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Original Article

The Impact of Orem's Model-Based Self-care Training on Self-care Behavior and the Quality of Life in Postmenopausal Kurdish Women: A Controlled Randomized Study

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Abstract
Objectives: Lack of information on the symptoms of menopause may aggravate symptoms and reduce the quality of life in postmenopausal women. This study aimed to determine the effect of self-care trainings, based on Orem's model, on self-care behavior, and the quality of life in postmenopausal women.
Materials and Methods: In this randomized controlled trial, postmenopausal women, referred to the health care centers of Saqqez city, were randomly assigned into 2 groups. Pre-test questionnaires including socio-demographic, SF-12 quality of life, and self-care questionnaires were filled out by all participants. The intervention group received 4 training sessions based on Orem's model. Participants in the control group were only given routine recommendations in the health care centers. Four weeks after intervention, participants filled out the questionnaires once again. Primary outcome was self-care behavior and secondary outcome was quality of life.
Results: In the present study, 130 participants were equally and randomly assigned into 2 groups. There was no significant difference between the 2 groups in terms of socio-demographic characteristics. Statistical analysis showed that the intervention group had significantly better performance compared with the control group in terms of the self-care behaviors and quality of life ($P < 0.05$).
Conclusions: Training is one of the most important factors in improving self-care behavior and quality of life. The use of self-care programs is a safe, noninvasive and inexpensive way to control physical and psychological problems. These programs can be easily taught to the patients (clients); and their impact on postmenopausal women is very important.
Keywords: Orem's self-care model, Menopause, Quality of life

Introduction

Menopause is accompanied with many symptoms that are associated with estrogen deficiency. The most important signs and symptoms of menopause include hot flashes, cardiovascular and sleep disorders, muscle and joint aches, as well as mental changes and urogenital problems. Studies have reported the prevalence of early symptoms of menopause, with great variety, from 50% up to 85% (1-3).

The symptoms of menopause reduce the quality of life in postmenopausal women (4,5). Lack of information about menopause and the existence of contradictory information in this regard are among the problems of women in this age that cause concerns about physical and mental changes in this period, negative attitude of women towards menopause, and their reduced quality of life (6).

Self-care is one of the everyday life skills which is acquired by the people to secure, maintain and improve their health (8). Self-care includes activities that people identify individually and do them to maintain their

health and have a permanent well-being feeling. These measures are taken without professional assistance; but the knowledge and skills to do them are taught to the people; so that they can be involved in their own care (9). Orem's self-care model as one of the most complete self-care theories is an appropriate clinical guide to plan and implement the principles of self-care. This pattern applies to people of all ages and to different diseases (10). Among the studies conducted in Iran and around the world on the impact of implementation of Orem's self-care model, the studies conducted on the quality of life in the patients undergoing hemodialysis (11), the quality of life and self-esteem of seniors (12,13), self-assessment during postpartum (14), type 1 diabetes (15), and so on can be mentioned. The study of women's health based on Orem's self-care model has also been conducted. For example, the impact of self-care based on this model has been investigated during postpartum. The results showed that the use of this model in postpartum period enhances their

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ability to adapt with the conditions of this period (14). In a number of studies, the effect of improving the health care of women in menopause has been evaluated.

For example, Doubova et al conducted a research with the aim of using pre-menopausal health care model in the form of individual and group counseling in Mexico. The results showed that the use of this model is effective on the quality of life, empowerment and awareness of women about the critical stage of menopause, the use of screening and improvements in lifestyle (16).

According to the statistics from a census conducted in 2011, middle-aged women (45-60 years old) account for approximately 5 million people in the country. With increasing life expectancy, women spend almost one-third of their lives in menopause (17-19). Therefore, the problems of this period are of very importance.

This study aimed to determine the effect of Orem's model-based self-care trainings on the self-care behavior and quality of life of postmenopausal women referred to health centers.

Materials and Methods

This study was a randomized controlled clinical trial. After obtaining approval from the Ethics Committee and registration of above-mentioned study in Iranian Registry of Clinical Trials (IRCT) website, researcher started the sampling process. The research environment was the health centers of Saqqez city, located in the province of Kurdistan, Iran. The primary outcome was self-care behavior, and the secondary outcome was the measurement of participants' quality of life.

Sampling method was a multistage method. At first, the list of postmenopausal women (aged 45 to 55 years) (based on a health survey) was extracted from the health records of 11 health centers of Saqqez city. Then, after calling them and studying the inclusion criteria by the researcher, they were invited to attend the briefing session. Sample size was determined using G-Power software, while taking into account $\alpha = 0.05$, and $\beta = 0.2$. Two-tailed test and the following values were extracted from the pilot study; and then, based on the self-care sub-domain of deviation from health care, 65 patients were selected for each group.

$m1 = 26.1$, $m2 = 50.9$

$SD1 = 15.5$, $SD2 = 7.9$

Effect Size = 0.5

Inclusion criteria were: women aged between 45-55 years and being physiologically menopause. Women who had taken hormone replacement therapy during 3 recent months, had mental disorders based on self-report and had experienced a stressful event in the last 6 months were considered ineligible.

In the briefing session, after explaining the purpose and method of the study, pre-test questionnaires (including demographic characteristics, quality of life, and Orem's model-based self-care questionnaires for each group in order to determine the self-care needs) were filled out by the participants. Before filling out the questionnaires,

written informed consent was obtained from all the participants. For those who were not sufficiently literate to fill out the questionnaires, the questions were asked orally by the researcher; and then filled out. Random allocation sequence was carried out using Random allocation Software, with regard to the method of random blocking, using blocks of 4 or 6 with the allocation ratio of 1:1 in the 2 intervention and control groups by a person not involved in this process. For allocation concealment, types of intervention were written on the papers; then they were put inside opaque envelopes and numbered sequentially. Allocation sequences were performed by a person not involved in the processes of participants' inclusion in the study, data collection and data analysis. Based on the sample size and the number of centers, 12 participants from each center were included in the study. From 2 centers, 10 participants were elected.

The intervention group received 4 training sessions (1 hour per session) based on Orem's model. Educational content was determined based on the leaflets of Ministry of Health and relevant literature review as follows:

Session I: Healthy lifestyle (nutrition, regular physical activity, social support, spiritual well-being),

Session II: Understanding menopause and its common problems (menopausal hot flashes and their control procedures, muscles and joint pain, and their control procedures, sleep problems during menopause),

Session III: Mental health and stress control,

Session IV: Sexual function and healthy sexual relationships during menopause.

Participants in the control group were given only routine recommendations in the health care centers.

For ethics in research, after reviewing the results and completion of the study, in those areas where there was a significant difference between the intervention and control groups, trainings provided to the intervention group were also identically given to the participants in the control group. To remind the performance procedure and eliminate possible ambiguities for all participants, follow-up phone calls were done by the researcher twice a week for 4 weeks. Based on the results of completed self-care questionnaires, pre-test was conducted in the first session. Based on extracted needs, participants were assigned into different groups and group training was provided for them. A personal training session was also conducted for each individual based on specific needs. Data collection tools included a demographic questionnaire, Orem's model-based self-care questionnaire, and the quality of life questionnaire (SF-12).

Demographic questionnaire included questions on age, menopausal age, education level, occupation, number of deliveries, adequacy of monthly income, family size, life satisfaction and type of house. Analysis of the study results was based on per protocol analysis.

Orem's model-based self-care questionnaire was a researcher-made questionnaire that measured self-care abilities.

The questionnaire consisted of three parts (on the basis of Orem's model): 1. Universal self-care needs, 2. Developmental self-care needs, and 3. Self-care needs in the event of deviation from health (20). In the questionnaire of the present study, universal self-care needs consisted of 16 questions about healthy life style including enough sleep, exercise, nutrition, social interaction, smoking and alcohol consumption.

Developmental self-care needs included 11 questions in relation to the recommended routine tests for middle aged people; namely, blood sugar and fat, mammography, Pap smear, and so forth. Diversion from health self-care needs consisted of 12 questions about the specific problems of menopause.

Answering each question was specified with 4 options of never, sometimes, often, and always. Scores from 0 to 3 were respectively assigned to the answers. Questions 12, 13 and 14, related to the universal self-care needs, were negative questions; therefore, they were scored reversely. Higher scores indicated higher levels of self-care.

To validate this tool, content and face validity were used, so that the questionnaires were administered to 10 faculty members. The necessity of being related, simplicity and clarity of the questions were measured by calculating content validity index (CVI) and content validity ratio (CVR). The results of calculated CVI and CVR were 0.722 and 711, respectively. The reliability was determined based on 2 aspects of reproducibility (ICC = intraclass correlation) and internal consistency (Cronbach α coefficient) through carrying out pre-test and post-test on 20 participants. Cronbach α for total scale was 0.814.

Standard quality of life questionnaire (SF-12) is a modified form of 12-question quality of life questionnaire. Reliability and validity of the Persian version of this questionnaire was examined in 2008 by Montazeri et al; and the results showed that the questionnaire SF-12 is reliable and valid enough (21). This questionnaire includes 12 questions related to the following 8 aspects: general health (Question 1), physical functioning (Questions 2-3), role (Questions 4-5), physical pains (Question 8), energy and vitality, emotional role (questions 6-7), mental health (Questions 9-11), and social performance (question 12), which include both physical and psychological subscales (22). Questions 1 to 5 and Question 8 measure the physical aspect; and questions 6 to 7 and 9 to 12 measure the mental aspect of the life quality. Physical subscale includes physical functioning, role limitations due to physical problems, general health perception, and physical pain. Psychological subscale includes role limitations due to mental-emotional problems, vitality, mental health and social functioning. The maximum score for each section or subscale is 100 and the minimum score is 0. Higher scores indicate better quality of life (21,22).

Four weeks after the intervention (last training session) all participants were invited to fill out self-care and SF-12 life quality questionnaires.

Data Analysis
Data analysis was performed using SPSS version 21.0. For comparing the individual and social characteristics, independent t test, chi-square and Fisher exact test were used. To compare self-care and quality of life scores, after intervention between the 2 groups, the linear model was used to adjust the base score. A $P < 0.05$ was considered significant in all analyses.

Results
Participants were included in the study from May to July 2016; and their follow-ups were finished on August 2016. All available participants were 200 individuals; of which 65 were excluded due to lack of eligibility criteria, and 5 other individuals were also excluded from the study because of unwillingness to cooperate. Thus, 130 participants were included in the study and finally 130 participants were followed-up until the end of fourth week after the intervention. The mean (standard deviation, SD) age of participants in this study was 50.0 (4.6) years. From among participants, 122 (93.8%) were housewives and 43 participants (33.1%) were illiterate. Socio-demographic characteristics of participants are shown in Table 1.

Independent t-test results showed that there was no significant difference between the scores of universal self-care ($P = 0.231$), developmental self-care ($P = 0.108$) and deviation from health self-care ($P = 0.112$) before the intervention. Based on general linear model (GLM) and through the adjustment of the baseline score, general self-care score, developmental self-care score and deviation from health self-care score, there was a significant difference between the groups,,4 weeks after the intervention (Table 2).

The results showed that there was no significant difference between the scores of physical subscale ($P = 0.651$) and mental subscale ($P = 0.581$) before the intervention. Based on GLM and through the adjustment of the baseline score, mental subscale score, as well as physical subscale score and their components, there was a significant difference between 2 groups, 4 weeks after the intervention. Table 3 shows scores of components of quality of life before and after the intervention.

Discussion
This study aimed to investigate the effect of Orem's model-based self-care on the quality of life in postmenopausal women. The results of this study showed that training based on Orem's model had a positive effect on quality of life and self-care behavior. After the intervention, participants in the intervention group improved scores on quality of life and self-care behavior. The difference between the 2 groups was significant.

The results of the present study showed that the quality of life of participants, before the intervention, was higher than average in subscale of physical and mental health. Four weeks after the intervention, the intervention group received higher scores than the control group in both

Table 1. Socio-demographic Characteristics of the Participants in 2 Groups

Characteristics	Intervention group, n= 65	Control Group, n=65	P
Age (y)[a]	50.5 (2.1)	49.5 (6.1)	0.228[b]
Age at menopause[a]	47.3 (5.8)	46.8 (5.9)	0.673[b]
Duration of menopause (y)[a]	2.5 (1.3)	2.7 (1.1)	0.356[b]
Number of deliveries[a]	3.5 (1.8)	2.9 (1.5)	0.043[b]
BMI[a]	29.0 (3.6)	28.0 (2.9)	0.075[b]
Occupation			0.565[c]
Housewife	61 (93.8)	61 (93.8)	
Employed	4 (6.2)	3(4.6)	
The economic situation			0.146[d]
Good	9 (13.8)	3 (4.6)	
Better than good	43 (66.2)	51 (78.5)	
Undesirable	12 (20.0)	11 (16.9)	
Education level			0.061[d]
Illiterate	29 (44.6)	14 (21.5)	
Primary/Secondary	24 (36.9)	39 (60.0)	
High School	7 (10.8)	7 (10.8)	
University	5 (7.7)	5 (7.7)	

[a] Mean (standard deviation).
[b] Independent *t* test.
[c] Fisher exact test.
[d] Chi-square test.

subscales and all sub-domains.

It seems that one of the reasons for the effectiveness of these trainings on improving the quality of life is indirectly because of the improvement of self-care behavior, especially in the field of deviation from health self-care. In this study, the field of deviation from health self-care focuses on self-care behavior in relation to coping with the symptoms of menopause. Studies have shown that the symptoms of menopause decrease the quality of life. Therefore, any activity that provides a better compatibility of a person with the menopausal symptoms, improves her quality of life.

Among the three sub-domains of self-care, participants in the pre-test, taken before the training course, obtained an average score of less than half (about one-third), indicating the poor performance of the participants about the general principles of self-care.

The lowest score in the field of general self-care, was related to the performance in the field of physical exercises (sports). Thus, in the intervention group, 4.6% of people often did exercise regularly. Four weeks after intervention, 52.3% of the participants often did regular exercises.

In developmental self-care, which emphasizes mostly on screening such as mammography, ultrasound and annual Pap smear, as well as measuring glucose and blood pressure, participants got less than half scores. The lowest scores were related to mammography. Before intervention, 13.8% of participants in the intervention group had a mammogram in the past 2 years; but four weeks after intervention, this rate reached to 44.6% during recent 4 weeks. In the field of deviation from health self-care which is specific to the menopausal problems, again participants got less than half scores. The lowest score was related to doing exercise for the aim of improving the symptoms of menopause. Before the intervention, only 1.5% of the participants exercised regularly for the improvement of the symptoms of menopause; while 4 weeks after the intervention this rate increased to 16.5%. Due to low prevalence of "public sports" in the Iranian population, especially among women, low score for physical exercise (sports) was expected.

Of the 3 sub-domains of Orem's questionnaire, the subdomain of "deviation from health" received the lowest score in the pre-test. This sub-domain is specifically related to women's performance in relation to the specific problems of menopause. The results showed that the participants had a very poor performance in terms of the ways to overcome the symptoms of menopause. Results of pre-test showed that most women need specific trainings about menopause and ways of coping with it. Various studies showed that women's knowledge about menopause is not desirable. The results of the study conducted by Donati et al in Italy showed that more than half of the middle-aged women had not received any training on menopausal symptoms, and therefore had not have appropriate knowledge in this field (23). In a study to determine the awareness of post-menopausal women on hormone therapy in China, Malaysia, Thailand and Taiwan, Huang et al concluded that more than half of the women had never done mammography (24).

In the study of Leon et al in Ecuador, about half of the participants had sufficient information about

Table 2. Comparison Between General, Developmental and Deviation From Health self-care Scores, Separately for Each Study Group (0-100)

	Intervention Group, n = 65		Control Group, n = 65		P[a]	AMD (CI 95%)[b]
	Before Intervention	4 Weeks After Intervention	Before Intervention	4 Weeks After Intervention		
General self-care[c]	39.1 (9.4)	69.9 (5.2)	37.5 (8.7)	36.6 (8.6)	<0.001	31.7 (30.2-33.3)
Developmental self-care[c]	39.3 (18.0)	86.3 (9.4)	37.4 (15.0)	37.7(15.2)	<0.001	43.9 (41.0 -46.8)
Deviation from health self-care[c]	26.1 (15.5)	88.,5 (7.9)	25.8(8.3)	25.8 (8.3)	<0.001	62.5 (60.2-65.4)

[a] Results are based on general linear model with adjustment for baseline score.
[b] The adjusted mean difference (95% confidence interval).
[c] Mean (standard deviation).

Table 3. Comparison of Quality of Life Scores (0-100) Before and After the Intervention, Separated for Each Study Group

	Intervention Group, n=65		Control Group, n=65		P^a	ADM (95% CI)[b]
	Before Intervention, Mean (SD)	4 Weeks After Intervention, Mean (SD)	Before Intervention, Mean (SD)	4 Weeks After Intervention, Mean (SD)		
Physical functioning	75.3 (30,8)	80.3 (22.4)	76.5 (26.3)	76.1 (25.4)	<0.001	19.4 (14.4-23.9)
Role-physical	65.2 (18.3)	75.8 (11.6)	66.3 (14.5)	66.1 (14.6)	<0.001	16.9 (14.0-19.9)
Bodily pain	62.5 (22.9)	72.0 (13.9)	62.4 (17.9)	62.4 (12.3)	<0.001	12.8 (10.1-15.5)
General health	36.4 (20.7)	59.3 (18.7)	36.3 (18.6)	36.3 (18.2)	<0.001	20.8 (17.4-24.2)
Vitality	62.1 (15.9)	75.3 (2.1)	61.1 (16.4)	61.5 (15.4)	<0.001	18.0(15.1-20.8)
Social functioning	61.0 (14.6)	73.1 (16.9)	63.0 (16.6)	63.1 (14.0)	<0.001	12.9(10.3-15.8)
Role-emotional	66.9 (18.7)	76.9 (10.1)	64.8 (15.0)	63.7 (15.5)	<0.001	16.1 (13.3-19.0)
Mental health	64.0 (13.6)	75.8 (15.8)	63.0 (16.2)	63.2 (13.2)	<0.001	14.1 (13.3-17.0)
Physical health subscale	61.6 (18.4)	70.1 (10.4)	61.0 (16.5)	61.1 (15.5)	<0.001	17.6 (15.3-19.9)
Mental health subscale	64.9 (13.1)	75.2 (14.3)	63.8 (13.8)	63.4 (12.6)	<0.001	16.2 (14.0-18.8)

[a] Results are based on general linear model with adjustment for baseline score.
[b] The adjusted mean difference (95% confidence interval).

menopause, but higher percentage of participants were demanding menopause training sessions (25). Results of the present study showed that Orem's model improved the performance of women in all three areas of self-care, especially in the area of deviation from health self-care. Improved performance of women in the field of deviation from health self-care reduces the symptoms of menopause such as hot flashes. Various studies have shown that the symptoms of menopause reduce the quality of life of women.

The study of Ceylan et al in Turkey to determine the prevalence of the symptoms of menopause and the relationship of these symptoms with quality of life, showed that those people who had experienced these symptoms had lower quality of life (26). In a study, Bhattacharya et al compared women with physiological menopause with those women underwent oophorectomy. Women who had done oophorectomy showed symptoms of menopause with more intensity and had lower quality of life compared with those women who had natural menopause (27).

Although Orem's model has not been used in postmenopausal women, the studies conducted in other areas using this model showed similar results. For example Mahmoudzadeh Zarandi et al and Heidarzadeh et al, in 2 separate studies on dialysis patients, concluded that self-care trainings on the basis of Orem's model significantly improves the quality of life (28,29). In a study on the quality of life of patients suffering from migraine using the mentioned model, Mahmoudzadeh Zarandi et al obtained similar results (30). Menopausal women are in need of information in order to know the signs and symptoms of menopause. Self-care empowers women, in addition to improving their health.

The present study has strengths and limitations. Using blocking for randomization is a strength. Lack of possibility to conceal the allocation is the limitation of this study.

Conclusions

Final conclusion in this study indicates the positive effects of self-care and the need to address this kind of trainings. Although the quality of life scores of women participating in this study were higher than half, their performance in the field of self-care, especially in the field of specific problems of menopause was not acceptable; and the obtained score was less than half, and in most cases, was about one-third of the total score. Results of the present study showed that training is one of the most important factors in improving self-care behaviors and quality of life. The use of self-care programs such as Orem's self-care program, which is a standard practice to provide care, and a safe, non-medical, non-invasive and cost-effective method in the control of physical and psychological problems is easily teachable to the clients; and its impact on postmenopausal women seems very important.

Conflict of Interests
None.

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