Mind your medication: A randomized, controlled trial using a TELEmedicine solution to improve MEDication adherence in chronic Heart Failure (TELEMED-HF)

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

Summary

ID

NL-OMON35787

Source
ToetsingOnline

Brief title
TELEMED-HF

Condition

- Heart failures

Synonym
cardiac failure, heart failure

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit van Tilburg
Source(s) of monetary or material Support: Ministerie van OC&W,Vitaphone Nederland B.V.

Intervention

Keyword: determinants of adherence, heart failure, medication adherence, telemonitoring

Outcome measures

Primary outcome

Primary: objective and subjective medication adherence, healthcare consumption,

and costs.

Secondary outcome

Secondary: QoL, self-care behaviour, disease severity (NYHA class, LVEF),

exercise capacity, number of hospitalizations.

Other study parameters are included to determine whether randomization was

successful, to assess their potentially moderating influence on adherence, and

to generate risk profiles of patients who may/may not benefit from the

intervention:

Psychological and sociodemographic: Type D personality, depression, anxiety,

quality of life, socio-economic status, age gender.

Clinical: self-reported medication side effects, Left Ventricular Ejection

Fraction (LVEF; echocardiography); time since heart failure diagnosis; heart

failure etiology; previous cardiac events (MI), previous cardiac procedures

(PCI, CABG), previous cardiac devices (ICD, pacemaker), hospitalizations for heart failure; NYHA functional class (structural interview); blood pressure; cholesterol; triglycerides; diabetes; atrial fibrillation; comorbidities; all cardiac medication, all other medication (incl. psychotropic medication); C-reactive protein; NT-pro-BNP; parameters measured in standard clinical practice (incl. liver function (ACAT, ALAT, Gamma GT), haemoglobin, hematocrit, leukocytes, and kidney function (urea and creatinine)).

Cost-benefit analysis: The TiC-P questionnaire (developed by the Trimbos Institute22) and event rate (and related DBC (diagnosis treatment combination, the Dutch system to allocate costs to treatments of specific patient groups)) will enable us to compare healthcare consumption in the intervention and control group. In examining the healthcare consumption, we will also include the costs of the telecare support system and the medication adherence monitor.

Study description

Background summary

The syndrome of systolic heart failure arises as a consequence of impaired cardiac pump function, and is a constellation of relatively nonspecific signs (e.g., edema, tachycardia) and symptoms (e.g., fatigue, breathlessness). Epidemiologic evidence shows that the prevalence of symptomatic heart failure is 6-10% in the elderly population, and is growing due to successful treatment of myocardial infarction and increased survival after an acute cardiac event. These patients are likely to end up with chronic heart failure (HF), and consequently have a more frequent need for rehospitalization, and poorer survival chances. Heart failure is therefore associated with major healthcare costs, e.g., in 2005 almost 390 million Euros were spent on heart failure care, and it is expected that these costs increase with the ageing population. Pharmacological treatment of HF typically consists of a combination of >=4

different types of medication. A major problem in heart failure management is poor medication adherence (only 50-70% of patients are adherent), which may to a great extent explain frequent readmissions in HF patients, as well as being associated with increased morbidity and mortality. Hence, improving medication adherence may enhance cardiac prognosis, reduce the number of heart failure-related hospital readmissions, improve quality of life and increase survival, and reduce healthcare costs. A recent longitudinal study showed that adherence rates above 88% were associated with a decreased number of rehospitalizations and mortality rates than patients who are less adherent. In this study, objective medication adherence was measured using an electronic chip in the medication cap (*Medication Event Monitoring*; MEMS) that records each moment the cap is removed from the medication bottle.

A novel tool to improve patient adherence is telemonitoring, permitting remote patient monitoring, either by structured telephone support, or using special telecare devices in conjunction with a telecommunication system that electronically transfers patient data. To date, few randomized controlled trials have studied the efficacy of telemonitoring to improve adherence in HF patients, and have yielded mixed findings. One study reported a clinically relevant improvement in some health behaviours using a health buddy® intervention, while another failed to reduce HF-related hospitalization or cardiac death by weekly transmissions of vital signs and telephone contact. Conversely, weekly assessment of patients* clinical status by home telemonitoring was associated with better medication adherence, and reduced mortality and hospitalizations. However, these results were based on small samples (<110), and most were time-consuming as the intervention involved telephone support. Further, only one small study tried to improve medication adherence using a specific adherence device (i.e. a medication box transferring data to an electronic record), finding that this device improved patients* compliance. However, this study did not examine the effect of the device on the clinical course of heart failure. Another recent study showed that home telemonitoring was associated with a significant increase in the use of beta-blockers, an essential medicine in congestive heart failure, and lower mortality rates and less rehospitalizations in the telemonitoring group than the control group5.

When trying to improve patient adherence, it is important to examine potential adherence modifiers. These can be of a clinical and pharmacological nature, i.e. disease characteristics and medication side-effects may cause people not to take their medication, but they may also be of a psychosocial nature. In effect, socio-economic status, social support, and patient related factors such as self-care behaviour, motivation, mood, and personality may affect medication adherence in heart failure patients. Previous studies on clinical and psychosocial factors that may affect medication adherence in HF failed to find determinants of adherence. However, these were all drug trials in which adherence was around 90%, which is not representative of the heart failure populations in general in which adherence to medication is around 50%.

In summary, medication adherence in chronic heart failure patients is poor and previous studies have not clearly demonstrated which method(s) is/are effective in improving medication adherence, ultimately improving the patient*s prognosis.

Study objective

The current proposal wants to examine the efficacy and cost-efficiency of a telemonitoring solution to improve medication adherence in chronic heart failure patients, to enhance the clinical state of the patients and to reduce health care consumption, while assessing the moderating roles of psychosocial factors on medication adherence. Specifically, we propose a randomized controlled trial (RCT) that examines the efficacy and cost-efficiency of a novel Medication Adherence Monitor (MAM) to improve medication adherence. This device not only dispenses all prescribed medication in the right dosage at the specified times, but also records adherence, reminds patients to take their medication (alarm, SMS or voicemail), and importantly, sends critical data about non-adherence to the HF nurse. The first aim of this RCT is to examine the efficacy of this device to enhance medication adherence in patients with HF. In addition, this study will examine the correspondence between objectively assessed adherence and self-reported medication adherence in these HF patients. Further, it is the aim of this RCT to examine clinical, demographic and psychological factors that may modulate the effect of MAM. This would delineate distinct profiles of patients who benefit from this intervention, and those who may not, and would help to tailor self-management programs to patients' individual needs.
Finally, as the effects of the implementation of a medication-specific adherence device on the clinical course of heart failure are yet unknown, the proposed RCT also aims to examine the effect of any changes in medication adherence on disease progression, physical functioning, quality of life and health care consumption in a large group of patients with HF.

Study design

This is a randomized controlled clinical trial with two conditions, i.e. an intervention arm and usual care arm, with a 12-month follow-up period. After a 6-month intervention period (see below for intervention), all patients continue to receive usual care, and participate in 4 follow-up occasions at 3-, 6-, 9- and 12-months post-intervention. These follow-ups coincide with regular clinic appointments and involve questionnaire assessments and a 6-minute walk test. The follow-up at 3 and 9 months will consist of a telephone call, only requesting information on healthcare consumption and adherence. Over the 18-month study period, retrospective refill rates are requested from the patients* pharmacies.

The timeline of one participant in the study is as follows: after inclusion,

the participants visit the heart failure nurse for their usual care visit. Participants in the treatment group then receive the medication adherence monitor and are instructed how to use it at the hospital pharmacy after the usual care visit. The intervention takes 6 months. During the intervention period, at 3 and 6 months usual care visits to the heart failure nurse take place. After completion of the intervention follow-up assessments take place at 3, 6, 9 and 12 months post-intervention. In total, the study duration for a participant is 18 months.

Based on the availability of patients visiting the outpatient clinic, weekly, six participants can in theory be included in the control condition and three in the treatment condition. With 80 medication adherence monitors at our disposal, we will be able to carry out the above-mentioned inclusion rate, resulting in a total duration of the inclusion period of 1.5 to 2 years. The final patient thus will have finished the study 3 to 3.5 years after the start of the study.

Intervention

Intervention: The intervention consists of the use of an electronic Medication Adherence Monitor for a 6-month period as well as 2 visits to the heart failure outpatient clinic of the TweeSteden hospital (usual care). This monitor (a) dispenses all prescribed medication in the right dosage at the specified time, (b) reminds patients to take their medications through an alarm, sms or voicemail service and records adherence, and (c) sends critical data about non-adherence to the heart failure nurse, via a web application (CarebyWeb). The Medication Adherence Monitor is provided to the patient by the hospital pharmacy, including an instruction how to use the device. After the intervention patients return to usual care only. We expect a training effect, with continued improved adherence in the intervention group.

Study burden and risks

Participation is considered to be safe, as patients will keep receiving the same medication as before, only in a different package, i.e. the MAM instead of regular, prescribed medicine boxes. The hospital pharmacy or patients* own pharmacy will ensure the delivery of the medication to the participants* homes for the duration of the intervention, depending on which organization of pharmacies they belong to. This is dealt with at the level of the pharmacy supplier, so the patient will be minimally burdened with this. Participation in the treatment group may be beneficial because of improved adherence to medication, but also may induce medication side effects (due to taking all their medications in prescribed dosages).

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

- Stable systolic heart failure
- New York Heart Association functional class II-III, with a decreased pump function (left ventricular ejection fraction (LVEF) <40%)
- Titrated to the most optimal doses of ACE-inhibitor or Angiotensin Receptor Blocker, and beta-blocker
- Receiving stable doses of at least 3 heart failure medications (at multiple times during the day) for 1 month with no plans to add or adjust heart failure medications or titrate further in the immediate future.

Exclusion criteria

- Diastolic heart failure (intact pump function)
- Myocardial infarction, invasive treatment (percutaneous coronary intervention (PCI) or coronary artery bypass grafting (CABG)), or hospitalization within 1 month prior to inclusion
- Life-threatening comorbid conditions (e.g., cancer)
- Diminished mental capacities (suspected cognitive decline will be confirmed by a mini mental state examination (MMSE))
- History of psychiatric disorders apart from affective disorders (depression and anxiety disorders)

Study design

Design

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

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-10-2011
Enrollment:	400
Type:	Actual

Medical products/devices used

Generic name:	Medication Adherence Monitor (PICO®)
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	20-04-2011
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

Approved WMO Date:	07-12-2011
Application type:	Amendment
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

No registrations found.

In other registers

Register	ID
CCMO	NL36135.028.11

Study results

Date completed:	21-12-2012
Actual enrolment:	25