The Box Heart Failure: using smart technology for early detection of decompensation in heart failure patients

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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.

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

Summary

ID

NL-OMON49254

Source
ToetsingOnline

Brief title
The Box Heart Failure

Condition

- Heart failures

Synonym
decompensated heart failure, heart failure

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: LUMC (Box 2.0)

Intervention

Keyword: Box, eHealth, Heart failure, Home monitoring

Outcome measures

Primary outcome

Primary Objective: 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, hospital admissions for decompensation and heart failure related, 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. Ischaemic 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.

Study objective

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.

Study design

This is a study with a before-after comparison.

Study burden and risks

Patients will have to measure their weight, temperature, blood pressure and heart rate on a regular basis. In addition they will use a sleepsensor and activity tracker. Regularly, they also will be asked questions about their general health and to monitor their fluid intake. They will fill in the Minnesota Living with Heart Failure Questionnaire (MLHFQ) when receiving the devices at the start of the study and 1 year afterwards. Patients who have an left ventricular assist device will be asked additional questions about the function of their device and necessary medication. These activities may take some of their time.
All devices used by patients for personal management in this study are

non-invasive, easy-to-use and electrically safe within its intended use. Using the devices is with very limited risks.
This study has some potential benefits for patients: First, patients can measure their own blood pressure, pulse and weight, which can reassure patients and give them more insight in their own health (the so-called *patient empowerment*). Furthermore, this data gives the doctor more insight in the health status of patients, potentially leading to earlier detection of heart failure progression, hypotension or arrhythmias such as atrial fibrillation. Due to the video connection system for e-consults, patients will not have to come to the hospital for an extra consult, which saves the patient both time and money.

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

-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 type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

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

Ethics review

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

Approved WMO Date:	03-09-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	30-05-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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: 26613
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
Other	Netherlands Trial Register Trial NL8492
CCMO	NL73432.058.20
OMON	NL-OMON26613