Lived experience of sleep disturbances, fatigue and Quality of life among patients undergoing Haemodialysis and the effect of cognitive behavioural therapy on their sleep, fatigue and Quality of life in selected hospitals, Puducherry

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ABSTRACT

Objective

The study was conducted with a primary objective of exploring the lived experience of sleep disturbances, fatigue and Quality of Life (QOL) among patients undergoing hemodialysis (HD) and evaluating the effect of Cognitive Behavioural Therapy (CBT) on their sleep, fatigue and QOL in selected hospitals in Puducherry.

Material and methods

Mixed method research approach was used in the study. In the first phase, the lived experience of sleep disturbances, fatigue and QOL was explored and analyzed using Van Manen's phenomenological approach. Data were collected from seven participants using a semi structured interview guide. During the second phase, after the pre-test (using Pittsburgh sleep quality index, Piper fatigue scale and QOL index) patients were allotted to experimental and control group by permuted block randomization. The sample size was 138. Experimental group received six sessions of CBT while the control group received the routine care. Post-tests were done thrice after the intervention.

Results

The themes that emerged from the lived experience were

* Sleep disturbances: accompanying discomforts, abounding thoughts, ongoing coping with difficult hours, interrupted sleep

* Fatigue: overwhelming physical toll, cornered to home, demanding rest, dynamic fatigue

* QOL: crestfallen life, support and comfort, accompanying death, unfulfilled wishes

Qualitative findings helped in the refinement of CBT protocol. CBT was found to be

effective in making a statistically significant difference in sleep, fatigue and QOL (P< 0.001).

There was a weak negative correlation (P< 0.01) between fatigue and QOL and a weak

positive relationship between sleep and fatigue (P< 0.05). There was a significant association

between the clinical variables, presence of diabetes mellitus, using sedatives and sleep. There

was a significant association between age, marital status, type of family, duration of diagnosis

of chronic renal failure, presence of diabetes mellitus, exercise schedule and fatigue.

Conclusion

CBT was found to be effective in making a statistically significant difference in sleep, fatigue

and QOL among patients undergoing HD.

Keywords: Lived experience; Hemodialysis; sleep; fatigue; Quality of life; Cognitive

Behavioural Therapy

Introduction

Chronic kidney disease (CKD) which is a gradual and usually permanent loss of kidney function is becoming a worldwide health problem. According to the Global Burden of Disease study, CKD was ranked 27th in the list of causes of total number of global deaths in 1990 (age-standardised annual death rate of 15 7 per 100,000), but rose to 18th in 2010 with an annual death rate of 16.3 per 100, 000 (Lozano et al., 2012). The final stage of CKD (Stage 5) marked by complete or nearly complete irreversible loss of renal function is End Stage Renal Disease (ESRD). In ESRD, the kidneys are functioning below 10 percent of their normal and are in a state where renal replacement therapy such has dialysis or transplant is needed. Based on the current Indian population of 1.2 billion, even a conservative estimate of End Stage Renal Disease (ESRD) burden in India would suggest that about 1,650,000 to 2,200,000 people develop ESRD every year (Parameswaran, 2012). There are approximately 6000 to 8000 patients suffering from ESRD in Kerala (Gracious, 2012).

Although kidney function is partially replaced through dialysis, patients endure many symptoms such as sleep disorders, fatigue and decreased quality of life (QOL). Several studies carried out in the last 30 years have demonstrated a high percentage of sleep disorders (Gusbeth- Tatomir, Boisteanu, Seica, Buga, & Covic, 2007). A cross- sectional study conducted among 69 patients on Maintenance Hemodialysis (MHD) from a dialysis center of a state-run tertiary care hospital in New Delhi, reported high prevalence of insomnia (60.9%) and increased risk of sleep apnea (24.6%) (Rai, Rustagi, Rustagi, & Kohli, 2011). The prevalence of fatigue ranges from 60% to as high as 97% in ESRD patients on long-term dialysis therapy (Weisbord et al., 2005). A study was conducted in India, among 47 patients on MHD to assess their fatigue, depression, sleep problems, and their co-relates. Of the patients, 44.7% reported fatigue (Joshwa, Khakha, & Mahajan, 2012). A cross-sectional study conducted in dialysis centres of J.S.S Medical College Hospital and Basappa Memorial Hospital, Mysore, revealed that the quality of life of hemodialysis patients was significantly impaired (p < .05) in comparison to healthy individuals of the general population (Sathvik, Parthasarathi, Narahari, & Gurudev, 2008).

Cognitive Behavior Therapy (CBT) has been tested for its effectiveness to improve sleep, fatigue, and QOL among patients with breast cancer and rheumatoid arthritis. Studies have been done testing its effectiveness on sleep and

fatigue among dialysis patients (Chen et al., 2011). The results are satisfactory, as sample had better sleep quality, less fatigue, and improved QOL (Chen et al., 2008). There is no study conducted in India testing CBT's effectiveness. A complete understanding of the patient's perceptions and their world may contribute to the effectiveness of CBT. However, in India there are no published qualitative studies available on these 3 aspects viz. sleep disturbances, fatigue, and QOL among hemodialysis patients. As sleep disorders and fatigue can have negative effect on hemodialysis patients, it is important that nurses collaborate with patients using CBT to help alleviate the effects of sleep disturbances, fatigue, and to improve their QOL.

Objectives

The objectives of the study were to

- explore and analyze concepts related to sleep disturbance, fatigue, and QOL among patients undergoing hemodialysis
- evaluate the effect of cognitive behavioural therapy on sleep quality, fatigue, and QOL among patients undergoing hemodialysis
- find the association of pre-test sleep, fatigue, and QOL score of patients undergoing hemodialysis with the selected demographic and clinical variables

Methods

Design and Sampling

A mixed method research design was used. The rationale for using a mixed method research was to explore and understand the real world of patients which would help to refine the CBT protocol that was targeted to increase sleep, QOL, and decrease fatigue. Though this is the target for the proposed main study, yet this small piece of research as pilot study has helped the researcher to get a clear direction on the path of the qualitative research and has given pretty good confidence to take over the prospective main study. It was a sequential exploratory design. At first the concepts of sleep disturbance, fatigue, and QOL were explored using van Manen's interpretive phenomenological approach. Phenomenology is a project of sober reflection on the lived experience of human existence i.e., reflecting on experience in a thoughtful manner and free from theoretical, prejudicial, and suppositional intoxications (van Manen, 2007). Three subjects were selected using purposive sampling to conduct phenomenological interviews. Two group pre-test post-test control group design was used for quantitative approach. Participants were selected based on the following inclusion criteria: Patients who were undergoing maintenance hemodialysis 1) twice a week 2) for more than 3 months.3) above the age of 18 years 4) and without active medical and psychiatric conditions. By simple random sampling using lot method, the day for dialysis was selected. The lot fell on Tuesday. So patients undergoing dialysis on Tuesday and Friday were selected (2 dialysis/ week). There were two shifts of dialysis at the Government Hospital - morning and evening. Group randomization of subjects was done based on the shift of dialysis to experimental and control group. Sample size was 10 in experimental and 10 in control group. Power analysis was done based on previous published research studies and estimated the sample size for pilot study to be 10 in each group (Chen et al, 2008; Duarte, Miazaki, Blay, & Sesso, 2009).

Instruments

The tools comprised of a socio-demographic proforma that included age, gender, occupation, monthly family income, marital status, and type of family and support. Clinical variables included were duration since diagnosis of renal failure and undergoing hemodialysis, suffering from co- morbidities, hemoglobin, use of sedatives, current smoking, and alcohol status. A semi structured interview guide was prepared to explore the lived experience of sleep, fatigue, and QOL and expert opinions were obtained for the same. It had one main question and multiple probes.

For quantitative approach three standardized tools were used. Pittsburgh Sleep Quality Index (PSQI), Piper Fatigue Scale (PFS), and Ferrans and Powers Quality of Life Index (QLI). Dialysis version were used to assess sleep, fatigue, and QOL among patients undergoing hemodialysis. The reliability of the tools was, PSQI ($r = .83$), PFS ($r = .98$), and QLI ($r = .93$). Permission was obtained for both using and translating the tools. Linguistic validation was done in three phases. In the phase one, forward translation was done from the source language to target language by two professional translators. The variations were discussed and a pooled version of the tools were produced which was mutually agreed by the translators. In the second phase, the backward translation was done by a local professional translator. This version was compared with the original version. The items were discussed and the second version of the tools was prepared. In the phase 3, the translated version was tested on patients to determine whether the tool was acceptable and if it was simple and appropriate. As it was found to be satisfactory, the third version of the translated questionnaire was proof read and was considered to be final. It was approved by the authors.

Data Collection

The study was conducted from June 2013 to March 2014 in Government Hospital Aluva. The data collection began after getting the approval from the institutional ethics committee. Written consent was obtained from the subjects.

Qualitative approach: Data was collected by in-depth interview using a semi structured interview guide. The interview was done with three purposively selected participants. One interview was conducted in the participant's home, while the other two were at a room adjoining the dialysis unit. The place for interview was decided based on the comfort expressed by the study participants. The average time taken for each interview was approximately 22 minutes. Data saturation was not attained, as the purpose of the pilot study was to check the feasibility and appropriateness of the study design, data collection (using the semi structured interview guide) and data analysis. Another purpose was to give the researcher an opportunity to reflect on her interviewing skill and to ensure that the technical aspects of recording the interviews were satisfactory. So to attain the above purposes, data were collected only from 3 selected participants.

Quantitative approach: Subjects who were willing to participate in the study were assessed for eligibility as per inclusion criteria. Pre-interventional assessment of sleep, fatigue, and QOL were done by trained data collectors using standardized tools in Government Hospital, Aluva. By lot method, the dialysis sessions were randomised into experimental and control group. Group CBT was administered by the investigator to the patients in experimental group for 8 sessions (twice a week) over a period of four weeks. Each session lasted for about 40-60 minutes and was held for the subjects prior to their dialysis session. CBT protocol contained the following elements: Stimulus control therapy, sleep restriction, sleep hygiene, cognitive restructuring, fatigue management skill training, social support, positivity, relaxation training, and maintenance of sleep and fatigue diary. Subjects in the control group received only the usual care with routine hemodialysis treatment. Post-interventional assessment was done at 2 weeks, 6 weeks, and 10 weeks after the 8th session.

The qualitative data were analyzed using hermeneutic phenomenological reduction (van Manen, 1990). The quantitative data were analyzed using descriptive and inferential statistics at .05 level of significance. Tests such as Chi-square, t test and ANOVA were used.

Concept Analysis: Two study participants were male and one was female. The age groups of two participants were above 60 years, while one person was forty four years old. The audiotaped interview was listened and it was transcribed on the same day. After verification, it was translated to English. In hermeneutic reduction (Adams & van Manen, 2008), researchers reflect on their pre-understanding, framework and biases. They also search for genuine openness to engage in a conversational relation with phenomena. To achieve this reduction and critical self-

awareness, a journal of personal reflections on the interview as well as researcher's thoughts throughout the study period was kept that has been of value in interpretation and discussion of participant's data.

Development of Concepts

It involved analyzing each interview separately, and going from parts (of the text) to the whole. Key words, phrases and ideas were grouped together and then concepts were developed from these groups by reading and re-reading the data, and spending considerable time dwelling on the meanings emerging from the text (van Manen, 1990). An example of a comment from participant 2 in reference to his experience of sleep disturbance is given below:

'When I don't get sleep, I used to experience aches in my legs… aches all over the body. I do experience severe body discomforts'.

The key words identified were body aches, leg aches, and discomforts. The possible concepts related to these key words were 'accompanying pains and discomforts'. Similar ideas within each interview, including the following quote by participant 1, were grouped together before identifying several passages that gave an overall impression of the interview.

'I have very little sleep. I have severe aches in my hands, legs and all over the body during sleeplessness. I experience severe discomforts in my body.'

The process of identifying similar concepts was repeated with each of the three interview transcripts. Those key words and concepts that were found to be common between the interview transcripts were then grouped together. Participant 2 recollections of his sleep disturbances reflected those of participant 1, and these were grouped together with similar thoughts from the third participant under the concept accompanying aches and discomforts. A similar process of analysis was undertaken using the interview transcripts of three participants and thus identified a number of key concepts for the sleep disturbance, fatigue, and QOL among patients undergoing hemodialysis in Table 1.

Sleep	Fatigue	Quality of life
Accompanying pains and discomforts	Unable to do insignificant activities - Walking - Eating	Hard pressed life - Difficult life (need to lie 4 hours for dialysis) - Controlled life (diet, money) - Restricted life (less travel and leisure) - Abandoned life - Coping with hardships
Thought filled nights - Past life - Loved ones	Accompanying aches	Support - Spiritual - Family
Dynamic sleep	Losing desire to live	Change filled life - Loss of job - Loss of finance - Dependent life - Loss of comfort filled life
Frightening dreams Relying on spiritual support to sleep	Family support Cornered to bed	Regrets over lost life Striving for independent life

The concepts emerged were authenticated by participant "member checks" to preclude erroneous data. This technique served to limit researcher bias and assure that the participants' viewpoints and understandings were accurately recorded. Documentation of procedures such as the recruitment of participants, interview process and the development of concepts, add to the trustworthiness of the research. There were no difficulties faced during the concept analysis.

Effect of cognitive behavioural therapy on sleep quality, fatigue, and QOL among patients undergoing hemodialysis

The baseline data showed that 70% of the subjects in both the groups were males with a median of 56.6 years in experimental and 57.9 yrs in the control group. Sixty percentage of the participants were illiterate in the experimental group, while 60% had high school education in control group. Majority of subjects in both the groups were unemployed, married, and defined family as their support and 80% of the subjects in the experimental group belonged to joint family, while 50% were from nuclear and 50% from joint in the control group. Majority of the subjects in both experimental and control group were suffering from diabetes and hypertension and 80% of the subjects in both groups were not on any sedatives, or any exercise regimen (100%). None of the subjects in both the groups were current smokers or alcoholic. Statistical tests (Chi-square, t test) revealed that subjects were homogenous in both experimental and control groups. Repeated measures ANOVA demonstrated that the mean difference of sleep (F=69.83) fatigue (F=201.20) and quality of life (F=298.52) between the experimental and

Table 2
Repeated Measure ANOVA to Assess the Effect of CBT on Level of Sleep Disturbances

Group	Control		Experimental	
	Mean	SD	Mean	SD
Pre	18.1	2.88	17.0	3.01
1st post	19.0	2.16	7.7	1.49
2nd post	19.1	2.23	7.6	1.77
3rd post	19.5	2.54	7.6	2.01
F-value	69.83			
p-value	.0001***			

***p<.001-highly significant

Table 3
Repeated Measure ANOVA to Assess the Effect of CBT on Level of Fatigue

Group	Control		Experimental	
	Mean	SD	Mean	SD
Pre	179.4	30.85	172.9	27.3
1st post	194.8	14.62	83.94	16.09
2nd post	194.8	14.62	84.4	15.87
3rd post	197.3	13.02	84.4	15.87
F-value	201.2			
p-value	.0001***			

***p<.001-highly significant

Table 4
Repeated Measure ANOVA to Assess the Effect of CBT on Level of Fatigue

Group	Control		Experimental	
	Mean	SD	Mean	SD
Pre	11.89	0.80	11.86	0.72
1st post	12.09	0.86	19.47	1.19
2nd post	12.09	0.86	19.47	1.19
3rd post	12.09	0.86	19.23	1.21
F-value	298.52			
p-value	.0001***			

***p<.001-highly significant

control group was significant (p < .001***)(See Table 2, 3, 4)

Association of pre-test sleep, fatigue, and QOL score of patients undergoing hemodialysis with the selected demographic and clinical variables

There was no significant association of sleep, fatigue, and QOL scores with the selected demographic variables except for educational status ($p < .01**$).

Discussion

The researcher identified that during the first interview, lot of probes were given to the study participants. But later during concept analysis, when this was identified, she consciously took efforts to refine her interview skills and thereby the data collection process.

This study provides evidence that the CBT improved the quality of sleep and QOL and has decreased the level of fatigue. These findings are similar to the results of a study conducted in Taiwan by Chen et al. (2011) among hemodialysis patients. They concluded that the adjusted posttrial primary outcome scores of the Pittsburgh Sleep Quality Index and Fatigue Severity Scale, significantly improved from baseline by therapy (tri-weekly cognitive-behavioural therapy lasting 6 weeks) compared with the control group(sleep hygiene education). The findings are also supported by a study conducted in Brazil among 85 patients who were on chronic hemodialysis and had been diagnosed with depression. The study revealed that the group that received CBT (three months of weekly 90-minute sessions) had a significant improvement in depressive symptoms and quality-of-life scores when compared to the control group (Andrade & Sesso, 2012).

There are some limitations in this study. Data were collected only from three participants. So the study did not help in deriving the themes or the essence of the Lived experience, as data saturation wasn't attained. The small sample size and relative homogeneity of the participants in terms of geographical location (one hospital) means that findings cannot necessarily be transferred to the general population. However, despite its limitations, this study helped the researcher to gain insights and clarity towards the main study.

Mixed method research draws on the strengths of both quantitative and qualitative approaches and has become increasingly recognized in outcome research. It helped to provide a broader perspective on the overall issue of sleep, fatigue, and QOL among patients undergoing dialysis. Thus the depth of qualitative data collection and analysis in the prospective study will help to capture the important data concerning the processes and challenges of developing a CBT among patients undergoing dialysis in India.

Lessons Learned

While doing interventional study, it was found that randomization of the patients based on dialysis session may be difficult for a larger sample because, patients sometimes do change the sessions due to certain inconveniences faced like illness, family occasions etc. If participants change sessions due to their inconvenience, the group of the other session can become contaminated. It was decided therefore that, for main study, it will be better to randomize each individual participant to either control or experimental group.

Another reality identified was that patients were reluctant and expressed difficulties in coming early or even to stay back after dialysis to attend group CBT. Their main problems were

 1) family members have trouble in waiting

2) transportation difficulties (no bus at specific timings)

3) physically exhausted after / before dialysis. They verbalized CBT as really useful, as it had brought a new perspective in their life. Participants also expressed that individual, ongoing CBT during dialysis session will be highly acceptable. A problem with group CBT was that, even if one or two patients come late for dialysis, the intervention in group CBT was affected. Also, for all patients, initiation and completion of hemodialysis was not at the same time. There was a delay of approximately 30 minutes between the first and the last patient who commences dialysis in a shift. The researcher strongly felt that individual ongoing CBT during dialysis will be a highly feasible therapy for the main study, acknowledging its limitations.

Conclusion

Those on maintenance dialysis often live lives of compromised quality due to the burden of illness, which includes managing multiple concurrent symptoms and the demands of dialysis. There are a number of studies which support the fact that nurse led CBT improves patient's general health problems like insomnia, fatigue, and QOL. Therefore active involvement of experienced nurses in the counseling program should be considered. In addition, further research must be conducted into the implementation of the nurse-led cognitive-behavioural intervention to a broader spectrum of patients. Improving the QOL of hemodialysis patients is as important as increasing the length of their lives.

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