Telerehabilitation

'Effect on exercise tolerance levels in patients after participation in app-guided cardiac rehabilitation program compared to traditional care'

Masterthesis

Clinical Sciences for Health Professionals,

Program in Clinical Health Sciences,

University Medical Center Utrecht,

Utrecht University, The Netherlands

Name student:	Maaike Kirch
Student number:	7598463
Date:	23-06-2023
Internship supervisor(s):	Lenny Nahar-van Venrooij
Internship institute:	Jeroen Bosch Hospital, s-Hertogenbosch, NL
Lecturer/supervisor Utrecht University:	Tim Takken

ONDERGETEKENDE

Maaike Kirch,

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Examiner

T. Takken, PhD

Assessors:

Lenny Nahar-van Venrooij

Maren van Rijssen

Masterthesis, Clinical Sciences for Health Professionals, Program in Clinical Health Sciences, University Medical Center Utrecht, Utrecht University, The Netherlands, 2023

ABSTRACT

Background: Cardiac rehabilitation (CR) after Acute Coronary Syndrome (ACS) intends to help patients learn to live with their heart condition, prevent future problems, and improve exercise tolerance. Previous research has shown that many patients refuse to participate, drop out prematurely, or relapse into old behaviours. A customized program with digital support potentially improves CR-participation, sustain lifestyle changes, and move care to the home-environment.

Aim**:** This study aimed to determine the effect of the CR-program via telemonitoring (TCR) using an app developed by the Jeroen Bosch Hospital (JBZ), compared with a traditional centre-based cardiac rehabilitation program (CB-CR), on lifestyle changes in patients after ACS measured by physical fitness tests and quality of life, emotional and social functioning by health-related questionnaires.

Methods: In this prospective longitudinal quasi-experimental study, two groups were compared; TCR (1: intervention group) and CB-CR (2: control group). The primary outcome was change in mean peak load measured by an ergometry performed before and after CR. The secondary outcomes were changes in the percentage of the peak load (responsiveness), and scores of the questionnaires KVL-H, GAD-7, PHQ-9, ESSI, and Five Shots, before and after CR. Also, differences in baseline characteristics between the groups were assessed.

Results: In total 55 participants were included (TCR: *n*=42; CB-CR: *n*=13), with no drop-outs. No significant difference in absolute change of peak load (p=0,316) or responsiveness (*p*=0,158) was found. It was not possible to determine the differences in the scores of the questionnaires because insufficient questionnaires were completed. No differences were found in the baseline characteristics.

Conclusion: TCR is non-superior to CB-CR on lifestyle changes in physical fitness in the short term measured by ergometry in patients after ACS.

Recommendations: Caution should be taken when interpreting these preliminary results, as the desirable sample size had not yet been reached. To investigate the sustainability and long-term effect of TCR, this study should continue and re-run the measurements after one year with an analysis of the incidence of new cardiac events. Qualitative research on patients' experiences would be useful to make TCR more responsive to patients' needs, improve self-management and provide better person-centred care.

Keywords:

Cardiac rehabilitation, telemonitoring, eHealth, acute coronary syndrome, ergometry

Samenvatting

***Achtergrond*:** Hartrevalidatie (CR) na een acuut coronair syndroom (ACS) is bedoeld om patiënten te leren leven met hun hartaandoening, toekomstige problemen te voorkomen en de inspanningstolerantie te verbeteren. Eerder onderzoek heeft aangetoond dat veel patiënten niet deel willen nemen, voortijdig afhaken of terugvallen in oud gedrag. Een gemodificeerd programma met digitale ondersteuning kan mogelijk de deelname aan CR verbeteren, veranderingen in leefstijl behouden en de zorg naar de thuisomgeving verplaatsen.

Doel: Deze studie had als doel om het effect te bepalen van het CR-programma via telemonitoring (TCR) met behulp van een door het Jeroen Bosch Ziekenhuis (JBZ) ontwikkelde app, in vergelijking met een traditioneel centrum-gebaseerd hartrevalidatieprogramma (CB-CR), op leefstijlveranderingen bij patiënten na ACS gemeten met fysieke fitheidstesten en kwaliteit van leven, emotioneel en sociaal functioneren door gezondheidsgerelateerde vragenlijsten.

Methoden: In deze prospectieve longitudinale quasi-experimentele studie werden twee groepen vergeleken; TCR (1: interventiegroep) en CB-CR (2: controlegroep). De primaire uitkomst was verandering in gemiddelde piekbelasting gemeten door middel van ergometrie voor en na CR. De secundaire uitkomsten waren veranderingen in het percentage van de piekbelasting (responsiviteit) en scores van de vragenlijsten KVL-H, GAD-7, PHQ-9, ESSI en Five Shots voor en na CR. Verschillen in baseline karakteristieken tussen de groepen werden beoordeeld.

Resultaten: In totaal werden 55 deelnemers geïncludeerd (TCR: n=42; CB-CR: n=13), zonder uitvallers. Er werd geen significant verschil gevonden in absolute verandering van piekbelasting (p=0,316) of responsiviteit (p=0,158). Het was niet mogelijk om verschillen in scores van de vragenlijsten te bepalen omdat er onvoldoende vragenlijsten waren ingevuld. Er werden geen verschillen gevonden in baseline kenmerken.

Conclusie: TCR is niet-superieur aan CB-CR op leefstijlveranderingen in fysieke fitheid op de korte termijn gemeten met ergometrie bij patiënten na ACS.

Aanbevelingen: Voorzichtigheid is geboden bij interpretatie van deze voorlopige resultaten, omdat de gewenste steekproefgrootte nog niet was bereikt. Om de duurzaamheid en het langetermijneffect van TCR te onderzoeken, moet dit onderzoek voortzetten en de metingen na een jaar opnieuw uitvoeren met een analyse van de incidentie van nieuwe cardiale events. Kwalitatief onderzoek naar patiënten ervaringen kan TCR beter afstemmen op de behoeften van patiënten, zelfmanagement verbeteren en betere persoonsgerichte zorg bieden.

INTRODUCTION

Cardiovascular disease (CVD) is the number one cause of death worldwide, according to the World Health Organization (WHO).[1] There are over one million patients with CVD in the Netherlands.[2] The population is aging and the number of patients with chronic conditions including CVD increases.[3] With age the risk of CVD rises. Treatments for potentially fatal cardiovascular events get better, allowing people to survive but subsequently suffer from more chronic CVD.[4] This increases the burden in professional healthcare, resulting in higher complexity and costs. To manage, it is necessary to implement new developments in the areas of prevention, patient empowerment, delivering the right care in the right place, and/or collaborating within a network.[5] The increase in patients makes it a challenge to have all these patients visit the hospital. Where possible, care should be moved to primary care/home-environment. The use of eHealth/telemonitoring can contribute to giving care in the right place.[6] Telemonitoring is convenient and accessible. It enables healthcare providers to monitor and manage patients' health status remotely, reducing the number of hospital visits, unnecessary hospital admissions, or emergency department visits, thus making more efficient use of healthcare resources.[7,8] To further decrease the healthcare burden, reducing the number of patients with cardiovascular events is important. Studies show that the estimated ten-year risk of recurrent cardiovascular events in patients, with previous CVD, ranges from 10% to 50%.[9] Lifestyle changes should be adopted and maintained to reduce the risk of subsequent heart attacks. Participation in exercise-based cardiac rehabilitation (CR) can help.[10] Previous research demonstrated that CR-programs significantly reduce morbidity, mortality, and cost of care.[11] The aim of CR is that patients learn how to live with their heart condition in the best possible physical, psychological, and social situations.[12] Another important function is secondary prevention.[13,14] Lifestyle factors known to influence the risk of CVD are improper diet, reduced physical activity, and smoking. Alcohol consumption, stress, sleep deprivation, and disturbed social situations are also associated with an increased risk of cardiovascular events.[15] Research has shown that up to 60% of patients relapse into old behaviours over the first six months after CR ends.[16,17] Physical activity levels often decrease after a successful CR-program and a significant number of patients do not meet the goals for secondary prevention.[18]

Traditional CR consists of a center-based program (CB-CR), in which patients attend training sessions/meetings at the hospital. Many patients experience it as a burden having to go to the hospital at fixed times. Partly for this reason, a proportion of patients refuse to participate or drop-out prematurely.[19] Other reasons for not attending CR are physical barriers, such as lack of transport, or financial cost, and personal barriers, such as misunderstanding the purpose of

CR.[20] Previous research shows that about 30% of patients with CVD participate in CR and drop-out rates range from 22% to 65%.[21,20,22,23,24] Literature suggests that if CR is tailored to patient preferences and focuses on preparing patients for independent training at home and physical activity, participation rates could improve, drop-out rates may reduce, and beneficial effects of CR may be maintained. A customized program can be achieved through digital support.[25,26] According to previous research multidisciplinary/exercise-based CR supported by telemonitoring (TCR), where patients rehabilitate in their home-environment under healthcare professionals' guidance via digital options such as an app, is a safe and cost-effective alternative to CB-CR.[27] Implementation of TCR can lead to increased CR-participation levels, improve long-term cardiovascular risk management, and lower healthcare- and societal costs.[28] Similar results were found for home-based CR and CB-CR regarding improvement in physical fitness and health-related quality of life, with compliance in the home-based CR-group being high and patient satisfaction significantly higher than with CB-CR.[25] Telemonitoring encourages patients to actively participate, become more engaged and proactively manage their health. Patients are empowered to make informed decisions and adopt healthier behaviours through educational tools, reminders, and personalized feedback.[29,30]

The increasing use of eHealth and its positive results, in addition to the increasing number of CVD-patients, led the Jeroen Bosch Hospital (JBZ) in 's-Hertogenbosch to deploy telemonitoring in the CR-program. In 2019, apps, which have been scientifically researched, were available that focused on monitoring the patient's vital signs during CR at home. Together with an external company Luscii, the JBZ developed an app to inform, motivate and coach through the app in addition to monitoring vital signs.[31] The hypothesis was that this could increase patients' level of self-management. This study was conducted to investigate whether the addition of counselling in the app is effective and contributes to reducing the burden of care, increasing participation in CR, and sustaining lifestyle changes. In addition, this study is the first that will use the maximum wattage achieved during ergometry to measure the level of physical capacity before and after TCR/CB-CR, to objectively determine whether there is a difference in fitness improvement between the two groups.

AIM

This study aimed to determine the effect of TCR using a JBZ-developed app, compared with CB-CR, on lifestyle changes in patients after ACS measured by physical fitness tests and quality of life, emotional and social functioning by health-related questionnaires.

METHODS

Study Design

This study was prospective longitudinal quasi-experimental. The design was chosen because it was not feasible or ethical to manipulate regular care. By conducting the study in a naturalistic setting, it was possible to reflect on real conditions and behaviours. For the reporting, the STROBE guidelines were followed.[32]

Participants

Patients who suffered from ACS and participated in the outpatient-CR-program at the JBZ in the period February-June 2023 and met the criteria described in Tables 4-5 in the appendix and following the guidelines of the Dutch Society of Cardiology (NVVC) and the Multidisciplinary Guideline Cardiac rehabilitation (MRH 2011) were eligible for inclusion.[14,33]

Ethics

Patients signed a consent form after receiving a patient-information form (PIF), by the physiotherapist during a trainingsession. The study was approved by the local Medical Ethics Committee (METC Brabant, nWMO NW2023-15, March 6, 2023) and the institutional board at the JBZ (2023.01.19.01, March 7, 2023).

Intervention

According to regular care from early 2020, the CR at the JBZ consists of two groups; TCR (1: intervention group) or CB-CR (2: control group). For all CR-patients, CR starts with an intake-meeting with the CR-nurse after completing validated health-related digital questionnaires. Figure 1 shows the flowchart of the CR-program for the study. Group assignment depends on patient preference and ability to participate in TCR. This is determined during the intake-meeting, which takes place approximately two weeks after hospital discharge. During this meeting, the patient's situation is discussed and rehabilitation-goals and optional components are determined. Optional components are the FIT-module, relaxation exercises, and CR-stress reduction training. The FIT-module is an exercise-program with the physiotherapist. Relaxation exercises and CR-stress reduction training are respectively provided by medical social worker/physiotherapist and clinical psychologist. TCR and CB-CR are similar, except for the FIT-module. During the FIT-module, the app is used for support. For this reason, only patients participating in the FIT-module were included in the study. In TCR the used product is a certified telemonitoring CR-application, developed by the JBZ and Luscii. Patients use the app via their cell phones with an internet connection. As preparation for CR, patients in TCR and CB-CR participate in a webinar, viewed at home, with information from the physiotherapist,

medical social worker, and dietician. After discharge, all patients participating in the FIT-module perform an ergometry. Training starts identically for both groups and takes place twice a week under physiotherapy supervision and consists of interval training with the bicycle, followed by exercises or relaxation exercises. Patients are divided into a training-group with peers with comparable training results. With TCR, after about four to six training sessions, the physiotherapist determines, based on training results, whether the patient can continue training at home under the guidance of the app. In TCR, guidance lasts for three months. Blood pressure and heart rate (HR) are transmitted through the app. Patients are asked to indicate if they have heart problems, want contact with the healthcare providers, monitor the duration of exercises, and perceived severity of exercise. Tips on exercise or lifestyle adjustments can be given to patients by healthcare providers via the app. Patients can also ask questions in the app. Figure 2 provides an overview of the TCR-program. In CB-CR, the physiotherapist evaluates with the patient after three weeks of training whether the goals of CR have been achieved. If necessary, training will continue and an evaluation will take place every week with a maximum duration of the trainingsessions of 7 weeks. For both groups of patients, CR ends after three months with an evaluation-meeting with the CR-nurse for which the patient again completes the digital questionnaires.

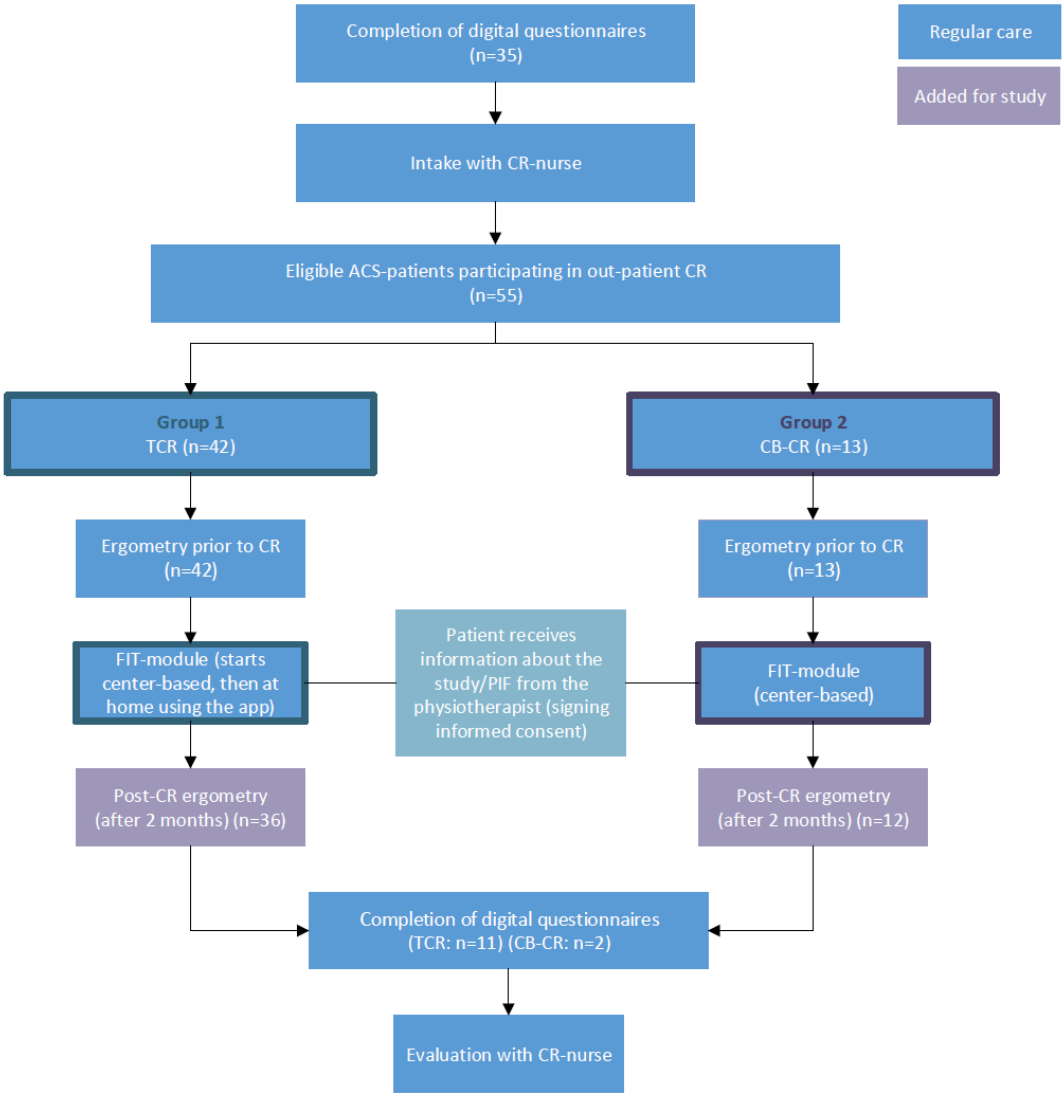

Figure 1. Flowchart of the CR-program for the study

CR: Cardiac rehabilitation; ACS: Acute Coronary Syndrome; TCR: Telemonitoring Cardiac Rehabilitation; CB-CR: Center-Based Cardiac Rehabilitation

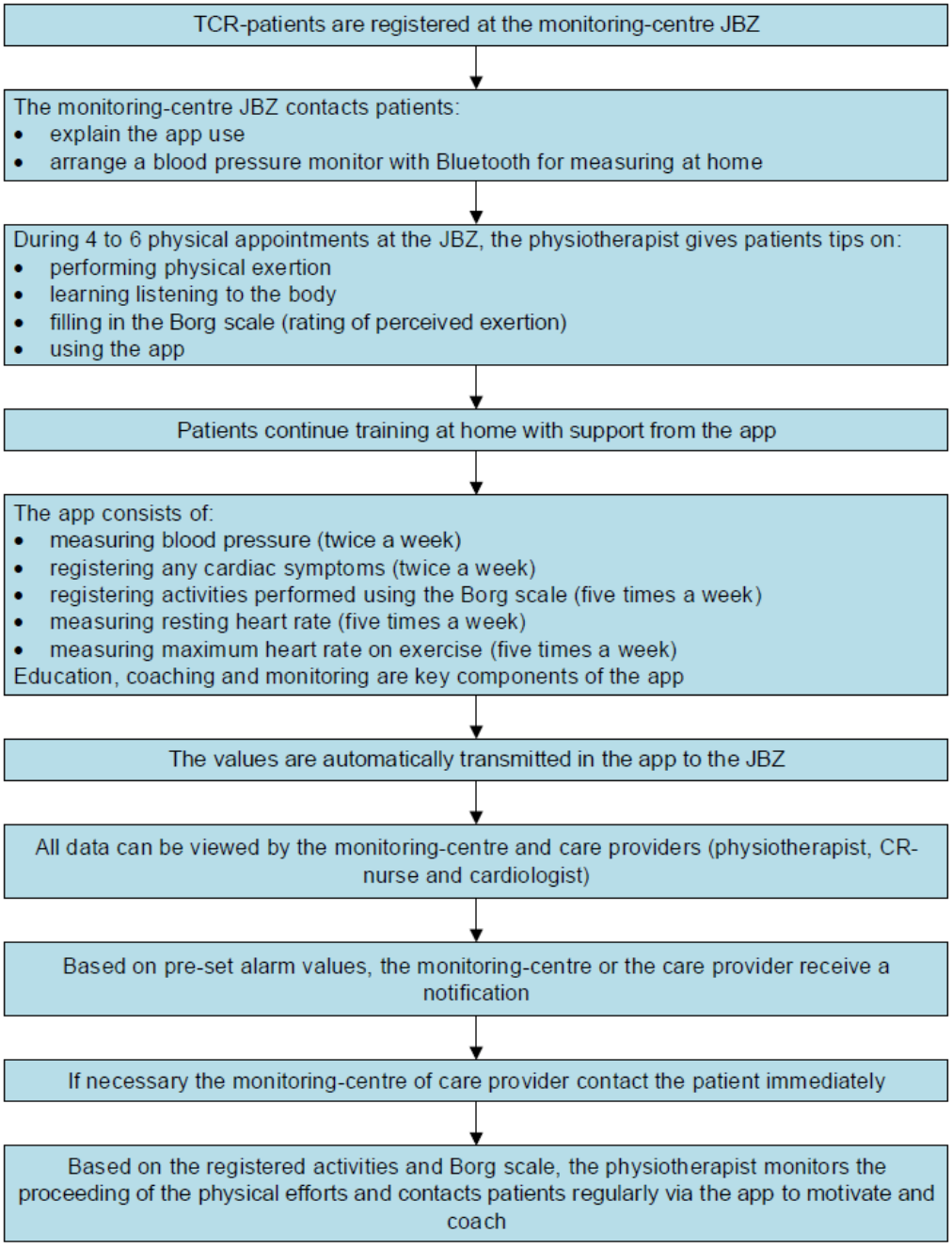

Figure 2. Flowchart illustrating the Telemonitoring cardiac rehabilitation (TCR) program at the Jeroen Bosch Ziekenhuis (JBZ)

Data collection

The ergometry performed before starting the FIT-module was considered a baseline measurement, as were the digital questionnaires completed before intake. Data is retrieved from HiX (electronic patient record). The different questionnaires assess the Quality of life-score (KVL-H), the presence of anxiety disorder (GAD-7), detection/following up of depression (PHQ-9), measuring the degree of social support (ESSI), and the alcohol consumption (Five Shots).[34,35,36]

Patient characteristics and outcomes

After completion of the FIT-module (two months), ergometry was performed again as well as the completion of the digital questionnaires. An ergometry is a maximum exercise bicycle test involving the continuous recording of the electrical activity of the heart (ECG) with analysis of presented symptoms, blood pressure progression, ST-abnormalities consistent with myocardial ischemia, arrhythmias, and exercise capacity. For several minutes, the patient has to cycle. Based on gender, age, height, and weight, an expected peak load (wattage) is automatically calculated. The expected maximum heart rate (HR) is calculated based on age. Every minute, the wattage is increased, requiring the patient to pedal harder. The duration of the exercise depends on the patient's condition, the possible onset of symptoms, or ECG/blood pressure changes.

The primary outcome was the mean change of the absolute increase of the peak wattage achieved during ergometry before and after CR-participation in patients using TCR compared to patients following CB-CR. To determine the mean change between the two ergometry's the absolute difference was calculated first for each patient. Secondary outcomes included the difference in relative change between maximum achieved wattage during ergometry before and after CR-participation for each patient (according to previous research, a 4% (and higher) increase in wattage falls under responsiveness[34]) and the absolute mean change difference per group of the total scores of the digital questionnaires KVL-H, PHQ-9, GAD, and ESSI. The method of scoring the different questionnaires can be found in Table 6 in the appendix. Analysis was performed on whether there was a difference in baseline characteristics between the groups. For each participant, age, gender, invasive treatment, BMI, smoking status, alcohol consumption, family history with CVD, previous history of hypertension/Diabetes Mellitus/ hypercholesterolemia, and the four-digit zip code were recorded. With the zip code, the average socioeconomic status (SES-WOA) was given. The status score is based on the financial wealth, educational attainment, and recent employment history of private households.[37] This data was compiled using data from the CBS System of Socio-Statistical Files (SSB). With a higher score, residents are more affluent and/or more educated and/or more long-term employed.[38]

Statistical analyses

G*Power software was used to calculate the sample size.[39] For detecting an effect size of 0,5 with 80% power and 0,05 alpha the sample size was calculated at 128, with 64 in TCR and 64 in CB-CR. The effect size of 0,5 was chosen because a moderate effect was expected. An intention-to-treat analysis was applied. Missing data were not imputated. For the primary

outcome measure the mean difference of increase of the mean peak load between TCR and CB-CR was compared using an independent t-test in IBM SPSS statistics version 27. The data were checked for normality. If the data would not be normally distributed, the Wilcoxon rank sum test or Mann-Whitney test would be used instead of the t-test in this study. For the secondary outcome, the relative change between the maximum achieved wattage before and after CR-participation was recorded into whether the increase was more or less than 4%. The results were plotted per group in a cross-tabulation and tested using a Chi-squared test. The differences between the first and second scores of the questionnaires for TCR and CB-CR were compared using an independent t-test. Differences in baseline characteristics between both groups of CR were examined using an independent t-test in the case of continuous data or by Chi-squared test in the case of categorical data. For the control of potential confounding variables that could influence the outcomes of the maximum wattage, examination of the effect of the treatments percutaneous coronary intervention (PCI) and coronary artery bypass grafting (CABG) an independent t-test was used. In addition, it was examined with an independent t-test whether there was a difference between the groups in the achieved peak load/HR compared to the expected peak load/HR.

Descriptive statistics

Numerical variables such as age, weight, and BMI were noted in terms of mean with standard deviation as the data was normally distributed. In the case of another distribution, data would be noted as median with an interquartile range. Results of categorical variables such as gender, smoking, and alcohol consumption were noted as frequencies and percentages per category.

RESULTS

From February to June 2023, a total of 55 of the 125 eligible patients participated in the study. No participant dropped out during the study. A total of 42 patients (76,3%) participated in the intervention group (TCR), and thirteen patients (23,6%) in the control group (CB-CR). Participants were predominantly male (n=45, 81,8%) and the mean age of all patients was 63,8 years (SD 9,9). In TCR, 27 (64,3% of 42) participants had PCI, and eleven (26,2% of 42) had CABG. In CB-CR, there were ten (76,9% of thirteen) and two (15,4% of thirteen) participants, respectively. All 55 participants performed the baseline ergometry. The second ergometry was performed by 48 participants (TCR: n=36; CB-CR: n=12). One participant was unable to perform the second ergometry due to a leg injury. Six patients rescheduled the ergometry to a date that falls beyond the scope of this report. The baseline questionnaires were completed by 35 participants. Seventeen participants (30,9% of 55) did not complete any

of the five digital baseline questionnaires. Two participants completed three questionnaires and one patient completed four questionnaires at baseline. Thirteen participants completed the second digital questionnaires (TCR: n=11; CB-CR: n=2) and 42 (76,4% of 55) did not complete any of the second questionnaires. No significant differences were found in baseline characteristics between the groups, as is shown in Table 1. The cardiovascular risk profile is similar in both groups in terms of diabetes mellitus, hypertension, hypercholesterolemia, a family history of CVD, smoking, and alcohol consumption. The total group of participants included 32 (58,2%) overweight patients (BMI between 25-30) and nine (16,4%) obese patients (BMI 30 and up). No difference was found in socioeconomic status between the groups (*p*=0,708).

Table 1. Baseline characteristics of participants of the Telerehabilitation trial

	TCR (intervention) (n = 42)	CB-CR (control) (n = 13)	*p*-value
Age at inclusion (mean, SD)	63.2 ±9.8	65.9 ±10.2	0.385
Males (n, %)	34 (81)	11 (84.6)	0.765
SES-WOA (mean, SD)	0.103 (0.164)	0.125 (0.219)	0.708
PCI (n, %)	27 (64.3)	10 (76.9)	0.396
CABG (n, %)	11 (26.2)	2 (15.4)	0.423
Family history (n, %)	29 (69)	10 (76.9)	0.585
Hypertension (n, %)	9 (21.4)	3 (23.1)	0.900
Diabetes Mellitus (n, %)	5 (11.9)	0 (0)	0.192
Hypercholesterolemia (n, %)	9 (21.4)	4 (30.8)	0.488
BMI (mean, SD)	27.1 ±3.4	26.4 ±2.9	0.521
Smoking (n ,%)	8 (19)	3 (23.1)	0.751
Alcohol consumption (n, %)	29 (69)	7 (53.8)	0.314

TCR: Telemonitoring Cardiac Rehabilitation; CB-CR: Center Based Cardiac Rehabilitation; SES-WOA: Sociaal Economische Status-welvaart, opleiding en arbeid; PCI: Percutaneous Coronary Intervention; CABG: Coronary artery Bypass Grafting; BMI: Body Mass Index

Outcome data

The maximum achieved wattage, during the ergometry, was higher at the end of the CR period than at baseline in both groups (mean increase peak workload= TCR (n=36): absolute 15,4 watt [SD 16,6], relative: 10,7%); CB-CR (n=12): absolute 10,0 watt [SD 14,1], relative: 5,5%). No significant difference in absolute (*p*=0,316) and relative (*p*=0,158) increase in maximum wattage was found between TCR and CB-CR. Responsiveness (a relative increase of > 4%) had been achieved by 24 participants (66,7% of 36 participants who performed the second ergometry) in TCR and by five participants in CB-CR (41,7% of twelve participants who performed the second ergometry). No significant difference was found (*p*=0,243) in the responsiveness between the groups. The results of the ergometry are summarised in Table 2.

Table 2. Results of the ergometry outcome measures

	TCR (intervention)			**CB-CR** (control)			
	Baseline (n = 42)	After CR (n = 36)	Difference	Baseline (n = 13)	After CR (n = 12)	Difference	*p*-value
Wattage (mean peak workload, SD)	157.7 ±42.0	175.6 ±45.9		161.5 ±68.5	176.7 ±78.4		0.809 0.952
Absolute difference			15.4 ±16.6			10.0 ±14.1	0.316
Relative difference			10.7 ±11.7			5.5 ±7.7	0.158
Workload relative to expected (mean %, SD)	96.9 ±22.0	111.2 ±19.0	-	99.9 ±24.2	107.1 ±29.7	-	0.672 0.773 -
>4% improvement	-	24	-	-	5	-	0.243
Max HR (BPM; mean, SD)	131.1 ±23.2	131.3 ±21.8	0.8 ±21.8	130.2 ±23.2	128.0 ±28.8	-2.9 ±16.0	0.902 0.674 0.588
Max HR relative to expected (mean %, SD)	84.4 ±15.4	83.7 ±13.6	-	77.8 ±24.1	81.8 ±13.9	-	0.247 0.680 -

TCR: Telemonitoring Cardiac Rehabilitation; CB-CR: Center-Based Cardiac Rehabilitation; CR: Cardiac Rehabilitation; HR: Heartrate; BPM: Beats per minute

Due to the small number of participants who completed the second digital questionnaires, it was not possible to perform an independent t-test for the differences between the first and second scores of the questionnaires. The results of the questionnaires are summarized in Table 3.

Table 3. Results of the questionnaires

	TCR (intervention)			**CB-CR** (control)			
	Baseline (n = 27)	After CR (n = 11)	Difference	Baseline (n = 8)	After CR (n = 2)	Difference	*p*-value
QoL (mean, SD)	5.1 ±0.9	5.8 ±1.2	-2.8 ±2.9	4.9 ±1.1	4.9 ±0.4	-3.2 ±3.7	0.595 - -
PHQ-9 (mean, SD)	3.7 ±3.4	3.7 ±5.2	-2.0 ±4.9	5.4 ±5.0	10.0 ±7.1	-2.6 ±2.9	0.245 - -
GAD (mean, SD)	2.0 ±2.3	2.5 ±5.5	-0.8 ±4.6	3.6 ±4.7	10.0 ±2.8	-1.3 ±2.3	0.187 - -
ESSI (mean, SD)	31.0 ±4.8	29.8 ±5.3	-19.2 ±15.8	30.6 ±3.6	29.0 ±2.8	-20.5 ±17.9	0.856 - -

TCR: Telemonitoring Cardiac Rehabilitation; CB-CR: Center-Based Cardiac Rehabilitation; CR: Cardiac Rehabilitation; QoL: Quality of Life; PHQ-9: Patient Health Questionnaire-; GAD: Generalized Anxiety Disorder; ESSI: ENRICHD Social Support Inventory

To control for potential confounding variables on the achieved maximum wattage the effect of PCI and CABG showed no difference (PCI: p=0,462; CABG: p=0,059). There was no difference between the groups in achieved workload relative to expected workload and in maximum achieved HR relative to expected HR in both the first and second ergometry (workload: p=0,773; HR: p=0,680).

DISCUSSION

This study found no additional effectiveness of TCR compared to CB-CR on the outcome measures. The absolute maximum wattage increased in both groups as did the responsiveness. It was not yet possible to determine the difference in the results of the questionnaires. No differences were found in the baseline characteristics between the groups. These findings indicate that TCR with the JBZ-developed app is a good alternative to CB-CR as participants in both groups demonstrated similar improvements in outcome measures. The results confirm the findings of previous research.[40,41]

Possible explanations for the lack of difference in effect between the groups may be related to differences in the training program's intensity and participants' motivation. During CB-CR, much use is made of exercise bikes. This provides targeted training to improve fitness on the bike.[42,43] Participants in TCR are allowed to choose their method of exercise. It is therefore possible that the cycling condition is not specifically improved in the TCR-group. It is not examined whether there is a difference in motivation between the groups. Group pressure during trainingsessions in CB-CR may cause participants to be inclined to train more intensely, whereas patients in the TCR-group may not feel this pressure during the training.[44] Participants in CB-CR may gain social support from exercising in a class with peers.[45] In contrast, patients in TCR may feel more supported because they are confronted with daily notifications from the app.[46] Patients in CB-CR do not feel this pressure outside of trainingsessions. Although no significant confounder was found, it should be noted that only a small group of participants underwent CABG. Exercise capacity may not improve as quickly after CABG compared with patients who did not undergo surgery.[47] The recovery process takes time, and improvements in exercise capacity usually become apparent after weeks to months.[48] A larger sample size and proper distribution of this variable across the groups can eliminate confounding or bias. In addition, assessing the results of the questionnaires was not possible because about a third of the participants did not complete the digital baseline questionnaires and about three-fourths did not complete the second questionnaires. As a result, it is not possible to analyse whether there is a difference in the degree of quality of life score, presence of anxiety disorder, depression, and social support. For a complete overview of the non-response rate of the baseline questionnaires, see Tables 7-10 in the appendix. The non-response rate would be expected to be lower in the CB-CR group, as this group often opts for CB-CR due to reduced digital capabilities. Analysis shows that there was no difference in the response rate between TCR and CB-CR. The analysis also showed no difference in non-response rates based on age or gender. For proper analysis, participants should be asked why the questionnaires were not completed.

Although randomized controlled trials are considered the gold standard for evaluating the effectiveness of interventions, this study was quasi-experimental. This was intentional because the intervention used was regular care. It was not intended to take away patient choice, as the rehabilitation process should meet patient needs. This also allowed the study to be conducted in a naturalistic setting and reflect real-life conditions under which the intervention was applied. Non-random assignments can introduce selection bias if there are systematic differences between the groups being compared and the distribution of confounding variables between the groups may be imbalanced. This was not the case in this study. Some limitations must be considered. Due to the short period after study approval, insufficient patients were included. The calculated sample size was not achieved during the study period, which forces careful interpretation of the results. A post-hoc power analysis was performed using G*Power with the sample size obtained (TCR: n=42; CB-CR: n=13) and the same alpha (0,05) and effect size (0,5) as in the a-priori power analysis. A power of 34% was calculated. Since the aim was to achieve a power of 80%, this study will continue until the desired sample size is reached. Especially in the control group, it was difficult to include a larger number of participants, as the majority of patients wanted to participate in TCR. TCR is so integrated into regular care that most patients prefer this form of CR, partly encouraged by healthcare providers. It was not possible to have an equally sized control and intervention group for the duration of this study. Despite the naturalistic setting, the specificity of the app used makes the results of this study only generalizable to other institutions using an app similar to the JBZ. The final limitation is that only eligible patients, who participated in the full training, were approached by the physiotherapist to participate in this study. Thus, this study does not provide insight into the drop-out rate of CR, and whether TCR reduces this rate. This could be explored with data research outside the scope of this study.

Implications for clinical practice and future research

It is still unknown whether there is a difference between TCR and CB-CR in the sustainability of the interventions and long-term effects, it is recommended to continue this study and re-run all measurements in one year. In addition, the app used will be updated in a few months. Education, coaching, and motivation will be expanded in the app, likely increasing its effectiveness. Also, an analysis can be conducted on whether there is a difference in the incidence of adverse cardiac events between the two groups. Since secondary prevention and reduction of adverse events are objectives of CR, it is interesting to investigate which form of intervention is most effective. To make TCR even more responsive to patient needs and because person-centred care is becoming increasingly important, qualitative research on patient experiences would be beneficial in the future. The app can be better tailored to patient's

preferences, which can lead to improved adherence, increased self-management, and better alignment with person-centred care.

CONCLUSION

TCR is non-superior to CB-CR on lifestyle changes in physical fitness measured by ergometry in the short term in patients after ACS. Caution should be taken when interpreting the preliminary results, as the desirable sample size had not yet been reached. It was not possible to analyse differences in quality of life, emotional and social functioning between the groups after CR-participation. Furthermore, no differences were found in baseline characteristics in the TCR and CB-CR groups. Future research is needed to investigate whether TCR will lead to increased participation in CR and better long-term management of cardiovascular risk factors.

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APPENDIX

List of abbreviations

ACS = Acute Coronary Syndrome
BMI = Body Mass Index
CABG = Coronary artery Bypass Grafting
CB-CR = Center-Based Cardiac Rehabilitation
CR = Cardiac Rehabilitation
CVD = Cardiovascular Disease
ECG = Electrocardiogram
ESSI = ENRICHD Social Support Inventory
GAD = Generalized Anxiety Disorder
HR = Heartrate
JBZ = Jeroen Bosch Ziekenhuis
PCI = Percutaneous Coronary Intervention
PHQ-9 = Patient Health Questionnaire
TCR = Telemonitoring Cardiac Rehabilitation
QoL = Quality of Life

Table 4. Inclusion criteria

- Stable medical condition
- Left ventricular ejection fraction > 40%
- Post-ACS (ST-elevated myocardial infarction (STEMI), non-ST elevated myocardial infarction (NSTEMI), with or without PCI (primary/elective) or CABG. *The ST segment is the representation on the ECG of the phase in which the ventricles are between depolarisation and repolarisation. Normally, the ST segment is slightly ascending. Elevation of the ST segment may indicate myocardial infarction.*
- Recently clinically discharged patient with an order for CR
- Stable angina-symptoms
- 18 years of age or older
- After intake indication for participation in the FIT-module of the CR-program
- Patient (or family caregiver) can speak Dutch
- Ability to complete digital questionnaires

For participation in the TCR-group, extra inclusion criteria had to be considered.

In possession of:
- Internet at home (Wi-Fi or 4G)
- Smartphone

Table 5. Exclusion criteria

- Severe mental and/or cognitive impairment
- Angina pectoris during exercise
- Cardiac arrhythmias during exercise
- Known ventricular arrhythmias
- Significant heart valve disease
- Congenital heart defects that limit exercise capacity
- Implantable cardioverter-defibrillator (ICD)
- Comorbidities affecting rehabilitation (e.g., chronic obstructive pulmonary disease, diabetes mellitus, movement disorders, orthopaedic- neurological or cognitive disorders)
- Heart failure from NYHA class III onwards

Table 6. Scoring of the digital questionnaires

Questionnaire	Focus	Scoring	Total score	Outcome
KVL-H	Quality of life-score	24 items are scored on a 7-point Likert scale; ranging from 1 (all the time) to 7 (never)	Adding up the scores of the 24 items and dividing by the number of questions	The higher the score the higher the experienced quality of life
PHQ-9	Detecting/follow up depression	9 items are scored on a 4-point Likert scale; ranging from 0 (not at all) to 3 (almost every day)	Summing the 9 items; minimum score is 0 points, maximum score 27 points	The higher the score the more severe the degree of depression is
GAD	Screening presence of anxiety disorder	Assigning scores of 0, 1, 2, and 3, to the response categories of "not at all," "several days," "more than half the days," and "nearly every day," respectively.	Summing the scores. The total score for the seven items ranges from 0 to 21	Scores of 5, 10, and 15 represent cut points for mild, moderate, and severe anxiety
ESSI	Measuring degree of social support	7 items are scored on a 5-point Likert scale; ranging from 1 (none of the time) to 7 (all of the time)	Adding up the scores of the 7 items. The minimum score is 7, the maximum score is 35	A high score reflects a high appreciation of social support
Five Shot	Detecting alcohol problem	Contains 5 questions which are scored in two different ways: responses to questions 1 and 2 are scored 0, 0.5, 1, 1.5, or 2, and questions 3 to 5 are scored 0 or 1	Adding up the scores of the 5 items. The minimum score is 0, the maximum score is 7	With a score of 2.5 or higher, there is a suspicion of alcohol abuse or alcohol dependence

Table 7. Missing responses (baseline) digital questionnaires total participants

	Total (n = 55)
Five shots (total, %)	12 (21.8)
KVL-H (total, %)	20 (36.4)
PHQ-9 (total, %)	17 (30.9)
GAD-7 (total, %)	18 (32.7)
ESSI (total, %)	19 (34.5)

Table 8. Missing responses (baseline) digital questionnaires based on group assignment

	TCR (intervention) (n = 42)	CB-CR (control) (n = 13)	*p*-value
Five shots (total, %)	10 (23.8)	2 (15.4)	0.520
KVL-H (total, %)	15 (35.7)	5 (38.5)	0.857
PHQ-9 (total, %)	13 (31)	4 (30.8)	0.990
GAD-7 (total, %)	14 (33.3)	4 (30.8)	0.863
ESSI (total, %)	14 (33.3)	5 (38.5)	0.734

Table 9. Missing responses (baseline) digital questionnaires based on age

Age category	40-44 (n = 2)	45-49 (n = 2)	50-54 (n = 6)	55-59 (n = 9)	60-64 (n = 8)	65-69 (n = 9)	70-74 (n = 10)	75-79 (n =8)	80-84 (n = 1)	*p*-value
Five shots	0	0	1	3	2	1	1	3	1	0.422
(total, %)	(0)	(0)	(16.7)	(33.3)	(25)	(11.1)	(10)	(37.5)	(100)	
KVL-H	0	0	1	5	2	3	4	4	1	0.468
(total, %)	(0)	(0)	(16.7)	(55.5)	(25)	(33.3)	(40)	(50)	(100)	
PHQ-9	0	0	1	3	2	3	3	4	1	0.631
(total, %)	(0)	(0)	(16.7)	(33.3)	(25)	(33.3)	(30)	(50)	(100)	
GAD-7	0	0	1	3	2	3	4	4	1	0.619
(total, %)	(0)	(0)	(16.7)	(33.3)	(25)	(33.3)	(40)	(50)	(100)	
ESSI	0	0	1	4	2	3	4	4	1	0.586
(total, %)	(0)	(0)	(16.7)	(44.4)	(25)	(33.3)	(40)	(50)	(100)	

Table 10. Missing responses (baseline) digital questionnaires based on gender

	Male (n = 45)	Female (n = 10)	*p*-value
Five shots (total, %)	8 (17.8)	4 (40)	0.124
KVL-H (total, %)	15 (33.3)	5 (50)	0.857
PHQ-9 (total, %)	13 (28.9)	4 (40)	0.492
GAD-7 (total, %)	14 (31.1)	4 (40)	0.588
ESSI (total, %)	14 (31.1)	5 (50)	0.256