USabiliTy and FeAsiBILIty of a personalised, web-based Education and self-management approach for patients with chronic Heart Failure across four European sites

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The main aim of this study is to establish whether patient-centred digital decision systems like the SanaCoach heart failure may be administered to patients as a Web app to improve patient self-management and lifestyle among patients with chronic...

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

Summary

ID

NL-OMON54253

Source
ToetsingOnline

Brief title
STABILISE HF

Condition

- Heart failures

Synonym
heart failure

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Interreg NWE

Intervention

Keyword: education, heart failure, monitoring, software

Outcome measures

Primary outcome

• Score on the System Usability Scale (SUS)

• UPDATE-HF sub study: Qualitatively assess the usability of SanaCoach and acceptability from patients* perspective.

Secondary outcome

Usability:

• % of users who rate SanaCoach heart failure as "easy to use"

• % of users who rate SanaCoach heart failure as "transmits information as intended"

• % of users who report satisfaction with the content of information received via SanaCoach heart failure

• % of users motivated/intending to use SanaCoach heart failure

• % of alerts/messages transmitted via the app that are rated "appropriate" by patient

• % of alerts/messages transmitted via the app that are responded to appropriately by patient

Feasibility:

• Total number of hours of initial training on the use of SanaCoach heart failure attended by staff, patients, cardiologist

• Total number of hours of refresher training on the use of SanaCoach heart failure attended by staff, patients, cardiologists

• Total number of minutes/hours for patient counselling over study duration

• Total number of minutes/hours spent on health record-keeping over study duration

Acceptability: recruitment and dropout statistics and the sociodemographic and comorbidity profile of consenting study participants, consenting nonparticipants, and all potentially eligible patients (Patients who decide not to participate will be given an option to complete an anonymous sociodemographic survey):

• Recruitment and retention rates

• Time required to recruit to target

• Number of eligible participants required to recruit the required sample size

• Rate of completion of the intervention (i.e. number of participants who access and complete all aspects of the intervention including lifestyle coach support)

• Sociodemographic survey on:

o Age, gender, comorbidities, education, income, family/marital status

o In addition, sociodemographic data (not including smartphone ownership or education) for study participants will be obtained from their medical records

by care provider.

• Among consenting nonparticipants, the sociodemographic survey will be administered anonymously (with no possibility of further data linkage) either using a paper or a Web-based survey.

• Technology readiness index (TRI)

Adherence rates

• number of screens viewed

• number of logins

• cumulative minutes using the app and over what time period (i.e. whether access is within a discrete period of time or over the entire intervention period)

• Number of alerts/messages/data transmitted to patient/health care provider by the app

• Number of alerts/messages/data transmitted between patient and health care provider via the app

• Number of emergency events where the app was used by patients to expedite treatment

• Number of events that prompted review by the health care provider

• Number of completed/uncompleted education sessions

• Number of completed/uncompleted monitoring sessions

• Number of goals set and goals met

• Number of advice followed/not followed

• UPDATE-HF sub study: Determine the changes perceived by relatives or informal caregivers in relation to the patient's disease management through the use of SanaCoach

Study description

Background summary

Heart failure (HF) is one of the most complex chronic disorders with high prevalence (1) that will continue to rise and is estimated to reach 3% of the population in Western countries by 2025 (2). It is the most important cause of hospitalisation in subjects aged 65 years or more, resulting in high costs and major social impact. Digital medicine offers a potential solution to this socially urgent problem.
The "SanaCoach heart failure" is an application on the internet that supports patients and care providers in the development, implementation and monitoring of patient self-management. The SanaCoach heart failure provides information about heart failure, treatment, and lifestyle modifications. It can also monitor the patient's wellbeing, symptoms, vital signs, and gives advice on whether review with a health care provider is advisable. Furthermore, it provides a repository for patient's care plan to give insight into the course and treatment of the disorder.

Study objective

The main aim of this study is to establish whether patient-centred digital decision systems like the SanaCoach heart failure may be administered to patients as a Web app to improve patient self-management and lifestyle among patients with chronic heart failure. The primary study objective is to evaluate the usability of the digital device named SanaCoach heart failure. The secondary objectives are to evaluate SanaCoach heart failure's feasibility, acceptability and clinical efficacy.

The aim of UPDATE-HF substudy is to capture and analyse qualitative data on patients' experiences dealing with SanaCoach, its user-friendliness (usability), patients' usage behaviour and self-management skills, as well as offering an indication on their acceptance towards the digital support system. Finally, UPDATE-HF evaluates the acceptance of SanaCoach from the relatives perspective, and its perceived influence on the care of patients with HF. For this purpose, a quantitative survey is used. Results of this study will provide valuable information on the improvement and implementation of SanaCoach from different stakeholder (i.e management, industry, etc.) perspectives. Such has

the potential to make an important impact on the further development process of the virtual assistant "DoctorMe" in the PASSION-HF project.

Study design

This is a pragmatic, observational, feasibility study. It will be sponsored by MUMC+ and founded by Interreg NWE. The study will recruit 600 patients across 4 clinical sites in Europe.
In addition, 300 relatives/informal caregivers will be included in the UPDATE-HF substudy across the four clinical sites.

Study burden and risks

During the study, patients will not be at risk by using the SanaCoach heart failure, as the investigational digital device is classified as a class I software in accordance with the Medical Device Coordination Group Document (MDCG 2019-11). All patients will receive the standard of care of at least 3 to 6 monthly scheduled cardiology visits. No bloodsamples, besides routine care, or other examinations are preformed on the patients. By participating in this study patients will fill out 5 questionnaires through the SanaCoach app. All other functions of SanaCoach heart failure (learning modules and vital check ups) are preformed at will of the patient. By using these functions, patients can feel safer because they will feel that they are better monitored by their doctor.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
• Adults (>=18 years) that own a device where SanaCoach heart failure can be used on
• Diagnosis of chronic heart failure according to ESC 2016 guidelines (HFrEF = LVEF <40%, HFmrEF = LVEF 40-49%, HFpEF = LVEF >= 50%), based on echocardiographic or MRI findings within the last year or considered stable before.
• Ability and willingness to give written informed consent and to comply with the requirements of the study

UPDATE-HF sub study:
Patient's inclusion criteria
• Be enrolled in the STABILISE-HF study
• Patient may not already use SanaCoach or have used it in the past
• Willingness to have the interview recorded and transcribed
• Sufficient Dutch language skills to answer questions
• Ability and willingness to give written informed consent and to comply with the requirements of the study

Patient*s relatives/informal caregivers inclusion criteria
• Relative/informal caregiver of a patient diagnosed with HF who has already been enrolled in the STABILISE-HF study
• Adults (>=18 years)
• Sufficient English language skills to answer questions
• Ability and willingness to give written informed consent and to comply with the requirements of the study

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

• Patients without access to a device where SanaCoach heart failure can be used on
• Uncontrolled or serious disease, or any medical or surgical condition, that may either interfere with participation in the clinical study, and/or put the subject at significant risk (according to investigator's judgment) if he/she participates in the clinical study.
• Patients that have been hospitalised for heart failure within the last 30 days.
• An underlying known disease, or surgical, physical, or medical condition that, in the opinion of the investigator might interfere with interpretation of the clinical study results.
• Treatment with other investigational products or devices within 30 days or five half-lives of the screening visit, whichever is longer.
• Planned use of other investigational products or devices during the course of the study.
• Any condition that according to the investigator could interfere with the conduct of the study, such as but not limited to:
• a. Subjects who are unable to communicate or to cooperate with the investigator.
• b. Unable to understand the protocol requirements, instructions and study-related restrictions, the nature, scope, and possible consequences of the study.
• c. Unlikely to comply with the protocol requirements, instructions, and study-related restrictions (eg, uncooperative attitude, inability to return for follow-up visits (as parts of standard care), and improbability of completing the study).
• d. Have any medical or surgical condition, which in the opinion of the investigator would put the subject at increased risk from participating in the study
• e. Persons directly involved in the conduct of the study.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	07-07-2021
Enrollment:	150
Type:	Actual

Medical products/devices used

Generic name:	SanaCoach heart failure
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	03-02-2021
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	01-06-2021
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	13-06-2022
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
ClinicalTrials.gov	NCT04699253
CCMO	NL75892.068.20