Original Article

The Effect of Continuous Care on the Lifestyle of Patients with Multiple Sclerosis: A Randomized Clinical Trial

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Abstract

Background: Multiple sclerosis is a common debilitating chronic disease of the central nervous system with a progressive and prolonged nature. Patients need an adjusted lifestyle and continuous care in order to prevent its recurrence and progressive disabilities. This study aimed to assess the effect of continuous care on lifestyle in patients suffering from multiple sclerosis. **Materials and Methods:** A randomized clinical trial was conducted among 72 patients with multiple sclerosis who referred to the Farshchian Educational Hospital in Hamadan, Iran in 2013. The patients were allocated to intervention and control groups using balanced block randomization with blocks of four. The steps of continuous care (orientation, sensitization, control, and evaluation) were implemented in the case group for 2 months. The patients' lifestyle was assessed before and 1 and 2 months after continuous care using the researcher-developed Lifestyle Questionnaire. The data were analyzed using the Chi-square test, *t*-test, and repeated-measures analysis of variance. **Results:** The mean score of lifestyle and its dimensions were significantly higher in the intervention group 1 and 2 months after the intervention compared to the baseline ($P = 0.001$). In contrast, the mean score of lifestyle and its dimensions had no significant difference in the control group 1 and 2 months after routine care compared to the baseline. **Conclusions:** Continuous care improved the patients' lifestyle. It could be designed as an appropriate care system into the hospitals or other health care centers. This care system could be used widely in order to improve adherence to suitable lifestyle in patients with chronic diseases.

Keywords: *Continous care, Iran, lifestyle, multiple sclerosis*

Introduction

Multiple sclerosis (MS) is a chronic and debilitating disease of the central nervous system with a progressive and prolonged nature, which usually begins during the ages 20 to 40.[1] Based on valid reports, MS is the second leading cause of disability after trauma among young adults.[2] The prevalence of MS in the world is estimated to range from 1 to 150 per 100,000 depending on the country;[3] including approximately 2.3 million patients worldwide.[4]

The occurrence of MS has increased in the Middle East,[5] especially in Iran recently.[6,7] The prevalence of the disease varies from 5.3 to 70.4 per 100,000 across different parts of Iran with a higher prevalence among females (female:male ratio ranged from 1.8 to 3.6).[6-10] The most prevalent subtype of MS was the relapsing-remitting form (65.8–87.8%). The sensory disturbance was the most initial presentation.[10] Hamadan province is one of the high-risk areas in the west of Iran with a prevalence 62.6 per 100,000.[7] There were 1100 confirmed cases with MS in this province in 2013, including 850 women and 250 men.[10] Moreover, MS poses particular problems to both patients and their families in non-adjusted lifestyle and health care system, adding to the burden of the disease.[11,12]

Lifestyle is a way that one may adopt for his/her life and is a very important factor for physical and mental health, especially for patients with chronic diseases such as MS.[13] Lifestyle includes different domains such as diet, self-care, physical activity, coping with stress, and sleep patterns.[14,15] MS patients have varied lifestyle problems such as depression, overweight,[14,16] inappropriate support resources with low knowledge about their job and family,[17] unhealthy diet, physical inactivity, and stressfull conditions.[18]

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Nursing theories and models guide the clinical activities and researches of this field; using nursing models is one of the main and important steps to achieve this goal.[19] Ahmadi *et al*. in 2010 suggested a care model for chronic patients with coronary artery diseases. This care model was composed of four stages including orientation, sensitization, control, and evaluation with a continuous and dynamic nature.[20] Many researchers in Iran have applied the care model in chronic diseases, such as myocardial infarction,[21] kidney transplant,[22] diabetes,[23] and hemodialysis,[20,24] in order to prevent re-hospitalization, reduction of signs and symptoms, and improvement of quality of life and sleep quality.

Community health nurses were trained in effective academic educations in the field of modifying and promoting health behaviors, which could play a role in the improvement of lifestyle in chronic diseases such as MS. Community health nurses also can play an important role in the post-discharge care, home care, and care in the society to prevent or at least reduce the secondary complications of the disease.[11,12] The continuous care model establishes and maintains a dynamic, flexible, and continuous communication between the nurse and the patient in order to improve the patients' lifestyle.[21] This study aimed to investigate the effects of applying a continuous care model on the lifestyle of patients with MS. The effect of continuous care model has been investigated on some chronic diseases, however, patients suffering from MS with respect to its characteristics, such as continuous care, has not been done yet. Hence, the question that arises is whether this model affects the lifestyle of these patients or not?

Materials and Methods

This single blind, randomized clinical trial registered in the registry of clinical trials (IRCT registration number: IRCT2013021112439N1). Study conducted among 72 patients with MS in the Farshchian Educational Hospital, affiliated with Hamadan University of Medical Sciences and Multiple Sclerosis Association, Hamadan, Iran, during July-October in 2013.

The patients who met the following criteria were included in the study: (a) 20–45 years of age, (b) MS confirmed by a neurologist, *c) lack of hearing and visual problems, (d) lack of cardiopulmonary diseases, (e) lack of mental disorders, and (f) patients with EDSS 1–6 in Expanded Disability Status Scale (EDSS) by a neurologist. The patients were excluded if they had any severe diseases leading to hospitalization or if they were reluctant to continue their participation.

According to the results of a previous study,[19] we arrived at a sample size of 30 for each group and a total sample size of 60 at 95% significance level and 80% statistical power. The final sample size anticipating 15% sample attrition was a total of 72 (36 patients in each group) participants.

The eligible patients were randomly assigned to the intervention and control groups using the balance block randomization. For this purpose, we prepared four sheets of paper, writing on two sheets "I" for "intervention" and on two "C" for "control." The sheets were pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets were drawn. The four sheets were then placed back into the container and this action was repeated until the sample size was reached.

The trial was carried out as single blind so that the examiner who evaluated the lifestyle of MS patients' responses was not aware of the allocated intervention. Furthermore, the statistical analyst was unaware of the trial groups until the data were analyzed and the labels were decoded.

The data collection tool was a 42-item self-reported questionnaire, which was developed by Payamani *et al*. in 2010.[25] The questionnaire's validity was approved by 10 faculty members of the Hamadan Universities of Medical Sciences, and its reliability was approved using test-retest, with a Cronbach alpha of 0.95. In the present study, the reliability of the questionnaire was also assessed by Cronbach's alpha coefficient (95%).

The questionnaire consisted of two sections, including demographic characteristics (13 questions) and 42 items in Likert scale (each question ranged from 1 to 3). The main questionnaire included six subscales; self-care (3 items), nutrition (23 items), physical activity and exercise (5 items), sleep and rest patterns (6 items), stress management (4 items), and smoking (1 item), which measured MS patients' lifestyle. Lifestyle scores were interpreted in general and at subscales which were categorized into undesirable (<50%), partly desirable (50–75%), and desirable (>75%).

Lifestyle of patients in both the control and intervention groups was assessed by MS patients' lifestyle questionnaire at the baseline before delivering continuous care. Then, patients in the intervention group received continuous care, according to its four stages, including (1) orientation, (2) sensitization, (3), control and (4) evaluation for 8 weeks. The patients in the control group received the routine care during these 8 weeks.

Continuous care in the first or the orientation stage included a 45–30 minute session with patients and their family members to explain the problems and motivating them to learn to express their expectations. Moreover, the necessity of a sustained and continuous relationship during the study period was emphasized. In the second or the sensitization stage, the patients underwent eight training sessions (30–45 minutes in three groups of 12 patients and one of their family members). Training sessions focused on the disease, complications, related limitations, healthy lifestyle, and necessity of family members' involvement in continuous care, encouraging,

and instructing them to participate in lifestyle changes for 4 weeks.

In the third or the control stage, we assessed the patients' lifestyle by questionnaire at first and then we followed-up the continuous care for 4 weeks. Control stage was conducted according to the patients' needs and conditions through face-to-face interviews or telephone counseling and education weekly. In the fourth or the evaluation stage, we evaluated the process of continuous care and the patients' lifestyle by filling the MS patients' lifestyle questionnaire. In the control group, the patients' lifestyle was evaluated at the baseline, after 4 weeks, and after 8 weeks as well using MS patients' lifestyle questionnaire.

All the statistical analyses were performed at the 0.05 confidence level using the Statistical Package for the Social Sciences version (SPSS Inc, Chicago, IL, USA) (version 16). The relationships between the dependent and independent variables were investigated using paired and independent *t*-tests, repeated measures analysis of variance (ANOVA) for continuous variables, and Chi-square tests for categorical variables.

Ethical considerations

All patients participated voluntarily in the study and signed an informed consent. The entire study process was approved by the Research Ethics Committee of the Hamadan University of Medical Sciences (approval no: p/16/35/9/49).

Results

Of the 157 patients identified, 54 were ineligible, 26 declined to participate, and 5 had other reasons. The randomization was based on the remaining 72 patients, of whom 36 patients were allocated to the intervention and 36 to the control group. Two patients declined follow-up [Figure 1]. Thus, the analysis was based on data from 70 patients.

The detailed demographic information of the 72 patients is shown in Table 1. The analysis was based on data from 72 patients, including 36 in the intervention and 36 in the control group (male:female ratio was 12/24 and 14/22 in the intervention and control groups, respectively; $P = 0.736$). According to the results presented in the table, there was no statistically significant difference between the intervention and control groups regarding the individual characteristics that might have an effect on continuous care. The results of this study showed that both the groups were similar regarding the variables of gender, marital status, age, education level, occupation status, type of disease, and financial support ($P > 0.05$).

The mean of lifestyle scores increased from 72.94 (5.91) before continuous care to 101.30 (5.24) 1 month, and to 103.16 (3.64) 2 months after continuous care in the intervention group. Whereas the mean of lifestyle scores were almost unchanged 72.94 (6.82) before routine care to 72.88 (6.91) 1 month, and 72.94 (6.90) 2 months after routine care in the control group.

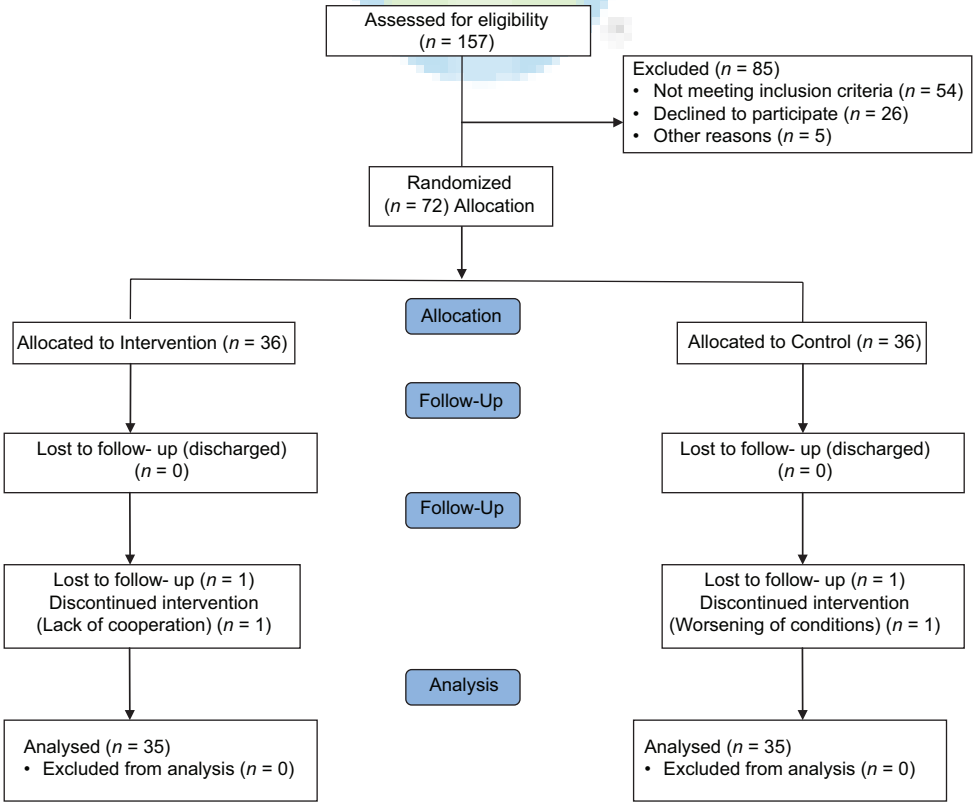

Figure 1: Trial profile

The mean level of lifestyle increased significantly in the intervention group compared to the control group. There was no significant difference between the mean of the total lifestyle score before continuous and routine care in intervention and control groups ($P = 0.99$). There was a significant difference between the mean of total lifestyle score 1 month ($P = 0.001$) and 2 months ($P = 0.001$) after continuous care in the intervention group and the control group. The intervention group improved significantly in terms of lifestyle. However, in the control group, the changes in the mean score remained stable over 1 and 2 months, and these changes, based on independent sample *t*-test, were not significant.

Moreover, statistical test of repeated-measures ANOVA showed the mean scores and standard deviations (SDs) for the intervention and control groups at the baseline and 1 and 2 months after continuous care, and the results are shown in

Table 1: Characteristics of the study population

Variables	Control group Number(Percent)	Intervention group Number(Percent)	*P*
Gender			
Male	14 (38.89)	12 (33.33)	0.736
Female	22 (61.11)	24 (66.67)	
Marital status			
Single	12 (33.33)	14 (38.89)	0.62
Married	24 (66.77)	22 (61.11)	
Age group (year)			
20-29	6 (16.67)	8 (22.22)	
30-39	17 (47.22)	17 (47.22)	0.80
40-45	13 (36.11)	11 (30.56)	
Educational level			
Primary and intermediate school	3 (8.33)	2 (5.55)	
High school	17 (47.22)	19 (52.78)	0.744
University	16 (44.45)	15 (41.67)	
Occupational status			
Working	25 (69.44)	27 (75.00)	0.82
Unemployed	11 (30.56)	9 (25.00)	
Type of disease			
Relapsing-Remitting	26 (72.22)	28 (77.78)	0.80
Secondary Progressive	10 (27.78)	8 (22.22)	
Financial support			
Family	31 (86.11)	27 (75.00)	
Relatives	2 (5.56)	4 (11.11)	0.55
Multiple Sclerosis Association	3 (8.33)	4 (11.11)	
Others	0 (0.00)	1 (2.78)	

Table 2: Mean score (standard deviation) of dimensions of lifestyle at baseline and 1 and 2 months after continuous care in intervention and control groups

Lifestyle and its dimensions	Time Group	Mean score (standard deviation) Baseline (T1)	One month after (T2)	Two months after (T3)	*P*
Self-care	Control	2.41 (0.60)	2.42 (0.60)	2.42 (0.60)	0.211
	Intervention	2.44 (0.69)	4.11 (0.39)	4.13 (0.54)	0.001
Diet	Control	42.61 (3.23)	42.62 (3.29)	42.65 (3.30)	0.569
	Intervention	42.02 (3.47)	59.16 (3.21)	60.13 (1.22)	0.001
Physical activity	Control	4.11 (2.69)	4.11 (2.74)	4.14 (2.76)	0.324
	Intervention	4.22 (2.82)	7.47 (1.81)	7.83 (1.93)	0.001
Pattern of sleep	Control	12.83 (2.04)	12.77 (2.11)	12.77 (2.11)	0.327
	Intervention	12.94 (1.85)	16.94 (1.72)	17.27 (1.40)	0.001
Coping with stress	Control	9.22 (1.39)	9.20 (1.36)	9.20 (1.36)	0.325
	Intervention	9.55 (1.27)	11.69 (0.52)	11.83 (0.44)	0.001
Lifestyle	Control	72.94 (6.82)	72.88 (6.91)	72.94 (6.90)	0.402
	Intervention	72.94 (5.91)	101.30 (5.24)	103.16 (3.64)	0.001

Table 2. The intervention group improved significantly on all related dimensions of lifestyle (self-care, diet, physical activity, pattern of sleep and coping with stress) as well as the total lifestyle score at 1 (P = 0.001) month after continuous care. However, in the control group, the changes in the mean score remained stable over 1 month compared to the baseline. This condition for the control group remained the same 2 months later, however, in the intervention group, mean scores compare with baseline and 1 month after continuous care improved significantly, with the increase from the first to the second month being less than the first month compared to the baseline.

The results of repeated-measures ANOVA indicated that the mean score of lifestyle on all its dimensions did not follow a similar trend in the intervention and the control group over time and, noting the aforementioned mean scores, the patients in the intervention group improved over time, confirming the significant difference between the intervention and the control group during the implementation of the intervention. Therefore, the intervention was, indeed, influential in the intervention group [Table 2].

Discussion

The results revealed that there was a significant difference between the mean lifestyle scores in the intervention and the control groups; the results of the present study indicated that the continuous care model could efficiently improve the patients' lifestyle in the intervention group. Because all domains of lifestyle were considered in this model and sensitization was repeated during the study period and family members were involved in the entire program, the patients' lifestyle remarkably improved in all domains. This result was consistent with that of the study conducted by Molazem *et al*. that showed the effect of continuous care model on the lifestyle of patients with myocardial infarction.[21] In their study, Ennis *et al*. showed that health promotion education program for patients suffering from MS produced changes in health-promotion behaviors.[26] Moreover, Chahkhoie *et al*. in their study showed that, in all dimensions of lifestyle, except sleep, there was a significant difference.[8]

Various studies have investigated the effect of continuous care on the lifestyle of the patients and have concluded that continuous care can improve patients' lifestyle and reduce the jeopardy of the disease.[27,28]

The score of self-care domain was significantly different between the intervention and control groups. This indicates the effect of continuous care model on self-care in patients with MS. This finding is consistent with the results of Chahkhoie *et al*.[8] Hemmati and Raiesi showed that implementing the self-management program along with regular follow-up increased the perception of self-efficacy in patients with MS.[9]

The score of sleep and rest domain was significantly different between the intervention and control groups. This indicates the effect of continuous care model on the quality of sleep in patients with MS. Consistent with our results, Khosravan *et al*. and Sadeghi *et al*. reported that continuous care could efficiently improve the quality of life and sleep status in patients with hemodialysis and diabetes;[23,24] in contrast, Chahkhoie *et al*. reported that collaborative care had no effect on sleep status of MS patients.[8] The discrepancy between the results of these studies may be due to the differences in the period of follow-up and the care model.

Evidence has shown that stress is common among patients with MS and can exacerbate the disease signs and symptoms. We noted that continuous care could efficiently help patients with MS in coping with stress as a component of lifestyle. Ebadifar *et al*. performed an educational program based on stress management using BASNEF model, and reported that the improvement of behavior in patients with MS could effectively help them in managing stressful conditions.[29]

MS progressively leads to physical disability. Motor disability (e.g., impaired walking) is one of the most common features of MS that changes patients' lifestyle depending on the stage of the disease. Sports and physical activities can promote health, reduce motor disability, and reduce stress and anxiety.[30] In this study, we trained patients how to engage in physical activities. Nancy *et al*. revealed that sport and physical activity can modify the MS-related outcomes, and suggested that physical activity, regardless of its intensity and duration, should be considered as a part of the treatment process in order to improve the patients' lifestyle and reduce their disabilities.[31] Erin *et al*. performed a meta-analysis to assess the enabling effect of physical activities on motor function in patients with MS. They indicated that physical activity can improve impairment of walking.[32] The findings of Chahkhoie *et al*. are consistent with our results.[8]

A healthy diet can promote health conditions of patients with MS. Pozuelo-Moyano *et al*. evaluated the role of diet in the clinical condition of patients with MS, and concluded that the severity of signs and symptoms of the disease and its recurrent attacks are associated with the type of diet.[33] Ghavami *et al*. investigated the effect of continuous care model on the amount of blood sugar in diabetic patients, and concluded that implementing this model can effectively reduce blood sugar in diabetic patients.[34]

There is a sufficient evidence that shows implementing continuous care model can have a significant effect on various domains of lifestyle in patients with MS. Therefore, a training course at discharge is suggested for patients with MS in order to improve their knowledge regarding the disease and to increase their self-efficacy to overcome the disease related limitations in daily activities and to reduce treatment costs.

The main limitation of the present study was that the blinding of the intervention to the patients was impossible.

This might raise the possibility of information bias. Another limitation of this study is its short follow-up phase due to the limitation of research time.

Conclusion

With regard to the chronic nature of MS and the fact that the present programs fall short of completely controlling the side effects and the various difficulties following this disease, the existence of a continuous care method that can affect the patients' lifestyle seems quite inevitable. The results of the present study indicated that the implementation of the continuous care model can improve the lifestyle in patients with MS with no additional cost. Therefore, training the patients with this model is suggested.

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Conflicts of interest

There are no conflicts of interest

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