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Research Article

Effects of Cognitive and Emotional Impairment Management Bundle among Patients with Coronary Artery Disease: A Randomized Control Double-blinded Trial

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Abstract

Background: Cardiovascular diseases are the major non-communicable disease causing increased mortality and morbidity worldwide. Among cardiovascular diseases, coronary artery disease is one of the life-threatening diseases. The majority of patients, after the acute event of coronary artery disease, suffer from mental stress, depression, and cognitive impairments. Therefore, this study mainly focuses on the effect of the Cognitive and Emotional Impairment Management Bundle (CEIMB) among patients with coronary artery disease.

Methods: This randomized, controlled, double-blinded trial was conducted in a tertiary care center among patients with coronary artery disease. The samples were recruited from the coronary intensive care unit through purposive sampling technique. After the sample selection, they were allotted to control (n_1 = 55) and intervention (n_2 = 56) groups through block randomization. The intervention was provided through three sessions. The study was registered under the Clinical Trial registry of the country. The statistical analysis was done using the SPSS ver. 25. The analysis was done by mean, standard deviation, frequency, percentage, and two-way repeated measures ANOVA.

Results: The mean age of the participants in the control group was 56.6 ± 6.1 years, and in the experimental group was 57.6 ± 6.4 years. The majority of the participants (39.3%) in the intervention group had severe depression, moderate levels of stress (30.4%), and medication adherence (96.4%). In the experimental group, depression, stress, medication adherence, and cognition had a statistically significant difference at different periods (<0.05).

Conclusion: The impaired mental status and cognitive level of the patients after the cardiac event negatively influences the patient's prognosis, contributing to readmission and premature death.

Keywords: depression, stress, medication adherence, cognitive level, coronary artery disease patients

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1. Introduction

Cardiovascular diseases (CVD) are noncommunicable lifestyle diseases contributing to 31% of mortality globally. According to the World Health Organization reports, among the 17.7 million deaths from CVD, 7.4 million are due to coronary artery diseases (CAD). The CAD changes not only the patients' physiological condition but also their psychological and cognitive levels [1].

An existing study reports that depression is one of the most common psychological problems in patients after the acute event of CAD [2]. Additionally, stress also negatively impacts the prognosis of these patients. The INTERHEART study supported the same fact that the stress level of the South Asian population was more than that of the European [3]. It affects the patients' quality of life and increases the mortality rate [4]. The long-term sequelae of depression includes brain damage, further damage to the heart, and a negative impact on the physical symptoms [5].

Apart from the psychological symptoms of the patients with CAD, the patients had a decreased adherence level to the medication, also negatively affecting the prognosis of the disease and increasing the mortality rate [6]. Many contributing factors are reported for the increasing medication nonadherence rate among patients with CAD. It includes increased cost of medicines, fear of side effects, and more dependency [7]. Cognitive deficit also plays an important factor among post-myocardial infarction patients, and it may lead to poor compliance with medication, lifestyle modifications, and treatment protocols [8].

Therefore, there is a need for more focus on the management of psychological and cognitive symptoms among patients with CAD [9]. There are different strategies to improve the mental health and cognitive level among patients with CAD. However, there are no studies that specifically focus on the group of interventions among the CAD patients to improve their mental and cognitive status. In this study, the researcher planned to provide a bundle of interventions for these patients to assess their mental and cognitive status.

The null hypothesis (H_0) for this study was there is no statistically significant difference in mental and cognitive status among patients with CAD before and after the intervention at 0.05 level of significance.

2. Methods

2.1. Research design

A randomized controlled, double-blinded trial was conducted in a tertiary care center in Bhubaneswar, Odisha, India, among patients with CAD. The samples were recruited from the coronary intensive care unit and followed up in the hospital's cardiology ward and cardiology OPD. The study duration was from February 2022 to March 2023.

2.2. Sampling technique and sample size

The samples were selected using purposive sampling method among those who met the inclusion and exclusion criteria. Considering that the mean anxiety score in the intervention group at the end of the study was 4.09 ± 3.2 and in the control group was 6.54 ± 3.92 with a 95% confidence interval and 90% power [10], and assuming a nonresponse rate of 10%, the final sample size of 100 (50 in each group) was decided. Open Epi v3.0 calculated the sample size. After the

pilot study, each group's sample size was revised to 60 (Figure **1**).

2.3. Study population

Sample were enrolled after obtaining informed consent. The inclusion criteria included: patients diagnosed with coronary heart disease, including angina or myocardial infarction, patients on pharmaco therapy or those who had undergone PTCI (Percutaneous Transluminal Coronary Intervention), aged >18 years, both male and female, able to read as well as understand the questions in the questionnaire, able to talk, and emotionally ready to answer the questions and willing to perform the mild level of exercise and relaxation techniques.

The exclusion criteria were patients with mental illness, cancer, dementia, patients in long-term care facilities, suffering from severe physical problems, having acute mental disorders, and being unwilling to continue cooperation.

2.4. Randomization

After the sample selection, using the block randomization method, samples were allocated to the experimental and control groups. The block size was four at a 1:1 ratio. The allocated sequence was sequentially numbered in opaque sealed envelopes (SNOSE). The samples enrolled from the intensive care unit completed the pretest over there. The study followed double blinding. The participants were not aware of whether they were in the experimental or the control group, and the data collector did not know the participants in the two groups. The blinding was planned after the pretest assessment. A validated research assistant did the pre- and posttest assessments.

After the pretest completion, the intervention (Table 1) was provided for the next day through three sessions in the respective wards or the special cabin rooms. The control received routine care from the hospital.

2.5. Data collection procedure

Patients' sociodemographic data were collected through the sociodemographic Performa. This includes the patient's age, gender, marital status, family history of hypertension, work status of the patient, smoking and alcohol abuse, and sleeping hour. Depression and stress were measured using the modified Depression, Anxiety, and Stress Scale (DASS-21) [14]. The anxiety part in the questionnaire was deleted and modified for the purpose of this study. Depression and stress had seven items and had to be scored on a rating scale of 0–3. The total score was multiplied by two to get the actual score. The medication adherence was assessed using the Medication Adherence Rating Scale (MARS) – 10 [15]. Here, the patient had to respond either "Yes" or "No" to each question – "No" for questions 1–6 and 9 and 10, and "Yes" for questions 7 and 8. A score of 0–3 indicated nonadherence, 4–6 showed partially adherent, and 7–10 was medication adherence. The patient's mental status was assessed with the help of The Short Portable Mental Status Questionnaire (SPMSQ) -10 [16]. It has a total of 10 questions with two responses; correct and incorrect answers. A 0–2 error score indicates normal mental functioning, a 3–4 error indicates mild cognitive impairment, a 5–7 error indicates moderate cognitive impairment, and ≥8indicates severe cognitive impairment. The two posttest follow-up assessments were done after two weeks and eight weeks, respectively. All participants were under telephonic follow-up weekly once to maintain the relationship.

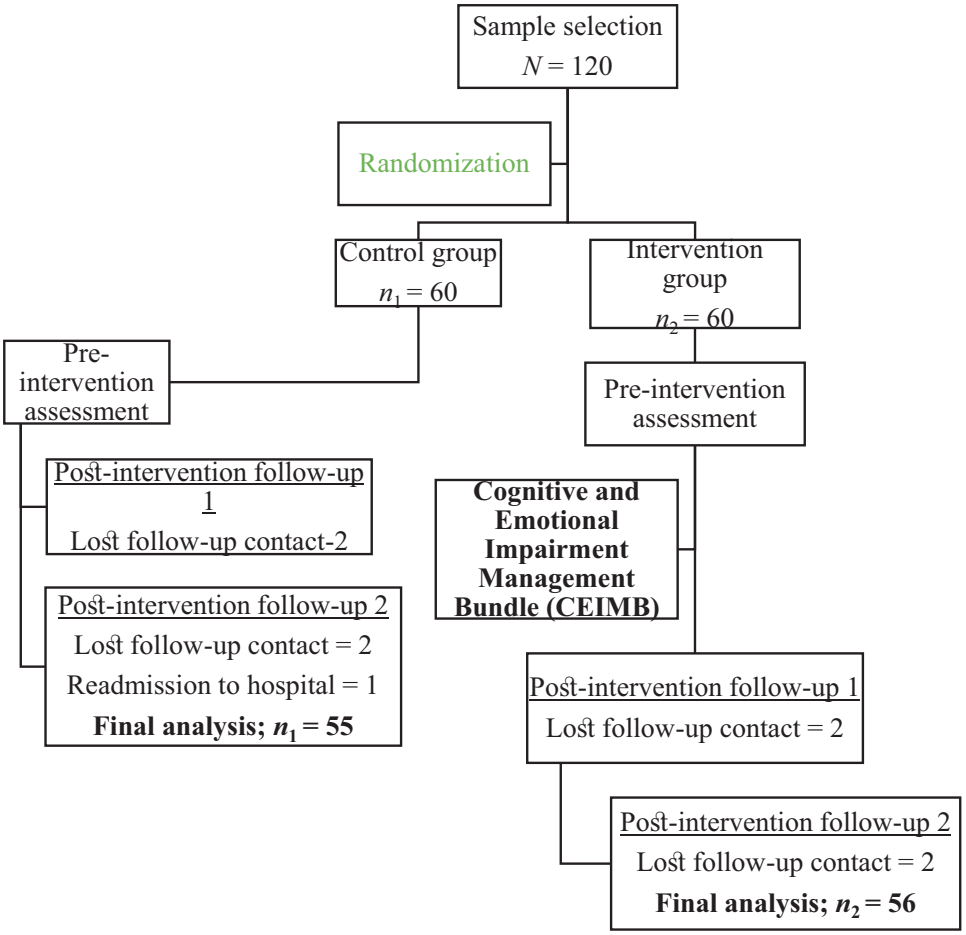

Figure 1: CONSORT diagram.

TABLE 1: Cognitive and Emotional Impairment Management Bundle (CEIMB).

Meeting/Session	Content
Preliminary session	Self-introduction and pretest assessment.
Session 1	This session was planned to have a discussion after the pretest. It included the following discussion points: Customized education on an overview of coronary heart disease; individual methods for regular medication; food pattern; weight balancing; physical exercise; problem identification; chest pain; dyspnea; or any specific sign.
Session 2	This session was planned for the second day. The session started with a brief overview of the last session and brain and lung exercise training. Lung exercise: Alternative nostril breathing for 10 min twice a day [11]. Brain exercise: Mental fitness exercise for 5 min twice a day [12].
Session 3	This session took place on the third day. The session started with a brief overview of the last session and relaxation technique. Relaxation technique used was Benson's relaxation [13].
Conclusion	Counseling and follow-up advice: Patient counseling on tailored need-based guidance, counseling, and follow-up advice.

2.6. Data analysis

Data were entered into an Excel data sheet and arranged by coding. Then, the tool validity was calculated by the Content Validity Index (CVI). After the data validation, the data sheet was transferred into the SPSS ver. 25. The tool reliability was calculated using Cronbach alpha and test–retest methods by correlation coefficient. The test–retest score (*r*) for DASS 21, MARS, and SPMSQ were

0.86, 0.87, and 0.92, respectively. The descriptive statistics include the mean, standard deviation, frequency, and percentage. The inferential statistics were obtained through the two-way ANOVA, repeated measures of two-way ANOVA, and chi-square test.

3. Results

The mean age of the participants in the control group was 56.6 ± 6.1 years and in the experimental group was 57.6 ± 6.4 years. The homogeneity analysis of the two groups revealed that they were both homogenous ($P > 0.05$) to compare, except for the family history of hypertension ($P < 0.05$). The participants in both groups were males, and all were married (Table 2). The majority of them were nonsmokers and nonalcoholics.

The majority of the participants (39.3%) in the intervention group had severe depression, moderate levels of stress (30.4%), and adherence to medication (96.4%) (Table 3). In the control group, the majority had extremely severe depression (41.8%), moderate levels of stress (25.5%), and adherence to medication (94.5%). The normal cognitive level in both group participants (Figure **2**).

A repeated measures ANOVA with a Greenhouse–Geisser correction showed that in the experimental group, depression, stress, medication adherence, and cognitive level had a statistically significant difference at three time periods (<0.05). In the experimental group, depression, stress, medication adherence, and cognition had a statistically significant difference at different periods (<0.05; Table 4). Post-hoc analysis with a Bonferroni adjustment showed a statistically significant decrease from pre-intervention to eight weeks in depression (mean difference [MD] = –2.29, Confidence Interval, CI = –2.36, –0.43), stress (MD = –3.96, CI = –5.58, –2.35), medication adherence (MD = 0.54, CI = 0.27, 0.80), and cognitive level (MD = 0.43, CI = 0.24, 0.62). In the control group, post-hoc analysis with a Bonferroni adjustment showed a statistically significant increase from preintervention to eight weeks in depression (MD = 3.05, CI = 1.04, 5.07), stress (MD = 3.27, CI = 1.48, 5.06), and medication adherence (MD = –0.47, CI = –0.75, –0.19).

Two-way ANOVA (Table 5) was used to check the effect of study groups and follow-up periods on depression, stress, medication adherence, and cognitive level. The report showed that there was a statistically significant interaction between the effect of study groups and follow-up period on depression ($F = 4.08$, $P = 0.02$), stress ($F = 6.35$, $P = 0.002$), and medication adherence ($F = 6.20$, $P = 0.002$).

4. Discussion

In this study, the mean age of the participants was 56.6 and 57.6 years in the experimental and control groups, respectively. The majority of the participants (39.3%) in the intervention group had severe depression, moderate levels of stress (30.4%) and adherence to medication (96.4%), and a normal cognitive level in both group participants.

A five-year follow-up study among CAD patients reported that their baseline depression had a significant association with their quality of life in the physical and psychological domains [4]. A study conducted in a public health institute reported that around 40% of hospital-admitted patients had significant levels of depression [9]. A similar prevalence rate of 30% and 22% were reported in a study conducted by Daniel *et al.* in 2018 and Murphy *et al.* in 2020 [17, 18].

Table 2: Sociodemographic distribution of participants in intervention and control group.

Variables		Control (n_1 = 55)	Intervention (n_2 = 56)	χ^2 (P-value)
Gender	Female	13 (23.6)	11 (19.6)	0.26 (0.61)
	Male	42 (76.4)	45 (80.4)	
Marital status	Married	55 (100)	56 (100)	
Education	Primary	21 (38.2)	22 (39.3)	1.59 (0.9)
	Matriculation	17 (30.9)	15 (26.8)	
	Higher secondary	7 (12.7)	7 (12.5)	
	Graduation	7 (12.7)	9 (16.1)	
	Postgraduation	3 (5.4)	3 (5.4)	
Family members have hypertension	Yes	38 (69.1)	26 (46.4)	5.84 (0.02)*
	No	17 (30.9)	30 (53.6)	
Work status	Not working	3 (5.5)	8 (14.3)	13.81 (0.09)
	Housewife	13 (23.6)	9 (16.1)	
	Government job	12 (21.8)	6 (10.7	
	Private job	11 (20)	6 (10.7)	
	Business	8 (14.5)	11 (19.6)	
	Labor work	4 (7.3)	6 (10.7)	
	Agriculture	1 (1.8)	8 (14.3)	
	Vehicle driver	3 (5.5)	2 (3.6)	
Smoking history	Nonsmoker	39 (70.9)	33 (58.9)	1.75 (0.19)
	Smoker	16 (29.1)	23 (41.1)	
Alcohol use	No	45 (81.8)	43 (76.8)	0.43 (0.8)
	Occasionally	6 (10.9)	8 (14.3)	
	Yes	4 (7.3)	5 (8.9)	
Sleeping hour	<6	17 (30.9)	16 (28.6)	0.37 (0.83)
	6–8	37 (67.3)	38 (67.9)	
	>8	1 (1.8)	2 (3.6)	

A recent study reported that around 82% of the patients with acute incidence of myocardial infarction experienced stress, and among them, around 5% had major depressive symptoms [19]. A Nigerian study reported that the prevalence of depression among the study samples was 54.9%. In that group, 16.5% were grouped into a major depressive group, and it showed that patients with stress have increased odds (Adjusted Odds Ratio = 2.78, 95% CI = 1.37, 5.64; *P* = 0.005) to develop depressive symptoms [20]. The two-year mortality rate of the patients with high-stress levels was reported to be more than that of moderate levels of stress (12.9% and 8.6% with a *P*-value of <0.05) [21]. A study conducted with 903 patients with acute myocardial infarction reported that most participants had severe stress (52.9%) while 38.4% had moderate stress levels [3].

A cross-sectional study among 315 patients with myocardial infarction showed a decreasing adherence to medication from 45% after seven days of the cardiac event to 19% after three months of the same [6]. A PREMIER study report showed

TABLE 3: Distribution of the participants based on their baseline depression, stress, and medication adherence level in experimental and control groups.

Variables		Control (n_1 = 55)		Intervention (n_2 = 56)	
		f	%	f	%
Depression	Normal	1	1.8		
	Mild	3	5.5	4	7.1
	Moderate	12	21.8	14	25.0
	Severe	16	29.1	22	39.3
	Extremely Severe	23	41.8	16	28.6
Stress	Normal	7	12.7	12	21.4
	Mild	10	18.2	6	10.7
	Moderate	14	25.5	17	30.4
	Severe	13	23.6	12	21.4
	Extremely Severe	11	20.0	9	16.1
Medication adherence	Partial adherence	3	5.5	2	3.6
	Adherent	52	94.5	54	96.4

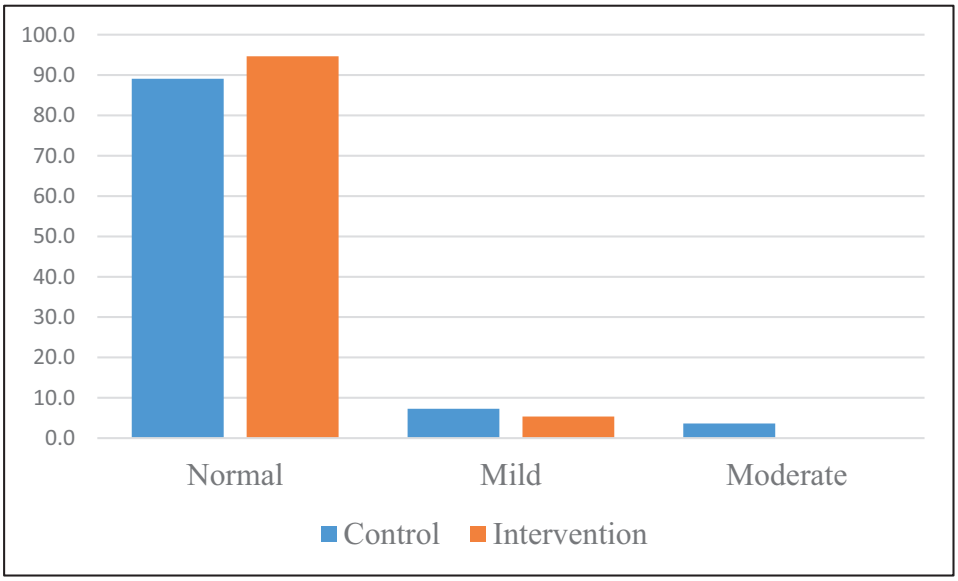

Figure 2: Cognitive level of participants in the experimental and control groups.

that 13.6% of the study group discontinued the anti-platelet medication after one month of the cardiac event [22]. A similar study report showed that compared to the nonadherence to the medication group, the medication adherence group had a 27% low risk of major adverse cardiovascular events (MACE) [23].

In this study, a significant decrease was seen in the depression and stress and an increased adherence to medication and cognitive level in the intervention group from the baseline values and after eight weeks of intervention. A smartphone-based care among the patients after the CAD showed increased medication adherence and compliance with treatment compared to routine center care [24]. A similar report was published by Glozier *et al.*, who assessed the effect of internet-based cognitive behavioral therapy [25]. In

Table 4: Mental status, cognitive level, and medication adherence among the participants.

Variables	Control (n_1 = 55)					Intervention (n_2 = 56)				
	Baseline	At two weeks	At eight weeks	F(P)	Partial eta squared	Baseline	At two weeks	At eight weeks	F(P)	Partial eta squared
Depression	25.2 ± 7.5	27.7 ± 7.5	28.2 ± 8.1	12.8 (<0.001)*	0.19	23.6 ± 7.1	22.7 ± 6.1	21.3 ± 5.7	8.9 (0.001)*	0.14
Stress	24.5 ± 8.0	26.7 ± 7.9	27.7 ± 6.5	15.3 (<0.001)*	0.22	23.4 ± 8.2	21.9 ± 7.6	19.4 ± 6.9	27.53 (<0.001)*	0.33
Medication adherence	9.1 ± 1.2	8.9 ± 1.3	8.7 ± 1.2	12.3 (<0.001)*	0.19	9.04 ± 1.1	9.3 ± 0.8	9.6 ± 0.6	18.9 (<0.001)*	0.26
Cognitive level	9.1 ± 1.3	8.9 ± 1.3	9.0 ± 1.3	2.81 (0.07)	0.05	9.2 ± 1.0	9.5 ± 0.7	9.6 ± 0.6	24.4 (<0.001)*	0.31

Table 5: Effect of two groups and follow-up period on mental status, cognitive level, and medication adherence using a two-way ANOVA.

Variables	df	F	P-value
Depression	2327	4.08	0.02*
Stress	2327	6.35	0.002*
Medication adherence	2327	6.20	0.002*
Cognitive level	2327	1.81	0.16

a quasi-experimental study to find out the effect of video and written education on the psychological symptoms of the patients who underwent coronary angiography showed a significant difference in the experimental and control groups [26]. A similar result was seen in a randomized control trial to identify the effect of pranayama on anxiety among the patients undergoing angiography with a reduction in the mean anxiety score from 53.4 to 40.7 [27].

5. Conclusion

CAD is noncommunicable and contributes to increased mortality rates globally. The impaired mental status and the cognitive level of the patients after the cardiac event negatively influence the prognosis of the patient and contribute to readmission and premature death. Therefore, a structured plan of action and a proper follow-up is necessary for them. The study recommends the same plan.

Declarations

Acknowledgments

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Ethical Considerations

The study was framed based on the current institution's ethical committee guidelines of IMS and SUM Hospital, Bhubaneswar. Written informed consent was taken from the participants before enrolling them in the study. Their identity and rights

were protected in accordance with the institution's norms. The study received the Institute Ethical Committee clearance under reference number: IEC/IMS.SH/SOA/2021/215. The trial was also registered under the CTRI (Clinical Trial Registry India) with registration number – CTRI/2022/02/040059.

Competing Interests

None.

Availability of Data and Material

All materials are available through mail request to the corresponding author.

Funding

None.

Abbreviations and Symbols

CEIMB: Cognitive and Emotional Impairment Management Bundle

CVD: Cardiovascular diseases

CAD: Coronary artery disease

PTCI: Percutaneous transluminal coronary intervention

DASS-21: Depression, Anxiety, and Stress Scale

MARS: Medication Adherence Rating Scale

SPMSQ: Short Portable Mental Status Questionnaire

OPD: Outpatient department

MD: Mean difference

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