Effect of Sleep Intervention Programs on the Quality of Sleep of Patients in Cardiac Rehabilitation Center

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Abstract

Background

Patients with cardiovascular problems experience sleep disorders. Due to the importance of adequate sleep and rest for the growth and repair of damaged cells, it is necessary to use appropriate interventions to improve it.This study determined the effect of sleep intervention programs during cardiac rehabilitation on patients' sleep quality.

Methods

In this clinical trial study, 35 individuals participated in the cardiac rehabilitation program as the experimental group and 35 served as the control group. The program included 12 weeks of exercise, 3 sessions per week, and 3 sessions of training programs each lasting for 45 minutes, and a special two-session sleep improvement program. Data were collected using the Pittsburgh sleep quality index and analysed with descriptive and inferential statistical methods.

Results

The two study groups were matched with age, sex, marital status, smoking and current disease diagnosis (P>0.05). The scores of sleep quality of patients were 9.2±1.58 before and 4.40±1.14 after intervention in the experimental group and 9.02±2.56 before and 7.48 ±1.86 after placebo in the control group. There was no significant difference before (P=0.73), but a significant difference after an intervention (P=0.0001). Also, scores of sleep quality of patients were significantly different in the experimental and control groups before and after the intervention (P=0.0001).

Conclusion

Findings indicated that the quality of sleep of cardiac patients improved after using the sleep intervention program during the cardiac rehabilitation program. Therefore, it is suggested to implement sleep improvement programs as an effective, easy, and feasible technique.

Introduction

Sleep is an important recurring and regular biological period accompanied by physical and mental power regeneration[1]. One-third of human life is spent sleeping[2]. Sleep physiology is not yet fully understood, but it is widely accepted that sleep is important for the human body in restoring metabolic and neural processes[3]. Sleep and rest are among the physiological and basic needs of human beings, the deprivation of which endangers human life and health Such as cardiovascular disease[4, 5]. When sleep is completely or partially limited, important brain functions are affected leading to mental and neurological disorders[3]. On the other hand, sleep disorders(SD) impair functions of the immune system, hypothalamus, pituitary and adrenal glands, leading to lower levels of ability to function[6]. Sleep disorder

over a significant period of time can also disrupt many aspects of quality of life, including general health, physical, cognitive, and psychological functions, and daily activities[7, 8].

Sleep is an important modulator of heart function, and can thus lead to lower activity and cardiac load, so that SD such as insomnia, sleeplessness and hypersomnia have also been considered as important factors in the pathogenesis and progression of cardiovascular diseases[9]. Cardiovascular disease is the most common cause of death and disability in the world and in Iran. Coronary artery disease has different risk factors that are related to the sympathetic system, and one of these factors is SD [4, 10]. Lower sleep duration increases heart rate, blood pressure and sympathetic activity, and increases a person's response to stressful stimuli. SD with disorders of the sympathetic system causes high blood pressure, obesity, as well as coronary artery disease and stroke. Sleep disturbance in heart patients delays recovery due to inflammatory factors. On the other hand, studies show that patients suffer from SD after heart accidents and coronary artery surgery[7]. In other words, there is a relationship between sleep quality(SQ) with cardiovascular disease and chronic disease [11]. SD has a prevalence of about 30% in human societies[12].SQ is an important clinical structure and a complex phenomenon that consists of mental indicators of how sleep experiences such as sleep satisfaction and feeling that arises after waking up are created[13]. Lower SQ is a common problem in cardiac patients[12] because patients with this complication are always exposed to sudden and imminent death. This feeling causes severe stress, anxiety, and worry that have many sides- effects on their mental and subconscious functions, including their sleep[4].

This is very important in cardiac patients because chronic diseases account for about half of the global burden of disease, and cardiovascular diseases account for the largest rate [7]. Researchers have tried to identify effective interventions to improve the quality of sleep in these patients. Cardiac rehabilitation(CR) program is another factor that has been suggested for quality of sleep in cardiac patients[14].

CR is defined as a medical care program designed to improve patients' cardiovascular health and function[7] and it is a comprehensive long-term program under the supervision of medical services including medical evaluation, exercise program, modification of cardiac risk factors, training, and counseling. This program is applicable for individuals with heart attack, heart failure, cardiac surgery, transplantation of coronary artery bypass, or coronary artery intervention[15]. CR has been known as an important measure for the effectiveness of heart disease and reducing its complications and a useful solution to improve quality of life, reduce disability and mortality, and increase physical, mental, and social abilities of patients, and in association with regular exercise, plays a role in stopping the progression of cardiac diseases, reducing their symptoms, improving mental health, increasing functional capacity, returning to life without dependence on others, and most importantly reducing mortality[16]. CR can reduce the effects of sleep deprivation by affecting the autonomic system and reducing inflammatory factors, and can improve the sleep cycle of patients by affecting depression and anxiety caused by heart disease. Benefits of exercise programs have been controversial on sleep habits and they have had positive effects in some cases, while other programs have not had any significant effect and it is possible that the duration or severity of exercise programs may have significant effects on results

[3].On the other hand, current interventions to treat sleep problems are often inaccessible, costly, and time-consuming[17]; hence, designing a short sleep behavioral intervention program may have significant benefits in improving sleep[18].In particular, there are few studies on interventions to improve sleep in patients undergoing CR[3], and a majority of studies are conducted on patients admitted to the intensive care unit and there are few studies on discharged patients. Therefore, it seems necessary to add sleep improvement programs to the heart rehabilitation program. On the other hand, adequate sleep is an important issue in improving the disease. Ensuring adequate sleep for patients is a basic task of nurses who should use appropriate nursing measures to manage SD in addition to assessing and determining their causes[19]. Therefore, the present study was conducted to determine the effect of a special sleep intervention program during CR on the quality of sleep in heart patients after discharge from the hospital.

Hypotheses

1. The mean score of sleep quality of patients in the experimental and control groups after cardiac rehabilitation is different.
2. The mean score of sleep quality of patients in the experimental group before and after rehabilitation is different.

Methods

Study design

The present study was a non-randomized controlled trials study which is registered with in Iranian Registry of Clinical Trials (IRCT20140307016870N6), on (14.06.2020). This research conducted in Afshar Heart Rehabilitation Center of Yazd, Iran which compared control and experimental groups. Our study adheres to CONSORT guidelines and the intervention is described in accordance with the CONSORT checklist (Figur1).

The research samples were selected from patients with heart problems who were discharged from Afshar Hospital in Yazd, Iran and referred to the rehabilitation center using a purposive sampling method based on inclusion and exclusion criteria.

Inclusion criteria:

Inclusion criteria were cardiovascular diseases requiring CR, age of 18 years and older, familiarity with the Persian language, and consent to participate in the study.

Exclusion criteria:

Exclusion criteria were sleep disorder requiring medication before the rehabilitation, history of hypnotic drug use for more than 6 months, history of depression and anxiety according to psychiatrist, cognitive impairment (vision or hearing problem), lack of participation in more than a session, loss of

consciousness during the intervention, exacerbated patient clinical condition during CR and canceling the continuation of study.

Sample size

The Sample size was equal to base on a study by Lin et al. (2016). **See equation in the supplementary files.**

Considering type 1 error equal to 0.05 and power of test equal to 0.95, it was obtained equal to 35 considering 25% non-response probability [20].

Procedure

Patients who participated in the rehabilitation program were considered as the experimental group, and patients who did not participate in the rehabilitation program or left the program despite being taught the need for rehabilitation were assigned to the control group. In both groups, the selection of samples continued until a sample size of 35 was achieved. After selecting patients and obtaining informed consent to participate in the study, participants' demographic characteristics and patients' SQ were completed using the Pittsburgh Sleep Quality Index (PSQI). Based on a complete examination and results of the initial exercise test of patients, having a companion, and other factors such as a history of heart surgery and myocardial infarction and patients' risk levels, the clinician specified the length and speed of exercise with treadmill and exercise program for any patient in the experimental group to perform the rehabilitation program. Accordingly, the intensity of training in the initial sessions started from 20% to 40% of the reserve heart rate and gradually increased to 60% in the last sessions. The CR program included 12 weeks of exercise, 3 sessions per week, and 3 sessions of training programs each for 45 minutes. Three collective question and answer sessions and lecture training were held by a team including a physician, nutritionist, psychologist, and health educator with an emphasis on the role and importance of CR in patients' recovery after cardiac surgery, strategies for correcting cardiac risk factors, diet modification, and adopting a healthy lifestyle including quitting smoking and exercise, improving quality of life, adapting to pain, anxiety, depression, postoperative problems, and sexual activity of patients after a heart attack; then, educational pamphlets were provided for patients. The patients' spouses or families were also invited to participate in training sessions to encourage home exercises and provide social support.

In addition, a special sleep improvement program was implemented in two 45-minute sessions for patients. It provided an explanation of 1- Definition of sleep and importance of adequate sleep, 2- Different types of SD, 3- Determination of sleep characteristics and habits, 4- Identification of a wrong behavioral pattern relating to sleep, and 5- Useful methods of controlling SD, especially sleep improvement methods in heart patients. Furthermore, videos and photos were displayed, and their experiences were discussed. Due to the fact that the rehabilitation program usually lasts for 3 months, the

questionnaires were completed face-to-face for the experimental group and by phone for the control group after this time.

Instruments

The data collection tool included a demographic and clinical profile form (age, sex, marital status, smoking, and diagnosis of current disease) and the Pittsburgh Sleep Quality Index (PSQI) [21]. The PSQI examines the quality of sleep over the past month. It has 9 items. Item 5 has 10 sub-categories that provide a general description of SQ, sleep delay, useful sleep duration, the ratio of useful sleep duration to the total time spent in bed, sleep disorder, and waking up due to the shortness of breath, nocturnal cough, body aches, extreme cold, extreme heat, use of sleeping pills to fall asleep, drowsiness, and inability and non-motivation to exercise during the day caused by insomnia. All 19 items were given three types of scores to score the PSQI. Note: Getting a total score above 5 in the whole PSQI means poor SQ[22]. The PSQI is a standard PSQI for assessing SQ over the past month. The validity and reliability of the PSQI have been proven in several studies. Buysse et al. reported the internal validity of α=0.83 and reliability in the re-test to be r=0.85[21]. Parker et al. also reported a sensitivity of 90% and specificity of 87%[23]; Bertolazi et al. reported the reliability coefficient of r=0.82 with high validity[24]. Furthermore, the reliability of the PSQI was obtained equal to r=0.88 by Hosseinabadi et al. in Iran[25]. Soleimani et al. measured the reliability of PSQI equal to r=0.85[26]. The PSQI is available at the following web address: https://www.psychiatry.pitt.edu/sites/default/files/inline-files/PSQI%20Article.pdf [21].

Statistical analysis

Data analysis was performed using SPSS16. The mean and standard deviation were used to describe quantitative variables of the study in two groups according to the normality of error in variables. The frequency and percentage were reported for qualitative variables. Kolmogorov – Smirnov test was used to determine the normality of the data distribution. Independent t-test and paired t-test were used to perform the relevant inferential statistics for comparing the mean scores of SQ in both groups and according to the normality of SQ score in each group (P=0.05).

Ethical approval, informed consent and trial registration

The present study was approved with a code of ethics (IR.SSU.REC.1398.200) on 14 **January** 2020 by the Ethics Committee of Shahid Sadoughi University of Medical Sciences in Yazd. Written consent was obtained from participants in the interventional group. Also, Oral consent was obtained from the participants in the control. This study is registered at ClinicalTrials.gov, IRCT20140307016870N6, on 14 September 2020.

Results

A total of 70 people completed the study in the experimental and control groups. According to the results, the mean ages of the experimental group (61.88 ±7.43 years) and control group (61.71±9.54 years) were not significantly different between the two groups (P=0.93). Furthermore, both groups were not significantly different in terms of gender, marital status, education level, employment status, smoking, and diagnosis of current disease (P>0.05); the groups were homogeneous and it was possible to evaluate the intervention effectiveness (Table 1).

Table 1: Demographic characteristics of the participants

Group **Variable**	**Experimental group**	**Control group**	**P-value***			
n	%	n	%			
Sex	Male	23	65.7	25	71.4	0.6
Female	12	34.4	10	28.6		
Marital status	Single	0	0	34	97.1	0.31
Married	35	100.0	1	2.9		
Education level	Under high school diploma	27	77.2	25	71.4	0.82
High school diploma	2	5.7	3	8.6		
Bachelor and higher	6	17.1	7	20		
Job	Employed	24	6.68	11	31.4	1.000
Unemployed	24	6.68	11	31.4		
Smoking	Yes	4	11.4	4	11.4	1.000
No	31	88.6	31	88.6		
Diagnosis of current disease	Heart attack	8	22.9	9	25.7	0.85
Heart surgery	15	42.9	14	40.0		
Heart failure	6	17.1	4	11.4		

Other findings indicated that mean scores of SQ of the participant in the experimental and control group were significantly different after the study (P=0.0001), but mean scores of SQ of the units did not differ significantly before the study (P= 0.73); however, there was a significant difference between the experimental and control groups after the intervention (P=0.0001) (Table 2).

Table 2: Comparison of mean scores of SQ of participants in the experimental group before and after intervention and control group before and after the study

Sleep quality	Number	Pre-intervention	Post-intervention	P-value*		
Mean	SD	Mean	SD			
Experimental group	35	9.2	1.58	4.40	1.14	0.0001
Control group	35	9.02	2.56	7.48	1.86	0.0001
P-value**	00.73	0.0001				

* Paired t-test

** Independent t-test

Discussion

The results indicated that the SQ of participants in the experimental and control groups were greater than 5 before the study. According to the interpretation of the PSQI obtained a total score higher than 5 in the whole, indicating worse sleep quality.Therefore, both groups had poor SQ and no significant difference was found between them at the beginning of the study, indicating that both groups were homogeneous at the beginning of the study and it was possible to investigate the intervention effectiveness. Consistent with results of the present study, Banack et al. (2014) wrote that 52% of participants reported poor SQ in the CR, and it was important to evaluate sleep in CR programs due to the relationship between disturbed sleep and lower quality of life relating to health[27]. Lin et al. (2016) wrote about patients with mechanical heart valves that all patients suffered from poor SQ after a month of admission [20]. Kurose et al. (2019) reported the patients' SQ scores higher than 5 and weak in patients with cardiovascular diseases in phase 3 of the CR[28]. Sepahvand et al. (2015) examined patients with acute coronary syndrome hospitalized in the intensive care unit and reported that 81% of patients had some degree of sleep disorder. Indeed, 50.9% of them had a poor sleep disorder, 39.5% had a moderate sleep disorder, and 0.5% of samples had a severe sleep disorder. Therefore, a comprehensive and complete examination of patients and the development of a care program and nursing measures were necessary to improve the sleep status of hospitalized patients[19]. Ranjbaran et al. (2014) found that the patients' awareness of causes and ways to overcome poor SQ was low after bypass coronary artery surgery. Only 9% of patients reported fear of dying in sleep and 24% reported fear of no recovery as causes of sleep problems, and only 24% considered the relaxation techniques effective in overcoming sleep problems after surgery[29]. Aslani et al. (2007) also reported a 51% increase in the prevalence of SD in patients with heart failure; hence, the prevalence of SD is higher in patients with heart failure than in the public population[10].

In the post-test, the overall scores of SQ significantly improved in the experimental group and were less than 5, indicating the good SQ in the patients. In the control group, the quality of sleep improved after the intervention, but the improvement rate was less than the control group and a significant difference was found. Based on a review of the literature, a lack of information in the intervention was displayed. Lin et al. (2016) wrote that the quality of sleep was better in patients using non-pharmacological methods after

mechanical heart valve placement than in the control group 5 days after surgery [20]. Ranjbaran et al. (2015) found that the SQ was significantly improved after performing the CR program compared to before the program (P<0.001)[7]. Martin et al. (2017) indicated that a four-session sleep intervention program had beneficial effects on sleep in the elderly[18].In a study on the effect of rehabilitation on SQ after ablation for atrial fibrillation, Risom et al. (2018) wrote that a large number of patients reported low SQ, and the rehabilitation program had no effect on SQ. No difference was seen between groups in terms of SQ [30]. The results were different due to the different nature of the disease. On the other hand, our special sleep intervention program was also designed and implemented during rehabilitation.

The findings also indicated that SQ was improved in both experimental and control groups in the posttest and there was a significant difference. Despite the higher improvement and no poor SQ in the experimental group, the control group was still weak despite the improvement in SQ. Risom et al. (2018) wrote in a study on the effect of rehabilitation on SQ after ablation for atrial fibrillation that both groups had improvement in the SQ [30]. Therefore, it seems that SQ improves over time after treatment interventions in patients who do not participate in the rehabilitation program.

A limitation of this study was treatment fidelity or the uncertainty of the full implementation of interventions taught to patients during sleep. Another limitation was the evaluation of outcome by one assessment. Due to the fact that some patients are not able to participate in the CR program, future studies are suggested investigating the effect of virtual education of sleep improvement interventions on the quality of sleep of patients in need of CR.

Conclusion

The findings of the present study indicated an improvement in SQ using a sleep intervention program during the CR. So, improving patients' SQ requires a team or multidisciplinary performance. Health care providers are advised to provide other care for heart patients, measure their SQ, and make appropriate interventions to improve it. On the other hand, they should use sleep improvement programs as easy and applicable techniques and educate patients. They are also advised to teach healthcare workers the importance of sleep and its quality and ways to improve it in training programs as essential requirements for human health, especially patients. Further attention should be paid to the CR issue, and rehabilitation centers should be developed to provide facilities for these programs

Declarations

Ethics approval and consent to participate

This study was carried out in accordance with the Declaration of Helsinki. The study was approved by the Committee of Ethics in Human Research at Shahid Sadoughi University of Medical Sciences in Yazd (IR.SSU.REC.1398.200). *The* i*nformed written consent or oral consent forms were* obtained from all participants.

Consent for publication:

Not Applicable.

Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Authors' Contributions

FG & KHN conceptualized and designed the study. FG & MGF collected the data. KHN & FM analyzed the data. All authors have met the criteria for authorship and had a role in preparing the manuscript. Also, all authors approved the final manuscript.

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Conflict of interests: The authors declared no conflicts of interests.

Abbreviations

Sleep Disorders: SD

Sleep Quality: SQ

Pittsburgh Sleep Quality Index: PSQI

Cardiac Rehabilitation: CR

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Figures

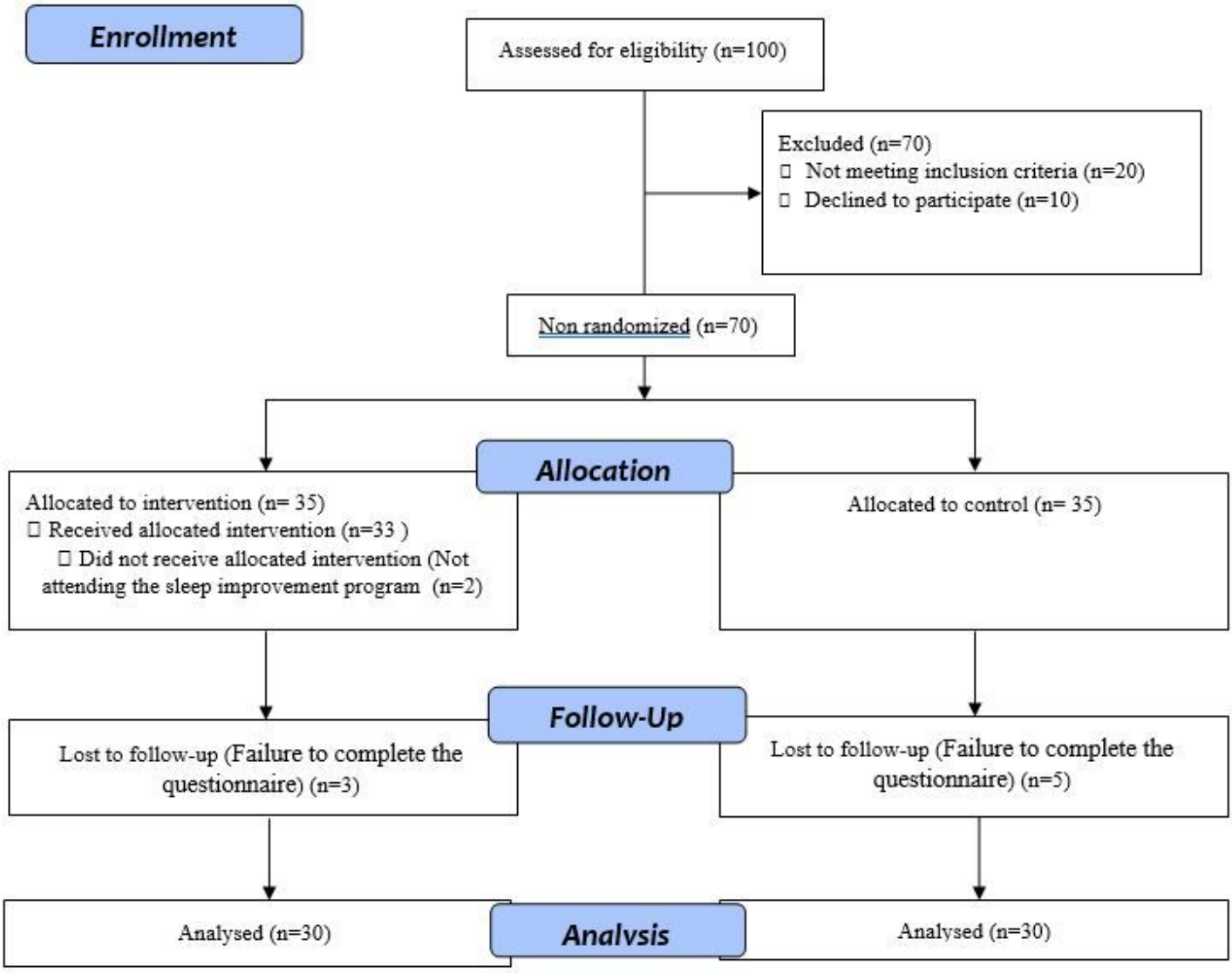

Figure 1

CONSORT Flow Diagram

Supplementary Files

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