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Research Article

Design and Clinical Trial of a Psychotherapy Protocol for Depression Based on the Explanatory Model of Depression in Patients with Multiple Sclerosis

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Abstract

Background: Depression is common in patients with multiple sclerosis (MS). The present study aimed to develop and clinically evaluate a depression psychotherapy protocol based on an explanatory model of depression in patients with multiple sclerosis (MS).

Objectives: To evaluate the effectiveness of the developed protocol in reducing depressive symptoms.

Methods: In an experimental pretest–posttest study with one-month follow-up, 40 patients with MS and depression aged 20–50 years in Hamadan, Iran, were recruited and assigned to experimental and control groups. Depression was assessed using the Beck Depression Inventory–Second Edition (BDI-II). The eight-session protocol addressed neuropsychopathological, emotional, and behavioral factors. Data were analyzed using ANCOVA.

Results: Significant between-group differences were found at posttest ($F(1, 27) = 743.92$, $p < 0.0001$) and one-month follow-up ($F(1, 27) = 887.41$, $p < 0.0001$), indicating reduced depressive symptoms with maintained effects.

Conclusion: These findings suggest that a psychotherapy protocol based on an explanatory model of depression in patients with MS can be developed and may effectively reduce depressive symptoms. Further investigation of this multicomponent approach is warranted, particularly in larger samples and with longer follow-up periods.

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Extended Abstract

Introduction

Multiple sclerosis (MS) is a chronic inflammatory, demyelinating, and neurodegenerative autoimmune disease of the central nervous system. Its unpredictable physical, cognitive, behavioral, and emotional symptoms can affect patients' daily functioning, independence, social relationships, and quality of life. Depression is a common psychological comorbidity in people with MS and may further increase their distress and impair their well-being. Although several interventions, including mindfulness-based approaches, acceptance and commitment therapy, cognitive behavioral therapy, physical activity, and cognitive rehabilitation, have been investigated for depression in this population, the findings have not been uniformly positive. One possible explanation is that conventional interventions may not adequately address the multiple factors contributing to depression in MS. An explanatory model developed for this population identifies neuropsychopathological factors as primary antecedents of depression, with emotional and behavioral factors also contributing directly or indirectly. The present study aimed to develop and clinically evaluate a depression psychotherapy protocol based on this explanatory model in patients with MS.

Method

The study employed an experimental pretest–posttest design with a follow-up assessment. The study population comprised patients aged 20–50 years with MS and a diagnosis of depression in Hamadan, Iran, during the Iranian calendar year 1400 (2021–2022). Eligibility criteria included a confirmed diagnosis of MS by a neurologist, at least six months since disease onset, and a diagnosis of depression based on a clinical interview and the Beck Depression Inventory–Second Edition (BDI-II). Forty participants were recruited through convenience and voluntary sampling and randomly assigned in equal numbers to experimental and control groups across two phases: a pilot phase involving 10 participants (five per group) and a clinical trial phase involving 30 participants (15 per group). The BDI-II was used to assess depressive symptoms. The protocol was developed based on the explanatory model of depression in MS, whose structural relationships had previously been examined using structural equation modeling. The intervention comprised six components: (1) psychoeducation about MS, its neurological effects, common physical and psychological symptoms, depression, and the relationships among neurological, emotional, and behavioral difficulties; (2) neuropsychological exercises using colored blocks and a modified Tower of London task; (3) emotion-regulation interventions drawing on concepts from dialectical behavior therapy; (4) coping-based behavioral interventions addressing responses to MS and supporting more problem-focused coping; (5) behavioral interventions targeting physical symptoms, incorporating mindfulness and identifying feasible activities in light of illness-related limitations; and (6) a review of the skills, exercises, and clinical changes addressed in previous sessions. The protocol was delivered over eight sessions: an initial clinical interview and pretest, six individual psychotherapy sessions, and a posttest session. Sessions were conducted weekly. The intervention was first evaluated in the pilot phase and subsequently administered in the clinical trial phase. Control participants received no intervention in either phase. Both groups were reassessed one month after the intervention. Pilot-phase group differences were examined using the Mann–Whitney U test. In the clinical trial phase, separate univariate analyses of covariance (ANCOVAs) were conducted for

posttest and follow-up scores, controlling for pretest scores. Statistical analyses were performed using SPSS version 21.

Results

In the pilot phase, the experimental and control groups differed significantly in depression scores at posttest ($Z = -2.61$, $p = 0.009$) and at the one-month follow-up ($Z = -2.62$, $p = 0.009$), supporting further evaluation of the protocol. In the clinical trial phase, ANCOVA revealed a statistically significant between-group difference in posttest depression scores after controlling for baseline scores, $F(1, 27) = 743.92$, $p \leq 0.0001$. A significant difference was also observed at the one-month follow-up, $F(1, 27) = 887.41$, $p \leq 0.0001$. These results indicate that the intervention significantly reduced depressive symptoms compared with the control condition at posttest and that its effects remained evident one month after treatment.

Conclusion

The findings indicate that a depression psychotherapy protocol grounded in an explanatory model of depression in MS can be developed and may significantly reduce depressive symptoms, with effects maintained at the one-month follow-up. By addressing neuropsychological, emotional, coping-related, and physical-symptom-related factors in a structured sequence, the protocol offers a multicomponent approach tailored to the difficulties experienced by patients with MS. However, the findings should be interpreted in light of the small sample size, convenience-based recruitment, and short follow-up period. Further studies involving larger and more diverse samples, longer follow-up assessments, and direct comparisons with established interventions are needed to determine the durability of the effects and the intervention's relative effectiveness.

Author Contributions: Authors 2 & 3 were responsible for leading the overall research process. Author 1 was responsible for research plan design, data collection and analysis. Authors 4 & 5 were consulted in this research .All authors discussed the results, reviewed and approved the final version of the manuscript.

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