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Rationale and Study Design

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eEduHeart I: a multi-center randomized, controlled trial investigating the effectiveness of a cardiac web-based eLearning platform – Rationale and study design

Short title: eEduHeart I, Rationale and study design

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Abstract

Objectives Cardiac telerehabilitation includes, in its most comprehensive format, both telemonitoring, telecoaching, social interaction and eLearning. The specific role of eLearning however, was seldom assessed. The aim of eEduHeart I is to investigate the medium-term effectiveness of the addition of a cardiac web-based eLearning platform to conventional cardiac care.

Methods In this prospective, multi-center randomized, controlled trial 1000 patients with coronary artery disease will be randomized 1:1 to an intervention group (receiving one-month unrestricted access to the cardiac eLearning platform in addition to conventional cardiac care) or to conventional cardiac care alone. The primary endpoint is health-related quality of life, assessed by the HeartQoL questionnaire at 1 and 3 months follow-up period. Secondary endpoints include pathology specific knowledge and self-reported eLearning platform user experience. Data on the eLearning platform usage will be gathered through web logging during study period.

Results eEduHeart I will be one of the first studies to report on the added value of eLearning.

Conclusions If the intervention is proven effective, current cardiac telerehabilitation programs can be augmented by including also eLearning. The platform can then be used as a model for other chronic diseases in which patient education plays a key role.

Introduction

Ischemic heart disease is a leading cause of death worldwide. Each year more than 7 million people experience a myocardial infarction and one year mortality rates are still in the range of 10% [1]. Secondary prevention by means of cardiac rehabilitation (CR) is recommended by the American Heart Association and the European Society of Cardiology (Class IB recommendation) after the initial coronary event [2]. Although proven effective, < 50% of eligible patients attend CR, as reported in EUROASPIRE IV (the European Society of Cardiology survey on the therapeutic management of ischemic heart disease patients from 24 European countries) [3]. Patients regularly choose not to attend center-based rehabilitation due to a lack of access to transport, ill-health, time and scheduling commitments associated with returning to work or reimbursement issues [4]. This leads to suboptimal secondary cardiovascular prevention efficacy.

Innovative care delivery strategies such as cardiac telerehabilitation have been proposed as potential adjuncts/alternatives to optimize rehabilitation uptake and long-term adherence rates [5]. In telerehabilitation, the patient is not restricted to the hospital or rehabilitation center environment for CR, but rehabilitates remotely by using one or several devices monitoring and communicating patient-specific information to the caregivers. In its most comprehensive format, it includes both telemonitoring (i.e. remote monitoring), telecoaching (i.e. coaching from a distance by email/SMS/telephone), social interaction and eLearning and focuses on all CR core components (physical activity, behavioural change, risk factor control, nutritional counselling, psychosocial support and education).

Recent research findings on cardiac telerehabilitation for coronary artery disease (CAD) showed non-inferiority and/or superiority of telerehabilitation on adherence to physical activity guidelines, quality of life and cardiovascular readmission rates [5-8]. In these studies however, telemonitoring and telecoaching were the two focus areas mostly applied. The specific role and value of eLearning were hardly assessed [9, 10]. Proper patient education however seems highly relevant. Patients who have a clear understanding of their after-hospital care instructions are 30% less likely to be readmitted or to visit the emergency department than patients who lack this information [11]. Unstructured conventional ways for informing/educating, small time dedicated to education, poor quality explanations by hospital health staff are determinants of poor implementation of secondary preventive measures [12].

A specific challenge for internet-based telemedical interventions appears to be the low uptake and high attrition rates [13]. Antypas K, et al. investigated an internet- and mobile-based tailored intervention to enhance the

maintenance of physical activity following cardiac rehabilitation [13]. They could only enroll 69 patients (out of 255 patients initially planned) and the enrolled patients had an unexpectedly high attrition rate (with 19/69 patients responding at 3 months follow-up period). Therefore, special attention to telemedical intervention characteristics that can increase patient uptake and adherence is needed.

The eEduHeart I trial is a randomized, controlled, multi-center study ($n = 1000$) designed to investigate the effectiveness of the addition of eLearning to conventional cardiac care; when compared to conventional cardiac care alone. In eLearning the patients are taught about the etiology, pathophysiology, clinical presentation and medical treatment of their cardiac disease using a repository of video material on a specifically developed web-based cardiac eLearning platform. The primary hypothesis is that the addition of eLearning improves patients' health-related quality of life with greater magnitude, when compared to conventional cardiac care alone. Secondary endpoints include cardiac pathology specific knowledge level, eLearning platform user experience and eLearning platform usage.

Methods

Study design

eEduHeart I is a multi-center, prospective, randomized, controlled clinical trial recruiting 1000 stable CAD patients. Patients with stable CAD are defined as a) patients in the revascularised, stabilized and asymptomatic phase following an acute coronary syndrome (ACS) (unstable angina, non-ST elevation ACS or ST-elevation ACS) or b) patients initially presenting with stable angina who are revascularised or asymptomatic under optimal medical treatment (not amenable to revascularization) [2]. Patients are randomized in equal proportions to one of two groups: web-based eLearning in addition to conventional cardiac care (intervention group) or conventional cardiac care alone (control group) (Fig. 1). Patients are enrolled after hospitalization for the initial coronary event. eEduHeart I patients were initially hospitalized for the following indications: stable angina with abnormal non-invasive cardiac stress tests, unstable angina, non-ST elevation ACS or ST-elevation ACS. All included patients underwent an invasive coronary angiography. Obstructive CAD for which revascularization was indicated was defined as: i. left main disease with stenosis $> 50\%$, ii. proximal LAD stenosis $> 50\%$, iii. two-vessel or three-vessel disease with stenosis $> 50\%$ and with impaired LV function ($LVEF < 40\%$), iv. single remaining patent coronary artery with stenosis $> 50\%$ and/or v. any coronary stenosis $> 50\%$ in the presence of limiting angina or angina equivalent, unresponsive to medical therapy [14]. They are followed for a minimum duration of 3 months. Eligible eEduHeart I patients are expected to be recruited from January 2016 to July 2017.

Patients are recruited from the Cardiology Departments of two Belgian community clinics i.e. Jessa Hospital (Hasselt) and Hospital East-Limburg (Genk). The Jessa Hospital acts as the coordinating center for the trial. Each participating site is responsible for the recruitment and scheduled follow-up of patients; but also for contingency patient management. Both sites have the capability for effective recruitment (yearly number of hospitalizations for coronary artery disease in Jessa Hospital: >1200 and Hospital East-Limburg: > 1500). However, premature closure of a recruiting site will be considered if 1) the recruitment rate is not sufficient, 2) the conduct of the study is not compliant with the study protocol, or 3) data quality is not sufficient. The premature closure of a site will be decided by the principal investigator. In this case, reserve trial sites, suitable for inclusion in eEduHeart I, will be contacted. eEduHeart I's principal investigator verifies on a monthly basis patient inclusion rate in both recruiting hospitals, study conductance and data quality by reviewing the clinical trial database. In case the patient inclusion rate < 60 patients/month for 2 consecutive months (for all recruiting centers combined), one additional reserve trial site is opened. Two back-up institutions (each of which with > 700 hospitalizations for coronary artery disease per year) were contacted prior to the start of eEduHeart I. Both confirmed their willingness to serve as reserve trial site. Upon the decision to include a back-up institution, approval from the institution's ethical committee to conduct eEduHeart I is asked for. Once approval has been obtained (this is expected 2 weeks after submission of the request), patient inclusion can start. In both reserve trial sites, a researcher is available to ensure patient inclusion and follow-up during eEduHeart I study period.

The study is conducted in accordance with the principles stated in the Declaration of Helsinki (reviewed version of 2008), local and national regulations. Written informed consent is obtained from all patients by predetermined site-specific eEduHeart I investigators prior to study enrollment. The study is approved by the appropriate ethics committee (Jessa Ethics Committee; reference number: 15.82/cardio15.11; dd. 20 November 2015, version No2). eEduHeart I is registered at ClinicalTrials.gov NCT02475967. Registration date 10 June 2015.

eEduHeart I adheres to the relevant standards of reporting. A completed CONSORT checklist can be found in Annex 1. The study protocol complies with the SPIRIT guidelines, the populated checklist of which can be found in Annex 2.

Study population

Patients with CAD, for which they were treated conservatively, with a percutaneous coronary intervention or with coronary artery bypass grafting and who signed the informed consent form; are eligible to participate. They are at least 18 years old and must have a personal computer with internet connection. The main exclusion criteria

are: insufficient reading and writing language skills in the relevant language (Dutch), the presence of pre-existing dementia, a cognitive impairment, visual and/or auditory impairments that unables the patient to understand the eLearning platform content.

Sample size

The sample size calculation is based on a small effect size of 0.1 for the primary outcome measure (HeartQoL score), which is expected [8]. In order to attain a minimal power of 80%, at an alpha error probability < 0.05 ; 998 patients should be recruited when taking into account a dropout rate of 5% during follow-up.

Randomization

During/after hospitalization for the initial coronary event, patients will be recruited by predetermined site-specific eEduHeart I investigators. They will first inform the patient about the study and hand out study information. Patients will be randomized (1:1) to the intervention group or to the control group, using sequentially numbered, opaque, sealed envelopes. Block randomization is used to ascertain equal group distribution in the different recruiting hospitals.

Study intervention

Patients in the intervention group are provided with access to a web-based cardiac eLearning platform in addition to conventional cardiac care.

The cardiac eLearning platform

Intervention patients are given six eLearning platform entry codes and passwords, within 2 days after randomization. They are provided with background and general information regarding the study design, content and main hypotheses of eEduHeart I. Patients are taught how to go to the web-based platform on their personal computer and how to enter. The codes and passwords enable unrestricted platform access for a one-month period, starting from the date of first platform log-in. One code and password is intended for study patient use only, the others can be distributed to family members and/or friends, thereby enabling a one-month platform access for them too.

The eLearning platform was designed and developed using a user-centric approach. Special attention was given to ensure a user-friendly platform design, also for elderly patients not familiar with internet-based interventions. The eLearning platform content was based on the CR core components for coronary artery disease patients as

defined in the European Society of Cardiology and European Association for Cardiovascular Prevention and Rehabilitation guidelines [15, 16]. It contains 20 main video units. Each video unit focuses on a different topic, relevant in secondary prevention for ischemic heart disease. The following topics are present: i. smoking as risk factor; ii. the cardiovascular risk factors; iii. drug therapy & side effects; iv. the signs and symptoms of coronary artery disease; v. lifestyle behavior change after the coronary event; vi. heart friendly diet; vii. exercise training; viii. cardiac rehabilitation; ix. cardiac telerehabilitation; x. leisure time activities; xi. anxiety & depression; xii. social support; xiii. importance of regular medical follow-up; xiv. quality of life; xv. driving a car after the coronary event; xvi. travel; xvii. return to work; xviii. discouraged activities; xix. being a caregiver for a coronary artery disease patient; xx. family & friends. Each video unit is composed of three videos, one or two with (a) (para-)medical caregiver(s) and one or two with (a) patient(s). The aim of the videos in which the (para-)medics participate is to provide eEduHeart I study patients with educational content on the video unit topic. The videos in which patients participate themselves, intend to enable the sharing of subjective experiences. Video length is between one and two minutes. Study patients can watch each video (unit) more than once if preferred.

Conventional cardiac care

Patients in both the control and intervention group are invited to follow the conventional center-based CR program; including a total of 45 pluridisciplinary sessions focusing on nutritional counselling, psychosocial wellbeing, behavioral change, risk factor modification, education and exercise training. One standard group session on nutritional counseling can be supplemented by one or two face-to-face session(s), according to the patient preferences. The CR center's psychologist invites all patients for a basic psychological screening consultation (aiming to detect anxiety, depression and personality disorders), and also follow-up visits if indicated desirable by the patient. The exercise training sessions are scheduled 2 to 3 times/week; with an average session duration of 45 min. Exercise modalities include both endurance training (walking, running and cycling) and resistance training. Training intensity is progressively increased from the first ventilatory threshold to the respiratory compensation point. Only one 60-minutes educational session is provided to CR patients at the start of CR. The educational session is performed by the hospital's cardiologist/rehabilitation physician and covers the following topics: physiology and pathology of the cardiovascular system (including coronary artery disease, rhythm disorders, heart failure and valvular disease), signs and symptoms of cardiac disease, drug therapy and side effects. In case control and/or intervention group patients decide not to participate in conventional CR, they are provided with standard bi-annually follow-up visits with the treating cardiologist only.

Outcome measures

For an overview of all measures over the different measurement time points, please see SPIRIT Table 1. Each premature termination of follow-up will be documented by the responsible investigator. If possible, date, circumstances of and reason for the termination will be documented in detail, and communicated to the principal investigator.

Demographic characteristics

The background variables that are assessed include age, gender, education, profession, cardiovascular risk factor profile, co-morbidities, type of initial coronary event (ST-elevation myocardial infarction, non ST-elevation myocardial infarction, unstable angina, stable angina), initial cardiac treatment option (percutaneous coronary intervention, coronary artery bypass grafting or medical treatment), number and type of coronary arteries involved and in- or exclusion in conventional CR.

Health-related quality of life

The 14-item offline validated HeartQol questionnaire will be used to assess health-related quality of life (HRQL) [17]. Mean (\pm SD) scores will be calculated for both the physical (10-item) and emotional (4-item) subscale. The proportion of patients at the floor (“floor effect”, defined as the lowest possible score on the questionnaire) and at the ceiling (“ceiling effect”, defined as the best possible score) will be determined to assess sensitivity to positive and negative changes in HRQL.

Pathology specific knowledge

Pathology specific knowledge will be evaluated using the eEduHeart knowledge questionnaire. This questionnaire was elaborated in a multi-step process involving all relevant coronary artery disease management (para-)medical stakeholders of Jessa Hospital, Hasselt, Belgium (including 1 cardiologist, 1 rehabilitation physician, 2 CR physiotherapists, 2 dieticians, 1 psychologist and 1 social nurse). For each step, all (par-)medical members evaluated the eEduHeart knowledge questionnaire questions in their field of expertise for question clarity, understandability, robustness and relevance. The pre-final version of the questionnaire was pilot tested in a sample of coronary artery disease patients; after which 8/14 questions were rephrased to improve patient understandability. The final eEduHeart questionnaire version includes 14 multiple choice questions (3 answer alternatives/question), all relating to the content of ≥ 1 of the 20 cardiac eLearning platform video units (cardiovascular risk factors: question 1; drug therapy & side effects: questions 2 and 3; signs and symptoms of

coronary artery disease: question 4 and 14; lifestyle behavior change after coronary event: questions 5 and 6; risk factor smoking: questions 7, 8 and 9; cardiac rehabilitation: question 10; heart friendly diet: questions 11 and 12; exercise training: question 13).

eLearning platform user experience

User experience of the web-based eLearning platform will be performed using the validated User Experience Questionnaire (UEQ) [18]. The UEQ consists of 26 items, items covering the same topic are pooled in the same scale (with a total of six scales: attractiveness, perspicuity, efficiency, dependability, stimulation and novelty). The items are scaled from -3 to +3. Thus, -3 represents the most negative answer, 0 a neutral answer, and +3 the most positive answer. Mean (\pm SD) scores will be calculated for each question separately. Also mean (\pm SD) scores will be calculated for each scale. The Cronbach-Alpha coefficients ($\alpha = n * r/1 + (n - 1) * r$, where r is the mean correlation of the items in a scale and n is the number of items in a scale) will be calculated for the six scales of the UEQ. The Alpha-Coefficient is a measure for the consistency of a scale, i.e. it indicates that all items in a scale measure a similar construct.

eLearning platform usage

Data on the eLearning platform usage will be gathered through web logging during whole study period. The number of log-ins per code (i.e. patient or family & friends), the total time logged in, the number and type of video units watched, and the time viewing each specific video unit will be registered.

Data management

Individual registered patient information will be entered into a database at the coordinating center (Jessa Hospital). Only allocation number is used for subject identification. The key to patient identity will be at each participating center only. All information will be stored without name and personal identification, or other identifying information. eEduHeart I's principal investigator must permit all authorized third parties access to the trial site and insight into the trial subjects' source data.

Study endpoints

The primary endpoint of eEduHeart I is the HeartQoL health-related quality of life at 1 and 3 months. The secondary endpoints include:

- eEduHeart pathology specific knowledge score at 1 month and 3 months

- UEQ eLearning platform user experience score at 1 month
- eLearning platform total log-in time during whole study period

All outcome assessors will be blinded to group allocation.

All patients will be contacted by telephone after 1 and 3 months of study period. During these phone calls, patients will be asked to answer the predefined questionnaire questions. The questionnaires will only be sent to the patients by email, if they explicitly ask for it. Furthermore, the phone calls will be used to ask for technical problems relating to the log-in and/or use of the platform. When needed, technical support will be provided.

Statistical analysis

Data analysis will be performed using SPSS v. 22 according to the intention-to-treat principle, by assigned treatment group. Nonparametric alternatives will be used for parametric statistics in case normality assumptions for the latter are violated. The Shapiro-Wilk test will be used to assess normality. Repeated measures ANOVA (parametric) or Friedman's ANOVA (non-parametric) will be used for within-group analysis (compare multiple dependent means); independent t-tests (parametric) or Mann-Whitney U tests (non-parametric) for between-group analysis. Chi-square tests will be used in case of categorical variables and Fisher's exact tests when expected frequencies are small. The significance level for tests will be 2-sided α of 0.05. Subgroup analyses will be performed to determine if the benefit of the intervention differs between groups like educational level, profession and whether or not the patient was included in conventional CR. Dose-response-analyses will be conducted with linear regression to see if the intervention effect depends on the total time logged in on the eLearning platform. Effect sizes for the HeartQoL questionnaire will be reported using the standardized response mean methodology [standardized response mean = $(A - B)/D$], where A and B are the mean scores at time 2 and time 1, respectively. D represents the score change standard deviation [17]. All available data will be used, no data imputation will be performed for missing values.

Discussion

The eEduHeart I trial will investigate the effectiveness of the addition of eLearning using a specifically developed cardiac web-based eLearning platform, to conventional cardiac care. eLearning comprises one of the components of a comprehensive cardiac telerehabilitation program. However, to the best of our knowledge, its specific role and value were hardly assessed.

Study strengths

The study follow-up duration is three months, while the patients' eLearning platform access period is only one month. This will allow us to investigate the medium-term persistence of the platform's educational value. Simple and wide spread technology was used for the construction of the eLearning platform, thereby not challenging our users that will be middle-aged to senior patients. The platform educational content is very robust and based on official recommendations by the European Society of Cardiology and the European Association of Cardiovascular Prevention and Rehabilitation. Another strength of the eEduHeart I trial is the level of user-involvement in the eLearning platform development. As the platform aims to fulfil the demands of both the rehabilitation center (para-)medics and the patients, it is by definition user-initiated. We succeeded in a high level of user-involvement by encouraging both caregiver and patient participation in the video elaboration and hence platform development. The study results are expected to have high external generalizability, since the inclusion criteria are very broad. This will increase the relevance of the results during the implementation of the intervention outside the strictly controlled clinical trial setting.

Expected outcomes and future contributions

The eEduHeart I trial addresses patients with CAD, one of the most important non-communicable diseases worldwide. It aims to provide evidence on the efficacy of a cardiac web-based eLearning platform for secondary prevention with high reach. If the intervention proves to be effective, the eLearning platform can be offered to patients in other cardiac rehabilitation centers. The used methodology can also be applied to other chronic diseases in which patient education plays a key role.

Trial status

The eEduHeart I study protocol and amendments were approved by the hospital's ethics committee prior to study start (B243201526134). The study is currently recruiting patients.

Abbreviations

CAD: coronary artery disease; CR: cardiac rehabilitation; HRQL: health-related quality of life; UEQ: user experience questionnaire.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

IF participated in the design of the study. She aids in the trial conduct, data analysis and interpretation. She drafted the current study design paper. TV participates in the trial conductance and data collection. He helped to draft this manuscript. LJ and AG participate in trial

conductance and data acquisition. They helped to draft the manuscript. PV helped in the trial conductance and critically revised this study design paper. PD participated in the study design and critically revised this study design paper. All authors read and approved the final manuscript.

Authors' information

IF is a medical doctor, currently completing her PhD on cardiac telerehabilitation and her specialization in cardiology. TV is completing his PhD on telemonitoring. LJ is a medical student. AG is a medical student. PV is professor in medicine at Hasselt University and cardiologist at the Hospital East-Limburg. PD is professor in medicine at Hasselt University and head of the department of cardiology at Jessa Hospital, Belgium.

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Figure legends

Fig. 1. Study flow chart. HeartQol: quality of life questionnaire; UEQ: user experience questionnaire.

Table 1. SPIRIT table for enrolment, interventions and assessments.

	<i>Enrolment</i>	<i>Allocation</i>	<i>Post-allocation</i>	
<i>Timepoint</i>	<i>-t₁</i>	<i>0</i>	<i>t₁</i>	<i>t₂</i>
<i>Enrolment</i>				
Eligibility screen	x			
Informed consent	x			
Allocation		x		
<i>Interventions</i>				
eLearning platform access (intervention group only)		↔		
<i>Assessments</i>				
Demographic characteristics		x		
Health-related quality of life		x	x	x
Pathology specific knowledge		x	x	x
Platform user experience (intervention group only)			x	

t₁ represents follow-up at 1 month; t₂ represents follow-up at 3 months.