Home-Based Cardiac Rehabilitation Among Patients Unwilling to Participate in Hospital-Based Programs

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Purpose: Asynchronous home-based cardiac rehabilitation (HBCR) is a viable alternative to center-based cardiac rehabilitation (CBCR). However, to achieve significant functional improvement, a high level of adherence and activity must be achieved. The effectiveness of HBCR among patients who actively avoid CBCR has not been effectively investigated. This study aimed to investigate the effectiveness of the HBCR program among patients unwilling to participate in CBCR.

Methods: A randomized prospective study enrolled 45 participants to a 6-mo HBCR program and the remaining 24 were allocated to regular care. Both groups were digitally monitored for physical activity (PA) and self-reported outcomes. Change in peak oxygen uptake (\dot{VO}_{2peak}), the primary study outcome, was measured by the cardiopulmonary exercise test, immediately before program start and 4 mo thereafter.

Results: The study included 69 patients, 81% men, aged 55.9 \pm 12 yr, enrolled in a 6-mo HBCR program to follow a myocardial infarction (25.4%) or coronary interventions (41.3%), heart failure hospitalization (29%), or heart transplantation (10%). Weekly aerobic exercise totaled a median of 193.2 (110.2-251.5) min (129% of set exercise goal), of which 112 (70-150) min was in the heart rate zone recommended by the exercise physiologist. After 4 mo, \dot{VO}_{2peak} improved by 10.2% in the intervention group versus -2.7% in the control group (+2.46 \pm 2.67 vs -0.72 ± 3.02 mL/kg/min; P < .001).

Conclusion: The monthly PA of patients in the HBCR versus conventional CBCR group were well within guideline recommendations, showing a significant improvement in cardiorespiratory fitness. Risk level, age, and lack of motivation at the beginning of the program did not prevent achieving goals and maintaining adherence.

Key Words: adherence • cardiovascular disease • motivation • telecardiac rehabilitation • telemedicine

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KEY PERSPECTIVES

What is novel?

- The study focuses on a group of patients who had previously not been well studied, namely, patients who had declined center-based cardiac rehabilitation (CBCR). These patients comprise the bulk (>60%) of all cardiac patients, but they do not usually sign up for home-based cardiac rehabilitation (HBCR) studies, since they generally refuse enrollment from the very beginning.
- The research focuses on medium- and high-risk cardiac patients.
- The adherence and results achieved by patients who evaded conventional CR and participated in HBCR were well within guideline recommendations.

What are the clinical and/or research implications?

- Asynchronous HBCR can be a good alternative to conventional CBCR for patients who lack motivation for treatment and actively avoid hospital CR.
- Asynchronous HBCR is shown to be a viable alternative to conventional CBCR for low- as well as high-risk patients.

Cardiac rehabilitation (CR) is well recognized as an essential intervention for the secondary prevention of coronary artery disease, heart failure (HF), and future heart-related complications.¹ Benefits of CR include improvements in morbidity, physical activity (PA) level, exercise capacity, and quality of life as well as decreased rate of hospital admissions.² A viable alternative to traditional, center-based cardiac rehabilitation (CBCR) is asynchronous home-based cardiac rehabilitation (HBCR).³ Similar to CBCR, HBCR has already been well established and shown to deliver similar outcomes and safety profile.⁴ However, unlike traditional CR programs, HBCR has the additional benefits of being more cost-effective and easily accessible.^{5,6}

Previous research^{7,8} has found that patients who are referred by their physicians to CR are often unwilling to actively participate in the traditional CR. The reasons for this unwillingness to participate in CR are varied and can be broken down into person-specific factors and reasons which are related to the CR program. Documented person-specific factors such as older age, female sex, patients with comorbidities, unemployed persons, lower education levels, and lower incomes were correlated to lower participation rates. Specific reasons, which were related to the CR program, included distance from CR facilities, lack of adequate transportation, and program hours.⁹ Other studies have documented outright patient refusal to initiate a traditional CR program, citing factors such as a general

lack of time and a belief that they could handle their own condition. $^{\rm 10}$

These factors lead to a significant proportion of patients who do not participate in a CR program.¹¹ This situation is detrimental to the health care system, as these patients subsequently either return for hospitalizations that could have been prevented or suffer clinical adverse events. These hospitalizations are not only a burden on the health care system but they generate additional costs for the patient. Therefore, a viable alternative of HBCR should be considered for patients who are unwilling to undergo CR.

Meaningful functional improvement in HBCR is dependent on a high level of patient adherence and PA, as well as their motivation to collaborate with a multidisciplinary care team. Previous studies have shown that telehealth interventions were as effective as center-based programs for improving modifiable cardiovascular disease risk factors and exercise capacity.^{12,13}

Despite numerous studies in the field of HBCR, previous studies have focused on patients attending a CR center who were already motivated. Our study was unique in that we addressed a group of patients of varying levels of risk who had declined CR. The aim of this study was to investigate through a randomized control trial the effectiveness of the HBCR program among higher-risk patients unwilling to attend CBCR versus usual care.

METHODS

This was a single-center, randomized-control double-arm, prospective study where all patients consented. The study protocol was reviewed and approved by the Ethical Review Board of the Sheba Medical Center. The study was conducted to evaluate the effects of HBCR on adherence, compliance, and the objective change in cardiorespiratory fitness in mostly moderate- or high-risk patients with cardiac disease.

In Israel CR is free of charge for the first 3 mo and all citizens have medical insurance, so travel cost is the sole expense. Following the initial medical visit to the CR center and program presentation, all eligible patients were offered the program. Some declared their unwillingness or inability to join CBCR. We approached individuals who elected not to start CBCR despite full reimbursement and lack of CR contraindications. Reasons for nonparticipation included distance from CR, service availability hours, travel constraints, time constraints, and other logistic or sociocultural barriers.

Study inclusion criteria were based on national guidelines and are accepted indications for CR. Exclusion criteria included: age < 21 yr, any unresolved cardiac condition associated with significantly increased risk during outpatient PA (ie, clinically significant ischemia, unresolved arrhythmia, high falling risk, etc), end-stage HF (New York Heart Association class 4) or decompensated HF, left ventricular ejection fraction $\leq 35\%$ without an implantable cardiac defibrillator or cardiac resynchronization therapy defibrillator, significant neurological or cognitive impairment, women of child-bearing potential, resuscitated cardiac arrest, severe angina, or severe orthopedic limitations.

A total of 69 patients after myocardial infarction, coronary interventions (cardiac surgery and percutaneous coronary interventions), or HF were referred to the outpatient Cardiac Rehabilitation Institute at the Sheba Medical Center, Israel. Patients were enrolled following eligibility verification and randomized 2:1 to the intervention or usual care control group, respectively (Figure 1). In the interventional arm, the program consisted of 6 mo of active HBCR with an additional 6 mo of follow-up. Patients in the control group received general recommendations on health management and exercise prescription, as well as periodic consultations by a cardiologist and their family physician. All patients received a smartphone mobile application to facilitate answering periodic questionnaires and counting daily steps.

The primary efficacy outcome was the percent change in peak oxygen uptake (VO_{2peak}) directly measured by the cardiopulmonary exercise test (CPX) immediately prior to program initiation and 4 mo later.¹⁴ The CPX was conducted according to the modified Balke protocol. The initial speed was selected following a discussion with the patient and the impression of the exercise physiologist. All patients were encouraged to reach a respiratory exchange ratio (RER) > 1.1.

The following variables were assessed monthly in the intervention arm: (1) number of aerobic and resistance exercise sessions completed, (2) percent of exercise time spent at the designated target heart rate (HR) zone, (3) average HR during the exercise, (4) the number of total aerobic exercise minutes (TAM), (5) percent of workout intensity (as average HR during workout/CPX maximum HR \times 100), (6) the Borg scale of perceived exertion, (7) daily step count, and (8) mobile application usage (number of times the mobile application was used).

Laboratory testing was also performed for fasting blood glucose, lipids, blood pressure, and hemoglobin A1c levels (in patients with diabetes). Clinical event adjudication (hospitalizations, emergency department visits) was performed throughout the 12-mo study period. Questionnaires defining mental and physical health (PROMISE 10)¹⁵ and the degree of behavior change, based on the model of Prochaska and DiClemente (Stages of Change Model)¹⁶ were assessed. These questionnaires were sent out at enrollment, after 1 mo of intervention, and every subsequent 3 mo during the 12-mo study period.

THE HBCR PROGRAM

The HBCR program is based on the national and global guidelines of the cardiology communities provided by the Israeli Heart Society for CR. A detailed description of the program was previously published as well as the Datos Health platform used for this study.^{17,18} In short, the main component of the program is structured exercise, monitored by a VA3 (Garmin) or M430 (Polar) smartwatch,¹⁹ which transmits data to the patient's smartphone application and to the medical operations center at the CR operation center.¹⁷ It is worth noting that the use of smartwatches is widely practiced in rehabilitation centers around the world. Despite the well-established fact that the HR measurement is not accurate (typically 5-10% mean average error), this has little clinical implication as patients are usually instructed to exercise within an HR zone and not at an exact value. The program includes remote synchronized follow-up with a multidisciplinary care team and easily accessible, extensive educational content on the mobile application of the patient. The Datos platform (see Supplemental Digital Content S1, available at: http://links.lww.com/JCRP/A477, and S2, available at: http://links.lww.com/JCRP/A478) allows tracking of various measurements (such as the HR above and below the target HR, steps, number of mobile app usage, and number and intensity of workouts), and interactions with a patient who is connected to a smartwatch, as well as the transmission of data to the portal of the care team. This enables monitoring, decision-making, and recommendations regarding patient PA and other elements of

Rehabilitation of the Unmotivated - Consort 2010 Flow Diagram



Figure 1. The flow diagram of the study. This figure is available in color online (www.jcrpjournal.com).

secondary prevention. The patient-generated data are presented so as to allow the care team to consider each patient individually and compare groups of patients within the same program. Patients were encouraged to be engaged in any form of aerobic PA at home or in their community, such as dancing, swimming, and walking. According to national PA guidelines, the program goals were as follows: >150 min of moderate-intensity aerobic PA/wk, 120 min of aerobic PA at target HR zone (HR zone previously set by exercise physiologist; in the majority of cases we used the anaerobic threshold or Karvonen formula when the anaerobic threshold was not clearly identified and respiratory compensatory thresholds [VT2], obtained during the CPX),²⁰ two weekly sessions of resistance training, and attaining 8000 steps/d. The daily step goal was based on literature suggesting this represents a realistic and clinically valid goal.^{21,22} Videos,

educational material, and phone coaching were used to educate and support patients. The control group also received a mobile application through which patients could answer questionnaires and track their daily step count. All participants received standard-of-care medical management by their family physicians and consulting cardiologists.

STATISTICAL ANALYSIS

Descriptive statistics are presented in accordance with variable characteristics and their distribution. Study participant demographics and clinical characteristics are presented as the median (IQR), mean \pm SD, or % as appropriate.

The paired sample *t* test or Wilcoxon signed-rank test was used to compare numeric baseline values and the respective values following 1, 3, 6, 9, and 12 mo for each of the study groups, following normality assumption testing. The

Table

Characteristics of the Study Group

Variables ^a	Intervention Group $(n = 45)$	Control Group $(n = 24)$	<i>P</i> Value
Age, yr	56.6 ± 12.3	54.5 ± 12.2	.521
Sex, male	36 (80)	20 (83.3)	.503
Body metrics			
Weight, kg	84.0 ± 16.5	81.7 ± 13.5	.563
Height, cm	173.9 ± 10.1	174.8 + 7.8	.686
BMI, kg/m ²	27.6 ± 4.3	26.7 ± 4.0	.383
Comorbidities			
Dvslipidemia	31 (68.9)	14 (58.3)	.381
DM	12 (26.7)	4 (16.7)	.349
HTN	19 (42.2)	9 (37.5)	.704
CVA	1 (2.2)	1 (4.1)	.647
PVD	4 (8.9)	0	.132
Metabolic laboratory values			
LDL, mg/dL	41,82.9 ± 32.1	21,87.4 ± 35.1	.610
TRIG, mg/dL	44,138.7 ± 113.1	24, 190.9 ± 162.2	.125
HDL, mg/dL	44, 43.8 ± 13.4	24, 45.2 ± 15.4	.703
Glucose, mg/dL	$43.103.4 \pm 34.2$	$22.107.2 \pm 34.2$.609
HbA ₁ c, %	8 6 1 + 0 95	459 ± 08	.668
CRP, mg/dL ^a	$12 125 \pm 285$	6,40+50	.488
Previous cardiac procedures	12, 12.0 = 20.0	0, 110 _ 010	
S/P MI-ACS	10 (22.2)	1 (4.2)	.051
S/P CABG	3 (6.7)	1 (4.2)	.672
S/P PCI-PTCA	9 (20)	3 (12.5)	.434
S/P valve surgery	5 (11.1)	0	.09
Main indication for CR			
CHF	13 (28.9)	7 (29.2)	.981
PCI-PTCA	18 (40)	12 (50)	.425
Valvo surgory	2 (11.1) 4 (8 0)	1 (4.2)	.330
MI-ACS	9 (20)	9 (37 5)	115
Cardiomyopathy	7 (15.6)	3 (12.5)	.731
Other	5 (11.1)	0	.09
Heart	4 (8.9)	3 (12.5)	.636
transplantation		. ,	

Abbreviations: BMI, body mass index; CABG, coronary artery bypass graft; CHF, chronic heart failure; CR, cardiac rehabilitation; CRP, C-reactive protein; CVA, cerebrovascular accident; DM, diabetes mellitus; HbA_{1c}, glycated hemoglobin; HDL, high-density lipoprotein; HTN, hypertension; LDL, low-density lipoprotein; MI-ACS, myocardial infarction/acute coronary syndrome; PCI-PTCA, percutaneous coronary intervention/percutaneous transluminal coronary angioplasty; PVD, peripheral vascular disease; S/P, status post; TRIG, triglyceride. ^aData presented as mean \pm SD; or n (%); or n, mean \pm SD.

differences between numeric values in the intervention and the control group were evaluated using the Mann-Whitney test or independent sample *t* test, as appropriate.

A P value < .05 was considered statistically significant, and all tests were two-sided. Statistical analyses were performed using the R foundation statistical package, version 4.1.0.

RESULTS

4

A total of 69 participants were recruited: 45 were randomized into the intervention group (42 completed the 6-mo HBCR program) and 24 participants into the control group (21 completed the 6 mo follow-up). Detailed characteristics of the group are summarized in the Table. Most participants were men (81%), and middle-aged (55.9 \pm 12.2 yr). The main indications for CR were percutaneous coronary interventions (41%), HF (30%), and myocardial infarction (25%). A total of 62% of the participants were at moderate or high cardiovascular disease risk level according to national CR guidelines classification. Baseline characteristics of study participants were similar in both study arms.

After 4 mo of intervention, the HBCR group showed significant improvement in \dot{VO}_{2peak} assessed by CPX compared with the control group: from 22.7 \pm 7.0 to 25.4 \pm 7.4 mL/kg/min, RER = 1.05 \pm 0.06 (*P* = .04), and from 26.6 \pm 8.1 to 25.7 \pm 7.9 mL/kg/min, RER = 1.04 \pm 0.08 (*P* = .8), respectively.

Figure 2 presents the change in VO_{2peak} and the O₂pulse baseline and 4 mo later (both P < .001). Except for these variables all other CPX-derived parameters changed similarly in both groups.

ANALYSIS OF THE WORKOUT PERFORMANCE IN THE HBCR GROUP

The aerobic exercise PA (assessed only among patients in the intervention group) across 6 mo is presented in Figure 3. The median aerobic min/wk was 193.2 (110.2, 251.5) min, which is 129% of the goal specified in the program (150 min/wk). The median period in the target HR personalized zone was 112.3 (70.4, 150.2) min (100% of the weekly program goal). The median workout intensity (percentage of the maximum HR achieved during the CPX) was 71 (57-78%) (100% of the goal). The median number of aerobic workouts/wk was 4.9 (2.9, 5.9) and resistance training sessions/wk was 0.65 (0.11, 1.35) (32.5% of the goal: 2 workouts/wk). The median number of daily steps was 9252 (5956, 2212) (116% of the goal: 8000 steps/d). Compared with the intervention group, the control group had significantly fewer average daily steps during the first 6 mo of the study (9145 \pm 3861 vs 4446 \pm 3006; *P* < .001), respectively. The number of mobile application entries/wk throughout the study was also significantly higher in the intervention group (4.9 \pm 1.3 vs 3.4 \pm 1.6) than in the control group (P < .001).

RESULTS OF BLOOD TESTS, QUESTIONNAIRES, AND CLINICAL EVENTS

After 4 mo of intervention, blood tests showed a significant difference between the groups in high-density lipoprotein levels: delta was 2.7 ± 8.3 mg/dL in the intervention group versus -1.8 ± 6.6 mg/dL in the control group as well as



Figure 2. Change in cardiopulmonary exercise testing values from baseline after 4 mo of HBCR intervention. Abbreviation: HBCR, homebased cardiac rehabilitation. This figure is available in color online (www. jcrpjournal.com).



Figure 3. Aerobic performance in the HBCR group across 6 mo. Abbreviation: HBCR, home-based cardiac rehabilitation. This figure is available in color online (www.jcrpjournal.com).

the hemoglobin A1c levels (in diabetics) $-0.12 \pm 0.09\%$ versus $0.25 \pm 0.07\%$ (P < .05), respectively. There was no significant difference in other blood tests performed.

Figure 4 presents the results of the PROMISE 10 survey in both groups for the 6-mo intervention period. During this period, there were no significant differences between the groups in the perception of health. There were also no changes in the stages of behavior change associated with PA. On average, patients were at the preparation and action stage, both at the baseline (3.6 ± 1.2) and at the end of 6 mo (4 ± 1.4) .

CLINICAL EVENTS

During the study, there were no hospitalizations or deaths related to the intervention program or related to PA. Only four participants (two in the control group and two in the HBCR) were hospitalized for a short period (1-4 d) for reasons unrelated to the intervention. The main reasons for dropping out of the HBCR program (three in each of the groups) were patient lack of engagement and unwillingness to cooperate with the care team, as defined by the minimal requirements in the study protocol.

DISCUSSION

This study aimed to examine the effectiveness of the HBCR program in patients unwilling to participate in CBCR, for various nonmedical reasons, including a significant proportion of higher risk patients. Most previous randomized studies in the HBCR field recruited participants willing to undergo CR. The comparison was usually made between HBCR and CBCR.²³ However, it is a known fact that most patients do not complete the prescribed program due to a variety of barriers,^{24,25} despite the well-documented evidence of the effectiveness of CR.²⁶

Recent studies that investigated patients who did not participate in CBCR focused on their willingness to participate in an HBCR program but ill informed to the outcome of such a program compared with the CBCR program.^{27,28} In other studies, the effect of patient motivation on CR achievement has been demonstrated only in CBCR but not in comparison to HBCR. At the same time, a recent study also suggests addressing the population of patients who declined rehabilitation and comparing them to a group that did not receive alternative care.²⁹ This study





indicates the effectiveness of a 6-mo program to improve the \dot{VO}_{2neak} consumption among elderly patients.

Our study aimed to confront the challenge described earlier and recruit specifically those patients who had expressed an unwillingness to participate in CBCR. This population is of great importance as it represents a significant segment of the population, as previous studies have shown. Our aim was thus to test the effectiveness of HBCR in conditions as close to real life as possible—addressing patients who initially decline to participate in CR programs and do not return to the CR centers after program presentation or the first intake meeting.³⁰

The results of the study demonstrate that even unmotivated patients can achieve significant physiological benefits within the framework of a properly constructed, patient-centered HBCR program that adequately addresses the needs of most patients. Almost all of the program goals assigned with the patients were successfully achieved. Program goals attained are consistent with previous studies.^{30,31} Patients have shown good adherence to all aspects of the program, the exception being lower than desired compliance with strength training. It is possible that patients find it difficult to focus simultaneously on adherence with the aerobic and strength goals and it is easier to adhere just to aerobic exercise. Also, the main emphasis of CR programs, perhaps mistakenly,³² is on the importance of aerobic exercise, which could possibly give patients the feeling that strength (resistance) training is not as essential.

Previous studies proved HBCR programs ability to improve the exercise capacity of participants.¹² Some recent studies suggest that HBCR is more economically advantageous than CBCR.³³ Even when considering patients with complex conditions such as HF, HBCR can reduce treatment costs.^{11,34} Additionally, the dropout rates from the HBCR program were minimal³⁵ compared with the previously described rates from hospital-based programs.³⁶

Until recently, most of these HBCR studies were conducted on smaller groups of patients, with a lower risk level. In light of the COVID pandemic, HBCR, such as other telemedicine services, has entered the spotlight of many researchers and has once again proved its advantages.^{18,37} The latest position papers of the cardiology associations suggested expanding the range of potential candidates for HBCR and including more complex patients as well. When no other type of CR is possible, it is clearly better to allow stable patients with any level of risk to be monitored remotely, despite a very low probability of some adverse events, rather than to completely deny them CR.^{2,38}

Another difference between this and previous studies was that our study was prospective, and the duration of the CR program was relatively long. Most previous studies presented relatively short programs of 8-14 wk. However, recent studies have shown that 12 wk is insufficient to significantly change behavior in CR.³⁹ Based on this understanding of behavioral changes in CR patients, we offered a 25-wk program, with an additional 25 wk for prospective monitoring of physical and psychological well-being, metabolic blood tests, and assessment of PA behavior. The fact that almost all patients in the intervention group were able to complete 25 wk of CR confirms our assumption that such a program can be useful for most patients avoiding CBCR.

There were no significant differences between the groups in the perception of health throughout the follow-up period. It is worth noting that despite poor physical health and a mostly high-risk level, our patients started with relatively high scores in the perception of health at baseline.^{40,41} This may explain the fact that there were no significant changes during the study.

STRENGTHS AND LIMITATIONS

The present study is one of the few providing a sufficiently long prospective follow-up of patients at various risk levels that declined participation in institution-based CR. In addition, this study uses novel platforms for the remote monitoring and care coordination of CR patients.

This research was not without limitations. First, the study was limited to one large academic CR center located in the center of Israel. Most of the patients lived in the most remote corners of the country and belonged to various segments of the population, which suggests that the program can be adjusted to the needs of most patients willing to cooperate. In addition, most patients were men, thus the results cannot be generalized to female patients. Lastly, a discrepancy was revealed after the recruitment of patients as there was an initial difference in baseline \dot{VO}_{2peak} between the intervention and control groups; \dot{VO}_{2peak} was lower in the intervention group. Subsequently, as expected, there was a significant improvement in VO_{2peak} in the intervention group, whereas no improvement was observed in the control group. The level of improvement in the cardiorespiratory fitness of the HBCR group in this study is similar to the values previously described.⁴² Since we believe that the randomization was done correctly, this is most likely a random difference, which occurred due to a small sample and, judging by previous studies, does not significantly alter our conclusions.

CONCLUSION

An HBCR program aligned with the patient needs can successfully attain the CR goals, not only among a small number of patients motivated for CR, but also among the vast majority of patients who outright refuse CR. Unmotivated patients, as well as patients with higher risk for cardiovascular events, can participate in HBCR programs. They can significantly improve their functional capacity, psychological health, as well as attain good adherence to the program and achieve guideline-recommended goals.

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