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Feasibility of home-based cardiac telerehabilitation: Results of TeleInterMed study

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Abstract

Background: *Cardiac rehabilitation (CR) is recommended as an important component of a comprehensive approach to cardiovascular disease (CVD) patients. Data have shown that a small percentage of eligible patients participate in CR despite their well established benefits. Applying telerehabilitation provides an opportunity to improve the implementation of and adherence to CR. The purpose of the study was to evaluate a wide implementation and feasibility of home-based cardiac telerehabilitation (HTCR) in patients suffering from CVD and to assess its safety, patients' acceptance of and adherence to HTCR.*

Methods: *The study included 365 patients (left ventricular ejection fraction 56 ± 8%; aged 58 ± 10 years). They participated in 4-week HTCR based on walking, nordic walking or cycloergometer training. HTCR was telemonitored with a device adjusted to register electrocardiogram (ECG) recording and to transmit data via mobile phone to the monitoring center. The moments of automatic ECG registration were pre-set and coordinated with CR. The influence on physical capacity was assessed by comparing changes — in time of exercise test, functional capacity, 6-min walking test distance from the beginning and the end of HTCR. At the end of the study, patients filled in a questionnaire in order to assess their acceptance of HTCR.*

Results: *HTCR resulted in a significant improvement in all parameters. There were neither deaths nor adverse events during HTCR. Patients accepted HTCR, including the need for interactive everyday collaboration with the monitoring center. There were only 0.8% non-adherent patients.*

Conclusions: *HTCR is a feasible, safe form of rehabilitation, well accepted by patients. The adherence to HTCR was high and promising.* (Cardiol J 2014; 21, 5: 539–546)

Key words: cardiovascular diseases, home-based cardiac telerehabilitation

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Introduction

Cardiac rehabilitation (CR) is now recommended as an important component of a comprehensive approach to cardiovascular disease (CVD) patients [1–5].

Research data demonstrate that participating in CR improves exercise tolerance, peripheral hemodynamics parameters, endothelial and autonomic functions, quality of life, and reduces rates of both total and cardiovascular mortality [1–5]. Exercise training (ET) also results in a modification of cardiovascular risk factors [1–4]. Despite these well established benefits, only a low percentage of eligible patients actually participate in CR programs [6, 7]. Based on the EUROASPIRE III survey only 44.8% patients after coronary events or revascularization reported being advised to attend CR, and of these 81.4% did so (36.5% of all patients) [7]. There are a lot of factors negatively affecting patients' participation in CR programs such as older age, low level of education, lack of motivation, depression, commuting, as well as social, economic and healthcare system issues [8]. Therefore, we do not discuss whether but how we should implement comprehensive CR in patients suffering from CVD. Introducing home-based cardiac telerehabilitation (HTCR) may eliminate most of the factors that result in the currently low number of patients undergoing outpatient-based rehabilitation programs and thus increase the percentage of those who will undergo CR [9]. To date, only a few studies including small numbers of patients have demonstrated favorable effects of telemonitored CR but the authors did not evaluate in detail patients' acceptance of HTCR [10–16].

The purpose of this prospective, nonrandomized study was to evaluate a wide implementation and feasibility of HTCR in patients suffering from CVD and to assess its safety, patients' acceptance of and adherence to HTCR.

Methods

The present study on HTCR formed a part of the "Establishment of TeleInterMed Teleconsulting Center" study which assessed a wide implementation of telemedicine in cardiology.

Patient population

The study group consisted of 365 patients who had a documented CVD and were referred for outpatient phase II CR from January 2009 to March 2011. They were enrolled in HTCR because of their preference or a long distance they would have had to travel from and to the outpatient rehabilitation center. We qualified patients with presence of known, stable CVD with low risk for complications with vigorous exercise [2].

The inclusion criteria were: left ventricular ejection fraction > 40%, New York Heart Association class I or II, no evidence of congestive heart failure and myocardial ischemia or angina at rest or on the exercise test at or below 6 METs, appropriate rise in systolic blood pressure during exercise, absence of sustained or nonsustained ventricular tachycardia at rest or with exercise, clinical stability for at least 3 weeks prior to the entry for the study and optimal, stable medical treatment, ability to satisfactorily self-monitor intensity of activity, and patients' willingness to comply with the HTCR program.

The exclusion criteria were: unstable angina, congestive heart failure, uncontrolled hypertension (blood pressure > 160/90 mm Hg at rest), symptomatic and/or exercise-induced cardiac arrhythmia or conduction disturbances, left bundle branch block, valvular or congenital heart disease requiring surgical treatment, impaired renal or hepatic function, anemia (hemoglobin ≤ 11.0 g/dL), acute and/or decompensated non-cardiac disease, physical disability related to severe musculoskeletal or neurological problems, severe psychiatric disorder, and patient's refusal to participate.

Study protocol

The study was approved by the Institutional Ethics Committee. Each patient gave a written informed consent. The study was designed as a prospective non-randomized trial. The patients underwent the following assessments at entry and after completing a 4-week training program: clinical examination, 6-min walking test (6-MWT), exercise treadmill or cycloergometer test.

Following the baseline measurements, eligible patients started HTCR program.

Six-minute walking test

The test was conducted using a standardized protocol between 11 am and 2 pm after taking usual medications [17]. Patients were required to perform a shuttle 6-MWT with markers placed at 25 m.

Exercise stress tests

Each subject performed a symptom limited exercise treadmill or cycloergometer test (each patient always the same type) according to the guidelines [2]. The exercise treadmill test was performed using a computerized system CASE 8000

(Marquette Electronics, Milwaukee, Wisconsin, USA) according to the Bruce protocol or modified Bruce protocol (always the same protocol for a particular subject before and after HTCR program so that each patient would be a control for him/herself). The exercise test on a cycloergometer was performed using Ergometric 800 s (Margot Medical Ergo-Line) connected to a computer system (Case 12, Marquette).

Home-based cardiac telerehabilitation

The methodology of HTCR has been described previously [10, 18, 19]. Briefly, we performed HTCR as a comprehensive procedure which included all core components of CR according to the guidelines [1]. All patients received remote-controlled equipment for tele-electrocardiogram (ECG)-monitoring and supervised ET (Pro Plus Company, Poland), which consisted of an EHO mini device and blood pressure measuring. The device allowed to record ECG data from 3 pre-cordial leads and transmit them via mobile phone network (using an integrated mobile phone) to the monitoring center. The mobile phone was also used for voice communication.

Performing HTCR consisted of two stages: an **initial stage** — conducted within an outpatient center (3 days), and a **basic stage** — conducted at home (4 weeks). The goals of the **initial stage** were: a baseline clinical examination, optimization of treatment, education, individual planning of ET, performing a few (3–6) monitored educational training sessions, and psychological assessment. The **basic stage**, which was conducted at home and consisted of two parts, was performed prior to each training session: the first part — **the training consent procedure** was required for a patient to access each training session, and the second part — **the training session**. The training consent procedure included: telephone conversation with a nurse during which the patient answered questions about their present condition, symptoms, medications taken and sent rest ECG and blood pressure data. When there were no contraindications to start the training, the patient was given consent to begin exercising.

The telemonitoring system had details of the training sessions pre-programmed for each patient (defined exercise duration, breaks, timing of ECG recording). The times of automatic ECG recording were pre-set and coordinated with the ET. The planned training sessions were executed with a device indicating what should be done via sound and light signals.

The timing of the ECG recordings corresponded to peak exercise. If the training session was completed uneventfully, the patient transmitted the ECG recording via the mobile phone to the monitoring center at the end of the session. The data were stored in a computer and analyzed by physicians who took final decisions.

The device had an external tele-event Holter ECG feature as well. This allowed patients to record and immediately send the ECG recording to the telemonitoring center whenever a worrying symptom occurred.

Exercise training was planned individually for each patient in line with the published guidelines [1–3]. The training heart rate (HR) was calculated using the HR reserve method, based on data achieved in exercise test. This method uses a percentage of the difference between maximum HR and resting HR, and adds this value to the resting HR [20]. The target training HR was 60–80% of the HR reserve. Each training session consisted of three parts: (1) a warm up lasting for 5–10 min, consisting of breathing, light resistance exercises and calisthenics; (2) an aerobic endurance training based on different forms i.e. either walking or nordic walking or cycloergometer training for 30 min each; (3) a 5-min cooling down period. Patients trained 5 times a week.

Satisfaction questionnaire

At the end of the study, patients filled in a 12-item questionnaire in order to assess their acceptance and satisfaction of HTCR. The questions are presented in Table 1.

Assessment of the adherence to HTCR

Adherence during the HTCR was assessed from daily telephone contacts with the monitoring center required to get permission for the training and to transmit the ECG data following each training session. Adherence was defined as the percentage of patients who carried out the prescribed exercise training. According to the present recommendations, in terms of their adherence, the patients were divided into three groups: the first category were adherent patients, i.e. patients who adhered both to the number of training sessions prescribed and to the duration of the prescribed cycle by at least 80%. The second group consisted of non-adherent patients, who adhered < 20% to the prescribed number of training sessions and their duration. The third group corresponded to the partially adherent patients who carried out the prescribed exercise, yet tended to omit some of

Table 1. Patients' acceptance of home-based cardiac telerehabilitation questionnaire.

Questions	Answers (%)
Did you control the device by yourself?	Yes: 100% No: 0%
Was operating the device:	Very easy: 40.2% Easy: 58.3% Difficult: 1.5% Very difficult: 0%
Was accurate placing electrodes on your skin difficult?	Yes: 0.6% No: 99.4%
Did you observe any significant skin reaction to electrodes?	Yes: 12.8% No: 87.2%
When using provided equipment to communicate with monitoring centre, was the sound quality satisfactory?	Yes: 37.2% No: 62.8%
Did you find it difficult to coordinate exercise with the instructions from the device?	Yes: 4.2% Sometimes: 4.8% No: 91.0%
Was transmitting data (ECG, blood pressure) troublesome?	Yes: 1.8%; Sometimes: 14.2% No: 84.0%
Did you ever miss doing a telerehabilitation session because of technical problems? If Yes, how many times?	Yes: 39.3% (averagely 1 session/ /20 sessions performed) No: 60.7%
When did you use the telemedicine equipment?	Only during exercise: 94.4% During exercise and when I felt unwell: 5.6%
Did HTCR stimulate you to do exercise?	Yes: 95.2% Moderately: 3.3% No: 1.5%
Did you feel safer during HTCR than when you did exercises at home without supervision?	Yes: 80.9% No: 19.1%
Did HTCR make you increase your everyday activities?	
Physical exercises	Yes: 80.0%; No: 20.0%
Mental	Yes: 77.1%; No: 22.9%
Social	Yes: 39.6%; No: 60.4%
Professional	Yes: 25.0%; No: 56.0%; No applicable: 19.0%
Sexual	Yes: 34.5%; No: 65.5%

ECG — electrocardiogram; HTCR — home-based cardiac telerehabilitation

them or did not carry them out for the prescribed duration (i.e. who adhered ≥ 20% < 80%) [14].

Statistical analysis

Estimation of sample size. According to the mean values and standard deviations of: the time of exercise, distance, MET, Watt and under the following assumptions: significance level = 0.05, power = 0.80 and differences of these parameters over 4 weeks = 10%, the sample size = 208, 42, 72, 87, respectively are satisfied. The normality of distribution of changes over time was verified using the Shapiro-Wilk test. For normally distributed continuous variables for changes over time the paired Student's t-test was used. The signed-rank test (for changes over time) was used for continuous variables that were not normally distributed. P-values less than 0.05 were considered significant. Statistical analyses were performed using SAS software (version 9.2; Cary, NC, USA).

Results

Of 405 patients screened for the purpose of this study 6.2% refused to participate and 2.2% fulfilled exclusion criteria. Telerehabilitation program covered 373 patients. Three patients discontinued HTCT due to personal obligations. Another 5 patients completed CR, but did not undergo examination after HTCR. The final evaluation included 365 patients. The baseline clinical and demographic characteristics of the patients are presented in Table 2.

Table 2. Baseline characteristics of HTCR group (n = 365).

Males	307 (84%)
Females	58 (16%)
Age [years]	58.3 ± 10.5
LVEF [%]	56.0 ± 8.1
Body mass index [kg/m^2]	27.5 ± 4.1
Cardiovascular diseases:	365 (100%)
Post an acute event[1]	310 (85%)
Chronic[2]	55 (15%)
Coronary artery disease	333 (91%)
Myocardial infarction	264 (72%)
PCI	227 (62%)
CABG	89 (24%)
Comorbidities:	
Hypertension	242 (66%)
Diabetes	63 (17%)
Hyperlipidemia	245 (67%)
Treatment:	
Beta-blocker	345 (95%)
ACEI	270 (74%)
Loop diuretics	83 (23%)
Spironolactone	29 (8%)
Aspirin	333 (91%)
Clopidogrel	179 (49%)
Anticoagulants	30 (8%)
Statins	343 (94%)

HTCR — home-based cardiac telerehabilitation; LVEF — left ventricular ejection fraction; PCI — percutaneous coronary intervention; CABG — coronary artery bypass grafting; ACEI — angiotensin converting enzyme inhibitors; [1]HTCR begun a week to 12 weeks following the event; [2]HTCR begun later than 12 weeks following the event

Safety of HTCR

There were no deaths or other major events or complications during ET. We did not observe episodes of exercise-induced prolonged chest pain of myocardial ischemia or acute infarction. There were no episodes of ventricular tachycardia. No patient developed musculoskeletal injuries related to HTCR. There were some minor events observed, though. One of the patients had a positive stress test and recurrent chest pain during final examination after HTCR cycle. He was referred to coronarography. In another patient's transmitted ECG (irrelevant of ET), ST-segment depression was once observed while he complained of feeling unwell. Further diagnosis revealed coronary artery stenosis. Two patients were directed to pacemaker implantation: a woman with paroxysmal atrial fibrillation, after implantation of artificial mitral valve and tricuspid valve annulus because of tachycardia-bradycardia syndrome, and a man after myocardial infarction treated primary percutaneous coronary intervention and implantation of 2 stents, because of symptomatic sinus bradycardia and necessity to intensify the treatment of supraventricular arrhythmias. Another patient with an implanted AAI pacemaker, due to developing atrio-ventricular conduction disturbances (irrelevant of ET) was referred to undergo ventricular electrode implantation.

Acceptance of HTCR

The patients' acceptance questionnaire was filled in by ninety percent of patients. All patients operated the device by themselves and almost 98% of them reported that the telemonitoring device was user-friendly. Placing electrodes on patients' skin accurately was not difficult and most of them did not observe any significant skin reactions to electrodes. About 39% of patients missed doing an ET session (averagely one for whole HTCR cycle) because of the fact that the particular mobile phone network operator was unavailable. During HTCR we used a new option of voice communication which was integrated with EHO mini device. Almost one third of patients reported that the sound quality was not satisfactory to them. A great number of patients undergoing HTCR reported that everyday contact with the monitoring center stimulated them to perform exercise. Moreover, they felt safer during HTCR than when they were exercising at home without supervision.

Most of the patients reported their everyday physical and mental activities got better. Around one third felt an improvement in their sexual performance. The results are presented in Table 1.

Adherence to HTCR

The adherence to HTCR was very high. There were only 3 non-adherent patients. The results are presented in Figure 1.

Assessment of physical capacity

The following variables improved significantly after HTCR: 6-MWT distance; exercise duration, patients' physical capacity and maximal HR. The results are presented in Table 3.

Discussion

Data have shown that only a small percentage of eligible patients participate in CR despite their well established benefits. Applying telerehabilitation provides an opportunity to improve the implementation of comprehensive CR.

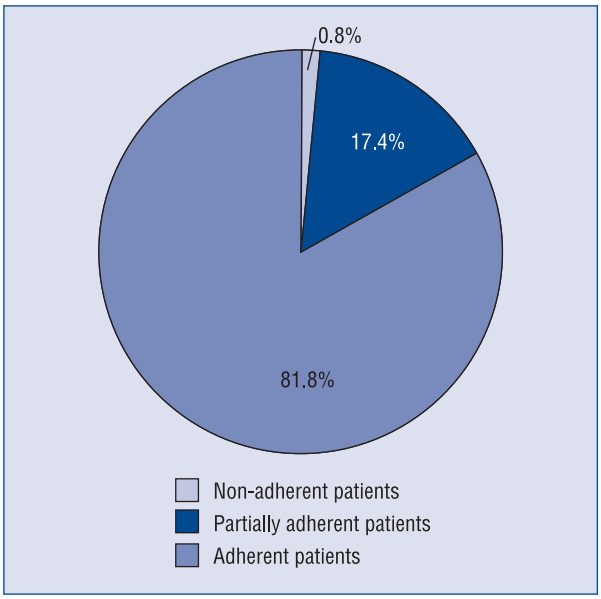

Figure 1. The adherence to home-based telemonitored cardiac rehabilitation.

The main finding of our study is that telerehabilitation is a feasible and safe procedure and could be widely implemented in patients suffering from CVD. Moreover, it was very well accepted by patients, and the adherence to HTCR was high.

To date, there have been only a few studies (mostly not randomized) in small numbers of patients assessing the effects of telerehabilitation in patients suffering from CVD. In contrast to the papers published so far, our study evaluated a much larger cohort of the subjects and thus our contribution seems much fuller and more valuable.

Safety of HTCR

Because of lack of direct medical supervision, the extremely important aspect of HTCR is to ensure patients' safety. The available data show that the benefits of regular ET significantly outweigh its potential risks [21, 22]. We did not observe major adverse events or complications during ET, no infarction developed related to the exercise and there were no deaths. Additionally, no worrying signs or symptoms were observed during the training sessions. Of special importance was everyday qualification to a training session within the inclusion consent procedure resulting in avoidance of unexpected events during ET sessions. Moreover, we recommended presence of another person who would always accompany the patient during exercise and would be able to provide first aid and call professional medical help in case of an emergency. Our study confirmed the results of other telerehabilitation studies which showed that regular ET in patients suffering from CVD was safe [10, 12, 13, 15].

Table 3. Comparison of outcomes before and after home-based cardiac telerehabilitation (HTCR).

	Before HTCR	After HTCR	P
Body mass index [kg/m^2]	27.5 ± 4.1	27.4 ± 4.0	0.0235
Six minute walking test:			
Distance [m]	498.1 ± 80.7	561.9 ± 77.9	0.0001
Borg RPE post-test	2.4 ± 0.9	2.5 ± 0.8	0.0233
Exercise test:			
Exercise time [s]	538.6 ± 196.0	573.9 ± 207.0	0.0001
Maximal workload [MET][1]	8.9 ± 1.9	9.8 ± 1.9	0.0001
Maximal workload [Watt][2]	137.7 ± 32.3	147.5 ± 33.5	0.0001
HR rest [bpm]	71.9 ± 10.9	72.5 ± 10.8	0.3245
HR max effort [bpm]	124.0 ± 16.4	127.0 ± 16.9	0.0001
SBP rest [mmHg]	120.3 ± 13.9	119.2 ± 13.4	0.4421
DBP rest [mmHg]	75.8 ± 7.9	75.4 ± 7.3	0.2725
SBP max effort [mm Hg]	178.7 ± 27.8	179.9 ± 26.6	0.4414
DBP max effort [mm Hg]	87.8 ± 11.8	87.7 ± 10.6	0.2429
DP rest [mm Hg/min]	8656.73 ± 1690.32	8637.90 ± 1547.85	0.7446
DP max effort [mm Hg/min]	22273 ± 5025.70	22947.00 ± 4909.54	0.0064

Data are presented as mean values ± standard deviation; p-values 0.05 were considered significant; RPE — rating of perceived exertion according to the Borg (6–20) scale; MET — metabolic equivalent; HR — heart rate; SBP — systolic blood pressure; DBP — diastolic blood pressure; DP — double product, i.e. product of HR and SBP at rest and at peak of exercise; max-maximum; [1]164 patients underwent treadmill test; [2]201 patients underwent cycloergometer test

Acceptance and adherence to HTCR

Patients' acceptance of a proposed model of rehabilitation is of crucial importance for its everyday implementation. Our experience showed that patients accepted this model of HTCR, including the need for interactive everyday collaboration with the monitoring center. All patients operated the equipment themselves and found the process easy. None of the patients had any problems in operating the telemonitoring equipment. Similarly, Scalvini et al. [11] confirmed that patients who undergo telerehabilitation were very satisfied with the nurse-tutor support, and the equipment was considered easy to use by 72% of patients. Fletcher et al. [15] reported the adherence to HTCR in patients after coronary bypass surgery, which was quite good (about 80%) similar to that in our patients.

A great number of patients undergoing our HTCR completed their 4-week exercise program. The advantages of ECG telemonitoring include also the fact that we can control whether patients are compliant. All authors reporting on telerehabilitation programs agree that the adherence to telerehabilitation seems to be superior to the adherence to out-patient CR [10, 12]. Our results confirm those findings. The most important advantage of HTCR is that patients following physicians' recommendations at the same time may become more independent in performing their everyday tasks.

Assessment of physical capacity

Lack of control group makes it impossible to assess the effectiveness of HTCR because we cannot exclude spontaneous improvement over time. However, favorable effects on the physical capacity after HTCR are worth noting. Similarly, Scalvini et al. [11] evaluated the feasibility of a 1-month HTCR in a small group of patients after cardiac surgery. As in our study, the authors observed a significant increase in the distance in 6-MWT [11]. Giallauria et al. [16] assessed the effects of CR at 3 sessions weekly for 2 months in patients after myocardial infarction. The patients were subdivided into three groups: an out-patient CR, a home-based telemonitored CR, and a home-based CR without ECG-monitoring. Physical capacity improvement was comparable in patients trained in an out-patient centers and at home with ECG monitoring. Yet, these favorable effects were not observed in those trained at home without telemonitoring. In our study, we also observed significant improvement in patients' physical capacity after home-based tele-supervised ET.

Limitations of the study

There are some limitations of our study. The study included only low risk patients so its results cannot be extrapolated to heart failure patients. Lack of a control group is another limitation. During patients' enrolment, both their preferences and problems resulting from the necessity to commute were taken into consideration. Consequently, some bias in patients' selection cannot be excluded.

A relatively short (4 weeks) telerehabilitation program might have influenced the adherence positively. Most of the target group included men (84%), and thus the results achieved cannot be fully extrapolated to the female population.

Ten percent of the patients did not fill in the questionnaire. This number might have included those less satisfied with HTCR.

Conclusions

Our study showed that HTCR was a feasible form of CR and included all core components of comprehensive CR. It also proved that HTCR was safe and well accepted by patients. The adherence to HTCR was high and promising despite the numerous factors impairing the participation in out-patient CR. Telerehabilitation thus seems to be a viable alternative for comprehensive CR. Yet, further multicenter studies are needed in order to establish an optimal model for this type of rehabilitation to be implemented in routine clinical practice, including the aspect of its cost-effectiveness.

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Conflict of interest: None declared

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