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Mindfulness-based Stress Reduction (MBSR) Program: the Effect of a Novel Psycho-interventional Method on Quality of Life, Mental Health, and Self-efficacy in Female Patients with Multiple Sclerosis: A Randomized Clinical Trial

Mohammadali Besharat[1], Seyed massood Nabavi[2], Shiva Geranmayepour[1], Damineh Morsali[3], Shima Haghani[4*]

[1] Department of Psychology, University of Tehran, Iran

[2] Neurology group, Department of Regenerative Biomedicine, Cell Science Research Center, Royan Institute for Stem Cell Biology and Technology, ACECR, Tehran, Iran

[3] Neurology group, Faculty of Medicine, Huston University, Huston, Texas, US

[4] Department of Clinical Research, Tehran University of Medical Sciences, Tehran Heart Center, Tehran, IRAN

*Correspondence should be addressed to Shima Haghani, Department of Clinical Research, Tehran Heart Center, Tehran University of Medical Sciences, North Kargar Street, Tehran-Iran; P.O.Box: 1411713138; Tel: +982188029256; Fax: +982188029256; Email: sh_haghani1@yahoo.com.

ABSTRACT

Multiple sclerosis (MS) is a disease of central nervous system affecting young population. Burden of the disease, lifelong confrontation with a complex disease with no cure and the need for continuous care lead to chronic stress in patients and their caregivers. Mindfulness stress reduction, as a novel psycho intervention method, might be helpful in MS patients to reduce this chronic stress. A group of female patients diagnosed with definite MS (According to MC Donald criteria 2010 by a neurologist) were randomized to either an immediate MBSR program (n=12) or waitlist (n=12). The intervention consisted of a weekly MBSR group lasting 2.5 hours for 8 weeks plus a 6 hours retreat. Patients completed questionnaires pre- and post- intervention or waitlist period. Preliminary analysis revealed that there was no significant improvement in physical symptoms and mental health (p>0.05). However, a significant improvement was observed in patients' quality of life (p>0.05). These results provide preliminary evidence for the feasibility and efficacy of MBSR intervention as a novel psychotherapeutic method for improving quality of life in patients with MS.

Key words: Mindfulness Based Stress Reduction (MBSR), Multiple sclerosis (MS), Quality of life, Mental health, Self-efficacy.

1. INTRODUCTION

Multiple sclerosis (MS) is a chronic progressive disease of central nervous system (CNS) that produces demyelination and axonal loss (1). It is thought to affect more than 2.5 million people worldwide (2). MS typically onsets in early adulthood, occurring between ages 20 to 40, and affects more women than men. MS produces a range of unpleasant and disabling symptoms. The real course of MS is unpredictable, the exact causes are unclear, and there is no known cure. Symptoms may include debilitating fatigue, loss of motor and sensory functions, loss of balance, loss of bowel and bladder control, sexual dysfunction, pain, cognitive dysfunctioning and emotional changes (3). MS provides challenges for both physical and psychological well-being. People with MS experience unpleasant and unpredictable symptoms, difficult treatment regimens, and drug side-effects which all contribute to increasing levels of physical disability. Indeed, the disease provides psychosocial consequences including disruptions to life goals, employment, income, relationships, leisure and daily living activities. Patients with MS are more likely to experience psychological disorders than the general population. Quality of life is compromised in patients with MS, and is

likely explained by several features of the disease, including an onset during the productive years of one's life, an uncertain and unstable disease course, diffuse effects throughout the CNS, and absence of a cure (4-6). Several researches have focused on improving the quality of life for individuals with MS. This might be accomplished by understanding psychological and behavioural factors that are associated with or influence quality of life in people with MS (7). The purpose of this study was to investigate the effects of a psycho intervention called "Mindfulness-based Stress Reduction programme", MBSR, as a new emerging psychotherapy plan on physical symptoms, quality of life, and mental health in female patients with multiple sclerosis.

2. MATERIALS AND METHODS

2.1. Participants

24 patients were enrolled after screening 70 women who visited in the MS clinic. Then, they were randomly assigned to either the experimental group or the control group by Table of random numbers. The average age of participants was 35 years in the experimental group (standard deviation (SD): 7.45) and 30 years in the control group (SD: 4.1). Mean expanded disability status scale (EDSS) of the experimental group and control group were 2.3 and 2.7 respectively. Mean disease duration in experimental group was 34 months and in the control was 39 months. One participant didn't complete post-test and hence was not permitted to enter the analysis. All others followed and completed all procedures. The inclusion criteria were as follows: (a) an established medical diagnosis of Multiple Sclerosis for at least 1 year (According to McDonald criteria 2010). (b) An EDSS-Score (Expanded Disability Scale), not exceeding 5.5. (To transfer properly) (c) Age between 18 and 51 years. (d) At least medium degree qualification to understand the training. The exclusion criteria were: (a) Relapse or an acute phase of the disease. (b) Patients with known psychiatric illness. (c) Patients who had received Psychotherapy in the history. (d) Patients that had concomitant acute or chronic physical diseases. The patients in two groups were allowed to follow their medications specially disease modifying therapies. No anti depressive or anxiolytic medications prescribed during the intervention. All patients signed the inform consents and were assessed before beginning the intervention program and at the end of program by scales of mental health, quality of life and physical symptoms checklist.

2.2. Measures

2.2.1. Short-Form (8)

The SF-36 contains 36 items and yields a profile of scores on eight health attributes: General Health Perceptions, Physical Functioning, Role Limit—Physical, Role Limit—Emotional, Social Function, Mental Health, Bodily Pain, and Fatigue/Vitality. Each item received a score from 0 to 100, and scores for each scale are calculated as the mean

performance across scale items. Thus, scale scores may range from 0 to 100 with high scores indicative of more positive functioning. Two higher order cluster scores were created that called the Physical Component Score (PCS; comprising general health, body pain, role—physical, and physical function scales) and Mental Component Score (MCS; comprising vitality, social function, role emotional, and mental health scales). Each of these scores has a mean of 50 and a standard deviation of 10 and will be used as dependent variables in regression analysis (9). Reported Chronbach's alpha's ranging from 0.61 to 0.91; while Marrie et al report test–re test reliabilities of 0.65 to 0.93. Reported reliability exceeds the minimum standard of 0.70, and most have exceeded 0.80 (10). The SF-36 was selected rather than HRQL measures specific to MS as using of more general measures allows for comparisons to the literature from other populations (11).

2.2.2. Expanded Disability Status Scale (12)

The EDSS is used to evaluate a person's disability numerically. A patient is evaluated on the EDSS by a neurologist. According to signs and symptoms observed during a standard neurological examination. The EDSS is an ordinal clinical rating scale ranging from 0 (normal neurologic examination) to 10 (death due to MS) in half-point increments. The patient is evaluated on eight Functional Systems (FS): pyramidal, cerebellar, brainstem, sensory, bowel and bladder, visual, cerebral, and other. Each FS uses an ordinal clinical rating scale ranging from 0 to 5 or 6. Since the EDSS is an ordinal rating scale, a 1-point difference in one part of the scale does not represent the same interval as a 1-point difference in another part of the scale, thus making change or group differences is difficult to interpret. Interpreter reproducibility is adequate for group comparison studies, while intra-rater reproducibility is more variable (13). Convergent and discriminant validity for the EDSS is supported. Both test–retest reliability and inter-rater agreement have varied considerably from study to study with some studies finding high values and other studies unacceptably low figures (14). Mental Health Inventory (MHI-28) (15) is the shortened form of a 34-question mental health scale. It is a 28-question test and measures two conditions of psychological well-being and psychological distress in a 5-degree Likert scale from 1 to 5. The subject's minimum and maximum score in psychological well-being and psychological distress subscales were 14 and 60 respectively. The psychometric characteristics of the 28-question form of this scale were studied in a sample composed of 760 subjects in two groups of abnormal (n=277; 173 female and 104 male) and normal (n= 483; 267 female and 216 male). Cronbach Alpha coefficients of psychological well-being and psychological distress subscales were measured 0.94 and 0.91 respectively for normal subjects' scores and 0.93 and 0.90 respectively for abnormal subjects' scores, which is indicative of the scale's good internal consistency. Correlation coefficients

between some normal subjects' scores (n=92) were measured twice with a two-week interval for test-retest reliability. These coefficients for psychological well-being and psychological distress were respectively r=0.90 and r=0.89 and were significant at the level of p < 0.001, which shows the scale's test-retest reliability is satisfactory. Correlation coefficients between some abnormal subjects' scores (n=76) were also measured twice with a one- to two-week interval for test-retest reliability. These coefficients for psychological well-being and psychological distress were respectively r=0.83 and r=0.88 and were significant at the level of p < 0.001, which shows the scale's test-retest reliability is satisfactory. Concurrent validity of Mental Health Inventory-28 was measured via simultaneous administration of General health Questionnaire to all subjects of both groups (16, 17). Pearson correlation coefficients results showed that there is a significant negative correlation (r= -0.87, p < 0.001) between the participants' general score in General Health questionnaire and the psychological well-being scale, and a significant positive correlation (r= 0.89, p < 0.001) for psychological distress subscale. These results confirm the concurrent validity of mental health scale. Differential validity of the General Health scale was measured via the comparison of the scores of psychological well-being and psychological distress of the two normal and abnormal groups and was approved. Also, the results of factor analysis confirmed psychological well-being and psychological distress subscales. Multiple Sclerosis Self-Efficacy Scale (MSSE-130) (18) is a 13-question self-efficacy scale and it measured the subject's minimum and maximum score in self-efficacy that were 0 and 1300 respectively. The psychometric characteristics of the 13-question form of this scale were studied, in a sample of patients with multiple sclerosis (n=174; 103 female and 71 male) and Cronbach Alpha coefficients of questions of scale was 0.91. Correlation coefficients between scores of some patients (n=123; 69 female and 54 male) were measured twice with a two-week interval r=0.87, p < 0.001 for test-retest reliability. This correlation shows the scale's test-retest reliability is satisfactory (18).

2.3. Procedure
The control group received standard medical care for MS from their primary care physician. Those assigned to the experimental group received eight 2.5 hours weekly group sessions in addition to their standard medical treatments.

2.4. Mindfulness based stress reduction program (MBSR)
The MBSR was scheduled as an 8-week group program with each lasting 2.5 hours, and there is an additional single all-day session on a weekend day. Each session covers particular exercises and topics that examined within the context of mindfulness. These include different forms of mindfulness meditation practice(Body scan and Sitting meditation), mindful awareness during yoga postures, and mindfulness during stressful situations and social interactions (6). Body scan meditation was carried out during the first two sessions with a focus on physical activities like conscious eating and walking. Sessions 3 and 4 were mainly concerned with training Mindful Yoga techniques which are for self-consciousness and self-awareness through looking at body and its internal systems during distressing circumstances. From session 5 onwards, sitting meditation trainings began, with its emphasis on the stress and methods of dealing with unusual circumstances. Throughout the final sessions, MBSR experience in everyday life in addition to issues related to stress were considered, focusing on preparing patients for application of these techniques in their daily lives. A daylong session (between sessions 6 and 7) was arranged following session 6, which lasted for 6-7 hours. During this session, an overall review on the entire trainings was presented. In addition to the sessions, an extensive program of daily 45-min homework assignments was required by all participants in order to fully benefit from the program. The findings of this study based on comparison between pre and post mean differences were analyzed.

2.5. Statistical methods
By using SPSS version 20, all statistical analyses were done. All statistical analyses will be appropriate to the nature and distribution of the collected data. Categorical data will be described by frequency and percentage, continuous data by mean and standard deviation. Paired samples t-test was used to evaluate changes in each group. For clinical scores, significance between groups was examined by Student's t test. P values less than 0.05 were considered statistically significant.

3. RESULTS AND DISCUSSION
Table 1 showed the demographics characteristics in each group. Paired samples t-test analysis was conducted to determine the effects of Mindfulness Based Stress Reduction program on physical symptoms, quality of life and mental health on MS patients. The repeated measures of mental health, quality of life scales and physical checklists were pre and post intervention by paired samples t-test. Independent t test indicated that there are a significant increment in quality of life and decrement in physical symptoms of the experimental group compared to the control group. But mental health in both groups did not show any significant changes (Table 2).

Table 1. Demographics characteristics in each group (N=23)

Characteristic	Categories	Experimental group(n=11) N(%)a	Control group(n=12) N(%)a	Total(n=23) N(%)a
Age	24-29 years	5(45)	3(40)	8(34)
	30-39 years	5(45)	7(58)	12(52)
	40-51 years	1(9)	2(16)	3(13)
Education	High school degree	3(27)	2(16)	5(21)
	University Student	3(27)	2(16)	5(21)
	Bachelor's degree	3(27)	7(58)	10(43)
	Master's degree	2(18)	1(8)	3(13)
Marital status	Unmarried	3(27)	4(33)	7(30)
	Married	7(63)	8(66)	15(65)
	Divorced	1(9)	0(0)	1(4)
Employment status	Housewife	6(54)	9(75)	15(65)
	Employed	5(45)	3(25)	8(34)

Table 2. Comparison of mental and physical characteristics in two groups

Characteristics	Group	N	Mean	SD	SEM
Physical symptoms	Experimental group	12	-0.06	0.06	0.01
	Control group	11	0.01	0.08	0.02
Mental health	Experimental group	12	1.5	7.97	2.30
	Control group	11	-2.27	2.83	0.85
Self-efficacy	Experimental group	12	-0.41	7.09	2.04
	Control group	11	-3	8.31	2.50
QOL	Experimental group	12	-3.1	4.74	1.37
	Control group	11	2.51	2.28	0.69

The main purpose of this clinical trial study was to investigate the effects of an intervention of Mindfulness-based Stress Reduction programme on physical symptoms, quality of life, and mental health in female patients with multiple sclerosis. 24 female MS patients were randomly assigned to either the experimental group or the control group. The results indicated that the experimental group, which received MBSR program, had improved in quality of life and physical symptoms, but mental health factor pre- and post-test in both groups didn't have any significant change. The results suggest a potential benefit from mindfulness training program, and it may be useful to speculate on what may have been the therapeutic ingredients. People with MS, are many obstacles to performing an appropriate movement. The physiological and neurological damage may be relatively fixed, but other factors, such as level of anxiety and depression and focus of attention will also determine the patients' quality of life. If attention is not focused on the disabilities but is instead concerned with "what will people think of me?" or "why did this happen to me?" then the quality of mind-body connection is impaired even beyond the neurological damage. Mindfulness training program can be thought as a way of bringing the attention fully into breath, body, thoughts, emotions and affects each moment of their lives. Thus, mindfulness aims to maximise mind-body integration and minimize the consequences of the neurological damage, so it can help patients to have better quality of life and fewer problems with the disease. Indeed, in a multicomponent intervention such as this, it is difficult to isolate the mechanisms of action or specific techniques that may account for the improvements (19). Other aspects of the group besides the meditation, such as relaxation, the opportunity to take an active role in their own care, social support, or cognitive techniques, may have been beneficial. The findings of this study are consistent with previous research and recommendations for conceptualizing the relationship between physical activity and QOL. MBSR can enhance functional status and well-being and reduce physical symptoms and psychological distress in a heterogeneous patient population (19). MBSR participation was associated with enhanced quality of life in the patients with breast and prostate cancer (7). MBSR results provide preliminary evidence for beneficial effects on QOL in women recently diagnosed with early stage breast cancer (4). MBSR-C may be a beneficial intervention for reducing symptoms in advanced-stage cancer patients and may also benefit caregivers (20). MBSR showed a moderate to large positive effect size on the mental health of patients with breast cancer and warrants further systematic investigation (5). Results suggest that MBSR may help a broad range of individuals to cope with their clinical and nonclinical problems (6). MBSR has small effects on depression, anxiety and psychological distress in people with chronic somatic diseases (21). MBSR intervention achieved a prolonged reduction in psychosocial distress (22). Indeed,

previous research has reported that physical activity is related with physical and psychological aspects of QOL through a path that includes self-efficacy in a sample of older black and white adults (23). Our data suggest that a similar pattern of relationships may exist in those with MS. However, there are several reasons why these results need to be treated with caution. First, the control group didn't have equality of input in terms of attention from a therapist or access to teaching materials. The second difficulty in interpreting these results is the nature of MS itself. MS is a disease that waxes and wanes in terms of symptom severity. Any attempt in evaluating an intervention faces the problem of separating natural variation of the disease from the effects of intervention.

4. CONCLUSION

This study suggests that training in mindfulness may offer MS patients a self-management of symptoms that increase physical and psychological functioning. Further research with a larger sample size needs to be done to show the interplay of the cognitive, affective and physiological mechanisms involved.

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AUTHORS CONTRIBUTION

This work was carried out in collaboration among all authors.

CONFLICT OF INTEREST

The authors declared no potential conflicts of interests with respect to the authorship and/or publication of this paper.

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