The Box Heart Failure

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In this study we would like to investigate the clinical effectiveness of a smart technology intervention (The Heart Failure Box) in heart failure patients from the department of Cardiology at Leiden University Medical Center.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Heart failures
Study type	Observational non invasive

Summary

ID

NL-OMON26613

Source
NTR

Brief title
The Box HF

Condition

- Heart failures

Health condition

Heart Failure

Research involving
Human

Sponsors and support

Primary sponsor: NA
Source(s) of monetary or material Support: LUMC

Intervention

- Medical device

Explanation

Outcome measures

Primary outcome

The primary objective of the study will be to investigate whether smart technology in the form of The Heart Failure Box can decrease the number of cardiac decompensation-related visits to the emergency department and/or- outpatient clinic, and hospital admissions for decompensation when compared to standard care, measured until 1 year after patients start using the smart technology.

Secondary outcome

Secondary Objective(s): 1. Quality of life 2. Patient satisfaction of care 3. Re-admission for heart failure 4. Cost-effectiveness 5. Time to admission for decompensation 6. Duration of admission 7. Total duration of decompensation phase 8. Admission for other causes 9. Overall mortality 10. Major adverse cardiac events a. Cardiac death b. Myocardial infarction c. Ischaemíc stroke

Study description

Background summary

Currently, heart failure patients are advised to regularly monitor their weight and contact the outpatient clinic when experiencing symptoms of heart failure. Nonetheless, 32% of patients are admitted within 30 days after the diagnosis heart failure has been made and 25% of heart failure patients are readmitted within the first month after an admission for heart failure, indicating a need for improved early warning for heart failure. A scientific statement of the AHA regarding transitions of care in heart failure shows that patients have difficulties recognizing symptoms and are uncertain when it comes to unsupervised self-monitoring. As a consequence, patients often contact the outpatient clinic too late with a higher risk of hospitalization. Smart technology (The Box) can support patients by giving them more insight into their own health status and may identify disease worsening at an early stage, which can lead to timely detection and treatment, possibly reducing hospitalization for decompensation. Therefore, in this study, we would like to investigate the clinical effectiveness of a smart technology intervention (The Heart Failure Box) in heart failure patients from the department of Cardiology at Leiden University Medical Center. This is a study with abefore-after comparison.

Study objective

In this study we would like to investigate the clinical effectiveness of a smart technology intervention (The Heart Failure Box) in heart failure patients from the department of Cardiology at Leiden University Medical Center.

Study design

12 months

Intervention

Patients who consent to take part in the study receive a box containing a weight scale, thermometer, activity tracker, sleep sensor and a blood pressure monitor. All data will be measured regularly by the patient and uploaded into a mobile app which is accessible for both patient and caregiver. In addition patients will be asked questions about their general health and to monitor their fluid intake.

Contacts

Public
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Scientific
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Eligibility criteria

Age
Adults (18-64 years)
Adults (18-64 years)
Elderly (65 years and older)
Elderly (65 years and older)

Inclusion criteria

-Patient has heart failure according to the ESC guideline -Patient is able to communicate in English or Dutch -Patient is treated in the outpatient clinic by a cardiologist from the Leiden University Medical Center

Exclusion criteria

-Patient is < 18 years old -Patient is pregnant -Patient does not have internet access at home -Patient is considered an incapacitated adult -Patient is unwilling to sign the informed consent form

Study design

Design

Study phase:	N/A
Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Historical
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-10-2021
Enrollment:	243
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Approved WMO

Date:	26-08-2020
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

ID: 49254
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8492
CCMO	NL73432.058.20
OMON	NL-OMON49254

Study results