Telerehabilitation in patients with recent hospitalization due to acute decompensated heart failure.

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To investigate if CTR in recently hospitalized congestive heart failure (CHF) patients improves their physical functional capacity when compared to usual care. Secondary objectives are recovery from submaximal exercise evaluated with a constant-load...

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

Summary

ID

NL-OMON56416

Source
ToetsingOnline

Brief title
Tele-ADHF

Condition

- Heart failures

Synonym
acute decompensated heart failure, Heart failure

Research involving
Human

Sponsors and support

Primary sponsor: Maxima Medisch Centrum
Source(s) of monetary or material Support: Philips,Topconsortium voor Kennis en Innovatie (TKI) Hightech Systemen & Materialen (HTSM)

Intervention

Keyword: Acute decompensated heart failure, Cardiac telerehabilitation, Remote Patient Monitoring (RPM)

Outcome measures

Primary outcome

The primary endpoint is physical functional capacity described using the Short Physical Performance Battery (SPPB) score, which is assessed at week 0, week 18 and week 26.

Secondary outcome

Secondary endpoints are recovery after submaximal exercise by evaluating VO2 recovery kinetics (tau-rec), subjective health status evaluated with Kansas City Cardiomyopathy Questionnaire (KCCQ), health related quality of life (HRQOL) evaluated with the Minnesota Living with Heart Failure Questionnaire (MLHFQ), compliance and acceptance to the rehabilitation program, and readmission rate.

Study description

Background summary

Cardiac rehabilitation (CR) has favourable effects in chronic heart failure (CHF) patients on exercise capacity, the risk at hospital (re-)admission and quality of life. Although CR is generally recommended, it is still under-utilized in daily clinical practice mainly due to patient related factors (e.g. dependence on others for transportation, high level of disability). Therefore, we hypothesize that home-based rehabilitation (cardiac telerehabilitation, CTR) tailored to individual disabilities is an attractive and feasible alternative for CHF patients with favourable long-term outcomes.

Study objective

To investigate if CTR in recently hospitalized congestive heart failure (CHF) patients improves their physical functional capacity when compared to usual care. Secondary objectives are recovery from submaximal exercise evaluated with a constant-load test, disease specific quality of life, adherence to the program and readmission rate.

Study design

Prospective randomised controlled trial.

Intervention

An 18-weeks multidisciplinary telerehabilitation program with exercise training by physical and occupational therapist, supported by a (remote) technology-assisted dietary intervention and mental health guiding by a physiologist. The training program starts with three centre-based and two home-based video exercise training sessions followed by video coaching sessions. The mental health and dietary program are executed using individual and group video sessions.

Study burden and risks

CR is associated with reduction of cardiovascular mortality, morbidity and disability and increases quality of life. The additional risk from CTR is expected to be low as previous research showed that home-based training in HF patients is safe. To minimize potential risks, all patients start with 5 supervised training sessions, followed by a personalized home-based training program with telemonitoring guidance.

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

- Age 18 years and above
- Diagnosed with congestive heart failure
- Hospitalization primarily for acute decompensated heart failure (ADHF) at the time of inclusion
- Sufficient digital capacity or caretaker with digital capacity
- Able to speak and read the Dutch language

Exclusion criteria

- Unable to understand the purpose and procedures of the study
- Unable to mobilize (e.g. due to orthopaedic limitations)
- Recent CR program followed (latest 12 months)
- No internet connection
- Untreated life-threatening cardiac arrhythmias
- Early phase after acute coronary syndrome (latest 3 months)
- Uncontrolled hypertension
- Advanced atrioventricular block
- Severe aortic stenosis
- Up-coming major (cardiac) surgery in 3 months

Study design

Design

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

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-10-2021
Enrollment:	90
Type:	Actual

Ethics review

Approved WMO Date:	08-10-2021
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	08-11-2021
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	21-02-2022
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	23-05-2023
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	15-08-2023
Application type:	Amendment

Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	08-05-2024
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	02-12-2024
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

ID: 27821
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL78154.015.21
Other	NL9619
OMON	NL-OMON27821