

Modello di riabilitazione cardiologica teleguidata durante pandemia da COVID-19

A novel @home cardiac rehabilitation/secondary prevention program during the COVID-19 outbreak in Italy

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ABSTRACT

Introduzione. La pandemia COVID-19 ha indotto molti governi a promuovere il lockdown nazionale. Sebbene la quarantena sia considerata tra le migliori strategie per interrompere la diffusione del SARS-CoV-2, per certi aspetti questo improvviso cambiamento dello stile di vita rappresenta un fattore di rischio per la salute fisica e mentale della popolazione generale e dei pazienti cardiopatici. L'attività fisica è la componente principale dei comuni programmi di riabilitazione cardiologica, che purtroppo sono stati interrotti bruscamente.

Scopo. Per contrastare l'inattività fisica durante l'epidemia di COVID-19 proponiamo un programma di riabilitazione cardiologica domiciliare teleguidato "the home-bAsed physiCal acTivity Intervention during cOvid-19 quaraNtine (ACTION) study", testandone la fattibilità.

Metodi e risultati. ACTION è uno studio osservazionale condotto su pazienti ambulatoriali che seguono un programma di riabilitazione cardiologica basato sull'esercizio fisico e bruscamente interrotto a causa del lockdown. Ai pazienti viene consigliato un programma composto da esercizi aerobici associati ad una selezione di esercizi di forza ed equilibrio, fattibili a domicilio. I pazienti vengono istruiti mediante l'invio di video e immagini tutorial con i dettagli degli allenamenti da seguire. Alcuni pazienti selezionati possono essere seguiti da un operatore del Centro di Riabilitazione durante le sessioni domiciliari di allenamento tramite connessione video, utilizzando le più comuni applicazioni per smartphone.

Conclusioni. Lo studio ACTION potrebbe fornire risultati utili per la prescrizione teleguidata sicura ed efficace di programmi di esercizio fisico a pazienti ambulatoriali con malattie cardiovascolari, prevenendo nel contempo che l'epidemia di COVID-19 generi conseguenze negative per la salute a causa della cessazione brusca dell'attività fisica. I risultati dello studio ACTION possono essere utili anche dopo la fine dell'epidemia di COVID-19 per i pazienti che non possono partecipare ai tradizionali programmi di riabilitazione cardiologica per difficoltà a raggiungere il Centro di Riabilitazione o ad uscire di casa.

Parole chiave: Riabilitazione cardiologica; COVID-19.

Background. *The COVID-19 pandemic has induced many governments to promote national lockdowns. Despite a period of quarantine is the best option and recommendation to stop the rapid spread of infections, this may have collateral effects on other dimensions of the isolated patients' physical and mental health. Physical activity is the major component of cardiac rehabilitation programs that have been abruptly discontinued.*

Aims. *To counteract physical inactivity during the COVID-19 outbreak we propose an home cardiac rehabilitation program un-*

der telemonitoring guidance, the home-based physical activity Intervention during COVID-19 quarantine (ACTION) study, testing its feasibility.

Methods and results. ACTION is an observational study in cardiac outpatients referred to an exercise-based cardiac rehabilitation program. A program consisting of aerobic recommendations combined with a selection of strength and balance exercises is recommended. Video tutorials providing details of the workouts will be sent to patients. Selected patients can be followed during the home-sessions via video connection using current smartphone applications.

Conclusions. The ACTION study could provide applicable results for safe and effective exercise therapy in outpatients with cardiovascular disease, while preventing the COVID-19 outbreak from generating adverse health consequences due to acute cessation of physical activity. Findings from the ACTION study can also be useful after the end of COVID-19 outbreak for patients who cannot participate in traditional center- or home-based cardiac rehabilitation programs.

Key words: Cardiac rehabilitation; COVID-19.

BACKGROUND

Cardiac Rehabilitation/Secondary Prevention (CR/SP) is considered a class IA recommendation by current international guidelines^{1,2}. CR/SP is a multidisciplinary intervention consisting of optimization of medical therapy and healthy lifestyle behaviour change. Physical activity (PA) is a major component of CR/SP. The health benefits of exercise and PA are well known, and PA should be promoted in any way^{3,4}.

In an attempt to hinder the spread of the novel Severe Acute Respiratory Syndrome Coronavirus 2 pandemic (COVID-19), many governments have instituted national lockdowns. Due to mandatory social distancing, the dangerous effects of increased physical inactivity should be considered⁵. Long-term adherence to a healthy active lifestyle is a problem in "normal" situations and is even more relevant during the ongoing pandemic. The runway nature of the COVID-19 outbreak moves resources and personnel from usual clinical services^{6,7}. Under these circumstances, the CR/SP centres are unable to maintain CR/SP programs for all eligible patients.

Although social distancing is considered among the best strategies for hindering the COVID-19 outbreak, this sudden lifestyle change has unintended consequences including increased emotional stress and anxiety, smoking, excess food intake, and alcohol abuse⁸. In addition, inactivity is associated with higher risk of several non-communicable chronic conditions such as diabetes, cancer, cardiovascular disease and osteoporosis. On the other hand, there

is general agreement regarding keeping fit during the quarantine⁹. Therefore, we aim to test the feasibility of the home-based physical activity Intervention during COVID-19 quarantine (ACTION) study to address this issue. The study sample involves a group of outpatients already included in an exercise-based CR/SP programme, while because of public health measures it is mandatory to remain confined to one's home.

METHODS

Study population

ACTION is an observational study in cardiac outpatients referred by their primary care physician or cardiologist to an exercise-based CR/SP program at the Centre for Sport and Exercise Science at the University of Ferrara, and the Public Health Department of AUSL Ferrara, Italy. Participants are clinically stable and asymptomatic at rest and during light-to-moderate PA. A detailed program outline has been previously published¹⁰. The study was approved by the Ethics Committee of the University of Ferrara, no. 22-13. All participants give written informed consent.

Physical Activity Intervention

The objective of the program is to counteract physical inactivity during the COVID-19 outbreak. A program consisting of moderate at-home walking to be performed in bouts of at least 10

minutes¹, on at least three and preferably seven days of the week, is recommended. Moderate intensity is perceptually regulated at 11-13/20 on the RPE Borg scale^{1,2}. As an alternative to indoor walking, patients were encouraged to perform similar sessions of indoor cycling. These aerobic recommendations are incorporated using a selection of strength and balance exercises based on the Otago Exercise Program. In this way, the exercise prescription parallels current international guidelines^{1,2}. Since patients are already included in the

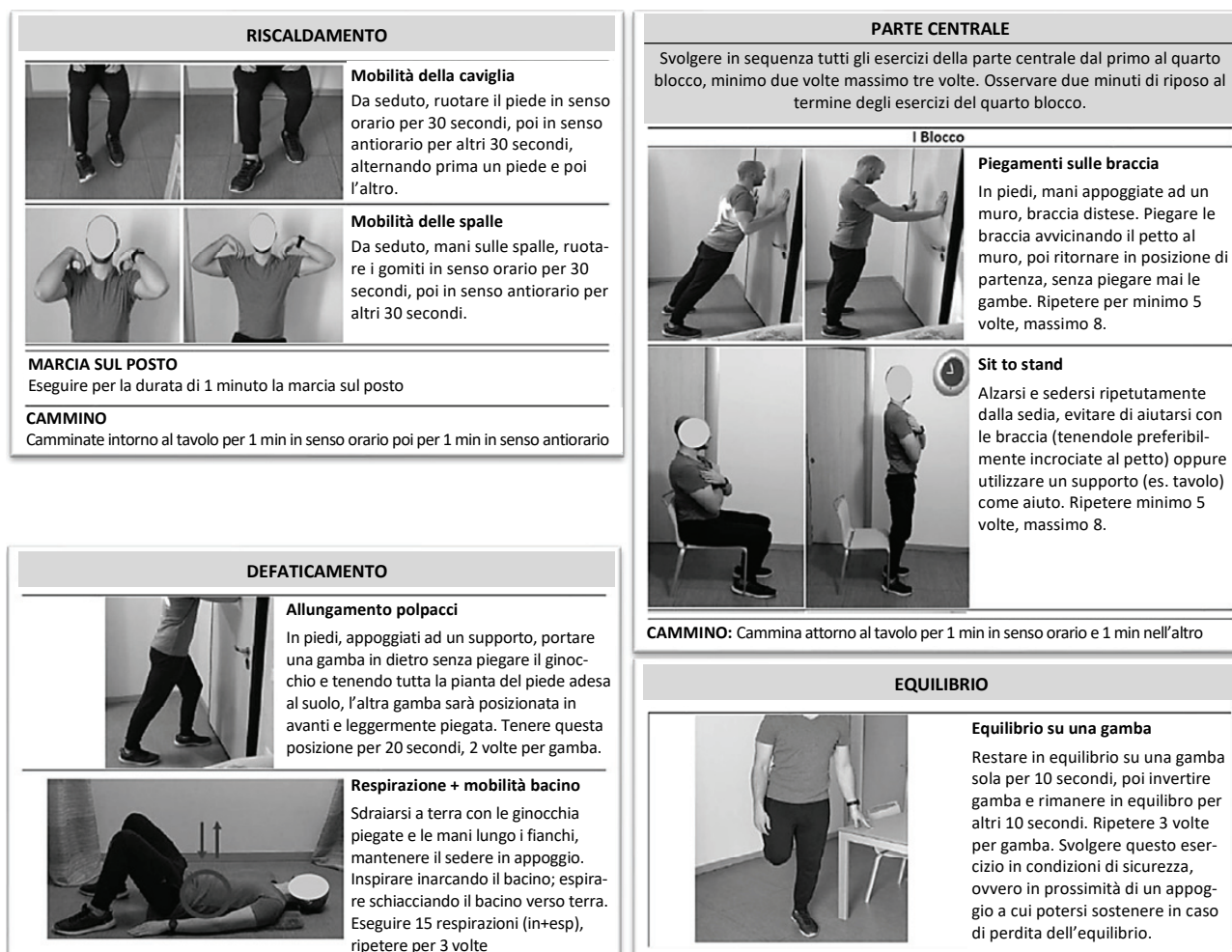
programme, they are familiar with the essentials of such prescription.

Patient educational materials

Three video tutorials will be sent to each patient. In these videos, a physician and a nurse will provide details of the workouts. The tutorials will be sent to patients through smartphone applications or via e-mail, along with infographics of the recommended workouts (**Figure 1**).

Figure 1

This infographic concisely summarizes a recommended workout. Only a few exercises for each training phase are represented.



Telemonitoring guidance and adherence

The intervention includes bimonthly booster phone calls to promote a physically active lifestyle up to the end of restrictions due to the COVID-19 outbreak. History of fever, symptoms, changes in exercise tolerance, adherence to treatment, and assessment of weekly PA are assessed during each call. The participants will have the opportunity to receive a bracelet with a QR code to record PA for later analysis. The use of tools capable of checking vital parameters during training, such as heart rate monitors and pulse oximeters, is encouraged. Patients who have been enrolled for less than 3 months and/or who had interrupted the initial centre-based supervised phase of the program can be followed during the home-sessions via video connection using current smartphone applications.

Study endpoint

The primary endpoint is weekly PA. Current international guidelines recommend at least 150 minutes per week of moderate-intensity PA. Self-reported PA is determined by the 7-Day Physical Activity Recall Questionnaire. For each activity, a metabolic equivalent (MET) score is assigned. The volume of the reported PA will be expressed as "MET-h/week", determined by multiplying the MET score per activity by the time spent in hours per week in such activity. The recommended target is 7.5 MET/h/week. The secondary endpoint is quality of life determined by the SF-12 questionnaire administered monthly during the scheduled telephone calls. Study endpoints will be collected monthly in 100 patients up to return to normalcy.

Data collection and analysis

Clinical characteristics of participants, laboratory

data, and medical treatments are collected and managed by members of the program staff. Continuous variables will be tested for normal distribution with the Kolmogorov-Smirnov test. Normally distributed variables will be presented as mean \pm SD and will be analyzed by t-test and ANOVA. Non-normally distributed variables will be presented as median value [interquartile range], and the Mann-Whitney U test will be used. Statistical significance is defined as $p < 0.05$. All analyses will be performed with MedCalc 19.2 software (Ostende, Belgium).

DISCUSSION

The ACTION study is designed to evaluate the benefits of an individualized, teleguided PA intervention in outpatients with cardiovascular disease. The major strengths of the study include: 1) a population reflecting the real-life scenario during the Covid-19 outbreak; 2) the inclusion of high-risk patients; and 3) the evaluation of a simple and low-cost intervention. Although the COVID-19 outbreak has disrupted conventional CR/SP services, it also represents an opportunity to implement innovative approaches. Interventions including telehealth support and prescription of individualized PA have been advocated⁵, particularly in patients with cardiovascular disease that are highly prevalent among those hospitalized with laboratory-confirmed COVID-19. The ACTION study could provide applicable results for safe and effective exercise therapy, while preventing the COVID-19 outbreak from generating adverse health consequences due to acute cessation of physical activity. Findings from the ACTION study can also be useful after the end of COVID-19 outbreak for patients who cannot participate in traditional center- or home-based CR/SP programs.

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