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Telemonitoring in patients with heart failure, the TEHAF study: Study protocol of an ongoing prospective randomised trial

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ABSTRACT

Background: As the prevalence of heart failure (HF) rises sharply, the costs related to the care of these patients increases in parallel. Considering the already limited resources and manpower, in the future the demand for care may exceed the supply. Therefore, health care systems are encouraged to develop innovative strategies to deal with the burden of HF to improve the quality of care in order to medical outcomes and patients' quality of life. For that reason new management systems – such as telemonitoring – have to be explored.
Objectives: This paper outlines the study protocol of a tailor-made telemonitoring program in ambulant patients with HF.
Design and methods: A prospective randomised controlled trial is carried out at 3 hospitals in the South-Limburg area in the Netherlands. Primary outcome measures are hospital admissions and cost-effectiveness. Secondary outcomes are effects on therapy compliance, level of disease specific knowledge and quality of life. Also determinants are studied of most and less benefited patients in the intervention group.
Power calculation: It is estimated that 390 patients have to be included in the study, with 185 in each arm.
Results: Inclusion started in September 2007 with a follow-up time of 12 months. First results are expected at the end of 2010.

What is already known about the topic?

- Non-adherence resulting in increased hospitalisations is common in patients with HF.
- Telemonitoring is one of the recently developed as part of chronic care management systems in patients with HF; however randomised controlled trials are lacking to proof its (cost-) effectiveness.
- The majority of the telemonitoring systems focuses on vital signs such as blood pressure, rate control and weight.

What this paper adds

- This paper presents a study of the value of a telemonitoring system, using a randomised controlled trial design.
- It focuses on education, adherence and self-management as a means to reduce symptoms or detect those at an early stage, rather than monitoring just vital signs using communication programs, tailored to the patients needs.
- To better meet with the specific patient needs, four telemonitoring programs were designed with different

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emphasis on the dialogues about knowledge, compliance and symptoms respectively.

1. Background

The most effective strategies to control chronic diseases contain multiple components as recommended by the European Society Guidelines (Dickstein et al., 2008; Coleman et al., 2009). Of these components, the most challenging is patient education (McAlister et al., 2004; Yu et al., 2006). Patient education is based on the assumption that giving information results in knowledge and skills gain. The majority of studies shows positive influences on the outcome of HF patients, although it is not clear which information is best for which patient (Yu et al., 2006). Although the body of educational programs for heart failure patients is extensive (Dickstein et al., 2008), knowledge is limited how these methods match with the patients needs. Moreover, the majority of patients with HF is 65 years of age or older, being a possible challenge for education programs to be effective (Yu et al., 2006). Co-morbidities such as diabetes, chronic lung and renal failure, peripheral atherosclerosis, depression and/or personality disorders are additional hurdles for patients to deal with (new) information and about how to deal best with health issues (Sloan and Pressler, 2009; Braunstein et al., 2003).

Patient education is an important component in the management of HF and should be provided through effective and well-evaluated integrated care strategies. HF education can further be improved by combining oral or written communication with new technologies such as telemonitoring (TM) (Strömberg, 2005). Trying to make TM applications generalizable to the HF population at large, may often fail to meet particular patient needs. Therefore subpopulations have been suggested to be categorized based on variables such as age, gender, specific medical problems, chronic disease, or cultural aspects and accordingly education should be adjusted to these categories (Alverson et al., 2008).

This article describes the design of a randomized controlled trial aiming at evaluating a TM system the Health Buddy® in HF patients, using tailor-made TM programs for patients with HF as the intervention, the TEHAF study. The development of the tailor-made program is based on the experience with the Health Buddy® in a preceding pilot study in the participating centres of Heerlen (Atrium Medical Centre), Maastricht (University Medical Centre) and Sittard (Orbis Medical and Care Concern), situated in the South-Limburg, the Netherlands (Boyne et al., 2008).

2. Methods

2.1. Study population

Eligible for inclusion are patients with chronic HF New York Heart Association (NYHA) classes II–IV treated by a cardiologist and in care of a HF nurse (HFN). Selection of patients occurs in the outpatient clinic from one of the participating centres and in the home situation when patients are visited by a HFN. Patients are excluded if being unable to give informed consent, have visual limitations, hard of hearing in combination with living as a single person, did not have command of the Dutch language, were planned for a hospital admission within 3 months and/or suffer from chronically obstructive pulmonary disease, Parkinson's disease, extracorporeal dialysis, (pre)dementia or another disease with a expectedly shortened life span.

2.2. Study design

A prospective, randomised controlled trial is conducted with a follow-up period of 12 months. Cardiologists and HFN select patients with HF, whereas the research nurses contact the patient in case of eligibility. After given informed consent, patients are randomised by a dedicated software system (SPSS 15.0) either to the control group, receiving usual care according the European guidelines or

Table 1
Study design.