scores for dyspnea and fatigue).

Secondary outcome

- To explore changes in functional exercise capacity assessed on 6 minute walk test.

- To explore changes on patient-reported outcomes using COPD Assessment Test and Hospital Anxiety and Depression Scale.

- To explore differences in physical activity between exercise and non-exercise days, assessed using an accelerometer (ActiGraph GT9X Link, Pensacola, FL, USA).

- To explore patient satisfaction using a structured interview and the Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST).

Study description

Background summary

There is strong evidence supporting the benefits of pulmonary rehabilitation for people with COPD, though exercise capacity and health-related quality of life diminish in the 12 months after program completion. Therefore, there is growing interest in the role of maintenance programs. Remotely supervised maintenance strategies are emerging in patients with COPD, however, the effectiveness of these remote home-based maintenance programs are still unclear.

Study objective

To evaluate the safety, feasibility and efficacy of an 8-week remotely supervised home-based maintenance exercise training program following pulmonary rehabilitation in patients with COPD.

Study design

Prospective observational pilot study

Study burden and risks

There is very low risk associated with participation in this study, since no invasive procedures will be performed. The burden of the study is mainly the investment of the patients' time. Patients will have to perform an 8-week home-based maintenance exercise training program and an extra visit to Ciro to perform an six-minute walk test and constant work rate cycle test. However, this time investment is expected to have beneficial effects in terms of improved exercise capacity and quality of life for the patients and therefore we consider the burden proportional.

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

- Confirmed diagnoses of COPD.
- Clinical stable as assessed by the chest physician.
- Participation in cycle training during pulmonary rehabilitation.
- No balance problems as assessed by the Tinetti test during the intake with the physiotherapist in the routine baseline assessment (score >= 24).
- Internet (Wi-Fi) access at home.
- Provision of informed consent prior to any study specific procedures.
- Complete data on study endpoints (i.e. constant work rate cycle test, six-minute walk test, COPD Assessment Test, Hospital Anxiety and Depression Scale).

Exclusion criteria

- Lack of motivation for voluntary participation in the study.
- Insufficient ability to read, write or understand the Dutch language.
- Incapability to follow study procedures (including but not limited to participate in the exercise training program or follow instructions of the research team).

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	29-01-2024
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	08-12-2022
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL81964.100.22