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Effectiveness of telemedicine and distance learning applications for patients with chronic heart failure. A protocol for prospective parallel group non-randomised open label study

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ABSTRACT

Introduction: Chronic heart failure in Baltic Sea Region is responsible for more hospitalisations than all forms of cancer combined and is one of the leading causes of hospitalisations in elderly patients. Frequent hospitalisations, along with other direct and indirect costs, place financial burden on healthcare systems. We aim to test the hypothesis that telemedicine and distance learning applications is superior to the current standard of home care.

Methods and analysis: Prospective parallel group non-randomised open label study in patients with New York Heart Association (NYHA) II–III chronic heart failure will be carried out in six Baltic Sea Region countries. The study is organised into two 6-month follow-up periods. The first 6-month period is based on active implementation of tele-education and/or telemedicine for patients in two groups (active run period) and one standard care group (passive run period). The second 6-month period of observation will be based on standard care model (passive run period) to all three groups. Our proposed practice change is based on translational research with empirically supported interventions brought to practice and aims to find the home care model that is most effective to patient needs.

Ethics and dissemination: This study has been approved by National Bioethics Committee (2011-03-07; Registration No: BE-2-11).

Trial Registration: This study has been registered in Australian New Zealand Clinical Trials Registry (ANZCTR) with registration number ACTRN12611000834954.

ARTICLE SUMMARY

Article focus

- Focus on feasibility of telemedicine (TM) and distance learning applications for chronic heart failure (CHF) patients after hospital discharge.

Key messages

- Patients, taking an active role in disease management, facilitated by appropriate diet, exercise, daily self-measurement (eg, weight scales and blood pressure devices), medication compliance, smoking and other behaviour control, education, recognition of disease-related symptoms live beyond the years normally expected.
- Home care supported by TM and tele-education (TE) has the potential to be integrated into the standard of home care with improvements in efficiency and effectiveness of care.

Strengths and limitations of this study

- The strengths of this study can be seen in the integration of TM and TE to standard home care model.
- Use of a quasi-experimental study rather than randomised controlled trial design. This can lead to the internal validity bias, mostly related to sample selection bias.
- The control strategies should help to minimise these potential biases. Our sample will be generated from the list of patients recently diagnosed with CHF. The allocation to the groups will be based on matching by age, sex, education level and New York Heart Association class—these criteria should ensure clinical and sociodemographic comparability of study and control groups.

INTRODUCTION

Background

Chronic heart failure (CHF) is a major public health problem in many regions characterised by significant mortality and high hospitalisation rates, as well as poor quality of life. The prevalence of CHF is increasing throughout the world.[1 2] In Europe, the prevalence of CHF is between 2% and 3%; in the elderly patients it is estimated to reach more than 10%.[1] Interestingly, CHF is

responsible for more hospitalisations than all forms of cancer combined and it is the leading cause of hospitalisation in the elderly patients.[2 3] In-hospital death rate is excessive and the readmission rate is very high. Overall 50% of patients die within 4 years; 40% of patients admitted to hospital with CHF die or are readmitted within 1 year.[1] Frequent hospitalisations, along with other direct and indirect costs, place an enormous financial burden on healthcare systems.[2 3] CHF accounts for approximately 2% of the national expenditure on healthcare in the EU countries.[4] Same, CHF represents a major burden for most Baltic Sea Region countries with a clear need for better home care of CHF patients.[5]

Therapies targeted at improving outcomes in CHF have been well studied over the past two decades; new therapy possibilities has been leading to an improvement of survival rates as well as a decrease in morbidity, mostly associated to ACE inhibitors, angiotensin receptor blockers (ARBs), β-blockers and mineralocorticoid antagonists availability.[6 7] However, despite advances in pharmacological therapies, the outlook remains poor.

Previous studies on traditional telemonitoring of CHF patients have determined that telemonitoring has the potential to reduce mortality, hospitalisations and costs as well as improve quality of life, self-care and New York Heart Association (NYHA) class.[8–11] However, the results of telemonitoring trials have been inconsistent due to diverse study interventions and common variations in the study designs. The findings also suggest that tele-education (TE) programmes give merit for CHF patients by reducing number of hospital stays, optimising medical therapy, improving quality of life and reducing mortality.[12] Furthermore, the potential for telemedicine (TM) and e-health is particularly promising for most cardiovascular patients.[10 12]

Rationale

CHF is a chronic condition where appropriate disease management is critical.[1] Effective disease management requires the patient to take an active role in his/her health. Indeed, CHF is a disease where patient empowerment is very important. Unfortunately, many CHF patients do not successfully manage their disease; therefore rehospitalisation and high death rates prevail.[1–3] Frequent communication between patient and healthcare professionals, intensive education programmes, and home health monitoring can help reduce hospitalisations and death rates.[12] Despite the dismal prognosis, there are several examples of CHF patients living beyond the years normally expected.[12 13] These successes are usually attributed to patients taking an active role in disease management, facilitated by appropriate diet, exercise, daily self-measurement (eg, weight scales and blood pressure (BP) devices), medication compliance, smoking and other behaviour control and education on recognition of disease-related symptoms.[2 7 13]

Objectives

Primary objective is to test the hypothesis that TM and distance learning applications is superior to the current standard of care after hospital discharge.

Secondary objectives are:

- To evaluate the feasibility of TM and distance learning applications for CHF patients after hospital discharge.
- To evaluate the efficacy of TM and distance learning applications on mortality, morbidity, symptoms and quality of life compared to standard care (SC).
- To evaluate the safety and patient satisfaction on selected TM and distance learning applications used for patient home care model.

METHODS/DESIGN

Study design

This is a prospective parallel group non-randomised open label study in patients with NYHA II–III chronic heart failure. Total follow-up period 12 months (6 months active following by 6 months passive periods).

Diagnosis

CHF (NYHA) II–III by NYHA.

Study participants

The study involves patients from six Baltic Sea Region countries (Lithuania, Poland, Sweden, Norway, Finland and Germany and seven participating study sites) who have had diagnosed CHF (II–III NYHA) and hospitalisation not earlier than 1 year before involvement to the study.

This study investigates the superiority and effectiveness in three groups (figure 1).

Group 1: SC+TM+TE: standard home care programme plus 6-month tele-monitoring programme and plus 6-month TE programme.

Group 2: SC+TE: standard home care programme plus 6 month TE programme.

Group 3: SC only (comparator): only standard home care.

Study organisation and management

The study is organised into two 6 month follow-up periods. First 6-month period is based on active implementation of TM and TE for patients in SC+TM+TE group and SC+TE group (active run period). SC group runs on SC model. Second period based on SC model (passive run period) to all three groups.

Patient visits and data collection

Patient visits scheduled at 0, 6 and 12 months (figure 2).

At visit 1, patient's eligibility for entering the study will be assessed by the investigator. Inclusion/exclusion criteria will be analysed (table 1). The patient should sign an informed consent form if he agrees for participation in the study. Informed consent should be provided

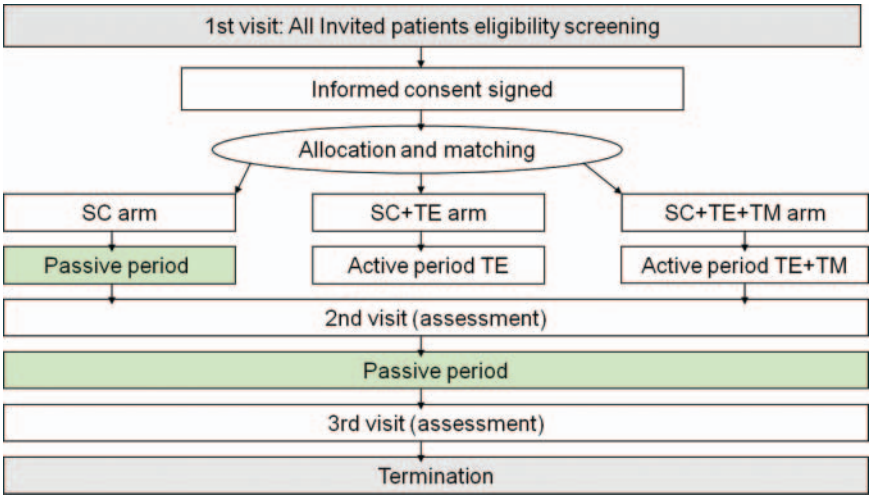

Figure 1 Study management scheme.

before any study-specific procedure will be performed. The patient will be registered to the electronic patient record (EPR) SALUDA.

During visit 1 patients will be assigned to one of the groups and will receive training how to install and use TM devices at home (BP monitor and scale), instructions on daily measurements and data collection; will be trained how to work with SALUDA EPR and SALUDA e-learning programme.

During all planned visits the staff will fill-in Clinical Data Collection Form and will perform measurements to collect clinical data. Patients will have to fill-in Patient Visit questionnaire; MacNew Quality of Live questionnaire; EQ-5D Quality of Live questionnaire (table 2).

Active run period

Duration—6 months: starts after randomisation and ends at tmonth 6. During the active period, the study group SC +TE will receive TE programme together with educative messages on individual risk factors. SC+TE+TM group will receive TE programme and will be involved in weight and BP tele-monitoring. SC only group in active run period will not be involved.

Passive run period

Duration—6 months: starts after visit 2 (month 6) and ends at the month 12. At this period all groups run only on SC programme. Patients (all groups) are advised to take control on individual risk factors, on daily self-measurements and to collect own health data (ie, patient empowerment and support for self-care).

Premature patient withdrawal

Discontinuation can be due to patient death, hospitalisation, other serious disease limiting participation or by patient or staff decision to stop the participation in the study.

1. In case of patient death: staff should fill-in the Death report form.
2. In case of patient long-term hospitalisation, other serious disease limiting participation: staff should fill-in the Drop-Out report form.

Interventions

SC+TM+TE group

The patients at the SC+TM+TE group will receive local standard of care supplemented by tele-monitoring and TE.

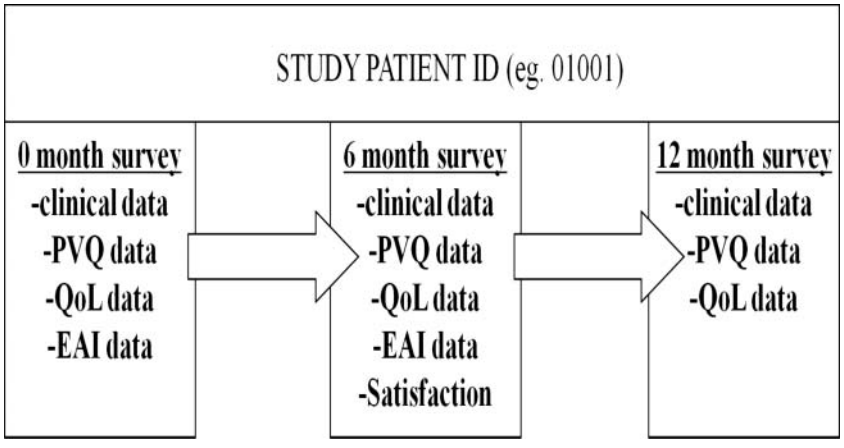

Figure 2 Data flow in the study. EAI, eHealth acceptance index; PVQ, patient visit questionnaire; QoL, quality of life.

Table 1 Key inclusion and exclusion criteria

Key criteria for inclusion	Key criteria for exclusion
1. Written informed consent obtained	1. NYHA I or IV at screening
2. Male and female patients over 18 years of age	2. Therapeutic education impossible
3. Chronic heart failure diagnosed at least prior to the involvement into the study. Treated with relevant long-term oral treatment	3. Severe renal insufficiency (serum creatinine >450 μmol/l [5 mg/dl]) or on dialysis
4. NYHA II–III at screening	4. Severe anaemia (blood haemoglobin <10 g/dl) at screening
	5. Other serious diseases limiting life expectancy considerably (eg, end-stage cancer)

NYHA, New York Heart Association.

All patients will be instructed to take their weight and BP measurements daily. The patient himself will send all telemetric reports to the Primary Investigational site (site responsible for patient involvement) or to the assigned Secondary Investigational site (site having right to access to the patient reports via internet). The Primary Investigational site is responsible for the patient data follow-up: patient consultations, instructing, treatment change or referencing to the general physician.

This group of patients will also receive basic distance learning with SALUDA e-learning programme. Patients on TE beside SALUDA TE programme will receive short educative messages on individual risk factors on a regular basis (every 2–3 weeks).

During the active implementation phase all patients start the web-based e-learning. The patients should continue self-measurements and reporting with allocated TM devices during the entire tele-monitoring period. The daily measurements should be filled-in to an electronic patient record at the SALUDA EPR system after each measurement. The Primary Investigational site should check the completeness of the tele-monitoring reports and patient study tasks once per week. The patient should be also advised for behaviour change according to the individual risk factors.

Table 2 The checklist for data collection

	Patient visit		
Data collection	**Month 0**	**Month 6**	**Month 12**
Staff checklist			
Informed patient consent	√		
Screening form	√		
Allocation to the group	√		
Clinical data collection form	√	√	√
Registration to the SALUDA	√		
Enter data to the SALUDA EPR	√	√	√
Advice patient on daily self-monitoring	√	√	√
Patient checklist			
Patient visit questionnaire	√	√	√
MacNew quality of live questionnaire	√	√	√
EQ-5D quality of live questionnaire	√	√	√
EAI questionnaire	√	√	
Patient satisfaction with service questionnaire		√	

EAI, eHealth acceptance index; EPR, electronic patient record.

SC+TE group

The patients at the SC+TE group will receive local standard of care supplemented by a TE programme.

This group of patients will also receive basic distance learning with SALUDA e-learning programme. Patients on TE beside SALUDA TE programme will receive short educative messages on individual risk factors on a regular basis (every 2–3 weeks).

During active implementation phase the patient starts the web-based e-learning. The patient should be advised for self-measurements and behaviour change according to individual risk factors. The daily measurements should be filled in to an electronic patient record at the SALUDA EPR system after each measurement.

SC group

The patients in SC group will receive local standard of care. The patient should be advised for self-measurements and for behavioural change according to the individual risk factors. The daily measurements should be filled in paper data collection sheets after each measurement.

TM and TE applications in use

The TM set includes a telemetric scale and telemetric BP monitor with possibility to transmit clinical data to the TM station by SMS via telephone line.

Electronic patient record

Web-based EPR SALUDA will be used for electronic patient record during active period. After patient involvement, the study staff should register patient to the SALUDA EPR with assigned study ID number. Any personal information cannot be used in the SALUDA EPR. SALUDA EPR will be used only for daily clinical data collection from TM devices and will allow investigators to review the alarm settings and clinical information.

Telemetric BP measurement device

The Communication BP monitor—Stabil-O-Graph will be used in the active implementation period (0–6 month). The communication BP measurement device is equipped with a Bluetooth interface, which enables the transfer of measured data to the online database.

Telemetric scale

The Communication scale—Libr-O-Graph will be used in the active implementation period (0–6 month). The communication scale is equipped with a Bluetooth interface, which enables the transfer of measured data to the online database.

Distance learning materials and content

Distance learning programme SALUDA will be used for CHF patient basic learning on disease patterns. Patients on TE programme beside SALUDA e-learning programme will receive short educative messages on individual risk factors at the regular basis (every 2–3 weeks). The aim of these messages is to update the information and to empower patients to control they own risk factors.

Educative message should include: problem statement, motivation and practical application.

Outcome measures

The primary outcome measures will be the number of days alive without worsening heart failure and median of time up to hospitalisation for the heart failure. In this study we will be able also to assess: umber of days experiencing worsening heart failure per 100 days at risk; number of days alive without worsening heart failure; number of hospitalisation days; number of contacts to any medical specialists; time to death or worsening heart failure; change in risk factor profile; quality-of-life changes, etc (table 3).Sample size

The target sample size calculated using ViSta V.6.4 and aiming to be not less than 198 for each intervention group, with an effect size of Cohen's d=0.60 will be statistically significant (90% power and 5% level), and is seen as a relevant difference between the conditions. On the basis of previous experience approximately 50% screen failure rate is anticipated. It is estimated that approximately 1600 patients will be screened.

Patient allocation to the groups

Recruitment of patients

At each investigational site, the doctor, the tele-nurse or the practice nurse is responsible for managing recruitment process. During the data collection period, all adult patients with CHF who meet the inclusion criteria will be contacted directly or by phone and invited to participate in the study. Participation and consent have to be subsequently discussed with the referring doctor or nurse at the screening appointment. Patients will be provided with written information about the study, and invited to give written consent for inclusion to the study.

Allocation method

Patient allocation to groups will be based on patient possibilities to use TM applications, availability of internet

Table 3 Outcome assessment

Outcome	How assessed?	When assessed?
Number of days alive without worsening heart failure	During study period all patient data will arrive to patient diary, all worsening events and contacts to the physicians will be recorded	At 6 and 12 months of observation
Number of hospitalisation days	During study period all patient hospitalisation data, all hospitalisations due to cardiovascular event will be recorded	At 6 and 12 months of observation
Number of contacts to any medical specialists	During study period all patient data will arrive to patient diary, all contacts to the physicians will be recorded as well	At 6 and 12 months of observation
Number of days experiencing worsening heart failure per 100 days at risk	During study period all patient data will arrive to patient diary, all worsening events and contacts to the physicians will be recorded	At 6 and 12 months of observation
Quality of life (QoL)	QoL will be assessed by MacNew QoL questionnaire	At 0, 6 and 12 months of observation
NYHA class change	Will be assessed at each visit. Possible changes will be analysed according to the medical assessment	At 0, 6 and 12 months of observation
Weight	Measured by scale daily. Dynamics will be analysed	Daily
Blood pressure	Measured by blood pressure monitor daily. Dynamics will be analysed	Daily
eHealth acceptance	eHealth acceptance will be assessed by EAI questionnaire.	At 0, 6 and 12 months of observation
Change in risk factor profile	Number of risk factors will be calculated as a risk factor profile for each patient. Possible changes will be analysed	At 0, 6 and 12 months of observation

EAI, eHealth acceptance index; NYHA, New York Heart Association.

Table 4 Patient allocation requirements

Group	Minimum requirement for selection
SC+TM+TE group	1. Internet connection available 2. Sufficient competence to use internet confirmed 3. Agrees for TE 4. Agrees for telemedicine application
SC+TE group	1. Internet connection available 2. Sufficient competence to use internet confirmed 3. Agrees for TE
SC group	1. Agrees to participate only in SC *Note*: internet connection and competence to use is not important for this group

SC, standard care; TM, telemedicine; TE, tele-education.

and internet use competences. Those who do not have internet access or are incompetent users should be assigned for the SC (table 4).

Matching

Patient baseline clinical and socio-demographic characteristics are aimed to be balanced between groups. To balance groups matching by age, gender, educational level, left ventricular ejection fraction and NYHA class at baseline will be performed.

Data protection

Regarding confidentiality assurance issues, each patient is uniquely identified in the study by a five-digit number. This number is a combination of his/her site number and patient number (eg,01001)—named PATIENT ID. Any data transferred and collected centrally will be collected only using PATIENT ID or DEVICE ID. All personal information will be collected at the Investigational site and protected according to local Data Protection Law. The patient in the study can be identified only by PATIENT ID at Investigational site and only when patient signed informed consent form.

Data analysis

The PP (perprotocol population) will be used for supportive analyses. The analysis will be presented, by the treatment group, to summarise the primary, secondary and all other variables. In addition, multifactor analyses will be performed for each of the components of the all events and risk factor profile changes.

DISCUSSION AND CONCLUSIONS

Currently, most healthcare systems are being oriented to the new methods in order to improve efficiency of the systems.[14] eHealth, TM and TE has the potential to be integrated into the standard of home care with improvements in efficiency and effectiveness of care.[9 15] However, TM and TE interventions must be examined critically by using rigorous methodology.[16]

This study addresses a significant knowledge gap by applying quasi-experimental clinical trial methodology to determine the effect of a TM and TE interventions on health outcomes after patient discharge to home.

RIGOUR AND LIMITATIONS

Limitations of our study protocol can be seen in use of a quasi-experimental rather than a randomised controlled trial design. This can lead to the internal validity bias including bias mostly related to a sample selection by concurrent allocation.[17] The control strategies should help to minimise these potential biases. Study sample will be generated from the list of patients recently diagnosed with CHF. Allocation to the groups will be based on matching by age, sex, education level and NYHA class—it should ensure clinical and socio-demographic comparability of study and control groups. Thus, bias related to sample selection and allocation will be addressed in part because the patient sample will include only eligible patient population. We will include adjustments in the data analysis, for example, bootstrapping can be used.

Strengths of this study protocol include the fact that we are seeking to find the way for better home care model in CHF patient care. Current standard of care is associated to high rehospitalisation and death rates. We hope that this study, aiming to analyse home care practice change by introduction of TM and TE facilities will facilitate improvements in home care quality. We also hope that the practice change will lead to more cost-effective use of healthcare resources.

Our proposed practice change is based on translational research with empirically supported interventions. It can help to find the most effective and to patient needs oriented home care model.

By this study it is expected to evaluate the feasibility of TM and distance learning applications for CHF patients after hospital discharge. This study aims at evaluating the efficacy of TM and distance learning applications to improve disease patterns and quality of life compared to current standard of care.

OTHER INFORMATION

Ethical approval

This study has been approved by National Bioethics Committee (2011-03-07; BE-2-11).

Patient will get all necessary information about the study and they will be asked to sign informed consent form adopted from templates developed by the WHO ERC. The informed consent form consists of two parts: the information sheet and the consent certificate. This should ensure the understanding of the information being provided.

Investigative site staff is responsible to keep personal identification information in accordance with the local Data Protection Law for coding and recoding.

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Contributors GV, participated in all phases of study protocol and manuscript preparation and planning, act as Principal Investigator; JU, participated in study protocol preparation and planning; RŠ, participated in study protocol preparation and planning.

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Competing interests None.

Patient consent Obtained.

Ethical approval Lithuanian National Bioethics Committee.

Provenance and peer review Not commissioned; externally peer reviewed.

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