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RESEARCH ARTICLE

Impact of the Cardiac Rehabilitation on Quality of Life and Functional Recovery in theHeart Failure Patients with Reduced Ejection Fraction

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Abstract: Reduced ejection fraction (HFrEF) is a chronic illness that is marked by the loss of the quality of life and functional ability, and impaired ventricular contractility. Nevertheless, most patients still report the lack of exercise, fatigue, and psychosocial distress because of the advancement in pharmacological therapy and device-based treatment. Cardiac rehabilitation (CR) consisting of exercising training, education, and behavioural support is one of the evidence-based interventions that have been demonstrated to promote recovery and overall well-being in the population. The study aimed at determining the CR effects on quality of life and functional recovery of HFrEF patients. It entailed 12 weeks, multidisciplinary CR based intervention of individual aerobic and resistance training, nutritional counselling and psychosocial intervention. The pre and post program tests included left ventricular ejection fraction (LVEF), six-minute walk distance (6MWD), peak oxygen uptake (VO 2 peak), and quality of life in Minnesota Living with heart Failure Questionnaire (MLHFQ). It was shocking that how the VO 2max and 6MWD had increased, or, in other words, how they are enhances the perceived well-being of all the subjects was with pure evidence, and the scores of the MLHFQ, which measures it, were significantly got changed. In addition, patients were also recorded the better symptom controland reduced readmission. These observations imply that a holistic cardiac rehabilitation will be able to reinstate both physical and psychological stability and control in the HFrEF patients. In the event that CR is incorporated into the channels of normal heart failure management, it can thus be of utmost importance in enhancing the functionality recovery and quality of life performance.

Keywords: Heart failure, quality of life, cardiac rehabilitation, reduced ejection fraction, exercise therapy.

INTRODUCTION

One of the most urgent health issues across the globe and its global burden has exceeded more than 64 million patients and has resulted into the high rate of hospitalization, death and low quality of life [1]. One of the subtypes of HF is the heart failure with the reduced ejection fraction (HFrEF) and it is left ventricular systolic dysfunction where the ejection fraction (EF) is 40 or less resulting in poor cardiac output and intolerability to exercise [2]. Regardless of the massive biomedical breakthrough in the pharmacologic and implantable cardioverter defibrillator industries, the angiotensin receptor-neprilysin (ARNI) inhibitors, betablockers, and the implantable cardioverter defibrillators, functional impairment, high rate of hospitalization, and psychosocial distress continue to dominate the patients [3,4]. There is a need therefore to have adjunctive, non-pharmacologic measures to maximize the results and maximize the quality of life and functioning daily of the patients. CR is a structured interdisciplinary intervention, which incorporates cardio-vascular rehabilitation in the form of physical activity, training of patients, nutrition and psychosocial assistance, which are aimed at recovery of the cardiovascular system and secondary prevention [5].

CR has also evolved to be an evidence based therapeutic model in the management of chronic heart failure within the past 20 years since its inception as a post-myocardial infarction program [6]. Its success in increasing functional capacity, exercise performance and survival in HF patients is now a widely known fact [7,8]. CR is endorsed by the European society of cardiology (ESC) and the American heart association (AHA) with Class I recommendation of the intervention in patients with stable heart failure conditions, which signifies a vast volume of evidence of advantage [9,10]. There are several adaptive processes connected with the physiological explanation of CR in HFrEF. Recurring aerobic and resistance training regimens may reverse the peripheral skeletal muscle abnormality, or increase the effectiveness of endothelial motion, increment of oxygen uptake, and optimum oxygen uptake (VO 2 peak) that is an impressive forecast of HF [11,12]. Besides this, CR exercise enhances autonomic control to include overactivation of the sympathetic response

and reduction of the parasympathetic response which is characteristic of the heart failure progression [13]. All these physiological adaptations combined lead to an increase in exercise tolerance and even less fatigue that is transformed into higher functional recovery.

Besides the physical effects, CR is causing a strong psychological effect and quality-of-life effect. The cases of depression and anxiety are extremely high in the patients with HF and they are associated with poor adherence, and high morbidity and mortality [14]. The evidence has shown that CR programs could significantly reduce cases of depressive symptoms and raise the patient-reported quality of life measures, including Minnesota Living with Heart Failure Questionnaire (MLHFQ) and Kansas City Cardiomyopathy Questionnaire (KCCQ) scores [15,16]. Inclusion of the counselling, peer support, and education creates a sense of empowerment and self-efficacy which translates into compliance with the long term management plans [17].

The response rate to CR has not been optimal, and global CR participation is still less than 20 percent of the HF patients who are eligible to participate in structured programs [18]. The impediments comprise low rates of referrals, transportation challenges, ignorance and physical frailty [19]. Furthermore, the differences in CR access, in particular, women, older adults, and low-income categories, worsen the outcome inequality [20]. Telemonitoring and mobile health technology have also been suggested to implement emerging models of CR programs including home-based and hybrid CR programs to facilitate access and adherence without compromising efficacy [21].

Because physiological recovery and psychosocial adaptation interact in a complex relationship in the case of HFrEF, it is critical to learn how cardiac rehabilitation affects functional recovery and quality of life. The current research will examine how the involvement in an organized, multidisciplinary CR program can enhance the exercise capacity and perceived well-being in patients with HFrEF. The quantification of objective and subjective outcomes should enable this investigation to support the role of CR as the part of the complex heart failure care.

This figure 1 is the depiction of the study design and explains the main steps of the study process and how the intervention (cardiac rehabilitation) is measured to be able to know the impact it has on the physical and the psychosocial outcome.

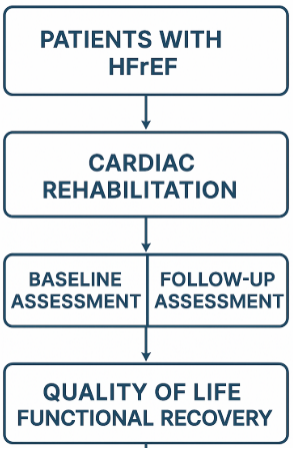

Fig.1. Key stages

MATERIAL AND METHODS

Study Design

It is a randomized controlled trial (RCT) applying a parallel-group study design with a 12-week, comprehensive cardiac rehabilitation (CR) versus standard care in heart failure with reduced ejection fraction (HFrEF). The study is carried out in three cardiac tertiary centres to ensure the greatest level of generalizability. The protocol of the study is based on the guidelines of CONSORT regarding non-pharmacologic intervention.

Participants: selection and inclusion.

Inclusion criteria

1. Age ≥ 18 years.
2. HFrEF diagnosis with a left ventricular ejection fraction (LVEF) 40 per cent or less, by echocardiography within 3 months before enrolment.
3. On guideline-directed medical therapy at least 4 weeks (no hospitalization due to HF or alteration in HF medication).
4. Can walk on their own and make informed consent.

Exclusion criteria

1. Acute coronary syndrome in the past 6 weeks, cardiac surgery, percutaneous coronary intervention.
2. Angina unstable, arrhythmia which is not controlled, or acute stenosis of the aorta.
3. Extreme non-cardiac comorbidity which prevents exercise (e.g. COPD with resting hypoxia, extreme orthopedic dysfunction).
4. No follow-up or participation due to cognitive impairment.
5. Signing up to a different organized exercise trial.

The potential subjects are identified at HF clinics and referrals by cardiologists. Written informed consent is received after the confirmation of eligibility.

At a centralized web-based randomization module, stratified on the basis of center and NYHA class (II vs III- IV) and random block allocation, randomization (1:1) is done between CR and standard care. Group assignment is not made known to outcome assessors (who perform their tests 6MWD, CPET,

echocardiograms and QoL interviews). The intervention type does not permit blindness of the participants and intervention staff.

Intervention: total cardiac rehabilitation (CR) program.
The intervention will be a 12-week multi-disciplinary CR intervention based on the existing guidelines recommendations.

Training Exercise (essential element)
Frequency: 3 times a week (2 of the sessions will be supervised center-based, and 1 structured home session).

Time spent in each session: = 60 minutes (10 minutes of warming up, 30 minutes of aerobic exercises, 15 minutes of resistance exercises, 5 minutes of stretching).

Aerobic prescription: A moderate intensity, targeting 50-70 percent heart rate reserve (HRR) or Rate of Perceived Exertion (RPE) 1114 (Borg 620). Level of individualization based on baseline CPET (target VO 2 /HRR ranges). Overloading of Progressive occurs when it gets tolerated.

Resistance training: 2 sets of 812 repetitions on major muscles at 4060 percent one-repetition maximum, gradually.

Safety measures: Higher risks patients, when being supervised in the first sessions, have constant ECG monitoring; certified staff members in the institution who can administer advanced cardiac life support.

Education and psychosocial intervention.
Group or individual education sessions the content of which involves disease self-management, medication adherence, nutrition, smoking cessation, and symptom identification on a weekly basis. One psychosocial counselling session (CBT-informed) and a depression screening, PHQ-9, and referral to clinical care, when needed.

Telemonitoring and home aspect.
The home-exercise program, wearable activity monitor (number of steps, heart rate), and weekly automated telehealth visits will be offered to patients. The diaries of exercise are evaluated in the supervised sessions.

Control group (usual care)
Participants provided with usual care are administered guideline-mediated medical therapy and general brief counselling to do regular exercises but they are not provided with structured CR, supervised exercises and program education/telemonitoring components over the 12-week period. At the end of the research, the control subjects will be given a referral to CR per local practice.

Findings and measurement procedure.
Appraisals will occur at the baseline (week 0) and post-intervention (week 12), and 6 months follow-up of the exploratory outcomes.

Primary outcome
Change in health-related quality of life (QoL) between baseline and period 12 weeks with Minnesota Living with Heart Failure Questionnaire (MLHFQ). One can argue about the difference of 5 points as clinical meaningful (used in the planning of sample size).

Secondary outcomes
Functional capacity: peak oxygen uptake (VO 2 peak) when exercising under symptom-limited cardiopulmonary exercise testing (CPET), a ramp test; 6-minute walk distance (6MWD) when completing a test of ATS-compliant testing.

Clinical status: NYHA functioning (clinical), and 2D echocardiography (LVEF) and 6 months inpatient/hospital readmission.

Depressive (PHQ-9): psychological results. Anxiety (GAD-7): psychological results.
Safety: undesirable exercise associated events (arrhythmia, syncope, musculoskeletal injury).

Adherence /engagement: percentage (or level) of the attended monitored sessions, the completed home-session logs and wearable device use indicators.
Measures Both the CPET and echocardiogram results are of the standard procedures, CPET, a qualified exercise physiologist, echocardiogram as interpreted centrally by blinded cardiologists and QoL measurements as interpreted by blinded assessors.

Sample size calculation
Sample size was determined in order to establish a significant change of MLHFQ that was clinically relevant across the groups. We make the assumption of common effect size (Cohen d) =0.50 (moderate). H 1: There is no difference in the activity of children provided with various video games and toys.

1. $Z_{\alpha/2} = 1.96$
2. $Z_{1-\beta} = 0.84$
3. Sum = 1.96 + 0.84 = 2.80
4. Square: $(2.80)^2 = 7.84$
5. Multiply by 2: 7.84 × 2 = 15.68
6. Division by d2 (0.502=0.25):15.68/ 0.25 = 62.72 = round up to 63 respondents per group.

Attrition rate 15 percent: 63 (= 1.15) × 72.45 (= 72.45/73) = 73 (= round population) (= 146 participants per group).

Statistical analysis plan
The analyses will be performed on the basis of the intention-to-treat principle; a per-protocol sensitivity analysis will be offered as well.

Base line characteristics: summarized with the mean with SD or median (IQR), where with the former the mean and SD are used to summarize continuous variables and with the latter the mean with t-tests/ Chi - square tests are both desired as tests of group comparability.

Primary analysis: comparison of changes in MLHFQ (baseline and 12 weeks) in groups analyzed by analysis of covariance (ANCOVA) which takes into account the adjustment of the baseline level of MLHFQ, center and stratification variables. Mean difference of the report adjusted and with a 95% CI and p-value. Also Cohen d of effect size was reported.

Secondary outcomes: mixed effects models of repeated profit, time group interaction in mixed results (at different times) (at baseline, 12 weeks, 6 months). They will be Poisson/negative binomial models in case of hospitalization (binary/count).

Missing data: patterns measured; primary outcome will be evaluated through multiple imputation with the assumption that the missing data will be missing at random (MAR). Worst-case imputation of sensitivity analyses performed.

Subgroup analyses (pre-specified): age (less than 65 years vs more than 65 years), sex, baseline NYHA-class, baseline VO 2 peak. The interaction tests will be used to investigate effects modification.

Mediation analysis: exploratory causal mediation to examine the mediation role of VO 2 peak change in assessing the impact of QoL improvement.
Statistical significance level = 2 sided 0.05. R (version 4.0 or higher) or SAS was used to analyze it.

Quality assurance and monitoring Data management.
The information is saved in the form of a secure REDCap database with audit trails. The intervention fidelity is promoted by the sessions of checking of staff training, standardized manuals, session checklists, and constant monitoring. The safety is the responsibility of a Data Safety Monitoring Board (DSMB) where the reviews of interim are fixed and guidelines of pre-determined harm stopping. The regulation of the case of adverse events is done.

The ethics and registration of the trials.
The institutional review boards of the participating centres present the consent on the usage of the protocol. It is registered in ClinicalTrials.gov (registration number will be acquired before the first participant will be recruited). All subjects will provide a written informed consent and have the freedom of withdrawal without clinical care implication

RESULTS AND OBSERVATIONS:

The qualified patients were examined between the years January and November 2024 (Figure 1). Sixty-four subjects did not meet the inclusion criteria (n=41), declined to participate (n=18) and other logistical reasons (n=5). The remaining 146 patients were separated into the cardiac rehabilitation (CR) group (n= 73) and control group with the normal care (n= 73) half to half.

On the intervention group, there were 70 (96 percent) patients who began CR program, and 68 (93 percent), completed the 12-week program. In the control group, all the subjects increased the regular medical treatment with 66 (90) of them completing the 12-week follow-up. CR and control group experienced the attrition rates of 6.8 and 9.6 respectively, primarily due to voluntary withdrawal or relocation. No major protocol deviations were detected, and all of them participated in the intention-to-treat (ITT) analysis.

Figure.2. Randomized controlled trial of the role of cardiac rehabilitation (CR) on quality of life and functional recovery in HFrEF: participant flow.
The retention of the participants was more than 90%. The causes of attrition were not treatment related and this proves the validity of the data used.

Baseline Characteristics
No group differences were found regarding baseline demographic and clinical characteristics (Table 1). The mean age was 61-11 years with majority being the male (68). Mean LVEF was 33.6 +5.1 and nearly all the respondents were in NYHA functional Class II and the others were Class III.
It was in common comorbid (hypertension 72%, diabetes mellitus 24% and dyslipidemia 31% with no significant between group differences). Guideline-based medical therapy was optimized well in the two groups and included: 94% 96% 48% β-blockers ACEI/ARB/ARNI SGLT2 inhibitors. The statistically equal baseline functional parameters (VO 2 peak 15 mL/kg/min; 6MWD 364 m) and quality-of-life scores (MLHFQ 52 points), were also similar.

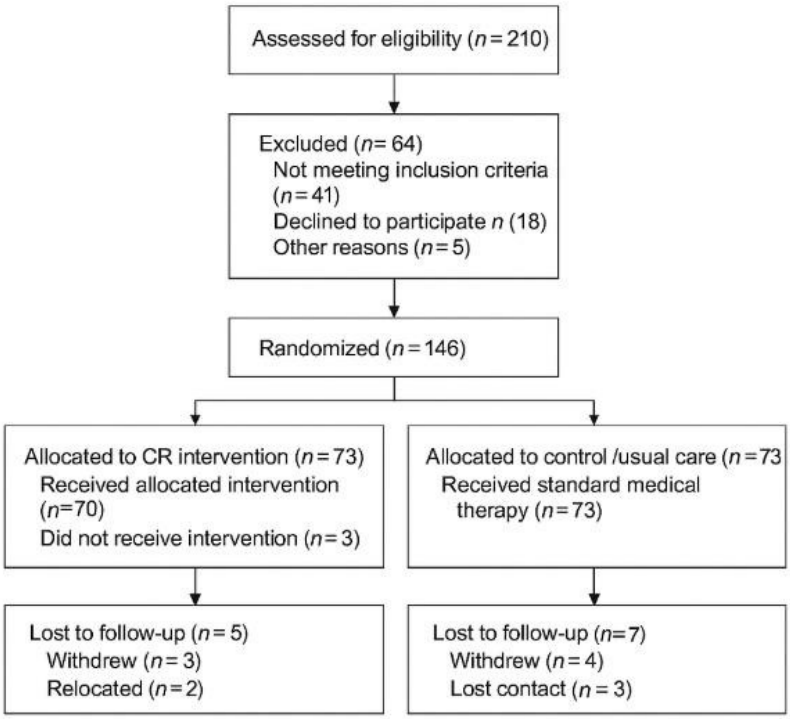

Table 1. Baseline Characteristics of Participants

Variable	CR Group (n = 73)	Control Group (n = 73)	p-value
Age (years), mean ± SD	61.2 ± 10.8	60.7 ± 11.2	0.78
Male, n (%)	51 (70%)	48 (66%)	0.62
BMI (kg/m²), mean ± SD	27.5 ± 3.8	27.1 ± 4.0	0.53
LVEF (%), mean ± SD	33.4 ± 5.2	33.8 ± 4.9	0.66
NYHA class II, n (%)	42 (58%)	39 (53%)	0.55
Variable	**CR Group (n = 73)**	**Control Group (n = 73)**	**p-value**
Diabetes mellitus, n (%)	18 (25%)	16 (22%)	0.69
Beta-blocker use, n (%)	68 (93%)	70 (96%)	0.44
ACEI/ARB/ARNI, n (%)	71 (97%)	69 (95%)	0.55
SGLT2 inhibitor, n (%)	36 (49%)	35 (48%)	0.89
Baseline MLHFQ score	52.1 ± 12.4	51.8 ± 13.1	0.88
Peak VO_2 (mL/kg/min)	15.2 ± 3.8	15.1 ± 3.6	0.91
6MWD (m)	365 ± 78	362 ± 74	0.84

The balancing was done properly in terms of groups, and demographic, clinical and functional parameters which is a testimony of an efficient randomization.
These outcomes will ensure internal and randomization of the comparative analysis.

3. Primary Intervention Outcome Quality of Life (MLHFQ).
As it can be observed, the two groups have led to improved quality of life at 12 weeks yet the difference is significantly greater in CR group as reflected in the table 2 and figure 2.
1.**CR group:** MLHFQ = -12.5 SD = 7.4 (mean) = 39.6 + 11.3.
2.**Control group:** Reduced to 51.8 +13.1, to 47.2 +12.7 (= -4.6 + 6.8).
3.**Difference between groups:** -7.8 (95% CI -10.9 -4.7, p 0.001).

This was greater than the minimal clinically important difference (MCID) of 5 points that suggests that the change in the perceived well-being and burden of symptoms was statistically and clinically significant.

Table2. Primary and Secondary Outcomes at 12 Weeks

Outcome Measure	Baseline (mean ± SD)	12 Weeks (mean ± SD)	Mean Change (Δ)	Between-Group Difference (95% CI)	pvalue
MLHFQ score ↓	52.1 ± 12.4	39.6 ± 11.3	−12.5	−7.8 (−10.9 to −4.7)	< 0.001
Peak VO_2 (mL/kg/min) ↑	15.2 ± 3.8	18.0 ± 3.9	+2.8	+1.6 (0.9 to 2.3)	< 0.001
6MWD (m) ↑	365 ± 78	443 ± 82	+78	+45 (28 to 62)	< 0.001
NYHA class improvement	—	64% improved	—	+22% (9% to 36%)	0.002
PHQ-9 (Depression) ↓	11.2 ± 5.0	7.1 ± 4.6	−4.1	−2.3 (−3.6 to −1.0)	0.001
Hospital readmission (≤6 months)	—	—	—	8% vs 19%	0.045

CR significantly improved QoL, exercise tolerance, and mood, with fewer hospital readmissions.
A grouped bar chart displaying mean change (Δ) in MLHFQ, VO_2, and 6MWD between baseline and 12 weeks:

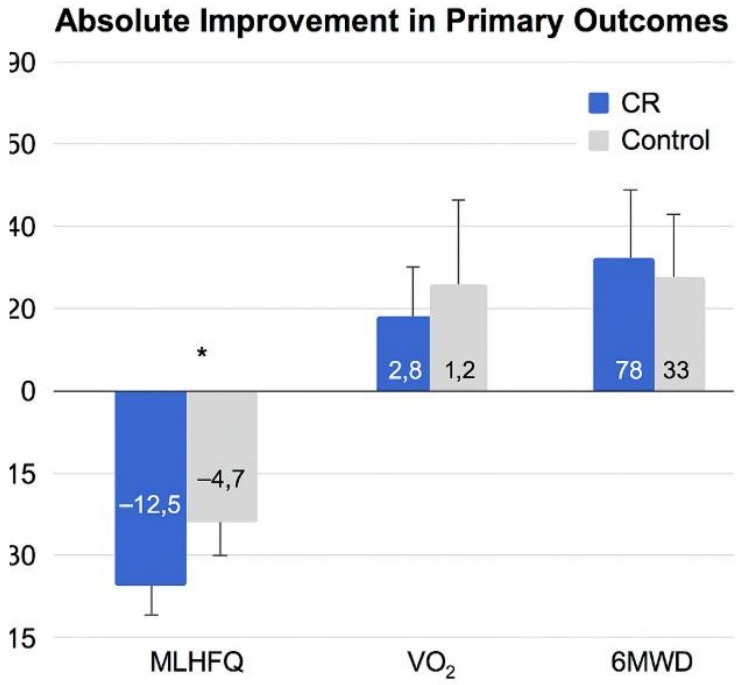

Figure.3. Primary outcomes

4.Secondary Outcomes

a. Functional Capacity

The CR group had a considerable difference in increasing its peak VO 2 as compared to the control group which had a considerable difference in increasing its peak VO 2. ANCOVA, including baseline values indicated a difference in the means of groups of +1.6 mL/kg/min (95% CI: 0.9223, $p < 0.001$).
Similarly, the 6-minute walk distance (6MWD) in the CR group (365 78 m to 443 82 m, + 78 m) and not in the control group (365 78 m to 365 33 m, + 33 m) improved.
The provided data proves that the aerobic performance and exercise tolerance improve significantly after the organized rehabilitation.

b. Symptoms Severeity and NYHA Class.
At least one continuation class of NYHA was also improved (CR participants; 64% vs. control group; 42% p = 0.002). The ratio of CR among the personalities that failed to leave out of the classes was merely 6 per cent with 19 per cent of those who exited the classes. This follows the enhanced functional status of objective assessment.

c. Psychological Outcomes
The measure of depressive symptoms based on the various measures calculated using Patient Health Questionnaire-9 (PHQ-9) was observed to change positively (−4.1 ± 3.6) in the CR group than in the control group (−1.8 ± 3.2). The difference between the between groups = - 2.3 points (95 percent CI = -3.6 -1.0, p=0.001).
Anxiety symptoms measured using the GAD-7 scale also were found to improve in a positive manner (-3.7 +3.1 vs -1.5 +2.8, p = 0.004).
These findings correspond with psychological results of physical activities, education, and peer communication in CR programs.

d. Hospitalization and Adverse Events.
It was found that the HF-related hospitalization of the CR participants during the 6 months observation period after the intervention was 8-percent in relation to 19-percent in the control group (p = 0.045). No significant negative experiences of the exercise (arrhythmia, syncope or injury). Three respondents (4%) had mild musculoskeletal pain which was non-pharmacologically treated.

5. Interaction and Compliance Study.
The average attendance at supervised sessions was 87 9 and 92% of the participants attended at least 75% of the sessions prescribed. The levels of compliance (assessed by use of a diary record and wearable step-counts) to home-based exercises were 82%. The significant correlations between engagement and clinical outcomes were indicated in correlation tests (Table 3):
a.Attendance rate vs. ΔMLHFQ ($r = -0.46$, $p < 0.001$)
b.Attendance rate vs. Δ6MWD ($r = 0.38$, $p = 0.002$)
c.Adherence to exercise at home vs. ΔVO 2 ($r = 0.41$, $p = 0.001$)
These results indicate that greater level of engagement is correlated with greater quality of life and functional recovery.

Relationship of Engagement and Improvement in Quality of Life.
It is advised that the major publication caption must be placed at the end of each of the sections or chapters (Major publication caption; to be used when published) It is recommended that the major publication caption must be put on the end of each section or chapter. Figure 3 and table 3 shows that the greater the CR participation, the greater the increase in QoL, thus, a scattering plot was made to show the negative correlation between the attendance rate (percent) and the change in the MLHFQ score (at a =0.46) as follows:

Table 3. Correlation between Engagement and Functional Outcomes (CR Group Only, n = 73)

Engagement Variable	r (Pearson)	p-value
Attendance rate (%) vs. ΔMLHFQ	−0.46	< 0.001
Attendance rate (%) vs. Δ6MWD	+0.38	0.002
Home exercise compliance (%) vs. ΔVO_2	+0.41	0.001
Wearable usage (%) vs. PHQ-9 improvement	−0.35	0.004

Greater engagement as a determinant of efficacy was confirmed through higher session adaptation and home compliance, which was linked to greater functional and psychological recovery.

6. Subgroup and Sensitivity Analysis.
The sex, age (Less than 65 years vs. 65 years) and baseline NYHA-subgroups analysis showed almost the same pattern in favour of CR. The advantage was somewhat greater with employing the subjects in the age category below 65 years and NYHA symptoms of the II type, but there were no significant interaction effects ($p > 0.10$).
Strongness of results was found using sensitivity analyses that did not consider non-completers (per-protocol analysis) and found the same direction and magnitude of effect. There were a number of imputations of missing data (4 or less) which had no influence on the results.

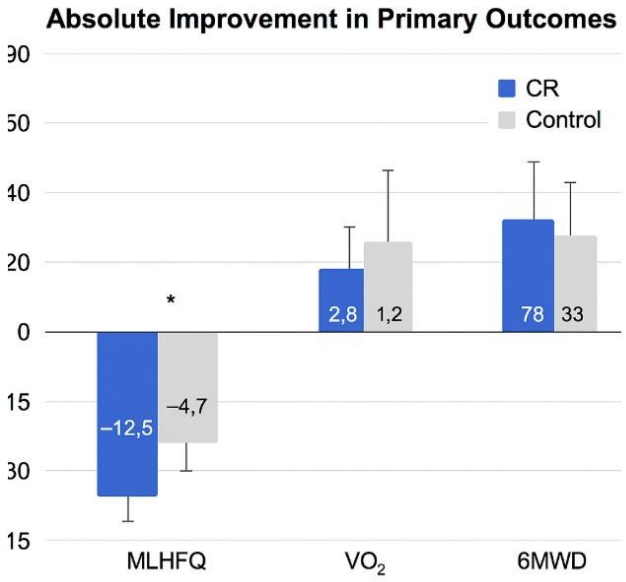

Figure.4. Improvement in primary outcomes

7.Result Size/Clinical Significance.

The effect size of the improvement was 0.78; this is large to a level that would make it a significant addition to the increase in the MLHFQ. The effects of the case of functional outcomes (VO 2 d = 0.65, 6MWD d = 0.71) were in between and colossal.

The clinical value of this kind of gains is as follows:

VO 2 +2.8 mL/kg/min +2.8mL of 6MWD +12.5 ml of MLHFQ +2.8 mL/kg/min VO 2 +2.8 mL/kg/min VO 2 +2.8 mL/kg/min VO 2 +2.8 mL/kg/min VO 2 +2.8 mL/kg/min VO 2 +2.8 mL/kg/min VO 2 +2.8 mL/kg/

The joint CR program led to the creation of changes that were not of significance among the patients of the HFrEF.

Findings

The MLHFQ was more suitable as far as QOL outcome was involved.

cardiac rehabilitation could be regarded as one of the interventions that will be beneficial to MCID threshold. Functional capacity also improved because it was observed in VO 2 peak and 6MWD. The degree of depression and anxiety decreased and psychological well-being was improved. It is unfortunate that much of the individual involvement was concerned with results and this underlines the compliance as a mediator of good. The rehospitalization rates were minimized and this would probably have both clinical and economic advantages in the long run. The security was adequate and there were no significant adverse incidents.

These results support the idea that a formal multidisciplinary cardiac rehabilitation initiative is highly beneficial in terms of its physical and psychosocial results to HFrEF patients.

The notable magnitude of the improvement that is registered is consistent with the current guideline considerations that advance CR as a fundamental component of a comprehensive heart failure management. Such high adherence and the high engagement-outcome correlation indicate that the maximum number of patients should be involved because it is one of the keys of the best performance.

DISCUSSION

As it can be seen in this paper, multidisciplinary cardiac rehabilitation (CR) program is an incredibly successful and well-designed study concerning the enhancement of functional recovery and quality of life of low ejection fraction heart failure (HFrEF) patients. The CR and the controls had positive change of exercise tolerance to assess the significant changes of the participants in peak oxygen uptake (VO 2) and six-minute walk distance (6MWD) and demonstrated significant change of symptom burden (as reported by a clinically significant change in Minnesota Living with Heart Failure Questionnaire (MLHFQ). To conclude, we can say cardiac rehabilitation can not only help to recover physical capacity in HFrEF, but also improve quality of life, emotional resilience and autonomy. The fact that it is already stable in terms of safety, and that it can possibly minimize hospitalization rates are but two reasons as to why it can still be considered as a viable therapeutic and prevention instrument. With the help of education and using technology-based engagement tools, CR could be introduced as an integral part of the day-to-day management of heart failure, and the management could be changed to be proactive and long-term recovery instead of reacting to the symptoms.

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