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Traditional versus extended hybrid cardiac rehabilitation based on the continuous care model for patients who have coronary artery bypass surgery in a middle-income country: A Randomized Clinical Trial

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Conflict of interest

The authors declare that they have no conflicts of interest. Also, the app is not being used for commercial purposes. It was only designed for this research.

Trial registration: IRCT20130211012439N3.

Traditional versus extended hybrid cardiac rehabilitation based on the continuous care model for patients who have coronary artery bypass surgery in a middle-income country: A Randomized Clinical Trial

Abstract

Objective: To compare traditional (1-month supervised) versus hybrid cardiac rehabilitation (CR; usual care) with an additional 3 months offered remotely based on the continuous care model (CCM; intervention), in coronary artery bypass graft (CABG) patients.

Design: randomized controlled trial, with blinded outcome assessment.

Setting: A major heart center in a middle-income country.

Participants: Of 107 eligible patients that were referred to CR during the period of study, 88 (82.2%) were enrolled (target sample size). Participants were randomly assigned 1:1 (concealed; 44 per parallel arm). There was 92.0% retention.

Intervention: After CR, participants were given an app and communicated biweekly with the nurse from months 1-4 to control risk factors.

Main Outcome Measures: Quality of life (QoL; SF-36; primary outcome), functional capacity (treadmill test), depression, anxiety and stress (DASS-21) were evaluated pre-CR, after one month, and three months after CR (end of intervention), as well as re-hospitalization.

Results: The analysis of variance interaction effects for the physical and mental component summary scores of QoL were <.001, favoring intervention (per protocol); there were also significant increases from pre-CR to 1 month, and from 1 month to the final assessment in the intervention arm (p-values<.001), with change in the control arm only to 1 month. The effect

sizes were 0.115 and 0.248, respectively. Similarly, the interaction effect for functional capacity was significant ($p<.001$), with a clinically-significant 1.5 MET increase in the intervention arm. There were trends for group effects for the psychosocial indicators, with paired t-tests revealing significant increases in each at both assessment points in the intervention arm. At 4 months, there were 4 (10.3%) re-hospitalizations in the control arm, and none in intervention ($p=.049$). Intended theoretical mechanisms were also impacted by the intervention.

Conclusion: Extending CR in this accessible manner, rendering it more comprehensive, was effective in improving outcomes.

Keywords: Cardiac rehabilitation, continuity of patient care, coronary artery bypass surgery, quality of life, telemedicine, secondary prevention, global health, randomized controlled trial, health services accessibility, nursing models

Abbreviations: CABG (Coronary Artery Bypass Graft Surgery, CCM (Continuous Care Model), CR (Cardiac Rehabilitation), CVDs (Cardiovascular Diseases), LMICs (Low- and Middle-Income Countries), MET (Metabolic Equivalent of Task), QoL (Quality of Life).

Introduction

Cardiovascular diseases (CVDs) are among the leading burdens of disease and disability globally.(1, 2) The burden is greatest in low-and middle-income countries (LMICs), with Iran having one of the highest age-standardized prevalence rates of CVD (>9000 cases per 100,000 people),(1) and among the highest burden of CVD in the Eastern Mediterranean Region.(3, 4) Coronary artery bypass graft (CABG) surgery is the major means of acute revascularization for CVD,(5) but the patients are at continued heightened risk of mortality and morbidity without secondary prevention.

Cardiac rehabilitation (CR) is a proven means of mitigating this risk.(6) Unfortunately, it is not highly available, particularly in LMICs, including Iran where an estimated 219,007 additional CR spots are needed annually.(7) Moreover, CR in LMICs is of lower dose or sessions,(7) which may impede the benefits that can achieve,(8) and less comprehensive,(7) such that all risk factors may not be sufficiently addressed.(9, 10) Moreover, alternative, lower-cost models (11) are needed if we are to increase capacity to meet need, and remote models in particular are necessary for the current era of the COVID-19 pandemic.(12) this could enable more dose and potentially more comprehensiveness.

Based on our forthcoming review of CR trials in LMICs, there have only been 26 trials to date.(13) None were theoretically-based. Meta-analyses revealed significantly greater functional capacity and quality of life (QoL) with CR when compared to usual care.(13) Only 4 trials assessed re-hospitalization,(14-17) and few assessed important psychosocial well-being indicators,(18-24) given the high burden of distress in those living with CVD.(25)

Therefore, we conducted a trial to test whether a hybrid model with an additional 3 months offered remotely based on the continuous care model (CCM) (26) was superior to traditional CR on QoL and functional capacity (primary outcomes), psychosocial well-being indicators (depression, anxiety, and stress), and re-hospitalization (secondary outcomes) in a low-resource setting. The effect of the intervention on perceptions of care continuity and chronic care quality as well CR beliefs were also investigated, to confirm intended mechanisms of action.

Methods

This randomized controlled trial was conducted in Farshchian Heart Center, affiliated with Hamadan University of Medical Sciences in Iran. The patients were enrolled voluntarily into the trial with informed consent. The Ethics Committee of Tarbiat Modares University approved the trial (IR.MODARES.REC.REC.1397.183). Note it is not ethical to have a no CR arm.

The protocol was registered with the Iranian Registry of Clinical Trials on January 16, 2019 (IRCT20130211012439N3). Some changes were made following registration but before recruitment, namely addition of functional capacity as a co-primary outcome given its' clinical importance, addition of an app to the intervention to support continuous care, and 2 exclusion criteria as outlined below.

Setting

As shown in Figure 1, at the time of discharge from the hospital, with the cardiac surgeon's confirmation of eligibility, all CABG patients were registered with the outpatient CR program of the same hospital. Two months post-discharge, they were called by the CR program to have an initial appointment.

At that time, after the patient's history was taken and they were seen by the doctor, an exercise test was performed. The symptom-limited treadmill test using a modified Bruce protocol informed the exercise prescription for each patient, after which patients were informed and invited to participate in the trial (FP).

All patients are offered 12 supervised group CR sessions, 3 times a week for 4 weeks. During the approximately 1-hour sessions, patients would warm-up, exercise according to their prescription on a bicycle, treadmill or arm ergometer, do weight training and finally cool down. There is no active risk factor management other than advice, formal patient education, nor post-program re-assessment.

The control group received no further care after one month (Figure 1). At the end of the study, an educational booklet regarding risk factor management was provided to these participants. Patients in the control group participated in CR on odd days of the week, and patients in the intervention group participated on even days (i.e., included weekends).

Intervention

Participants in the intervention group received this traditional CR during the first month, with additional education and care also delivered to them in-person and through small discussion groups. Indeed, participants in the intervention group received care from the start of CR through four months in line with the 4-stage CCM.(26) Details about content at each stage is provided in the supplemental materials; in the first month when patients were coming on site for CR it was delivered in-person, and in the subsequent 3 months it was delivered via smartphone (Figure 1). Overall, the participants in the intervention group were offered 8 in-person sessions based on the CCM during the first month (including their CR visits), as well as approximately 4 group

discussion sessions. In the remote phase, each participant in the intervention group was contacted 24 times over 3 months through the mobile application.

The app, designed and created by the researcher and information technology team for the trial, then revised following input by senior authors and CR providers, was installed on participants` mobile phones. Based on research on mobile-based learning,(27-29) we developed the software which comprised educational content about cardiac diseases (including videos about heart attack, CABG), control of medical risk factors (high blood pressure, cholesterol and blood sugar) with cardiac medications, control of lifestyle risk factors (diet, tobacco harms and cessation strategies, stress management), and cardiac resuscitation.

The app also provided a means for patients to communicate with the treatment team whenever they needed help. From months 1-4, twice a week, the patients` status was checked in the app, and patients were guided towards treatment targets for risk factors (stage 3 of CCM).(30)

Design and Procedure

Randomization

After the first CR visit, eligible patients were randomly assigned to the intervention or control groups (1:1, parallel) using the balance block randomization method. As with most CR trials, participants and providers could not be blind to randomization.

Allocation remained concealed throughout the study. To achieve this, we prepared four sheets of paper: two sheets were demarcated “I” for “intervention” and two “C” for control”. The paper sheets were pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets were drawn. The four sheets of paper were then

placed back into the container, and this process repeated until the needed sample size was reached. This was done by the researcher (FP).

All assessments were completed pre-CR, after one month (after 12 sessions of supervised CR in both arms, and 1 month in-person CCM in the intervention arm only) and 3 months after the end of CR (i.e., 4 months from pre-CR, during which the intervention arm had the remote CCM intervention; Figure 1). This involved self-report questionnaires (all in Persian) and exercise testing. The same CR nurse (ZG) performed the assessments at each time point; she was blinded to random allocation.

Measures

Sociodemographic and clinical characteristics were assessed at baseline. Full details on all measures can be found in the Supplement.

Intervention Process Indicators

The intervention impact in improving patient engagement with the secondary prevention and care was assessed using 3 psychometrically-validated tools, namely the Patient Assessment of Chronic Illness Care (PACIC),(31) Heart Continuity of Care Questionnaire (HCCQ),(32-34) and the Beliefs About Cardiac Rehabilitation scale (BCR-Q).(35)

Outcomes

The primary outcome of interest was QoL, evaluated using the SF-36 (Version 1.0), using its' two summary measures: the Physical component summary (PCS) score and Mental Component Summary (MCS) score, each ranging from 0 to 100, with higher scores reflecting better QoL.(36, 37) The 8 subscale scores were also considered.

For the other primary outcome of functional capacity, participants in the intervention and control groups were tested on a treadmill before starting CR. One and three months later, both groups were re-tested. The symptom-limited exercise stress test was performed on treadmill according to a modified Bruce protocol.

The secondary outcomes of interest included psychosocial well-being indicators, namely depressive symptoms, anxiety and stress (DASS-21).(38) Finally, all-cause re-hospitalization was assessed one and three months after CR through checking the computer system and directly querying patients.

Participants

The study population comprised patients having CABG at the center from October 2019-April 2020. Patients with any of the following were excluded: (a) New York Heart Association class III or IV; (39) (b) Severe musculoskeletal issues; (c) Positive exercise test (i.e., ischemia); (d) no smartphone; and (e) serious mental illness (indicated by taking medication for psychiatric disorders). The latter 2 criteria were added after the start of the study.

Sample Size

Needed sample was determined based on the results of the somewhat similar clinical trial by Hojskov et al.,(40) using their mean QoL PCS and MCS scores in the exercise and in the psycho-education groups at follow-up. We planned for an estimated 30% loss to follow-up. Through manual sample size calculation,(41) to detect a group difference at the 95% significance level with 80% statistical power, it was determined 44 participants were needed in each group (total N=88).

Statistical Analyses

All analyses were performed using the Statistical Package for the Social Sciences version (SPSS Inc, Chicago, IL, USA) (version 16). Differences in sociodemographic and clinical characteristics by arm, and between those retained- versus- lost to follow-up, were tested using independent samples t-tests and chi-square analyses.

Outcome analyses were performed per-protocol. The relationships between the dependent and independent (i.e., arm) variables were investigated using ANOVA for continuous variables, and Fisher's exact test for the categorical variable (i.e., re-hospitalization). With many outcomes when considering subscales, a Bonferroni correction was applied, with $P<0.004$ considered statistically significant. Finally, given the design nature, unplanned exploratory analyses were also performed using paired t-tests, to test for change in process and outcome indicators by time point in each arm.

Results

Participant Characteristics

The study flow is depicted in Fig. 2; 82.2% of indicated patients were included in the trial, with one excluded for retinal damage. Their characteristics shown in Table 1 convey effective randomization.

Moreover, there were no differences by arm in pre-CR values of the primary and secondary outcomes measures (not applicable for re-hospitalization; means shown in Table 2, all p-values >0.05) nor process indicators (means shown in Table 3, all p-values >0.05). Sixty-three (71.6%) participants had elevated depressive symptoms, 71 (80.7%) elevated anxiety symptoms, and 48 (54.5%) elevated stress.

Of the 88 participants, 7 individuals were lost to follow-up or discontinued intervention (92.0% retention). Differences between participants who were retained versus lost to follow-up are shown in Supplemental Table 1. The only difference was with regard to educational attainment, in that those participants lost to follow-up patients had significantly lower education.

Intervention Process Indicators

Figure 2 shows 1 participant in control and 1 participant in intervention group dropped out of the 1-month traditional exercise-based CR program. No intervention participant withdrew from the remote CCM intervention in months 1-4.

Table 3 shows the intervention process indicators by time and arm. There was a significant time by arm interaction effect for arm for every subscale, supporting hypotheses, with all but the practical barriers and perceived personal suitability subscales of the Beliefs about CR scale surviving the Bonferroni adjustment (there was still a significant group effect for the latter). Moreover, in support of hypotheses, there was a significant increase in every process indicator from pre-CR to 1 month, and through the final assessment point in the intervention arm (all p-values <.001). In the control arm, there were similar increases from pre-CR to one month (no change in practical barriers), without change from 1 month to the final assessment point in all but relational continuity; all PACIC subscales and the total score had significant decay.

Outcomes

PCS and MCS scores are also shown in Figure 3 (primary outcomes); for both, the interaction effects from the ANOVAs were significant, such that there were significant increases from pre-CR to 1 month, and from 1 month to the final assessment point in the intervention arm (all p-values <.001), with change in the control arm only to the 1-month assessment point and

only maintenance thereafter. The effect size (Eta-squared) for the PCS and MCS scores of QoL were 0.115 (standard error [SE] of intervention=1.532, control=1.590) and 0.248 (SE of intervention=1.109, control=1.151), respectively. The effect size for the PCS would be considered moderate (>0.06) and for the MCS as large (>0.14).(42,43) Moreover, given the minimal clinically-important difference of 5 for both the MCS and PCS in CVD,(44-46) as shown, clinically-significant improvements were evidenced with CR in both arms to one month, but only in the intervention arm to the final assessment.

The results of the repeated-measures ANOVAs for the QoL subscales are shown in Table 2. For 7/8 subscales, there were significant interaction effects (trend for physical functioning), favoring intervention, with the following subscales surviving adjustment: general health, social functioning, and emotional well-being. The unplanned post-hoc analysis revealed a significant increase in every subscale from pre-CR to 1 month, and from 1 month to the final assessment point in the intervention arm (all p-values <.001). Increases would be considered clinically significant.

For functional capacity (Table 2), the interaction effect from the ANOVA was <.001, and there were significant increases from pre-CR to 1 month, and through to the final assessment point in the intervention arm (both p-values <.001), but no change in the control arm. Indeed, in the intervention arm there was a 1.5 MET increase, considered clinically significant.(47)

Regarding secondary outcomes, results in Table 3 show for all 3 DASS subscales, there were no significant interaction effects, but trends for group effects (same for total). However, the post-hoc analyses again revealed a significant increase in every subscale from pre-CR to 1 month, and then to the final assessment point in the intervention arm (all p-values <.001), with only change to 1-month in the control arm.

Finally, at 1 month, there was 1 (2.4% of participants) hospitalization in the control arm (wound infection), with none in intervention (P=0.049). At the final assessment, there were still none in intervention participants, but 4 (10.3%) in the control arm (2 with non-cardiac 1 each with chest pain, hypertension, and renal failure; P=0.049).

Discussion

This trial has, as hypothesized, confirmed the benefits of the CCM, applied in a hybrid CR model including remote delivery, on outcomes that are important to patients, namely morbidity, functional capacity, QoL and psychosocial well-being. Indeed, the improvements in functional capacity and QoL were clinically significant, with the improvement degree in cardiorespiratory fitness leading to reduced mortality.

To our knowledge, this is the first theoretically-informed CR trial in a LMIC. The CCM was effective in not only improving the primary and secondary outcomes in this trial, but also impacting the process indicators as hypothesized. Indeed, CR participants exposed to the CCM had significantly more positive perceptions of the quality of their care and its continuity. It even resulted in more positive CR beliefs through to 4 months; this may be the first trial to demonstrate change in such beliefs; this could be of great utility when trying to engage cardiac patients in their acute care and early outpatient's phases who are reluctant to engage in CR. This is consistent with Moosavinasab et al.'s review of 51 articles applying the CCM, concluding this model is effective in ameliorating various outcomes of patients with acute and chronic diseases.(48) Indeed, the CCM lent itself nicely to the CR setting, raising an important theoretical basis to CR approaches, that should be more widely tried given these positive results. A study by Mojalli et al. (2018) in a CR setting specifically also showed that the CCM had a

significant effect on empowerment and improved cardiovascular indicators (blood pressure, cholesterol and blood sugar) in patients with ischemic heart disease.(49) The effectiveness of this model is also evident in a few other CR studies,(49) but there are not yet many. Clearly, more are warranted.

Directions for Future Research

These compelling findings suggest the CCM-based hybrid CR program with remote delivery should be tested in other settings, to determine if findings are replicable. Indeed, Iran is a leader with regard to hybrid CR delivery in LMICs.(50) Use of the app with more heterogeneous cardiac patients indicated for CR could be tested. Also, this would ensure findings are generalizable with other intervention deliverers (although given the number of CCM studies, it appears well-standardized and translates well across deliverers).(48) A future trial could perhaps be powered for so-called "hard outcomes" such as mortality, given the promising differences in re-hospitalization observed in this trial. Cost-effectiveness should also be investigated. The hybrid nature of the program could render the model particularly efficient, as shown with other CR interventions.(11) Another issue that requires future research would be how to implement the model more broadly should it prove its' advantages.(51)

Implications

The CCM ensured CR was more comprehensive, in line with clinical practice guidelines.(52) Pending cost analysis as suggested above, the remote aspect may render it more cost-efficient, such that dose of CR could be increased. Indeed, this is imperative given CR is less comprehensive in Iran, the Eastern Mediterranean Region, and beyond, lessening benefits.(53) In order to implement this model more broadly, it is important to ensure that supervised and

unsupervised CR delivery are reimbursable services,(54) as is acute care. Iran is a real success story in that it successfully advocated for health insurance coverage of CR.(55) It will be important to ensure that the full hybrid model, including the app, are reimbursed services, so patients are not paying-out-of-pocket.

Study Limitations

Caution is warranted in interpreting these results. This was single-center trial, limiting generalizability; whether results would hold in other parts of Iran, the Eastern Mediterranean Region, and beyond warrants investigation, as outline above.

With regard to design, another limitation of the present trial was that blinding of arm to the patients or providers was not possible. Moreover, outcome data were not imputed, so analyses were not done based on intention-to-treat.

Conclusions

This trial demonstrates that applying the CCM to CR in a hybrid delivery model results in clinically-significant improvements in QoL and functional capacity, as well as reduced re-hospitalization. The CCM, a theoretical framework lending itself nicely as a foundation to CR, positively impacts patient perceptions of care quality, continuity and their beliefs about CR. Although replication is warranted in broader samples, these compelling results suggest there is hope to augment CR dose in an effective and potentially cost-efficient manner, so more patients can achieve the benefit from these life-saving services.

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Table 1: Pre-cardiac rehabilitation sociodemographic and clinical characteristics of trial participants by arm

	Intervention group N=44	**Control group** N=44	**p**[†]
Sociodemographic			
Sex (% male)	36 (81.8)	38 (86.4)	0.772
Age (years)	62.6 (8.1)	62.9 (9.8)	0.859
Residence (% city)	40 (90.9)	37 (84.1)	0.521
Work Status (%)			
Part-time	18 (40.9)	14 (31.8)	0.815
Full-time	6 (13.6)	7 (15.9)	
On disability	5 (11.4)	7 (15.9)	
Retired	15 (34.1)	16 (36.4)	
Highest Educational Attainment (%)			
Less than high school	4 (9.1)	7 (15.9)	0.621
High school	21 (47.7)	20 (45.5)	
Post-secondary or greater	19 (43.2)	17 (38.6)	
Clinical			
Risk Factors			
Diabetes mellitus (% yes)	20 (45.5)	16 (36.4)	0.386
Family History of CVD (% yes)	23 (52.3)	29 (65.9)	0.193
Hypertension (% on medication)	29 (65.9)	31 (70.5)	0.647
Body Mass Index (kg/m^2)[*]	26.3 (3.7)	26.78 (4.3)	0.601
Waist Circumstance (cm)[*]	88.8 (9.5)	86.0 (9.2)	0.171
High Density Lipoprotein (mg/dl)[*]	36.1 (6.9)	35.1 (6.8)	0.447
Low Density Lipoprotein (mg/dl)[*]	89.4 (33.6)	87.4 (33.9)	0.786
Triglycerides (mg/dl)[*]	156.7 (69.3)	144.5 (60.0)	0.378
Cholesterol (mg/dl)[*]	164.5 (41.8)	149.5 (45.6)	0.111
Tobacco Use (%)			
Current	5 (11.4)	6 (13.6)	0.564
Former	16 (36.4)	20 (45.5)	
Never	23 (52.3)	18 (40.9)	
Comorbidities (%)			
Arthritis	6 (13.6)	5 (11.4)	0.747
Other musculoskeletal issues	5 (11.4)	9 (20.5)	0.244
Drug addiction	3 (6.8)	7 (15.9)	0.179
Cardiac Medications (%)			

Beta-blockers	26 (59.1)	24 (54.5)	0.667
Statins	36 (81.8)	39 (88.6)	0.367
ACE/ARB	19 (43.2)	16 (36.4)	0.513
Anti-Diabetic	18 (40.9)	16 (36.4)	0.661

[†]based on chi-square or t-test as applicable

CVD=Cardiovascular Diseases; ACE/ARB=Angiotensin II Receptor Blocker/ Angiotensin-Converting-Enzyme inhibitors

Note: mean (standard deviation) or n (%) shown.

Table 2: Primary and Secondary Outcomes by Arm and Time, in retained sample

Primary Outcome	**Group**	Assessment Point			**P for group**	**P for interaction**
		Pre-CR	**1 month later** (both groups had supervised CR, intervention group also CCM)	**3 months later** (intervention group remote delivery CCM only)		
SF-36 Domains*						
General Health	Intervention	52.7 (16.5)	75.2 (8.2)‡	81.3 (7.1)‖	<0.001	<0.001
	Control	54.8 (14.7)	65.8 (10.5)‡	65.6 (10.3)		
Physical Functioning	Intervention	68.5 (24.1)	84.9 (8.8)‡	88.5 (7.3)‖	0.038	0.068
	Control	70.0 (19.6)	77.1 (14.8)	79.5 (11.4)		
Role Limitation due to Physical Health	Intervention	50.0 (31.1)	70.9 (23.1)‡	80.4 (17.1)‖	0.066	0.009
	Control	48.3 (32.1)	61.3 (23.6)§	62.8 (24.2)		
Role Limitation due to Emotional Health	Intervention	59.8 (31.8)	89.1 (15.8)‡	94.4 (12.6)‖	0.212	0.038
	Control	62.1 (31.1)	78.6 (23.1)‡	83.8 (18.5)		
Pain	Intervention	71.9 (15.1)	82.4 (13.1)‡	88.9 (9.7)‖	0.014	0.009
	Control	69.4 (16.1)	74.5 (14.9)§	77.4 (16.1)		
Social Functioning	Intervention	61.1 (14.3)	73.5 (12.3)‡	84.5 (12.0)‖	<0.001	<0.001
	Control	58.2 (14.5)	68.2 (11.8)‡	69.6 (13.4)		
Energy-Fatigue	Intervention	55.7 (9.3)	70.6 (11.6)‡	73.2 (11.0)‖	<0.001	0.016
	Control	51.6 (11.1)	62.6 (9.8)‡	62.4 (9.5)		
Emotional Well Being	Intervention	58.8 (9.7)	79.4 (7.4)‡	81.7 (6.6)‖	<0.001	<0.001
	Control	57.7 (8.2)	62.2 (9.0)§	61.6 (9.0)		
Metabolic equivalent of task (METs)	Intervention	6.0 (1.8)	7.0 (1.9)‡	7.5 (1.9)‖	0.027	<0.001
	Control	5.7 (1.8)	6.1 (1.9)	6.0 (1.7)		
Secondary Outcomes						
DASS-21†						
Depression	Intervention	13.6 (7.6)	5.5 (5.2)‡	4.5 (4.4)‖	0.063	0.234
	Control	15.1 (8.8)	8.0 (5.8)‡	7.7 (5.3)		
Anxiety	Intervention	13.7 (7.8)	4.1 (3.8)‡	3.8 (3.4)‖	0.028	0.938
	Control	15.6 (8.3)	6.8 (4.2)‡	6.3(4.2)		
Stress	Intervention	15.5 (7.6)	6.9 (5.8)‡	5.6 (5.4)‖	0.022	0.170
	Control	17.8 (8.0)	10.1 (6.1)‡	9.7 (6.6)		

Total score	Intervention	41.0 (20.9)	16.3 (12.2)‡	14.0 (10.6)‖	0.001	0.327
	Control	47.6 (24.7)	24.4 (15.0)‡	23.7 (13.7)		

CR=cardiac rehabilitation; CCM=continuous care model

*scores range from 0 to 100. Note the physical and mental component summary scores are the primary outcomes (see Figure)

†scores range from 0 to 42

paired t-test by arm from baseline to 1 month assessment point, ‡p<.001, §p<.05

§paired t-test by arm from 1 month to final assessment point, ‖p<.001

Table 3: Intervention Process Indicators by Arm and Time, in retained sample

Variables	Group	Pre-CR	1 month later (both groups had supervised CR, intervention group also CCM)[§]	3 months later (intervention group remote CCM delivery only)[‖]	P for group	P for interaction
Heart Continuity of Care[*]						
Informational	Intervention Control	2.3 (0.4) 2.3 (0.3)	4.7 (0.2)[§] 3.4 (0.3)[§]	4.8 (0.2)[‖] 3.3 (0.3)	<0.001	<0.001
Relational	Intervention Control	2.5 (0.3) 2.5 (0.3)	4.1 (0.3)[§] 3.4 (0.4)[§]	4.3 (0.3)[‖] 3.2 (0.4)[‖]	<0.001	<0.001
Management	Intervention Control	1.9 (0.5) 2.0 (0.6)	2.6 (0.7)[§] 2.8 (0.6)[§]	3.0 (0.7)[‖] 2.7 (0.5)[‖]	0.786	<0.001
Chronic Illness Care[†]						
Patient Activation	Intervention Control	1.8 (0.4) 1.8 (0.4)	4.1 (0.5)[§] 3.0 (0.5)[§]	4.1 (0.5)[‖] 2.8 (0.6)[‖]	<0.001	<0.001
Delivery System Design/Decision Support	Intervention Control	2.3 (0.5) 2.2 (0.5)	3.9 (0.7)[§] 3.2 (0.5)[§]	4.4 (0.5)[‖] 2.4 (0.6)[‖]	<0.001	<0.001
Goal Setting	Intervention Control	1.9 (0.4) 1.9 (0.4)	4.5 (0.5)[§] 2.8 (0.4)[§]	4.6 (0.4)[‖] 2.1 (0.5)[‖]	<0.001	<0.001
Problem- Solving/ Contextual Counseling	Intervention Control	2.0 (0.4) 2.0 (0.4)	4.3 (0.5)[§] 2.62 (0.5)[§]	4.5 (0.4)[‖] 2.3 (0.5)[‖]	<0.001	<0.001
Follow-up/ Coordination	Intervention Control	1.7 (0.4) 1.7 (0.5)	4.2 (0.7)[§] 2.9 (0.5)[§]	4.4 (0.5)[‖] 2.1 (0.5)[‖]	<0.001	<0.001
Overall	Intervention Control	1.9 (0.3) 1.9 (0.3)	4.3 (0.4)[§] 2.9 (0.3)[§]	4.4 (0.3)[‖] 2.3 (0.3)[‖]	<0.001	<0.001
Beliefs about CR[‡]						
Perceived Necessity	Intervention Control	2.8 (0.4) 2.8 (0.4)	4.5 (0.3)[§] 3.8 (0.4)[§]	4.7 (0.2)[‖] 3.8 (0.4)	<0.001	<0.001
Concerns about CR	Intervention Control	2.8 (0.5) 2.6 (0.5)	4.2 (0.6)[§] 3. 6 (0.5)[§]	4.6 (0.3)[‖] 3.7 (0.4)	<0.001	<0.001
Practical Barriers	Intervention Control	2.9 (0.73) 2.8 (0.7)	3.2 (0.7)[§] 3.0 (0.6)	3.5 (0.6)[‖] 3.0 (0.6)	0.015	0.032

Perceived Personal Suitability	Intervention	2.3 (1.0)	3.9 (0.7)[§]	4.3 (0.5)[‖]	0.002	0.017
	Control	2.3 (0.9)	3.5 (0.7)[§]	3.6 (0.7)		

CR=Cardiac Rehabilitation; CCM=continuous care model.
Note: mean (standard deviation) shown.
[*]scores range from 0 to 5
[†]scores range from 1 to 5
[‡] scores range from 1 to 5
[§] paired t-test by arm from baseline to 1 month assessment point, [§]p<.001
[‖] paired t-test by arm from 1 month to final assessment point, [‖]p<.001

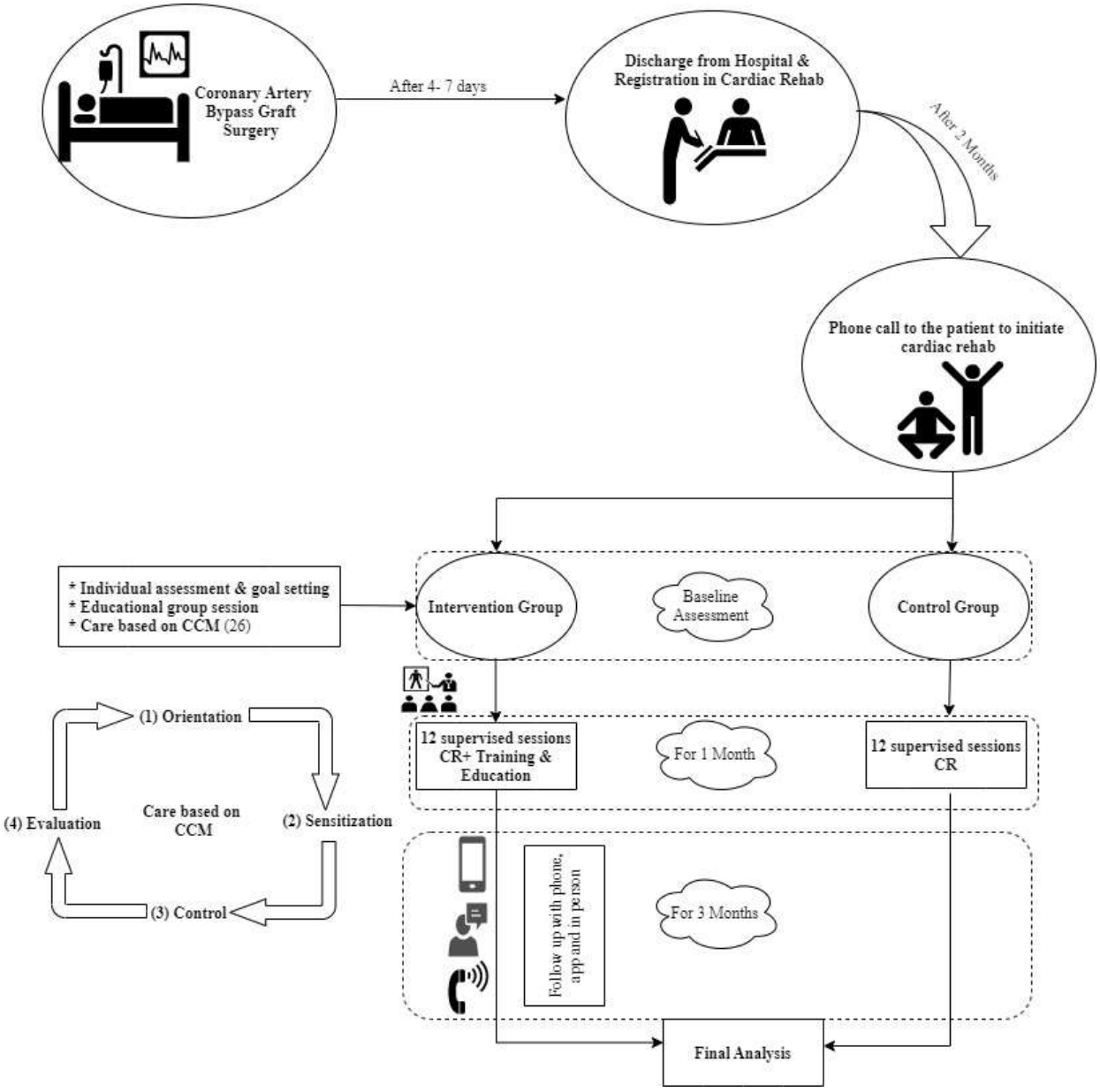


Figure 1: Trial and Intervention Design

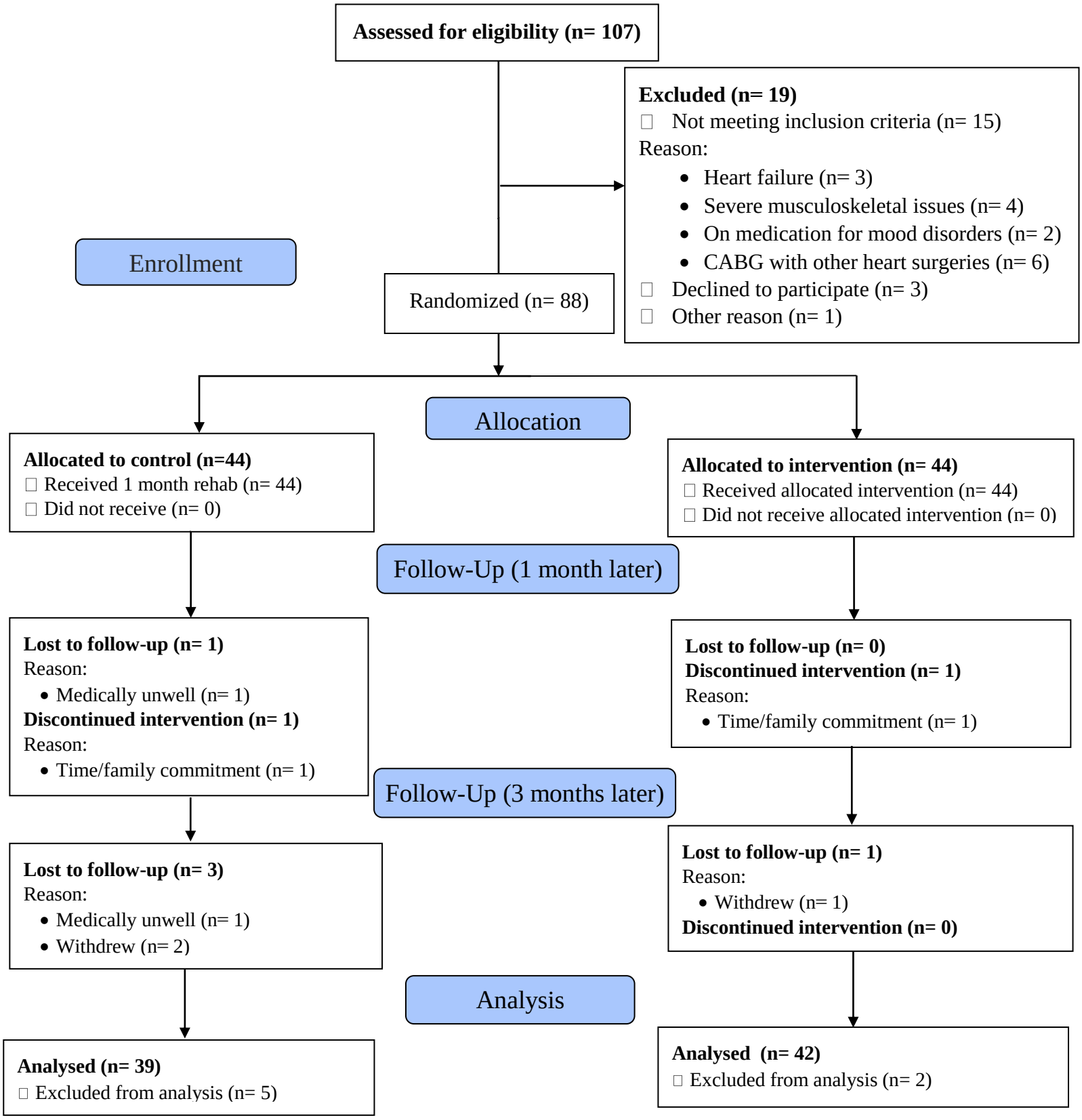
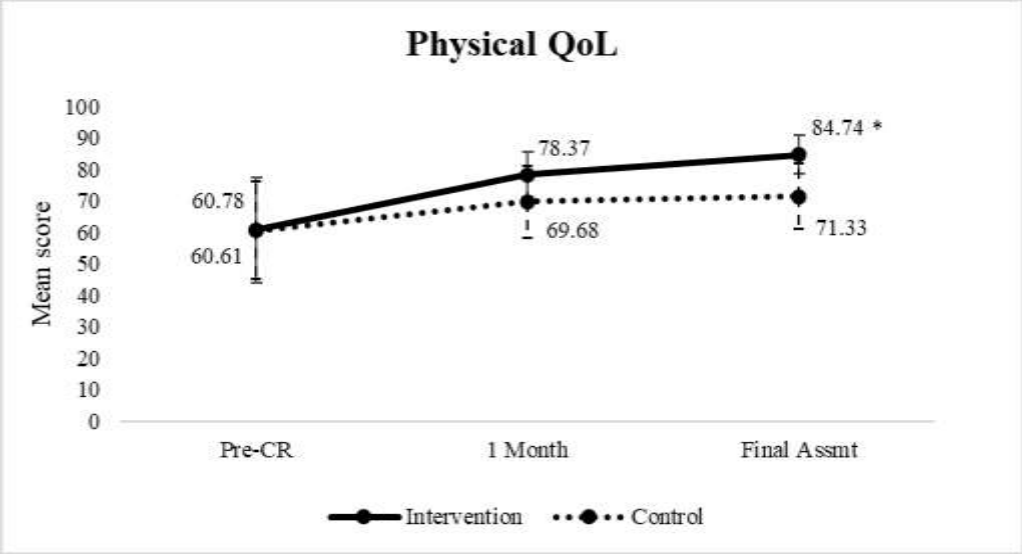


Figure 2: Consolidated Standards of Reporting Trials flow diagram



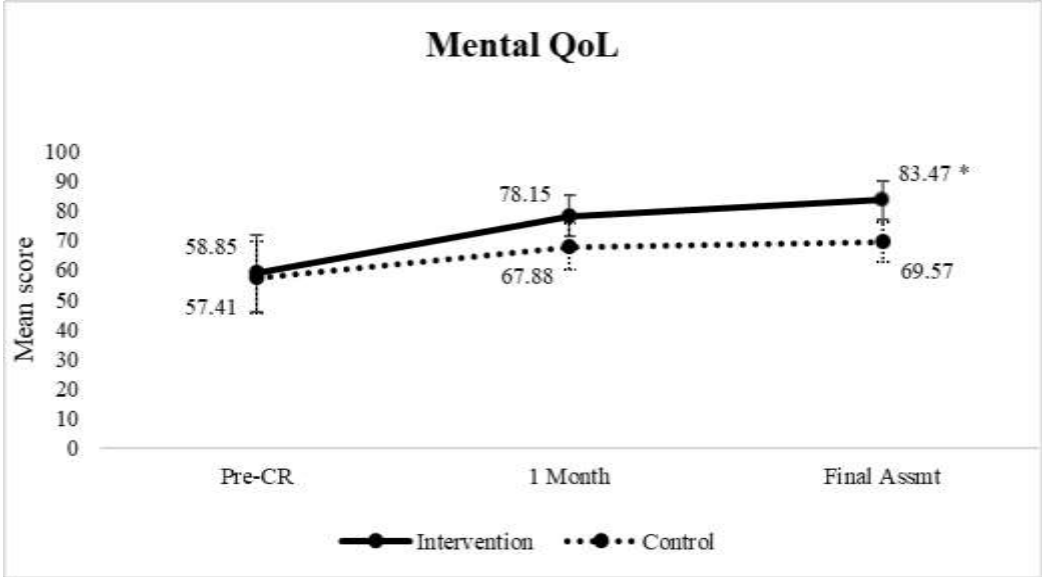


Figure 3: Physical (a) and Mental (b) Quality of Life by Arm and Time in Retained Sample. Scores range from 0-100, with higher scores representing better QoL. *repeated mesures ANOVA by arm and time, p<.001

Supplementary:

Measures:

Sociodemographic variable including sex, age, work and educational status, as well as clinical variables including risk factors, comorbidity and cardiac medications were assessed at baseline (Table 1). The CR nurse took the patient's history and reviewed their medical documents.

Intervention Process Indicators

The Patient Assessment of Chronic Illness Care (PACIC) (1) comprises 20 items corresponding to each of the 5 subscales of Wagner's chronic care model, namely Patient Activation (3 items), Delivery System Design/Decision Support (3 items), Goal Setting (5 items), Problem-Solving/Contextual Counseling (4 items), and Follow-up/Coordination (5 items). Each item is scored on a scale from 1 = "almost never" to 5 = "almost always." Each subscale is scored by averaging the items completed within that subscale, with higher scores indicating better chronic care; The overall PACIC is scored by averaging scores across all 20 items. It has high internal consistency (1).

The original Heart Continuity of Care Questionnaire (HCCQ) (2) is a 33-item self-report questionnaire which measures continuity along three dimensions: informational (17 items), relational (10 items), and management (6 items). Items were rated on a 6-point Likert-type scale from 0=" not applicable" to 5=" strongly agree", as well as the option to choose 'not applicable'. Each subscale is scored by averaging the items completed within that subscale, with higher scores indicating better continuity of care; The HCCQ is reported to be comprehensive, valid, and reliable (2-4).

The final process measure was the Beliefs About Cardiac Rehabilitation scale (BCR-Q) (5), which is comprised of 4 subscales: perceived necessity of CR (5 items), concerns about

exercise (3 items), practical barriers (3 items), and perceived personal suitability (2 items). All items on the BCR-Q are rated on a 5-point Likert scale from 1=”strongly disagree” to 5=”strongly agree”, with the exception of one item on the necessity scale (i.e. ‘some aspects of the CR program are unnecessary for me’), which is reversed-scored. A mean score for all four subscales was calculated, with higher scores indicating more positive CR beliefs. The scale has good internal reliability and demonstrated validity (5, 6).

There were no validated Persian translations of the above scales as there were with the outcome measures, and thus this was undertaken by our group in accordance with best practices (7). The validity of the translated items was then reviewed by 10 nursing faculty members of the university. The overall content validity ratio of the BCR-Q was 0.92, of the PACIC was 0.93, and the HCCQ was 0.91; all acceptable (8). The content validity index scores for all items across all three instruments were above 0.79, which is also considered appropriate (9).

The overall reliability of the scales was also assessed in the sample. For the BCR-Q this was 0.84, for the PACIC was 0.83, and for the HCCQ was 0.92, all considered acceptable. Also, on all the sub-scales of these tools, Cronbach's alpha was acceptable and favorable.

Outcomes

The primary outcome of interest was QoL, evaluated using the SF-36 (Version 1.0) (10), comprising 8 domains: physical functioning (PF; 10 items); role limitations due to physical problems (RP; 4 items), bodily pain (BP; 2 items), vitality (VT; 4 items), general health perception (GH; 5 items), social function (SF; 2 items), role limitation due to emotional problems (RE; 3 items), and mental health (MH; 5 items). These eight scales can be aggregated into two summary measures (primary outcomes): The Physical component summary score (PF,

RP, BP, and GH; PCS) and Mental Component Summary score (SF, RE, MH, and VT; MCS). Scores range from 0 to 100, with higher scores reflecting better QoL (10, 11). The validity and reliability of this questionnaire in Iranian population were confirmed by Montazeri et al. (12).

Functional capacity was also a primary outcome. As outlined above, participants in the intervention and control groups were tested on a treadmill before starting CR. One and three months later, both groups were re-tested. The symptom-limited exercise stress test was performed on treadmill according to a modified Bruce protocol.

The secondary outcomes of interest included psychosocial well-being indicators, namely depressive symptoms, anxiety and stress. The DASS-21 is a self-report questionnaire with 7 items per subscale. Patients were asked to score every item on a scale from 0 (did not apply to me at all) to 3 (applied to me very much). Summary scores are computed by adding up the scores on the items for each subscale and multiplying them by 2. Summary scores for the total DASS-total scale thus ranged between 0 and 126, and those for each of the subscales ranged between 0 and 42 (13, 14). The reliability and validity of this scale in the Iranian population have been established

CCM Intervention

In the first, orientation stage, a 30- to 45-minute face-to-face session with the patient and a partner/informal caregiver was held with a nurse (Figure 1). The objectives were: (1) to introduce the intervention, (2) provide some initial education regarding their cardiac condition, (3) motivate patients and their families to engage in the risk reduction process (4) express the need for contacts throughout the intervention, and (5) the need to continue the care relationship until the end of study.

In the second, sensitization stage, about 3 to 5 training sessions were held in groups of 2 to 3 patients with their families (spouses, or adult children). In which patients and their families became aware of and sensitive to their cardiac problem.

In the control (third) stage, to work towards risk reduction targets, according to the patients` needs and physical activity adherence, care consultations were continued (as frequently as daily). At this point, the bi-weekly follow-ups on the app were completed for the full 3 months (months 1 to 4, when usual care group was receiving no intervention; Figure 1). Patients were encouraged to walk at least 30 minutes, 5 days a week.

The evaluation stage is the fourth and final step of the CCM, the goal being to examine success and failure in risk factor management, such as diet and physical activity, as well as medication adherence; any necessary recommendations were made where patients were not achieving targets.

Supplementary Table 1: Participant characteristics by 3-month retention status

	Retained N=81 (92.0%)	Lost to follow-up N=7 (8.0%)	p*
Sociodemographic			
Sex (% male)	70.0 (86.4)	4.0 (57.1)	0.077
Age (years)	62.3 (9.0)	67.6 (7.1)	0.135
Residence (% city)	71.0 (87.7)	6.0 (85.7)	0.621
Work Status			
Part-time	28.0 (34.6)	4 (57.1)	0.547
Full-time	13.0 (16.0)	0.0 (0.0)	
On disability	11.0 (13.6)	1.0 (14.3)	
Retired	29.0 (35.8)	2.0 (28.6)	
Educational (Less than high school)	7.0 (8.6)	4.0 (57.1)	0.001
Less than high school	39.0 (48.1)	2.0 (28.6)	
High school	35.0 (43.2)	1.0 (14.3)	
Post-secondary or greater			
Clinical Risk Factors			
Diabetes mellitus	34.0 (42.0)	2.0 (28.6)	0.394
Family History of CVD[1]	48.0 (59.3)	4.0 (57.1)	
Hypertension (% on medication)	55.0 (67.9)	5.0 (71.4)	0.607
Body Mass Index (kg/m2)	26.5 (3.8)	27.6 (6.0)	0.476
High Density Lipoprotein (mg/dl)	35.6 (7.0)	35.4 (5.1)	0.967
Low Density Lipoprotein (mg/dl)	89.3 (34.4)	77.7 (21.1)	0.384
Triglycerides (mg/dl)	152.0 (64.2)	134.7 (74.2)	0.502
Cholesterol (mg/dl)	159.0 (44.3)	134.3 (38.7)	0.151
Waist Circumstance (cm)	86.8 (8.8)	94.9 (13.1)	0.157
Tobacco			
Current	11.0 (13.6)	0.0 (0.0)	0.566
Former	33.0 (40.7)	3.0 (42.9)	
Never	37.0 (45.7)	4.0 (57.1)	
Comorbidities			
Arthritis	10.0 (12.3)	1.0 (14.3)	0.882
Other musculoskeletal issues	12.0 (14.8)	2.0 (28.6)	0.340
Drug addiction	10.0 (12.3)	0.0 (0.0)	0.323
Cardiac Medications			
Beta-blockers	47.0 (58.0)	3.0 (42.9)	0.348
Statins	69.0 (85.2)	6.0 (85.7)	0.970
ACE/ARB[2]	31.0 (38.3)	4.0 (57.1)	0.278
Anti-Diabetic	32.0 (39.5)	2.0 (28.6)	0.446

Note: n and %, or mean and standard deviation shown
*based on chi-square or t-test as applicable.
[1] Cardio Vascular Diseases
[2] Angiotensin II Receptor Blocker/ Angiotensin-Converting-Enzyme inhibitors

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