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MODESTUM

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Integrating behavioral interventions into exercise rehabilitation for the well-being of patients with chronic heart failure

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ABSTRACT

Background: In recent years, the integration of psychological interventions into the rehabilitation of patients with chronic heart failure (CHF) has become more apparent. The effectiveness of these interventions varies, with some having a positive impact while others showing no effect. It is unclear which psychological interventions are considered effective for patients with heart failure.

Aim: We aimed to examine the impact of psychological interventions, encompassing psychoeducation, positive reinforcement, and stress management, on levels of stress, depression, and life satisfaction in patients with CHF.

Methods: Thirty-six consecutive CHF patients in stable condition (mean age: 56 ± 10 years, left ventricle ejection fraction < 50%) were randomly assigned to the intervention group (IG) (n = 18) or the control group (CG) (n = 18). All participants engaged in a structured rehabilitation program three times a week for a duration of 12 weeks. The IG received additional emotional support through 12 sessions of psychoeducation, stress resilience techniques, and positive behavior reinforcement. Measurements were conducted both pre- and post-intervention, with values expressed as mean and standard deviation.

Results: Following 12 weeks of rehabilitation, the IG demonstrated a substantial reduction in depression rates (from 3.4 [4.0] to 1.6 [2.4], p < 0.01), in contrast to the CG (from 3.6 [3.4] to 4.0 [3.7], p = 0.32). Stress levels were significantly diminished (p < 0.01) in both the IG (from 14.3 [8.6] to 9.1 [7.4]) and the CG (from 13.2 [9.8] to 8.6 [5.9]). Moreover, life satisfaction markedly increased in the IG (from 23.8 [5.2] to 30.8 [3.5], p < 0.01), while it decreased in the CG (from 26.0 [6.91] to 20.2 [6.5], p < 0.01). Noteworthy between-group differences were observed in depression rates and life satisfaction (p < 0.01).

Conclusions: Psychological interventions, alongside a structured exercise rehabilitation program, featuring psychoeducation, stress management techniques, and positive reinforcement, emerges as a potent strategy for alleviating depressive symptoms and enhancing the mental well-being of patients. This underscores the potential of a comprehensive approach that seamlessly integrates both physical and psychological interventions.

Keywords: psychological intervention, psychoeducation, positive reinforcement, stress management, cardiac rehabilitation, heart failure

INTRODUCTION

Chronic heart failure (CHF) patients face an almost twice as high as possible likelihood of manifesting symptoms of stress and depression compared to the general population [1, 2], surpassing rates observed in individuals contending with other medical conditions. Illuminating the psychological burden carried by CHF patients, a retrospective analysis encompassing adults with initial diagnoses of heart failure, breast cancer,

prostate cancer, or gastrointestinal cancer spanning 1,274 general practices from 2000 to 2018 unveiled compelling results. Within five years of diagnosis, 23.1% of heart failure patients exhibited heightened levels of depression and anxiety, outstripping rates in gastrointestinal cancer patients (22.1%) and prostate cancer patients (15.0%), while slightly trailing behind breast cancer patients (25.7%) [3].

Specifically, within the literature, the coexistence of heart failure with stress or depression escalates the probability of developing circadian rhythm disorders [4], metabolic disorders

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[5], accelerated loss of gray matter regulating emotion [6], and a twofold increase in inflammatory reactions [1]. Stress, as revealed in [7], may induce vasoconstriction, resulting in the rupture of atherosclerotic plaques leading to thrombosis and embolism [7]. Additionally, stress has been linked to heart rhythm disorders [8] attributed to sudden and excessive adrenaline secretion [9]. The extensive mental comorbidity in heart failure patients is associated with heightened rates of repeated hospitalizations, a bleak prognosis [10] and an increased likelihood of disease incidence [11, 12]. Furthermore, individuals grappling with anxiety, depression, or dissatisfaction with life are prone to neglecting self-care routines and they do not adhere to the therapeutic recommendations of specialists [13]. It is well documented that factors contributing to elevated mental comorbidity are multifaceted, categorized into disease-oriented psychosocially oriented factors [8, 14]. Disease-oriented factors encompass chronicity, consequent fatigue, and the intensity of symptoms (dyspnea, tachycardia, and chronic fatigue), diminishing functionality and prompting gradual withdrawal from daily life. Among crucial psychosocial factors is the significant lack of information regarding the disease and appropriate self-care methods [15]. Patients informed about their condition and self-care protocols exhibit better treatment adherence and prognosis [15]. Chronic illness correlates with reduced social activities, limited interpersonal relationships, and often diminished or absent social support [16].

The nexus between physical and psychological health has spurred efforts to enhance cardiac rehabilitation programs through psychosocial interventions, aiming to augment patient knowledge and ameliorate aggravating psychological parameters. Given the distinctive psychology of chronic disease patients and the sobering fact that about half do not survive within 5 years of heart failure diagnosis [17] selecting psychological interventions tailored to heart failure becomes a pivotal undertaking. Considering the prevalent medical advice for heart failure patients to avoid intense emotional experiences, it becomes imperative for psychotherapeutic techniques to cater to the specific needs of this population.

In light of these considerations, we conducted a clinical randomized study to investigate the effects of a three-level psychological intervention encompassing psychoeducation, stress management techniques, and positive reinforcement on stress, depression, and life satisfaction in patients with CHF. An additional objective was to discern whether an enhanced cardiac rehabilitation program surpasses a standard cardiac rehabilitation exercise program. The hypothesis posited anticipated a greater reduction in stress and depression, coupled with an enhancement in life satisfaction within the enhanced cardiac rehabilitation compared to the standard cardiac rehabilitation exercise program.

METHODS

Study Design

We conducted a randomized controlled study employing a parallel-group design with a 1:1 ratio. Participants were randomly assigned to either the intervention group (IG) or the control group (CG), employing stress score at baseline as the stratification criterion. The study's dependent variables encompassed stress, depression, and life satisfaction, while the independent variables included group assignment (IG and

CG) and time (before and after intervention). All variables were of a quantitative nature. Evaluation of all groups occurred both before and after the intervention. Our study is in accordance with the ethical guidelines of the Declaration of Helsinki and approved by the Administration Board and the Ethics Committee of 'Evangelismos' General Hospital in Athens, Greece (protocol number: 387 30/11/18). All participants were informed and provided their consent for the participation in the study. They also were assured about secure filing of their data in a form that protects their anonymity.

Participants

Patients were referred to the rehabilitation program by their attending physicians. Inclusion criteria included stable cardiac insufficiency under maximum tolerated medication, an ejection fraction of less than 50%, and an overall health status conducive to exercise. Exclusion criteria included individuals recently diagnosed with heart failure (within the last three months), those who had experienced changes in antidepressant/antipsychotic medication in the month prior to program enrollment, as well as those with severe heart valve disease, uncontrolled arterial hypertension, severe chronic obstructive pulmonary disease, severe peripheral vascular disease, neuromuscular disease, or contraindications for cardiorespiratory fatigue testing. The majority of patients were undergoing medication regimens including diuretics, betablockers, aldosterone antagonists, or angiotensin-converting enzyme inhibitors. Patient randomization began with the first participant in the spring of 2017 and concluded with the last participant in the spring of 2019. The flow of participants through the study is depicted in Figure 1.

Experimental Groups

Control group

Participants assigned to the CG underwent a rehabilitation exercise program, engaging in sessions three times a week over a span of 12 weeks, accumulating a total of 36 sessions. The exercise protocol included both aerobic exercise and strength training, as previously described in detail in a study conducted in our laboratory [18].

Intervention group

The IG underwent the same exercise rehabilitation program as the CG, augmented with a three-tiered psychological intervention program administered over 12 weeks (one session per week, lasting 45 minutes each). This intervention included:

- (1) psychoeducation,
- (2) stress management techniques, and
- (3) positive reinforcement on self-care behaviors.

The term "psychoeducation" finds its origins in the mental hygiene movement of the 1920s and the de-institutionalization movement of the 1950s, both aiming to critique mainstream psychiatry for ethical and effectiveness concerns [19]. Although introduced in the literature in the 1970s, psychoeducation goes beyond mere information provision; it is a dynamic process engaging patients actively in learning, comprehending, and effectively managing their illness [20]. During psychoeducation sessions, patients were educated about the risk factors associated with disease recurrence and informed about appropriate strategies for behavioral changes [21].

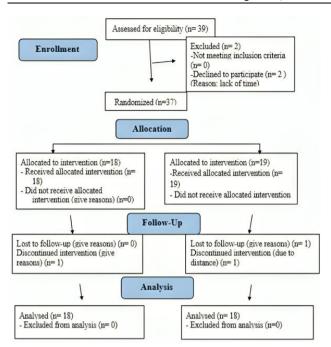


Figure 1. Flow of participants through the study (**Appendix A**) (Adapted from [22])

The stress management techniques employed included diaphragmatic breathing and Jacobson's progressive neuromuscular relaxation [23]. These techniques were chosen based on evidence demonstrating their benefits for patients with cardiovascular disease, stimulating the parasympathetic nervous system, improving heart rate [24], regulating blood pressure, and enhancing attention and coordination of movements [25]. Patients were encouraged to incorporate these techniques into their daily routine during the program, with the additional use of thought journals.

Positive reinforcement in self-care behaviors was implemented, emphasizing the achievement of health goals set by individual patients, such as increased walking or choosing healthier snacks. Patients themselves selected reinforcing factors through discussions, which included provisions such as a disc with relaxation techniques or extended time in sessions. Encouragement was given for patients to maintain a personal diary to track their progress towards these goals. The three methods employed are considered fundamental tools of cognitive-behavioral therapy and were deemed appropriate precisely because they cannot exacerbate patients' emotions, do not involve exposure to traumas and unnecessary distress at such a critical moment in their lives, and provide them with knowledge and goal-directed focus.

Blindness

Due to the nature of the psychological intervention, researchers were not blinded to the study or the group assignments. However, participants were kept uninformed about their group allocation, and they remained unaware of the manipulations occurring in the other group. Importantly, laboratory staff responsible for the evaluation and implementation of interventions were kept blind to the grouping of patients, ensuring an unbiased and objective assessment.

Table 1. Demographic & clinical characteristics for patients with CHF enrolled in the cardiac rehabilitation program

Variables	Total	IG	CG
Gender			
Men/women	25 /11	13/5	12/6
Age (M ± SD)	56.2 ± 10.0	55.7 ± 10.0	56.6 ± 10.0
Marital status			
Single	12	6	6
Married	20	10	10
Divorced	3	1	2
Widowed	1	1	0
NYHA stages			
Stage I	24	15	9
Stage III	7	2	5
CHF type			
Diastolic heart failure (%)	27.8	16.7	33.3
Ischaemic heart failure (%)	55.6	50	61.3
Other (%)	11.1	22.2	5.6
CHF severity			
> 80 normal	4	2	2
71-79 mild decrease	9	7	2
51-70 moderate decrease	9	6	3
< 50 severe decrease	9	2	7
History of depression (%)			
No	26	12	14
Yes	10	6	4
Antidepressants (%)			
No	29	14	15
Yes	7	4	3

Note. M: Mean & SD: Standard deviation

Randomization

To achieve randomization in the two experimental groups, a random number table was employed. Additionally, stratification based on stress levels was conducted using the distress scale derived from the self-report four-dimensional symptom questionnaire "4DSQ." Stratification was categorized as follows: distress scale ≤ 10 indicating light stress and a scale of 10 for moderate or severe stress. This approach ensured a more refined and balanced distribution of stress levels within the experimental groups.

Scales & Measures

Demographic data, including gender, age, and marital status, were systematically collected from all participants, alongside an in-depth health history review encompassing clinical indicators such as a history of depression, ongoing antidepressant treatment, body mass index, stage of heart failure, ejection fraction, and the specific type of heart failure. Demographic and clinical characteristics of patients with CHF enrolled in the cardiac rehabilitation program are presented in **Table 1**.

Additionally, self-report scales were administered to gather relevant information.

Finally, a cardiopulmonary exercise testing was performed for prescription of aerobic exercise intensity and evaluation of peak oxygen uptake (VO_{2peak}), an index of functional capacity, as a secondary outcome.

Terluin's Dutch self-report scale

To assess stress and depression, we employed Terluin's Dutch self-report scale [26], specifically designed for evaluating common psychological symptoms in primary care patients. This scale effectively distinguishes general distress from

depression, anxiety, and somatization. Notably, the tool exhibits robust psychometric properties, with reported indices ranging between 0.82 and 0.92.

The four-dimensional symptom questionnaire

The 4DSQ questionnaire has undergone validation and translation into Greek [27, 28], adhering to double and reverse translation guidelines outlined by the MAPI Research Institute. The Greek-translated scales demonstrated commendable reliability, as indicated by Cronbach's alpha values falling between 0.88 and 0.91. From the four dimensions of the questionnaire, we selectively utilized items related to the dimensions of stress (18 questions, e.g., "During the past week, did you feel that you could not cope?") and depression (6 questions, e.g., "During the past week, did you feel that everything was meaningless?"). Responses were recorded on a 3-point scale, ranging from 0 = never to 2 = often. It is noteworthy that the choice of a 3-point response scale deviates from the original 5-point scale in the English version. This modification was made considering that older patients may comprehend better options within a smaller response range [27].

The decision to use only specific dimensions of the questionnaire was motivated by the need to streamline the completion process, particularly recognizing the potential fatigue of laboratory patients due to extensive medical history documentation. Moreover, the exclusion of somatization and anxiety scale items aimed to minimize confounding factors associated with symptoms resembling those experienced by patients with heart failure. The questionnaire was freely available for educational and research purposes.

Satisfaction with life scale

The assessment of life satisfaction utilized the 5-point satisfaction with life scale (SWLS), developed in 1985 [29]. Comprising 5 statements that prompt individuals to critically evaluate their lives at a conscious cognitive level, questions include, for example, "I am satisfied with my life?" Responses are recorded using a 7-point Likert scale, ranging from 1 ("I strongly disagree") to 7 ("I completely agree"). The total score range is from 0 to 35, with scores between 5 and 9 indicating extreme dissatisfaction and scores between 31 and 35 indicating utmost satisfaction with life.

The SWLS is recognized for its validity and reliability in measuring overall life satisfaction, with an alpha coefficient ranging from 0.79 to 0.89, indicating high internal consistency. The scale underwent translation into Greek and validation by Lyrakos and colleagues [27]. Notably, the questionnaire was freely available for educational and research purposes, with the stipulation that proper attribution to the creators be made.

Statistical Analyses

A power analysis (G*Power 3.1) was conducted prior to recruitment to determine the required sample size. Assuming a moderate effect size of η^2 : 0.12 and an alpha level of 0.05, the analysis suggested that a sample size of 40 participants would be required to achieve a power of 0.80. That size increased by 15%, to account for dropouts. Due to the onset of the COVID-19 pandemic and related restrictions, 37 patients were ultimately enrolled.

The normality of distribution was assessed using the Kolmogorov-Smirnov test. Between-group comparisons before and after the intervention were conducted using a 2×2

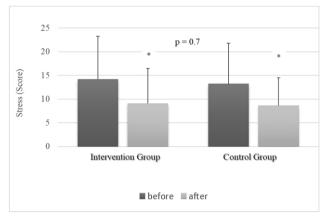


Figure 2. Changes in stress scores pre- and post-intervention among the two participant groups (*significant within-group differences [p < 0.05]) (Source: Authors' own elaboration)

(time × group) factorial analysis of variance. Effect sizes for these comparisons were evaluated with partial η^2 .

Within-group comparisons and baseline comparisons between the two groups were analyzed using Student's paired t-test and independent t-test, respectively (or the Wilcoxon and the Mann-Whitney test in case of non-normal distribution). Relationships between variables were explored with Pearson or Spearman correlation tests. The data were analyzed with IBM SPSS Statistics software version 26.0. Continuous variables are presented as mean \pm standard deviation. Significance was set at the level of p < 0.05.

RESULTS

In the initial screening, 39 patients were considered, with 37 ultimately randomized (2 patients opted out due to time and distance constraints). The breakdown comprised 19 individuals in the 3-level behavioral IG and 18 in the CG. One patient from the IG withdrew before the third interview, citing time constraints. Therefore, the final analysis included 36 patients, evenly distributed with 18 in each group (**Figure 1**).

Baseline assessments revealed no significant differences between the two groups for stress (p = 0.72), depression (p = 0.71), and life satisfaction (p = 0.28). Patients' adherence to treatment, measured by meeting attendance, was commendable, with both groups demonstrating an 89% attendance rate (IG: $87\% \pm 3.4$, CG: $91\% \pm 2.6$). Additionally, a 71% consistency rate for IG patients based on weekly tasks was noted.

Overall, there was a significant increase in VO_{2peak} levels from 19.4 (3.9) to 22 (6.5) ml/kg/min (p = 0.04). Both IG (from 19.5 [3.9] to 22.0 [6.5] ml/kg/min) and CG (from 17.0 [3.7] to 19.1 [3.1] ml/kg/min) were similarly improved (p = 0.80).

Furthermore, stress levels decreased in both IG (from 14.3 [8.6] to 9.1 [7.4], p < 0.01) and CG (from 13.2 [9.8] to 8.6 [5.9], p < 0.01), with no significant difference between them (p = 0.73, η^2 = 0.004, power: 0.06) (**Figure 2**).

Following the psychological intervention, depression decreased in the IG (from 3.4 [4.0] to 1.6 [2.4], p < 0.01), while remaining unchanged in the CG (from 3.6 [3.4] to 4.0 [3.7], p = 0.32). A significant between-group difference was observed (p < 0.01, η^2 = 0.31, power: 0.96) (**Figure 3**).

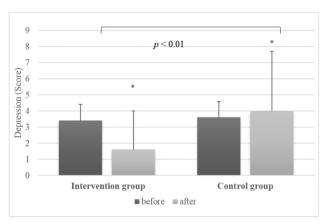


Figure 3. Changes in depression score pre- and post-intervention among the two participant groups (*significant within-group differences [p < 0.05]) (Source: Authors' own elaboration)

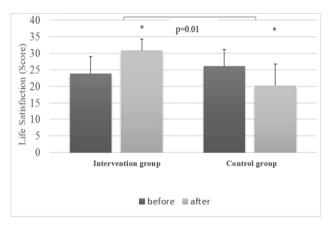


Figure 4. Changes in life satisfaction score pre- and post-intervention among the two participant groups (*significant within-group differences [p < 0.05]) (Source: Authors' own elaboration)

Regarding life satisfaction, it improved in the IG (from 23.4 [5.2] to 30.8 [3.4], p < 0.01), whereas it decreased in the CG (from 26.0 [6.9] to 20.2 [6.5], p < 0.01). A significant difference between the two groups was found (p = 0.01, η^2 = 0.70, power: 1.00) (**Figure 4**). Finally, the change in stress rate was not correlated with the change in depression rate and life satisfaction rate (p > 0.05). However, the change in depression rate was correlated with the change in life satisfaction (r=-0.46, p < 0.01).

Correlations of Changes in Main Study Variables

From the correlations among the main variables of the study, it was evident that the change in stress is not significantly related to the change in depression (p > 0.05). However, there is a negative correlation between the change in stress and life satisfaction (r = -0.486, p < 0.01), suggesting that as stress increases, life satisfaction tends to decrease.

DISCUSSION

In our study, the incorporation of psychological intervention, encompassing psychoeducation, stress management techniques, and positive reinforcement, in cardiac rehabilitation with exercise, manifests superior efficacy

in mitigating depression and augmenting life satisfaction compared to rehabilitation solely focusing on exercise. Similar results are observed in studies investigating the efficacy of a conventional cardiac rehabilitation program compared to an enhanced program that incorporates psychological interventions. In a related study in [30] involving 151 patients and employing two experimental groups (CG: exercise, IG: exercise and cognitive behavioral therapy), both groups exhibited diminished stress levels and amelioration in clinical indicators.

Moreover, the enhanced program showed a more noticeable decrease in both stress and depression. Consequently, given the prevalence of cardiac rehabilitation programs globally and locally devoid of psychological support, the findings of our study are encouraging regarding the value of fortifying rehabilitation through the incorporation of psychological interventions.

The incorporation of psychological intervention, specifically employing three behavioral techniques, also demonstrated a notable elevation in patients' life satisfaction. This phenomenon is postulated to arise from patients feeling heard within a secure and supportive environment. While satisfaction is a relatively broad concept, the use of a questionnaire assessing an individual's overall life satisfaction could potentially yield varied results if more granular inquiries were made into satisfaction within distinct domains such as work, financial situation, and personal life.

One key finding from this investigation revolves around the $strategic\,selection\,of\,psychological\,intervention\,techniques\,for$ rehabilitation purposes. A comprehensive review of existing literature reveals a conspicuous knowledge deficit among cardiac patients concerning heart failure and cardiovascular health management [15]. Consequently, the inclusion of psychoeducation in the program, elucidating both supportive and detrimental behaviors along with recommendations, was deemed imperative. Recognizing that information dissemination alone is insufficient unless complemented by education and practical application, psychoeducation affords individuals a stepwise training approach to modify behavioral patterns, replacing detrimental habits with those conducive to psychosomatic well-being. As evidenced in the study in [20], psychoeducation confers diverse benefits to the health and functionality of patients with coronary artery disease. To facilitate behavioral change and stress reduction, our intervention was enriched with diaphragmatic breathing and progressive muscle relaxation techniques. These practices, associated in the literature with a multitude of cardiovascular benefits [23, 24, 31], specifically target the mitigation of psychosomatic tension. Additionally, the utilization of positive reinforcement as a technique to foster favorable selfbehavioral patterns aligns with Skinner's behaviorism theory, positing that the establishment and perpetuation of a behavior necessitate positive reinforcement of the desired conduct [32].

Of heightened significance is the principle of differential reinforcement, where positive reinforcement is strategically applied to encourage the desired behavioral pattern in one context, while simultaneously withholding reinforcement for the undesired behavioral pattern in another. The incorporation of reinforcement was envisioned to enhance treatment compliance and alleviate patient anxiety stemming from restrictive measures [33]. It is pertinent to mention that the decision to encompass all three interventions, was informed by a rationale underscored in prior studies exploring the nuanced

psychological characteristics of patients grappling with CHF [34, 35]. A deliberate effort was made to avoid methods that might induce negative experiences or trigger adverse emotions in this vulnerable population. Furthermore, the application of positive reinforcement in fostering health-promoting behaviors, as articulated in [32] plays a pivotal role in instigating behavioral repetition, thereby contributing to an upswing in self-care behaviors. Affirming this perspective, the study in [36] highlight that positive reinforcement strategies significantly enhance patients' self-efficacy in maintaining exercise adherence, which is a key component of self-care in heart failure management. The incorporation of these psychological interventions proves advantageous in the context of cardiac rehabilitation, given their relative costeffectiveness, simplicity, and practicality. Notably, they require no special conditions, tools, or dedicated spaces, making them adaptable for implementation in an inpatient setting. Most importantly, these interventions impose no financial burden on the patient, mitigating potential disincentives. In considering the baseline levels of stress and depression within our sample, it is crucial to emphasize that they exceeded those observed in the general population [8]. This aligns logically with the chronic disease status of our patient and, simultaneously, aligns with the prevalence rates of depression and anxiety documented in similar studies involving patients [10, 37]. It is noteworthy to emphasize that, in this study, the CG underwent an exercise intervention and was not devoid of experimental manipulation. In the medical literature, exercise has been linked to a myriad of benefits, both physical and mental, for cardiovascular patients [38-40]. Interestingly, in our current investigation, the CG demonstrated a substantial reduction in stress comparable to that of the IG. Importantly, in the present study, both the intervention and CGs exhibited significant improvements in VO₂peak and substantial reductions in stress levels, with no significant differences between them. These findings reinforce the strong role of exercise in both improving physical performance and alleviating psychological stress among patients with heart failure. Exercise-based rehabilitation has long been recognized for its efficacy in reducing stress and enhancing mental wellbeing, with benefits comparable to those of structured psychological interventions in similar populations [41].

We postulate also that the duration of the two interventions may have influenced this outcome, given that the exercise intervention occurred three times a week, whereas psychotherapy sessions were conducted once a week. Therefore, exploring the effects of the psychological stress intervention across a greater number of sessions would be insightful. Furthermore, exercise is recognized as a particularly stress-relieving activity, as evidenced in the literature by its association with enhanced mood and feelings of relief [40]. This phenomenon can be elucidated by the reciprocal relationship between a healthy body and a healthy brain, wherein a robust physical state supports mental well-being and, conversely, a healthy brain fortifies bodily resilience.

The value of the present study lies mainly in the combination of the three psychological tools used after study and review of the literature, tools that we believed from the beginning to be appropriate for the needs of patients suffering from CHF. This study further contributes to increasing knowledge around the effect of positive reinforcement, which is studied little as a tool for patients with chronic disease. This study may be useful to the multidisciplinary team of therapists

working in the context of cardiac rehabilitation, given the fact that the behavioral method of three therapeutic tools is a relatively inexpensive and simple method that can be integrated into the daily routine of patients with CHF. By knowing the psychological profile of patients with cardiac problems, we can better organize in order to classify a patient into high and low risk of psychological distress based on their history, and so as to organize a more specific action plan for preventing psychological distress and indirectly preventing any poor treatment compliance or even abandonment of treatment.

Our study has several limitations that warrant consideration. The reliance on self-report scales introduces potential drawbacks associated with the use of non-objective indicators. An alternative strategy, rather than solely relying on self-report tools, could involve incorporating biological measures, such as salivary cortisol and urinary catecholamines, which serve as objective indicators of stress, along with other relevant markers. Another limitation stems from the inherent nature of the study being a psychological intervention, rendering it impractical to achieve researcher blindness. This lack of blinding introduces a potential source of bias that needs to be acknowledged.

Furthermore, there are broader considerations regarding the use of psychological interventions in rehabilitation that extend beyond the scope of this study. Investigating the impact of the effort-reward imbalance of psychometric properties on health, as proposed in [42], would be intriguing. Understanding the perception of imbalance between the effort's patients exert to improve their health and the subsequent payoff in terms of quality and clinical indicators is crucial for informing their adherence to treatment. Future research should also focus on studying behavioral techniques that assist patients in adhering to physicians' recommendations and achieving desirable behavioral changes in their daily lives. Additionally, investigating the long-term effects of combining these interventions on both physical performance and mental health would provide valuable insights into optimizing rehabilitation programs for CHF patients.

CONCLUSIONS

Enhancing cardiac rehabilitation by incorporating psychological interventions, such as psychoeducation, stress management techniques, and positive reinforcement, proves to be highly beneficial for patients with CHF. These interventions contribute to significant improvements in emotional well-being, depression, and life satisfaction, providing essential support in addressing the mental health challenges faced by these patients. However, it is important to emphasize that exercise alone also led to substantial reductions in stress and improvements in physical capacity, underscoring the key role of physical activity in both mental and physical recovery. While both approaches-exercise and psychological support-demonstrated significant benefits, the combination of these interventions appears to offer a synergistic effect, where exercise helps alleviate stress and improve physical health, while psychological interventions specifically target emotional well-being and behavioral changes. Thus, integrating both physical and psychological strategies into cardiac rehabilitation programs may offer the

most comprehensive approach, optimizing health outcomes for heart failure patients.

Future research should focus on studying behavioral techniques that assist patients in adhering to physicians' recommendations and achieving desirable behavioral changes in their daily lives. Additionally, investigating the long-term effects of combining these interventions on both physical performance and mental health would provide valuable insights into optimizing rehabilitation programs for CHF patients. Understanding how psychological interventions can enhance exercise capacity and improve overall patient engagement could further inform clinical practice and lead to more effective, holistic rehabilitation strategies.

Author contributions: AP: conceptualization, methodology, investigation, formal analysis, writing - original draft; PK: conceptualization, methodology, supervision, writing - review and editing; MAS, DD & VL: investigation; VB: methodology, writing - original draft; CR: project administration, writing - review and editing; EM & IV: supervision, writing - review and editing; NR: methodology, writing - review and editing; SN: conceptualization, methodology, project administration, writing - review and editing; EK: conceptualization, methodology, formal analysis, project administration, writing - original draft. All authors have agreed with the results and conclusions.

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Declaration of interest: No conflict of interest is declared by the authors.

Data sharing statement: Data supporting the findings and conclusions are available upon request from the corresponding author.

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APPENDIX A

Table A1. CONSORT 2010 checklist of information to include when reporting a randomized trial

Section/topic	IN	Checklist item	RPN
Title and abstract			
	<u>1a</u>	Identification as a randomized trial in the title	√
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for	
		abstracts)	
Introduction			
Background and	<u>2a</u>	Scientific background and explanation of rationale	√
objectives	2b	Specific objectives or hypotheses	√
Methods			
Trial design Participants	3a	Description of trial design (such as parallel and factorial) including allocation ratio	√
	3b	Important changes to methods after trial commencement (such as eligibility criteria) with reasons	<u>√</u>
	4a	Eligibility criteria for participants	/
	4b	Settings and locations where the data were collected	√
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	√
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they	√
		were assessed	V
	6b	Any changes to trial outcomes after the trial commenced with reasons	
Sample size	7a	How sample size was determined	√
	7b	When applicable, explanation of any interim analyses and stopping guidelines	
Randomization: SG	8a	Method used to generate the random allocation sequence	√
	8b	Type of randomization; details of any restriction (such as blocking and block size)	
ACM	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers),	
ACM	9	describing any steps taken to conceal the sequence until interventions were assigned	
luculous cutation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to	
Implementation	10	interventions	
Blinding	11-	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	
	11a	assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	
C+-+:-+: + -	12a	Statistical methods used to compare groups for primary and secondary outcomes	√
Statistical methods	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	
Results			
Participant flow (a	12-	For each group, the numbers of participants who were randomly assigned, received intended treatment, and	,
diagram is strongly	13a	were analyzed for the primary outcome	√
recommended)	13b	For each group, losses and exclusions after randomization, together with reasons	√
	14a	Dates defining the periods of recruitment and follow-up	√
Recruitment	14b	Why the trial ended or was stopped	√
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	√
		For each group, number of participants (denominator) included in each analysis and whether the analysis was	,
Numbers analyzed	16	by original assigned groups	√
0	17-	For each primary and secondary outcome, results for each group, and the estimated effect size and its	,
Outcomes and	17a	precision (such as 95% confidence interval)	√
estimation	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing	√
		pre-specified from exploratory	
Harms	19	All-important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	
Discussion	22	Tablification addresses and a constant of the state of th	,
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	<u>√</u>
Generalizability	21	Generalizability (external validity, applicability) of the trial findings	<u>√</u>
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	√
Other information			
Registration	23	Registration number and name of trial registry	
Protocol	24	Where the full trial protocol can be accessed, if available	
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	,

Note. IN: Item no; RPN: Reported on page no; SG: Sequence generation; ACM: Allocation concealment mechanism; & *We strongly recommend reading this statement in conjunction with the CONSORT 2010 explanation and elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomized trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consortstatement.org