Integrated telemonitoring and telecare for patients with heart failure.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26293

Source
NTR

Brief title
INTEL-HF

Health condition

Heart failure

Sponsors and support

Primary sponsor: University of Tilburg and PoZoB
Source(s) of monetary or material Support: European Commission

Intervention

Outcome measures

Primary outcome

The primary outcome measure will be assessed by questionnaires at baseline, 3 6 and 12 months.

Secondary outcome

Hospitalization and patient satisfaction assessed by questionnaires.

Study description

Background summary

Background:

Heart failure is a prevalent chronic disease with a poor prognosis and a large negative impact on quality of life. Due to the general rise in life expectancy and improved treatment options for cardiovascular disease, the incidence and prevalence of heart failure are expected to increase. Since heart failure is an important cause for hospitalization, prevention of exacerbation of symptoms is important in order to facilitate timely intervention and preserve quality of life. Telemonitoring of symptoms may be a feasible and effective method for managing the health of heart failure patients.

Methods/Design:

This randomized controlled trial will examine the effects of integrated telecare and telemonitoring of blood pressure and weight in 200 older primary care patients with heart failure compared to usual care. The main outcomes are quality of life and hospitalization. Quality of life will be assessed with questionnaires at baseline and after 3, 6 and 12 months.

Discussion and implications of the research:

This study will show if integrated telemonitoring and telecare is feasible and affects quality of life and hospital admissions of older patients with heart failure in primary care.

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.

Study design

Baseline, 3, 6 and 12 months.

Intervention

Patients will be randomized to care as usual or integrated telemonitoring and telecare for the duration of one year.
Care as usual consists of regular care by a general practitioner, practice nurse and/or cardiologist.
The integrated telemonitoring and telecare consists of remote monitoring of blood pressure and weight and a social alarm which will be handled by a case manager on a call center. The integrated telemonitoring and telecare takes place in addition to care as usual.

Contacts

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Eligibility criteria

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)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2010
Enrollment:	200
Type:	Anticipated

Ethics review

Positive opinion

Date:	23-10-2010
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 34749
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL2476
NTR-old	NTR2592
CCMO	NL30930.008.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON34749

Study results

Summary results
N/A