The effect of continuous care model-based intervention on the quality of sleep in menopausal women: A clinical trial study

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Abstract

BACKGROUND Sleep disorder, brings in many physical, behavioral, and mental problems. Applying continuous care model leads to proper recognition of the patient’s problems and involves the patient in solving health problems. This study aimed to determine the effect of continuous care model on the quality of sleep in menopausal women.

METHODS AND MATERIALS A random clinical trial study was carried out with participation of 110 menopausal women visiting Kermanshah-based clinics (the west of Iran) in 2017. The participants were randomly assigned to intervention (n=55) and control (n=55) groups. The control group received the routine cares and in addition to the routine cares the intervention group attended four weekly group consultation sessions (60-90min). The quality of sleep in the two groups was assessed using Pittsburg Sleep Quality Index before, immediately after, and one month after the intervention. Data analyses were done using independent t-test, ANOVA with frequent measures, Friedman’s test, Wilcoxon’s post hoc test, and X2 test in SPSS (24).

RESULTS The mean scores of quality of sleep before and after the intervention were significantly different in the intervention group (p=0.001). There was no significant difference between the two groups in terms of quality of sleep before (p=0.140) and immediately after the intervention (p=0.168). However, one month after, the difference between the two groups was significant (P<0.001).

CONCLUSION Implementation of the continuous care model led to an improvement of quality of sleep in the menopausal women.
Background

Menopause is a natural process that is experienced by women at old age. As a result, menstrual cycle is halted due to a decrease in the level of ovarian hormone. Normally, it happens at the age range 45–55 years (1). The number of menopausal women in 1990 was estimated about 467 million worldwide; this figure is expected to be 1.2 billion by 2023. This means 47 million new menopausal women each year (2). According to Iran National Statistic Annual Report, the population of women at the age range 45–64 was 8.5 million in 2011 (11.33% of the population) (3). The main concerns about menopausal women's health include vasomotor symptoms, vaginal urine atrophy (urogenital) osteoporosis, cardiovascular diseases, cancer, decrease in cognitive function, and sexual problems (4). Among these symptoms, sleep problem is one of the main challenges (5). Sleeping is a physiological need that is good for health and accelerates recovery from diseases (6). Sleeping has a critical role in the cardiovascular function (7) so that the risk of cardiac ischemic attacks is higher in individual with low quality of sleep. In addition, there is a relationship between insomnia and cardiac ischemic diseases (8). Sleep refreshes mental, spiritual, and physical energy so that it is renowned as one of the most vital needs of man (9). Along with cognitive problems, sleep deprivation negatively affects the physiological systems (including immunity system), which in return affects the whole physical health. There are also evidences that sleep deprivation attenuates glucose level, increases sympathetic neural system activity, and increases cortisol. Thus, sleep deprivation might be effective in development of disorders like diabetes, blood pressure, and obesity (10). Quality and quantity of sleep affects individual's quality of life not to mention disorders or mental and social functions.
and inter-personal interactions (11). According to the national sleep foundation (NSF) the sleep disorder that happens during menopausal period does not necessarily influence the quantity of sleep, and the problem may appear as poor quality sleep (6). One way to improve quality of life is to provide education to individuals through proper educational models and theories. A model was designed in Iran by Ahmadi in 2001. It is consisted of four stages of introduction, creating sensitivity, control, and assessment. The care-seeker in this model acts as the agent of continuous and effective care (12). Continuous care in the model is a regular process to create an effective and continuous interaction between the care-seeker (as the agent of continuous care) and nurse or midwife (as the provider of health care services). The process tries to recognize the needs and problems and creates sensitivity in the care-seekers to accept and continue healthy behaviors and improve their health in a continuous process. Therefore, a key feature of this type of care is a continuous, dynamic, and effective care relationship that is perfectly matched with the specification of chronic diseases and dynamism of the problems caused by them. Nurse’s expert intervention is emphasized in the model as a dynamic and continuous factor (13). Using the model enables the practitioners to recognize the patient’s problems and motivate and involve the patient in solving the problem (14). Studies have supported the positive effect of the model on the quality of sleep of hemodialysis patients and blood pressure in diabetics (12–14). Using the model leads to proper recognition of the patient’s problems, motivation, and involvement of the patient in solving the problem (14). In light of the above introduction, the present study is an attempt to determine the effect of interventions based on continuous care model on the quality of sleep of menopausal women visiting Kermanshah-based clinics.
Methods

*Study setting and design:*

A randomized clinical trial study was carried out on 110 menopausal women who visited Kermanshah-based clinics. The participants were randomly assigned to control (n = 55) and intervention (n = 55) groups (Fig.1).

In this study, a simple randomization method was used to implement random allocation.

In this way, 110 cards matched in appearance were prepared. Fifty five of them were coded “1”, which specifies the intervention group, and fifty five of them were coded “2”, which specifies the control group. Then, each eligible entry person randomly selected one of these cards, thus the random allocation of patients to each group was determined without the participants being aware of the nature of the numbers 1 or 2.

Sampling was carried out from May 2017 to September 2017. Inclusion criteria were at least three and at most four years since the last menstrual cycle, no mental disease (based on medical file), no history of smoking, drinking, or drug abuse, no history of hormone therapy over the past six months, Pittsburg Sleep Quality Index (PSQI) score >5, no malignant disease (cancer, thyroid, epilepsy, diabetes) according to the attending physician’s examinations, reading and writing literacy, and using no drug effective on sleep (Antihypertensive, benzodiazepines, antihistamines, etc.). Exclusion criteria were reluctance to participate, experiencing sad and traumatizing experiences, diagnosed with mental disorder, and missing more than one session.

In addition to the routine cares provided to menopausal women in the clinics, the
intervention group (n = 55) attended four weekly group (n = 11) consultation sessions (60-90min). The control group only received the routine interventions. Immediately and one month after the last intervention sessions, the questionnaires were filled in by the participants. The content of the session and the steps of intervention are listed in Table 1.

To avoid observer bias, random allocation and assigned participants to intervention and control groups and the whole process of distributing and collecting the questionnaires was perform by a third person who had no role in the study.

**Sampling techniques:**

Following Mehdizadeh et al. (2010), and assuming $\delta_1 = 5.12$, $\mu_1 = 15.31$, $\delta_2 = 5.3$, $\mu_2 = 11.86$, $\alpha = 0.05$, and $\beta = 0.1(17)$, the sample size was estimated to be 48. Taking into account probable leaves, 55 participants were selected for each group. Initially, in order to select the clinics, the geography of Kermanshah city was divided into 4 geographic categories according to the socio-economic status, which includes 20 clinics. Then a clinic was randomly selected from each region and the required number of samples based on the quotas of each clinic were selected by the convenient sampling. Finally the participants were randomly assigned to control (n = 55) and intervention (n = 55) groups.

**Data collection:**

Data gathering tools were a demographics form and PSQI. The latter is featured with 90% sensitivity, and specificity of 87%. Several studies have supported validity and reliability of the questionnaire for a wide spectrum of patients and healthy individuals (15).

Farahi et al. reported sensitivity, specificity, and Croanbach’s alpha of the Farsi
version of PSQI in Iran equal to 100%, 93%, and 0.89 respectively (16). The index contains nine questions and since the question No.5 includes 10 secondary questions, there are 19 questions in the index. It is designed based on Likert’s four-point scale (0–3) and includes seven subscales including mental quality of sleep, delay in falling asleep, sleep term, sleep performance, sleep disorder, using sleep medicines, and performance disorders during the day.

Data analysis:

Data analyses were performed in SPSS (24) using descriptive statistics (frequency, mean, SD) and analytical tests (independent t-test, ANOVA with multiple measures, Friedman’s test, Wilcoxon Post Hoc Test, and $X^2$ test). (P<0.05).

Ethics:

In observance of ethical concerns, the participants were briefed on the objectives of study and signed an informed letter of consent. The time and place of consultation sessions were determined by the participants and they were ensured about confidentiality of their information. Participation was voluntarily and they could leave the study at any stage.

The study was confirmed by the Ethics Committee, Kermanshah University of Medical Sciences (KUMS.RES.1395.754) and registered on Iran Clinical Trial Website (IRCT2017042614333N73).

Results

Married participants constituted 90% of the sample group and education level of 81% of the participants was lower than high school diploma. In addition, 98% of the participants were living in city and 91% had a monthly income of 1–3 million Tomans. In general, 68% of the women had three or four children and 91% had one
or two married kids. Moreover, 11% of the participants had a history of using medicines and 48% had a normal body mass index (BMI). There was one drug addict in family of 2% of the participants. There was no significant differences between the two groups in terms of demographical information (Table 2). The mean and standard deviation of sleep quality score and the subscales before, immediately after, and one month after the intervention for the intervention and control groups are listed in Table 3 and 4.

Discussion

The effect of intervention based on continuous care model on the quality of sleep in menopausal women was examined. The results showed that the intervention led to an improvement of the quality of sleep in menopausal women. This is consistent with other studies on the effect of continuous care model on the quality of sleep of victims of chemical weapons (17), dialysis and hemodialysis patients (18), diabetics (12), and hemodialysis patients (14). To elaborate more, continuous care and education are the bedrocks of continuous care model so that every care-seeker has their own basic needs and fulfilling them entails endeavor and responsibility. The main goal of the model is to design a program that leads to acceptance and improvement of attitude toward and performance of efficient and individual cares. The model follows an empowerment approach and among its main functions is changes in life style and model (12). To improve the quality of sleep of the care-seekers, non-pharmacological interventions were performed and the required educations about how to observe sleep health were provided. Such as, giving up unhealthy habits, adopting good pre-bedtime habits, how to increase useful sleep hours, the factors effective in sleep (nutrition, exercising and physical activity,
using medicines, smoking), and the principles of sleep hygiene (asleep and awake hours, stimulators, nutrition, using medicine, physical activity, and sleep environment). All these explain the improvement in the quality of sleep of the participants in intervention group.

The total score of quality of sleep in the intervention group decreased to the normal and desired level (5 or less). However, Mehdizadeh et al. (2007) examined the effect of continuous care model on the quality of sleep of chemical weapons victims with obstructive bronchiolitis and reported an improvement in the total score of sleep quality (14.36±4.85 vs. 11.86±5.3) while the decrease was not at a desired level (17). Moreover, Sadedi et al. (2013) used the continuous care model to improve the quality of sleep of hemodialysis patients and reported improvements, while it was not at a normal and desired level (14). These studies are not consisted with the present study. This can be explained by the role of different factors in the quality of sleep such as development of chronic sleep disorders and necessity of pharmacological or surgical interventions. On the other hand, using only care models is not enough to attenuate or solve all sleep problems and chronic ones in particular. It is notable that all the cases beyond the field of expertise of the researchers were introduced to physicians. The level of commitment of the participant to follow the process and visiting the clinics when needed also explain the different results by different studies.

As the results showed, before and one month after the intervention, a significant difference appeared between the two groups in terms of the mean score of the subscales mental quality of sleep, delay in falling asleep, effectiveness of sleep, and disorder in performing daily activities, and the scale quality of sleep. However, the intervention was not effective on subscales length of sleep, sleep disorders, and
using sleep medicines.

Golafroz (2012), found a significant difference between intervention and control group in terms of the mean score of quality of sleep in the subscales mental quality of sleep, length of useful sleep, delay in falling asleep, and disorder in performing daily functions. However, the difference between the two groups in terms of using sleep medicine after the intervention was not significant (19). Mahdizadeh (2007), reported a significant difference after intervention between control and intervention groups with regard to mental quality of sleep, sleep disorders, sleep medicine dosage, and total score of quality of sleep. The study showed no significant difference between the mean score of the four other scales (17).

To explain the difference between the studies, factors like different study populations including hospitalized or outgoing patients, special disease patients (e.g. diabetics, chemical weapons victims, and obstructive bronchiolitis) who suffer sleep disorders are notable. Another notable factor is inclusion criteria. For examine, among the inclusion criteria in Golafroz (2012), were using no medicine effective on sleep (e.g. antihypertensive, benzodiazepines, and antihistamines) (19). This explains why the model was not effective in the subscale using sleep medicine. Proper sample size, randomization, and attendance of the participants in education and consultation session were of the advantages of the present study; while the short follow-up term (one month) was a limitation.

There are several factors effective in the quality of sleep that were beyond the researcher’s control and might confound the results. In addition, other factors like quality of life and BMI are effective on the quality of sleep and this study failed to measure them. Future works may take these two variables into account.
Conclusions

Implementation of the continuous care model led to an improvement of quality of sleep in the menopausal women. Therefore, implementation of the model to improve quality of sleep in menopausal women is recommended.

List of Abbreviations

National sleep foundation (NSF)
Pittsburg Sleep Quality Index (PSQI)

Declarations

Ethics approval and consent to participate

This study was approved by the Ethical Committee of the Kermanshah University of Medicine Science (approval number KUMS.RE.S1395.754)

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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Tables
Table 1: Content of the session and steps of the intervention

| Steps of the model | Content                                                                                                                                   | Presentation method                        |
|--------------------|-----------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|
| Introduction       | - Greeting, introduction and making arrangement for time and place of the next sessions;                                                  | Group discussion                           |
| (session one)      | - Emphasizing confidentiality of the subjects discussed during the sessions;                                                             | Giving lecture                            |
|                    | - Creating the needed sensitivity about the care-seeker’s problem;                                                                     |                                            |
|                    | - Learning about care-seeker’s problem;                                                                                                 |                                            |
|                    | - Motivating the care-seeker.                                                                                                           |                                            |
|                    | - Creating a sense of need and necessity for continuous of the care in the care-seekers, explaining expectations of the care-seeker and providing health care to each other; |                                            |
|                    | - Elaborating on the necessity of continuing and keeping health care contact between the parties until the end of the intervention; and |                                            |
|                    | - Explaining about the time of telephone contacts and how to telephone the researcher.                                                  |                                            |
| Creating sensitivity| - The process of menopause, the problems like hot flashes, overnight sweating and non-pharmacological intervention to improve quality of sleep in the care-seekers | Consultation, discussion, lecture, asking and answering questions, handing education pamphlet | sessions two, three and (four) |
|                    | - Importance of paying attention to health, giving up unhealthy habits, learning how to adopt healthy habits like sleeping, how to try to increase useful sleeping time, introduction to the factors that affect sleep (e.g. nutrition, exercising, physical activity, using medicines, smoking, etc.) |                                            |
|                    | - Introduction to the principle of sleep hygiene such as sleep and wake up time, motivators, nutrition, using medicine, physical activity, sleep environment; introduction to different types of sleep disorders such as insomnia, excessive sleepiness, and the like; |                                            |
|                    | - Creating an effective and continuous care relationship between the health care provider and care-seeker to ensure mutual perception and understanding; |                                            |
|                    | - Reemphasizing the importance of telephone consultation and keeping the care relationship.                                             |                                            |
|                    | - Introducing the help-seeker to other specialists if needed.                                                                           |                                            |
| Control            | keeping continuous care consultation through weekly checks (telephone or visiting) depending on the care needs                            |                                            |
| Assessment         | Refilling the PSQI immediately and one month after the continuous care intervention                                                      |                                            |

Table 2: Individual characteristics of the menopausal women in the intervention and control group
| Variable                                      | Intervention group | Control group | P - value |
|----------------------------------------------|--------------------|---------------|-----------|
| Women’s age                                  | 62/53±88/2         | 53.55±3.29    | , P=0.618 |
| Time interval from menopause                 | 2.22±07/1          | 2.29±1.27     | P=0.782   |
| Mother’s education level                     |                    |               | P=0.202   |
| Under Diploma                                | 43 (86)            | 38 (76)       |
| Diploma and Academic                         | 7 (14)             | 12(24)        |
| Mother’s marriage status                     |                    |               | P=0.999   |
| Married                                      | 45 (90)            | 45 (90)       |
| Single parent                                | 5 (10)             | 5 (10)        |
| Income level                                 |                    |               | P=0.08    |
| Less than ten million IRR                    | 2 (4)              | 7 (14)        |
| ten to three million IRR                     | 48(96)             | 43 (86)       |
| Residence                                    |                    |               | P=0.247   |
| Urban                                        | 48 (96)            | 50 (100)      |
| Rural                                        | 2 (4)              | 0 (0)         |
| Children’s number                            |                    |               | P=0.502   |
| 1-2                                          | 5 (10)             | 9 (18)        |
| 3-4                                          | 36(72)             | 32(64)        |
| ≥5                                          | 9 (18)             | 9 (18)        |
| Having an addict member in the family        |                    |               | P=0.753   |
| Yes                                          | 1 (2)              | 1 (2)         |
| No                                           | 49(98)             | 49(98)        |
| BMI                                          |                    |               | P=0.696   |
| <18.5                                        | 8 (16)             | 6(12)         |
| 18.5-24.9                                    | 22(44)             | 26(52)        |
| >25                                          | 20(40)             | 18(36)        |
| use of medications                           |                    |               | P=0.749   |
| Yes                                          | 6(12)              | 5(10)         |
| No                                           | 44(88)             | 45(90)        |

Table 3: Comparison of mean and standard deviation of sleep quality score and its subscales before, after and one month after intervention between the intervention and control group
|                                      | Intervention group                                      |                                           | Control group                                     |                                           |                                           |                                           |
|--------------------------------------|---------------------------------------------------------|------------------------------------------------|------------------------------------------------|------------------------------------------------|------------------------------------------------|------------------------------------------------|
|                                      | Before | After | One month later | P - value | Before | After | One month later |
| subjective sleep quality             | 0.64±1.78 | 0.57±1.44 | 0.54±0.54 | 0.001 | 0.55±1.88 | 0.59±1.88 | 0.68 |
| sleep latency                        | 1.78±0.81 | 1.56±0.78 | 0.9±0.67 | 0.001 | 1.78±0.88 | 1.60±0.90 | 1.68 |
| sleep duration                       | 0.62±0.83 | 0.38±0.60 | 0.22±0.41 | 0.001 | 0.36±0.48 | 0.44±0.70 | 0.36 |
| habitual sleep efficiency            | 0.72±1.03 | 0.26±0.56 | 0.080±0.27 | 0.001 | 0.40±0.67 | 0.42±0.78 | 0.32 |
| sleep disturbances                   | 1.60±0.53 | 1.48±0.54 | 1.34±0.47 | 0.001 | 1.30±0.46 | 2.16±6.48 | 1.22 |
| use of sleeping medications          | 0.12±0.38 | 0.16±0.46 | 0.12±0.38 | 0.607 | 0.16±0.37 | 0.16±0.46 | 0.20 |
| daytime dysfunction                  | 1.78±0.64 | 1.48±0.57 | 1.08±0.52 | 0.001 | 1.56±0.54 | 1.5±0.58 | 1.56 |
| Overall sleep quality                | 09/3 ±40/8 | 20/2±76/6 | 79/1±28/4 | 0.001 | 98/1±44/7 | 75/6±16/8 | 10/2 |

Table 4: Comparison of mean and standard deviation of total score and subscales of sleep quality between intervention and control groups before, after and one month after intervention
|                           | Intervention group |                        | Control group |                        | One month later | Before |
|---------------------------|--------------------|------------------------|---------------|------------------------|-----------------|--------|
|                           | Before             | After                  | One month     | Before                 | After           |        |
|                           |                    |                        | later         |                       |                 |        |
| subjective sleep quality  | 0.64±1.78          | 0.57±1.44              | 0.54±0.54     | 0.55±1.88              | 0.59±1.88       | 0.68±2.16 | 0.341 |
| sleep latency             | 1.78±0.81          | 1.56±0.78              | 0.9±0.67      | 1.78±0.88              | 1.60±0.90       | 1.68±0.86 | 0.927 |
| sleep duration            | 0.62±0.83          | 0.38±0.60              | 0.22±0.41     | 0.36±0.48              | 0.44±0.70       | 0.36±0.48 | 0.213 |
| habitual sleep efficiency | 0.72±1.03          | 0.26±0.56              | 0.080±0.27    | 0.40±0.67              | 0.42±0.78       | 0.32±0.58 | 0.166 |
| sleep disturbances        | 1.60±0.53          | 1.48±0.54              | 1.34±0.47     | 1.30±0.46              | 2.16±6.48       | 1.22±0.46 | 0.004 |
| use of sleeping medications| 0.12±0.38          | 0.16±0.46              | 0.12±0.38     | 0.16±0.37              | 0.16±0.46       | 0.20±0.57 | 0.401 |
| daytime dysfunction       | 1.78±0.64          | 1.48±0.57              | 1.08±0.52     | 1.56±0.54              | 1.5±0.58        | 1.56±0.57 | 0.906 |
| Overall sleep quality     | 09/3±40/8           | 20/2±76/6              | 79/1±28/4     | 98/1±44/7              | 75/6±16/8       | 10/2±50/7 | 0.140 |

Figures
Figure 1

The chart of the study protocol

Supplementary Files

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