Integrated telemonitoring and telecare for patients with Heart Failure: A randomized controlled trial in primary care

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

Summary

ID

NL-OMON34749

Source
ToetsingOnline

Brief title
INTEL-HF

Condition

- Heart failures

Synonym
Heart failure

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit van Tilburg

Source(s) of monetary or material Support: Europese Commissie

Intervention

Keyword: Heart failure, Hospitalization, Quality of life, Telehealth

Outcome measures

Primary outcome

The primary study outcome is quality of life measured with the KCCQ (Kansas

Secondary outcome

The secundary study outcome is hospitalization.

Study description

Background summary

Heart failure is an important cause of hospitalization, with acute heart failure syndromes being the first cause of hospitalization for elderly people in the USA and Europe. In addition, quality of life is lower for heart failure patients compared to other cardiac patients, and patients with heart failure report large numbers of distressing symptoms. This implies that delaying the progression of heart failure by optimal treatment and adequate management of symptoms may lead to health related quality of life benefits. In addition, acute heart failure is the primary cause of hospitalization in elderly patients, with acute heart failure mostly resulting from decompensated chronic heart failure. Taken together, these findings suggest that prevention of exacerbation of heart failure might reduce the risk of hospitalization.

Progression of heart failure is associated with hemodynamic changes which can result in fluid retention and changes in blood pressure. Because the progression of heart failure can lead to an exacerbation of the condition, it is important to recognize changes in blood pressure and weight. Monitoring of blood pressure can provide important information for care providers, may improve patient compliance and may be used as a prognostic marker. In addition, daily weighing and recognition of rapid weight gain are very important in detecting a deterioration in the condition.

Telemonitoring can be used to assess and guard the clinical status of patients, by using communication technology. A system with frequent monitoring can facilitate early detection of deterioration in heart failure. Telemonitoring of

heart failure patients to track symptoms is a feasible method, as patient acceptance is high. Moreover, a meta-analysis by Clark, Inglis et al. indicates that telemonitoring reduces hospitalization and mortality. However, the effects of telemonitoring on quality of life are unclear. Some studies have found a significant beneficial effect of telemonitoring on health-related quality of life while other studies found no effects on quality of life. However, only a few RCTs studied quality of life as an outcome parameter.

Study objective

The aim of the present study is to examine the effect of integrated telemonitoring and telecare, compared to usual care, on quality of life and hospitalization in patients with heart failure in primary care.

Primary
To examine the effect of integrated telecare and telemonitoring versus usual care on quality of life in primary care patients with heart failure.

Secondary
To investigate the effect of integrated telecare and telemonitoring versus usual care on hospitalization in patients with heart failure in primary care.

Study design

The study design is a randomized controlled trial, with randomization at patient level. Assessments will take place at baseline (i.e., prior to randomization), and at 3-, 6- and 12 months. Primary care patients with heart failure (N=200) will be recruited from general practitioners (GP*s) affiliated with the primary care organization Praktijkondersteuning Zuidoost Brabant (POZOB).

Intervention

The duration of the intervention will be 12 months. The integration of telehealth and telecare consists of several elements:

Telehealth monitoring of symptoms of heart failure
Patients in the intervention group will receive a weighing scale and a blood pressure monitor. They will be trained to monitor their weight and blood pressure once a day at a set time. Data from the weighing scale and the blood pressure monitor will be sent automatically every day to a case manager at a call centre. For each patient, individual alert-values will be determined and stored on a server. When the measured values cross the determined threshold, the case manager will take action and call the patient. In case of a life-threatening emergency, the ambulance will be called. If there is no life-threatening emergency, the case manager will ask the patient to measure

again to eliminate errors. If there still is an alert, after medical triage, the case manager will call either the GP or the NP for an appointment or a visit to the patient*s home. All relevant alerts will be stored electronically in the patient files at the call centre, and this information will be sent to the GPs. In addition to alerts, the NP can also access an overview of the telehealth data for a patient, and use the telehealth data for monitoring symptoms of heart failure.

Case management
The second element of the intervention is the integration of social and medical care. In contrast to the usual care group, patients in the intervention group can contact the call centre 24 hours a day, 7 days a week. The call centre can be contacted by phone or by pressing a social alarm button. In addition to medical questions or issues, patients can also contact the call centre when they need social services. Instead of one function (usual medical care during evenings, nights and weekends), the call centre will provide three services:
1. Handling medical questions and concerns.
2. Arranging social services or answer questions about social services.
3. Handling social alarms.
This results in one integrated point of access for the patient for medical and social assistance. In addition, a secure web-based system will allow easy communication and access to patient records for case managers and NPs. This is also linked to the GP system, with the GP always being the primary responsible for the care provided.

Study burden and risks

The burden on patients of this study will be filling in a questionnaire 4 times in 1 year. This means burden on patients is relatively low.

Since the intervention consists of an addition to regular care, consisting of extra assistance and monitoring by use of modern communication technology, risks of this study are estimated to be negligible.

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 aged between 65-85 years with diagnosed heart failure according to the most recent guidelines , who live at home.

Exclusion criteria

Patients with a history of severe psychiatric illness other than mood or anxiety disorders, with cognitive impairments (e.g. dementia) determined by the GP, with a terminal illness, with insufficient mastery of the Dutch language, or those who are illiterate or cannot read due to visual impairments, will be excluded.

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):	01-01-2011
Enrollment:	200
Type:	Actual

Medical products/devices used

Generic name:	Telehealth
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	12-10-2010
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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: 26293
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL30930.008.10
OMON	NL-OMON26293