Telerehabilitation in patients with recent hospitalization due to Acute Decompensated Heart Failure.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27821

Source
NTR

Brief title
Tele-ADHF

Health condition

Congestive heart failure

Sponsors and support

Primary sponsor: Máxima Medisch Centrum, Dominee Theodor Fliednerstraat 1, 5631 BM Eindhoven, The Netherlands
Source(s) of monetary or material Support: Internal funding

Intervention

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-12), 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). We hypothesize that comprehensive home-based rehabilitation with remote guidance (cardiac telerehabilitation, CTR) tailored to individual disabilities has beneficial effects on the functional capacity in patients after hospital admission due to acute decompensated heart failure.

Study objective

We hypothesize that comprehensive home-based rehabilitation with remote guidance (cardiac telerehabilitation, CTR) tailored to individual disabilities has beneficial effects on the functional capacity in patients after hospital admission due to acute decompensated heart failure.

Study design

Inclusion: during admission to the hospital primarily due to acute decompensated heart failure (ADHF).
Pre-intervention: uptitration of heart failure medication, follow-up with Remote Patient Monitoring (RPM).
Randomization: after stabilization and first outcome measurement (T0) the participants will be randomized to control or intervention group.
Intervention: 18 weeks telerehabilitation program vs. no rehabilitation.
T1: 18 weeks after start intervention.
T2: 26 weeks (6 months) after starting the intervention.

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.

Contacts

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Eligibility criteria

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

- Symptomatic aortic stenosis
- Up-coming (cardiac) surgery in 6 months

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2021
Enrollment:	64
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 56416
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL9619
CCMO	NL78154.015.21
OMON	NL-OMON56416

Study results