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Efficacy, efficiency and safety of a cardiac telerehabilitation programme using wearable sensors in patients with coronary heart disease: the TELEWEAR-CR study protocol

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ABSTRACT

Introduction Exercise-based cardiac rehabilitation (CR) is a beneficial tool for the secondary prevention of cardiovascular diseases with, however, low participation rates. Telerehabilitation, intergrading mobile technologies and wireless sensors may advance the cardiac patients' adherence. This study will investigate the efficacy, efficiency, safety and cost-effectiveness of a telerehabilitation programme based on objective exercise telemonitoring and evaluation of cardiorespiratory fitness.

Methods and analysis A supervised, parallel-group, single-blind randomised controlled trial will be conducted. A total of 124 patients with coronary disease will be randomised in a 1:1 ratio into two groups: intervention telerehabilitation group (TELE-CR) (n=62) and control centre-based cardiac rehabilitation group (CB-CR) (n=62). Participants will receive a 12-week exercise-based rehabilitation programme, remotely monitored for the TELE-CR group and standard supervised for the CB-CR group. All participants will perform aerobic training at 70% of their maximal heart rate, as obtained from cardiopulmonary exercise testing (CPET) for 20 min plus 20 min for strengthening and balance training, three times per week. The primary outcomes will be the assessment of cardiorespiratory fitness, expressed as peak oxygen uptake assessed by the CPET test and the 6 min walk test. Secondary outcomes will be the physical activity, the safety of the exercise intervention (number of adverse events that may occur during the exercise), the quality of life, the training adherence, the anxiety and depression levels, the nicotine dependence and cost-effectiveness. Assessments will be held at baseline, end of intervention (12 weeks) and follow-up (36 weeks).

Ethics and dissemination The study protocol has been reviewed and approved by the Ethics Committee of the University of Thessaly (1108/1-12-2021) and by the Ethics Committee of the General University Hospital of Larissa (3780/31-01-2022). The results of this study will be disseminated through manuscript publications and conference presentations.

Trial registration number NCT05019157.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Telerehabilitation as an alternative tool to contemporary centre/community-based cardiac rehabilitation.
⇒ Intergrading real-time supervision and group-based exercise sessions in cardiac telerehabilitation.
⇒ Objective monitoring and evaluation of physical activity and exercise intensity in cardiac rehabilitation interventions.
⇒ Inability, by study design, to blind participants to treatment allocation.
⇒ Possible selection bias, since only low and moderate cardiac risk patients will be recruited.

INTRODUCTION

Cardiovascular diseases (CVDs) are the leading cause of morbidity and premature mortality globally.[1–5] Coronary artery diseases (CAD) account for the largest proportion of CVD mortality.[6] A systematic review by the Global Burden of Disease (GBD) reveals an increase of 11.8% in the mortality rates due to ischaemic CVDs in Greece[6] with cardiac risk factors[7] being very common among Greek patients and without signs of future decline.[8] The increased rates of CVDs put additional pressure on the healthcare systems, especially under the ongoing austerity climate across Europe.

Cardiac rehabilitation (CR) can play a key role as a multidisciplinary secondary intervention aiming to the reduction of CVDs' risk factors, the adoption of healthy lifestyle behaviours and the minimisation of disability among patients with CVD.[9] Recent guidelines on CVD prevention recommend a multifaceted approach addressing exercise training, dietary counselling, smoking cessation, risk factor modification and psychosocial support.[10–12] A number of meta-analyses confirm the effectiveness

of exercise training in reducing cardiovascular mortality, morbidity, rehospitalisation rates,[13 14] physical inactivity and all CVD risk factors including blood pressure, blood lipid profile, glucose metabolism and weight status.[15 16] Despite global recommendations, patients' participation in CR programmes is low mainly due to insufficient medical referral, travel distance, low self-efficacy, perceived body image and lack of time.[17–19] Moreover, during the COVID-19 pandemic, new barriers have arisen, such as the suspension of centre-based CR and in-person sessions, travelling and circulation restrictions.[20 21] Thus, the need to avoid the downgrading of CR is imperative.[22]

Rapid development in information and communication technologies may help overcome the barriers to CR.[23–25] Telerehabilitation is proposed as a feasible,[26 27] safe and cost-effective intervention,[28 29] leading to long-term improvement of CVD risk factors, reduced healthcare costs and increased CR participation adherence.[30] Recent systematic reviews advocate to the use of telehealth interventions as an adjunct to CR[31–33] for the continuance of CR through pandemic circumstances.[20 21]

A recent review proclaims the integration of remote technologies and wearable sensors in the telerehabilitation, mentioning though the need for further investigation.[34] Another systematic review indicates that software-enabled systems reduce timing-related barriers to patients' participation.[32] The feasibility and safety of cardiac telerehabilitation need further investigation since most relevant studies are not addressing safety matters and a formal cost-effectiveness analysis.[32 34]

Our study focuses on the objective recording and monitoring of the exercise implementation and physical activity (PA) through the use of wearable sensors (heart rate (HR) monitors, accelerometers). Based on thorough literature review, it is the first study to integrate real-time supervision (use of videoconference platforms) and a group-based design for home exercising (up to five participants).

The primary aims of this study are to compare the effects between telerehabilitation and regular outpatient CR methods, related to cardiorespiratory fitness (CRF) and functional capacity, while possible effects in PA, training adherence, health-related quality of life (HRQoL), anxiety and depression levels, safety, nicotine dependence and cost-effectiveness are considered as secondary aims.

The hypothesis of the study will be that the telerehabilitation intervention will have at least the same efficiency with the regular, centre-based rehabilitation and that it will be as safe as and even more cost-effective than the centre-based rehabilitation intervention.

METHODS

Study design

A supervised, parallel-group, single-blind randomised controlled trial with 6 months of follow-up will be employed. The study includes patients with CAD, enrolled in a telerehabilitation group (TELE-CR), and a control centre-based group undertaking regular outpatient CR (CB-CR) for comparison reasons. Three assessments will take place at baseline (A_0), end of intervention (A_{12}) and follow-up at 36 weeks (A_{36}). A Consolidated Standards of Reporting Trials (CONSORT) flow diagram is shown in figure 1.

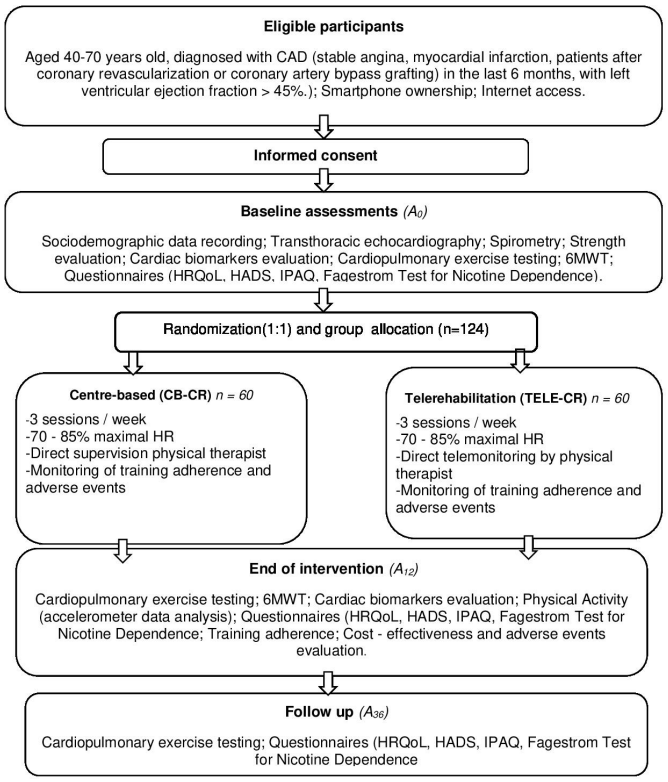

Figure 1 Flow chart of the study design. CAD, coronary artery disease; CR, cardiac rehabilitation; HADS, Hospital Anxiety and Depression Scale; HR, heart rate; HRQoL, health-related quality of life; IPAQ, International Physical Activity Questionnaire; 6MWT, 6 min walk test.

The study protocol complies with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) 2013 statement guidelines[35] and the intervention procedures are described according to the CONSORT-EHEALTH checklist.[36] We used the SPIRIT checklist when writing our report.[35] The trial is registered at ClinicalTrials.gov with registration number NCT05019157.

Table 1 presents a summary of the study schedule and assessments.

Patient population and eligibility

Patients will be recruited prior to their hospital discharge from the Cardiology Department of the General University Hospital of Larissa in Greece and will be screened for eligibility by the medical staff (cardiologists and medical physicians) of the corresponding hospital, according to the criteria shown in box 1. Through risk stratification and pre-exercise assessment, only low and moderate cardiac risk patients will be included in the study groups (table 2). Risk stratification and pre-exercise procedures will be implemented by cardiologists and an exercise physiologist, trained in the cardiopulmonary exercise

Table 1 Summary of study schedule

	Enrolment	Baseline (A_0)	End of intervention (A_{12})	Follow-up (A_{36})
Eligibility screening	X			
Informed consent	X			
Randomisation		X		
Allocation		X		
Interventions				
Centre-based CR		◆———	———◆	
Telerehabilitation		◆———	———◆	
Assessments				
Demographic characteristics		X		
Spirometry, TTE		X		
Strength evaluation test		X		
Cardiac biomarkers (BNP, NT-proBNP, troponins, creatine kinase)		X	X	
CPET–6MWT		X	X	X
HRQoL		X	X	X
HADS		X	X	X
IPAQ		X	X	X
FTND		X	X	X
Cost analysis			X	
Training adherence			X	

BNP, B-type natriuretic peptide; CPET, cardiopulmonary exercise testing; CR, cardiac rehabilitation; FTND, Fagerstrom Test for Nicotine Dependence; HADS, Hospital Anxiety and Depression Scale; HRQoL, health-related quality of life; IPAQ, International Physical Activity Questionnaire; 6MWT, 6 min walk test; NT-proBNP, N-terminal pro-brain natriuretic peptide; TTE, transthoracic echocardiography.

testing (CPET), from the corresponding hospital. Those who consent to participation will be screened for eligibility and will be provided with a trial information sheet (explanation of the study design and scopes, participants' responsibilities, confidentiality of the collected data) and a consent form to be signed. Basic sociodemographic data including sex, age, weight, height, cardiac diagnosis, pharmacological treatment, educational level, place of residence and profession will also be collected.

Randomisation and blinding

A total of 124 eligible patients will be randomised via a computerised randomisation system in a 1:1 ratio (adjusted for age and gender) into two groups: CB-CR and TELE-CR. The allocation will be hidden until the completion of the baseline assessment in sequentially numbered, sealed, opaque envelopes. Due to the nature of the intervention, both the participants and the hospital's staff supervising the exercise programmes are unable to be blinded to the treatment allocation. The researchers, responsible for all study assessments, will be blinded to the intervention allocation. Primary investigators will be unaware of the randomisation allocation until the completion of the intervention and the collection of all study data.

Patient and public involvement

There was no patient or public involvement in the design of this study (setting of the research question or the outcome measures). The patients will not be asked to take part either in the interpretation or the writing procedures of the results of this study.

Interventions

Individually determined CR programmes will be implemented in both study groups based on the participants' referral diagnosis, physical fitness level and expected training goals. All participants will undertake a 12-week, exercise-based CR programme, including three training sessions of 60 min/week. Exercise will be prescribed individually, according to the results of the baseline CPET and to the frequency, intensity, time (duration) and type of exercise model.[37] Participants will exercise with an intensity of 70% of their maximal heart rate, as assessed during baseline CPET.[10] Each exercise circuit will consist of 20 structured stations for aerobic, strength and balance training of 2 min duration/station (tables 3 and 4). Aerobic progression will go through the duration, followed by an increase of 5%–10%/week in the exercise intensity.[38 39] Progression in the resistance training involves primarily the achievement of the desired volume

Box 1 Inclusion and exclusion criteria

Inclusion criteria

⇒ Adults >18 years old.
⇒ Diagnosed with coronary artery disease (CAD) (stable angina, myocardial infarction, patients after coronary revascularisation or coronary artery bypass grafting) in the last 6 months, with left ventricular ejection fraction >45%.
⇒ Current outpatients, stable for at least 4 weeks prior to the intervention enrolment.
⇒ Able to perform physical exercise.
⇒ Able to speak, read and write Greek.
⇒ Possession of a mobile phone/smartphone.
⇒ Internet access at home.

Exclusion criteria

⇒ Severe ventricular arrhythmia, with functional or prognostic significance or exercise-induced myocardial ischaemia as assessed by cardiopulmonary exercise testing (CPET) at baseline.
⇒ Heart failure.
⇒ Comorbidity precluding exercise training (eg, orthopaedic, neurological or cognitive conditions).
⇒ Unstable angina.
⇒ Uncontrolled atrial or ventricular arrhythmia.
⇒ Acute pulmonary embolism.
⇒ Acute myocarditis or pericardial effusion.
⇒ Uncontrolled diabetes mellitus (type I, II).
⇒ Severe obstructive respiratory disease (forced expiratory volume in 1 s (FEV_1) <50%).

(number of training sets), followed by the gradual increase in intensity (amount of load lifted) and adaptations in density (rest periods).[38 40] Resistance training will follow a low-pace rest/recovery to work/contraction ratio of 2:1.[37] Participants in the CB-CR group will use free weights or machines for their resistance training, while participants in the TELE-CR group will exercise using their body weight or resistance bands. At the completion of the intervention, the effectiveness of the training programme will be assessed and patients will be encouraged to maintain a physically active lifestyle. However, no specific exercise prescription or face-to-face feedback will be provided until the follow-up assessment.

Blood samplings will be taken in all assessment endpoints from all study participants to assess any effects of the intervention on the cardiac biomarkers' blood concentration (B-type natriuretic peptide, N-terminal pro-brain natriuretic peptide, troponins, creatine kinase).

All patients will be receiving educational and informational videoconference sessions regarding issues of upright exercising, PA, diet/nutritional and smoking cessation counselling (based on recent guidelines)[10] and psychosocial support (via psychotherapy) on stress and anxiety management. Consultation sessions may include a family member or a friend, especially for elderly patients.[41] Communication strategies such as motivational interviewing, during telephone calls or videoconferences, will be integrated, as they appear to be useful in helping to promote patients' adherence and avoid incidents of early dropouts. Motivational interviewing will be based on the open-ended questions, affirmation, reflective listening and summarising principle that helps patients to present their perceptions and clinicians to summarise.

Any adverse effects that may occur during the intervention period will be reported for safety monitoring and future data interpretation analysis.[42] Adverse effects are defined as all-cause mortality, hospitalisation for CVD or serious atrial or ventricular arrhythmia, musculoskeletal problems (muscle, tendon or joint problems) or other diseases preventing exercise participation. Constant supervision of the CB-CR exercise programme and the existence of a defibrillator will ensure the participants' safety, while for the TELE-CR group, real-time exercise telemonitoring via videoconference platforms and exercise training within the prescribed HR zone will ensure safety. Box 2 summarises the indications for dropping out training sessions.

Participants who might withdraw from the study will consent for follow-up assessment of at least the primary outcomes and will be willing to continue with assessments for other outcomes, if they wish to.

Auditing of the study is planned to be performed by periodic in-person visits of the trial investigator at the

Table 2 Cardiac risk stratification

Low risk	Moderate risk	High risk
► Absence of angina or other symptoms (eg, unusual shortness of breath, mild headache or dizziness). ► Functional capacity >7 METs, left ventricular ejection fraction (LVEF) ≥50%. ► Absence of arrhythmia at rest. ► Absence of depression.	► Presence of angina or other symptoms (eg, unusual shortness of breath, mild headache or dizziness, dizziness occurring at high levels of exercise ≥7 METs). ► Mild to moderate silent ischaemia (ST eruption <2 mm). ► Functional capacity >5 METs. ► LVEF=40%–49%.	► Presence of arrhythmias. ► Presence of angina or other symptoms (eg, unusual breathlessness, mild headache or dizziness, dizziness occurring at high levels of exercise <5 METs). ► Silent ischaemia (ST stroke ≥2 mm). ► Presence of abnormal haemodynamics during exercise (reduction of BP) or postexercise hypotension. ► LVEF<40%.

BP, blood pressure; METs, metabolic equivalents.

Table 3 CB-CR exercise programme

Warm-up	
Cycling or mild treadmill walking	5 min
Stretching activities ► Upper back ► Chest ► Lower back, waist mobility ► Calf ► Hamstring ► Quadriceps	5 min
Main training part	
Aerobic training	
► Cycling or treadmill walking	Exercise with an intensity of 70% of the patients' maximal heart rate (HR_{max}) at a level of 12/20–14/20 of Borg scale
Strengthening training	
► Biceps curls ► Shoulder press ► Triceps ► Lateral fly ► Front deltoid raise ► Mini squats ► Hamstring curls ► Plantar flex ► Side leg raise	12 repetitions 1 set/exercise, starting at 30% and 70% of one-repetition maximum (1RM) for the upper body and lower body, respectively Increase gradually to 70% and 80% of 1RM for the upper body and lower body, respectively
Balance training	
► Standing on one foot ► Walking heel to toe ► Reaching front Lateral Back	Starting with the patient's own body weight. Later add unstable surfaces.
Duration 40 min 1RM: the maximum weight a patient can lift in one complete repetition for a given exercise in a controlled way through a full range of motion with good posture	
Cool-down	
► Cycling or mild treadmill walking ► Moving hands slowly ► Stretching exercises	10 min

CB-CR, centre-based cardiac rehabilitation group.

hospital facilities or via telephone conducts with the leading physiotherapist of the corresponding hospital.

Any substantive protocol amendments will be reviewed by the institutional review boards/research ethics committees (IRBs/RECs) of the University of Thessaly and will be communicated to all relevant stakeholders (RECs/IRBs, trial registries).

CB-CR group

Participants will attend a supervised, individually tailored, exercise-based CR programme at the hospital's facilities. CB-CR participants will be instructed to wear an accelerometer during the entire study period. Due to the accelerometer's storage capacity of 30 days, recorded data will be uploaded with a USB connection and stored in the hospital server in an encrypted way on a monthly basis. Total training attendance rate will be documented by the hospital's staff

TELE-CR group

Participants in the TELE-CR group will undertake three training sessions (or more if needed) in the hospital's outpatient clinic for familiarisation with the use of the wearable sensors, the uploading of the training data to the web application (Polar Flow) and the exercising within their individually determined exercise intensity.

Following the training period, TELE-CR participants will be lent a Polar H10 chest strap that records HR data and a sports wristwatch (Polar M430, Kempele, Finland) and will proceed with the telerehabilitation programme at their homes. Both wearable sensors are validated and reliable tools, allowing effective assessment of exercise

Table 4 TELE-CR exercise programme

Warm-up	
Marching on the spot	5 min
Stretching activities ► Upper back ► Chest ► Lower back, waist mobility ► Calf ► Hamstring ► Quadriceps	5 min
Main training part	
Aerobic training	
► Box stepping ► Knee raises only With hand to opposite knee Hand to opposite ankle ► Knee bends only With swinging arms With reaching arms ► Side steps Just tapping With half-arm lift Reaching over ► Marching Heal lift only With arms moving	10 repetitions 2 sets/exercise
Strengthening training	
► Biceps curls ► Shoulder press ► Triceps ► Lateral fly ► Front deltoid raise ► Mini squats ► Hamstring curls ► Plantar flex ► Side leg raise	12 repetitions 1 set/exercise, starting at 30% and 70% of one-repetition maximum (1RM) for the upper body and lower body, respectively Increase gradually to 70% and 80% of 1RM for the upper body and lower body, respectively
Balance training	
► Standing on one foot ► Walking heel to toe ► Reaching Front Lateral Back	Starting with the patient's own body weight Later add unstable surfaces
Duration 40 min 1RM: the maximum weight a patient can lift in one complete repetition for a given exercise in a controlled way through a full range of motion with good posture	
Cool-down	
► Marching on the spot gently ► Moving hands slowly ► Stretching exercises	10 min

TELE-CR, telerehabilitation group.

intensity[43] and will be used only during the exercise training sessions. The sports wristwatch will display continuous HR reading from the Polar H10 chest strap, enabling patients to exercise within their prescribed HR zone and exercise data (duration, training mode, PA tracking). Participants in the TELE-CR group will be exercising in groups of up to maximum five participants in each session. Real-time supervision of this group-based exercise session by a specialised physiotherapist will be implemented via videoconference web platforms or applications. At the end of every training session, patients will upload training data to the web platform (Polar Flow) via Bluetooth or USB connection. Each patient will have his/her username and login account and can check his/her training data graphically and correlate it to his/her personal goals. CR-specialised staff from the corresponding hospital will have access to all patients' accounts so as to monitor successful data uploading, assess the

Box 2 Indications for dropping out training sessions

- ⇒ Exercise-induced angina.
- ⇒ Fatigue, shortness of breath, dizziness, sweating, cyanosis, headache.
- ⇒ Orthostatic hypotension, drop in SBP >20 mm Hg during exercise.
- ⇒ SBP ≥220 mm Hg, DBP ≥110 mm Hg.
- ⇒ HR drop (>10 bpm) during exercise.
- ⇒ Ventricular tachycardia (>120 bpm).
- ⇒ When participant reaches the intensity limit of the exercise.

DBP, diastolic blood pressure; HR, heart rate; SBP, systolic blood pressure.

collected data and provide them with training feedback once a week via telephone video calls. Uploaded data will be further backed up to an external hard drive to be processed and evaluated by the trial investigator after the completion of the intervention.

Additionally, all patients will be lent a triaxial accelerometer (ActiGraph wGT3X) that they will wear around their waist during the 12-week intervention period. Patients should visit the hospital's outpatient clinic on a monthly basis to upload the recorded data to a secure PC application in an encrypted manner. Training adherence will be monitored by the specialised physiotherapist supervising the telerehabilitation exercise sessions.

Outcome measures

Primary outcome

The primary outcome will be the assessment of the CRF, at baseline, the completion of the intervention (A_{12}) and follow-up (A_{36}) in all study groups (CB-CR, TELE-CR).

Secondary outcomes

Secondary outcomes will be the PA level, safety, HRQoL, training adherence, depression and anxiety levels, nicotine dependence and cost-effectiveness. PA, HRQoL, nicotine dependence and psychosocial well-being will be measured and assessed at baseline, end of intervention (A_{12}) and follow-up (A_{36}). Training adherence and cost evaluation will be assessed at the completion of the intervention (A_{12}).

Measurements

Cardiorespiratory fitness

CRF will be assessed in all study groups by peak oxygen uptake (peak VO_2), determined by CPET and a 6 min walk test at the corresponding hospital at baseline, at the completion of the intervention (A_{12}) and follow-up (A_{36}). CPET will be set according to recommendations of European Society of Cardiology (ESC) and the American Heart Association.[44 45] The test will be performed on a cycle ergometer using an individual ramp protocol aiming at total test duration of 8–12 min. Patients will be instructed to maintain a pedalling frequency of 60–70 rounds/min. A 12-lead ECG and blood pressure will be recorded continuously during the test. Peak VO_2 will be defined as the average value during the last 30 s of exercise. Patients will be encouraged to exercise until they reach respiratory exchange ratio (RER) ≥1.10. If a participant fails to achieve an RER ≥1.10, he/she will be excluded from the study. A cardiologist will be present while testing to deal with any emergencies that may arise.

Physical activity

Daily PA will be measured via a triaxial accelerometer (ActiGraph wGT3X) at baseline and at the completion of the intervention (A_{12}). The ActiGraph will be worn continuously and has been previously identified as a reliable PA tool[46 47] validated in healthy and cardiac patients.[48 49]

The self-reported PA will be assessed at all three assessment endpoints by the offline International Physical Activity Questionnaire adopted in the Greek language that presents acceptable reliability and high repeatability values.[50]

Cost-effectiveness

The cost-effectiveness analysis will be performed using the assessment of quality-adjusted life-years (QALYs) at baseline (A_0) and end of intervention (A_{12}). Patients will complete the EuroQol-5 Dimension questionnaire individually[51] and their final scores will be converted into QALYs. The cardiovascular readmission costs (as derived from the invoices from the hospital's financial department), the cardiologist follow-up visits and the diagnostic tests will constitute the healthcare costs. The CB-CR costs will be calculated based on the price list of medical expenses provided by hospital regarding professional wages (physiotherapist, cardiologist), exercise testing assessment costs and transportation costs to and from the patients' homes to the hospital. In the TELE-CR group, the costs will include the purchase of the necessary equipment and consumables (internet connection subscription, telephone communication cost).

The cost/benefit analysis will result from the calculation of the incremental cost-effectiveness ratio (ICER):

$$\text{ICER} = (\text{cost}_{\text{intervention group}} - \text{cost}_{\text{control group}}) \,/\, (\text{effectiveness}_{\text{intervention group}} - \text{effectiveness}_{\text{control group}}).$$

Incremental cost refers to the difference/patient in the total average cost between the intervention group (TELE-CR) and the control group (CB-CR). Incremental effectiveness is defined as the difference in the mean change in QALYs between the study groups.

Anxiety and depression/smoking cessation

Anxiety/depression rates and nicotine dependence will be assessed at all three assessment points. Anxiety levels will be evaluated through the Greek version of the Hospital Anxiety and Depression Scale (HADS) that comprises seven items, each for anxiety and depression subscales.[52] HADS is a validated measure to assess anxiety and depression symptoms, recommended for patients with CAD.[53 54] Nicotine dependence will be assessed through the Fagerstrom Test for Nicotine Dependence.

Training adherence

Patients' training adherence is defined as a percentage of the total number of completed training sessions (100%=36). Patients' adherence in both study groups will be recorded by the supervising hospital outpatient clinic's staff and will be evaluated at the end of intervention (A_{12}). Based on the percentage of the sessions attended, participants will be categorised in adherence (>80%), partial adherence (20%–80%) and non-adherence (<20%).

Statistical analysis

Normality of data will be examined with Kolmogorov-Smirnov tests. Descriptive statistics will be used to report demographics and baseline characteristics. Between-group and within-group differences in the outcome measures will be evaluated using multivariate analysis of variance (MANOVA). The effectiveness of the control group (CB-CR) and intervention group (TELE-CR) will be examined with dependent t-test for each group (prescores and postscores). All participants will be included in an intention-to-treat analysis, regardless of adherence, for at least the assessment of the primary outcomes. Significance level will be set at p=0.05. Statistical Package for Social Sciences (SPSS) V.25 will be used for all data analyses.

Sample size calculation

The calculation of the sample size was performed with G*Power V.3.1.9.4 software. For test F, h detection of moderate effect size (f=0.3) after the interaction test (α level=0.05, 80%), a total of 111 participants were required to examine the recurrent MANOVA. After adjusting for potential dropouts (estimated attrition rate ≤10%), a minimum sample of 124 participants is required. Therefore, at least 62 participants will be recruited in each group.

ETHICS AND DISSEMINATION

The study protocol was approved by the Ethics Committee of the University of Thessaly (1108/01-12-2021) and by the Ethics Committee of the General University Hospital of Larissa. Written informed consent will be obtained from all study participants prior to their enrolment to the study intervention.

The findings of this study will be disseminated at local, national and international levels through publications in peer-reviewed journals, national and international conference presentations, and social, broadcast and print media. Additionally, all study participants will receive the study findings through electronic and postal mails.

DISCUSSION

This trial is aiming to evaluate the efficacy, efficiency and safety of an exercise-based telerehabilitation programme using wearable sensors and web applications compared with a traditional supervised centre-based CR.

The objective assessment of functional capacity through CPET and the objective monitoring and recording of exercising and PA via the use of wearable sensors are the main features of this study that increase its reliability. The objective measurement of PA and training intensity using accelerometer and HR data is suggested to be more reliable than using questionnaires than self-reported PA[55–57] or than the perceived rate of exertion on its own.[55]

Although a cost-effectiveness analysis is almost prerequisite for any novel intervention, only a few telerehabilitation studies have performed one. Frederix *et al* have shown the cost-effectiveness of an internet-based telerehabilitation programme[28] while Kidholm *et al* outlined the non-cost-effectiveness of a telerehabilitation programme compared with centre-based CR.[58] In our study, we intend to include a comprehensive cost-effectiveness analysis to evaluate any possible economic gains.

Moreover, the geographical features of Greece, with many islands and remote areas, contribute to the care inequality being observed, combined with the high variability of access to primary care professionals.[59] CR is almost absent from the Greek public health system, partly owing to the lack of clinics and training in its delivery. Furthermore, while some studies have already investigated the implications of telerehabilitation in other diseases, such as chronic obstructive pulmonary disease, with favourable outcomes,[60] no similar study, to our knowledge, has not yet been carried out for patients with CAD, leaving a great gap open. In accordance to these statements, recent guidelines support the implementation of home-based CR, telehealth and mHealth interventions, with the use of wearable activity trackers to increase cardiac patients' participation rates and long-term adherence to healthy behaviours.[11] Furthermore, although digital literacy of patients with CVD is presented as a barrier to CR participation,[61] data from a recent study reveal encouraging results concerning the successive use of smartphones and wearable technology by an elderly cardiac population.[62] Additionally, adherence in telerehabilitation interventions appears to present higher rates.[63–65]

Therefore, there is an urgent need for innovative, safe, more cost-effective CR strategies. If an exercise-based telerehabilitation programme, using wearable sensors, meets these prerequisites, it can act as a supplement and/or substitution (according to the needs) to traditional centre-based CR in patients with CAD of low to moderate cardiac risk, thus allowing more patients to have access to CR with the least possible economic burden.

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Contributors VA and GP conceived the study design. AX, GG, KIG, JS, CD, EK and VS contributed to the conception of the design. VA, GP and LB drafted the manuscript and all authors reviewed several drafts of the manuscript. All authors approved the final manuscript to be published.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

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