



ORIGINAL ARTICLE

Cardiac telerehabilitation in a middle-income country: analysis of adherence, effectiveness and cost through a randomized clinical trial

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ABSTRACT

BACKGROUND: The benefits of cardiac rehabilitation (CR) are already well established; however, such intervention has been underused, mainly in low- and middle-income countries.

AIM: To compare adherence, effectiveness, and cost of a home CR with the traditional CR (TCR) in a middle-income country (MIC).

DESIGN: Single-blind randomized control trial.

SETTING: A university hospital.

POPULATION: Individuals with coronary disease that were eligible were invited to participate. A randomized sample of 51 individuals was selected, where two participants were not included by not meeting inclusion criteria.

METHODS: The home-CR group participated in health education activities, carried out two supervised exercise sessions, and was instructed to carry out 58 sessions at home. Weekly telephone calls were made. The TCR group held 24 supervised exercise sessions and were instructed to carry out 36 sessions at home.

RESULTS: 49 individuals (42 male, 56.37±10.35years) participated in the study, 23 in the home-CR group and 26 in the TCR group. After the intervention, adherence in the home-CR and TCR groups was 94.18% and 79.08%, respectively, with no significant difference (P=0.191). Both protocols were effective for the other variables, with no differences. The cost per patient for the service was lower in the home-CR (US\$ 59.31) than in the TCR group (US\$ 135.05).

CONCLUSIONS: CR performed at home in an MIC demonstrated similar adherence and effectiveness compared to the TCR program, but with a lower cost for the service. The results corroborate the possibility of using home CR programs, even in MICs, after exercise risk stratification and under remote supervision.

CLINICAL REHABILITATION IMPACT: Home-CR can contribute to overcome participants' barriers with compatible cost. Home-CR is effective in improving functional capacity and risk factors control. Perform risk stratification and remote supervision are essential to offer Home-CR.

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KEY WORDS: Cardiac rehabilitation; Patient compliance; Direct service costs; Home care services.

The burden of cardiovascular diseases (CVD) is growing, particularly in low- and middle-income countries (LMICs). Cardiac rehabilitation (CR) is a multidisciplinary

program designed to prevent and control CVD. The core components of CR have been established by national¹ and international associations.²

Although the benefits of CR are well established,^{1, 2} the availability of CR programs worldwide are insufficient to meet the requirements of all patients,³ specially in LMICs.⁴ It is estimated that CR programs are available in half of countries around the world, concentrated in high-income countries (HICs).³ CR programs are available only in 40% of LMICs, but most of them offer only exercise-based programs, not comprehensive.⁴ Barriers in health systems, CR programs as well as related to health providers and patients, have been identified specifically in LMICs.⁵ Frequently identified barriers are related to difficulties in personal participation. These include the distance of the CR sites, transportation difficulties, and work schedule. Recently, another important barrier to participation in CR programs has occurred with the social isolation imposed by the COVID-19 pandemic, which reinforces the need for alternative models of CR.^{6, 7}

The inclusion of mobile health technologies through cardiac telerehabilitation programs and the possibility of carrying out exercises at home can help to increase participation in CR programs. In HICs, home CR has been considered safe^{8, 9} and contributed to overcoming participation barriers with similar positive effects, as observed in CR delivered in the outpatient settings, in mortality,¹⁰ functional capacity,¹¹⁻¹⁴ quality of life,^{10, 15} control of cardiac risk factors,^{13, 15} and depressive symptoms.¹⁵ Some studies have also shown a lower cost of CR delivered at home.¹⁶

Alternative models of offering CR in LMICs, including home-based programs, have been proposed to reduce the cost and improve the participation rate. CR offered without the requirement of a facility would be the most feasible and improve participation in LMICs. Thus, the objective of this study was to evaluate the adherence, effectiveness, and cost of a home CR (home-CR) program in comparison with the traditional CR (TCR) program in a middle-income country (MIC). It was hypothesized that the home-CR program would have the same adherence and effectiveness as the TCR, but with lower cost.

Materials and methods

This study was conducted according to the Declaration of Helsinki and was approved by the University Ethics Committee (#CAAE 51528615.3.0000.5149). The protocol was registered at clinicaltrials.gov (NCT03605992) and published.¹⁷

All the participants were asked to carefully read and sign an informed consent.

Design

A single-blind and single-site randomized control trial was conducted according to the Consolidated Standards Of Reporting Trials (CONSORT).¹⁸ All volunteers signed the informed consent form and were randomly allocated to two parallel groups: Home-CR and TCR. Adherence and cost were evaluated after 12 weeks of the CR program. Effectiveness related to control of risk factors and health behaviors were evaluated before randomization (pre-CR), after 12 weeks of CR programs (post-CR), and 12 weeks after completion of the CR programs (follow-up).

Setting

The trial was conducted in Brazil, one of the MICs with a high incidence of CVD and high CR demand.^{3, 19} Because of the low availability of CR programs, it is not included in the public CVD line of care,²⁰ a system that is used by 80% of the Brazilian population.²¹ The study was undertaken in a publicly funded CR department of one academic center (Clinical Hospital of UFMG in Belo Horizonte, Minas Gerais, Brazil).

Participants

Volunteers ≥ 18 years, with coronary artery disease, post-myocardial-infarction, or those who had undergone percutaneous coronary intervention or coronary artery bypass graft surgery and had been advised CR or were eligible to enroll were invited to participate. Volunteers presented clinical stability and were stratified by cardiologist as low or moderate risk to physical exercise.²² The exclusion criteria were cardiac events <1 month previously; any comorbid physical or serious mental condition, such as heart failure, or any visual or cognitive condition; that could preclude the participant from participating in the CR programs proposed.

The sample size was determined to the primary outcome (adherence) for an alpha of 5% and a power of 80% in the Fisher exact t test and based on the results of previous study.¹⁴ The sample size should be at least 36 participants per group. After a pilot study with 20 volunteers, it was adjusted to 33 participants. Additional details and the calculation for the secondary outcome are described in the published protocol.¹⁷

Intervention groups

The Home-CR and TCR groups were evaluated with maximal treadmill exercise test, submaximal exercise test (Incremental Shuttle Walk Test) before and after the program, and offer risk factor management (e. g., lipid control, blood

pressure (BP) control). Both programs had a duration of 12-week exercise regimen and systematized education programs.^{23, 24} There is no charge to the volunteers.

The parameters for monitoring the exercise prescription compliance were the same for the Home-CR and TCR groups. The sessions consisted of 5 to 10 min of warm-up, 40 min of aerobic activity with heart rate varying between 60% and 80% heart rate reserve (60%, 70% and 80% heart rate reserve in the first, second and third month, respectively) and 5-10 min cool-down.²⁵

The difference in the exercise plan between groups was the number of supervised sessions delivered and the method of monitoring the exercise intensity. Both groups were instructed to reach the frequency of five times a week, totaling 60 sessions. TCR group (control) attended 24 (40%) supervised sessions at the CR center (3 per week in the first month, 2 per week in the second month and 1 per week in the third month) with exercise intensity monitored by HR monitor (G Pulse®) and based on the Borg Scale, and 36 non-supervised sessions at home (intensity based on the Borg Scale). Home-CR group did two supervised sessions at the CR center monitored by HR monitor and 58 (96.7%) non-supervised sessions at home also accompanied by a HR monitor. The HR monitor used in both groups monitored the HR through a strap attached to the participant's chest and the HR was transmitted to a watch. The home-CR group also received weekly phone calls to check the correct use of the monitor as well as to encourage and check the correct execution of exercises and use of the pedometer (HJA-310-Omron®) as an incentive. Individual information about exercise intensity and the number of sessions during the week were registered manually in a personal diary.

Education program

Both groups received six 14-minute education sessions in person delivered at the CR center and a version of the Cardiac College Manual (available at <https://www.healthuniversity.ca/pt/CardiacCollege/Pages/default.aspx>). Doubts related to physical exercise or symptoms were also clarified during these sessions.

After graduating from the 12-week CR program, participants were instructed to continuously practice physical exercise, controlling the risk factors, and to schedule an evaluation at the CR center, if necessary.

Procedure

Consecutive volunteers were approached between January 2017 and October 2018 by a doctorate student. After

informed consent signed and physician evaluation, volunteers were scheduled for an initial assessment consisting of a functional test and a questionnaire about demographic and clinical characteristics. Additional information related to actual clinical conditions was obtained from the medical file.

After the initial assessment, participants were randomized to one of the research groups. The randomization sequence was generated by a professor not involved in the study using the website www.randomization.com in random blocks of four: for every 4 volunteers, 2 could be randomly allocated to the home-CR group and 2 to the TCR group. To ensure allocation concealment, the principal investigator had the allocation sequence in a password-protected file, and only provided randomization information to the PhD student once it was confirmed that the participant was eligible. Due to the nature of the intervention, participants could not be blinded to treatment allocation.

A physiotherapist blinded to the random allocation was responsible for pre and post-test assessment and data entry. Another physiotherapist was responsible for CR sessions at the center, according to the usual CR program. The home-CR program was controlled by physiotherapy students previously trained by the PhD student and based on a systematized protocol. To avoid missing the scheduled CR sessions at the center, volunteers received reminder calls.

Measures

Primary outcome

Adherence is one of the factors responsible for promoting positive behaviour changes.^{13, 26} It was analysed by the percentage of sessions realized by each group at the end of the intervention. The number of sessions was identified in the TCR and home-CR groups through the physical therapist's record in the face-to-face sessions and the personal diary manually filled in by the participant himself in the home sessions.

Secondary outcomes

Functional capacity was evaluated using the incremental shuttle walk test (ISWT) as the distance walked.²⁷ Morbidity was determined by the number of hospitalizations, complications or the presence of adverse clinical events.

The risk factors evaluated were BP, waist circumference, glucose, and lipids. BP was assessed using a validated 7670-06 mobile stand (Welch Allyn®). Mean systolic and diastolic BP values were recorded, and hypertension was considered where values exceeded 140/90 mmHg

and/or participants were taking a BP-lowering medication. A weight scale and measuring tape were used to assess anthropometrics. Waist circumference was assessed at the superior border of the iliac crest.²⁸ Glycaemia and lipid values were extracted from the clinical charts. Dysglycemia was considered present where fasting blood glucose exceeded 126 mg/dL and/or participants were taking a glucose-lowering medication. Dyslipidemia was considered present where total cholesterol values exceeded 240 mg/dL and/or participants were on a lipid-lowering agent.²⁸

Health behavior: quality of life was evaluated using the *Short Form-36*^{29, 30} with scores calculated for the physical and mental domains³⁰ on a scale of 0 (worst) to 100 (better). Depressive symptoms were identified by the Patient Health Questionnaire-9,³¹ which has a total score varying from 0 to 27³² and indicates major depression if the total score is ≥ 10 . The Duke Activity Status Index Score (DASI)³³ was used to evaluate the self-reported functional capacity. The final score is between 0 (worst) and 58.2 (better).³⁴ Participants' knowledge about cardiac disease was evaluated using the Coronary Artery Disease Education Questionnaire-Short Version,³⁵ a questionnaire with 20 items related to the clinical condition, risk factors, exercise, nutrition, and psychosocial risk; each correct answer was equal to 1 point, with a maximum total of 20 points.

The cost for the service was defined as the expenditure to participate in the CR program. The expenditure for availing the 12 weeks of intervention were considered while analyzing the cost of the CR programs. This analysis considered the sum of the expenses of the procedures delivered for each group of the study based on the median price of health materials during the period and by the payment values considered by the hospital for each health procedure and service. The procedures delivered at the same cost to the two groups were not considered, as the intention was to analyze the difference between the groups.

Statistical analysis

A researcher who did not participate in the other stages performed the statistical analysis. Continuous data are presented as measures of central tendency and dispersion (95% confidence interval) and categorical data as frequency. To analyze the normal distribution of the data, the Shapiro–Wilk test was performed. To compare sociodemographic and clinical characteristics between groups, independent *t*-test or χ^2 Test were performed.

Adherence (in percentage) was compared by independent *t*-test. For comparisons of the other variables between moments (within analysis - pre-CR, post-CR, and follow-

up three months after the end of intervention) and between groups (between analysis - home-CR and TCR), a mixed factorial ANOVA was performed, and an α of 5% was considered significant. The power was calculated for within and between analysis to demonstrate the measure of confidence in detecting the effect, if it exists. Outcome analyses were performed on the basis of intention-to-treat using the last observation carried forward to mitigate bias and as per protocol.

Data availability

The data associated with the paper are not publicly available but are available from the corresponding author on reasonable request.

Results

Participants characteristics

The flow diagram is shown in Figure 1. Of the 51 eligible volunteers, 49 were selected. As shown in Figure 1, among those randomized to one of the CR groups after baseline evaluation, 47 (96%) initiated the program, 23 with TCR, and 26 with home-CR. Five (22%) participants in the TCR

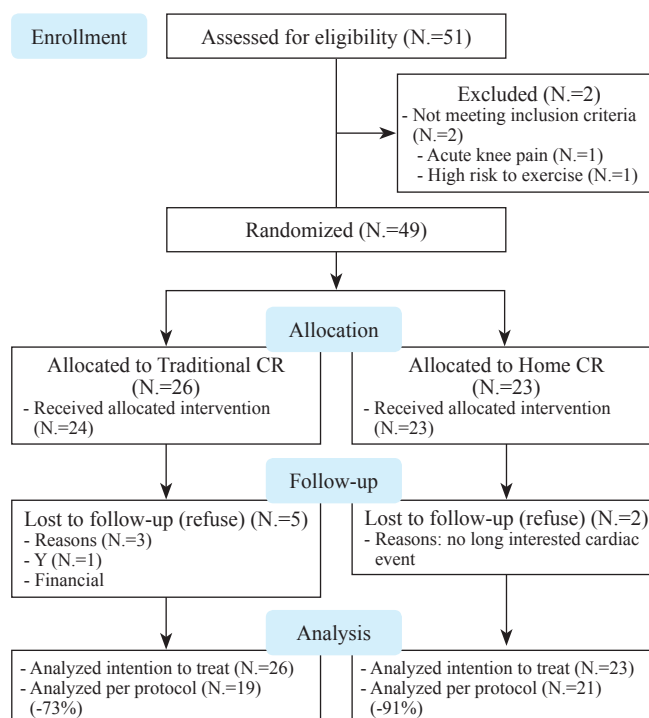


Figure 1.—Consolidated standards of reporting trials flow chart for cardiac rehabilitation.

and two (8%) in the home-CR had valid clinical reasons for missing sessions.

Supplementary Digital Material 1, Supplementary Table I presents the sociodemographic and clinical characteristics of the 49 participants who attended the first day assessment and were randomly assigned to one of the CR programs. Randomization was effective in ensuring equivalence ($P>0.05$) across the groups in most characteristics.

Adherence

The retention rate at the end of the CR program (after 12 weeks) was 91% in the home-CR group and 73% in TCR. Participants in the home-CR group had adhered to 94.18% (95% CI 79.75-108.62) of the 60 sessions initially predicted versus 79.08% (95% CI 61.04-97.12) in TCR; the difference of 15.1% was not significant ($P=0.191$). In these sessions, 82.83% volunteers in the home-CR group achieved the exercise intensity prescribed (95% CI 66,57-99.08) versus 65.76% (95% CI 46.47-85.05) in TCR. The adherence to education activities was similar between groups ($P=0.057$): 81.27±30.50% in the TCR group versus 94.91±17.04% for home-CR. The home-CR participants had 100% adherence to phone calls.

Morbidity

No differences were observed between groups in the number of clinical events (11 in home-CR, including four by cardiac causes; compared to seven in TCR, one cardiac) as well as of hospitalizations (four in home-CR and one in TCR). None of these events was considered to be due to the CR intervention.

Effectiveness: functional capacity, clinical control of risk factors and health behaviors

Supplementary Digital Material 2, Supplementary Table II shows the functional capacity and risk factors pre-CR, post-CR (12 weeks) and follow-up (12 weeks after the end of the program). The functional capacity improved post-CR in both groups and was maintained at follow-up. Risk factors were controlled in the first assessment and no significant changes were observed post-CR or at follow-up in both groups, with no difference between them.

Supplementary Digital Material 3, Supplementary Table III shows an improvement in the quality of life with respect to physical and mental health from pre - to post-CR in both groups, with no significant differences between them. However, the reported physical health decreased at follow-up in both groups ($P>0.05$). The volunteers' per-

ception of functional capacity improved and the patient's knowledge about the disease had the same pattern: improvement post-CR and maintenance at follow-up (Supplementary Table III).

Major depression was not identified on the initial assessment. Both groups showed reduced symptoms of depression post-CR and the results were maintained at follow-up ($P=0.715$ for group comparison).

Cost

As shown in Supplementary Digital Material 4, Supplementary Table IV, the total cost (12 weeks) for the service was approximately 44% lower for offering home-CR compared to TCR.

Discussion

In this randomized control trial, for the first time in Brazil and Latin America, we identified similar adherence and effectiveness, with lower cost, for the delivery of exercise and education through home-CR programs in comparison with traditional CR programs.

Besides the low availability of CR programs in LMICs, patient participation and adherence are also important challenges. Although home-CR volunteers participated in 15.1% more sessions than TCR, it was not statically significant. As we did not achieve the sample size calculated for this outcome, a type II error may have occurred, not finding a significant difference where it exists due to insufficient sample size. However, proving the hypothesis of equality between the home-CR and TCR groups already demonstrates clinical relevance. Other studies conducted in HICs showed higher adherence to home-CR compared to outpatient CR.^{9, 13, 14} The adherence per group in our study was similar to that in a previous study,¹⁴ wherein it was 94% in home-CR and 68% in traditional-CR. It could be related to the capacity to improve volunteers' participation as it is possible to have flexibility to adapt the time dedicated to CR according and reduce the challenges related to transport.³⁶ Moreover, barriers to participating in CR have been reported worldwide, including other LMICs and in Brazil, and frequently worries related to work, financial situation, and family issues were found.^{37, 38} Home-CR could contribute to overcoming these barriers. The high adherence of both groups to education activities also reinforces the viability of delivering home-CR when it is more appropriate because of different conditions, such as living in rural areas, transport issues, family demands, and recent situations like the COVID-19 pandemic.

Considering the clinical events identified during the study period, only one patient in the home-CR had to be hospitalized because of restenosis. This complication, independent of the CR model, can be expected after angioplasty, as it is more common between three to six months after the procedure.³⁹ Furthermore, in a systematic review with meta-analysis, it was observed that the chances of having events during exercise at home were similar to those during exercise in a CR center when the risk stratification, adequate evaluation as well as individual exercise intensity are attended.⁴⁰ Therefore, it is essential to perform risk stratification to determine if an individual can receive the CR program at home or if it is necessary to have direct supervision.

It is also important to note that in the risk stratification,²² one of the aspects evaluated is the capability of the patient to monitor and respect the exercise intensity prescribed as well as observe symptoms and promptly report them to the health staff. In the present study, we chose to give heart-rate monitors to monitor volunteers at home. A heart-rate monitor is a low-cost and easy-to-use device. Although HR monitors with electrodes are more accurate for monitoring during moderate to intensive training,⁴¹ the monitor with a strap attached to the participant's chest allows usability in clinical practice. A strength of our study was the use of the pedometer, which ensured validity. Moreover, telephone calls allowed volunteers to improve safety and promote auto-efficacy during exercise.¹³ The home-CR model does not imply that volunteers will be unsupervised; rather it implies that the patient will be supervised remotely.²²

As observed in previous studies, both CR programs are effective in improving the functional capacity^{14, 42} and contribute to maintaining control of risk factors^{15, 42} and health behavior.^{10-12, 14, 15} Recently because of the COVID-19 pandemic, the demand for home-CR services and programs has increased, showing that it is necessary to further explore such programs.^{6, 7}

The low cost of delivering home-CR reinforces that it is viable to offer such programs in LMICs as a way to overcome barriers to patients' participation in these programs, as well as to improve the availability of slots. Previous studies have also identified low cost of home-CR;^{11, 16} however, some studies show similar⁴³ or even higher costs.⁴⁴ This discrepancy could be related to the different models of intervention, number, type, and price of health professionals' hours and equipment, considering that the characteristics of CR worldwide have variations.

To ensure the benefits of CR, it is necessary to continue exercising and changing habits to maintain the long-term effects. Other components besides aerobic exercise are

usually included as the short component of CR. The protocol of study does not carry out strength training due to the difficulty of implementing and guaranteeing the performance of this type of exercise by the home-CR group. Therefore, we only performed aerobic exercise prescription to ensure the internal validity of the study. The performance of strength training without guaranteeing equality between the groups could be a bias for the analysis of the results and threaten the internal validity of the study.⁴⁵

Limitations of the study

Limitations must be considered when interpreting the results of this study. Only volunteers with low and moderate risk for exercise were considered. Participants were selected from only one CR center of one LMIC. A type II error should be considered as the sample size for the primary outcome was not achieved. Manual recording of information on exercise intensity and number of sessions performed by home-CR participants in a diary. Finally, it is not possible to identify which technique was more effective in home-CR, as phone calls, pedometers, and heart-rate monitors were used simultaneously.

Conclusions

The home-CR program, based on physical exercise and patient education, showed similar adherence and effectiveness as the TCR program, but with low cost for the service in one MIC. The model of home-CR used in this study could be viable to be offered in other countries, since eligible volunteers were identified based on previous assessment for risk stratification as well as monitored remotely.

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