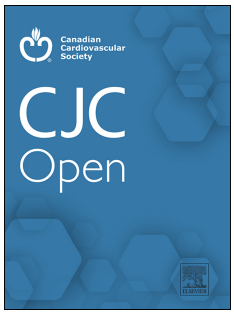

Effectiveness of cardiac rehabilitation with mHealth through smartphone functionalities: a systematic review protocol.

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Effectiveness of cardiac rehabilitation with mHealth through smartphone functionalities: a systematic review protocol.

Short title: Home-based cardiac rehabilitation with mHealth use.

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Brief Summary: Patients with cardiovascular diseases requires support to manage symptoms and improve prognosis. Cardiac rehabilitation is part of the optimized clinical treatment of these patients. Smartphones are considered mHealth technology and have the potential to be used as an interface for home-based cardiac rehabilitation. This systematic review aims to examine these modalities and identify the most effective for improving exercise capacity, quality of life and patient compliance.

Declarations of interest: none

ABSTRACT

Background: Cardiovascular diseases are the leading cause of mortality worldwide, requiring support to manage symptoms and improve prognosis. Home-based cardiac rehabilitation is a realistic resource for this purpose; however, it requires patient's self-management skills in order to change behaviors. Smartphones are considered mHealth technology and have the potential to provide modalities for cardiac rehabilitation. This systematic review aims to examine these modalities and identify the most effective for improving exercise capacity, quality of life, and patient compliance.

Methods: Randomized controlled trials (1994 to 2022) performed with adults with coronary artery disease (post-myocardial infarction, angina, post-coronary artery bypass graft surgery) or heart failure eligible for home-based cardiac rehabilitation (mHealth) will be selected. Studies published in English, Spanish, or Portuguese language comparing rehabilitation-specific mobile apps or smartphone-based features with conventional cardiac rehabilitation will be included. Searches will be conducted in MEDLINE, Cochrane Central Register of Controlled Trials, EMBASE, LILACS, PEDro, grey literature, and ongoing or recently completed studies. Data and risk of bias will be accessed, and, if appropriate, a meta-analysis will be carried out.

Ethics and dissemination: No ethical considerations are necessary, as the results of the systematic review will be based on previously published studies. The dissemination plan of this study aims to encourage health professionals and government policies, through results disclosure in conferences and manuscripts publication.

Keywords: Telerehabilitation. Cardiac rehabilitation. Mobile applications. Heart Disorders.

Systematic review registration: registered in PROSPERO - CRD42021272524.

Word count: 3789 words**.**

BACKGROUND

According to the World Health Organization, cardiovascular diseases (CVD) are the leading global cause of death.[1] Failure to value health promotion and primary prevention results in risk factors and consequent development of CVD.[2,3] Chronicity of CVD increases morbidity rates, especially in low- and middle-income countries.[4] Due to CVD, many people live with disability, incapacity, difficulty in performing activities of daily living, reduced quality of life (QoL) and increased need for support to manage symptoms; thus, prognoses worsens.[5]

Cardiac rehabilitation (CR) programs are important strategies to manage CVD risk factors, modify behavior, support symptom relief, improve exercise capacity and quality of life, reduce disability, hospitalization and mortality. [6,7] According to clinical guidelines,[3,6] CR programs are provided in specialized centers by a multidisciplinary team and performed under supervision to allow adequate prescription, monitoring, exercise volume, and emergency support.

However, as demand overcomes program capacity, only a fraction of 5 to 30% of patients eligible for CR programs is referred to specialized centers.[1,3] Patient-related factors (e.g., logistics, emotional aspects, and difficulties in incorporating physical training into daily life) are also barriers to adherence and completion of inpatient and outpatient CR programs.[8] Moreover, after a successful outpatient CR program, lifestyle behavioral changes are usually not maintained in the long term without supervision; therefore, the achieved physical activity levels decreases. Unsuccessful self-management decreases healthy lifestyle achieved in CR of specialized centers. Thus, many patients fail to achieve secondary CVD prevention related to risk of coronary artery disease.[9]

Barriers to patient participation in conventional CR programs increased the need for innovative telerehabilitation models to provide essential components and motivational and educational contributions to CVD patients.[10] According to a Cochrane systematic review by Taylor *et al.*,[11] remote CR changed modifiable risk factors and guaranteed similar levels of safety, mortality and cardiac events reduction and exercise capacity as compared to those who physically exercised inside specialized centers. Furthermore, remotely supervised home-based exercise programs are effective if patient autonomy is well empowered in the face of secondary prevention, ensuring maintenance of behavioral changes and self-management skills to monitor progress and provide objective feedback.[9, 12]

Mobile technological resources in health care (mHealth) enables remotely supervised home-based exercise programs. Smartphones provided advancements in mHealth in the last decade and have the potential to revolutionize treatment, secondary prevention of CVD and different intervention delivery modalities.[13,14] Smartphone functionalities offer the possibility to educate and monitor patients either through specific apps for self-managing CVDs or other basic functions (e.g., phone calls, video streaming, video conferencing, e-mail, internet, high-quality images, short message service [SMS], multimedia messaging service [MMS], interactive voice response [IVR], and global positioning system [GPS]).[15]

Telerehabilitation is effective, safe and is accepted by patients and caregivers.[10] Cochrane systematic review[5] concluded that home-based mHealth CR is equally effective than performed in a specialized center; however, authors did not demonstrate the most effective smartphone-based mHealth strategy. Two recent systematic reviews[16,17] evaluated the effectiveness of mHealth for remote-CR programs and emphasized differences between smartphone-based mHealth interventions and traditional CR in specialized centers. Authors demonstrated a significant increase in patient adherence to remote-CR using mHealth and concluded that apps might improve CR participation. However, this technology is still recent, and the effectiveness of programs needs to be verified in the long term by high-quality scientific studies.

Evidence is limited and rigorous high-quality studies on efficacy and effectiveness of mHealth initiatives are lacking[18]. Due to difficulty in understanding the effects of intervention strategies, a systematic review is needed to identify which modalities of smartphone functionality effectively improves exercise capacity and health-related QoL. Moreover, whether basic functions would be sufficient or a more advanced technology would be needed. Thus, to provide a more rational application of technology in home-based CR, our systematic review aimed to verify whether smartphone-based home CR programs using specific apps effectively improves exercise capacity, health-related QoL and patient adherence than the model offered through other smartphone functionalities.

METHODS AND ANALYSIS

The protocol was performed following the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) guideline,[18] which will also guide the systematic review.

ELIGIBILITY CRITERIA

Randomized clinical trials (RCT) full texts published in English, Spanish, or Portuguese language between 1994 to 2022 will be considered eligible according to PICOT model.

Participants

We will include studies conducted with adults (> 18 years of age), of both genders with coronary artery disease (post-myocardial infarction, angina, post-coronary artery bypass graft surgery) or heart failure from various causes or both who were eligible for home-based CR. Studies with participants in primary prevention and those who performed CR previously will be excluded.

Intervention

We will consider studies with smartphone-based home CR with mHealth supervised by professionals using one of the following functionalities:

a) Modality 1 (mod 1) - advanced, with mobile apps developed specifically for CR;

b) Modality 2 (mod 2) - basic, with phone calls, voice recordings, video streaming, videoconferences, e-mail, internet access, high-quality images, SMS, MMS, IVR, and GPS.

Mod 1 will include trials in which the app use occurs without full automation. Mod 2 can be guided by human intervention and associated with other mHealth technologies, such as wearable sensors (e.g., wearables, GPS, accelerometer, gyroscopes, and portable electrocardiogram), web portals not linked to a smartphone or self-measured blood pressure (SMBP).

Comparison

We will consider clinical trials in which usual care was offered to the control group, whether home-based or traditionally in specialized centers. However, usual care may (or may not) be associated with mHealth tools. Regarding mod 2, we will exclude studies offering smartphone-based technology for CR to the control group.

CR outcomes offered by these two mHealth modalities will be compared.

Outcomes

Primary outcomes are self-management and disease perception. Effect sizes will be related to functional capacity, health-related QoL and CR program adherence.

The following variables will be used as primary outcomes: functional capacity assessed by peak oxygen consumption (VO_2peak) during cardiopulmonary exercise test (CPET) and walking distance in the six-minute walk test (6MWT), health-related QoL assessed by generic tools (scales/questionnaires) or tools related to heart failure and patient adherence to CR program. Values obtained after home-based CR will be compared between smartphone-based mHealth modalities and the modality providing to be the most effective for behavioral change will be identified.

Secondary outcomes are related to smartphone-based mHealth technology; both efficacy and effectiveness will be verified using mHealth Evidence Reporting and Assessment (mERA) instrument.[19] Sixteen pre-established items will assess content, context and technical characteristics of these mobile interventions. Mortality, cardiac event rates and modifiable risk factors for coronary disease (e.g., lipids, total cholesterol, low-density lipoprotein, high-density lipoprotein, triglycerides, blood pressure and smoking behavior) will also be used as secondary outcomes.

If studies do not report any of above-mentioned outcomes we may consider other outcomes. For this, we will classify these new outcomes as relevant or not and discuss further inclusion. We will contact authors or sponsors to verify key study characteristics and obtain missing quantitative data when possible.

Study Type

RCTs with at least eight weeks of intervention will be included.

DATA SOURCES

Literature search will be performed using the following electronic databases: MEDLINE (Ovid SP; 1946 up to present date), Cochrane Central Register of Controlled Trials (CENTRAL, via Cochrane Register of Studies, from inception up to present date), EMBASE (Ovid SP; 1974 up to present date), LILACS (VHL provider) and PEDro. Relevant references from included studies will be identified manually (Pearl Growing) and searches will also be conducted in grey literature. Ongoing or recently completed trials will be identified via US National Institutes of Health Ongoing Trials Register (www.clinicaltrials.gov) and World Health Organization International Clinical Trials Registry Platform (www.who.int/clinical-trials-registry-platform). A more specific manual search will be performed in case the search identifies eligible study protocols. Authors may be contacted whenever needed to retrieve additional information.

SEARCH STRATEGY

Electronic search strategy was developed considering the Peer Review of Electronic Search Strategies (PRESS)[20] and descriptors adapted from Medical Subject Headings (MeSH). Filters will be used to search RCT studies dated from 1994 (beginning of the commercialization of smartphone technology) up to present date. Preliminary search strategy (Medline and Cochrane Central Register of Controlled Trials) of this systematic review is described in appendices 1 and 2.

STUDY SELECTION

Potentially eligible references will be stored and organized into specific groups using Mendeley software. References duplicated, overlapping or complementary to a study will be merged to the main reference to avoid inconsistencies in data extraction.

Study selection will be performed independently by MCP and PFC. Preprints and full-texts of potentially relevant articles will be examined and reasons for exclusions will be recorded. Study selection process will be reported using PRISMA flowchart.[21]

DATA EXTRACTION

Two blinded reviewers (MP and PFC) will perform data extraction and analysis of eligible studies using an Excel spreadsheet. PRISMA guidelines and Cochrane Handbook for Systematic Reviews of Interventions[22] will guide data extraction, if necessary, authors will be contacted to retrieve additional information. Discrepancies or disagreements will be discussed and a third reviewer (AAC) may be involved to assist with the decision.

Data will be grouped (mod 1 and mod 2) and extracted according to study characteristics: author, year of publication, country, clinical characteristics of the patient, number of centers involved, sample size, mean age, sex, follow-up time, losses, intervention, comparison, primary and secondary outcomes.

RISK OF BIAS

Critical evaluation of each clinical trial will be performed by two reviewers (MP and PFC) using the Cochrane Collaboration tool for assessing the risk of bias (RoB 2 CRT)[23] (randomization, participant identification or recruitment, deviations from intended interventions, missing outcome data, measurement of the outcome, selection of the reported result). Risk of bias for each domain will be classified as low, medium, or high. Tendency to deviate, or not, from truth will affect the conclusive synthesis of this review, indicating the need for new studies or sufficient quality of evidence to ensure reliability. Disagreements will be solved through discussion or with a third author (AAC).

DATA SYNTHESIS

Dichotomous outcomes will be presented as risk ratio (RR) and corresponding 95% confidence interval (CI), while continuous outcomes by mean difference (MD) or standardized mean difference (SMD) with respective 95% CIs.

A meta-analysis will be performed in the case of similar populations, interventions, and underlying clinical questions. Heterogeneity between studies will be measured by prediction interval.[24] Possible causes for substantial heterogeneity will be performed.

METABIAS (ES)

Identification of study protocols and comparison with published trials will help minimize selective reporting bias. If the protocol is unavailable, published outcomes of each trial will be compared using their methodology. World Health Organization International Clinical Trials Registry Platform and other clinical trial registry platforms will also be consulted if needed.

Publication bias can be considered when effects of small studies are different from large studies. In this case, funnel plots may be used (if more than ten studies are identified) to present the effects of small studies and observe if clinical trials with larger sample sizes and statistically non-significant data were not published.

CUMULATIVE EVIDENCE CONFIDENCE

Grading of Recommendations Assessment, Development and Evaluation (GRADE)[25] will be used to critically evaluate certainty of evidence as high, moderate, low, or very low. Thus, quality of evidence will be assessed using GRADE domains: risk of bias, imprecision, indirectness of evidence, inconsistency, and publication bias. Poor quality studies will not be excluded.

DISCUSSION

The potential of smartphones is evidenced as being able to revolutionize CR,[13,14] so recent systematic reviews have included studies in which home-based CR with App use resulted in greater patient participation and proved to be a better form of intervention delivery , compared to traditional CR in specialized centers.[16,17] Although there are previous analyzes in the literature using mHealth technology in the context of home-based CR and CR in specialized centers, there is no specific analysis for interventions generated by the modalities (basic or advanced) of smartphone functionalities.[5] The literature review of this systematic review will suggest the best way to use mobile phone technology in the scope of the provision of rehabilitation services for patients with chronic heart disease.

ETHICS AND DISSEMINATION

No ethical considerations are necessary, as the results of the systematic review will be based on previously published studies. The dissemination plan of this study aims to encourage health professionals and government policies, through results disclosure in conferences and manuscripts publication.

AMENDMENT PROTOCOL

Additions, removals, or reprioritizations after protocol will be reported as amendments. In this case, a summary table with descriptions, dates, and reasons for changes will be incorporated.

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ABBREVIATIONS

CVD: cardiovascular diseases; QoL: quality of life; CR: cardiac rehabilitation; SMS: Short Message Service; MMS: Multimedia Messaging Service; IVR: Interactive Voice Response; GPS: Global Positioning System; Apps: mobile applications; PROSPERO: International Prospective Register of Systematic Reviews; mod 1: modality 1; mod 2: modality 2; mHealth: mobile health technology resources; SMBP: self-measured blood pressure; RCTs: randomized controlled trials; PRESS: Peer Review of Electronic Search Strategies; MeSH: Medical Subject Headings; VO_2peak: peak oxygen consumption; CPET: cardiopulmonary exercise test; 6MWT: six-minute walk test; RoB 2 CRT: Cochrane Collaboration tool for assessing the risk of bias; RR: risk ratio; CI: confidence interval; MD: mean difference; SMD: standardized mean difference; GRADE: Grading of Recommendations Assessment, Development, and Evaluation.

AUTHORS CONTRIBUTIONS

MCP, PFC, ICSO, MNM and WBS drafted the review protocol, designed search strategy, and developed selection criteria, risk of bias assessment, and criteria for data extraction. MCP and PFC will perform data acquisition and quality assessment. AAMC may be involved to assist with decisions when a third opinion is needed. GFS, AAMC, and ACCM read, provided feedback, approved the final manuscript, and will perform statistical analyses. All authors approved the final version and authorized publication of this protocol, contributed to conception and design of the review, and will be involved in data analysis and interpretation of results.

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