Smart system for the management of Heart Failure in older adults

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

Summary

ID

NL-OMON45815

Source
ToetsingOnline

Brief title
SmartBEAT

Condition

- Heart failures

Synonym
Heart Failure

Research involving
Human

Sponsors and support

Primary sponsor: SGE
Source(s) of monetary or material Support: Active and Assisted Living Programme (AAL-programme);uitvoeringsorganisatie in Nederland is ZonMW

Intervention

Keyword: heart failure, management, real-time feedback, telemonitoring

Outcome measures

Primary outcome

This study:

1. Test of accuracy, reproducibility and user interface of the SmartBEAT system

(method Jakob Nielsen heuristics):

Outcome: accuracy, reproducibility and user-friendliness

2. Pilot test:

Outcome measure: usability

Reporting usability issues, and where necessary, changes to the

SmartBEAT solution.

3. Field test:

Outcome measure: perceptions

Factors: user experiences user-friendliness, acceptance, usability,

design and comfort, and the influence of the human factor

On the reliability of the system

No part of this study:

- Medium-sized RCT

Outcome measure: congestion

- Large scale RCT

Outcome measure: hospitalizations

Secondary outcome

not applicable

Study description

Background summary

More and more older people are in bad health for 20-25% of their lives, suffering from one or more chronic conditions such as chronic heart failure (CHF). In this light, the SMARTBEAT project (ie the development of an intelligent heart failure management system) is funded by the AAL program (EU) (see also http://www.aal-europe.eu/smartbeat/).

In SMARTBEAT, a care system is established to measure physiological parameters via telemonitoring devices. On an online platform, the data is safely stored and processed with intelligent algorithms, in order to make the comparison with baseline values **to detect deviations in the patient's health pattern. Then feedback and coaching are provided for the patient using a smartphone application. Formal as informal caregivers have secure access to a 'Caregivers portal' (a web application). Depending on the type of healthcare provider (ie formal or informal), the details of the medical data can be filtered.

The care system uses devices that measure the following parameters:
- Continuous monitoring: heart rate, physical activity
- Daily determination: blood pressure, heart rate at rest, weight, impedance, oxygen saturation, heart rhythm.

Study objective

The SmartBEAT project aims to address the needs of senior Chronic Heart Failure (CHF) patients and their formal and informal caregivers, by offering an integrated solution to leverage patient self-care through autonomous condition monitoring and real-time feedback to their caregivers. This objective will be achieved through remote measurement of patients* physiological data and a smart phone application integrated with a monitoring engine and a caregivers gateway

for data analysis, management and reporting.

Goal of the study is to evaluate the SmartBEAT alpha prototype from a user perspective.

Study design

Research Protocol:
In order to achieve a high level of acceptance - for both CHF patients and caregivers - the system must be attractive in terms of functionality, design and interaction.

Before the care system is tested with CHF patients and caregivers, all SmartBEAT modules and interfaces are tested at the technical level and evaluated by multiple gerontologists and interface designers. This way, technical errors and malfunctions, important user issues and design errors can be solved before using the technology in the study with patients.

Then patients and caregivers are asked to use the care system.
The SMARTBEAT study consists of two phases:
- Pilot study (Sept / Oct 2017): Evaluation of functionality, design and level of interaction (3 patients)
- Fieldtrail (Jan - June 2018): Daily use of care system (10 patients)

The selection of the patients for the study is performed by the nurse in consultation with the GP. Patients who meet the inclusion criteria are approached for participation. In a conversation, the patient receives the necessary information about the study (including patient information letter, informed consent) and the request for participation.

Care protocol:
Patients participating in SMARTBEAT get the required telemonitoring devices installed at their home. After that, they get education about the use of the devices, the app and the time when the measurements should take place. Each patient should measure the following parameters after his / her morning ritual:
- blood pressure
- Weight
- Heartbeat at rest
- Oxygen saturation
- Impedance
- heart rhythm

Active heart rate and physical activity are recorded continuously.

If the patient measures deviant values **for 2 consecutive days, he will be prompted to fill in a digital questionnaire via the app that checks possible symptoms of CHF. In addition, the app will also monitor patient's medication in

the context of his / her heart failure, and indicate the doses for daily intake. The patient must indicate via the app whether he has taken the medication. Non-heart failure-related medication is not followed by the app.

Study burden and risks

The study concerns a research into the functionality, design and the embedding of telemonitoring in daily patterns of both patients and healthcare providers. The SmartBEAT care system is applied in this study in addition to regular care (i.e. not replacing regular care, this will be investigated later in a RCT in Portugal)

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 should be 65 years of age or older;
- patient has chronic heart failure with NYHA Classification II or III;
- patient has an ejection fraction (EF) < 40%;
- patient has been clinically stable and has not been hospitalized for CHF in the past 2 months.

Exclusion criteria

- Patient is not yet 65 years of age;
- Condition of the patient is not suitable;
- Patient had been hospitalized in the past 2 months.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2018
Enrollment:	13
Type:	Actual

Medical products/devices used

Generic name:	set of devices/sensors;smartphone application and caregivers portal
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	06-04-2018
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	NL61587.100.17