Effectiveness of an interactive web-based platform and a disease specific information website in patients with heart failure: a 3-arm randomised trial.

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- To assess whether a disease specific educational website improves self-care behaviour and quality of life of patients with HF as compared to usual care.- To assess whether a disease-specific educational website plus an interactive web-based...

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

Summary

ID

NL-OMON40041

Source
ToetsingOnline

Brief title
E-Vita heart failure

Condition

- Heart failures

Synonym
congestive cardiac failure, Heart failure

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: Stichting Zorg Binnen Bereik

Intervention

Keyword: E-health, heart failure, quality of life, RCT., self care

Outcome measures

Primary outcome

The primary outcomes are self care behaviour and quality of life measured with the validated European Heart Failure Self Care Behaviour Scale (EHFScB scale) and the short-form health survey with 36 questions (SF36), EuroQol 5 Dimensions (EQ-5D), and Minnesota Living with Heart Failure Questionnaire (MLHFQ) respectively.

Secondary outcome

Secondary outcome are all-cause mortality, HF related hospitalisations, duration of HF related hospitalisations and disease specific knowledge measured with the Dutch Heart Failure knowledge scale, heart function and evaluation of use of website measured with the *use of website* and website user satisfaction (WUS) questionnaire. A cost-effectiveness analysis will be part of the study.

Study description

Background summary

Heart failure (HF) is a major health care problem. Ageing of the population and improved survival after acute coronary events will further increase the number of patients affected. Notably hospital admissions for exacerbations of HF place a great burden on the patients and the health care system. Efficient incorporation of a disease-specific educational website and telemonitoring facilities may increase quality of life and functional capacity of patients, while partly reducing the burden on health care workers and thus increasing the

number of patients they can care for.

Study objective

- To assess whether a disease specific educational website improves self-care behaviour and quality of life of patients with HF as compared to usual care.
- To assess whether a disease-specific educational website plus an interactive web-based platform with telemonitoring facilities improves self-care behaviour and quality of life of patients with HF as compared to usual care.
- To assess whether a disease-specific educational website plus an interactive web-based platform with telemonitoring facilities improves self-care behaviour and quality of life of patients with HF as compared to a disease-specific educational website alone.
- To assess whether both interventions result in lower all-cause mortality, HF related hospitalisations, duration of HF related hospitalisations, improve knowledge about the HF and its treatment and influences HF biomarkers.To determine whether the interventions are cost-effective.

Study design

A prospective, three-arm parallel randomised trial.
The study will be conducted in about ten HF outpatient clinics in the Netherlands. Individual patients will be randomly allocated to one of the three study arms and followed for twelve months.

Intervention

Arm 1. Usual care; 2. Disease specific educational website (in addition to usual care). This website is the very recently completed Dutch translation of the European informative website about HF developed by the Heart Failure Association of the European Society of Cardiology (ESC). The website is targeted at patients, their relatives, and carers (www.heartfailurematters.org). 3. Adjusted care pathway, including both the educational website and an interactive web-based platform with telemonitoring facilities. In this arm all routine consultations with HF nurses and GP will be substituted by this combination of telemonitoring facilities connected to an interactive web-based platform plus the Dutch version of the ESC website on HF.

Study burden and risks

Randomised patients will not be exposed to specific health risks. The main burden for participants and their care takers will be time and effort taken to fill out questionnaires (all patients); giving blood; receive training on the information website (arm two) and to receive training on the interactive care platform including daily measurements of body weight, blood pressure and heart

rate (arm three).

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

- HF established according to the guidelines of the European Society of Cardiology (ESC), and confirmed with echocardiography at least three months ago.
- Sufficient cognitive and physical function to understand the aim of the study and perform or undergo the required measurements and sign informed consent.
- Aged 18 years or over.

Exclusion criteria

- Non-availability of internet and email.
- Inability to work with internet and e-mail.
- Inability of the patient and his/her family or care takers to read and understand Dutch.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-09-2013
Enrollment:	414
Type:	Actual

Ethics review

Approved WMO Date:	07-03-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	27-05-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	13-10-2014

Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	05-02-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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
Other	00000000000
CCMO	NL40993.041.12