A Digitally-Supported Shared Decision Making Approach for Patients during Cardiac Rehabilitation: Protocol for a Randomized Controlled Trial.

DOI: 10.21203/rs.3.rs-3786180/v1
Handle: http://hdl.handle.net/1942/45699

A Digitally-Supported Shared Decision Making Approach for Patients during Cardiac Rehabilitation: Protocol for a Randomized Controlled Trial.

Sevda Ece Kizilkilic

sevda.kizilkilic@uhasselt.be

Hasselt University

Wim Ramakers

Hasselt University

Maarten Falter

Hasselt University

Martijn Scherrenberg

University of Antwerp

cindel bonneux

Hasselt University

Dominique Hansen

Hasselt University

Paul Dendale

Hasselt University

Karin Coninx

Hasselt University

Study protocol

Keywords: Shared Decision Making, Cardiac Rehabilitation, Coronary Artery Disease, Decision Aids, Physical Activity, eHealth

Posted Date: January 5th, 2024

DOI: https://doi.org/10.21203/rs.3.rs-3786180/v1

Additional Declarations: No competing interests reported.

Abstract

Background: Physical activity is a key component of cardiac rehabilitation. However, EUROASPIRE V concluded that intending 48% of coronary artery disease (CAD) patients do not intend to do physical activity in the next six months. Patient involvement improves patient satisfaction, adherence, and health outcomes and is a prerequisite for good clinical practice. Unfortunately, patients currently have only limited input in their exercise prescription. We developed SharedHeart, a digitally-supported shared decision making (SDM) approach that assists patients with heart disease and their caregivers in collaboratively setting up exercise goals and creating an exercise plan for the patient.

Objective: The aim of the study is to determine the effectiveness and cost-effectiveness of the combination of center-based CR and shared decision making based telerehabilitation. The study investigates the influence of a SDM approach supported by digital applications on the patient's quality of life, exercise capacity, motivation to exercise, perception of rehabilitation and engagement in the shared decision making process.

Methods: The study is a prospective double-arm, randomized controlled trial that includes a usability study of the applications. In the usability study, instantaneous user friendliness and patients' motivation will be investigated by testing the designed applications with 10 CAD patients and 5 physiotherapists. In the RCT, 80 patients will be randomized 1:1 between an intervention group and a control group. The intervention group will follow the SharedHeart approach, consisting of SDM encounters with caregivers and using the digital tools during phase II cardiac rehabilitation (i.e. 3 months). The primary outcome measure is patients' quality of life, assessed with the HeartQoL questionnaire. Secondary outcomes are related to patients' exercise capacity, motivation to exercise, perception of rehabilitation and engagement in the shared decision-making process.

All methods were performed in accordance with the relevant guidelines and regulations by including a statement in the Ethics approval and consent to participate section to this effect.

Discussion: This will be one of the first study to investigate the effects of a digitally-supported shared decision making approach. If the SharedHeart approach and supporting applications are found to be effective in increasing patients' quality of life, exercise capacity, motivation to exercise, perception of rehabilitation and/or engagement in the shared decision making process, this can be a cost-effective and accessible solution to increase patient outcomes and patient involvement during cardiac rehabilitation.

Trial registration: ClinicalTrials.gov NCT05026957.

Introduction

Due to a stabilization of the incidence of myocardial infarction (MI), an ageing population, the increased prevalence of diabetes and obesity, and a decrease in case-fatality, the number of patients who would benefit from cardiac rehabilitation (CR) in Europe is growing (1-4). Literature demonstrates high

recurrence rates of MI and new revascularisations (5-7). Despite these high recurrence rates, the EUROASPIRE surveys demonstrate that in many countries secondary prevention and CR are undervalued elements in the long-term management of CVD (8). The latest survey has shown that the majority of patients with heart disease in Europe have an inadequate risk factor control and do not receive guideline-based medical therapy (8). While CR is a key element of secondary prevention, the duration is often limited to 3 months, whereas secondary prevention should be a lifelong process. It is important that patients maintain their healthy behaviours also after the cardiac rehabilitation program has ended. The aim of our proposed approach is to also intervene at home to prepare patients to maintain their healthy lifestyle on the long-term.

Nowadays, in most telerehabilitation systems patients have only small input in their exercise prescription. Research demonstrated that patient involvement improves patient satisfaction, adherence, and health outcomes and is a prerequisite for good clinical practice (9). Based on the experience of Telerehab III (10) and the Hearthab pilot study and prospective cross-over trial (11,12), this study wants to investigate how digital applications can support healthcare professionals in involving their patients in the shared decision making process in the context of physical activity. Patients and their caregivers set up goals together to construct a tailor-made exercise program in order to get patients involved to make their own decisions about their physical activities, try to improve long-term adherence to physical activity. We combine the best available evidence and the patient's personal preferences, values, goals and context to come to an exercise program that is in line with the current European guidelines for physical activity and the patient's personal preferences.

Cost-effectiveness of different methods of telerehabilitation was shown in multiple trials (13-17. The emphasis of this research project is to determine the effectiveness and cost-effectiveness of the combination of center-based CR and shared decision making based telerehabilitation. The developed telerehabilitation solution SharedHeart (18) is composed of several digital applications supporting patients and caregivers. The applications are based on the already validated EXPERT tool (19, 20) and HeartHab (12).

Objectives

The study is a prospective randomized controlled trial that includes a usability study of the applications. The aim of the study is to investigate the effectiveness of the proposed shared decision making (SDM) approach supported by digital applications in improving quality of life, exercise capacity, motivation to exercise, perception of rehabilitation and engagement in the shared decision making process in patients with heart disease in a cardiac rehabilitation setting. Furthermore, it studies the overall user experience when following the approach and using the different applications.

The study consists of two phases, each one addressing a specific research question for the specific target group of patients with heart disease in a (supervised) CR setting:

1. Usability study:
   The first research question deals with patients' motivation and instantaneous user friendliness of the applications and brings along the following sub questions. Are the developed applications for SDM regarding physical activity user-friendly? Does it seem motivating for the target patients to use the approach, be involved in the shared decision making process and exercise more?
2. Randomized controlled trial:
   The research questions includes the impact on quality of life as primary outcome and improvement of exercise capacity, motivation to exercise, perception of rehabilitation and engagement in the decision making process as secondary outcomes.

Methods

Usability study and RCT

Preceding to the RCT, a lab-based usability study of the applications is performed to discover features of the applications that are unclear or misinterpreted by the end users and as such, improve these before the RCT (in the second phase of the study) starts. Task-based usability tests will be executed with 10 CAD patients undergoing cardiac rehabilitation at Jessa Hospital Hasselt as well as 5 physiotherapists guiding these patients. The patients that participate in this usability test will not be included in the RCT. The physiotherapists included in this test will not be excluded from participating in the RCT. The primary endpoint of the usability test is the usability of the different applications supporting the shared decision making approach and is measured with custom-made questionnaires. We hypothesize that the applications developed to support the SDM approach are easy to use, user-friendly and have a good understandability. Only basic socio-demographic and technology related parameters of the participants will be collected, all in the pre-test questionnaire. After the task-based usability testing, with relevant scenarios of use, a post-test questionnaire probes for the user experience during lab testing.

The clinical study is a prospective randomized controlled trial to study the user experience of the approach with the supporting applications, and the impact on patients' quality of life, physical activity, perception of rehabilitation and engagement in the decision making process. 80 subjects who start CR at Jessa Hospital Hasselt will be included. Subjects who do not violate any of the predefined exclusion criteria and have provided informed consent will be randomly assigned in a 1:1 ratio to one of the treatment strategies.

Patient population

Inclusion and exclusion criteria are mentioned in Table 1:

Table 1: inclusion and exclusion criteria.

Inclusion criteria	Exclusion criteria
Indication for cardiovascular rehabilitation in a center-based cardiac rehabilitation center	Orthopedic, neurologic or any other pathologic condition which makes the patient physically unable to follow a technology-supported shared decision making program
Recently having started cardiac rehabilitation in Jessa Hospital Hasselt	Planned interventional procedure or surgery in the next three months
Be clinically stable without inducible ischemia or high-risk ventricular arrhythmia, confirmed by the last available maximal ergospirometry test	Pregnant females
Age ≥18 years	Present cardiovascular complaints
Willing and physically able to follow a technology-supported shared decision making program and other study procedures in a three months follow-up period	Participation in other cardiac rehabilitation program trials, focusing on exercise outcome
Show evidence of a personally signed and dated informed consent, indicating that the subject (or a legally-recognized representative) has been informed of all pertinent aspects of the study	Current or recent participation in other technology-supported programs, even when not directly targeting exercise capacity
Possession of and/or able to use an Android based smartphone	Any condition which in the opinion of the investigator would make it unsafe or unsuitable for the patient to participate in this study or a life expectancy of less than three months based on investigators judgement
Possession of internet connectivity	
Dutch speaking and understanding	

Recruitment

All 80 patients will be recruited from the Cardiology Department of Jessa Hospital Hasselt. Patients who are eligible for participation will be contacted by the study staff before their baseline cardiopulmonary exercise test (CPET) at the start of the CR programme. The study will start for the patient at his/her next exercise session in the rehabilitation center.

Study design

Patients in the intervention group will follow the regular cardiac rehabilitation program (typically 12 weeks) offered at Jessa Hospital Hasselt, supplemented with the shared decision making approach supported by the SharedHeart applications and a personalized training prescription for the patient constructed with support of the EXPERT tool. The patients will participate in SDM encounters with their caregivers and use the SharedHeart mobile application at home to follow up on their physical activity.

The frequency of the SDM encounters will decline gradually. During the first six weeks of the study, patients will have a SDM encounter with a physiotherapist each week. In the following six weeks, they will have such an encounter every two weeks (as depicted in Figure 1).

Patients in the control group will follow the regular CR program (typically 12 weeks) offered at Jessa Hospital Hasselt. This usual care CR program at the Jessa Hospital Hasselt consists of 3 CPETs, trainings 3 times in a week, education and dieticians, psychologists, and smoking cessation consultants.

Intervention

At the start of their supervised rehabilitation program, patients in the intervention group have a first encounter with their cardiologist. Patients use the SharedHeart tablet application to create their personal preference ranking of physical activities and enter information about their physical limitations and context. This occurs at the start of this encounter together with a caregiver.

During the SDM encounter, the patient and cardiologist discuss the patient's preferences for physical activity and construct the patient's exercise program for the upcoming week. The SharedHeart dashboard stimulates discussion and provides guidance in creating the exercise program.

Between the encounters, patients use the SharedHeart mobile application on their smartphone to report on the physical activities that they do and monitor their progress. The mobile app gives patients the possibility to report the activities from the pre-constructed program that they perform. In addition, they can add new activities. Furthermore, patients can consult their history of physical activity, watch videos to improve their knowledge, report on the non-exercise related physical activities that they do as a part of their daily living (e.g. cleaning, gardening and mowing the lawn) and take notes about things that they want to discuss in an upcoming appointment with their physiotherapist. During the week, physiotherapists can follow up on the physical activities that their patients do, with the SharedHeart dashboard. In addition, they can prepare for the encounter by consulting the notes that patients took and following up on the patient's long-term progress.

At the next SDM encounter, the patient and physiotherapist meet again and discuss the activities of the past period aided by the SharedHeart dashboard. They discuss the patient's adherence to the exercise program and alter the program to encourage the patient to comply with it. During the upcoming week(s), the patient tries to follow the adapted program and at the next SDM encounter, the process repeats. As already mentioned, the frequency of the SDM encounters with discussion of the exercise program gradually decreases, since week by week the exercise program will become more feasible and fit to the patient's profile. When the patient finishes the supervised rehabilitation in the rehabilitation center, the SDM encounters and support from the mobile application end.

Outcome measures

At baseline (day one of the cardiac rehabilitation program), socio-demographical information, a blood sample, clinical information and current medication therapy will be collected of all patients. Furthermore,

a fasting blood sample is done after 6 weeks (+/- 1 week) of CR and is part of standard care in the CR program in Jessa Hospital Hasselt. The fasting blood sample is used to determine lipid profile, which includes low-density lipoprotein (LDL), high-density lipoprotein (HDL), triglycerides and total cholesterol. Blood glucose and HbA1c are also tested to identify possible diabetes risk factors. In addition, at the beginning of the study, all patients will be asked to fill in a background questionnaire, including their socio-demographic background and their familiarity with technology. The data of this questionnaire will be used to correlate the patient's background with the other data e.g. their preference for involvement in the shared decision making process and their perceptions of the approach and supporting applications.

The primary endpoint of the RCT is the difference in quality of life measured with the HeartQoL questionnaire (21) at the start of the CR program and the end of the CR program (this is typically three months after randomization). We hypothesize that patients in the intervention group have a bigger improvement in quality of life compared with patients in the control group due to the intervention on shared decision making.

In addition, the following secondary endpoints will be investigated:

- Improvement of exercise capacity (change in VO2peak) at the end of the CR program, determined using the maximal cardiopulmonary exercise test (CPET);
- Difference in the first and second ventilatory threshold measured at the start and at the end of CR;
- Amount of METs (metabolic equivalent of task) used by physical activity in the last week of the CR program and the difference in the amount of METs used by physical activity in the first week of the CR program, measured by the reported activities in the SharedHeart mobile application (intervention group) or a patient-reported paper diary of physical activity (control group);
- Amount of physical activity, assessed with the International Physical Activity Questionnaire (IPAQ, long version) (22) at the start, mid and end of the CR program;
- Amount of steps, determined with an external hip-worn accelerometer during the first and the last week of the CR program;
- Motivation to exercise and user experience, both gathered with custom-made questionnaires and a semi-structured interview;
- Qualitative data describing the patients' perceptions and feelings related to their rehabilitation (e.g. engagement in the shared decision making), gathered with the Control Preference Scale (23), a custom-made questionnaire at the start, mid and end of the CR program to assess their current perception of rehabilitation (e.g. knowledge of disease, involvement in the rehabilitation process, and confidence in self-management), and a semi-structured interview;
- Patient engagement, determined based on application logs and physiotherapists' recordings;
- Qualitative data related to the discussion during the SDM, determined by automatically recording how long each screen is used during the SDM encounter and prompting the physiotherapists at the end of the encounter to fill in the discussion points of the encounter;

- The feasibility assessed by the difference in time spent on a SDM consultation and time spent on a regular patient consultation, determined by automatic measurement of the duration of a SDM encounter and asking the physiotherapist if there was a disruption;
- The change in generic health status for the period from the start of the CR program to the end of the CR program, assessed with the EQ-5D (24).

At the start of the study, patients will be asked if we may contact them in a period of 1 to 5 years for a long-term follow-up. At the long-term follow-up, we assess the impact of the SDM approach and supporting applications on the patients' long-term adherence to physical activity and perceptions related to rehabilitation of a 12-week use of the application. There is no organised use of the app after 12 weeks. The following secondary endpoints will be assessed:

- Change of exercise capacity (change in VO2peak) at the long-term follow-up (change from the end of the CR program);
- Difference in the first and second ventilatory threshold measured at the end of the CR program and at the long-term follow-up;
- Amount of METs used by physical activity in the week of the follow-up, and the difference in the amount of METs used by physical activity in the last week of the CR program, assessed with the IPAQ;
- Amount of steps, determined with an external FitBit
- Qualitative data on the patient's perception of their rehabilitation, assessed with a custom-made questionnaire;
- The change in generic health status for 1) the period from the start of the CR program to the end of the CR program and 2) for the period from the end of the CR program to the long-term follow-up, assessed with the EQ-5D.

For the proposed approach to be implemented in usual care in hospitals, we need to demonstrate that it is feasible for caregivers to invest the time and that the approach is cost-effective. All patients will be asked to fill in the EQ-5D at the beginning of the study, at the end of the study and at the long-term follow-up (if they agreed with a long-term follow-up). The cost-effectiveness will be compared for two different periods of time: 1) from the start of the CR program to the end of the CR program, and 2) and from the start of the CR program to the long-term follow-up.

This study aims to investigate not only the effects of the approach on the patients' feelings and health, but also on the caregivers' way of working. Therefore, the qualitative data on the caregivers' user experience and the impact of the applications on their involvement of patients in the shared decision making process measured with custom-made questionnaires and a semi-structured interview are secondary outcomes as well.

Statistical analysis

Data analysis will be performed using SPSS according to the intention-to-treat principle by assigned treatment group. Nonparametric alternatives will be used for parametric statistics when needed. The Shapiro-Wilk test will be used to assess normality. Paired t tests (parametric) or Wilcoxon signed rank tests (nonparametric) will be used for within-group analysis; independent t tests (parametric) or Mann-Whitney U tests (nonparametric) for between-group analysis. Chi-square tests will be used in case of categorical variables; Fisher's exact tests will be used when expected frequencies are small. The significance level for tests is 2-sided $\alpha=0.05$.

The cost-effectiveness evaluation will be conducted from a society and patient perspective, taking into account both intervention and health care resource costs. As the majority of patients will be retired, productivity losses due to illness-related absence from the workplace will not be taken into account. Health care costs will be the combination of cardiovascular readmission costs, the costs due to cardiologist follow-up visits and performed diagnostic tests. The cardiovascular rehospitalizations' related costs will be derived from invoices retrieved from the recruiting hospital's financial departments. INAMI/RIZIV's nomenclature-based tariffs will define specialist visits and diagnostics denominations. Quality adjusted life years (QALYs) will be used as a generic measure of effectiveness. Estimates of QALYs will be derived from the EQ-5D questionnaire. The EQ-5D scores will be converted to utility scores. The incremental cost-effectiveness ratio (ICER) will be calculated (ICER (Cost intervention group – Cost control group)/(Effectiveness intervention group – Effectiveness control group)) to compare costs and outcomes (effectiveness) across both treatment groups.

Results

The protocol and amendments have been submitted to, and approved by the medical ethical committees of Hasselt University and Jessa Hospital in 2019–2021. All methods were performed in accordance with the relevant guidelines and regulations by including a statement in the Ethics approval and consent to participate section to this effect. The mobile application, the tablet application and the caregiver dashboard were iteratively designed and developed in 2019–2020. Due to government regulations for COVID-19, the start of the study and patient recruitment have been deferred from 2020 to 2022. Recruitment for the RCT will start shortly after the usability tests have been finalized and the applications are updated based on the findings of these tests. The final results of the study, apart from the long term follow-up, are expected at the end of 2023.

Discussion

The SharedHeart study will be one of the first studies to investigate the effects of a digitally-supported shared decision making approach during CR. The study design was determined by a multidisciplinary team of researchers, ensuring that perspectives and research questions from different disciplines (e.g. human-computer interaction, physiotherapy and cardiology) are accurately represented. Nevertheless, the study also has some limitations. Since this study has a lot of research questions combined in one protocol, each with their specific data collection, overall chances of missing data are higher. Furthermore,

it is possible that patients assigned to the control group will have a higher dropout rate due to not receiving immediate access to the intervention. To prevent this, the control group will get a personalized exercise prescription with the EXPERT tool.

Since the SharedHeart mobile application is developed for Android, only patients that have an Android smartphone are allowed to participate. Physiotherapists are allowed to participate in the usability study of the caregiver dashboard and the RCT, which could influence the results related to the usability and user experience in the RCT. However, it is not feasible to have different physiotherapists participating in these two phases, because there are only a limited number of physiotherapists in the hospital, guiding patients during CR.

In the current study, the digital intervention ends completely at the end of the supervised rehabilitation program, as it coincides with the time that is considered for the SDM approach. In future studies and clinical use, extended use of the digital intervention can be considered, in particular the mobile app might support the patients at home in a self-management context.

If results are positive, this can be seen as an advocacy to implement a SDM approach supported by digital tools in clinical practice. However, this study focuses only on SDM for physical activity, which is only one component of a comprehensive cardiac rehabilitation program. Future studies should investigate the effects of a digitally-supported SDM approach for all components of the CR program.

Abbreviations

CAD: coronary artery disease

CPET: maximal cardiopulmonary exercise test

CR: cardiac rehabilitation

MET: metabolic equivalent of task

MI: myocardial infarction

SDM: Shared Decision Making

RCT: randomized controlled trial

Declarations

Ethics Approval and Consent to Participate: This study was conducted in accordance with the ethical standards outlined in the Declaration of Helsinki. The research protocol received approval from the Ethics Committee of of Hasselt University and Jessa Hospital in 2019-202. Informed consent was obtained from all participants prior to their inclusion in the study.

Consent to Publish: All participants provided written consent for the publication of the study's findings. The consent form explicitly outlined the nature of the research, the use of data, and the assurance of anonymity. Participants were informed that they could withdraw their consent at any point without consequences.

Availability of Data and Materials: The datasets and materials utilized in this study will be made available to interested researchers upon reasonable request. Access to the data is subject to approval by the corresponding author and is intended to support transparency and the reproducibility of the research. Requests can be submitted to sevda.kizilkilic@uhasselt.be.

Competing Interests: None declared.

Funding: PD, HK, KC, WR and SEK received funding through the Horizons 2020 CoroPrevention project, project number 848056. MF received funding through the Flanders Research Foundation FWO, file number 1SE1222N.

Acknowledgements: The design of the the SharedHeart concept and the experimental design for the RCT, as well as the initial software development and usability evaluation were supported by UHasselt special research fonds (BOF PhD BOF18DOC26). Next steps in the study and the RCT are supported by H2020 CoroPrevention (grant 848056) and FWO (grant number 1SE1222N). An International Coordination Action “the EXPERT Network” (FWO-ICA G0F4220N) supports maintenance of the exercise prescription algorithm in the EXPERT tool.

Authors Contribution: The SharedHeart concept and study protocol were designed by CB and MS, with finetuning by EK, MF and WR. Software development was done by CB and WR with EXPERT algorithm check by DH, and usability testing by CB, WR, MS and KC. The draft of the article was authored by CB, MS, with revision and updates by EK, MF, WR, PD, DH and KC. Approval for submission of the SharedHeart RCT protocol and the article was given by PD, DH and KC.

Funding: PD, HK, KC, WR and SEK received funding through the Horizons 2020 CoroPrevention project, project number 848056. MF received funding through the Flanders Research Foundation FWO, file number 1SE1222N.

Guarantor: Paul Dendale

Contributorship: SEK: manuscript writing and editing; MS and CB: conceptualization, experiment conduction; MF, WR: writing – review and editing; KC, DH, PD: conceptualization, writing – review and editing, resources, and supervision.

References

1. Pedersen F, Butrymovich V, Kelbæk H,et al. Short- and longterm cause of death in patients treated with primary PCI for STEMI. J Am Coll Cardiol 2014; 64: 2101–2108.

2. Steg G, James SK, Atar D, et al. ESC Guidelines for the management of acute myocardial infarction in patients presenting with ST-segment elevation. Eur Heart J 2012; 33: 2569–2619.
3. Roffi M, Patrono C, Collet JP, et al. 2015 ESC Guidelines for the management of acute coronary syndromes in patients presenting without persistent ST-segment elevation. Eur Heart J 2016; 37: 267–315.
4. Piepoli M, Corrà U, Adamopoulos S, et al. Secondary prevention in the clinical management of patients with cardiovascular diseases. Core components, standards and outcome measures for referral and delivery: A policy statement from the cardiac rehabilitation section of the European Association for Cardiovascular Prevention & Rehabilitation. Endorsed by the Committee for Practice Guidelines of the European Society of Cardiology. European Journal of Preventive Cardiology 2014, 21(6), 664–81.
5. Li S, Peng Y, Wang X, et al. Cardiovascular events and death after myocardial infarction or ischemic stroke in an older Medicare population. Clin Cardiol. 2019;42(3):391–399. doi:10.1002/clc.23160
6. Briffa TG, Hobbs MS, Tonkin A, et al. Population trends of recurrent coronary heart disease event rates remain high. Circ Cardiovasc Qual Outcomes. 2011;4(1):107–13. doi: 10.1161/CIRCOUTCOMES.110.957944. Epub 2010 Dec 7. PMID: 21139089.
7. Vyas MV, Chaturvedi N, Hughes AD, et al. Cardiovascular disease recurrence and long-term mortality in a tri-ethnic British cohort. Heart. 2020;107(12):996–1002. doi: 10.1136/heartjnl-2020-317641. Epub ahead of print. PMID: 33067326; PMCID: PMC8165149.
8. De Bacquer, D., Astin, F., Kotseva, K., Pogosova, N., De Smedt, D., De Backer, G., Rydén, L., Wood, D., & Jennings, C. (2021). Poor adherence to lifestyle recommendations in patients with coronary heart disease: results from the EUROASPIRE surveys. European Journal of Preventive Cardiology. https://doi.org/10.1093/eurjpc/zwab115
9. Bombard Y, Baker GR, Orlando E, et al. Engaging patients to improve quality of care: a systematic review. Implement Sci. 2018;13(1):98. Published 2018 Jul 26. doi:10.1186/s13012-018-0784-z
10. Frederix I, Solmi F, Piepoli M, et al. Cardiac telerehabilitation: A novel cost-efficient care delivery strategy that can induce long-term health benefits. European Journal of Preventive Cardiology, 2017; 24(16), 1708–1717.
11. Sankaran S, Frederix I, Haesen M, et al. A Grounded Approach for Applying Behavior Change Techniques in Mobile Cardiac Tele-Rehabilitation. In: Proceedings of the 9th ACM International Conference on PErvasive Technologies Related to Assistive Environments. New York, NY, USA: ACM; 2016 Presented at: PETRA'16; June 29-July 1, 2016; Corfu Island, Greece
12. Sankaran S, Dendale P, Coninx K. Evaluating the Impact of the HeartHab App on Motivation, Physical Activity, Quality of Life, and Risk Factors of Coronary Artery Disease Patients: Multidisciplinary Crossover Study. JMIR Mhealth Uhealth. 2019;7(4):e10874. doi: 10.2196/10874. PMID: 30946021; PMCID: PMC6470465.
13. Kraal JJ, Elske Van Den Akker-Van Marle M, Abu-Hanna A, Stut W, Peek N, Kemps HMC. Clinical and cost-effectiveness of home-based cardiac rehabilitation compared to conventional, centre-based

cardiac rehabilitation: Results of the FIT@Home study. Vol. 24, European Journal of Preventive Cardiology. 2017. p. 1260–73.

14. 8. Hwang R, Morris NR, Mandrusiak A, Bruning J, Peters R, Korczyk D, et al. Cost-Utility Analysis of Home-Based Telerehabilitation Compared With Centre-Based Rehabilitation in Patients With Heart Failure. Hear Lung Circ [Internet]. 2019;28(12):1795–803. Available from: https://linkinghub.elsevier.com/retrieve/pii/S1443950618319954
15. 9. Maddison R, Rawstorn JC, Stewart RAH, Benatar J, Whittaker R, Rolleston A, et al. Effects and costs of real-time cardiac telerehabilitation: Randomised controlled non-inferiority trial. Heart [Internet]. 2019;105(2):122–9. Available from: http://www.embase.com/search/results?subaction=viewrecord&from=export&id=L623800385
16. 10. Cowie A, Moseley O. Home- versus hospital-based exercise training in heart failure: An economic analysis. Br J Cardiol. 2014;21(2):76.
17. Scherrenberg M, Falter M, Dendale P. Cost-effectiveness of cardiac telerehabilitation in coronary artery disease and heart failure patients: systematic review of randomized controlled trials. Eur Heart J Digit Health. 2020;1(1):20–29. doi: 10.1093/ehjdh/ztaa005. PMID: 37056294; PMCID: PMC10087016.
18. Bonneux, C., Hansen, D., Dendale, P., Coninx, K. (2022). The SharedHeart Approach: Technology-Supported Shared Decision Making to Increase Physical Activity in Cardiac Patients. In: Lewy, H., Barkan, R. (eds) Pervasive Computing Technologies for Healthcare. PH 2021. Lecture Notes of the Institute for Computer Sciences, Social Informatics and Telecommunications Engineering, vol 431. Springer, Cham. https://doi.org/10.1007/978-3-030-99194-4_29
19. Hansen D, Dendale P, Coninx K, et al. The European Association of Preventive Cardiology Exercise Prescription in Everyday Practice and Rehabilitative Training (EXPERT) tool: A digital training and decision support system for optimized exercise prescription in cardiovascular disease. Concept, definitions and construction methodology. Eur J Prev Cardiol. 2017;24(10):1017–1031. doi: 10.1177/2047487317702042. Epub 2017 Apr 18.
20. Hansen D, Coninx K, Dendale P. The EAPC EXPERT tool. Eur Heart J. 2017;38(30):2318–2320. doi: 10.1093/eurheartj/ehx396. PMID: 28810673.
21. Oldridge N, Höfer S, McGee H, et al. The HeartQoL: Part I. Development of a new core health-related quality of life questionnaire for patients with ischemic heart disease. Eur J Prev Cardiol. 2014;21(1):90–7.
22. Booth ML. (2000). Assessment of Physical Activity: An International Perspective. Research Quarterly for Exercise and Sport, 71 (2): s114-20.
23. Degner LF, Sloan JA, Venkatesh P. The Control Preferences Scale. Canadian Journal of Nursing Research, 1997; 29(3), 21–43.
24. Herdman M, Gudex C, Lloyd A, et al. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). Qual Life Res. 2011;20(10):1727–36. doi: 10.1007/s11136-011-9903-x. Epub 2011 Apr 9. PMID: 21479777; PMCID: PMC3220807.

Figures

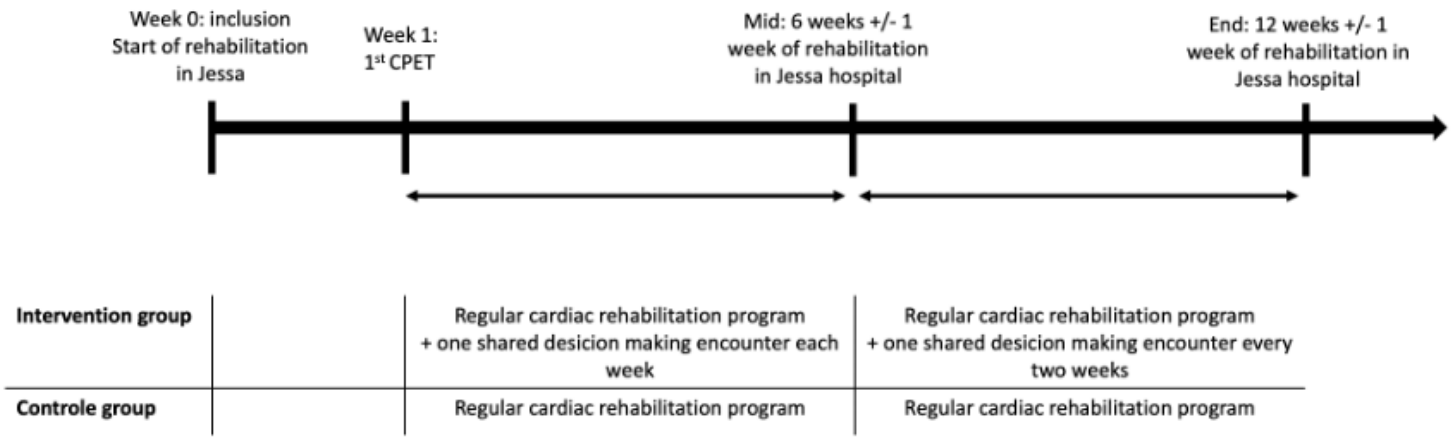

Figure 1

timeline for the intervention and control group.