NWE-Chance - A feasibility study of a home hospitalisation strategy for patients with an acute episode of heart failure using integrated eHealth applications.

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The aim of the feasibility study is to test the home hospitalisation platform (care pathway empowered by the integrated home hospitalisation platform) through small scale pilots in three different hospitals: Isala, Jessa hospital and Maastricht UMC...

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

Summary

ID

NL-OMON49043

Source
ToetsingOnline

Brief title
NWE-Chance

Condition

- Heart failures

Synonym
heart failure

Research involving
Human

Sponsors and support

Primary sponsor: Isala Klinieken
Source(s) of monetary or material Support: Interreg North-West Europe;European Regional Development Fund

Intervention

Keyword: eHealth, Heart Failure, Home hospitalisation

Outcome measures

Primary outcome

Study objective 1: Feasibility of home hospitalisation for HF patients.

Outcome measures: Acceptance of the technology by the patient will be assessed with the SUTAQ (9,10). Satisfaction of the patient for the home hospitalisation program supported by the integrated home hospitalisation platform will be assessed with the *patiënt tevredenheid vragenlijst*. Furthermore, we will assess the satisfaction of the cardiologist and nursing team with respectively; *Vragenlijst evaluatie thuishospitalisatie voor Hartfalen * Cardioloog* and *Vragenlijst evaluatie thuishospitalisatie voor gespecialiseerd verpleegkundigen*. The SUS questionnaire will be used to assess the usability of the home hospitalisation system for patients and the caregiver dashboard for nurses.
To get an idea of the digital literacy of patients, a questionnaire on smartphone usage will be filled in by the patients.
All questionnaires will be provided by the study nurse to the target group and will be filled in on paper (source document).

Questionnaire

Target Moment

SUTAQ10

Patients End of the home hospitalisation

Satisfaction Home hospitalisation program Patients End of

the home hospitalisation

Satisfaction Home hospitalisation program Cardiologists At the end

of the home hospitalisation of the last patient

Satisfaction Home hospitalisation program Nurses At the

end of the home hospitalisation of the last patient

SUS questionnaire for patient application Patients End of

the home hospitalisation

SUS questionnaire for caregiver dashboard Nurses At the

end of the home hospitalisation of the last patient

Smartphone usage/digital literacy questionnaire Patients End of the

home hospitalisation

Caregiver Strain Index

Caregiver End of the home hospitalisation

Safety of the platform and the home hospitalisation program will be assessed by

the number of adverse events:

- Any type of medical problem or inconvenience for the patient related to the

use of the devices (patch, BP devices, weighing scale, etc)

- Occurrence of delirium for which medical treatment is started/up titrated

- Occurrence of infection for which antibiotic treatment is started

- Occurrence of falling trauma that requires trauma treatment

- Major adverse cardiovascular events (MACE)

- All-cause mortality

- % of unsuccessful treatment defined as death or regular hospitalisation within 30 days after inclusion

MACE is a composite of death from cardiovascular causes, non-fatal myocardial infarction, or non-fatal stroke in 30 days after the start of home hospitalisation.

* Death from cardiovascular causes are defined as deaths resulting from immediate cardiac causes (acute myocardial infarction, acute HF, fatal arrhythmia). Unwitnessed death and death of unknown cause will be considered as cardiac death. Vascular deaths are defined as deaths due to cerebrovascular disease, pulmonary embolism, ruptured aortic aneurysm, dissecting aneurysm, or other vascular cause.

* A non-fatal myocardial infarction is defined as a rise and/or fall of cardiac biomarkers (preferably troponins) with at least one value above the 99th percentile of the upper reference limit and with at least one of the following: i. symptoms of ischemia, ii. new or presumably new significant ST-T changes or new left bundle branch block (LBBB), iii. development of pathological Q waves on the electrocardiogram (ECG), iv. imaging evidence of new loss of viable myocardium or new regional wall motion abnormalities [2].

* A non-fatal stroke is defined as an episode of focal or global neurological deficit lasting > 24 hours with at least one of the following characteristics:

hemiplegia, hemiparesis, numbness with lateralisation, sensory loss with lateralization, aphasia, dysphasia, hemianopia, change in the level of consciousness.

Medium term safety will be assessed through follow-up till 30 days after the start of the home hospitalisation intervention. All major cardiovascular events, rehospitalisations and death will be recorded.

Lastly, platform use by the patients will be assessed by amount of missed measurements by the patient and amount of reported technical problems.

Secondary outcome

Mapping the induced costs. Outcome measures: The induced cost will be calculated as a composite cost of the estimated technical costs (devices and platform), staff cost (time spent by nurses and cardiologist), transport cost (number of kilometres, maintenance of car) and logistic costs (medical material). The time spend by nurses will be calculated with the Toggl application. Toggl is time tracking software that will be installed on the smartphone of the project. The nurses can record their time spend for every patient, logistics and transport. A informed consent with information about the Toggl application and the use of data will be provided to the nurses.

The estimated technical cost will be delivered by the technical partners. For equipment that can be used for several patients, there will be calculated a unity cost per day. The study team will do the mapping of staff costs. The

logistic cost and transport cost will be calculated by mapping kilometres.

Study description

Background summary

1.1 Introduction into the NWE-Chance INTERREG project
Heart failure (HF) is a growing epidemic: in the European Union about 15 million people are now living with HF. Between 1-2% of total healthcare expenditure can be associated with this condition, of which 50% is due to hospitalisation. Digital health is widely recognised as one of the most promising solutions to this societal challenge: in the field of cardiovascular diseases, current eHealth tools primarily focus on rehabilitation and monitoring after hospitalisation (~disease management strategies). Today, there is a transition taking place from dedicated hospital care to the home setting, combined with eHealth applications and miniaturised diagnostic and therapeutic devices. This INTERREG project, NWE-Chance, aims at enabling co-creation of eHealth concepts for admitting HF patients at home. By combining the expertise of eHealth focused companies, hospitals specialised in HF treatment and research institutes, a home hospitalisation platform will be developed. This platform integrates portable devices for blood pressure (BP) and weight (W) measurements and a wearable patch to monitor vital functions like heart rate (HR), respiration rate, activity level and posture and an eCoach.

NWE-Chance will support during the project three eHealth companies in further developing and testing their technologies accompanied by strategic recommendations for successful clinical implementation. The NWE-Chance Innovation Hub, which will be established at the end of the project, will support the collaboration and knowledge exchange between SMEs and hospitals in the process of developing and implementing new digital health technologies to support hospitalisation at home.
Part of the project is a feasibility study, where the feasibility of the technology and organisational aspects are tested in a patient/healthcare environment. In this study the technology will be assessed without interfering with treatment policy.

1.2 Introduction into the NWE-Chance feasibility study
HF is associated with a reduced quality of life, frequent hospitalisation and high mortality. (1)
Up to 50% of the patients are readmitted in the hospital within the 60 days post discharge period. Hospital admissions, especially for the elderly, have a substantial additional hazard for serious complications. (2) These complications are amongst others: delirium, falling trauma, and hospital infection. They result in longer hospital stay, higher ICU admission rate,

higher mortality and irreversible loss of physical and/or mental condition. (3)

Because of these hospitalisation related complications, we notice that worldwide hospitals increasingly explore the possibilities of providing clinical healthcare at home as a safe alternative for hospitalisation. (4) Hospital-at-home care has been evaluated (mostly in pilot setting and/or with small number of patients) for different groups of patients; surgical and non-surgical. The general conclusion is that the hospital-at-home formula is feasible, can be conducted safely and is cost-effective for specific groups of patients (5,6,7) Admitting patients at home is not only highly innovative but is also a promising approach both from health care and economic perspective. NWE-Chance will explore the possibilities of providing hospital care at home supported by digital technologies in three centers with different levels of experience in home care, within a feasibility study. To take the next step in implementing hospital-at home strategies there is a need for bigger multicenter studies.
From 2005 hospital-at-home care in the Zwolle area has been provided for HF patients who are severely decompensated and need intravenous treatment (8). The experiences were positive; low incidence of delirium and infections and high patient satisfaction. Modern technologies are able to facilitate hospitalisation at home; point of care laboratory testing, telemonitoring, eHealth and mobile broadband communication service, make expansion of these services possible. eHealth is widely recognised as being one of the most promising solutions for a sustainable healthcare organisation.

In this NWE-Chance feasibility study we will evaluate the technical and organisational feasibility of home hospitalisation for HF patients using an integrated home hospitalisation platform. This platform is supported by different technological companies:
* HC@Home, a Dutch company specialised in eHealth solutions, created a telemonitoring platform that forms the basis of the home hospitalisation platform. Currently only BP, pulse, activity and W can be measured in the home setting of HF patients. For this project, HC@Home developed an expansion of the platform with functionalities such as monitoring of posture and movement and the possibility to videoconference and measure pulsoximetry.
* Sensium, a UK based company, developed a wearable patch to remotely monitor vital signs (e.g. HR, RR, posture, movement) of hospitalised patients.
* Sananet, a Dutch company specialised in eCoaches for telemonitoring and tele-education on a distance.

Each technology has separately been validated and is certified for commercial use in Europe by a CE certificate. For the INTERREG NWE-Chance, the two technical partners integrated their technology into an integrated eHealth home hospitalisation platform. During this NWE-Chance feasibility study, we will evaluate this integrated home hospitalisation platform for HF patients.

In summary, HF has a major societal impact. Hospitalisation at home seems to be

an attractive alternative for clinical hospitalisation and modern insights and technology may support large-scale implementation.

Study objective

The aim of the feasibility study is to test the home hospitalisation platform (care pathway empowered by the integrated home hospitalisation platform) through small scale pilots in three different hospitals: Isala, Jessa hospital and Maastricht UMC+ hospital. The aim of the pilots is to prove the technical and organisational feasibility of the concept of home hospitalisation of HF patients. Through these pilots, knowledge will be acquired for further development of the technologies and implementation strategy. Decisions on treatment policy can be made from the findings of the assessed technology. Results of the platform can be compared with traditional / standard care.

The primary objective of the NWE-Chance feasibility study is to investigate whether a home hospitalisation strategy for HF is technically and organisationally feasible for the patient and the professional. Feasibility will be assessed with following endpoints:
I. Acceptance of patients and professionals for both: technology & hospital-at-home care with a questionnaire
II. Satisfaction of patients and professionals for both: technology & hospital-at-home care with a questionnaire
III. Usability of the patient application by the patient and usability of the caregiver dashboard by the professional with a questionnaire
IV. Digital literacy of patients will be assessed with a questionnaire
V. Burden on the primary informal caregiver will be assessed with a questionnaire
VI. Safety of the technology & hospital-at-home care organisation
VII. Actual use of the patient application and the caregiver dashboard

The second objective is to get an image of the induced costs of a home hospitalisation programme. We will use following endpoints to assess the induced costs.
I. Purchase price of the devices and costs to use the home hospitalisation platform
II. Staff costs
III. Transport and logistics costs

The third objective is making a blueprint of the operational organisation plan based on experiences of this feasibility study. We will use following endpoints to create the blueprints.
I. Evaluation of logistics and organisation of care
II. Time spend for education and patient follow-up
III. Communication between patient, nurse and cardiologist

The main hypothesis of the study is that the NWE-Chance programme is a feasible

strategy for clinical HF treatment in the living environment of the patient.

The main goal of this research is to investigate the feasibility of home hospitalisation for HF not only for patients but for health care professionals as well. Secondary goals are to map the organisational issues, patients* and health professionals* comments to optimise the home hospitalisation strategy for the randomised controlled trial that is planned in the future.

Study design

The NWE-Chance feasibility study is an international, multicenter, single-arm prospective and interventional study.

Intervention

Patients participating in the NWE-Chance study will be transferred to their home supported by the integrated home hospitalisation platform and a daily visit by a specialised nurse. The home hospitalisation platform allows monitoring vital signs of patients by using the Sensium patch and a connected weighing scale and BP equipment of HC@home and an eCoach of Sananet. Patients will get a smartphone to receive reminders for measurements of BP and W and will be able to see the evolution of their BP and W values. The patient application also contains educational information for the patient on home hospitalisation and on how to take the measurements correctly.
Patients are treated by a team of specialised nurses under supervision of a cardiologist. The nurses visit patients at least once a day and are equipped with laboratory equipment and IV medication administering equipment. These devices and equipment are currently used in standard HF care and are not part of the newly developed home hospitalisation platform. Patients receive treatment similar to in-hospital treatment, according to the cardiologist*s best knowledge and insight.

In the case of Jessa Hospital, if there would be a need for IV medication during the home hospitalisation period, this will lead to rehospitalisation of the patient and the ending of the intervention. In Isala, the nurses have a 24/7 duty service and can be called by patients or their relatives on their own initiative. In Jessa hospital and MUMC+, the nursing team can be contacted between 9 AM and 17 PM. During other hours, the patients can contact the cardiologist on call.
In case of treatment failure or severe deterioration, patients will be transported to the hospital. In case of emergency, ambulances will transport patients to the hospital (conversion to regular hospitalisation). If in follow-up, condition worsens, the patient can be readmitted at home again. In theory, patients may undergo repeated hospitalisations at home.

The home hospitalisation period will last at least 5 days and can be extended,

till a maximum of 13 days, after consultation of a cardiologist. Patient will be asked to fill in questionnaires to assess feasibility at the end of the home hospitalisation period (last visit of nurse). At the last visit of the nurse, they will take all the devices with them.

Study burden and risks

not applicable

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

Patients with known and well assessed chronic heart failure

Age >18 years
Indication for hospital admission for acute decompensated heart failure
Stable physical condition with or without IV medication
Living within a wide proximity of the hospital
-<30 km for Jessa Hospital and Isala
-Within the region Maastricht Heuvelland for MUMC
Living independently and/or sufficiently supported at home and/or living in nursing homes (or other supported living modalities)
Signed written informed consent

Exclusion criteria

Indication for IC/CCU admission
Not fulfilling the inclusion criteria for home hospitalisation
Mental implairment leading to inability to cooperate
Severe comorbidity requiring simultaneous hospital care
History of severe liver disease
Unstable blood pressure (Systolic blood pressure <90mmHg)
Unstable heart rhythm (in case of synus rhythm heart rate >110/min, in case of atrial fibrillation >150/min
Need for intravenous inotropic medication
Unstable respiratory condition (spO2<90% without additional O2

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-11-2020
Enrollment:	75
Type:	Actual

Medical products/devices used

Generic name:	Sensium Patch
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	16-01-2020
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	15-06-2020
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)

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	NCT04084964
CCMO	NL71016.075.19