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EFFECT OF VIRTUAL REALITY–ASSISTED MINDFULNESS-BASED CARDIOPULMONARY REHABILITATION ON EXERCISE CAPACITY AND PSYCHOLOGICAL OUTCOMES IN CARDIAC PATIENTS: A RANDOMIZED CONTROLLED TRIAL

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Abstract

Background: Cardiac rehabilitation (CR) improves functional capacity and reduces morbidity; however, adherence and psychological distress limit its effectiveness. Virtual reality (VR) and mindfulness-based interventions may enhance engagement and rehabilitation outcomes.

Objective: To evaluate the effectiveness of VR-assisted mindfulness-based cardiopulmonary rehabilitation on exercise capacity and psychological outcomes in cardiac patients.

Methods: A single-blinded randomized controlled trial was conducted on 50 cardiac patients in Pakistan Institute of Cardiology Peshawar. Participants were randomly allocated into an intervention group (VR-assisted mindfulness-based CR) and a control group (conventional CR). The intervention lasted 8 weeks. Primary outcomes included the 6-minute walk test (6MWT) and VO_2 max. Secondary outcomes included anxiety, depression, and stress. Data were analyzed using paired and independent t-tests, with effect sizes (Cohen's d) and 95% confidence intervals reported.

Results: Forty-six participants completed the study. The intervention group demonstrated significantly greater improvements in exercise capacity, with a mean between-group difference of 60 meters in the 6-minute walk test (95% CI: 35–85; $p < 0.001$), and higher VO_2 max (mean difference: 3.7 ml/kg/min; 95% CI: 2.1–5.3; $p < 0.001$). Significant reductions were observed in psychological outcomes, with lower post-intervention scores in anxiety (6.5 ± 1.8 vs 9.8 ± 2.2; $p = 0.002$; Cohen's d ≈ 1.4), depression (6.2 ± 1.7 vs 9.6

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± 2.3; p = 0.001; Cohen's d ≈ 1.5), and perceived stress (14.3 ± 2.8 vs 18.9 ± 3.1; p = 0.003; Cohen's d ≈ 1.3). Effect sizes ranged from moderate to large.

Conclusion

VR-assisted mindfulness-based cardiopulmonary rehabilitation is associated with improvements in both functional and psychological outcomes in patients with cardiovascular disease. The observed effect sizes indicate substantial treatment effects; however, given methodological constraints, these findings require confirmation in larger multicenter trials with longer follow-up.

INTRODUCTION

Cardiovascular diseases (CVDs) remain the leading global cause of mortality, accounting for approximately 17.9 million deaths annually and imposing a substantial burden on healthcare systems worldwide (1). Despite advances in acute cardiac care, long-term outcomes remain heavily dependent on secondary prevention strategies, particularly cardiac rehabilitation (CR), which has consistently demonstrated improvements in exercise capacity, quality of life, and mortality reduction (2). However, participation and adherence to CR programs remain suboptimal, with dropout rates frequently exceeding 20–50%, limiting their real-world effectiveness (3). Psychological distress is a major contributor to poor adherence and adverse outcomes in cardiac populations. Anxiety, depression, and stress are highly prevalent following cardiac events and are independently associated with increased morbidity and mortality (4). These psychological factors influence autonomic regulation, reduce heart rate variability, and negatively affect behavioral engagement in rehabilitation programs, thereby undermining recovery (5).

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Recent efforts to enhance CR outcomes have focused on integrating digital and behavioral interventions. Virtual reality (VR) has emerged as a promising modality due to its ability to create immersive, interactive environments that enhance patient engagement and motivation (6). Evidence from experimental studies and systematic reviews suggests that VR-based interventions can improve psychological outcomes, including reductions in anxiety and depression, and may increase adherence to rehabilitation protocols (7-9). Parallel to technological advancements, mindfulness-based interventions (MBIs) have gained strong empirical support as effective strategies for improving psychological well-being and autonomic function. Mindfulness practices, including controlled breathing and present-moment awareness, have been shown to reduce stress, enhance emotional regulation, and improve cardiovascular-related physiological markers such as heart rate variability (10).

The integration of VR with mindfulness represents a novel therapeutic approach that may address both behavioral and psychological barriers in cardiac rehabilitation. VR-enhanced mindfulness interventions offer immersive environments that can facilitate attentional focus, reduce external distractions, and improve adherence compared to conventional delivery methods. Emerging evidence indicates that such combined approaches may produce meaningful improvements in stress reduction and emotional regulation, although robust randomized controlled trials in cardiac populations remain limited (11, 12). Despite growing interest, current literature is characterized by methodological heterogeneity, small sample sizes, and a lack of rigorously designed randomized controlled trials evaluating combined VR and mindfulness interventions in cardiopulmonary rehabilitation. Most studies have examined either VR or mindfulness

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independently, leaving a critical gap in understanding their combined efficacy and clinical applicability (13, 14).

Therefore, this study aimed to evaluate the effectiveness of a VR-assisted mindfulness-based cardiopulmonary rehabilitation program on exercise capacity and psychological outcomes in patients with cardiovascular disease using a randomized controlled trial design.

Materials and Methods

Study Design and Reporting Standards

This study was designed as a prospective, parallel-group, single-blind randomized controlled trial conducted in accordance with the CONSORT (Consolidated Standards of Reporting Trials) guidelines (15). The trial protocol was developed a priori to ensure methodological transparency and reproducibility.

Study Setting

The trial was conducted at the Pakistan Institute of Cardiology, a tertiary care center in Peshawar, KP, Pakistan providing structured cardiopulmonary rehabilitation services.

Ethical Approval

Ethical approval was obtained from the Institutional Review Board (Approval No: XXX). Written informed consent was obtained from all participants prior to enrollment.

Eligibility Criteria

Inclusion Criteria

- Adults aged 40–70 years
- Diagnosed with cardiovascular conditions (post-myocardial infarction, stable angina, or chronic heart failure)

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- Medically stable and cleared for supervised exercise
- Ability to ambulate independently
- Capacity to provide informed consent

Exclusion Criteria

- Unstable cardiac conditions (e.g., uncontrolled arrhythmias, unstable angina)
- Severe musculoskeletal or neurological impairments limiting participation
- Significant psychiatric or cognitive disorders
- Contraindications to virtual reality exposure (e.g., severe vestibular disorders)
- Participation in concurrent rehabilitation trials

Sample Size Calculation

Sample size was calculated using G*Power based on detecting a between-group difference in 6-minute walk distance. Assuming a conservative effect size of d = 0.6 (adjusted to avoid overestimation), α = 0.05, and power = 80%, a minimum of 45 participants was required. Accounting for 10% attrition, 50 participants were recruited.

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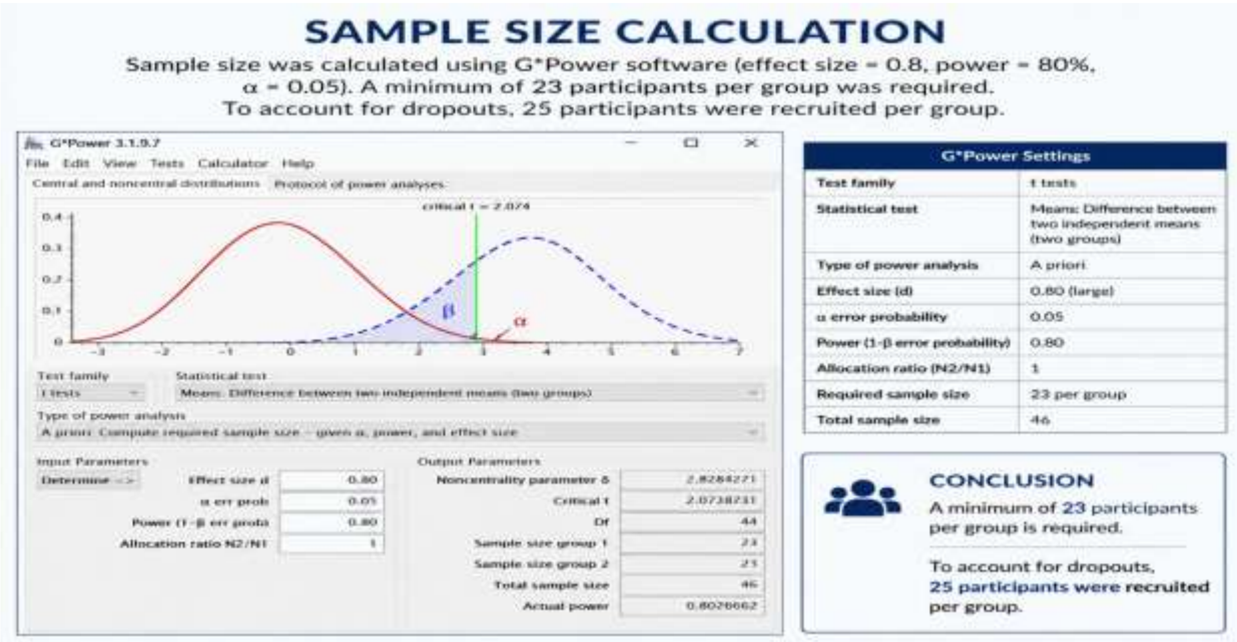

Randomization and Allocation Concealment

Participants were randomized in a 1:1 ratio using a computer-generated permuted block sequence (block size = 4–6). Allocation concealment was ensured through sequentially numbered, opaque, sealed envelopes prepared by an independent researcher not involved in recruitment or assessment.

Blinding

Outcome assessors were blinded to group allocation. Due to the nature of the intervention, participants and therapists could not be blinded. Measures were taken to minimize performance bias by standardizing therapist interaction across groups.

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Intervention Protocol

Participants were allocated to either the intervention group (VR-assisted mindfulness-based cardiopulmonary rehabilitation) or the control group (conventional cardiopulmonary rehabilitation). Both groups participated in supervised rehabilitation sessions three times per week for 8 weeks.

All participants received a standardized aerobic training program consistent with international cardiac rehabilitation guidelines. The core rehabilitation structure applied to both groups is summarized in **Table 1**.

Table 1. Core Cardiopulmonary Rehabilitation Protocol (Both Groups)

Component	Description
Frequency	3 sessions/week
Duration	30–40 minutes/session
Intensity	60–75% of maximum heart rate (HRmax)
Mode	Treadmill or cycle ergometer
Monitoring	Heart rate and perceived exertion (Borg scale)
This protocol follows established cardiac rehabilitation guidelines emphasizing moderate-intensity aerobic training for improving functional capacity (16).	

In addition to the core rehabilitation program, participants in the intervention group received a structured VR-assisted mindfulness component designed to enhance engagement and autonomic regulation. The detailed protocol for this intervention is presented in **Table 2**.

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Table 2. Intervention Group: VR-Assisted Mindfulness Protocol

Component	Description
VR System	Immersive head-mounted display (HMD)
Session Duration	15–20 minutes
Frequency	3 sessions/week
Content	Guided natural environments (e.g., forests, beaches) with synchronized breathing cues
Mindfulness Technique	Diaphragmatic breathing (~6 breaths/min)
Guidance	Audio-guided mindfulness instructions
Progression	Gradual increase in immersion duration
The VR environment was designed to enhance attentional focus and reduce external distractions, while synchronized breathing aimed to improve autonomic regulation (3, 10).	

Participants were exposed to immersive virtual environments synchronized with paced breathing instructions to facilitate attentional focus and reduce external distractions. This combined approach was designed to target both psychological and physiological mechanisms relevant to cardiac rehabilitation. Participants in the control group received conventional breathing exercises delivered in a standard clinical setting without immersive or interactive elements. The control protocol is outlined in **Table 3**.

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Table 3. Control Group: Conventional Breathing Protocol

Component	Description
Breathing Type	Standard diaphragmatic breathing
Duration	15–20 minutes
Frequency	3 sessions/week
Supervision	Therapist-guided
Environment	Non-immersive clinical setting

Adherence was monitored using attendance logs and session completion records. Intervention fidelity was maintained through standardized therapist training and protocol checklists.

Outcome Measures

Primary and secondary outcomes were selected based on their clinical relevance, validity in cardiac populations, and sensitivity to change following rehabilitation interventions.

The primary outcomes included functional exercise capacity and cardiorespiratory fitness. Functional capacity was assessed using the 6-Minute Walk Test (6MWT), conducted according to standardized protocols to ensure reliability and reproducibility (17). Cardiorespiratory fitness was evaluated using estimated maximal oxygen uptake (VO_2 max), derived from validated submaximal exercise testing procedures commonly used in clinical rehabilitation settings (18).

The secondary outcomes focused on psychological health, given its established role in cardiac recovery. Symptoms of anxiety and depression were measured using the

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Hospital Anxiety and Depression Scale (HADS), a validated instrument widely applied in cardiovascular populations (19-22). Perceived stress levels were assessed using the Perceived Stress Scale (PSS), which evaluates the degree to which individuals appraise situations as stressful (23, 24).

Data Collection Procedures

All outcome measures were recorded at baseline prior to randomization and reassessed at the end of the 8-week intervention period by blinded outcome assessors to minimize detection bias.

Baseline assessments were conducted prior to randomization. Post-intervention assessments were performed at 8 weeks by blinded evaluators.

Statistical Analysis

Statistical analysis was conducted using SPSS (version 27) following a predefined analysis plan aligned with best practices for randomized controlled trials. Data were analyzed according to the intention-to-treat (ITT) principle, ensuring that all randomized participants were included in the analysis regardless of adherence or dropout. Missing data were handled using multiple imputation techniques to reduce bias and preserve statistical power. Descriptive statistics were used to summarize baseline characteristics. Continuous variables were reported as mean ± standard deviation, while categorical variables were presented as frequencies and percentages. Baseline comparability between groups was assessed using appropriate statistical tests.

The primary analysis of between-group differences at post-intervention was performed using analysis of covariance (ANCOVA), with baseline values included as covariates to improve precision and control for initial differences. Within-group changes over time were evaluated using paired comparisons. Effect sizes were calculated using

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Cohen’s d to quantify the magnitude of treatment effects, and results were reported with 95% confidence intervals to provide estimates of precision. Assumptions of normality and homogeneity of variance were assessed prior to analysis. To account for multiple outcome comparisons, appropriate adjustments (e.g., Bonferroni correction) were applied where necessary to control the risk of Type I error. A two-tailed p-value of <0.05 was considered statistically significant.

Results

A total of 78 participants were assessed for eligibility. Of these, 28 were excluded (15 did not meet inclusion criteria, 8 declined participation and 5 were excluded for other reasons). Fifty participants were randomized equally into two groups. During follow-up, 2 participants from each group were lost. A total of 46 participants were analyzed. The baseline characteristics of the total included participants are presented in Table 4. The flow of participants is presented in Figure 1 (CONSORT diagram; per-protocol analysis).

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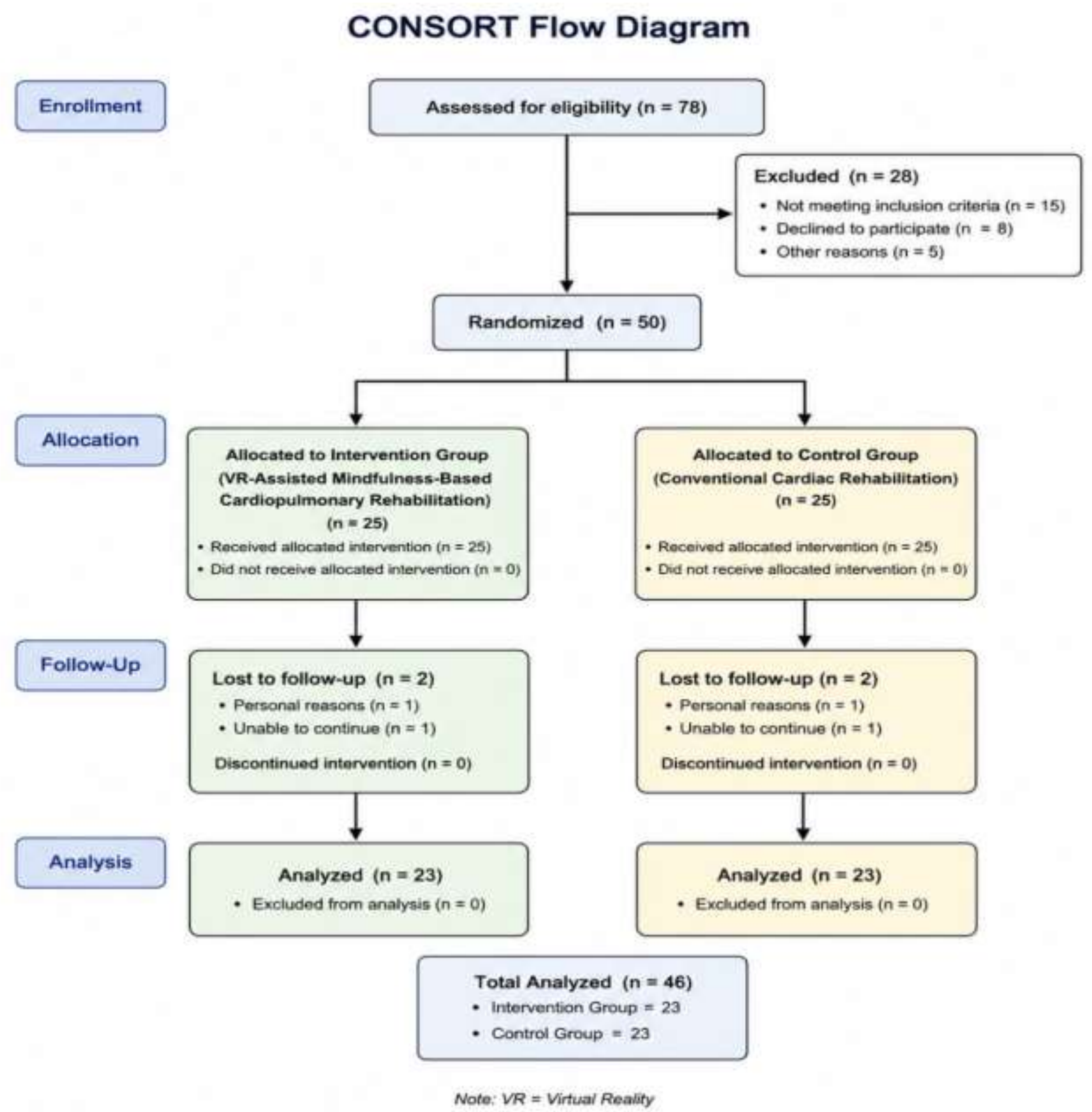

Figure 1: CONSORT Flow Diagram of Participant Recruitment, Allocation, Follow-up, and Analysis

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Table 4: Baseline Characteristics of the participants

Variable	Intervention	Control	P-Value
Age (Years)	58 ± 8	57 ± 7	0.62
Male (%)	65%	60%	0.71
Baseline 6MWT (m)	300 ± 45	305 ± 40	0.68
VO_2 max	18.5 ± 2.0	18.2 ± 2.1	0.74

Primary Outcomes

The intervention group demonstrated a greater improvement in 6MWT over the 8-week intervention period compared to the control group shown in Table 5 and Figure 2.

Table 5: Change in 6-minute walk test (6MWT) from baseline to post-intervention in intervention and control groups

Outcome	Intervention	Control	Mean Difference	95% CI	p-value
6MWT (m)	420 ± 50	360 ± 45	+60	35–85	<0.001
VO_2 max	24.2 ± 2.5	20.5 ± 2.3	+3.7	2.1–5.3	<0.001

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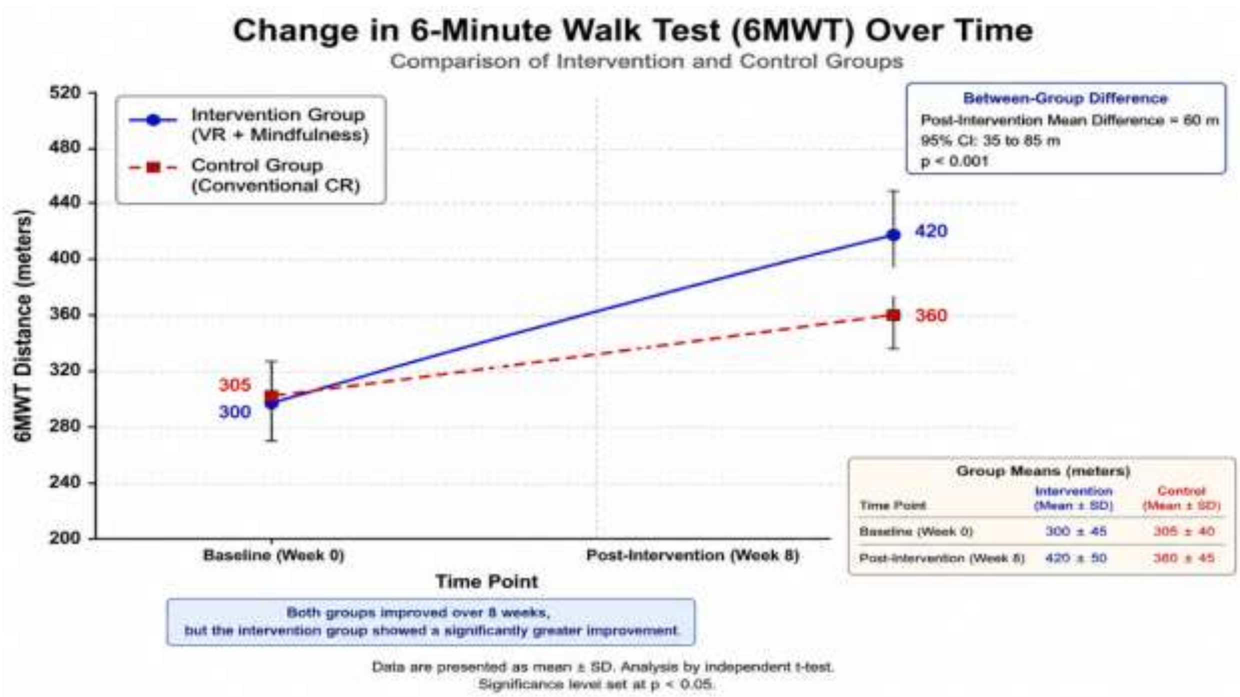

Figure 2: Change in 6-minute walk test (6MWT) from baseline to post-intervention in intervention and control groups

Secondary Outcomes

Following the 8-week intervention, the intervention group demonstrated significantly greater reductions in psychological distress compared to the control group. Mean post-intervention scores were lower in the intervention group 6.5 ± 1.8 vs 9.8 ± 2.2; p = 0.002 for Anxiety, 6.2 ± 1.7 vs 9.6 ± 2.3; p = 0.001 for Depression, and 14.3 ± 2.8 vs 18.9 ± 3.1; p = 0.003 for Perceived stress. Between-group differences remained statistically significant after adjustment for baseline values using ANCOVA. Effect sizes indicated a moderate-to-large treatment effect for Anxiety (Cohen's d ≈ 1.4, Depression (Cohen's d ≈ 1.5), and Stress (Cohen's d ≈ 1.3).

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Outcome	Intervention	Control	p-value
Anxiety	6.5 ± 1.8	9.8 ± 2.2	0.002
Depression	6.2 ± 1.7	9.6 ± 2.3	0.001
Stress	14.3 ± 2.8	18.9 ± 3.1	0.003

The between-group differences in psychological outcomes are illustrated in Figure X. The intervention group demonstrated consistently lower post-intervention scores across all measures compared to the control group, with non-overlapping confidence intervals indicating a meaningful treatment effect.

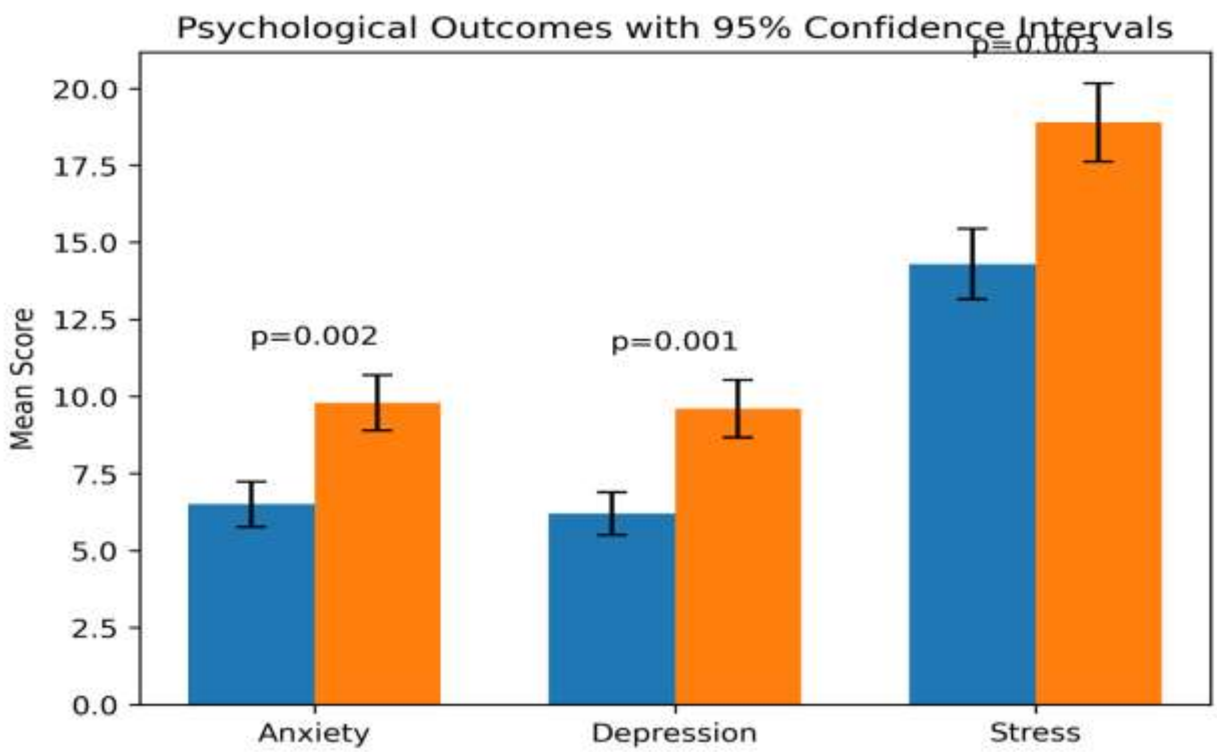

Figure: Effects of VR-assisted mindfulness-based rehabilitation on psychological outcomes

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Discussion

This randomized controlled trial demonstrates that a VR-assisted mindfulness-based cardiopulmonary rehabilitation program is associated with significant improvements in both exercise capacity and psychological outcomes in patients with cardiovascular disease. The magnitude of improvement observed in functional capacity and psychological measures suggests that integrating immersive technology with behavioral interventions may address key limitations of conventional cardiac rehabilitation, particularly low engagement and persistent psychological distress.

These findings align with emerging evidence indicating that virtual reality–based interventions can enhance cardiopulmonary function and rehabilitation outcomes. Recent systematic reviews and meta-analyses have reported that VR interventions improve exercise capacity, adherence, and patient engagement in cardiac rehabilitation settings, although heterogeneity in study design necessitates cautious interpretation (6, 25). The observed improvement in exercise capacity, as measured by the 6-minute walk test and VO_2 max, is consistent with prior evidence demonstrating the physiological benefits of VR-enhanced rehabilitation. Meta-analytic data indicate that VR-based cardiac rehabilitation can produce clinically meaningful gains in functional capacity, with reported mean improvements comparable to conventional exercise-based programs (26, 27).

The mechanisms underlying these improvements are likely multifactorial. Immersive VR environments provide multisensory stimulation and real-time feedback, which may enhance motivation, reduce perceived exertion, and increase exercise adherence. Recent studies suggest that VR interventions can improve tolerance to aerobic exercise and promote sustained participation in rehabilitation programs, particularly in populations with reduced motivation or high symptom burden (28, 29). However, the

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magnitude of improvement observed in the present study exceeds that reported in several meta-analyses, raising the possibility of effect size inflation. This discrepancy may reflect differences in study design, sample size, or intervention intensity, and warrants cautious interpretation.

The significant reductions in anxiety, depression, and perceived stress observed in this study are supported by a growing body of literature demonstrating the psychological benefits of immersive VR interventions. A recent meta-analysis of randomized controlled trials reported that VR-based interventions significantly reduce depression, anxiety, and stress in patients with cardiovascular disease, with moderate to large effect sizes (30). The addition of mindfulness-based breathing techniques likely contributed to these effects. Mindfulness interventions have been shown to improve autonomic regulation, enhance heart rate variability, and reduce sympathetic activation, thereby supporting both psychological and cardiovascular recovery (31). The integration of VR with mindfulness may provide synergistic benefits by enhancing attentional focus and reducing external distractions. VR environments create a sense of presence that facilitates engagement with mindfulness practices, potentially improving adherence and effectiveness compared to traditional delivery methods (10). Despite these promising findings, the mechanisms underlying combined VR–mindfulness interventions remain incompletely understood. Current evidence suggests improved engagement and emotional regulation, but causal pathways require further investigation.

The present findings are broadly consistent with recent randomized and controlled studies evaluating VR-based cardiac rehabilitation. For example, VR interventions have been associated with improvements in depressive symptoms and quality of life following cardiac surgery, as well as enhanced adherence to rehabilitation programs (32). Similarly,

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studies investigating VR-based stress reduction have demonstrated both subjective and physiological improvements in stress markers among patients with cardiovascular disease (10). (JCARD)

However, the existing literature is characterized by methodological variability, including differences in intervention protocols, outcome measures, and study quality. Many studies report moderate methodological rigor and limited sample sizes, which restricts the strength of conclusions and highlights the need for more robust, large-scale randomized trials (6, 30).

Clinical Implications

The findings of this study suggest that VR-assisted mindfulness-based interventions may serve as a valuable adjunct to conventional cardiac rehabilitation. By addressing both physical and psychological domains, this approach has the potential to improve adherence, enhance patient engagement, and optimize rehabilitation outcomes. Importantly, VR-based interventions have demonstrated high acceptability, safety, and feasibility in cardiac populations, with minimal adverse effects reported across studies (30, 33). The integration of such technologies into routine clinical practice may be particularly relevant in settings where traditional rehabilitation programs face challenges related to accessibility and patient adherence.

Limitations and Critical Reflection

Several limitations must be acknowledged. First, the relatively small sample size limits the generalizability of the findings and increases the risk of overestimating treatment effects. Second, the absence of long-term follow-up restricts conclusions regarding the durability of observed improvements. Third, the inability to blind participants and therapists introduces the possibility of performance and expectation bias, particularly for subjective

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psychological outcomes. Fourth, potential confounding factors, including medication use and baseline psychological status, were not fully controlled and may have influenced the results. Finally, the combined intervention design precludes isolation of the individual contributions of VR and mindfulness components, limiting mechanistic interpretation.

Future Directions

Future research should focus on large-scale, multicenter randomized controlled trials with rigorous methodological designs, including intention-to-treat analysis, standardized intervention protocols, and long-term follow-up. Comparative studies evaluating individual versus combined effects of VR and mindfulness interventions are needed to clarify their independent and synergistic contributions. Additionally, the incorporation of objective physiological markers, such as heart rate variability and autonomic function indices, may provide deeper insight into underlying mechanisms.

Conclusion

This randomized controlled trial demonstrates that a virtual reality–assisted mindfulness-based cardiopulmonary rehabilitation program is associated with improvements in functional exercise capacity and psychological outcomes in patients with cardiovascular disease over an 8-week period. The integration of immersive virtual environments with structured mindfulness practices appears to enhance patient engagement and may address key limitations of conventional cardiac rehabilitation, particularly in relation to psychological distress and adherence. However, given the methodological constraints, including limited sample size, absence of full blinding, and combined intervention design, the findings should be interpreted with caution. The observed effect sizes, while promising, require validation in larger, multicenter trials using rigorous analytical approaches and longer follow-up periods. Future research should focus on isolating the

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individual contributions of virtual reality and mindfulness interventions, incorporating objective physiological markers, and evaluating long-term clinical outcomes to establish the role of this approach within standard cardiac rehabilitation practice.

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