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Research Article

The Effect of Self-Regulation Education on Psychosocial Outcomes in Women with Multiple Sclerosis: A Randomized Controlled Trial Protocol

Mahsa Hosseini [1], Soheila Shamsikhani * [2], Fatemeh Rafie [3], Ali Jadidi [4]

[1] *MSc, Shazand School of Nursing, Arak University of Medical Sciences, Arak, Iran*
[2] *Ph.D in Nursing, Shazand School of Nursing, Arak University of Medical Sciences, Arak, Iran*
[3] *Department of Biostatistics, School of Medicine, Arak University of Medical Sciences, Arak, Iran*
[4] *Department of Nursing, School of Nursing, Arak University of Medical Sciences, Arak, Iran*

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ABSTRACT

Introduction: Multiple sclerosis (MS) is a progressive neurological disorder that imposes significant physical, functional, and economic burdens, severely impacting patients' quality of life. Given the multifaceted psychological and physical challenges associated with this condition, there is a critical need for structured interventions. This study will implement an intervention based on the Leventhal Self-Regulation Model (SRM), utilizing a three-stage framework of representation, coping, and appraisal to address both physical and emotional dimensions.

Objectives: This study aimed to assist patients in gaining a deeper understanding of their condition, thereby enhancing their capacity to adapt to the complex emotional and psychological distress inherent in living with MS.

Methods: This randomized controlled trial will be conducted on 64 MS patients who are selected based on inclusion criteria and classified into two groups: control and intervention, using block randomization. Individuals in the intervention group will receive educational content designed according to the steps of Leventhal's SRM, while the control group receive no intervention. The educational content for the intervention group is designed in a multimedia format, using the trial and free version of Storyline 360 software. All sessions will be conducted virtually, with one to two in-person sessions (group or individual) as needed and requested by participants. The virtual training program includes synchronous (online) and asynchronous (offline) training.

Conclusions: This article will be the first randomized trial to focus on both physical and emotional aspects of Leventhal's SRM in women with MS. The study aims to determine the efficacy of this intervention in improving illness perception and reducing the severity of psychological symptoms, including depression, anxiety, and stress. This trial is registered with the Iranian Clinical Trials Registry (IRCT) under the code: IRCT20220703055351N3.

Corresponding Author: *Ph.D in Nursing, Shazand School of Nursing, Arak University of Medical Sciences, Arak, Iran*
Email: *shamsikhani@arakmu.ac.ir*

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1. Introduction

Multiple sclerosis (MS), also known as demyelinating sclerosis, is a disease with no known cause that affects young and middle-aged adults and significantly impacts their physical, functional, and economic well-being, as well as their quality of life (1). The prevalence and occurrence of this disabling disease are increasing in both developing and developed countries (2). Approximately three-quarters of those affected by this disease are female (3). Compared to the worldwide average, Iran exhibits a higher prevalence of MS among women, indicating a unique pattern in the occurrence of the disease (4).

In addition, many individuals with MS also suffer from psychological problems (5). Compared to the general population, MS patients are more likely to suffer from mental health conditions (6). In other words, most individuals with MS experience anxiety, stress, and depression resulting from the disease (7). Additionally, increased awareness of the disease can play a crucial role in mitigating the associated challenges, such as psychological problems. There is a lack of understanding of MS among many individuals with the disease (8). This disease remains an ambiguous and unpredictable condition for many affected individuals, characterized by loss of function, changes in role, and a wide range of disabilities (9). Therefore, it is imperative to increase awareness of perception of MS.

A patient's illness perception refers to a psychological framework in which positive and negative beliefs are formed about the disease. These beliefs significantly impact an individual's ability to cope with the illness and influence health-related behaviors (8). Leventhal's self-regulation model (SRM), based on rational thinking, is an educational model designed to promote adaptive behaviors in dealing with the disease (10). According to Leventhal's SRM, individuals with chronic illnesses develop a personal representation of the illness known as "illness perception". Their perception ultimately affects their coping strategies and emotional reactions (11). The model helps reduce vulnerability and anxiety in individuals due to their awareness of the illness (12). In other words, Leventhal's model affects patients' mental manifestations and behaviors by improving their understanding of the disease (13). Additionally, it promotes adaptive behaviors in disease management (14), leading to compliance with treatment plans and medications (15).

Rakhshan et al. also found that Leventhal's SRM can be used in patients with chronic diseases to help control and treat the disease (16). Saranjam et al.'s study found that Leventhal's SRM improves quality of life and understanding of the disease in people with high blood pressure (17). Consequently, Leventhal's SRM can be used to develop educational interventions to increase awareness and understanding of MS among many individuals. In addition, improving illness perception can reduce vulnerability and mitigate the adverse consequences of the disease. In this way, this therapeutic intervention may contribute to the well-being of individuals living with MS if it is effective.

2. Objectives

This study aimed to assist patients in gaining a deeper understanding of their condition, thereby enhancing their capacity to adapt to the complex emotional and psychological distress inherent in living with MS.

3. Methods

3.1 Study Design

This study is a randomized controlled trial protocol designed to evaluate the efficacy of an educational intervention based on the Leventhal SRM. The trial will investigate how this program impacts psychological outcomes in women with MS. The trial follows a structured three-stage framework (representation, coping, and appraisal) to address both the physical and emotional dimensions of chronic illness. The study is currently ongoing, and all procedures are conducted in accordance with the pre-defined protocol. This protocol is designed according to the proposed guidelines for SPIRIT clinical protocols (18) and Shakarchi's recommendation (19) (additional file 1). The study aims to assess the effectiveness of self-regulation training on anxiety, stress, depression, and illness Perception in patients with MS. This protocol has been registered at the Iranian Clinical Trials Registry (IRCT) under the unique identifier IRCT20220703055351N3, which can be accessed at www.irct.ir. A primary outcome of this study was disease understanding, stress, anxiety, and depression. The outcomes will be assessed in three stages: before, after, and four weeks after the intervention (Figure 1).

3.2 Participants

Participants in this study will be recruited from MS patient associations in Arak, Iran.

The criteria for participating in the research include confirmed disease based on medical records and specialist diagnosis; age between 18 and 50 years; a history of illness for at least one year; having a smartphone; minimum literacy; and the ability to use a smartphone, as self-declared. Other criteria include not

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being in the relapse stage of the disease, not suffering from uncontrolled acute illness according to self-report and medical records, the ability to speak (speech and hearing), not using drugs, and not receiving other training related to coping with stress, anxiety, and depression in the last month. The score on the Expanded Disability Status Scale should be between 0 and 5.5.

The criteria for exiting the study include patient disability due to continuing participation in the research for any reason (accident, death, or migration to another city), relapse of MS and hospitalization for this or other diseases, lack of willingness to continue cooperation, pregnancy, and specific changes in lifestyle or treatment process for individuals. (M.H will enroll participants)

	Study Period							
	Enrolment	Allocation	Post-allocation					Close-out
TIMEPOINT**	-4W	0W	0W	1W	2W	3W	4W	4W/ 8W
Enrolment:								
Eligibility screen	X							
Informed consent	X							
[Design training based on needs]	X							
Allocation		X						
Interventions:								
[Intervention group] Levant self-regulation training			—	—	—	—	—	
[control group] Conventional training			—	—	—	—	—	
Assessments:								
Needs Assessment	X							
Illness Perception		X						X
Anxiety		X						X
***S*tress**		X						X
Depression		X						X

Figure 1: SPIRIT Figure for the Schedule of Enrollment, Interventions, and Assessments

3.3 Randomization and Allocation

Based on a similar study (20) and the average comparison formula, the required sample size for each group was estimated at 32 people, with a 10% drop. The present study will use the convenience sampling method and randomly divide the participants into two groups: control and intervention.

$$n = \frac{\left(z_{1-\frac{\alpha}{2}} + z_{1-\beta}\right)^2 \left(s_1^2 + s_2^2\right)}{\left(\mu_1 - \mu_2\right)^2}$$

To achieve randomization concealment, randomization is carried out using random blocks. Therefore, Participants are allocated to two control and intervention groups (F.R. generates the allocation sequence). For this purpose, the website sealedenvelope.com is utilized (block size = 4, allocation ratio = 1:1) (21).

3.4 Study Procedures

This study implements a structured educational intervention based on Leventhal's SRM, designed specifically to enhance illness perception and coping mechanisms in women with MS. Unlike traditional models that focus solely on physical symptom management, this protocol integrates both physical and emotional dimensions of the illness. (Table 1)

3.4.1 Structure and Framework

The curriculum follows a three-stage framework, delivered progressively over the study period:

Representation: Helping patients construct a realistic cognitive model of their illness, covering identity, timeline, cause, consequences, and cure/control.

Coping: Providing evidence-based strategies for managing physical limitations and addressing the emotional impact, including anxiety and stress common in MS patients.

Appraisal: Empowering participants to evaluate the effectiveness of their coping strategies and adjust their behaviors for better adaptation.

3.5 Study Timeline

Following SPIRIT 2013 guidelines, the study consists of four phases: enrolment and baseline, involving eligibility screening, informed consent, and baseline

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assessments; allocation, where participants are randomly assigned (1: 1) to either the Leventhal Self-Regulation training or conventional training groups; intervention, consisting of the implementation of the respective training protocols during the study period; and close-out, involving post-intervention assessments of illness perception (BIPQ) and psychological distress (DASS-21) to evaluate the impact of the intervention.

Table 1: Structure and Content of the Multi-dimensional Psychoeducational Intervention Program

Session	Dimension	Topic	Description	Format
1	Orientation	Research and Needs Assessment	Survey on platforms and training on content usage.	Online/Offline
2	Cognitive	Identity and Pathophysiology	Introduction to MS, mechanisms, and incidence statistics.	Offline
3	Emotional	Stress Management	Stress mechanisms, stressors, and their link to MS.	Offline
4	Cognitive	Etiology and Risk Factors	Genetics, environment, nutrition, and lifestyle factors.	Offline
5	Emotional	Problem-Solving Skills	Identification, generation, evaluation, and prioritization of solutions.	Offline
6	Social	Peer Support Group	Experience sharing and group discussions.	Online
7	Cognitive	Disease Timeline	MS types, relapse/remission cycles, and disease progression.	Offline
8	Emotional	Anger Management	Identifying triggers and techniques (e.g., situational withdrawal).	Offline
9	Cognitive	Complications and Control	Signs, consequences, and strategies for complication management.	Offline
10	Emotional	Depression Management	Mechanisms, aggravating factors, and the MS-Depression link.	Offline
11	Social	Peer Support Group	Experience sharing and group discussions.	Online

Abbreviations: MS, multiple sclerosis

3.6 Outcomes and Measures

3.6.1 Demographic Data

The demographic information questionnaire is a self-report tool developed to collect essential data in two categories:

1. **Personal information:** including age, gender, marital status, level of education, occupational status, and socioeconomic status.
2. **Disease-related information:** including the duration of the illness, type of treatment (e.g., medication, surgery, or therapy), history of hospitalizations, and presence of any comorbid conditions

This tool was designed to ensure a comprehensive understanding of the participants' background and to facilitate the analysis of potential confounding variables.

3.6.2 Depression: Anxiety: Stress: Scale (DASS):

In the present study, the researchers aim to assess levels of anxiety, stress, and depression using the Depression: Anxiety: Stress: Scales-21 (DASS21). Lovibond and Lovibond (1995) developed the DASS-21(22). The DASS-21 was validated for the Iranian population and is suitable for use.in psychological research and clinical settings (23). This self-report instrument consists of 21 items, categorized into three subscales: depression, anxiety, and stress (7 items each). The Persian version of the DASS-21 exhibited strong internal consistency (Cronbach's alpha = 0.93) and satisfactory validity (24). The questionnaire consists of 21 questions and uses a 4-point Likert scale ranging from (not at all), (little), (a lot) to (very much). The final score for each subscale is calculated by summing the scores of the relevant seven items. The DASS-21 consists of three subscales (depression, anxiety, and stress), each containing seven items. Scores for each subscale range from 0 to 21. Higher scores indicate greater symptom severity.

3.6.3 Brief Illness Perception Questionnaire

Levels of illness perception are measured using the Brief Illness Perception Questionnaire, which was developed by Broadbent and colleagues (25). The questionnaire contains eight items and one question related to causality. A scale of 0 (no impact) to 10 (profound impact) is used to rank each dimension, except the causality question. A score closer to 10 indicates a more negative perception of the disease. Resulting in a total score range of 0 to 80. The reliability of the entire questionnaire and its subscales ranged from 0.59 to 0.73. The Persian version of the BIPQ demonstrates satisfactory reliability and validity when applied to patients with chronic diseases (26).

3.7 Analysis Plan

The data is entered into SPSS software (version 26). Descriptive statistics are used to summarize quantitative variables, including the mean and standard deviation. For qualitative variables, frequency and percentage are reported. To analyze qualitative variables across groups,

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the chi-square test and Fisher's exact test are used. First, the Kolmogorov-Smirnov test is used to determine whether quantitative variables are normally distributed. Mann-Whitney U test will be used. If a confounding variable is present and assumptions are met, analysis of covariance will also be used. To examine changes in means of quantitative variables across different time points within two groups, either the analysis of variance with repeated measures or the non-parametric Friedman test will be performed. The significance level for all tests will be set at 0.05.

3.7.1 Potential Confounder

During the study, demographic characteristics and disease-related information will be examined and recorded. During statistical analysis, confounding effects are considered and adjusted for. In addition, every effort is made to prevent information from being shared between participants in the control and intervention groups. Participants are also requested not to attend disease-related educational classes during the study period.

3.7.2 Participant Compliance

Adherence to the training is monitored weekly by SMS and, if necessary, daily for follow-up. Also, a reminder message will be sent to participants on the training days determined in advance.

3.8 Ethical consideration

It was ensured that all confidential information would be protected before starting the research. Before starting the study, the patients provided informed consent. In addition, participants could withdraw at any time. As part of the current protocol, the best possible implementation method has been considered to prevent participants from suffering physical or financial harm, and if adverse events occur, the responsible parties will compensate the participants. The present study has been approved with the ethical code IR.ARAKMU.REC.1402.199.

4. Discussion

The present protocol is designed to assess the effectiveness of an educational intervention based on the SRM of Leventhal in women with MS. This model considers the individual's perception of the nature, causes, duration, consequences, and controllability of the disease, as well as the related emotional responses in the process of dealing with the disease. Therefore, the current intervention focuses not only on providing information about MS but also on cognitive and emotional components and coping skills within a staged framework comprising representation, coping, and evaluation. This structure is designed to foster the connections among disease awareness, emotional reactions, the implementation of coping strategies, and their evaluation.

Previous studies have shown that interventions on Leventhal's self-regulatory method differ in executive structure and human resource composition. In the study by Khodaparast et al. (20) on women with gestational diabetes, the researcher deliver intervention individually and face-to-face over three consecutive sessions, each lasting 60 to 90 minutes, in a private setting. The intervention components included educating patients about disease perception, exploring their feelings and ambiguities, providing personalized education, goal setting, feedback, and behavior evaluation. In a study on patients with hypertension (17), the intervention was conducted over five weekly 60-minute sessions with a nurse, psychologist, and nutritionist, focusing on cognitive, emotional, and lifestyle-related components in different sessions. Additionally, in the study by Karampour et al. (27) on MS patients, the self-regulatory program was implemented over five weekly sessions, each lasting approximately 60 minutes, based on the cognitive dimensions of Leventhal's model, and individual counseling was provided as needed. Overall, these studies demonstrate that interventions based on the Leventhal model can range from individual and intensive education to multi-session programs with team involvement and individual counseling. In contrast, the current protocol, given the chronic and variable nature of MS, combines in-person education, offline content, and online sessions to increase access to the intervention and reduce the need for frequent physical presence by the patient and the implementing team.

One operational strength of this protocol is the combination of cognitive and emotional training with peer support and the asynchronous delivery of educational content. The program includes topics such as disease recognition, progression, and manageability, stress management, and problem-solving, alongside opportunities for interaction and experience-sharing with other patients. This approach allows patients to receive educational content gradually while staying engaged with the program without the need for frequent in-person sessions.

In terms of human resources and costs, utilizing pre-prepared content and asynchronous training can reduce the need for continuous researcher presence and continuous use of educational spaces. However, creating multimedia content initially requires time and resources; thus, this approach reduces some operational needs and associated costs of in-person sessions rather than completely eliminating them.

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Based on the population's characteristics, content localization has been taken into account. The program also contains information on MS as well as stress management, problem-solving, anger management, depression management, and peer support. This is not just a translation of the content and is focused on the educational and psychological requirements of the target patients.

Despite these benefits, challenges are anticipated in implementing the intervention. Excessive dependence on smartphones for part of the training and technological skills may limit some people, and it is therefore proposed to conduct preliminary training on the educational platform and SMS tracking and reminders. Other practical difficulties to be addressed include a stage-by-stage approach to the content, follow-up with participants, and avoiding information transfer between the two groups (to maintain engagement throughout the intervention). Further, the findings may be limited to the sample used, as random and blocked allocation of participants will minimize allocation bias. Peer support may also face challenges, such as differences in member participation levels or inconsistent sharing of experiences with educational content; therefore, group interactions will be conducted within a defined framework and guided by the researcher.

Overall, the current protocol adheres to the theoretical underpinning of the self-regulating Levonthal model, adapting the length and type of intervention to the MS patient's characteristics, while aiming to maintain a balance between personalization, flexibility and feasibility. Furthermore, from the beginning the design has considered problems of technology, engagement, 'information overload' and generalizability, and procedures have been thought of to lessen the impact of these.

4.1 Limitation

This study protocol acknowledges several potential limitations. First, the generalizability of the findings may be limited by the specific patient population and the single-center setting. Second, the study relies on self-reported data, which may have introduced social desirability or recall bias among participants. Some factors also cannot be fully controlled, even though participants with MS relapses, hospitalizations, major changes in treatment, or pregnancy may be withdrawn from the study. These include differences in family/social support, unexpected stressful life events, adherence to the educational program, coping strategies, resilience, and minor changes in medications not meeting the exclusion criteria. These variables could affect psychological outcomes and illness perception and should be considered when interpreting the study results.

4.2 Conclusion

This article will be the first randomized trial to focus on both physical and emotional aspects of Leventhal's SRM in women with MS. The study aims to determine the efficacy of this intervention in improving illness perception and reducing the severity of psychological symptoms, including depression, anxiety, and stress. This trial is registered with the Iranian Clinical Trials Registry (IRCT) under the code: IRCT20220703055351N3.

Statements

AI Use: AI tools were utilized solely for proofreading and improving the clarity of the text.

Authors' Contribution: M. H. made substantial contributions to methodology, investigation, data curation, analysis, and writing of the article draft. S. Sh. was responsible for project administration, supervision, writing, and editing of the article. A. J. served as the official dissertation advisor and contributed to reviewing and editing the article. F. R. supervised data analysis and contributed to review and editing. All authors reviewed and approved the final version of the manuscript and agree to be accountable for its content.

Conflict of Interests: The authors declared no conflicts of interest.

Ethical Approval: The present study has been approved under ethical code IR.ARAKMU.REC.1402.199 and has undergone review by Arak University of Medical Sciences. Informed consent for participation will be obtained from all participants.

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