Effect of self-management program on treatment adherence in patients with multiple sclerosis

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A R T I C L E   I N F O

ABSTRACT

Background: Multiple sclerosis (MS) is one of the chronic diseases of the central nervous system, management and treatment of which are hinged upon proper treatment adherence. In this study, we sought to determine the effect of self-management program on treatment adherence in patients with MS.

Methods: In this clinical trial study was conducted on 78 patients with MS referred to MS Association of Zahedan, Iran, in 2016. The participants were selected through convenience sampling and randomly divided into two groups of intervention and control. The educational program was implemented for the intervention group in the form of five 90-minute in-person sessions based on problem solving. Treatment adherence of patients was measured before and two months after the last educational session using Multiple Sclerosis Treatment Adherence Questionnaire (MS-TAQ). Data analysis was performed in SPSS, version 16, using Chi-square test, as well as paired and independent t-tests.

Results: After the intervention, mean score of treatment adherence deteriorated in dimensions of barriers to treatment adherence (P=0.004) and disease side effects (P<0.0001), compared to pre-intervention, while this score increased in the dimension of Coping strategies (P<0.0001). The difference between the groups was significant in all the three dimensions (P<0.0001).

Conclusion: Self-management program reduced side effects and barriers to treatment adherence, while enhancing Coping and treatment adherence in patients with MS. Therefore, applying this method as a nursing intervention is recommended to promote patient health.

1. Introduction

Multiple sclerosis (MS) is the second most common disorder among the youth, which is characterized by progressive degeneration of the myelin of the nervous system.[1, 2] According to the reports, approximately 2.5 million individuals have been diagnosed with MS worldwide.[3] According to the reports published in the 10th International Congress on MS, 63,000 individuals are suffering from MS in Iran.[4]

This disease produces a wide range of symptoms including fatigue, pain, cognitive impairment, sensory-motor impairment, intestinal and bladder problems, as well as ataxia and muscle cramp.[5, 6] Given the unknown etiology of MS, there is no definitive cure for this disease. Therefore, the treatment objective for this disease is Coping of the immune system with betaferons and control of symptoms and non-pharmacological interventions.[7,8] While these treatments can control disease symptoms and progression to some extent, patients are often faced with difficulties in treatment adherence due to the long-term nature of treatments.[9] This lack of treatment adherence is mainly due to long-term treatment, repeated injections, fear of side effects , frustration, and lack of motivation and awareness.[10]

Adherence is defined as the degree to which individuals act on the health and treatment recommendations.[11] According to the world health organization (WHO), it has been estimated that mean treatment adherence is below 50% in patients with chronic diseases.[12]

Evidence suggests a high level of nonadherence in patients with MS.[13] In a study by Treadaway et al. (2009), treatment nonadherence was indicated in 37% of MS patients.[14] Therefore, use of practical and cost-effective alternative methods seems crucial to control chronic diseases.[15] In this regard, one of these programs is self-care program, which encourages active participation of patients with chronic diseases in controlling factors affecting their disease course and symptoms and making decisions to manage the disease and its side effects .[16-18] In general, this program is comprised of five main skills: 1) problem-solving, 2) decision-making, 3) resource utilization, 4) formation of a patient-provider partnership, and 5) action planning.[19]

Given the nature of MS and its long-term problems, having access to simple services and programs, which can be implemented by patients, is of paramount importance.[20]

Self-management refers to the ability of individuals in managing physical and mental side effects and living with a chronic disease.[21] According to the literature, self-management program exerts a positive effect on treatment adherence, through improved behavioral adaptability, and various health dimensions of patients with different diseases.[22-25] In addition, Pourverdi et al. (2015) marked the positive effect of self-management on blood glucose and glycosylated hemoglobin management in diabetic patients.[26] In another study by Baljani et al. (2013), the beneficial impact of self-management on treatment adherence and weight loss between two dialysis sessions was confirmed.[27]

Baljani et al. (2012) ascribed that self-management program improved treatment adherence in patients with cardiovascular diseases.[22] Moreover, Kaf'ami et al. (2009) reported that self-management program mitigated various health dimensions in patients with MS.[23] Results obtained by Inouye et al. (2001) were also indicative of the positive effect of self-management program on enhanced behavioral adaptability of patients with AIDS.[24] In a study by Chapman et al. (2014), self-management intervention caused a short-term improvement in treatment adherence of patients.[25] However, contradictory results were obtained, as well. In a study by Forjuoh et al. (2014), self-management program did not decrease HbA1c in patients with diabetes,[28] which could be indicative of failure in treatment adherence. In addition, Pouryusef (2012) pointed out that while motivational interviewing had significant impact on decreased barriers to treatment adherence in patients with MS, this positive impact was not observed in other subscales of treatment adherence

questionnaire (i.e., side effects and Coping strategies).[29]

MS can affect daily activities of patients and undermine the performance efficiency of individuals. This chronic disease requires long-term treatment, which indicates that treatment adherence of cardinal importance in MS patients. Given that studies undertaken on this disease have yielded conflicting results,[28, 29] in this study, we attempted to determine the effect of self-management program on treatment adherence in patients with MS.

2. Methods

2.1. Design

In this clinical trial study was conducted on MS patients referred to MS Association in Zahedan, Iran, 2016.

2.2. Participants and settings

Sample size was estimated at 37 for each group according to the results obtained by Pourseyf[29] with confidence interval of 95% and test power of 90% and using the following formula:

$\overline{X}_1 = 7.48$, $Z_{1-\beta} = 1.28$, $S_1 = 8.1$, $\overline{X}_2 = 15.36$, $S_2 = 12.54$, $Z_{1-\alpha} = 1.96$.

$$\frac{(Z_{1-\frac{\alpha}{2}} + Z_{1-\beta})^2 (S_1^2 + S_2^2)}{(\overline{X}_1 - \overline{X}_2)^2}$$

However, considering the possibility of sample attrition, a total of 80 participants (40 cases in each group) were entered in the study. The inclusion criteria were age>18 years, literacy, lack of communication problems (e.g., blindness and deafness), ability to make phone calls, lack of mental diseases, and not being in the active phase of the disease. All the mentioned information was obtained by interviewing the patients and using their medical records. The exclusion criteria consisted of relapse of the acute phase of the disease and lack of participation in more than one self-management class during the intervention process.

2.3. Instruments

The data collection tools included a demographic characteristics form (including items on age, educational level, marital status, occupational status, age, duration of the disease, and interval between two doctor visits) and the Multiple Sclerosis Treatment Adherence Questionnaire (MS-TAQ).

MS-TAQ was designed by Wicks et al. (2011), and its reliability and validity were confirmed.[30] This tool is comprised of three dimensions, including barriers to treatment adherence, side effects , and Coping strategies.

Barriers to treatment adherence dimension comprised of 13 items on the most important barriers to treatment adherence of patients, who forgot at least one dose during 4 weeks. This dimension is rated based on a 4-point Likert-scale (not important=0 to extremely important =3). For this dimension, the possible scores range between 0 and 39.

On the other hand, the side effects dimension contains 10 items evaluating reoccurrence of the side effects caused by treatment. This dimension is scored based on 5-point Likert scale (never=0 to always=4), with the possible scores ranging between 0 and 40.

In two dimensions of treatment adherence and side effects, lower scores are indicative of improved adherence. In the Coping strategies component, measures taken by patients during 4 weeks to reduce treatment side effects were evaluated by answering yes (1 score) or no (zero score) to seven items. In this part, the score range is 0-7, with higher scores suggesting enhanced Coping strategies.

Reliability of the tool was established in a study by Wicks et al. (2011) with the Cronbach's alpha of 0.86.[30] In addition, its validity was confirmed in a study by Pouryusef (2011) in Iran, and its reliability was approved with Cronbach's alpha of 0.87.[29] In the present study, the mentioned instrument was given to 10 MS patients, who were eligible for the study but not part of the study subjects, and its reliability was confirmed at Cronbach's alpha of 0.85.

2.4. Data Collection

To collect the data, the researcher presented to the MS Association of Zahedan and selected the participants by considering ethical issues and using convenience sampling method. Then, the participants were randomly (lottery method) divided into two groups of intervention and control.

After forming two study groups, the demographic characteristics form and MS-TAQ were completed by the participants at the MS Association and in the presence of the researcher. Following that, schedule of the educational program was provided to the intervention group. To arrange participation in the program, all the patients in the intervention group were contacted via phone calls.

In addition to the routine care and trainings provided by the association, subjects of the intervention group participated in self-management education sessions. To participate in the classes, the patients were divided into five groups of eight. In total, five 90-minute sessions were held for the participants. All the self-management education sessions were held in a separate room in the selected clinic using similar equipment (PowerPoint, whiteboard, and identical educational videos).

The self-management program was designed to enable patients maintain their health and manage their disease condition through focusing on common problems caused by the disease and teaching coping strategies, including problem solving, feedback, and decision making. The applied contents were prepared according to valid scientific books and articles on the areas of relaxation techniques and fatigue and treatment management.[31-34]

The contents were presented based on the problem-solving process by active participation of the patients in discussions, as well as questions and answers. In so doing, the patients were asked to provide examples from their own real-life situations or explain the measures they would take to improve problems that are common among MS patients. The patients actively participated in finding solutions for problems related to the disease, treatments, and side effects . Contents of the five educational sessions are presented in Table 1.

It should be noted that before all the sessions, the patients were asked to provide a summary of the contents presented in previous sessions. At the end, the educated content was provided to subjects of the intervention group in the form of an educational booklet. After the intervention, the patients were followed up on a weekly basis by the researcher for one month. Two months after the intervention, treatment adherence of the patients in both study groups was evaluated.

Meanwhile, the control group only received the usual routine education provided by the selected association and participated in no further educational classes. In order to prevent the dissemination of information about the intervention, patients of the control and intervention groups visited the association in different weeks, so that no contact was made between the two groups. Study implementation process is presented in Diagram 1.

Table 1. Educational contents of the self-management program

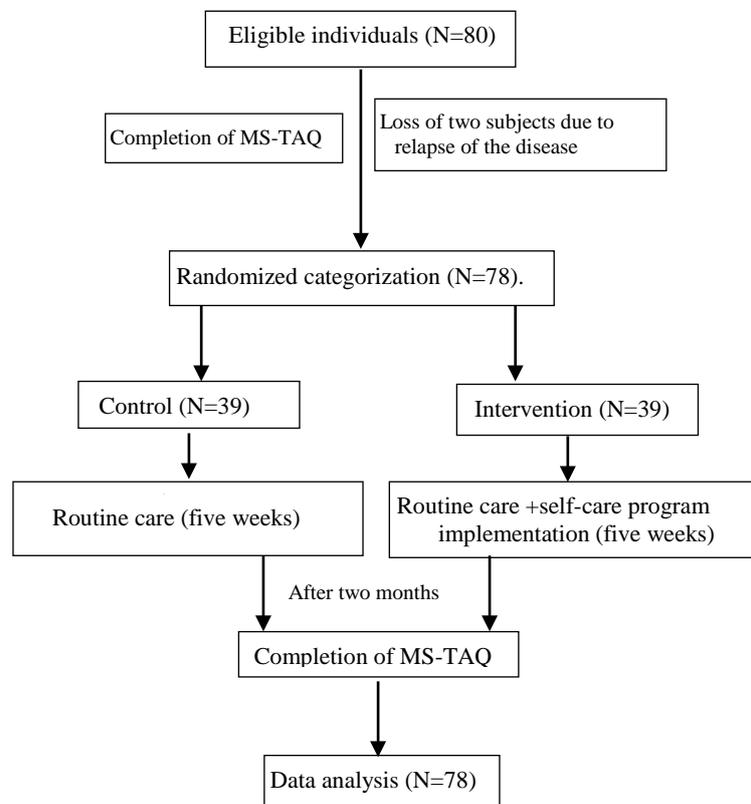| Sessions	Educational contents
First session	Discussion on basic information of MS disease, treatment methods, diagnosis methods, disease side effects , and available resources
Second session	Discussion on treatment use (the most important treatments for MS, application methods, treatment side effects, and drug interactions); expressing the mutual problems of patients, seeking possible solutions and teaching them in the form of self-care and problem-solving skills; discussion on new advancements in the treatment and treatments under study (oral immunosuppressive products, repair of damaged myelin sheath with stem cells and skin cells converted to brain cells)
Third session	Discussion on problems stated by patients, such as dysfunctional elimination syndrome, memory loss, and chronic fatigue; teaching self-care skills in order to resolve these problems
Fourth session	Discussion on control of mental symptoms caused by the disease using Jacobson's progressive relaxation and deep breathing techniques
Fifth session	Problem solving and putting patients in similar situations (whatever occurs in their daily life) and proper decision-making for evaluating the effect of contents and preparing patients for applying the contents in their daily lives

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                    ┌─────────────────────────────┐
                    │  Eligible individuals (N=80)  │
                    └─────────────────────────────┘
                                   │
   ┌──────────────────────┐       │       ┌────────────────────────┐
   │ Completion of MS-TAQ │       │       │ Loss of two subjects due to │
   └──────────────────────┘       │       │ relapse of the disease      │
                                   ▼
                    ┌─────────────────────────────────┐
                    │ Randomized categorization (N=78). │
                    └─────────────────────────────────┘
                         │                    │
                         ▼                    ▼
              ┌────────────────┐      ┌────────────────────┐
              │ Control (N=39) │      │ Intervention (N=39) │
              └────────────────┘      └────────────────────┘
                      │                         │
                      ▼                         ▼
          ┌──────────────────────┐   ┌──────────────────────────────┐
          │ Routine care (five   │   │ Routine care +self-care program │
          │ weeks)               │   │ implementation (five weeks)    │
          └──────────────────────┘   └──────────────────────────────┘
                      │     After two months    │
                      └───────────┬─────────────┘
                                  ▼
                    ┌───────────────────────┐
                    │ Completion of MS-TAQ  │
                    └───────────────────────┘
                                  │
                                  ▼
                    ┌───────────────────────┐
                    │ Data analysis (N=78)  │
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Diagram 1. Study implementation process

2.5. Ethical considerations

In order to observe the ethical considerations, the study objectives were explained to the participants prior to initiation of the study, and written informed consents were obtained from the subjects while ensuring them of the confidentiality terms regarding their personal information. At the end of the study and due to professional ethical considerations, the same educational classes were held for the subjects of the control group; they received the educational booklets containing the contents of classes at the end of the education process.

2.6. Statistical analysis

Data analysis was performed in SPSS, version 16, using descriptive statistics (frequency distribution, mean, and standard deviation tables),

Chi-square (to evaluate the homogeneity of the groups in terms of age, educational level, marital status, and occupational status of all the participants), independent t-test (to compare mean age, disease duration, distance between two doctor visits, and mean score of dimensions of treatment adherence between the control and intervention groups) and paired t-test (for intragroup comparison of mean scores of dimensions of treatment adherence in all the groups pre- and post-intervention). P-value less 0.05 was considered statistically significant.

3. Results

In this study, two individuals (1 from each study group) were excluded due to relapse of the disease,

and the research process ended with 39 patients. According to the tables, no statistically significant difference was noted between the control and intervention groups in terms of the studied variables.

After implementation of the self-management program for the intervention group, mean score of treatment adherence diminished in dimensions of barriers to treatment adherence (P=0.004) and disease side effects (P<0.0001). In addition, the educational program elevated mean score of Coping strategies dimension of treatment adherence (P<0.0001). Independent t-test reflected a significant difference between the control and intervention groups in all three dimensions after the intervention (P<0.0001).

Table 2. Demographic and clinical characteristics of the participants

Variable	group	Intervention	Control	P
		N(%)	N(%)	
Gender	Male	7(17.9)	8(20.5)	
	Gender	32(82.1)	31(79.5)	0.77*
Educational level	Diploma and below	23(59)	25(64.1)	0.64*
	Academic education	16(41)	14(35.9)	
Marital status	Single	8(20.5)	8(20.5)	1*
	Married	31(79.5)	31(79.5)	
Occupational status	Employed	9(23.1)	13(33.3)	0.31*
	Unemployed	30(76.9)	26(66.7)	
Age	M±SD	36.61±9.99	35.64±10.58	0.67**
Disease duration	M±SD	6.44±5.47	6.20±3.28	0.81**
Interval between two doctor visits	M±SD	1.76±1.20	2.17±2.39	0.34**

*Chi-square; **Independent t-test

Table 3. Comparison of mean scores of treatment adherence dimensions in the intervention and control groups

Variable	Time	Pre-intervention	Post- intervention	Variations	P*
		M±SD	M±SD	M±SD	
Barriers to treatment adherence	Intervention	17.58±7.25	13.79±6.50	3.79± 7.84	0.004
	Control	19.71±7.89	20.30±6.60	-0.58±5.48	0.5
	P**	.21	<0.0001	0.005	
Side effects	Intervention	17.71±7.37	11.26±4.65	6.44±6.08	<0.0001
	Control	16.89±6.13	17.48±6.89	-0.58±4.56	0.425
	P**	0.6	<0.0001	<0.0001	
Coping strategies	Intervention	0.92±0.66	1.74±0.84	0.82±0.85	<0.0001
	Control	1.00±0.79	0.74±0.71	-0.25±0.59	0.01
	P**	0.64	<0.0001	<0.0001	

*Paired t-test; **Independent t-test

4. Discussion

According to the results of the current study, implementation of the self-management program boosted treatment adherence. It seems that implementing such programs aligned with the understanding level of patients, in-person educations, group discussions with patients, follow-ups through phone calls, and provision of the

necessary tips for disease management were effective in treatment adherence.

Baljani et al. (2011) suggested that self-management program influenced treatment adherence of patients with cardiovascular diseases,[22] which was consistent with our findings. This similarity in results might be due to reliance on principles, such as considering the level of

knowledge, awareness, and perception of patients, importance of self-assessment and motivation, and active follow-ups, and maintenance of patient-nurse relationship in designing self-management programs.In line with the results of the present study, Kaf'ami et al. (2009) marked that self-management program improved some health aspects of patients with MS. However, the positive effect of self-management program was not observed in the subscales of pain and social performance.[23] It *seems* that self-management program requires to be more prolonged to be effective in the mentioned variables. Given the fact that treatment adherence has attracted the attention of researchers just recently, limited studies have been carried out to determine the effect of self-management programs on treatment adherence of patients with MS.Currently, the positive effects self-management sessions on patients with chronic diseases, including cardiovascular diseases,[22] dialysis, and diabetes,[27] have been confirmed. In this regard, Pourverdi et al. (2015) concluded that self-management programs influenced blood glucose and glycosylated hemoglobin management in diabetic patients,[26] which is in congruence with our findings. These results are indicative of improved treatment adherence of patients through empowering them in terms of self-care. However, in that study, the self-management program was held according to the self-management model provided by Stanford University, holding educational sessions twice a week for three weeks. In the present study, self-management program was held on a weekly basis. In another study by Rae-Grant et al., the importance of the implementation of self-management strategies for patients with chronic nervous diseases and conducting further accurate studies was emphasized.[35] Similarly, Chapman et al. (2014) pinpointed the short-term effect of self-management intervention on improved treatment Coping. However, this benefit was not apparent in the long run.[25] In line with the mentioned results, while the use of self-management program improved treatment adherence, it is recommended to evaluate the effect of such programs in longer follow-ups. In some studies, including a study by Forjuoh et al. (2014), self-management program had no effect on HbA1c of patients with diabetes. In other words, the designed program was ineffective in improvement of treatment adherence of patients, which might be due to lack of attention to patient needs.[28]

Meanwhile, in the current study, patients expressed their problems and proper solutions were presented during each educational session. Pouryusef (2011) also marked that motivational interviewing had no positive effect on subscales of side effects and Coping strategies,[29] which was inconsistent with our findings. This discrepancy in results might be due to the type of intervention and smaller sample size (54 patient) in the study by Pouryusef.

One of the major limitations of this study was collecting information through self-report, which might have undermined accuracy of the results. In order to control this problem, the researcher asked all the participants to answer the questions honestly. In addition, the generalizability of the results is limited due to the type of study and sampling method.

5. Conclusion

According to our results, implementation of self-management program with an emphasis on skills such as problem-solving and decision-making promoted treatment adherence in all its subscales and enabled patients to control disease side effects and better use coping strategies. Given the results of the present study, holding educational workshops on self-management for patients can improve the life condition and disease treatment in MS patients.

On the other hand, given the mentioned limitations of this study and to promote generalizability of the data, future studies are recommended to be performed in the form of clinical trials to evaluate the effect of self-management.

Conflicts of interest

The authors declare no conflicts of interest.

Authors' contributions

Nafiseh Mohammadpour: contributed with project implementation, data collection, and drafting of the manuscript, Fariba Yaghoubinia: supervised the project, participated in data analysis, scientific editing, and final confirmation of the article, Ebrahim Ebrahimi Tabas: cooperated in drafting the manuscript, as well as reviewing, and modifying the article.

Acknowledgments

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