RCT Extended and Comprehensive E-health Modalities to Improve OutcomE in Patients with WorseneD Heart Failure (EXCEED-HF)

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

Summary

ID

NL-OMON51343

Source
ToetsingOnline

Brief title
EXCEED-HF

Condition

- Heart failures

Synonym
'heart failure'

Research involving
Human

Sponsors and support

Primary sponsor: OLVG

Source(s) of monetary or material Support: interne financiering via afdeling cardiologie research van het OLVG

Intervention

Keyword: 'Heart Failure', 'Remote monitoring', 'Telemedicine', 'Telemonitoring'

Outcome measures

Primary outcome

The primary endpoint is a composite of time to all-cause mortality or first WHF event, comparing the intervention on top of standard HF care with standard HF care alone at 180 days of follow-up.

The co-primary endpoint is the total number of (recurrent) WHF events at 180 days of follow-up.

The definition of a WHF event is a HF hospitalization (unscheduled admission > 6 hours), urgent HF visit resulting in iv diuretic treatment, outpatient treatment with iv diuretics or outpatient intensification of oral diuretics.

Secondary outcome

The main secondary endpoints are the total number of the individual components of WHF events (HFH, UHF, outpatient treatment with iv diuretics and outpatient intensification of oral diuretics) at 30 and 180 days follow-up and time to (all-cause and cardiovascular) mortality and first WHF event at 180 days follow-up. Also, the effect of the RM strategy on total number of all cause hospitalizations at 30 and 180 days follow-up will be analysed.

Finally, change in quality of life assessed with the KCCQ questionnaire between baseline (T0) and 180 days follow-up is analysed.

Exploratory endpoints include health care consumption, cost-effectiveness,

medication adherence and patient and caregiver satisfaction.

Study description

Background summary

Remote Monitoring (RM) or telemonitoring (TM) has been widely used in patients with heart failure (HF) to monitor for signs and symptoms of worsening HF (WHF) aiming to reduce HF (re)hospitalization rates. However, the efficacy of RM in achieving this goal remains debatable as multiple randomized clinical trials reported neutral outcomes opposed to meta-analyses demonstrating beneficial effects of RM on HF (re)hospitalization rates. Previous studies differed in study design, endpoints and organization of HF care and used a broad variety of different RM modalities in distinct and heterogeneous HF patient populations, which may explain the ambiguity in outcome results observed in RM trials and registries. Nevertheless, continuous development of novel TM modalities, (HF) nurse guided home care programs and multidisciplinary network collaborations provide HF care specialists with new tools that could potentially contribute to improved guidance and outcomes of HF patients. However, to demonstrate the efficacy of RM and outpatient multidisciplinary home care based programs in improving prognosis, the need for properly designed randomized controlled clinical trials unequivocally remains. In this regard, the current study will investigate the efficacy of a combined intervention including TM, HF nurse guided home care and multidisciplinary network collaboration (using Virtual Ward and cBoards system) in improving all-cause mortality and WHF events (including HF hospitalizations, urgent HF visits and outpatient worsening) in different WHF patient populations. Our hypothesis is that an extended and comprehensive RM strategy on top of standard HF care, consisting of regular outpatient cardiologist and HF nurse treatment and guidance, is superior to standard HF care alone to reduce WHF events and mortality in patients with WHF.

Study objective

The primary objective is to demonstrate efficacy of an extended remote monitoring intervention, including a TM app, HF nurse guided home care and multidisciplinary network collaboration using the Virtual Ward platform, on top of standard HF care consisting of regular outpatient cardiologist and HF nurse treatment and guidance in patients with worsening heart failure.
Secondary and exploratory
Secundaire en exploratieve objectives include to determine the effect of the intervention versus standard care on quality of life and cost-effectiveness of the intervention.

Study design

A single center, prospective, unblinded, randomized clinical trial.

Intervention

Group 1: an extended multimodality remote monitoring intervention including telemonitoring with the Luscii heart failure app, nurse home visits by Cordaan heart failure home care and a network care platform using Virtual Ward and cBoards.
Group 2: control group receiving standard heart failure care.

Study burden and risks

The burden of participating in the trial is limited to 4 study visits including physical examination and a limited laboratory assessment that is part of the standard heart failure care (so no additional laboratory assessments). Furthermore, patients are asked to fill in two questionaires concerning quality of life and the impact of heart failure symptoms at the start end end of study. The intervention group will be asked to add measurements in the smartphone application twice a week and will receive home visits by heart failure nurses ranging from once a week to once every two weeks.
No potential harm is to be expected from using the Luscii or Virtual Ward application and remote monitoring.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Age > 18 years
- Written informed consent
- Permission for data sharing through Luscii heart failure application and/or Virtual Ward and cBoards telemonitoring programme
- Availability of a proper computer device (including smartphones) for the use of Luscii heart failure application
- Diagnosis of new onset or chronic heart failure, independent of LVEF, with an episode of WHF requiring intravenous treatment with diuretics* in the past 7 days before randomization
*WHF for inclusion defined as: HF hospitalization, urgent HF visit resulting in iv diuretic treatment or outpatient treatment with iv diuretics.

Exclusion criteria

- New onset heart failure in case of primary reason of admission being supraventricular tachycardia accompanied by mild decompensation without need for continuation of diuretics at time of hospital discharge
- Glomerular Filtration Rate (GFR) <20 ml/min (obtained within 2 weeks of the baseline visit), refractory to diuretic therapy, or on chronic renal dialysis
- Unable to use and/or unavailability of a computer device or smart phone application
- Simultaneous participation in any other intervention study or remote monitoring programme is not allowed.

Study design

Design

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

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	27-10-2022
Enrollment:	243
Type:	Actual

Medical products/devices used

Generic name:	Luscii heart failure application and cBoards
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	21-07-2022
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	NL81244.100.22