

Effect of Orem-based self-care education program on disease-related problems in patients with multiple sclerosis: A clinical trial

Hanieh Dahmardeh¹, Toktam Kianian¹, Seyyed Abolfazl Vagharseyyedin²

1. Instructor, Department of Nursing, Community Nursing Research Center, School of Nursing and Midwifery, Zahedan University of Medical Sciences, Zahedan, Iran

2. Assistant Professor, Department of Nursing, School of Nursing and Midwifery, Birjand University of Medical Sciences, Birjand, Iran

*Correspondence: Toktam Kianian, Community Nursing Research Center, Zahedan University of Medical Sciences, Zahedan, Iran.
Email: t.kianian67@gmail.com

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ABSTRACT

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Background: Globally, multiple sclerosis (MS) is one of the leading causes of disability and is associated with a wide range of complications. Therefore, identifying patient needs and providing education based on an appropriate nursing model seems crucial. In this study, we aimed to evaluate the effect of Orem-based self-care education program on MS complications.

Methods: This clinical trial was conducted on 88 MS patients, who were members of MS Association of Zahedan, Iran, during 2014-15. The subjects were randomly selected through convenience sampling method and divided into intervention and control groups (n=44). In total, nine 45-minute group training sessions were held for the intervention group based on the patient needs and Orem's model. Before and three months after the intervention, the form of assessment of disease complications was completed by both groups. Data analysis was performed in SPSS, version 16, using Chi-squared test, as well as paired and independent t-tests.

Results: After the intervention, all the reported complications, including balance disorder, muscle cramp, fatigue, urinary incontinence, constipation, fecal incontinence, myasthenia, reduced memory, and double vision, significantly improved (P<0.001), except for blurred vision.

Conclusion: Implementing self-care programs based on Orem's model ameliorated disease complications in MS patients. Thus, we recommend healthcare organizations use this self-care program as an easy and beneficial intervention.

1. Introduction

Multiple sclerosis (MS) is a chronic progressive disease of the central neural system, associated with a wide range of complications and disabling symptoms, which decrease the individual and social performance of patients.¹

The prevalence rate of MS was reported to be 2.5 million individuals worldwide.^{2,4} Up until 2011, 41.81 out of 100 individuals suffered from this disease in Iran.⁵ Given the wide range of complications associated with MS, early diagnosis of this disease seems to be critical.^{1,6}

In previous evaluations performed in Sistan and Baluchestan Province, the prevalence of MS was 13.96 cases per 100,000 of the population.⁷ However, these statistics require accurate evaluations and providing proper solutions to enhance the quality of life among patients with MS essentially because MS has been identified as the

third cause of disability within the age range of 20-40 years, which is the most active and productive period of human life.^{8,9}

Early onset of MS and high levels of disability impose financial burdens and adverse effects to patients, their family members, healthcare systems, and societies.³ The primary symptoms of this disease include visual disturbance, pain, urinary incontinence, and weakness,¹⁰ which have a significant impact on the independence and ability of individuals for active cooperation in the family and society and all aspects of their daily lives.¹¹ Therefore, self-care education is of paramount importance for these patients and plays an important role in the prevention of hospital readmission and enhancement of self-confidence.¹

Self-care model

Orem's self-care model is the foundation of clinical work in nursing care, which is a suitable

clinical guide for designing and implementing self-care programs. This model is applied as a conceptual framework to guide self-care programs.⁸ In this model, patients are not considered as passive individuals, who are only the receivers of healthcare services, but rather, they are deemed as strong with high accountability and ability to perform healthcare-related tasks.¹² Accordingly, the proposed program for a patient must be based on the self-care needs of that patient and his/her abilities.

Orem's self-care model has been employed in various studies conducted on MS patients, and its effect was approved on improved physical and mental aspects of quality of life and decreased fatigue.^{8, 11, 13, 14} Madani et al. (2008) ascribed that self-care programs could diminish a number of MS complications. However, no indication was made to Orem-based self-care education program in the mentioned study. Given the fact that in Orem's model human is recognized as active and powerful, education of this important issue only through direct education by the researcher is not sufficient. In fact, active participation of patients and obtaining their opinions is crucial for providing an accurate self-care program to empower patients and boost their strength.¹⁵

On the other hand, Edmonds et al. (2010) regarded non-use of group techniques and professional teams as one of the most common drawbacks of healthcare systems in provision of education for patients with MS. They also emphasized on the necessity of patient-healthcare provider communication to provide supportive care.¹⁶ Furthermore, Plow et al. (2011) marked that while there are various interventions for improvement of disease self-management among MS patients, there is still a need for the use of systematic methods with a specific combination.¹⁷

Given the importance of self-care education based on nursing theories and models,¹⁸ and with regards to the various needs of patients in different societies and the growing trend of MS in Sistan and Baluchestan⁶, this study aimed to determine the effect of Orem-based self-care education program on disease-related problems in patients with MS.

2. Methods

2.1. Design

This clinical trial was conducted on MS patients referring to the MS Association of Zahedan, Iran, during 2014-15.

2.2. Participants and settings

The sample size was estimated at 38 according to the study by Aghabagheri et al.¹⁹. However, the total sample size was calculated at 44 with regards to 15% possibility of sample attrition. In addition, sample size was calculated according to the sample size formula for estimating the difference in means between two independent populations as follows:

$$n = \frac{(z_{1-\frac{\alpha}{2}} + z_{1-\beta})^2 (s_1^2 + s_2^2)}{d^2} = \frac{(1.96 + 1.28)^2 (2.91^2 + 3.02^2)}{2.2^2} = 38$$

In total, 88 individuals were recruited through convenience sampling method and randomly divided into intervention and control groups. To this end, 88 numbers were prepared according to random number table and with respect to the number of samples. After referring the eligible patients to the association, they were assigned a number according to the order of their referral. According to this randomized allocation of numbers, the patients were assigned to the intervention and control groups.

The inclusion criteria were age range of 20-50 years, literacy, wheelchair independence, lack of acute stage of the disease, and lack of diagnosis of other chronic or acute physical or mental disorders, such as severe depression or speech or auditory impairment, confirmed according to medical records and examinations.

The exclusion criteria were the incidence of serious physical-mental complications and disorders during the intervention, lack of participation in more than one educational session, lack of regular implementation of the educational program at home, or lack of daily completion of the record sheet of the Orem-based self-care program.

2.3. Instruments

The data collection tools included a demographic characteristics form, needs assessment form, and record sheet of the self-care training program. The demographic characteristics form contained items on age, gender, educational level, marital status, and disease duration, which was completed by all the participants before the intervention.

The needs assessment form included a list of common complications among MS patients, gathered by evaluation of various studies^{8, 20, 21} and based on the opinions of professors of Birjand University of Medical Sciences, in order to be used to detect the problems patients commonly face and take the necessary measures. These complications include double vision, blurred vision, balance disorder, muscle cramp, fatigue, constipation,

urinary and fecal incontinence, myasthenia, and reduced memory. Patients were required to determine the severity of their problems using four alternatives (1=always, 2=frequently, 3=rarely, 4=never). In this scale, higher scores were indicative of fewer problems.

Content validity of the needs assessment form was approved by using the opinions of 10 faculty members of School of Nursing and Midwifery, Birjand University of Medical Sciences. Its reliability was confirmed using test-retest method through providing the scale for 10 patients before the study and completing the form by the same individuals after a 10-day interval. Reliability of the needs assessment form was estimated at 0.89. The record sheet of the Orem-based self-care program was designed according to the educational program aligned to the needs stated by the patients in the pretest.

Record sheet of the self-care training program. This sheet contained the actions necessary to eliminate the needs and problems of the patients, such as bowel disorder (bowel retraining, high-fiber diet and plenty of fluids, laxatives and suppositories, abdominal massage, activity and physical exercise), urinary disorders (bladder retraining, training habitual urination, pelvic floor muscle exercises, intermittent catheterization, and energy retention), visual impairments (sorting the objects in one second, use of blindfolds, accessibility of objects, more use of other senses, analysis of tasks), memory impairments (use of notepads, repetition of content, logical categorization of content, content summarization, and coding the information), active and resistance training, coordination and balance exercises, and exercises to reduce muscle cramps, in front of all of which was days of the week, so that patients could record the actions performed in their specific days.

2.4. Data Collection

In order to control the effect of communication between the participants of the control and intervention groups, a pretest was performed on the control group, which only received the routine training of the association. A posttest was conducted three months after the intervention, followed by requiring the subjects of the intervention group to complete a needs assessment form after providing general information about the study and its goals. In addition, the subjects were divided into two groups of 19 and 20 due to the large number of patients and to enhance the quality of the educational program. The educational program was carried out on separate days for the two intervention groups. The educational program was held one week later to

evaluate the patient needs and design an educational program according to their requirements.

In this study, the independent variable was Orem-based self-care education program. The self-care program was in the form of the conceptual Orem's model designed according to the educational needs of the subjects, which were determined by filling out the needs assessment form. We strived to keep patients active during the educational course, the content of which was confirmed by 10 faculty members, including two neurologists, of Birjand University of Medical Sciences.

The educational content was provided according to Table 1. In total, nine 45-90-minute sessions were held for the intervention group by the researcher and under the supervision of a neurologist for three weeks at the location of the association.⁸

The program was based on discussions, questions and answers, reflecting on the experiences of the patients, as well as rectifying wrong behaviors and substituting them with correct ones. In the first session, the order of content presentation was explained to the patients, and they were asked to prepare their questions prior to each session.

In addition to presenting the content by the researcher through lectures, visual aids, and performing exercises in each session, patients directly asked their questions from the neurologist, who was present in the classes. Meanwhile, the patients were asked to share their experiences about the methods used to deal with their problems, followed by other patients expressing their opinions in this regard. Further, the present physician proposed his scientific opinions and confirmed, rejected, or corrected the opinions of the patients.

In terms of physical exercises, the patients were required to perform the exercises with the researcher in order to reduce fatigue. During this time, any wrong movement was corrected by the neurologist and researcher. At the end of each session, the patients were asked to briefly review the educational contents of that session or voluntarily perform some of the exercises.

In the final session (ninth session) and after complementary explanations, the record sheet for the self-care program was provided for the patients, and the method to complete the form was explained to the subjects in detail. After ensuring accurate implementation of the program and its recording on the sheet, the patients were followed up for three months and had the support of the researcher.

During this time, in addition to phone calls by the researcher, Thursdays were allocated to patient

visits to resolve their problems. At the end of the three months, the patients were called to visit the

association in order to complete the problem determining form one more time (Diagram 1).

Table 1. Educational content of the designed sessions

Sessions	Educational content
First	Introduction, explanation of the nature, goals, and time of the study
Second	Explanation about the disease and its causes, symptoms, treatment methods, diagnostic methods, and problems of multiple sclerosis (MS)
Third	Self-care skills to treat impaired physical activity and muscle weakness
Fourth	Self-care skills related to fatigue
Fifth	Causes of muscle cramps and treatment methods and self-care skills for impaired physical mobility
Sixth	Self-care program for urinary and fecal incontinence
Seventh	Self-care skills for impairments in physical and perceptual functions
Eighth	Self-care skills for mental disorders
Ninth	Review of contents of the previous sessions and answering the questions of the participants

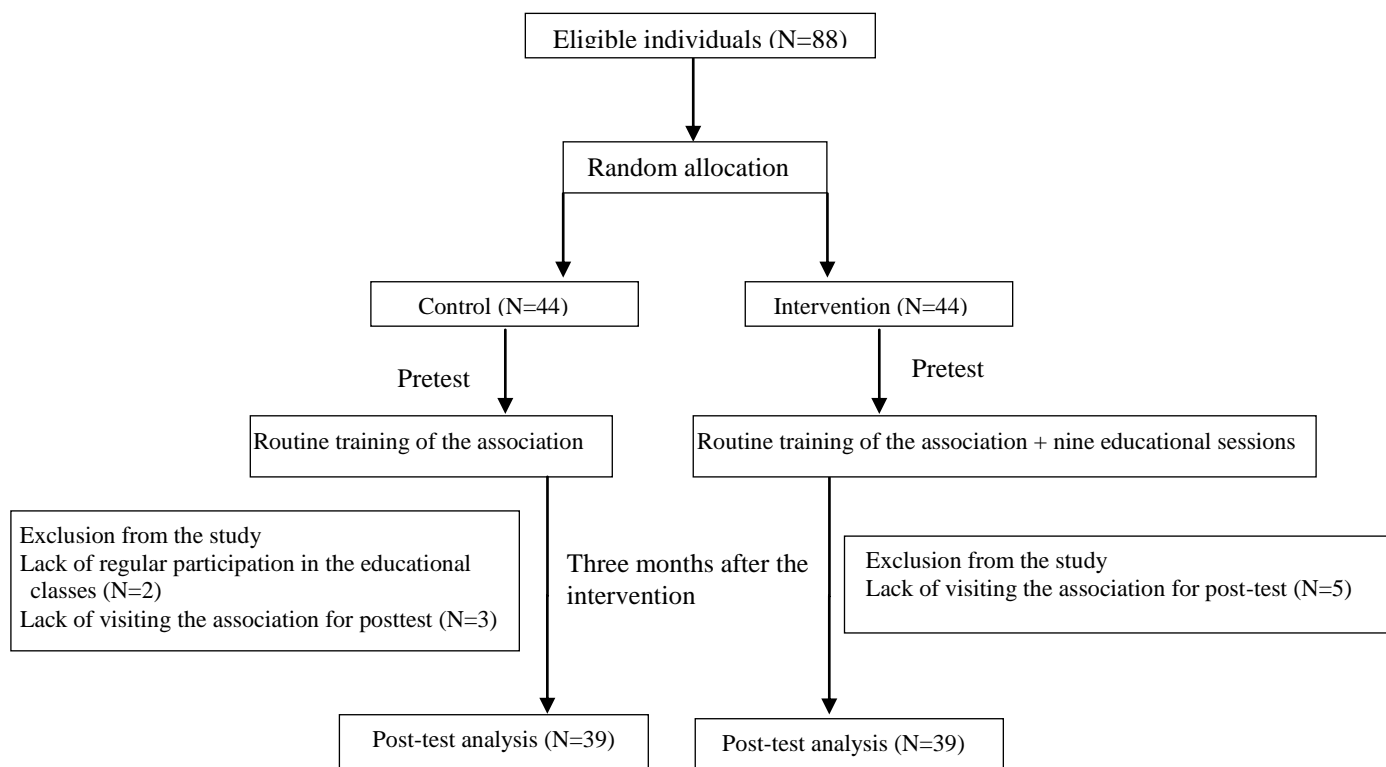


Diagram 1. Research stages

2.5. Ethical considerations

To observe the ethical principles, the study objectives were explained to the patients individually, and it was marked that their participation in the study was voluntary and had no effect on their treatment process. Moreover, written informed consents were obtained prior to initiating the study, and educational pamphlets were provided

for the subjects of the control group at the end of the educational program.

2.6. Statistical analysis

Data analysis was performed in SPSS, version 16 using, Kolmogorov-Smirnov (to evaluate the normal distribution of the variables), Chi-square test (for evaluation of the difference between the study groups in terms of gender, educational level, and

marital status), independent t-test (to assess the difference between the two groups regarding age and disease duration), and paired t-test (for comparison of problems caused by MS in the study groups before and after the intervention). In addition, P-value less than 0.05 was considered statistically significant.

3. Results

Out of the 88 subjects, 78 were able to complete the study protocol. Five subjects were excluded from the intervention group due to lack of regular participation in the educational sessions and lack of visiting the association after the test, and five participants of the control group were excluded from the study due to lack of visiting the association for the posttest. It should be mentioned that three participants, who were unwilling to cooperate with

the study due to the long interval between sampling and beginning of the intervention, were replaced with other subjects.

Information related to demographic characteristics of the subjects is shown in Table 2, according to which no statistically significant difference was observed in the demographic and disease-related characteristics of the participants between the control and intervention groups.

After the intervention, disease complications, such as balance disorder, muscle cramps, urinary incontinence, constipation, fecal incontinence, myasthenia, reduced memory, and double vision, significantly improved ($P < 0.001$). According to this table, while the mean score of double vision increased after the intervention, this increase was not significant (Table 3).

Table 2. Demographic characteristics of the participants

Variable	Group	Intervention	Control	P
		N(%)	N(%)	
Gender	Male	8(20.5)	13(33.3)	0.2*
	Female	31(79.5)	26(66.7)	
Educational level	Elementary	5(12.9)	7(17.9)	0.56*
	Secondary	13(33.3)	9(23.1)	
	Higher education	21(53.8)	23(59.0)	
Marital status	Single	9(23.1)	8(20.5)	0.78*
	Married	30(76.9)	31(79.5)	
Mean age (year)	M±SD	34.1±8.2	35.6±8.4	0.43**
Disease duration (year)	M±SD	5.72±4.92	4.81±3.58	0.35**

*Chi-squared; **Independent t-test

Table 3. Comparison of the problems caused by diabetes in the study groups before and after the intervention

Problems	Group	Pre-intervention	Post-intervention	P*
Blurred vision	Intervention	3.05±1.23	3.28±1.09	0.06
	Control	3.48±0.60	2.87±1.21	0.12
Myasthenia	Intervention	1.66±0.89	1.74±0.90	<0.001
	Control	3.28±0.64	1.84±0.96	0.63
Muscle cramp	Intervention	1.48±0.82	1.82±0.94	<0.001
	Control	3.28±0.68	1.79±0.97	0.90
Fatigue	Intervention	1.05±0.22	1.12±0.33	<0.001
	Control	2.94±0.75	1.38±0.74	0.05
Urinary incontinence	Intervention	2.74±0.81	2.86±0.74	<0.001
	Control	3.76±0.48	2.74±0.78	0.88
Constipation	Intervention	2.71±0.91	2.79±0.86	<0.001
	Control	3.82±0.38	2.94±0.79	0.23
Fecal incontinence	Intervention	3.33±0.62	3.43±0.59	<0.001
	Control	3.89±0.30	3.23±0.70	0.49
Muscle weakness	Intervention	1.41±0.90	1.74±1.09	<0.001
	Control	3.46±0.68	1.64±0.01	0.66
Memory loss	Intervention	2.0±1.02	3.28±0.60	<0.001
	Control	3.28±0.60	2.25±1.01	0.27
Double vision	Intervention	2.53±1.21	2.64±1.15	<0.001
	Control	3.53±0.64	2.66±1.08	0.92

*Paired t-test

4. Discussion

According to the results of the present study, Orem-based self-care training program could ameliorate the disease complications, such as myasthenia, muscle cramp, fatigue, renal incontinence, constipation, fecal incontinence, muscle weakness, memory loss, and double vision.

Madani *et al.* (2008) reported that implementation of a self-care program for MS patients for one month significantly decreased some complications, including muscle cramp, fatigue, constipation, and forgetfulness.⁹ The significant changes in only four disease complications in the mentioned study might be due to differences in the study populations and demographics of the subjects, type of intervention, and duration of follow-ups. In the current study, we attempted to hold patient-oriented sessions, so that they were able to obtain information from experiences of each other in the presence of a physician and an informed individual (the researcher). After the intervention, the patients were followed up for three months.

Consistent with our study, Afrasiabifar *et al.* (2016) performed Orem-based self-care education and follow-up of patients for one month, indicating that the program caused a reduction in fatigue.²² Moreover, Masoudi *et al.* (2008) introduced the Orem-based self-care program, which is based on the educational needs of patients, as a valuable nursing intervention to improve fatigue in patients.²³ Some studies also highlighted the positive effect of Orem-based self-care program on physical and mental aspects of quality of life among MS patients.^{8,11}

Moreover, Beer *et al.* (2012) underscored the necessity of alignment of goals and therapeutic methods to individual needs in a review study, and regarded them as important factors in the improvement of disability, increased participation, and enhancement of quality of life among patients with MS.²⁴ These results were in congruence with our findings since the quality of life is an internal and general concept, which can be affected by the disease-related problems.

Altay *et al.* (2013) also reported that Orem-based self-care education played a significant role in adjustment of patients with their current situation, which led to their independence.²⁵ The results of the mentioned study confirmed our findings regarding the importance and status of Orem-based self-care program in the improvement of complication caused by MS.

One of the major limitations of the present study was individual differences of the patients and completing the record sheet of the program at home by the participants, which might have been affected by various factors. However, these factors were attempted to be controlled through regular follow up of the patients, weekly visits at the association, and phone calls. On the other hand, the researcher was not able to invite a control group from another center due to lack of access to MS patients. Therefore, sampling was first carried out for the control group in order to prevent communication between the control and intervention groups.

5. Conclusion

According to the results of the current study, implementation of the Orem-based self-care program diminished MS complications. Accordingly, it seems necessary to design educational programs for these patients based on their educational needs and patient training principles and using Orem's model, so that it could be used as a nursing intervention to improve disease complications and promote health in MS patients.

Conflicts of interest

The authors declare no conflicts of interest.

Authors' contributions

Hanieh Dehmardeh: study design, data collection, participation in the compilation of the article, Toktam, Kianian: participation in data analysis, research compilation, Seyyed Abolfazl Vagharseyyedin: study design, data analysis, participation in research compilation.

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