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Exploring the feasibility, acceptability, and safety of a real-time cardiac telerehabilitation and tele coaching programme using wearable devices in people with a recent myocardial infarction.

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Abstract

Background

Cardiac rehabilitation (CR) constitutes the recommended nonpharmacological approach for cardiac patients with cardiovascular disease such as people following a recent (i.e., < 4 week) myocardial infarction (MI). Recent evidence suggests that cardiac telerehabilitation may be as effective as traditional (i.e., in person) CR in people following a recent MI. Nevertheless, the feasibility, acceptability, and safety of such an exercise programme has yet to be examined.

Methods

Forty-four (11 women, 33 men) people following a recent MI were randomly allocated into two groups (online home-based and gym-based groups). The groups underwent a 24-week CR programme thrice per week. All patients performed the baseline, and 24 weeks follow up measurements where feasibility, acceptability, and safety were assessed.

Results

Eligibility and recruitment rates were found to be 61.5% and 42%, respectively. Compliance to the thrice weekly, 24-week exercise programme for the online- and gym-based groups were 91.6% and 90.9%, respectively. There were no dropouts during the exercise programmes, however four participants, two from each group, were lost to follow up at 6 months. The average percentage of peak HR (% HR_{peak}) for the online group was 66.6% ± 4.5 and for the gym-based group was 67.2% ± 5. The average RPE and affect during exercise was for both groups 12 ± 1 (“somewhat hard”) and 3 ± 1 (“good”), respectively. During the 6-month exercise intervention period for both groups, the exercise-induced symptoms were minimal to none. The user suitability evaluation questionnaire revealed that the online real time telerehabilitation and tele coaching programme was enjoyable (4.85 ± 0.37) and did not induce general discomfort (1.20 ± 0.41).

Conclusion

Our cardiac telerehabilitation programme seems to be feasible, acceptable, safe, and enjoyable for people with a recent MI. Our participants had an overall positive experience and acceptability of the cardiac telerehabilitation and tele coaching using wearable devices.

Trial registration: ClinicalTrial.gov, ID: NCT06071273, 10/02/2023, retrospectively registered.

Key words: cardiac exercise, cardiac patients, aerobic exercise, resistance training

Introduction

Myocardial infarction (MI), otherwise known as "heart attack," is caused by decreased or complete cessation of blood flow to a portion of the myocardium. MI remains the leading cause of death globally[1]. The global prevalence of MI was found to be 3.8% and 9.5% in individuals < 60 years and > 60 years, respectively[2].

Cardiac rehabilitation (CR) constitutes the recommended nonpharmacological approach for cardiac patients with cardiovascular disease[3]. The beneficial effects of CR have been demonstrated for patients with various cardiac diseases, such as for patients following MI[4]. CR in MI patients can improve exercise capacity including cardiorespiratory fitness, cardiovascular functional capacity, and quality of life[4,5].

Although CR has proven to be effective, participation levels of eligible patients following an acute event are discouraging[6,7]. Some of the barriers to CR participation include lack of referral from the clinicians, travel time and complexity of transport to the centre, as well as personal (i.e., work or family) commitments[8,9]. To overcome these barriers, alternative modalities of CR delivering have been proposed such as cardiac telerehabilitation.

Home-based cardiac telerehabilitation has been demonstrated to be safe for cardiac patients promoting thus regular physical exercise to this population[10]. It has also been highlighted that evolving technological progress and advances could form an even safer home-based cardiac telerehabilitation environment via an improved communication between patients and CR providers[10]. More recent technological advances assisting to remotely monitor CR programmes using wearable sensors recording in real time hemodynamic responses such as heart rate (HR) and electrocardiogram (ECG)[11] could potentially enhance the overall programme's safety, however, evidence is limited in people with a recent MI. A study that assessed the feasibility of a home-based cardiac rehabilitation using wearable sensors (i.e., HR and ECG recordings) in elderly patients with heart failure demonstrated that the real-time supervision was feasible and safe[12].

Cardiac telerehabilitation supported by advanced technology (i.e., digital platform indicating the hemodynamic responses via wearable sensors) could help patients to adhere to the exercise protocol securing thus the protocol's effectiveness. Some factors that could influence the use of this advanced technology in cardiac rehabilitation concern the perceived ease of use and usefulness, content quality and accuracy. Therefore, the evaluation of aspects such as usability, user acceptance and satisfaction via certain questionnaires (e.g., User Satisfaction Evaluation Questionnaire; USEQ[13]) are considered critical.

Recent evidence suggests that cardiac telerehabilitation may be as effective as traditional (i.e., in person) CR in cardiac patients[14,15] as well as in people following a recent (i.e., < 4 weeks) MI[11]. Namely, cardiac telerehabilitation was comparable to two in person CR programmes[16,17] with respect to improvements ($P<0.05$) in low-density lipoprotein, blood pressure and physical activity levels as those assessed pre- and post-intervention. Furthermore, telerehabilitation might be able to improve CR's accessibility and adherence rates[18,19]. Although the current evidence suggests that cardiac telerehabilitation could be effective in people with a recent MI, less in known about the feasibility and acceptability in this population. To our knowledge, this was the first clinical trial to assess the feasibility and acceptability of a real-time online cardiac telerehabilitation and tele-coaching against a traditional (e.g., in person gym-based) CR programme in people with a recent MI.

Methods

Study design

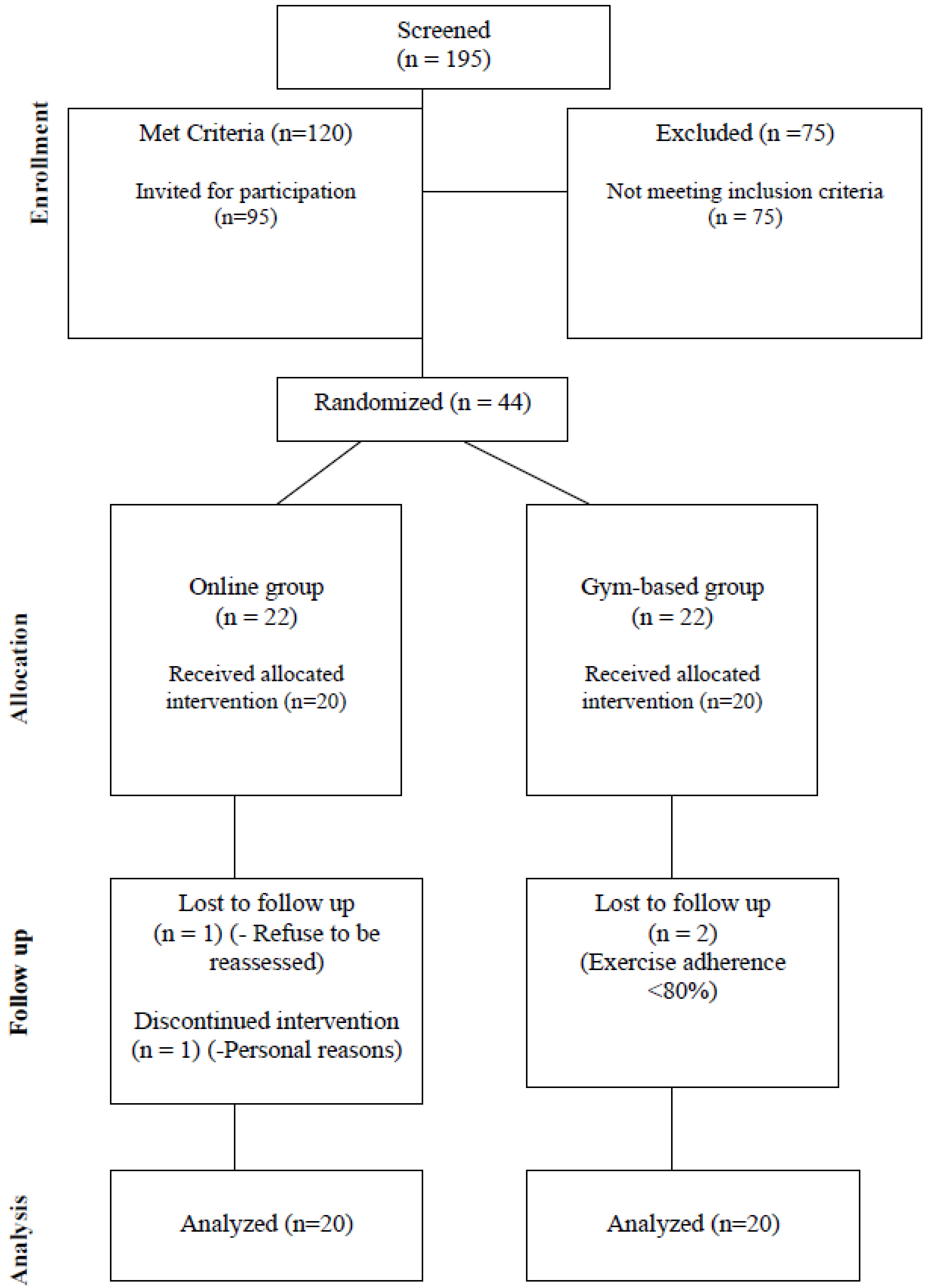
Forty-four people (11 women, 33 men) following a recent (i.e., < 4 week) MI in October 2023. Eligible participants were recruited from the Cardiology Clinics of the University and private Hospitals of Thessaloniki, Greece, as well as private physicians' practices. The eligibility criteria, ethical approval and study design have been described previously[11]. The study has also been registered in ClinicalTrial.gov (ID: NCT06071273).

Following the baseline assessments (i.e., Visit 1) participants were randomly allocated (stratified randomisation) by an independent statistician blinded to study's procedures into two groups: online- (n=22) and gym- groups (n=22). Details of the randomisation procedure have been described previously[11].

The exercise groups followed an identical exercise protocol for 24 weeks thrice per week. A Consolidated Standards of Reporting Trials (CONSORT) flow diagram is shown in Figure 1. Our current RCT is presented based on the CONSORT 2010 statements (Additional file 1). All baseline assessments (i.e., Visit 1) were repeated at 24-weeks (i.e., visit 2).

From the 195 screened patients via our database, patients were invited on a day-to-day basis via the cardiology clinics (i.e., n=95) until the recruited target was reached (i.e., n=44). From the 95 patients that were invited, 44 were recruited and randomised. The rest of the patients were: i) not interested (n=20), ii) not able to commit to a long-term exercise programme (n=10), iii) lacking availability due to other family commitments (n=10) and iv) were not able to travel in case they would randomly allocate to the gym-based group (n=11) as shown in Figure 1.

Figure 1. Consolidated Standards of Reporting Trials (CONSORT) flow diagram


Enrollment
Screened
(n = 195)
Met Criteria (n=120)
Invited for participation
(n=95)
Excluded (n =75)
Not meeting inclusion criteria
(n = 75)
Randomized (n = 44)
Allocation
Online group
(n = 22)
Received allocated
intervention (n=20)
Gym-based group
(n = 22)
Received allocated
intervention (n=20)
Follow up
Lost to follow up
(n = 1) (- Refuse to be
reassessed)
Discontinued intervention
(n = 1) (-Personal reasons)
Lost to follow up
(n = 2)
(Exercise adherence
<80%)
Analysis
Analyzed (n=20)
Analyzed (n=20)

Study outcomes

Primary outcomes

Demographics

Demographics such as anthropometrics, medical profile including medication, clinical outcomes, comorbidities, and essential cardiovascular outcomes (e.g., echocardiographic indices, peak oxygen uptake on a treadmill, blood pressure) were performed at the baseline assessment and were retrieved from the patient's medical file wherever that was considered appropriate (e.g., comorbidities). Details of the collection of the cardiovascular outcomes at baseline have been published previously[11].

User Suitability Evaluation Questionnaire (USEQ)

USEQ is a validated[13], easy to understand questionnaire, with an affordable number of questions (n=6). USEQ was administered to the online group only.

The USEQ is consisted of 6 questions and uses a 5-point Likert scale for responses. The total score of the USEQ questionnaire ranges from 6 (poor satisfaction) to 30 (excellent satisfaction). The estimation of the total score considers all the questions to be positive, except of a negative question (i.e., Q5). The total score is calculated using the sum of the positive questions (for instance, if the patient selects 4 in Q1, then 4 is added to the total score). The negative question subtracts the numerical value of the response from 6 and then adds this result to the total score (for example, if the patient selects 2 in Q5, then 4 is added to the total score). The USEQ score is evaluated using the following classification: poor (0-5), fair (5-10), good (10-15), very good (15-20), (20-25) satisfaction or (25-30) excellent satisfaction[13].

Feasibility and acceptability of the exercise programme

The recruitment rates were calculated as rate of acceptance to participation by the invited individuals who deemed eligible to assess the feasibility of the intervention. The attrition rates and the comparison between the two groups (e.g., examining reasons for dropout) were the main outcomes to assess acceptability of allocation (i.e., feasibility outcome). Discontinuation of intervention and loss to follow-up measurement defined the attrition rate for both groups (i.e., feasibility and acceptability outcome). The session attendance and compliance data were the main two factors that evaluated the overall acceptability of the exercise programme. The perceived exertion (using the Borg 6-20 scale[20]) and affect[21] scale (e.g., +5 'Very Good', -5 'Very Bad') were also recorded throughout each training session which outcomes were used to strengthen the evaluation concerning the acceptability of exercise. The total dropouts from the exercise programme and the reasons of those dropouts, as well as the number and type of adverse events that occurred during the exercise intervention were recorded and reported to assess the overall safety of the exercise programme.

Success criteria for feasibility and acceptability outcomes

The success criteria for the adherence rates for our study were based on previous studies that assessed a home-based cardiac rehabilitation programme[22,23] and was set at >60% (i.e., acceptability of exercise outcome). The target for the recruitment rates was to >33% since only one third of post-MI patients take part in CR programmes[24] (i.e., feasibility of the exercise intervention). The attrition rate target was set at >20% based on a general report concerning the dropout rates of patients who participate in CR programmes[25] (i.e., feasibility and acceptability outcome). The exercise attendance rate was set at >80%[26] (i.e., acceptability outcome).

Secondary outcomes

Exercise-related symptoms during the exercise-based cardiac rehabilitation programme

Exercise-related symptoms during the 24-week cardiac rehabilitation programme period were also reported for both groups. Moreover, the management approach of each occasion was noted.

Exercise programme

Each session consisted of 30 minutes of moderate intensity (i.e., corresponding to the 1st ventilatory threshold which marks the limit between the slight and moderate intensity of exercise) aerobic training, approximately 15 minutes of resistance training (resistance bands: whole body muscle groups, 1–3 sets per exercise, 90 s rest between sets, and 8–10 repetitions for each set, corresponding to an intensity of 13–15 on the Borg scale[20]) and 15 minutes of balance and flexibility training.

The training principle of progression in our study was applied in both the aerobic and resistance training elements. To ensure the training progression of the aerobic protocol for each of our participants, the intensity was adapted based on the participant's Borg scale responses. For example, following consistent (>3 consecutive times) RPE responses that were below the lowest point of the target range (i.e., <13), the intensity was increasingly adjusted by the tele coach in real time by encouraging and providing live feedback to the participants. Similarly for the resistance training, the intensity was increasingly adjusted by altering either the participant's distance from the resistance band or the intensity of the resistance band (i.e., changing the colour of the band corresponding to a higher intensity).

The detailed exercise protocol including exercise intensity, progression and monitoring has been published previously[11].

Online home-based Group

The online group was monitored (e.g., hemodynamic responses) via wearable devices. The online session was delivered in real time by a health instructor and supervised by a cardiologist. Further details for the hemodynamic monitoring, wearable devices and the online platform can be found in Mitropoulos et al.[11].

Gym-based Group

The local community-based health clubs were utilised to accommodate the cardiac rehabilitation programme for the gym-group. Each session was delivered by an experienced trainer. Heart rate, blood pressure, and saturation of oxygen were assessed prior- and 5 minutes post each session (to assure safety for the participants to exercise and that all values have reached the resting levels prior to their release from our facilities).

Statistical analysis

We used rates of eligibility, recruitment, attrition, outcome completion, exercise adherence and adverse events to assess the feasibility and acceptability of the intervention. Frequency counts and percentages were provided for categorical data. Continuous variables were summarized with descriptive statistics. All data analysis was conducted at the end of data collection, using SPSS software (version 23, IBM SPSS, New York, USA). Data are presented as mean ± SD.

The sample size calculation for our study estimated the critical metrics needed to assess the feasibility of conducting the definitive study, with sufficient precision[27]. The critical metrics are the consent rate (i.e., the proportion of eligible patients who consented to participate and be randomised, compliance with treatment, and attrition rates. Twenty-two patients in each group ($n = 44$ in total) provided a sufficiently precise (within 15 percentage points for a 90% confidence interval) estimate of the proportion willing to be randomised, assuming 35% intention to be randomised.

Results

Demographics

No statistically significant differences were found between groups for our demographic outcomes (Table 1). Two participants per group were lost during the follow ups and were not included in the analysis (Figure 1).

Table 1. Demographics

	Online Group (n=20)	**Gym Group (n=20)**	**p-values**
Gender (Males/Females)	16/4	15/5	0.69
Age (yrs.)	54.0 ± 7.8	53.1 ± 6.4	0.69
Body Mass (kg)	85.2 ± 16.9	84.4 ± 12.6	0.88
Stature (cm)	176.8 ± 7.4	175.0 ± 7.4	0.46
Body surface area	2.0 ± 0.2	2.0 ± 0.2	0.64
Ejection fraction	52.1 ± 11.2	52.6 ± 9.2	0.88
Heart rate (bpm)	68 ± 13	68 ± 10	0.97
Systolic blood pressure	119 ± 15	124 ± 13	0.23
Diastolic blood pressure	74 ± 9	73 ± 11	0.75
VO_{2peak} (ml/kg/min)	27.0 ± 3.4	27.0 ± 3.1	0.95
Risk factors			
Hypertension	8(20)	7(20)	0.74
Diabetes mellitus	3(20)	3(20)	1.00
Dyslipidemia	9(20)	8(20)	0.75
Smoking	9(20)	7(20)	0.52
Family history	6(20)	8(20)	0.51

Medication			
Beta blockers	18(20)	17(20)	0.63
Antiplatelet	20(20)	20(20)	1.00
ACE inhibitors	17(20)	16(20)	0.68
Statin	19(20)	18(20)	0.55
Hypoglycemic	3(20)	4(20)	0.68
Clinical			
STEMI	16(20)	15(20)	0.71
Anterior	7(20)	8(20)	0.74
Inferior	9(20)	7(20)	0.52
NSTEMI	4(20)	5(20)	0.71
PCI	18(20)	19(20)	0.55
CABG	2(20)	1(20)	0.55

User Suitability Evaluation Questionnaire

Each question within USEQ was analysed individually (Table 3). The findings demonstrated that the participants in the online group (n=20) enjoyed the cardiac telerehabilitation, felt accomplished using the system, felt that it was easy-to-understand instructions, had no general discomfort, and felt that the overall system will support them in the rehabilitation process.

Table 2. Responses to USEQ items

Questions	**Online group (n=20)**	**Classification**
Q1. Did you enjoy your experience with the system?	4.85 ± 0.37	

Q2. Were you successful using the system?	4.85 ± 0.37	
Q3. Were you able to control the system?	4.95 ± 0.22	
Q4. Is the information provided by the system clear?	5 ± 0	
Q5. Did you feel discomfort during your experience with the system?	4.8 ± 0.41	
Q6. Do you think that this system will be helpful for your rehabilitation?	5 ± 0	
Total score	29.3 ± 1.2	Excellent satisfaction

Feasibility and acceptability of cardiac telerehabilitation

Of 195 people with a recent MI screened for participation, 120 met eligibility criteria and 95 were invited. From those invited, 44 were recruited (online group, n=22 and gym-based group, n=22), giving eligibility and recruitment rates of 61.5% and 42% respectively. There were no dropouts during the exercise programmes, however, two participants per group (4 in total) were lost to follow ups and twenty (per group) were analysed (Figure 1).

Adherence to the thrice weekly, 24-week exercise programme for the online- and gym-based groups were 91.6% and 90.9%, respectively. The average percentage of peak HR (% HR_{peak}) for the online group was 66.6% ± 4.5 and for the gym-based group was 67.2% ± 5. The average RPE and affect during exercise was for both groups 12 ± 1 (“somewhat hard”) and 3 ± 1 (“good”), respectively.

Symptoms during the cardiac rehabilitation programme

During the 6-month exercise intervention period for both groups, the exercise-induced symptoms were minimal to none. Namely, no symptoms were presented for 20 participants (online group, n=11 and gym group, n=9, p=0.53) throughout the 6-month exercise interventions. For a single occasion from a total of 72 sessions (i.e., frequency < 1.5%), 20 participants (online group, n=9 and gym group, n=11, p=0.53) did present some symptoms which are demonstrated in detail in Table 2. Three patients from the gym group and one in the from the online group (p=0.29) needed emergency ambulance use, from whom hospitalisation was required for two participants in the gym group and one for the online group (p=0.55). The diagnosis for the hospitalisation for the gym group was respiratory infection (n=1) and acute coronary syndrome (n=1). For the online group the participant was diagnosed with atrial fibrillation. The hospitalisations were unrelated to the exercise sessions as the symptoms were expressed prior to the initiation of the exercise sessions. Emergency response was provided, and the sessions were cancelled on all three occasions for the patients that were affected.

Table 3. Symptoms during cardiac rehabilitation programme (n=patients)

Symptoms	**Online group (n=9/20)**	**Gym group (n=11/20)**	**p-values**
Unexpected fatigue and arrhythmias	4	3	0.68
Dyspnoea and discomfort	2	4	0.38
Dizziness	3	4	0.68
Exercise-unrelated hospitalisations	1	2	0.55

Discussion

The findings of our study suggest that the real-time cardiac telerehabilitation using wearable devices in people with a recent MI is feasible, safe, and suitable. These findings constitute the basis for the implementation of our CR programme to a large cohort that will aim to assess the clinical- and cost-effectiveness of the intervention.

The USEQ responses demonstrated that our online telerehabilitation and tele coaching programme could be considered feasible as it was rated by our participants to be enjoyable (i.e., Q1), safe, with easy-to-follow guidance and with no general discomfort. Other studies have also attempted to evaluate cardiac telerehabilitation programmes in cardiac patients. Namely, cardiac patient's experiences suggest that telerehabilitation could be beneficial for their education and eHealth literacy skills[28], improve recovery after a cardiac surgery and overall QoL[29], and easy to be integrated within their daily lives due to its flexibility (e.g., not limited to the hospital setting)[30]. Therefore, it seems that cardiac patients believe that an online telerehabilitation programme is acceptable, beneficial, and pragmatic to be integrated in their daily lives.

The high rates of compliance and retainment to the implemented exercise programme (91.6% and 90.9% for the online and gym-based groups, respectively) is an encouraging sign of the feasibility and acceptability of our novel intervention, aiming at people with a recent MI. Participants appeared to enjoy the overall experience with the advanced technology and were motivated to adhere to the exercise programme. Undoubtedly, the use of the wearable devices for the remotely-monitoring of the online group was found to be the key element of maintaining the exercise intensity at the intended exercise prescription for this population maximising thus the benefits (i.e., training dose-response). A recent scoping review supports that home-based CR using wearable devices can be a comparable alternative to traditional CR for cardiac patients maintaining thus the same effectiveness between these two CR modalities[31].

The remote monitoring (i.e., real time monitoring of the hemodynamic responses during exercise by a cardiologist and supervision by an experienced fitness specialist) in our study allowed the participants to feel safe. Namely, the symptoms during the 6-month exercise intervention were minimal to none. Most importantly, in our study there were no exercise-induced symptoms and/or hospitalisations. The use of the wearable devices for the remotely-monitoring in combination with the real time supervision (i.e., fitness specialist) and the hemodynamic responses assessment (i.e., by the cardiologist) of the online group was found to be the key element of patients' safety during the CR programme.

Overall, the exercise programme stressed the cardiovascular system moderately (~ 67% of HR_{peak} for both groups), the RPE also depicted a light to moderate intensity (12 ± 1 "light to somewhat hard", Borg scale) and the mean affect was reported as good throughout the whole exercise session (+ 3 "good"). Our data indicated that the online group adhered to the prescribed exercise intensity equally to the gym-based group. These findings come in agreement with previous research that has demonstrated the exercise adherence (i.e., time spent at the prescribed training intensity) in phase two cardiovascular rehabilitation for both the telehealth and outpatients training groups[32]. Adhering to a prescribed exercise intensity during a CR programme is critical for the attainment of the expected cardiorespiratory and cardiovascular adaptations[33]. In turn, these adaptations will lead to an improved physical and functional fitness concomitantly improving QoL in people with a recent MI[11].

Evidently, our exercise programmes both for the online- and gym-based groups were almost asymptomatic with the symptoms-frequency being at 1.4% across a 6-month exercise intervention. To highlight none of the symptoms were exercise-induced originated. Although the safety of cardiac telerehabilitation has previously been demonstrated[34], this is the first telerehabilitation trial exclusively in MI patients with a combination of telemonitoring and tele-coaching event using a plethora of wearable devices demonstrating its safety and feasibility. The wearable devices were able to control in real time a series of physiological responses (i.e., HR, ECG, saturation of oxygen and blood pressure) based on which an experienced cardiologist could secure patients' safety. Therefore, our participants were able to exercise in an appropriate prescribed intensity that would allow for beneficial cardiovascular adaptations securing simultaneously their safety.

Limitations

In our study, all our participants were holding a basic computer literacy thus they were able to use a laptop/tablet and perform online meetings. However, it needs to be mentioned that we did not exclude any participants due to computer illiteracy. The mean age of our participants could potentially justify the basic (i.e., using smart devices) computer literacy. Another potential limitation might be the 'Hawthorne effect'[35] on the USEQ responses as a result of studying human behaviour under laboratory conditions. In future telerehabilitation studies, it would be useful to include cardiac patients without computer literacy to evaluate the feasibility of telerehabilitation in this group of people.

Conclusion

Our participants had an overall positive experience and acceptability of the cardiac telerehabilitation and tele coaching using wearable devices. Our cardiac telerehabilitation programme seems to be feasible, acceptable, safe, and suitable for people with a recent MI. Future studies shall investigate the cost-effectiveness of such a cardiac telerehabilitation programme in a large cohort of people following a recent MI for a longer period (i.e., >6 months) including people from low socioeconomic backgrounds[36,37].

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Ethics statement

The studies involving humans were approved by the Research Ethics Committee of the School of Physical Education and Sport Science at Thessaloniki (Greece). The studies were conducted in accordance with local legislation and institutional requirements. The participants provided their written informed consent to participate in this study.

Consent for Publication

Not applicable.

Author contributions

AM: Conceptualization, Formal Analysis, Methodology, Writing – original draft, Writing – review & editing. MA: Conceptualization, Formal Analysis, Methodology, Writing – original draft, Writing – review & editing. GK: Conceptualization, Formal Analysis, Methodology, Writing – original draft, Writing – review & editing. AN: Formal Analysis, Methodology, Writing – original draft, Writing – review & editing. KA: Formal Analysis, Methodology, Writing – original draft, Writing – review & editing. EK: Conceptualization, Formal Analysis, Methodology, Supervision, Writing – original draft, Writing – review & editing.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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