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A Randomized Controlled Trial to Investigate the Effect of Relaxation Technique on Sleep Quality of Hemodialysis Patients

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ABSTRACT

Objective(s): To examine the effect of a relaxation technique on the sleep quality of patients undergoing hemodialysis and to find out relationship between effect of a relaxation technique and demographic variables.
Methods: A randomized clinical trial was carried out between February 22, 2023 and May 1, 2024. The study was conducted at two hemodialysis centers situated in Al-Nasiriyah City: Al-Hussein Teaching Hospital and Al-Nasiriyah Teaching Hospital. Following the determination of the sample size, a total of 154 patients were chosen and separated into two groups: 77 patients allocated to the experimental group and 77 patients assigned to the control group. In the experimental group, Benson relaxation technique was used, and the sleep quality was assessed using Pittsburgh Sleep Quality Index. The SPSS 26.0 was used to analyze the data. Descriptive and inferential statistics (frequency, percentage, mean score, data was analyzed using paired-samples T-test and independent t-test.
Results: The data analysis showed that all 154 patients had poor sleep quality in the pre-test for all two groups. The post-test findings demonstrated a substantial improvement in sleep quality for the study group who used the relaxation approach, with an average score of 2.774±23.731.
Conclusion: A statistically significant disparity was observed regarding sleep quality among hemodialysis patients from the experimental group before to and after the implementation of a relaxing strategy. The research showcased that the use of Benson's relaxation method resulted in a substantial improvement in the sleep quality of patients undergoing hemodialysis.
Recommendations: The findings recommend the use of the relaxation technique in trial to all patients who undergo hemodialysis to generalize the findings of experiment to hemodialysis units in hospitals.

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تجربة معشاه منضبطة لدراسة تأثير تقنية الاسترخاء على جودة النوم لمرضى الديلزة الدموية

المستخلص

الأهداف: لدراسة تأثير تقنية الاسترخاء على جودة النوم لدى المرضى الذين يخضعون لغسيل الكلى. والتعرف على العلاقة بين تأثير تقنية الاسترخاء والمتغيرات الديموغرافية.

المنهجية: تم إجراء تجربة سريرية عشوائية في الفترة ما بين ٢٢ فبراير ٢٠٢٣ و ١ مايو ٢٠٢٤. أجريت الدراسة في مستشفى الحسين التعليمي ومستشفى الناصرية التعليمي من ٢٢ فبراير ٢٠٢٣ إلى ١ مايو ٢٠٢٤. بعد اختيار العينة، قُسِّم ١٥٤ مريضًا إلى مجموعتين: مجموعة تجريبية ضمت ٧٧ مريضًا، ومجموعة ضابطة ضمت ٧٧ مريضًا. ولتحقيق هدف الدراسة، استُخدمت تقنية بنسون للاسترخاء في المجموعة التجريبية. وقُيّمت جودة النوم باستخدام مقياس بيتسبرغ لجودة النوم، واختار الباحثون أسلوب المقابلة لجمع البيانات.

النتائج: وأظهر تحليل البيانات أن جميع المرضى البالغ عددهم ١٥٤ يعانون من سوء جودة النوم في الاختبار القبلي للمجموعتين، وأظهرت نتائج الاختبار البعدي تحسنًا كبيرًا في جودة النوم لمجموعة التجريبية التي استخدمت أسلوب الاسترخاء، بمتوسط درجة ٢,٧٧٤ ± ٢٣,٧٣١.

الاستنتاجات: يستنتج من نتائج الدراسة أن تطبيق تقنية استرخاء بنسون فعالة في تحسين جودة النوم لدى المرضى الخاضعين لغسيل الكلى.

الاقتراحات: توصي الدراسة باستخدام تقنية استرخاء بنسون لتحسين جوده النوم لدى مرضى غسيل الكلى.

الكلمات المفتاحية: تقنية الاسترخاء، جودة النوم، مرضى غسيل الكلى، التمريض..

Introduction

Hemodialysis is considered the most effective and widely accepted therapy for end-stage renal illness. It removes urea, creatinine, and excessive fluids. Approximately half of renal failure patients get hemodialysis [1–4].

Hemodialysis is the treatment of choice for around 70 percent of those who have reached the end stage of renal failure. (approximately 3 million people worldwide) [5]. Although it is an efficient method for survival, hemodialysis therapy is associated with poor outcomes (every year, one in six persons who get the treatment finally die), and it is a quite expensive treatment [6]. Hemodialysis patients often have the problem of inadequate sleep quality. [7] Research shows that over 80% of individuals suffering from chronic renal failure have sleep difficulties [8,9].

The evaluation of sleep quality is based on subjective factors, including the sensation of being rejuvenated upon awakening and overall satisfaction with the sleep process [10]. The incidence of insomnia in end-stage kidney disease (ESKD) patients on conventional hemodialysis or chronic ambulatory peritoneal dialysis (CAPD) varies between 19 and 71 percent [11]. Insomnia is a notable contributor to psychological and physiological distress, and is associated with an increased chance of experiencing mortality among affected individuals [11,12].

Relaxation response was first used by Herbart Benson [13], to describe a physiological and homeostatic state that functions as a counteractive mechanism to the stress response. Several approaches may be used to induce the relaxation response, such as visualization, muscle relaxation, energy healing, massage, acupuncture, different breathing techniques, meditation, prayer, and yoga. The term “relaxation response” is characterized by a decrease in oxygen usage and a reduction in sympathetic nervous system activity [5]. Herbert Benson came up with the Benson relaxation technique, one of the most popular relaxation techniques which is easy to learn and has proved to be a

complete muscular relaxation. Relaxation is a technique that controls the physiological functioning of several bodily systems. During the relaxation reaction, the body transitions from a state of heightened physiological activity to a state of physiological tranquility. Relaxation technique characterized by decreased breathing, as well as lowered systolic and diastolic blood pressure, norepinephrine blood pressure, heart rate, and body temperature. As a result, the levels of anxiety diminish, resulting in a feeling of relaxation, relief from stress, and increased energy reserves.

Benson relaxation therapy (BRT) is a relaxation method that reduces stress responses by promoting relaxation and relieving muscle tension. Relaxation is an effective and affordable training strategy that prioritizes user comfort and security [14]. Therefore, this study was conducted to evaluate the effect of Benson relaxation technique on sleep quality for hemodialysis patients. Also, to investigate the correlation between the quality of sleep among hemodialysis patients.

Methods

Study Design and Setting

A randomized clinical trial was used to study patients who suffered from poor sleep quality who were undergo hemodialysis. The research began on February 22,2023 to May 1st, 2024. The study was carried out at the hemodialysis units at in AL-Hussein Teaching Hospital and AL- Al-Nasiriyah Teaching Hospital.

Sample and sampling

A simple random sampling (probability) simple technique was used to select 154 patients who underwent hemodialysis. Slovin's Formula. [15] was used to determine the sample size. The whole patient population amounted to 250 individuals. The confidence interval was 95% confidence. The estimated error was 5%. Thus, 5 divided by 100 was 0.05. In the following formula,

N = 250 n = sample size, E = margin of error
= N / [1 + (N) (E) 2]
n = 250/ [1+250 (0.05)2],
n = 250 / [1+250 (0.0025)],
n = 250/ [1+0.625], n = 250 / 1.625, n = 153
n= 154 patients (approx.) [15].

Inclusion and Exclusion criteria

The study's inclusion criteria required participants to be 18 years old or older, male and female, having hemodialysis (HD) sessions at least twice a week for a minimum of three consecutive months and patients who accepted to participate in the research.

The study exclusion Criteria However, individuals who were diagnosed with unstable angina, arrhythmia, throughout the research were excluded. As an exclusion criterion, one needed to have physical limitations that slowed down learning either before or during the relaxation treatment, participants who had emotional distress in the previous month, patients who do not accept to participate in the research.

Data Collection and the study Questionnaire

The researcher conducted one-on-one interviews with the patient after the completion of the dialysis session in order to gather data. Subsequently, data was gathered for both the experimental and control groups in order to conduct a pre-test aimed at assessing sleep quality. Subsequently, the Benson Relaxation Technique (BRT) was applied to patients assigned to the experimental group. The post-test was also given to both groups as shown in Figure 1.

Figure 1: Flow Algorithm Diagram of the Study.

Before the intervention, the researcher first assessed the patient's sleep quality in the pre-test using Pittsburgh Sleep Quality Index (PSQI). Sleep quality in the pre-test using Pittsburgh Sleep Quality Index (PSQI) [16]. Data were collected using a questionnaire via direct interviews with patients from February 22, 2023 to May 1, 2024. The participants had interviews and were provided with information on the objective of the research. Demographic data of all participants were obtained. The researcher obtained consent

from all participants to record their replies and store them for the purpose of data analysis.

The Pittsburgh Sleep Quality Index (PSQI) is a self-report survey to evaluate the quality of sleep and disruptions experienced within a period of one month. There are nineteen separate elements that contribute to the estimation of seven "component" scores. These scores are based on the subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disruptions, usage of sleeping medication, and daytime dysfunction. The total score is calculated by the sum of its seven components and ranges from 0 to 21. A total PSQI score of 5 is indicative of poor sleep quality, while good quality of sleep is shown by a total PSQI score of<5. PSQI has been used in recent studies for these seven components result in one global score. As for the reliability and validity, several studies examined the psychometric properties of the scale. The first review by the developers revealed an internal reliability of a = .83, a test-retest reliability of .85 for the global scale, a sensitivity of 89.6%, and a specificity of 86.5% [16,17].

The intervention

The intervention began when patients with HD were situated in individual rooms, lying in bed, and in a supine posture. Each patient had a 20-minute BRT procedure. The patients were asked to: (1) assume a comfortable posture, (2) shut their eyes, (3) progressively relax all muscles beginning from their feet moving upwards, and (4) inhale through their nostrils with a focus on the sound of their breath, quietly repeating the word 'one' to themselves when exhaling. This process continued for 20 minutes. The patients were directed to ascertain the time by just opening their eyes. Nevertheless, the use of an alert was forbidden. The interventionist assessed their performance abilities. The patients were instructed to practice the method for the following two days following the training session. To make sure they had learned enough, patients then executed the technique once more in front of the interventionist. Until the interventionist was certain that the patients had learned the necessary skills, the process was repeated. However, the control group the patients in the control group participated in the pre- and post-tests. They just received the routine treatment and care.

Randomization

The 154 patients were randomly divided into two groups. 250 participants were targeted to comprised patients who were registered in the HD units within hemodialysis patient. 86 patients were excluded due to (Did not have the inclusion criteria (n = 16), The study exclusion Criteria However, individuals who were diagnosed with unstable angina, arrhythmia, throughout the research were excluded. As an exclusion criterion, one needed to have physical limitations that slowed down learning either before or during the relaxation treatment, participants who had emotional distress in the previous month, patients who do not accept to participate in the research.

Had exclusion criteria (n= 43), Refused (n = 18), and lack of interest (n =8). The simple randomization (i.e., verification randomization) was used with two cards, one blue and one red in a box. The former represented the experimental group while the latter represented the control group. the remaining Randomized (n = 164), after follow up divided into two group study group (Failed to follow-up (n = 4), Discontinue intervention due to kidney transplant (n= 0) the remaining Analyzed (n= 77) experimental teaching, and the control group (Failed to follow-up (n= 1), Discontinue due to kidney transplant (n= 1), Analyzed (n= 77) control group.

Ethical Considerations

The researcher distributed the informed consent forms to all patients undergoing hemodialysis in order to get their permission to participate in the study. The participants were informed that they had the choice to withdraw from the research, refuse to answer a specific question, or participate in the intervention at any time.

The research methodology underwent a thorough evaluation and received approval from the Ethics Committee of the College of Nursing, University of Baghdad in Bagdad, Iraq.

The clinical trial aimed to ascertain if the innovative treatment exhibited greater

effectiveness or a reduced occurrence of side effects in comparison to the existing therapies. The trial was registered in the Clinical Trial Register. The NIH certification number was RCTID (76277), https://www.irct.ir/trial/ (https://irct.behdasht.gov.ir/trial/76277).

Data Analysis

SPSS Version 26.0 was used to analyze the data. Descriptive and inferential statistics (frequency, percentage, mean score, paired-samples *T*-test and independent t-test for compare mean between study and control groups, whereas ANOVA is used to compare the means among three or more groups. The determination if there are statistically significant differences between the quality of sleep among hemodialysis patients and their socio-demographic variables were used to analyze the study findings.

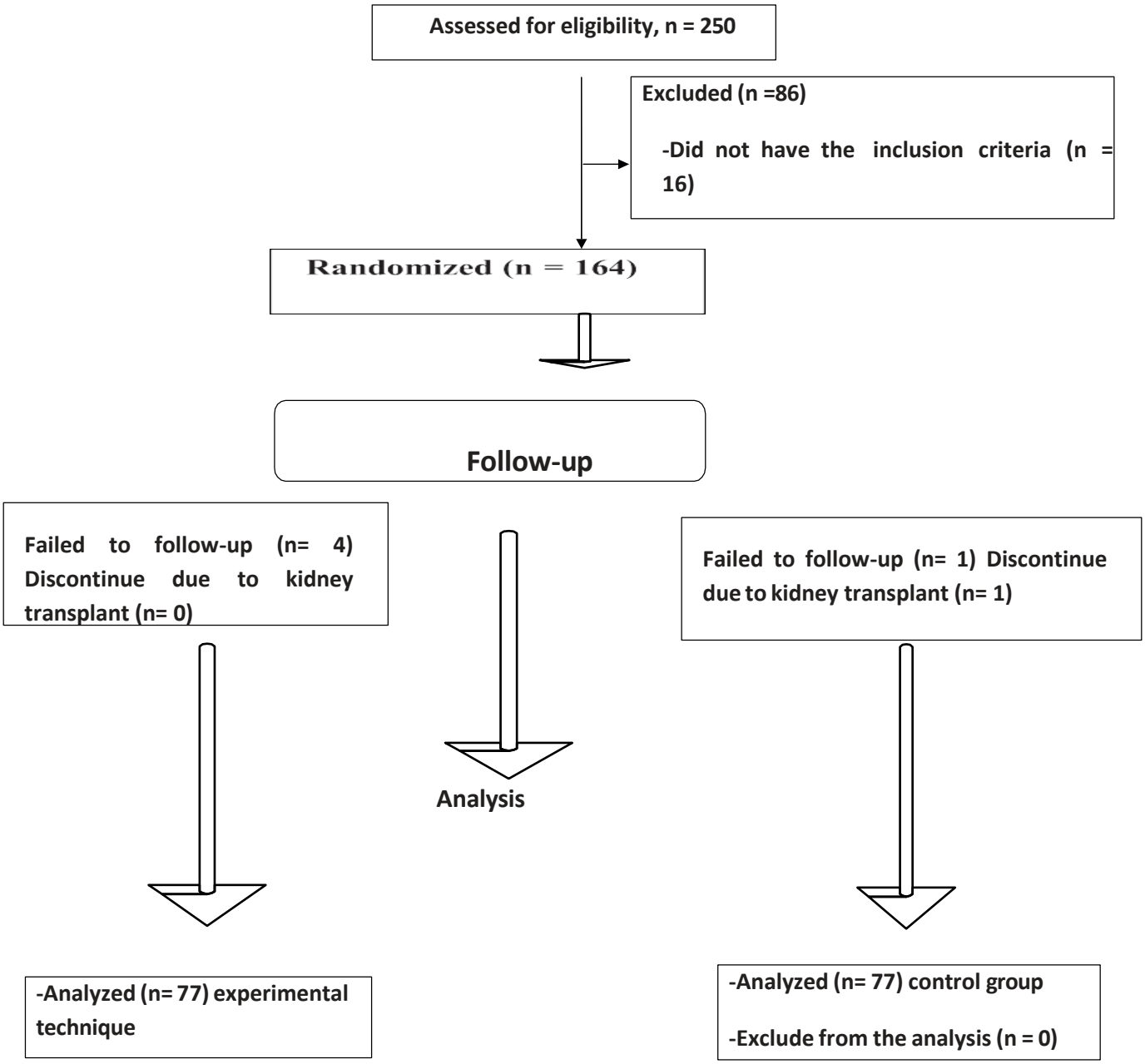

Figure 1. Clinical trial flow diagram

Results

Table 1. Socio-Demographic characteristics of patients undergoing Hemodialysis in the study and control groups

Variable	Groups	Study group		Control group	
		F.	%	F.	%
Age Groups	27-36 years	6	7.8	18	23.4
	37-46 years	11	14.3	19	24.7
	47-56 years	9	11.7	11	14.3
	57-66 years	22	28.6	9	11.7
	67 years and more	29	37.7	20	26.0
	Mean ± *SD*	58.69 ± 13.66		51.31±14.532	
Sex	Male	46	59.7	41	53.2
	Female	31	40.3	36	46.8
Educational Level	Neither read nor write	27	35.1	31	40.3
	Primary school graduate	29	37.7	29	37.7
	Intermediate graduate	12	15.6	9	11.7
	Preparatory school graduate	3	3.9	6	7.8
	Graduate of institute/college	6	7.8	2	2.6
Length of time on dialysis Per Months	1-6 months	14	18.2	17	22.1
	7-12 months	19	24.7	22	28.6
	13-18 months	17	22.1	23	29.9
	19-24 months	17	22.1	10	13.0
	25 months and more	10	13.0	5	6.5

F= Frequency, **%**= percentage. **SD=**Standard deviation.

Table (1) shows that the average age of participants in the experimental group was 58.69 years, years, whereas in the control group was 51.31 years. More than half (59.7) of participant in the experimental group were male, whereas (53.2) were male in the control group.

Table 2. Comparison of Pre- and Post-test Pain Scores for the Experimental and Control Groups

Periods	Group	Total M and S.D.	N	T-test	P. value
Pre- Benson Relaxation Technique	control	20.189±19.211	77	0.186	0.853
Post- Benson Relaxation Technique	control	19.659 ±15.804	77		
Pre- Benson Relaxation Technique	study	16.270 ±2.629	77	23.731	0.000*
Post- Benson Relaxation Technique	study	2.774±23.731	77		

N = number, **M** = Mean of Score, **SD**= Standard Deviation**, NS** =non-significant at P>0.05, **S**= significant at P<0.05

Table (2) shows that the Benson relaxation technique had a significant effect on the experimental group (P value= 0.000). The average post-test result was **Mean ± SD**= 2.774±23.731. In contrast, the control group did not exhibit any statistically significant changes between the pre- and post-tests.

Table 3. Significant Differences between PSQI of Experimental Group at Post-test with Incident Hemodialysis Patients Socio-Demographic Characteristics

Demographic Variables	Source of variance	Sum of Squares	df	Mean Square	F	P-value
Age	Between Groups	32.681	8	4.085	3.171	0.012*
	Within Groups	33.490	26	1.288		
	Total	66.171	34			
Sex	Between Groups	.954	8	0.119	0.398	0.912
	Within Groups	7.789	26	0.300		
	Total	8.743	34			
Educational Level	Between Groups	19.336	8	2.417	1.477	0.214
	Within Groups	42.550	26	1.637		
	Total	61.886	34			

df: Degree of freedom, **F**= F-statistic. **S**= significant at P<0.05

Table 3 showed no significant differences between the PSQI of the experimental group at the post-test in terms hemodialysis Patients' demographic variables (e.g., sex, educational level), but only significant differences between the PSQI within age (p value =0.012).

Discussion

Distribution of the study sample according to study group consists of patients who were 67 years old or older and were male. However, the study conducted by Alkhafaji & Al-Mayahi, 2023 [18], indicates that majority of study and control group are males with percentage (56.7%, 63.3%) respectively, with the age group (50-59), (40-49) respectively, with mean and standard deviation for the study and control group (48± 12.37, 48± 13.74) respectively. This study findings relatively agree with study done at Nasiriyah city 2023 that were revealed that the most of study sample at age were study results indicates that most hemodialysis patients are within age group of (48 – above years), study group (n= 21; 52.5%) and control group (n= 22; 55%) , also supported come from study done by Kim et al., 2023 [19], included 52,574 patients, the accounted of patients who were 65 years old. It's thought that aging process significantly contributes to the decline in the overall health of several body systems, including the renal system. Additionally, the development or presence of chronic diseases such as diabetes plays a crucial role in causing kidney failure. Similarly, chronic illnesses specifically impact the kidneys, however, this is not true. One of the primary factors leading to renal failure in One of the primary factors leading to renal failure is the presence of chronic diseases such as diabetes and hypertension, which ultimately results in the need for hemodialysis."

Findings of the current study showed more males than females in both the study group and the control group. A study conducted by Djukanović et al., 2022 [20], Findings agree with current study results which revealed that throughout the five-year investigation, the proportion of males on haemodialysis was consistently around double that of female. However, men's kidneys may lack the protective benefits of oestrogen, a hormone that is more abundant in women until they reach menopause.

The Benson relaxation method had a statistically significant impact on the experimental group. The current study results of experimental group's pre- and post-test show significant results, Conversely, the control group exhibited no effect indicated that there were statistically significant differences between the pre- and post-tests.

Patients receiving hemodialysis showed a significant statistical change in their quality of sleep before and after the Benson relaxation therapy was implemented (p<0.005). Findings demonstrated that there were no-significant differences Global PSQI Scores at posttest with regards patients' length of time on dialysis per months (p=0.105), Study

conducted by [23], study results about long dialysis duration patients had poor sleep quality, evident by their high median PSQI score, though their excessive daytime sleepiness was less evident by their score in the high normal values. Additionally, the current study found a high prevalence of poor sleep quality, whereas excessive daytime sleepiness was less prevalent. Finally, no significant association was found between either of the two scores and the participants' demographic or clinical characteristics surveyed in this study.

The present findings revealed no statistically significant differences in the PSQI in the post-test in the experimental group, in terms of demographic variables of Hemodialysis patients, including sex, education level. The experimental group at the post-test and hemodialysis patients showed significant differences in the PSQI with respect to their demographic factors, specifically age ($p=0.012$). The study posits that the aging process has both physical and psychological impacts on technique performance. Additionally, the implementation of technique is influenced by residency, since several factors such as culture and environmental conditions in urban areas, including heavy traffic, noise and pollution, play a significant role. The results are agreed with research conducted in Jordan [23] showed no statistically significant differences in socio-demographic features pertaining Depression Anxiety Stress Scale (DASS21) between the intervention group and the control groups before the implementation of intervention, hence enhancing the validity of between-group comparisons. The comparison of data collected after the intervention and before intervention showed that the experimental group exhibited significantly lower levels of DAS than the control group. This finding suggests that BRT is effective in mitigating Depression Anxiety Stress Scale (DASS21) among patients diagnosed with multiple sclerosis. Some other research, however, reported different findings by Rambod et al., 2013 [24], as in the intervention and control groups, the subjects' average age was 49.07±13.31 and 50.72±11.68, respectively. There was no statistically significant between-group difference in terms of age, sex, marital status, and educational level ($p > 0.05$). Both groups showed similar durations of HD usage (36.53 ± 36.05 vs. 47.67 ± 40.42; $t = 1.34$, $p > 0.05$).

Researcher's opinion about Overall finding of this study are Benson Relaxation Technique is important and valuable of nursing intervention for patients undergoing hemodialysis, The researcher believes that the effectiveness of BRT essential factors for improving sleep quality in hemodialysis patients. In addition, the technique is simple, safe, inexpensive, and easy to apply in clinical settings without requiring special equipment or causing adverse effects. also considers that improving sleep quality may positively influence other aspects of patients' health, including emotional status, daily functioning, treatment adherence, and overall quality of life. Therefore, Benson Relaxation Technique can be considered an important supportive nursing strategy that may contribute to holistic patient care in hemodialysis units.

Study Limitations

The primary limitation of this study result of time constraints and difficulties in transportation to the hemodialysis unit. Additionally, the health condition of some participants negatively affected their ability to fully engage in the relaxation training sessions. Some patients reported that the noise produced by hemodialysis machines and other medical equipment interfered with their concentration and reduced the effectiveness of practicing the relaxation technique. Finally, lack of National publication resources to support the present study's findings.

Conclusion

The current study identified a statistically significant disparity in hemodialysis patients within the experimental group, both before to and during the implementation of the relaxation approach. The study demonstrated that the use of Hemodialysis patients' sleep quality significantly improved as a result of using Benson's relaxation technique (BRT).

Recommendations

The study recommends using Benson relaxation technique for all patients undergo hemodialysis at all hemodialysis units. The Iraqi Ministry of Health might benefit from intensify efforts to implement awareness programs for health care providers. Conducting continuous training programs for using Benson relaxation technique to develop and improve nurses' knowledge and practices to reduce complications of prolonged hemodialysis. Also, provide instructional quid for used Benson relaxation technique among hemodialysis patients to supported them for getting.

Implications

1.Impact on self-care improvement. The instructional program enhances patients' knowledge about managing constipation, potentially improving their overall quality of life.

2.Improvement of clinical intervention strategies. The findings can contribute to developing more effective clinical strategies for addressing constipation in CAD patients, leading to better patient outcomes.

3.Guidance for health policies. The results can inform health policies related to CAD patient care and improve protocols for managing constipation, making healthcare practices more effective.

4.Development of future educational programs. The study provides a reference for designing similar educational programs for other patient groups or in different medical contexts, broadening the scope of educational interventions.

Conflicts of interest

The authors declare that there is no conflict of interests regarding the publication of this review article.

Ethical Approval

The authors state that their systematic literature review did not require ethical approval. This research is based on a master thesis, adhering to established protocols.

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Author contribution

AMN designed, conducted, and analyzed the study, and drafted the manuscript. AKJ supervised the research and Ak provided critical review.

Data availability statement

The data that support the findings of this study are available from the authors, but restrictions apply to the availability of these data, which were used under license for the current study and are not publicly available. However, the data can be obtained from the authors upon reasonable request and with appropriate permissions.

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