**ZTitle: Improving The Quality of Life of Caregivers of Patients With Multiple Sclerosis: The Application of One of The Nursing Models**

**Running title: Improving The Quality of Life of Caregivers in Patients with MS**

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**Improving The Quality of Life of Caregivers of Patients With Multiple Sclerosis: The Application of One of The Nursing Models**

**Abstract**

**Background**: Caregivers of patients with Multiple sclerosis (MS) due to physical and stressful consequences of patients, have inappropriate quality of life. Orem’s self-care model is a method that has a special approach to humans and health care issues. Therefore, the aim of this study was to improve the quality of life of caregivers of patients with multiple sclerosis.

**Objective:** The purpose of the present study was to determine Improving The Quality of Life of Caregivers of Patients With MS.

**Methods:** This is a quasi-experimental study. participants were 76 main family members caring for MS patients in Bandar Abbas and were randomly selected and allocated into the control and intervention groups. The intervention group received educational program based on Orem’s self-care model during 7 sessions in 40 minutes. To assess the quality of life of caregivers, the SF-36 questionnaire was used and the questionnaire was completed before and after the intervention in both groups. The results of the research were analyzed with SPSS-26 software and statistical tests such as Qui Square, t-test and Covariance analysis. A significant level of less than 0.05 was considered.

**Results:** finding showed the mean age of caregivers was 39.74±11.34 and 38.94±11.32 in intervention and control groups respectively. The overall mean score of quality of life in the intervention and control groups before study was52.31±8.47 and 57.04±14.01 and after intervention was 61.10±12.8 and 55.23±10.20 respectively, that was statistically significant (P<0.05) in intervention group.

**Conclusion:** Nurses can help caregivers to promote their abilities and adaptation to consequence of these chronic disease. Educational programs can play a major role to increasing the quality of life of caregivers of Multiple sclerosis patients during the long period of care.

**Key words**: Caregiver, Orem’s self-care model, Multiple sclerosis

**Highlights:**

**What is current knowledge?** Multiple sclerosis is a chronic disorder that has many physical and emotional consequences. Tthese problems affect not only the patient, but also the caregivers and can decrease their quality of life.

**What is new here?** Nurses can help caregivers to promote their abilities and adaptation to consequence of these chronic disease. Self-care education based on the Orem’s self-care model can improve quality of life of caregivers in patients with multiple sclerosis.

**Background**

 Chronic diseases are increasingly becoming the leading cause of disability and mortality around the world. The prevalence of chronic diseases is increasing. These diseases account for about 60% of deaths and 46% of the global burden of disease, and are expected to account for 73% of deaths and 60% of the global burden of disease by 2030 (1). MS is a chronic non-traumatic, autoimmune, and demyelinating disease of the central nervous system and most often occurs in people between the ages of 20 and 50, or more specifically in the third and fourth decades of life. MS is one of the most debilitating chronic neurological diseases in young adults. The course of this disease is unique and unpredictable and the exact cause and definitive treatment for it have not been well predicted (2).

The disease affects 2.5 million people around the world (3). According to the World Health Organization, its prevalence is 80, 14.9, 8.3, 5, 2.8 and 0.3 per 100000 people in Europe, the Eastern Mediterranean, the Americas, the western Pacific, Southeast Asia and Africa, respectively (4). The prevalence of MS is very high in different geographical areas of Iran. In a regular survey conducted in 2013, researchers found that the overall prevalence ranged from 5.3 to 74.28 per 100000 people in Iran (5). The common symptoms of this disease include sensory impairment, weakness, muscle cramps, visual impairment, cognitive impairment, fatigue, tremors, impaired urination and defecation, sexual dysfunction, imbalance, forgetfulness, hearing loss, numbness, blurred vision, and speech disorder (2). It threatens the independence and ability of the individual to be effective in the family and society and affects all aspects of the patient's daily life (4).

The increasing trend of MS disease in Iran requires paying attention to the issues and medical problems of these patients (6). About 30% of MS patients need supportive care at home, and 80% of this care is provided by informal or unpaid caregivers. Caring for MS patients is a crucial issue since the disease is often diagnosed between the ages of 20 and 30 years. Thus, caring for these patients takes several years. As the disease progresses, patients also need more care, and caregivers take on heavier responsibilities. The results of studies have revealed that caregivers of MS patients experience many psychological, physical, social and economic problems during care. Patient caregivers are exposed to the process of death, pain, and fear of the patient's death during care. Therefore, it may affect their quality of life. Thus, since the quality of life of caregivers directly affects the quality of life of patients, it is necessary to provide more support to caregivers. Although many studies have been conducted in the area of MS disease and in patients with this disease, there is very little information on the support of caregivers of MS patients (7).

Health-related quality of life is a multidimensional structure that includes those aspects of quality of life or function that are affected by health status such as symptoms and physical health, psychosocial factors and psychological conditions. Health-related quality of life criteria includes people's perceptions of their overall health and how their health affects their daily lives, including views to physical, mental, and social functioning (8). Complications of care are another important factor affecting the quality of life. Care-related stress plays a role in causing the disease in the caregiver. Caregivers who were under stress had higher levels of stress hormones than other caregivers. This long-term physical and rational response to high stress may put caregivers at greater risk for hypertension, diabetes, and other diseases (9).

Being caregiver has both physical and stressful consequences. The characteristics of specific diseases are likely to determine its effect on the caregiver. Caregiver’s suffering is a multidimensional response to the physical, emotional, psychological, social, and financial pressures associated with caring for another person (10). Families of MS patients are vulnerable and need attention due to long-term care of patients and enduring high level of stress. Owing to the unpredictable nature of the disease, the activities of the families of MS patients are unplanned and their spouses often feel pressure because of their spouses' limited involvement in life.

Due to the various problems and issues of these patients and the involvement of their families with many challenges, one of the aspects of improving the treatment process after diagnosis and starting to use the drug is to provide educational-supportive services to patients and then to caregivers and families with the aim of raising the level of knowledge of families and caregivers about the disease and the situation of their patients, increasing social skills for more effective communication with patients, accepting the disease, expressing emotions, paying attention to themselves, strengthening optimistic aspects and spiritual dimensions (11).

The Orem’s self-care model is a good clinical guide for planning and implementing self-care principles. This model is used as a conceptual framework to guide self-care programs (12). The Orem’s self-care model is one of the most complete theories of self-care. He argues that man is the only being who has the ability to take care of self. Orem considers self-care as an activity that a person uses to maintain or improve life, health, prevention and treatment of diseases. Orem's self-care model is based on the fact that the person needs self-care activities and the nurse helps the person to maintain life, health and well-being (13).

Given the situation and needs of patients when deviating from health and the role of the nurse in this model, three types of care systems have been designed: complete compensation system, partial compensation system and supportive-educational system. In the supportive-educational system, this method is used when the patient is ready to do and learn something, but cannot do it without help. In this system, nurse plays mostly the role of consultant. The self-care education program based on the Orem's self-care model in MS patients in this study is based on the supportive-educational nursing system (6).Given what was stated above and due to the high prevalence of this disease in Iran and due to adverse consequences such as loss of income and costs of health care and limited study in this area, the present study was conducted to determine the effect of self-care education based on the Orem’s self-care model on the quality of life of caregivers in patients with MS.

**Methods**

This quasi-experimental study was conducted in march 2020 to January 2021, after approving the proposal and obtaining the code of ethics and permission from the research and technology deputy of medical sciences of Bandar Abbas and after explaining the research and its purpose to participants. The statistical population of this study included caregivers of MS patients referred to the MS clinic in Bandar Abbas. Samples were selected using convenience sampling method. After assimilation them, they were randomly allocated into intervention and control groups.

Accordingly, the researcher referred to the MS clinic. Then, the samples were selected according to inclusion criteria. After introducing self and obtaining written consent from the patients about participating in the study, based on the random list obtained from the randomization main software, they allocated into one of the intervention and control groups. Inclusion Criteria included: first-degree family member, age of 18 and older, having a history of at least 6 months of caring for the patient, not participating in similar training courses in the past (3), and not suffering from mental illnesses (2). Exclusion of criteria included: not participating in more than two training sessions, acute stress and crisis during the intervention period (4), unwillingness to continue cooperation in any part of the study (2), and use of a private caregiver at home (14). Then, the demographic characteristics questionnaire and quality of life questionnaire were presented to both groups to complete them. The self-care needs assessment form was completed in patients in intervention group. It was designed by Khodaveisi et.al (2018) and includes questions on the patient's level of knowledge and attitude towards the disease, the patient's skill level and performance, the patient's pain level, learning ability and memory problems, disease symptoms and the patient's willingness to self-care plan (2). Educational interventions were performed in 7 sessions of 40 minutes, one day per week, in the presence of the caregiver for 2 months in the MS center and performing the items taught in each session, was followed-up by phone calls. The content of this educational program is described in table 1. Diagram 1 shows the process of sampling and carrying out the intervention. the total number of samples included in the study was 76 people and the number of samples withdrawn from the study was 7 people, the reason for leaving two of them was migration, the other three due to unwillingness to continue cooperation and two others due to not participating in more than two training sessions, they were excluded from the study.

At the end of the sessions, educational materials were presented in the form of written booklets approved by 10 faculty members and research advisors. Since the self-care needs of each patient were different from the others, the method of education was individualized and face-to-face. 3 months after the intervention, a quality of life questionnaire for caregivers in both control and intervention groups were completed. The results of the research were analyzed with SPSS-26 software and statistical tests such as Qui Square, t-test and Covariance analysis. A significant level of less than 0.05 was considered. It should be noted that during this period, the control group samples received only the routine interventions of MS clinic. To observe the principle of justice in research, ‌a complete booklet‌ was also donated to ‌the caregivers ‌in the control group after ‌conducting the study.

**Results**

Results of the present study showed that most of the caregivers in the control group (61.8%) and intervention group (80%) were patients' spouses. The mean age of caregivers was 38.94±11.32 years in the control group and 39.74±11.34 years in the intervention group. Most caregivers in the control (%88.2) and intervention (%91.4) groups were married. The mean duration of care given for patients in the control and intervention group was 4.86±3.61 and 7.94±5.31 years respectively.

No statistically significant difference was between two groups in terms of distribution of the variables of age, gender, level of education, marital status, income, current job, type of family relationship with patient, insurance status, housing status, chronic disease of caregiver, membership in the MS association, number of caregivers, duration of care given for patient and the number of people with chronic disease in the family and the grade of disease (P>0.05). Some demographic characteristics of the subjects are described in Table 2.

The difference between the means of quality of life in the control and intervention groups before the intervention was not statistically significant (P>0.05). Total score of quality of life in the intervention group before the intervention was 52.31±8.47 which increased to 61.10±12.81 three months after the intervention, which was statistically significant (P<0.05). This increase was significant in all aspects of quality of life in the intervention group. The score of quality of life in the dimension of role disorder due to physical health in the intervention group before the intervention was 58.03±23.7 and it was 69.39± 29.9 after the intervention. This increase was statistically significant (P<0.05).

The score of quality of life in the physical function dimension in the intervention group before the intervention was 64.5±25.6 and after the intervention, it was 82.5±24.9, which this increase was statistically significant (P<0.05). The mean and standard deviation of quality of life in the dimension of role disorder due to emotional health in the intervention group was 64.8±25.8 before the intervention and 79±35.1 after the intervention, which this increase was a statistically significant increase (P<0.05).

The score of quality of life in energy / fatigue dimension in the intervention group was 49.6±13.9 before the intervention and 63.3±20.1 after the intervention, which this increase was statistically significant (P<0.05). Paired t-test also showed a statistically significant difference (P <0.05). The mean and standard deviation of quality of life in the emotional well-being dimension in the intervention group was 48.2±11.4 before the intervention and 57.8±13.7 after the intervention, which this increase was statistically significant (P<0.05). In the social function dimension, the mean and standard deviation in the intervention group was 38.00±14.6 before the intervention and 47.1±10.6 after the intervention, which the paired t-test showed this increase significant (P<0.05).

In the general health dimension, the mean and standard deviation in the intervention group was 56.14±6.8 before the intervention and 66.2±14.5 after the intervention was, which this increase was statistically significant (P<0.05). In the pain dimension, the mean and standard deviation of pain in the intervention group was 22.9±9.9 before the intervention and 31.4±10.2 after the intervention, which was statistically significant (Table 3).

**Discussion and Conclusion**

This study showed that self-care education based on the Orem’s self-care model can improve quality of life of caregivers in patients with MS. Researchers suggest that increasing social support for caregivers can reduce the suffering of the caregiver and thus improve the mental health aspects of the caregiver's quality of life (8). In a study conducted by Rivera-Navarro et al. aimed to analyze the problems of caregivers of MS patients with an emphasis on perceived suffering, the results showed that patients' health-related quality of life was related to caregivers' suffering (15). Thus, it can be stated that self-care education based on the Orem’s self-care model can also improve the quality of life of caregivers by reducing their suffering.

Jahan Bakhshian carried out a study that showed the participation of caregivers in educational-supportive programs can be effective in reducing emotional stress, increasing self-confidence, the tendency to solve the problem and its reflection in healthy mutual communication, and reducing the level of patients' mental disorders (11). McMillan et al. conducted a showed that a maximum of three educational sessions can improve the quality of life of caregivers and reduce the suffering of families (16). Alshubaili et.al found that more special attention must be paid to caregivers who are vulnerable, less educated, unemployed, and afraid of contracting the disease and their patients suffer from longer period of disease (17). This is the issue of training caregivers.

In the study of Polin et al, while examining the burden and psychological injuries of spouses who take care of chronic patients, state that these people suffer a lot of pressure in the process of taking care of patients. These pressures can cause a decrease in their quality of life as well as a decrease in the quality of care provided (18). According to Brandon's study, nurses can help caregivers take control. People are living longer because of improved medical care, and the number of people living with a chronic illness or disability who depend on family and friends to care for them is increasing. Nurses can empower these caregivers to take control of their condition by providing education, resources, support, and interventions (19).

Nurses are in a unique position to help caregivers share their feelings, foster realistic perceptions, promote adaptation to the changing illness, and reduce burden. Evaluating caregiver burden helps nurses to better understand the needs and capacities of the family, enables family members to stay longer in their caring role and guarantee the desired results for the patient. Therefore, it can be said that in this study, the empowerment of the member caring for a patient with MS can play an important role in the quality of care provided to patients by reducing the level of burden of the caregivers (10).

Orem's self-care model could enhance the quality of life in caregivers of MS patients. No study was found on the implementation of the Orem’s self-care model in people caring for MS patients. The studies conducted in this regard mainly included a wide range of patients needed for home care. In a study on the life satisfaction predictors among caregivers of MS patients, Waldron-Perrine et al. found that caregivers' social support increases life satisfaction of caregiver. They concluded that lower levels of social support might be associated with lower levels of help and assistance along with the suffering of care (20).

The results of this study indicate that self-care activities by MS patients and their caregivers are quite possible and with education and implementation of self-care program according to Orem’s self-care model, a significant difference is created in their quality of life, so that the implementation of self-care program is associated with increasing the quality of life of caregivers of patients. If the implementation of the self-care program continues based on patients' self-care needs and is designed in accordance with their level of understanding, it can lead to positive results in health performance. Accordingly, the use of models that can persuade caregivers and pay attention to patients' participation in self-care can enhance the quality of life. Also, the use of this model provides valuable information and can be applied in examining, identifying, and evaluating in the care system of MS patients.

Since the sampling and intervention were done during the Covid-19 outbreak, subjects did not cooperate adequately due to fear of being infected with Covid-19, and it was more difficult to communicate with them. Despite the researcher's efforts to control the sampling conditions and collect data in appropriate conditions, mind occupations and the usual weakness and discomfort with these patients and caregivers might have been effective in responding to the questionnaire questions that researcher was unable to control them. Caregivers normally acquire some skills during these educations in the long process of caring for these patients, which might influence the results of this study. Also, the care of these patients is usually done in the family and is not limited to a specific person, so only the most effective individual was examined in the present study, while caring for the patient is not an individual matter and is influenced by other family members. The large number of questions in the questionnaire might also result in boredom in completing the questionnaire, which was beyond the control of the researcher due to the standard nature of the questionnaire.

**Acknowledgments**

This study conducted as a thesis for Master's degree in medical surgical nursing with the code 990588 and with the financial support of Hormozgan University of Medical Sciences. The authors appreciated all colleagues and professors, as well as patients and caregivers of these patients who sincerely participated in this study.

**Author's Contributions**

 N.D: Initial design of the article, data collection and analysis, initial and final editing and writing of the manuscript

E.I: Initial design of the study, initial and final writing and editing of the manuscript

A.A.N: Initial design and final editing of the manuscript

S.H.T: data analysis, final editing of the manuscript

**Funding sources:** This project was financially supported by Research and Technology Deputy of Hormozgan University of Medical Sciences

**Ethical considerations:** The protocol of this study was approved by the Ethics Committee of Hormozgan University of Medical Sciences under the reference code of IR.HUMS.REC.1399.518.

**Conflict of interest**: The authors of this study declared no conflict of interest for writing or publishing this article.

**Diagram 1. The consort diagram for levels of the study**

Consent to participate in the study

received only the routine interventions

Individualized and face to face training

Gathering data 3 months after the end of the intervention

Data analysis

Data analysis

Gathering initial data

control group: 38

participants: 76

intervention group: 38

Consent to participate in the study

Gathering initial data

Gathering data 3 months after the end of the intervention

control group: 34

intervention group: 35

**Table 1. Contents taught caregivers in educational sessions**

|  |  |
| --- | --- |
| Content | Sessions |
| Definition of multiple sclerosis, symptoms and complications of the disease, self-care behaviors and maintaining health in controlling complications  | 1 |
| fatigue (training of exercise program, prioritization of tasks, teaching energy conservation methods and environmental design)  | 2 |
| urinary incontinence (such as bladder training, use of incontinence absorption pads, pelvic floor muscle exercises, habitual training of defecation time, and the Valsalva maneuver method)  | 3 |
| defecation incontinence (regulating defecation time, diet training, training to regulate fluid intake), constipation (training for exercise and mobility planning, regulation of defecation time, training of pelvic floor muscle massage and diet training)  | 4 |
| training and familiarity with the movement problems created and reducing its complications (patient transfer and movement, prevention of blood accumulation in the arteries of the lower limbs, exercises for range of motion of the joints, prevention of deformity of the limbs and placement in a proper position), familiarity with equipment and assistive devices to prevent bed sores (improving skin blood flow, improving nutritional status, reducing friction and tensile force and minimizing bed and seat moisture)  | 5 |
| visual disturbances (training the way of using the colors), muscle weakness, muscle cramps and imbalance (relaxation and coordination exercises, training the way of using assistive devices)  | 6 |
| familiarity with the psychological problems after the lesion in MS patients, financial and social resource management (using insurance services and support institutions)  | 7 |

**Table 2- Demographic characteristics of the participants in the control and intervention groups**

|  |  |  |
| --- | --- | --- |
| P value | Group | Variable |
| Control | Intervention |
| N (%) | N (%) | Levels | Gender |
| 0.267 | 20 (%58.8) | 16 (%45.7) | Female |
| 14 (%41.2) | 19 (%54.3) | Male |
| 0.179 | 3 (%8.8) | 0 (%0.0) | Illiterate | Level of education |
| 9 (%26.5) | 11 (%31.4) | High school |
| 14 (%41.2) | 19 (%53.3) | Diploma |
| 8 (%23.5) | 4 (%11.4) | Bachelor's degree |
| 0 (%0.0) | 1 (%2.9) | higher |
| 0.660 | 30 (%88.2) | 32 (%91.4) | Married | Marital status |
| 4 (%11.8) | 3 (%8.6) | Single |
| 0.537 | 11 (%32.4) | 13 (%37.1) | Less than adequate | Income level |
| 23 (%67.6) | 21 (%60.0) | Adequate |
| 0 (%0.0) | 1 (%2.9) | More than adequate |
| 0.371 | 15 (%44.1) | 14 (%40.0) | Housewife | Current job |
| 18 (%52.9) | 16 (%45.7) | Employee |
| 0 (%0.0) | 2 (%5.7) | Unemployed |
| 1 (%2.9) | 3 (%8.6) | Retired |
| 0.535 | 21 (%61.8) | 28 (%80.0) | Spouse | Type of family relationship with patient |
| 7 (%20.6) | 4 (%11.4) | Parents |
| 3 (%8.8) | 1 (%2.9) | Children |
| 2 (%5.9) | 1 (%2.9) | Sister |
| 1 (%2.9) | 1 (%2.9) | Brother |
| 0.307 | 33 (%97.1) | 35 (%100.0) | Insured | Insurance status |
| 1 (%2.9) | 0 (%0.0) | Non-insured |
| 0.906 | 17 (%50.0) | 18 (%51.4) | Personal | Housing status |
| 17 (%50.0) | 17 (%48.6) | Rental |
| 0.186 | 17 (%50.0) | 23 (%65.7) | Yes | Membership in MS association |
| 17 (%50.0) | 12 (%34.3) | No |
| 0.851 |  38.941±11.3269 |  39.745±11.3458 | Age (Mean± SD) |
| 0.052 |  4.868±3.6162 |  7.943±5.3134 | duration of care given for patient (Mean± SD) |
| 0.080 |  1.655±0.6548 |  1.850±0.7844 | Disease grade (Mean± SD) |

**Table 3: The mean score of quality of life dimensions before and 3 months after the intervention in control and intervention groups**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Paired t test results | after  | Before  | Group | Dimensions of quality of life |
| Mean± SD | Mean± SD |
| <0.00010.565 | 82.57±24.9470.38±22.01 | 64.57±25.6672.91±18.86 | InterventionControl | Physical function |
| 0.0140.362 | 69.39±29.9167.08±28.26 | 58.03±23.7484.25±118.73 | InterventionControl | Role disorder due to physical health |
| 0.0030.855 | 79.69±35.1364.16±29.36 | 64.84±25.8765.13±29.38 | InterventionControl | Role disorder due to emotional health |
| <0.00010.600 | 63.33±20.1855.83±17.09 | 49.69±13.9753.75±17.90 | InterventionControl | Energy / Fatigue |
| 0.0040.337 | 57.81±13.7152.44±15.38 | 48.24±11.4849.77±16.60 | InterventionControl | Emotional well-being |
| <0.00010.906 | 47.12±10.6841.38±13.76 | 38.00±14.6941.66±10.95 | InterventionControl | Social function |
| 0.0040.127 | 66.21±14.5263.61±14.07 | 56.66±14.8262.22±12.33 | InterventionControl | general health |
| 0.0020.280 | 31.42±10.2724.79±08.77 | 22.93±09.9029.65±09.16 | InterventionControl | Pain |
| 0.0020.529 | 61.10±12.8155.23±10.20 | 52.31±08.4757.04±14.01 | InterventionControl | Total quality of life score |

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