IJBMC
International Journal of Body, Mind and Culture

Volume 12, Issue 4, pp 110-119
DOI: 10.61838/ijbmc.v12i4.957

Article type:
Original Research

Effect of Virtual Reality on Anxiety Levels in Patients After Percutaneous Coronary Intervention: A Randomized Clinical Trial

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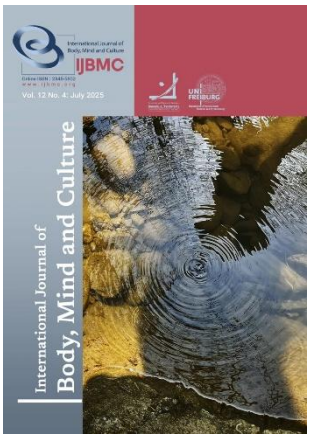

Article history:

Received 28 Dec 2024
Revised 19 Feb 2025
Accepted 29 Feb 2025
Published online 21 May 2025

How to cite this article:
Shutnan, A. H., & Athbi, H. A. (2025). Effect of Distraction Technique Using Virtual Reality on Anxiety Level in Patients After Percutaneous Coronary Intervention: A Randomized Clinical Trial. International Journal of Body, Mind and Culture, 12(4), 110-119.

ABSTRACT

Objective: Various non-pharmacological methods, including virtual reality (VR), are presently employed as adjunctive tools in the management of anxiety. Anxiety and its related problems are prevalent among people with cardiovascular disease and can substantially affect heart function. This study aimed to investigate the effects of virtual reality (VR) technology on post-percutaneous coronary intervention anxiety.

Methods and Materials: Randomized clinical trial, where participants were randomly divided into 77 patients in the control group and 77 patients in the intervention group, admitted to the Karbala Center for Cardiac Disease and Surgery in Karbala city, Iraq, from September 16, 2024, to January 20, 2025. In the intervention group, 3D videos are shown with smoothing. Data were collected using a socio-demographic information sheet and the visual analogue scale for Anxiety (VAS-A). Statistical analysis was performed using an independent t-test, Spearman's correlation coefficient, Mann-Whitney U, Kruskal-Wallis H, and ANOVA with SPSS software version 27.

Findings: The majority of participants in the intervention group were male (56.9%), while those in the control group were predominantly female (54.2%). The (Mean ± SD) age of them in the intervention and control groups was (57.38 ± 6.514) and (60.53 ± 7.530) years, respectively. A significant difference (P<0.01) was noted for the mean score of anxiety between intervention and control groups, while the control group showed no significant differences (P>0.05).

Conclusion: The virtual reality protocol-based distraction strategy dramatically reduces post-PCI anxiety levels. It is advised that simulation be used as a proactive strategy to reduce anxiety following PCI.

Keywords: Virtual Reality, Anxiety, Percutaneous Coronary Intervention, Distraction Technique.

Introduction

The World Health Organization states that cardiovascular disease (CVD) is the leading cause of morbidity and mortality worldwide and a significant contributor to deaths attributable to CVD (World Health Organization, 2021). Nearly everywhere in the world, cardiovascular diseases (CVDs) are the primary cause of death (Mahmood, 2023). Cardiovascular disease is the most significant cause of death for adults between the ages of 35 and 70 (Dagenais et al., 2020). Internationally, cardiovascular disease is the primary cause of death, with ischemic heart disease accounting for almost half of these deaths (Sagheer & Dawood, 2024). Cardiovascular diseases are the most common causes of mortality worldwide. They are frequently the reasons for patient hospitalization, their incapability for work, and disability (Winnige et al., 2021).

In Korea, heart disease ranks second in terms of cause of death after cancer. In 2018, the mortality rate from coronary artery disease, which includes myocardial infarction and angina, was 28.3 per 100,000 people. Over 65,00 PCI procedures are carried out annually at roughly 140 institutions in Korea (Yujeong, 2022). In the holy city of Karbala, the Karbala Center for Cardiac Disease and Surgery conducted 2,976 percutaneous coronary interventions in 2023 (Ministry of Health/ Environment/ Karbala Health Director/ Department's statistics, 2023).

One appropriate technique for the diagnosis of CHD is percutaneous coronary intervention. A typical therapeutic approach for treating coronary artery disease is percutaneous intervention, or PCI. This is especially true for patients who arrive with acute coronary syndromes (Keshvari et al., 2023). Although PCI is successful in improving patient outcomes and resting coronary blood flow, significant physical and psychological side effects, most notably anxiety, are frequently experienced (Johnson et al., 2020).

Up to 15% of patients with coronary artery disease have anxiety disorders, and over 50% of these patients also have depression or anxiety. Anxiety is present in 24–72% of patients having percutaneous coronary intervention (Palandacic et al., 2022). Patients' recuperation is negatively impacted by the anxiety that cardiac treatments frequently cause. Due to the limitations of pharmaceutical therapies, new digital options, such as virtual reality (VR), are being investigated (Micheluzzi et al., 2024).

Anxiety symptoms are experienced by a sizable portion of patients (32% to 49%) during cardiac procedures; these symptoms are frequently related to insufficient anxiety management and inadequate procedural comprehension (Bashir et al., 2024).

Anxiety and cardiovascular symptoms have always been tightly associated. Conversely, anxiety is a state of disquiet and apprehension. There are physical, physiological, and mental symptoms associated with anxiety. Tremulousness, palpitations, and hyperhidrosis are examples of somatic symptoms. The physiological aspect includes elevated muscle tension, tachycardia, hyperventilation, and an irritated bladder. Worry is a cognitive symptom that is defined as an excessive dread of something bad happening (Saini et al., 2022).

In individuals with coronary heart disease, anxiety is a predictor of a poor prognosis. Although high anxiety levels were observed in patients with coronary heart disease receiving percutaneous coronary intervention (PCI), nothing is known about how anxiety levels changed following the treatment (Ashour et al., 2023).

It can be complicated to control the anxiety that is brought on by surgical procedures. Incorporating non-pharmacological strategies has been a priority of medical care reform in recent decades. This study used an experimental design to determine the effectiveness of VR as a non-pharmacological approach in reducing anxiety after percutaneous coronary intervention PCI, and with the assessment of subjective and objective parameters (Khan & Ludman, 2022).

In cardiovascular care, patients can utilize virtual reality (VR) and augmented reality (AR) for various purposes, including motivation and education, distraction during procedures, and post-intervention training. As a result, VR and AR may aid in early rehabilitation and help minimize delirium and anxiety (Jung et al., 2022). The VR/AR therapy may also help prevent boredom and reduce anxiety or delirium in critically ill patients in the intensive care unit. VR thus lowers the anxiety levels of patients during their hospital stay, especially in ICUs, or during treatments like percutaneous coronary intervention (Bruno et al., 2020).

Methods and Materials

Study Design and Participants

This is a Randomized controlled trial (RCT). This study was conducted at the Karbala Center for Cardiac Disease and Surgery and the Al-Iman Al-Hassan Al-Mujtaba teaching hospital in Karbala city, Iraq. The study period was conducted from September 13, 2024, to January 23, 2025.

The minimum sample size was calculated using a free sample size calculator, considering a 0.05 error margin and a 95% confidence level. A sample size of 144 participants was identified; these patients were divided equally between the intervention (VR) and control groups. The patients who met the inclusion criteria, without hearing or vision impairment, with verbal communication skills and intellectual capacity, and who were at least eighteen years old, as well as patients with

PCI, were informed of the study aims and completed the consent form.

Instruments

This section includes ten questions: age, sex, marital status, educational level, occupation, smoking status, weight, height, body mass index, chronic diseases, and medication use. As for the process of measuring patients' weight and height, a device of the type DETECTO was available in the study setting. DETECTO was established in 1950 and has its headquarters and manufacturing in Webb City, Missouri, in the United States.

Part two: Visual Analogue Scale for anxiety (VAS-A)

The second part include the visual analogue scale for anxiety (VAS-A) is one of the scale that used to evaluate the anxiety, it is consist of horizontal line that is 10 centimeter in long and has the phras (no anxiety) at one of the end and (very anxious) at the opposite end, participants marked anxiety severity at the line. Anxiety levels are categorized as no anxiety (0), mild anxiety (1-3), moderate anxiety (4-6), and severe anxiety (7-10).

The Visual Analog Scale for Anxiety (VAS-A) is a commonly used measurement tool both nationally and internationally. The VAS-A is a useful self-rating tool for state anxiety because of its sufficient psychometric qualities and ease of use. The VAS-A (Hornblow & Kidson, 1976) is free to use.

The rating and scoring of body mass index (BMI) measures weight and height and applies the following formula: BMI = weight in kilograms / (height in meters)2. BMI was categorized according to the classification by Hughes (2022). As follows: underweight less than 18.5, normal body weight between 18.5-24.9, overweight about 25.0- 29.9, obesity classified I between 30.0-34.9, obesity classified II about 35.0-39.9, and obesity classified III more than 40.

The anxiety was classified into following cut of points were determined on a 10 cm VAS-A: no anxiety (0) cm, mild anxiety (1-3) cm, moderate anxiety (4-7) cm, and sever paianxiety (7-10) cm (Mohamed Eldesoky & Elesawy, 2021).

Intervention

For the VR group, as shown in Figures 1 and 2, after placing the patient in a semi-Fowler's position, the VR glasses were applied following completion of percutaneous coronary intervention (PCI) in the coronary care unit (CCU). The virtual reality goggles were then worn for 15 minutes. After that, a variety of smoothing 3D videos are shown, including a natural video with smoothing music. The patient has the option to stop or switch to a different video at any time. The used VR glasses are KUSSTOM SMART ITEMS VR headset made in China, and the P9 Plus Max headset. After that, the participant's anxiety severity was evaluated by using the visual analogue scale for anxiety (VAS-A).

Figure 1

Flowchart of Sample groups of interventional, control, and excluded

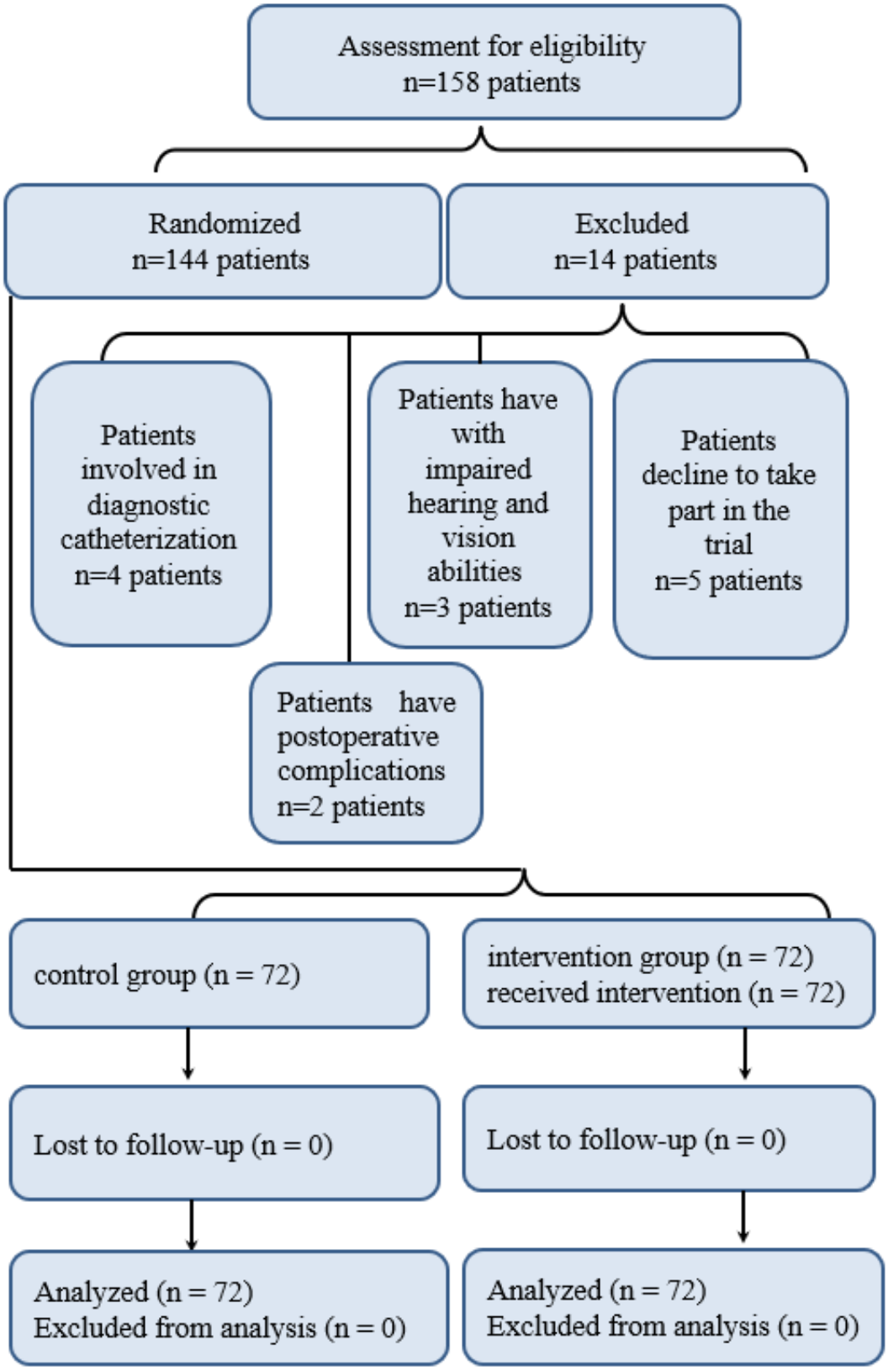

Figure 2

Using virtual reality to distract patients after percutaneous coronary intervention.

Data Analysis

Data analysis was conducted using SPSS version 27 and AMOS version 21. Descriptive statistics, including mean, standard deviation, frequency, and percentage, were calculated to summarize participant demographics and study variables. The relationships between health anxiety and other variables (chronic fatigue symptoms, spiritual vitality, social support, and lifestyle) were examined using Pearson correlation coefficients.

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E-ISSN: 2345-5802

Additionally, a Structural Equation Modeling (SEM) approach was employed to test the hypothesized causal model and its mediating effects. Model fit indices such as CFI, TLI, RMSEA, and χ^2/df were used to evaluate model adequacy.

Findings and Results

With the study's present objectives, the finding incorporates both descriptive and inferential statistics, including the following:

Table 1

Distribution of the study sample according to sociodemographic data (N= 144)

Demographic and clinical	Subgroup	Control		Intervention		Levene S.
		f.	%	f.	%	P. value
Age group	41 - 49 years	8	11.1	12	16.7	.330
	50 - 59 years	21	29.2	30	41.7	
	60 - 69 years	36	50.0	28	38.9	
	≥ 70 years	7	9.7	2	2.8	
	Total	72	100.0	72	100.0	
	Mean ± SD 60.53 ± 7.530 Min- Max 41 - 77 years			Mean ± SD 57.38 ± 6.514 Min- Max 45 - 72 years		
Sex	Male	33	45.8	41	56.9	.343
	Female	39	54.2	31	43.1	
	Total	72	100.0	72	100.0	
Marital Status	Single	6	8.3	3	4.2	.356
	Married	58	80.6	58	80.6	
	Widower	8	11.1	11	15.3	
	Total	72	100.0	72	100.0	
Educational level	Not Read and Write	40	55.6	34	47.2	.455
	Read and Write	22	30.6	26	36.1	
	Primary School	0	0	4	5.6	
	Middle School	0	0	1	1.4	
	Secondary School	2	2.8	0	0	
	Institute	0	0	1	1.4	
	College or Above	8	11.1	6	8.3	
	Total	72	100.0	72	100.0	
Occupation	Employee	10	13.9	21	29.2	.000
	Retired	11	15.3	5	6.9	
	Gainer	51	70.8	46	63.9	
	Total	72	100.0	72	100.0	
Smoking Status	Never Smoked	6	8.3	11	15.3	.249
	Previously	25	34.7	13	18.1	
	Currently	41	56.9	48	66.7	
	Total	72	100.0	72	100.0	
Types of Smoking	Cigarettes	31	43.1	27	37.5	.093
	Hookah	8	11.1	14	19.4	
	Mix	2	2.8	7	9.7	
	Total	72	100.0	72	100.0	
Duration of Smoking	Less than 1 year	0	0	3	4.2	.004
	1 - 5 years	3	4.2	14	19.4	
	6 - 10 years	6	8.3	16	22.2	
	More than 10 years	32	44.4	15	20.8	
	Total	72	100.0	72	100.0	
Chronic diseases	Diabetes Mellitus	20	27.8	12	16.7	.990
	Hypertensive	33	45.8	38	52.8	
	Chronic Kidney Diseases	3	4.2	4	5.6	
	Chronic Respiratory Diseases	5	6.9	7	9.7	
	Diabetes Mellitus and Hypertension	11	15.3	11	15.3	
	Total	72	100.0	72	100.0	
Drugs for Chronic Diseases	Antihyperglycemic Drugs	20	27.8	12	16.7	.990
	Antihypertensive Drugs	33	45.8	38	52.8	
	Chronic Kidney Disease Drugs	3	4.2	4	5.6	
	Bronchodilators Drugs	5	6.9	7	9.7	
	Antihypertensive and Antihyperglycemic Drugs	11	15.3	11	15.3	
	Total	72	100.0	72	100.0	

f= frequencies, %=Percentages, M = Mean of score, S.D = Standard Deviation, Min= minimum and Max= maximum

Table 1 presents the distribution of 144 patients after percutaneous coronary intervention (PCI), categorized by sociodemographic data into two groups: control (n = 72) and virtual reality (n = 72). The age range in the control group is from 60 to 69 years, with a mean of 60.53 years. In contrast, the age range in the intervention group (VR group) is from 50 to 59 years, with a mean of 57.38 years. Regarding the sex of the patients, most (54.2%) were female in the control group. In comparison, in the VR group most (56.9%) were male, regarding the marital status in the both study groups the majority married patients (80.6%), the educational level in both VR and control group with not read and write status (47.2% and 55.6%), regarding the occupation of the participants were most in both group gainer in control group (70.8%) and intervention group (63.9%), the smoking status in both groups were smoking cigarettes currently (56.9% control, 66.7% VR), regarding the duration of smoking in the control group more than ten years and from five to ten years.

Upon analyzing the clinical data of study participants, it was found that both groups were overweight, with 43.1% in the control group and 47.2% in the VR group. The study also related chronic disease to hypertension, which was observed in 45.8% of the control group and 52.8% of the intervention group, with both groups using antihypertensive drugs.

Table 2

Assess and compare the level of anxiety for control and intervention (distraction technique by using virtual reality) groups in patients after PCI.

Level of anxiety	Range	Control		Intervention		Mann-Whitney U		
						M.D	Z	p. value
		f.	%	f.	%			
No anxiety	0	0	0	0	0			
Mild	1-3	8	11.1	61	84.7			
Moderate	4-6	52	72.2	8	11.1			
Severe	7-10	12	16.7	3	4.2			
	Total	72	100.0	72	100.0			
	Min – Max	3	7	2	7			
	Mean ± SD	5.15	1.252	2.90	1.177			
						2.250	-8.480-	.000

Z = Standardized value, M. D = mean difference, P = probability value, NS: Non-Significant at P > 0.05, S: Significant at P < 0.05, HS: Highly Significant at P < 0.001.

The result in Table 2 shows the level of anxiety for control and VR groups in patients after PCI, and there were highly significant statistical differences in the level of anxiety between control and intervention groups at P<0.000. The mild anxiety level percentage in the intervention group was 84.7%, and the mild anxiety level in the control group was 11.1%, 4.2% for severe anxiety level in the intervention group, and 16.7% for the control group.

Discussion and Conclusion

The study findings indicate that the most common age group for the control group (50.0%) was 60 to 69 years, and for the intervention group, it was 41.7%, aged 50 to 59 years. These results are consistent with Rakhshani et al. (2014). According to the study by Athbi and Hassan (2019), the majority (75%) were above 50 years old (Athbi & Hassan, 2019; Rakhshani et al., 2014). This finding supports the findings of the current study. The average age of participants in this study was 57.06 ±8.9 years. In current research most the PCI patient in intervention group male (56.9%) and (45.8%) in control group, these findings supported by Assari, et al., (2017) the predominant gender of participants was male (71.25%), with a Mean ± SD age of 50.95 ± 4.120 years in the intervention group and 52.08 ± 4.002 years in the control group (Assari et al., 2017). Regard the marital status the majority of the percutaneous coronary intervention with married status (80.6%) thas was supported by Aboalizm, et al., (2016) stated that the majority of the study and control groups were married

and lived in rural areas while (38% and 30%) respectively (Aboalizm et al., 2016).

Regarding the body mass index the (Mean ± SD 29.24 ± 4.920) in control group and (Mean ± SD 28.05 ± 4.463) in VR group with being overweight and (26.4%) being obesity class I in the control group as supported by as consistent with finding the study that was conducted by (Morgan & Gallagher, 2019).

Regarding the anxiety level in the control group and study group was statistically significant with eight patients (11.1%) mild anxiety level and sixty one patients (84.7%) with same level of anxiety in the VR group with Mean ± SD 5.15 and Mean ± 2.90 in the VR groups, and regarding the mild anxiety level in control group was fifty two patient (72.2%) and eight patients (11.1%) in intervention group, for the last anxiety level for control group was twelve patient (16.7%) and three patient (4.%) in VR group, as agree with results by Gu, et al., (2016) that he stated which significantly increased one day after surgery (54.70 %, $\chi 2 = 13.75$; $p < 0.001$). There was no significant difference in the prevalence of anxiety symptoms between one day and one month after surgery ($\chi 2 = 1.18$; $p = 0.278$) (Gu et al., 2016).

The study conducted by Brown & Foronda (2020) stated that patients using VR reported lower anxiety scores post-surgery compared to pre-operation. Both patients and healthcare providers expressed great satisfaction with the VR experience (Brown & Foronda, 2020). According to the review by Ioannou et al. (2020), a VR intervention is more successful for treating anxiety than the control or usual care. In various situations and illnesses, including cancer, virtual reality can effectively alleviate these symptoms (Ioannou et al., 2020). Kodvavi et al. (2023) demonstrated that the use of VR was significantly associated with a reduction in post-procedural anxiety (SMD = -0.73, 95%, $P < 0.0001$) (Kodvavi et al., 2023).

Upon analysis of the anxiety levels among patients after percutaneous coronary intervention (PCI), the results demonstrated highly significant statistical differences between the control and intervention groups ($P < 0.000$). In the intervention group, the percentage of patients with mild anxiety levels was notably higher at 84.7%, compared to only 11.1% in the control group. Conversely, severe anxiety was observed in only 4.2% of patients in the intervention group, while the control group reported a significantly higher percentage of severe anxiety at 16.7%. These findings align with recent studies emphasizing the role of virtual reality (VR) interventions in reducing anxiety levels in patients undergoing medical procedures. For instance, a study by Ko et al. (2024) found that VR interventions significantly decreased anxiety scores among patients in various clinical settings, attributing this to the immersive and distraction-inducing nature of VR technology (Ko et al., 2024). Similarly, a systematic review by Sariköse et al. (2024) highlighted that VR distraction therapy effectively alleviated preprocedural and postprocedural anxiety in cardiac patients, showcasing its therapeutic potential in reducing psychological distress (Sariköse & Turan, 2024). The significant reduction in anxiety levels in the intervention group observed in the current study is consistent with these findings and further supports the efficacy of VR as a nonpharmacological tool for anxiety management. The immersive experience provided by VR likely contributed to the patients' ability to shift focus away from their anxiety, thereby achieving better emotional regulation during and after PCI (el Mathari et al., 2024).

Virtual reality technology can proficiently alleviate anxiety after percutaneous coronary intervention procedures. However, further research is needed to ensure the safe implementation of this technology across various medical specialties.

Virtual reality often entails substantial expenses, limited resolution, and performance inconsistencies across various systems, which can impact experimental outcomes. Additionally, some patients expressed concerns that such modern technology would compromise cardiac performance, and some participants may require time to become accustomed to VR systems. When conducting additional studies on the use of VR in individuals with specific somatic disorders, this is a crucial topic to consider.

Acknowledgments

The author wishes to express gratitude to the library staff at the College of Nursing, University of Karbala, and to all patients who participated in the study.

Declaration of Interest

The authors of this article declared no conflict of interest.

Ethical Considerations

The study protocol adhered to the principles outlined in the Declaration of Helsinki, which provides guidelines for ethical research involving human participants. Ethical considerations in this study were that participation was entirely optional. The trial protocol received approval for registration in the Iranian Registry of Clinical Trials (IRCT) on November 18th, 2024. The trial identification number is IRCT20241114063711N1, membership number 63711, and trial ID 80184. And Institutional Review Board approval (code: uok.oon.24.050) was obtained (October 27th, 2024).

Transparency of Data

Following the principles of transparency and open research, we declare that all data and materials used in this study are available upon request.

Funding

This research was carried out independently with personal funding and without the financial support of any governmental or private institution or organization.

Authors' Contributions

All authors equally contribute to this study.

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