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Published in:
International Journal of Cardiology Cardiovascular Risk and Prevention

DOI (link to publication from Publisher):
10.1016/j.ijcrp.2024.200239

Publication date:
2024

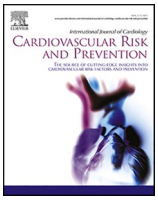
Document Version
Publisher's PDF, also known as Version of record

International Journal of Cardiology Cardiovascular Risk and Prevention 20 (2024) 200239

Contents lists available at ScienceDirect

International Journal of Cardiology
Cardiovascular Risk and Prevention

journal homepage: www.journals.elsevier.com/international-journal-of-cardiology-cardiovascular-risk-and-prevention



"Future patient II" telerehabilitation for patients with heart failure: Protocol for a randomized controlled trial

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ARTICLE INFO

Handling editor: Dr D Levy

Keywords:
Heart failure
Telerehabilitation
Research design
Quality of life
Patient education

ABSTRACT

Background: Heart failure is a global problem affecting millions of people worldwide. Current care of heart failure patients follows standard protocols and often overlooks the patients' specific needs, which leads to low compliance in the rehabilitation phase. Telerehabilitation, where the patients communicate with health care professionals about their rehabilitation program and monitor their vital signs, aims to increase the degree of compliance as well as enhancing their quality of life.
Objective: The aim of this study is to investigate whether application of the Future Patient Telerehabilitation Program II can improve the health-related quality of life for patients with heart failure.
Methods: A randomized controlled trial will be conducted. A total of 70 patients will be enrolled, 35 in the intervention group, 35 in the control group. The intervention group will follow an add-on to traditional care, while the control group will follow the conventional Danish cardiac rehabilitation program, which is based on periodic visits to the clinic. The patients will be followed for a period of six months. The intervention group will have access to an online HeartPortal and will use various home-based devices for self-monitoring. The primary outcome to be investigated is health-related quality of life as measured by the EuroQol-5 Dimension. Secondary outcomes are the number of visits to the outpatient clinic, number of readmissions and number of telecommunications contacts (phone and video) with health care professionals. The primary and secondary outcomes will be assessed using questionnaires and through the data generated by digital technologies for self-monitoring.
Results: Enrolment began in August 2020. The results will be published in peer-reviewed journals. Results from the Future Patient II Telerehabilitation program are expected to be published in 2024.
Discussion: This study is a further development of the Future Patient Telerehabilitation I study, and it is expected to explore the use of video consultation and a weight calculator in relation to telerehabilitation as well as the quality of life for heart failure patients.
Conclusion: The expected outcomes are increased quality of life, increased number of phone- and video-consultations with health-care professionals, and the enhanced ability of patients to manage their own disease with the use of a calculator for weight.

1. Trial registration

Clinicaltrials.gov NCT04490525, registered on July 29th, 2020. Approved by The North Denmark Region Committee on Health Research Ethics N-20200037.

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https://doi.org/10.1016/j.ijcrp.2024.200239
Received 3 December 2023; Accepted 18 January 2024
Available online 24 January 2024

2. Introduction

Heart Failure (HF) is a global burden and a life-threatening disease, affecting over 60 million people worldwide, a survival-rate at approximately 35 %, and an increasing prevalence with age [1,2]. HF is associated with high healthcare costs and is a growing burden within the healthcare sector. Due to the increasing numbers of elderly in the population, it is predicted that HF will continue to increase in prevalence, costs and burden [3,4]. As a part of treating HF, cardiac rehabilitation (CR) plays an important role, as it aims to improve recovery through setting up programs and offering advice for patient's physical activity, diet disease management, and control of risk-factors associated with HF [3,4]. The major HF risk-factors include diabetes, high blood pressure, smoking, and obesity [1]. Furthermore, CR aims to improve recovery by enhancing the health-related quality of life in patients, which may be assessed using various quality of life surveys and questionnaires [4].

Patients with HF often receive a standardized CR program, which is often not tailored to their specific needs or life situation. This results in a lack of patient motivation to follow the program and low compliance, as the rehabilitation program fails to meet their personal needs, despite evidence showing a positive impact on the prognosis of HF [1,4]. Furthermore, the CR program is often conducted in the venue of a rehabilitation centre, or at the local hospital, which poses a challenge to some patients in terms of transport [3,4]. A possible approach to overcome these challenges (both motivation and logistics) is to implement a program of telerehabilitation (TR), the aim of which is to increase compliance and participation in patients with HF [4]. The TR program provides information and communication with health care professionals, training, and monitoring of the disease through technology and provides means for the patient to measure blood pressure, pulse, weight, sleep, and provide additional information via questionnaires [1,5]. These patient-generated measurements and data are then sent to the healthcare professionals, who can act on the data if they observe that the patients' condition has worsened [4,5]. By involving the patients and implementing the program in their daily routines at home, their needs may be better accommodated, thus contributing to an increase in compliance and a more effective rehabilitation process [1].

A review from 2021, investigating the effects of TR on management of HF including QoL and adherence to the TR program, concluded that TR had a noticeable positive effect on the outcome [4]. Patients participating in a TR program had improved QoL compared to patients receiving the conventional CR program [4]. Patients' preferences regarding the use of TR have been assessed in an earlier version of the Future Patient Telerehabilitation program (FPT) I which aimed to increase QoL in patients with HF [6,5]. The FPT I program was designed and developed in cooperation with HF patients in order to customize and provide a digital toolbox, including the choice of online communication and information about the disease. In this study, we found that the experimental group using the technology scored significantly higher than the control group who relied on conventional rehabilitation [6]. The patients also showed an increase in compliance when provided with digital services [6]. These findings confirmed that TR had become more integrated in the treatment of patients with HF, and that it may have a positive effect on both the QoL as well as management of the disease. Results from the FPT I program showed an increase in well-being for the HF patients, indicating that early initiation of rehabilitation can lead to more positive results [7]. The major purpose of the FPT program is to educate patients about their disease and to help them understand and monitor changes in symptoms on their own [8]. The monitoring activity includes symptoms such as sudden weight gain (>2 kg in 2 days), a criterion set in cooperation with healthcare professionals, who educate the patients in how to self-manage the required increase in diuretics, and when to contact a healthcare professional if there are sudden changes in vital signs like weight [8]. The use of video consultation as part of the TR-program has not been widely investigated, despite studies showing that video consultations has positive effects on patients [4]. Therefore, the primary aim of this study is to investigate whether the use of TR, including video consultation and a calculator for weight gain and loss, will lead to an improvement in HF patients' QoL in patients with HF.

3. Materials and methods

3.1. Future Patient Telerehabilitation program

The Future Patient Telerehabilitation (FPT) program consist of 2 phases: 1) Titration of medicine and/or monitoring of vital signs and telerehabilitation (months 0–3), and 2) rehabilitation in healthcare centre and/or telerehabilitation (months 4–6). The phases are illustrated in Fig. 1.

3.2. The Future Patient – telerehabilitation of HF patients program

The TR connection between patients and healthcare professionals is a web portal called the HeartPortal (hjerteportalen.dk) (see Fig. 2). Through Heart Portal, patients and healthcare professionals have access to a visualisation of the patients' recorded data. The portal also provides for patient education and communication between patients and health professionals. The HeartPortal consists of four main elements: an information site for patient education, a platform for communication with healthcare personnel, a visualisation of the measured values, and Patient-reported Outcome (PRO) recordings, all of which are obtained every second week through questionnaires. As part of the TR program, data are measured, monitored and visualised on the HeartPortal. The technologies used for measuring and visualising data are.

- A tablet (iPad Air 2), used to access HjertePortalen.dk and as a hub for the sensors (mentioned below);
- A blood pressure monitor (iHealth Neo/BP5s) used to measure systolic and diastolic pressure and pulse;
- A weight scale (iHealth Linea) used to monitor the patient's weight. For each patient, a lower and upper weight limit is set by a healthcare worker.
- An activity tracker (Fitbit Inspire or Charge 3), used to track daily activity (steps, calories burned, pulse and sleep data, if worn during sleep);
- A sleep sensor (Emfit QS) used to monitor pulse and respiration during sleep, sleep time, and stages;
- Video device software (Video VDX, MedCom) used for visual consultations between the patient and health care professionals.

A new add-on to the HeartPortal is a calculator, which can indicate whether patients increase in weight, based upon weight measurements from the previous two weeks for the individual patient. The calculator is created for the patients in order to indicate whether any weight-change lies within the acceptable upper and lower range. In order to analyse the patient's weight data, a point system is applied: 0 points = weight is OK, 1 point = be aware of your weight, 2 points = be extra aware of your weight, 3 or more points = consider contacting your doctor or the Cardiology ward.

3.3. Eligibility criteria

The inclusion criteria for this study are as follows: patients with HF, based on a HF diagnosis according to the New York Heart Association (NYHA) Class II-IV [9]; patients currently hospitalised for acute decompensated HF, or patients who have visited the HF outpatient clinic within the past two weeks. In addition, all patients must be residing in Viborg or Skive municipalities in Denmark, they must be capable of caring for themselves, have basic computer skills or have a close relative who has basic computer skills. Patients may be excluded from the study if they are pregnant, have a drug addiction, present and/or previous neurologic, musculoskeletal, or cognitive disability or active psychiatric

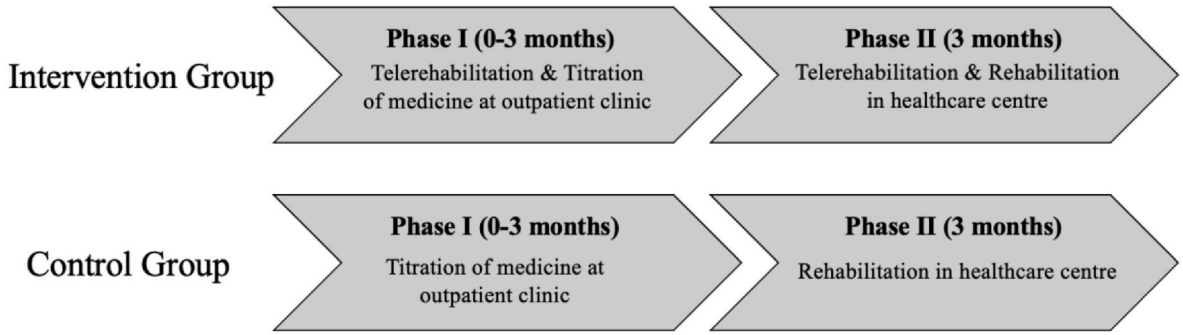

Fig. 1. The two phases of the future Patient Telerehabilitation program in both the intervention group and the control group.

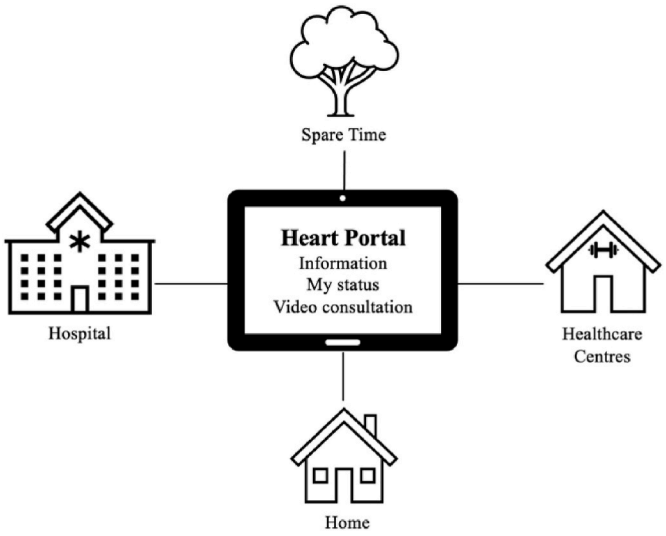

Fig. 2. The context and basic principles of the Future Patient Telerehabilitation program.

history (as noted in the medical record) other than depression or anxiety related to cardiac or other chronic illness, does not cooperate or does not understand Danish.

3.4. Research design

The study is a multicentre randomised controlled trial (RCT) that employs both qualitative and quantitative data collection techniques. The intervention group will participate in the FP TR program, whereas the control group will follow a conventional rehabilitation program [10]. Participation in each group is expected to last up to 6 months. The randomisation is conducted in blocks of 2, 6 and 8 patients and the randomisation will be digital and blinded for the telerehabilitation coordinator who recruits patients for the study. Enrolment of patients began in August 2020.

3.5. Power calculation

As the primary outcome of this study is an increase in health-related quality of life, we have used another study that measured health-related quality of life [11] as a means of determining the power of this study. In this study, the health-related quality of life was improved by 20 % compared to usual rehabilitation. With a power of 80 %, there must be n = 32 participants in each group. Assuming a 10 % dropout rate, the total number of participants in the study is n = 70 with n = 35 in each group.

4. Theoretical framework

4.1. Self-determination theory

Self-determination theory (SDT) was used as the theoretical starting point for understanding the patient's perspective [12]. Patients with HF must be motivated to engage in treatment and sustain needed lifestyle changes in order to achieve their goal. Hence, ensuring patient motivation is a key part of rehabilitation. SDT describes human motivation as the satisfaction of three basic needs: autonomy, competency and relatedness. It is therefore necessary that the patient experience simultaneous satisfaction of all three needs in order to be intrinsically (or autonomously) motivated rather than simply externally motivated [13]. If the patient finds that the goals for better health align with their own internal values and beliefs (autonomy), the patient will feel that they have the knowledge and skills to achieve their goals (competency) and will also feel supported by others (relatedness). This intrinsic motivation will generate a greater chance of success in maintaining the required lifestyle and health behaviour over time [14].

4.2. Inter-organizational theory

Inter-organisational theory will be used to analyse how the development and implementation of the telerehabilitation program operate across the different sectors of the healthcare system from an organisational perspective [15]. The aim of inter-organizational theory is to explore how the sectors of the healthcare system develop and implement the TR program.

4.3. Ethics

The study is conducted according to the Helsinki Declaration, and all participants provided will an informed consent. The study is approved by The North Denmark Region Committee on Health Research Ethics (N-20200037). A data agreement between partners in the project has been concluded. The trial is documented in the database ClinicalTrials.gov (NCT04490525).

4.4. Baseline data

Baseline data will be collected on age, gender, age, cause of HF, NYHA-class, primary and secondary diagnosis, education, civil status, work status, IT competences, clinical parameters (weight, blood pressure, resting pulse, hours of sleep, respiration and steps) and current prescribed medicine. Furthermore, three questionnaires will be provided, as specified below.

4.5. Outcome measures

Measurement of primary and secondary outcomes will be collected through questionnaires at different intervals in the program, as shown in

Table 1
Primary and secondary outcome measures.

Outcomes	Time of Measurement													
	Baseline	2 w	4 w	6 w	8 w	10 w	12 w	14 w	16w	18w	20w	22w	24w	26 w
Primary														
Health-related quality of life	(I,C)		(I)		(I)		(I, C)		(I)		(I)		(I, C)	
Secondary													(I, C)	
Reduction of visit to outpatient clinic													(I, C)	
Number of readmissions													(I, C)	
Number of tele-communication (phone and video) contacts													(I, C)	
Experiences of patients with HF and healthcare professionals with the use of video consultations													(I)	
Testing a calculator on weight based on adherence	(I)	(I)	(I)	(I)	(I)	(I)	(I)	(I)	(I)	(I)	(I)	(I)	(I)	(I)
Degree of depression	(I,C)						(I, C)						(I, C)	
Use of the website “Hjerteportalen.dk"													(I)	

W = weeks.
I = Intervention group.
C = Control group.

Table 1. See below for further details on the data collection process and description of the questionnaires.

4.6. Health-related quality of life

The primary outcome in this study is health-related quality of life which is measured using the EuroQol- 5 Dimension (EQ-5D) [16]. The EQ-5D is a questionnaire that assesses five dimensions of life quality: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. For both the intervention and control groups, the data will be collected at baseline (day 0), at start of rehabilitation (after 0–3 months of titration of medicine) and at the end of the participation in the study (up to 6 months).

4.7. Progression in clinical data

All clinical data (blood pressure, pulse (day/night), weight, steps, sleep and respiration) will be collected and analyzed at the end of the study. Baseline clinical data are available for the control group.

4.8. Evaluation of healthcare services

The patients' use of the healthcare service will be evaluated in alignment with Drummond [17]: the parameters to be measured are numbers of visits to the outpatient clinic, number of readmissions and number of tele-communicational (phone and video) contacts. All data will be collected by data extraction. The data will be collected at baseline, continuously throughout the study and at the end of the 6 months.

5. Experiences of HF patients and healthcare professionals with the use of video consultations

Interviews will be performed according to the methods outlined in Brinkman & Kvale, 2014 [18].

5.1. Patients

A group of patients from within the TR group will be randomly selected for intensive interviews. The interviews will be conducted until data saturation has been reached. Interviews will be transcribed and analyzed using NVivo 12.0 (qualitative software program for data analysis) [19].

5.2. Healthcare professionals

Representatives from management and staff across sectors will be interviewed at the end of the study (month 6). In order to be selected for further interviews, the healthcare professionals must have been involved in the FPT program. Interviews will be conducted until data saturation has been reached and will be transcribed and analyzed using NVivo 12.0 [19].

5.3. Testing and evaluating the use of a calculator for weight-based adherence

A calculator to monitor and analyse the patient's weight measurements has been developed, tested and evaluated, and data are being will be collected to evaluate the patients' adherence. The calculator uses a combination of statistical analysis and techniques so as to indicate changes in the patient's weight based on baseline data. The calculator has been developed in order to provide feedback and alert patients if they exceed their recommended weight limits. An online questionnaire is collected at baseline, and additional questions are asked every other week throughout the study and at the end for participants in the intervention group.

5.4. Degree of depression

The degree of depression is measured using the Hospital Anxiety and Depression Scale (HADS) questionnaire [20]. The data are collected at baseline, at the start of the rehabilitation program and at the end of the study.

5.5. Use of the 'Hjerteportalen.dk' web portal

The use of "Hjerteportalen.dk" is measured by tabulating log files. Data are only available for the intervention group and is measured at baseline, continuously throughout the study and at the end of the study.

5.6. Risks, side effects and disadvantages

The risks related to this study are considered low. Patients may experience technical problems with the equipment that may give rise to frustrations and mild stress. However, the patients can contact the project nurse if they experience anxiety during the study period. The

patients may feel that they are under close surveillance during the study period. If they find this stressful, they can leave the study at any time. The wristband of the activity tracker may cause irritation of the skin. If the skin irritation continues, the patient is instructed to contact the project nurse. The patients will be informed to contact their general practitioner or the hospital if they are unwell or if the measured values deviate from the range of normality defined for each patient individually. When participating in a video consultation, the internet connection may be disconnected, which may lead to frustration. If necessary, the patient might need to attend a physical, face-to-face consultation. The resolution and lightning of the video solution might be blurred.

5.7. Statistical analysis

A power calculation was performed to determine how many patients were required to enrol in the study so that it could have optimum validity. Prior to analysis, any missing data will be addressed, and data will be evaluated with regard to their normal distribution. A *t*-test will be used to assess the aims of the study as it pertains to outcomes in the intervention and control groups, and a two-way ANOVA will be carried out pending the normal distribution of data.

6. Results

Enrolment for the study began in August 2020. The findings will be published in peer-reviewed journals. Results from the Future Patient II Telerehabilitation program are expected to be published in 2023.

7. Discussion

7.1. Telerehabilitation program

The aim of this study is to assess whether the use of telerehabilitation, including video consultation and a calculator for weight gain and loss, causes improvement in the health-related quality of life of patients with heart failure. A review of the literature indicates no other studies of TR tested on patients with HF and with the same goals as the FTP.

To improve the design of the FTP, this study aims to include the use of video consultation and a calculator to measure weight gain and loss. To our knowledge, there is no evidence regarding the potential positive effect of video consultation versus physical visits at the hospital, nor has any study developed and tested a calculator and its ability to detect a change in weight for HF patients, where weight changes may be a sign of worsening of the disease.

The study was divided into two phases. In phase one, all patients had their medicine adjusted to their individual needs; in phase two, the patients attended rehabilitation at a health care centre. The intervention group, however, received additional telerehabilitation during both phase one and two.

When compared with the control group, we expect that the telerehabilitation group will have a higher degree of quality of life and fewer contacts with the hospital. This study is also expected to shed light on the experiences on how HF patients experience and use video consultations with healthcare professionals.

The calculator for weight gain and loss is operated as an app within the HeartPortal. Here the patients can monitor their own weight and other personal metrics by themselves while also communicating with the health care professionals. This addition to traditional patient education programs could increase patients' adherence to the telerehabilitation program, as the patients would become more health literate and capable of taking actions before their symptoms become too severe. Furthermore, telerehabilitation enhances patient education and empowering patients to manage their own disease [21].

7.2. Limitations

This study was severely affected by the COVID-19 pandemic, which delayed the enrolment of patients. However, it also sheds light on the possible benefits of telerehabilitation when patients and physicians are unable to interact in person, although it may affect our primary outcome for this study.

As the study population consists of elderly people with heart failure, there is a risk that the patients can die due to their disease and must therefore be considered as drop-outs.

The video consultations rely on the patient's private network connection. Therefore, if the network connection at the patient's home is bad or unreliable, there is a risk of low or insufficient use of the video consultation, resulting in non-useable results.

The devices used in the study, all commercially available, automatically transfer the data to the HeartPortal. If regulations or availability change during the study period, it may be necessary to utilize other devices, which could lead to inconsistency in the data.

8. Conclusion

The expected outcomes of this study are increased quality of life, increased number of phone- and video-consultations with health-care professionals, patients' improved management of their disease due to the use of the weight calculator. We expect the study to have a clinical impact for future telerehabilitation of patients with HF.

CRediT authorship contribution statement

Birthe Dinesen: Conceptualization, Funding acquisition, Investigation, Methodology, Project administration, Supervision, Writing – review & editing. **Emma Thunbo Hansen:** Data curation, Writing – original draft, Writing – review & editing. **Jens Refsgaard:** Writing – review & editing. **Søren Villumsen Lundsgaard:** Writing – original draft, Writing – review & editing. **Lars Dittmann:** Writing – review & editing. **Knud Larsen:** Project administration, Software, Supervision, Writing – review & editing. **Helle Spindler:** Writing – review & editing. **Mads Jochumsen:** Writing – review & editing. **Malene Hollingdal:** Writing – review & editing.

Acknowledgements

We wish to thank Aage and Johanne Louis-Hansen's Foundation for financial support for this study. The Future Patient II project is also financed by Aalborg University and by several partners in the project: health care centers in Viborg and Skive municipalities; the Danish Heart Association; the Cardiology wards at the Regional hospitals in Viborg and Skive; the Technical University of Denmark; Aarhus University Department of Psychology and Behavioral Sciences; and the Laboratory for Welfare Technology – Digital Health & Rehabilitation, Sport Sciences – Performance and Technology, Department of Health Science and Technology, Aalborg University, Denmark. We also wish to thank the projectnurses: Pia Børding, Rikke Nørgaard Kristensen and Line Kaagaard.

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