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COGNITIVE BEHAVIOURAL THERAPY FOR SLEEP DISTURBANCES AMONG PATIENTS UNDERGOING HEMODIALYSIS – A TRUE EXPERIMENTAL STUDY

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ABSTRACT

Background: According to previous studies, 50 - 80% of dialysis patients have problems associated with sleep disorders, including difficulty in falling asleep, waking up early, daytime sleepiness, leg jerking and trembling [1]. Compared with the general population, the prevalence of sleep disorders is significantly higher in End Stage Renal Disease (ESRD) patients treated by dialysis [2]. Objective: The objective of this study was to determine the effect of Cognitive Behavioural Therapy (CBT) on sleep among patients undergoing Hemodialysis (HD) in selected Hospitals, Kerala. Methodology: A quantitative research approach was used with true experimental: pre-test post-test control group time series design. The sample size was 138 (69 each in experimental and control group). Pre-test was conducted using socio-demographic data and Pittsburgh sleep Quality Index. Experimental group received six sessions of CBT while the control group received the routine care. Post-tests were done thrice (2, 6 and 10 weeks after the intervention). The collected data was analyzed using descriptive & inferential statistics. Results: CBT was found to be effective in making a statistically significant difference in sleep ($P< 0.001$) scores of dialysis patients. There was a significant association between sleep and the clinical variables, presence of diabetes mellitus and using sedatives. Interpretation & Conclusion: CBT was found to be effective in making a statistically significant difference in sleep among patients undergoing HD. This can be applied in nursing practice to improve the patient comfort.

Key words: End Stage Renal Disease, Hemodialysis, Cognitive Behavioural Therapy, Sleep.

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INTRODUCTION

High incidence of sleep disorders (35.5 - 68.1%) are reported among patients undergoing Hemodialysis in India [3,4,5]. The reported prevailing sleep disorders are insomnia (65.9%), Restless Leg Syndrome (RLS) (42%) and Obstructive Sleep Apnea (OSA) (31.8%) [6]. Sleep disorders are associated with physical, behavioural and psychological problems and lead to problems in mental and social performance as well as in interpersonal interactions. They are known negative prognostic factors for morbidity and mortality [7].

However, there is no effective therapy for sleep disturbances, except some drugs, such as hypnotics or anxiolytics. Possible side effects of hypnotic drugs, such as benzodiazepines include impairment of motor skills, attention, memory and judgment, leading to confusion and uncoordinated behaviours in severe cases. Individuals who take these drugs are at risk of accidental falling while getting out of bed or going down stairs and the risk of injury is especially pronounced in HD patients who suffer from osteoporosis or from orthostatic hypotension or dizziness secondary to unstable blood pressure [8].

Cognitive Behavioural Therapy (CBT), the most widely used psychological intervention, has been proven to be effective for chronic insomnia. A randomized control study was conducted in 2008 to investigate the effectiveness of CBT on changes in sleep quality among 24 Peritoneal Dialysis (PD) patients with insomnia in

Taiwan [9]. The intervention group (n = 13) received CBT for 4 weeks and sleep hygiene education, whereas the control group (n = 11) received only sleep hygiene education. Median percentages of change in global Pittsburgh Sleep Quality Index scores were -14.3 (interquartile range, -35.7 to - 6.3) and -1.7 (interquartile range, -7.6 to 7.8) in the intervention and control groups, respectively (P = 0.3).

A systematic review and meta-analysis [10] was undertaken in 2014 to summarize and quantify the effects of non-pharmacological interventions on sleep quality improvement in uraemic patients on dialysis, using PubMed (inception to June 2014), EMBASE (inception to June 2014), Cochrane controlled trials register (issue 5, 2014), Web of Science (inception to June 2014) and http://clinicaltrials.gov/. The result revealed that CBT resulted in a greater PSQI score reduction compared to controls; in terms of sub-scores, it was found that CBT might shorten sleep latency, alleviate sleep disturbance and reduce the use of sleep medications.

The conceptual framework of the study was based on Imogene M. King's Theory of Goal Attainment (1981) [11].

MATERIAL AND METHODS

Research approach

Quantitative research approach

Research design

True experimental, pre-test post-test control group time series design. The researcher registered her study in the Controlled Trial Registry of India (CTRI). The CTRI number was CTRI/2015/02/005503 [Registered on: 05/02/2015] - Trial Registered Retrospectively.

Research setting

Regional Dialysis Centre, Aluva and Lourdes Hospital, Ernakulam

Sample size

The sample consisted of 138 patients undergoing HD. Sample size was estimated based on the findings of the pilot study [12] at a conventional significance level of 0.05. A sample size of 126 was determined. With the estimated response rate, 140 patients were selected for the study. During the data collection period, one patient in the experimental group was admitted in the Intensive care unit and one in the control group died. Therefore a total of 138 patients (69 in experimental and 69 in control group) completed the study.

Sampling Technique

Purposive sampling was used to select patients undergoing HD who met the sampling criteria. After inclusion in the study and baseline measurements, patients were randomized into CBT group or control group by permuted block randomization procedure.

Criteria for sample selection

a) Inclusion Criteria

Patients undergoing Maintenance Hemodialysis

1. for more than three months
2. twice a week
3. above the age of 18 years
4. who are willing to participate in the study

b) Exclusion criteria

Patients undergoing Maintenance Hemodialysis who

1. are admitted in the ward
2. are critically ill
3. have history of psychiatric illness
4. cannot respond to instructions

Data collection instruments

Tool 1: Demographic and clinical data sheet

a. Demographic data sheet

It contains eight items for obtaining information regarding patient's age, gender, education, occupation, monthly family income, marital status, type of family and support.

b. Clinical Data sheet

It contains seven items for obtaining information regarding patient's duration since diagnosis of chronic renal failure, duration since undergoing HD, shift of undergoing dialysis, suffer diabetes, last hemoglobin value, on exercise regimen and use of sedatives/tranquilizers

Tool 2: Pittsburgh Sleep Quality Index (PSQI)

This standardized tool developed by Buysee, et al, measures sleep quality of the previous month. It contains 19 self- rated questions and five questions rated by the bed partner. The seven components include: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleep medications and daytime dysfunction. Total scores were arbitrarily classified as: Poor sleep (14-21) Average sleep (6-13) Good sleep (0-5). Numerous studies that had used PSQI, in a variety of adult populations throughout the world have supported high validity and reliability (Cronbach's alpha 0.736)

Researcher received permission from the author concerned, to translate and use the tool. Linguistic validation of the tool was done. The process that was used to translate the instrument from English (Source Language) to Malayalam (Target Language) is as follows: Forward Translation, Backward translation, pre-testing of the tool and preparing a final version.

CBT Intervention

The researcher was certified to be proficient in administering the CBT. Based on the literature review and qualitative study findings (conducted by the researcher)

the CBT intervention protocol was prepared. The content validity index of the CBT protocol was 0.90. CBT protocol consisted of the following components: a) Stimulus control therapy b) Sleep restriction c) Sleep diary d) Sleep hygiene and e) Cognitive restructuring

Ethical considerations

Ethical clearance and permission were obtained from Lourdes Institution Ethics Committee and Regional Dialysis Centre, Aluva. Written informed consent was obtained from the patients participating in the study. Confidentiality and anonymity were maintained.

Data Collection Process

Formal written permission was obtained from the selected hospital authorities. The data collection was from November 2014 to March 2015. Purposive sampling was used to select patients undergoing HD who met the sampling criteria. After obtaining informed consent, pre-test was obtained from 140 patients. Using permuted block randomization, patients undergoing HD were randomized to experimental and control group. During each shift of dialysis, patients were randomized using computer-generated numbers into equal blocks, 70 each for control and experimental group. During the data collection period, one patient in the experimental group got admitted to the intensive care unit, due to respiratory distress and one in the control group died. Therefore, a total of 138 patients (69 in experimental and 69 in control group) completed the study. The researcher administered individual Cognitive Behavioural Therapy to patients in the experimental group while they were on dialysis. The experimental group received six sessions of CBT (two sessions per week for three weeks). The duration of each session lasted for 20-25 minutes. The CBT was given based on the validated CBT protocol. The patients in the control group received the routine care. Post test was conducted for both the groups thrice – two weeks, six weeks and 10 weeks after the intervention. The patients were thanked for their participation.

RESULTS

1. Description of patients undergoing Hemodialysis and comparison of groups based on their demographic and clinical variables.

It was found that age differed significantly between the groups (p=0.038). Results of chi-square tests indicated that the groups did not significantly differ with regard to other demographic variables and clinical variables. They were found to be homogenous as the p value was greater than 0.05.

2. Effect of CBT on sleep among patients undergoing Hemodialysis

There was significant difference in the pre-test Global PSQI score among the experimental and control group at 0.01 level of significance. But the groups were found to be homogenous with respect to sleep subscales (Table 1).

Sleep disturbance among patients undergoing Hemodialysis in experimental group gradually decreased from baseline value to 2nd week after administering Cognitive Behavioural Therapy. The sleep disturbance in the control group slightly increased from pre-test to 2nd week and there after they show almost the same rate of increase up to 10th week (Fig 1).

ANCOVA (Analysis of Covariance) was performed to test the effect of CBT on Global PSQI score by adjusting for the covariate. Covariates were evaluated with a global t pretest value of 16.5072. Interaction between group and the different levels of measurement was found to be significant (F = 7399.385, 5798.617, 5819.639, P< 0.0001). This shows that there is significant difference in the Global PSQI sleep scores among the control and experimental groups after administering Cognitive Behavioural Therapy (Table 2).

There was a significant effect of CBT on all the sleep subscales among patients undergoing Hemodialysis. Post-hoc analysis (Bonferroni) indicated that pre scores were significantly higher than all the post test scores (Table 3).

3. Association between sleep and the selected demographic and clinical variables of patients undergoing hemodialysis

None of the demographic variables were found to have any significant association as the p-value calculated was greater than 0.05. There was significant association between the clinical variables, diabetes mellitus (P< 0.01), sedatives (P<0.001) and quality of sleep. Presence of DM and use of sedatives were associated with poor sleep quality.

Table 1: Comparison of pre-test sleep score of patients undergoing Hemodialysis between control and experimental group **N = 138**

Component	Mean (SD) of sleep		t-value	p-value
	Experimental (69)	Control (69)		
Global PSQI	16.04(1.56)	16.97(1.9)	3.119	0.002**
Sleep Subscales				
Sleep duration	2.95(0.20)	2.95 (0.20)	0	1.00^{ns}
Sleep disturbance	2.52(0.50)	2.60(0.49)	1.027	0.306^{ns}

Sleep latency	2.97(0.17)	2.94(0.23)	0.45	0.651 ns
Sleep day dysfunction	2.32(0.52)	2.30(0.62)	0	1.00 ns
HSE	1.98(0.99)	1.68(1.11)	1.691	0.093 ns
Sleep quality	2.55(0.53)	2.63(0.48)	1.007	0.316ns
Medications	0.72(1.15)	0.78(1.25)	0.283	0.778ns

****significant at 0.01**

Table 2: Summary of Repeated Measure ANCOVA on effect of CBT on overall sleep score (Global PSQI) among patients undergoing Hemodialysis

N = 138

Global PSQI	Adjusted means		F	Partial Eta Squared
	Control group	Experimental group		
Post-test 1(2weeks)	17.234	1.795	7399.385***	0.982
Post-test 2(6 weeks)	17.336	1.795	5798.617***	0.977
Post-test 3(10 weeks)	17.326	1.790	5819.639***	0.977

***** Significant at 0.001**

Table 3: Summary of Repeated Measure Between subjects ANOVA on effect of CBT on sleep subscale scores among patients undergoing Hemodialysis

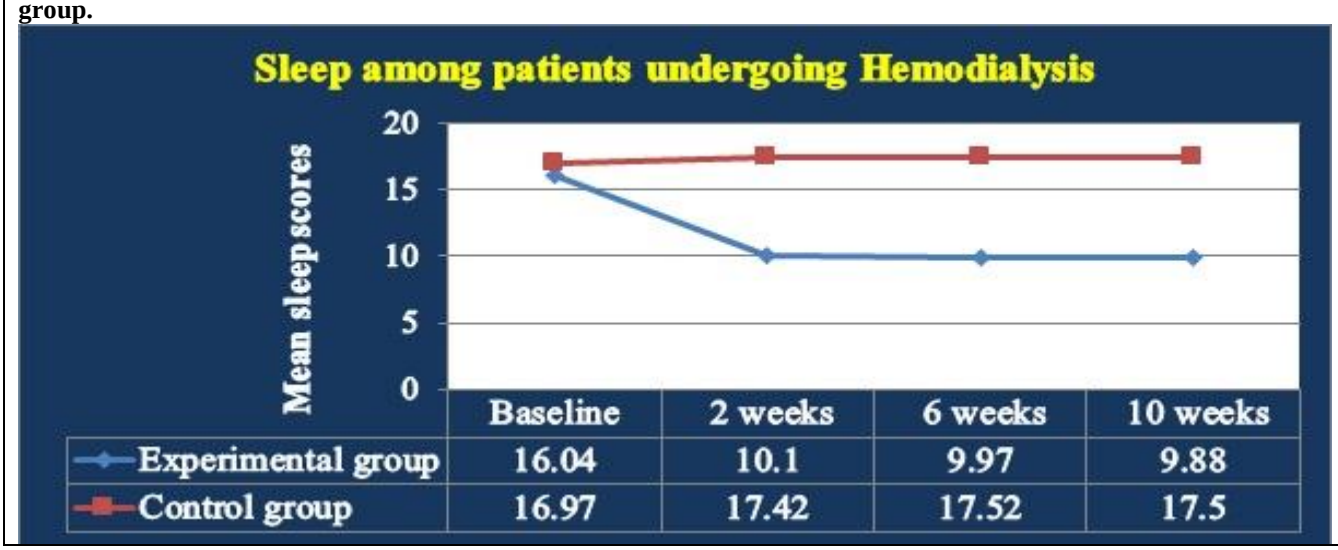
N = 138

Sleep subscales		ASSESSMENTS				Between periods (time)	Between groups (group)	Period x group interaction
		PRE	POST1	POST2	POST3			
		Mean (SD)				F-value (p-value)		
Sleep duration@	E	2.95 (0.2)	1.60 (0.77)	1.60 (0.77)	1.60 (0.77)	227.67***	185.91***	237.68***
	C	2.96 (0.2)	2.97 (0.16)	2.97 (0.16)	2.97 (0.16)			
Sleep distribution@	E	2.52 (0.50)	2 (0.56)	2 (0.56)	2 (0.56)	4.32*	121.32***	88.99***
	C	2.60 (0.49)	2.94 (0.23)	2.94 (0.23)	2.94 (0.24)			
Sleep latency@	E	2.97 (0.17)	2.31 (0.46)	2.31 (0.46)	2.31 (0.46)	85.30***	131.86***	121.84***
	C	2.94 (0.23)	3.0 (0)	3.0 (0)	3.0(0)			
Day time Dysfn@	E	2.32 (0.52)	1.66 (0.56)	1.66 (0.56)	2.63 (0.48)	49.56***	96.23***	96.12***
	C	2.32 (0.60)	2.83 (0.38)	2.83 (0.38)	2.83 (0.38)			
HSE@	E	1.98 (0.99)	0.68 (0.73)	0.68 (0.73)	0.68 (0.73)	2.708ns	201.120***	126.158***
	C	1.68 (1.11)	2.65 (0.56)	2.65 (0.56)	2.65 (0.56)			
Sleep quality@	E	2.55 (0.52)	1.34 (0.53)	1.30 (0.52)	1.24 (0.43)	95.403***	202.373***	49.734***
	C	2.64 (0.48)	2.43 (0.49)	2.43 (0.58)	2.43 (0.58)			
Medications@	E	0.72 (1.14)	0.46 (0.77)	0.37 (0.66)	0.34 (0.59)	12.445***	1.712ns	4.518*
	C	0.78 (1.25)	0.59 (1.00)	0.69 (1.16)	0.68 (1.14)			

@ - Pre scores were significantly different from post1, post2 and post3

***** Significant at 0.001 * Significant at 0.05 ns- not significant**

Fig 1: Comparison of mean sleep scores of patients at different time intervals in the experimental and the control group.



DISCUSSION

In the present study, most of the patients (75% and 78%) in experimental and control group were males. This is in accordance with the statistics given in National CKD fact sheet [13] 2014 which states that men with CKD are 50% more likely than women to have kidney failure. In the present study, 42% of subjects in the experimental group and 50.7% in the control group had diabetes. It is supported by the result of a study on prevalence of CKD, which reported that in India, diabetes and hypertension accounts for 40–60% cases of CKD [14].

In the present study, majority of patients in the pre-test, reported poor quality of sleep in both the experimental (95.7%) and control group (97.1%). A similar finding of a very high prevalence of insomnia (60.9%) was observed in a cross-sectional study that was conducted in 2011 among 69 outpatients on maintenance HD from a dialysis center of a state-run tertiary care hospital in New Delhi [15].

The present study revealed that as a result of CBT, there was a difference in the quality of sleep among patients undergoing HD in the experimental group compared to the control group.

A similar finding was seen in a randomized controlled interventional study that was carried out in 2011 to determine whether alleviation of sleep disturbance in HD patients also leads to less inflammation among 72 sleep-disturbed HD patients recruited at the Far Eastern Memorial Hospital in Taiwan [16]. The results suggested that CBT is effective for correcting disorganized sleep patterns, and for reducing inflammation and oxidative stress in HD patients. Thus the compared studies are consistent with the present study findings.

The study was conducted in only two dialysis centres and only individual CBT was administered to patients. As a direct consequence of this methodology, the study encountered a number of limitations which need to be considered. The present study draws the strength of a true experimental design (two group pre-test post-test control group time series design) having the features of randomization and control group.

CONCLUSION

Nurses with compassion, and knowledge on CBT can create a marked difference in the life of each patient, who undergoes HD. Consistent with conventional practice, nurses must be competent to use non-pharmacological measures like CBT to improve the sleep quality in patients undergoing HD. More research studies are warranted to illuminate and intensify the knowledge in this area.

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CONFLICT OF INTEREST

There was no conflict of interest reported.

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