ORIGINAL RESEARCH

The Effect of Mindfulness-Based Stress Reduction on Restless Legs Syndrome in Hemodialysis Patients: A Randomized Clinical Trial

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Article Info	Abstract
	Background: There is currently no definitive cure for restless legs syndrome (RLS), and the common treatments are only used to reduce symptoms. Mindfulness-based stress reduction (MBSR) is an intervention that has shown beneficial effects in many mental and physical disorders. **Purpose:** This study aimed to determine the effect of MBSR on RLS in hemodialysis patients. **Methods:** This study was a randomized clinical trial involving 60 hemodialysis patients with RLS recruited by convenience sampling each group. Inclusion criteria were patients with RLS diagnosis, age 18-65, Hb>10, no cognitive disorders, ability to read and write, no vision or hearing problems, and history of hemodialysis ≥6 months. The intervention group received eight sessions of the MBSR program, and the control group received routine care in a government dialysis center. International Restless Legs Syndrome Scale and Restless Legs Syndrome Severity Scale were used to measure RLS. Statistical analyses were conducted using independent and pair t-test and ANCOVA. **Results:** Significant difference was found in the severity of RLS scores (Mean(SD)) between the intervention group (12.90(4.58)) and the control group (22.27(4.19)) (95% CI:-11.66 to -7.08, p<0.0001). The effect size between groups was obtained based on Cohen's d of 2.13. **Conclusion:** MBSR showed a significant reduction in the severity of RLS in hemodialysis patients. This preliminary study suggests that MBSR can be a promising treatment option in the management of RLS patients.

1. Introduction

Restless legs syndrome (RLS) is a sensory-motor disorder of the limbs that is very prevalent among the general population (Darvishi et al., 2020); it is characterized by unpleasant sensations and an irresistible urge to move the legs (de Menezes et al., 2018). The most prevalent and important complications in patients undergoing hemodialysis (HD) include muscle cramps, sleep disorders, and RLS (de Menezes et al., 2018; Kusuma et al., 2018). In addition, RLS can be associated with mental disorders, sleep disorders, increased risk of cardiovascular diseases, and increased risk of mortality in these patients. The prevalence of RLS in HD patients has been reported to be 40.7% in China (Zhang et al., 2020), 16.8 in Turkey (Turk et al., 2018), and 31.7% in Tehran (Chen et al., 2022). Some factors affect RLS severity, including lifestyle factors, such as stress and anxiety, lack of physical activity, obesity, cigarette smoking, alcohol intake, and consumption of coffee (Batool-Anwar et al., 2016).

People with RLS may experience chronic insomnia, daily drowsiness, and stress. These conditions interfere with patients' daily functional roles, prevent them from enjoying life, have negative effects on their social activities and family life, and increase the anxiety and depression of these patients (Basaran & Tas, 2022). A study found that RLS is one-third of sleep disorders in people over 60 years of age (Myc et al., 2018). A study has also shown that this syndrome has a negative effect on the quality of daily life of patients (Rikos et al., 2019). There is currently no definitive cure for RLS, and the common treatments are only used to reduce symptoms (Selfe et al., 2019). Pharmacotherapy, alternative therapies, and psychological therapies are among the

available treatments for RLS (Bablas et al., 2016; Cochen De Cock, 2019; Hashemi et al., 2015). Pharmacotherapies include sedatives, anxiolytics, dopaminergics, and analgesics, all of which have serious side effects such as nausea, vomiting, hypotension, dizziness, insomnia or drowsiness, and blurred vision (Guay et al., 2020; Silber et al., 2021; Song et al., 2020). Due to the side effects of drug treatments, the use of alternative and psychological therapies has been considered. Cognitive-behavioral therapy (Hornyak et al., 2008), yoga (Innes et al., 2013), and progressive muscle relaxation (Mousavi et al., 2016) are some of the effective psychological therapies in RLS which have been investigated in different studies.

Today, Mindfulness-Based Stress Reduction (MBSR) is used as one of the treatments for a wide range of psychological problems, such as anxiety, depression, and sleep disorders (Chen et al., 2022). MBSR means to focus one's intentional attention on the experience which is currently going on. This attention has a non-judgmental character accompanied by acceptance (Norouzi et al., 2020). Although there is no definitive treatment for RLS, and this disorder is one of the psychiatric disorders in the family of sleep disorders, and its symptoms and consequences include anxiety problems, and depression, there are limited studies investigating the effect of mindfulness on the severity of RLS (Bablas et al., 2016). The researchers recommend further studies in this area and in different conditions (Yang et al., 2020). Therefore, given the high prevalence of RLS in HD patients, its complications and consequences, and the need for psychological therapies to help these patients, this study was conducted to determine the effect of mindfulness-based stress reduction on restless legs syndrome in hemodialysis patients.

2. Methods

2.1 Research design
This study was a randomized, single-blind, clinical trial study.

2.2 Setting and samples
This clinical trial was conducted from November to December 2020 on 60 hemodialysis patients with RLS in a government dialysis center in Kashan, Iran. According to the mean estimates of 9.85 and 9.69, and the standard deviation difference of 7 in the previous similar study (Mousavi et al., 2016), as well as the 95% confidence level and 80% test power, the sample size was determined to be 30 subjects in each group.

Inclusion criteria were patients with RLS diagnosis (receiving a score of 4 from the International Restless Legs Scale), 18-65 years old, full consciousness, Hb>10, no peripheral neuropathy, no cognitive disorders based on the patient's clinical record, ability to read and write, no vision or hearing problems that interfere with the study, and a history of at least six months of hemodialysis. Exclusion criteria included absence in more than two sessions of intervention and migration during the study. The patients were then allocated to the intervention and control groups by block randomization (selection of quadruple and senary blocks). The sample selection is illustrated in Figure 1. The study was single-blind, so data collection was done by a nurse as a research colleague who did not know the type of groups.

2.3 Intervention
The intervention group underwent eight of 1.5-hour sessions (two sessions per week) at intervals of two days and in 3-4-subject groups by the first author, who was trained in an MBSR program in a course (16 sessions), under the supervision of the second author who has more than eight years of experience in leading group therapy in the area of psychological treatments, during her MSc psychiatric nursing. Given the Covid-19 pandemic, the intervention was performed in a room with a calm and suitable environment for education in the dialysis center and observing the health protocols and social distancing, and using a mask. The control group received routine care. They also received a training pamphlet on RLS care designed by the North American Nursing Diagnosis Association (NANDA). MBSR content was designed based on the study protocol of Bablas et al. on patients with RLS according to Kabat-Zinn's protocol (Bablas et al., 2016). In this intervention, techniques such as body scanning, yoga, sitting meditation, mindfulness of emotions and physical pain, mindful breathing, mindful walking, recognition of strong emotions and accepting and acknowledging their presence, self-reflection and self-management were used in a classroom in the HD center. The content of the intervention is presented in Table 1.
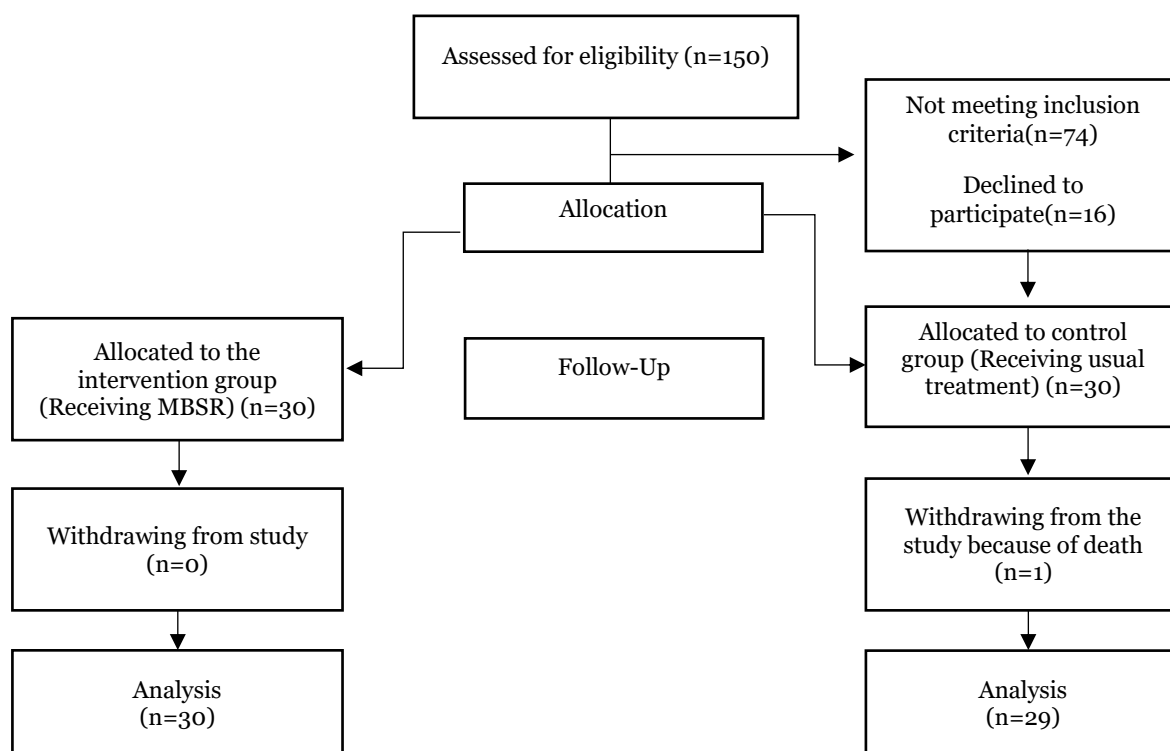
Figure 1. Sample selection chart

Table1. The mindfulness stress reduction program content for HD patients with RLS

Week	Summary of the program
One	Mindful sitting meditation-expanding awareness (15 mins); body scan (25 mins); mindful walking meditation (7 mins); mindful yoga (60 mins [30 mins laying postures and 30 mins standing postures]); mindfulness of emotions and physical pain (15 mins); mindfulness of the breath (8 mins); 3-minute breathing exercise (3 mins).
Two	Participants were guided through sitting with the breath and expanding awareness of the body as a whole, sitting with sound, sitting with thoughts and feelings and choiceless awareness (20 mins), practice breathing meditation for 10-15 minutes
Three	This session involved an introduction and practice of an inactive meditation: the body scan technique. Participants were guided through a 20 min body scan followed by a discussion of their experience. As RLS symptoms can often be brought on by long periods of inactivity, the walking meditation (20 mins) was also introduced and practiced following the body scan.
Four	This included laying and standing yoga postures (45 mins). This was followed by a discussion of their experience and discussion of the benefits of cultivating strength, balance, and flexibility.
Five	The focus of this session was on the identification and recognition of strong emotions and the acceptance and acknowledgment of their presence. In addition, mindfulness was discussed as a stress reduction strategy, and mindfulness of emotions and physical pain (10-15 mins) guided meditation was performed.
Six	The second half of this session focused on the effects of 'autopilot' and mindfulness in everyday life. The formal and informal practice was discussed, and a discussion of how to incorporate these into everyday routines. Participants were instructed to incorporate the informal practice into their routines as much as possible and to continue with their choice of formal meditation (30-45 mins) for at least six days that week.
Seven	Sitting meditation, body scan meditation, yoga, awareness of breathing meditation, loving-kindness meditation, being with baby meditation, mindfulness exercises for activities of daily living,
Eight	The final session was used primarily for self-reflection and to generate a summary of the program. Participants discussed their experiences and adhered to their understanding of how mindfulness can be used to self-manage RLS and related symptoms.

2.4 Measurement and data collection

The questionnaire consisted of three parts: 1) International Restless Legs Syndrome Scale (IRLSS); 2) Demographic information questionnaire including age, sex, education, marital status, occupation, history of underlying diseases, number of dialysis sessions per week, dialysis history, and number of children; and 3) Questionnaire to assess the severity of restless legs syndrome.

2.4.1 International restless legs syndrome scale

IRLSS, which has been recommended by the International Restless Legs Syndrome Study Groups (Walters et al., 2003), includes 1) Frequent movement of the legs with abnormal sensation in the skin of the legs; 2) Temporary relief of unpleasant symptoms by moving the legs; 3) The onset or exacerbation of symptoms while resting or not moving the legs, and 4) The onset or exacerbation of symptoms in the evening or night. The individuals with all four criteria were considered patients with RLS. The RLS scale is a standard instrument whose validity and reliability have been measured in previous studies. In this study, we used the Persian version of the scale based on the Iranian culture. The reliability of this questionnaire was estimated to be 0.95 by using Cronbach's alpha method (Hemmati & Alidosti, 2012).

2.4.2 Restless legs syndrome severity scale

The questionnaire has 10 five-choice questions, and each question is scored between 0 and 4. The total score is between 0 and 40, indicating the severity of the disorder. The higher the score, the more severe the restless leg syndrome will be. Habibzadeh et al. (2011) have confirmed the reliability of this questionnaire with a Cronbach's alpha coefficient of 0.97.

Measurements were conducted two times; the beginning of the study (pre-test) and the fourth week study (post-test). Indeed, post-test was at the end of eight MBSR sessions in the intervention group and fourth weeks after the start of the study in the control group.

2.5 Data analysis

The Kolmogorov-Smirnov test was used to test the normality of variables. Data were normally distributed; thus, parametric tests were used. The exact Fisher test and independent t-test were used to compare demographic variables in the two groups. Paired t-test and independent t-test were used to compare the Mean(SD) of RLS within and between groups, respectively. Cohen's d effect size (ES) was calculated between the group. Between-group comparisons in score changes were performed using analysis of covariance (ANCOVA), controlling for baseline score. The significance level was set at less than 0.05 in all the tests. Statistical analyses were performed using SPSS version 16 (SPSS Inc., Chicago, IL, USA).

2.6 Ethical considerations

This study was confirmed by the institutional review board and the ethics committee of the University of Medical Sciences (IR.KAUMS.MEDNT.REC.1398.068). The objectives of the study were stated for all patients, and informed written consent was signed by them. The current research was registered at the Iranian Registry of Clinical Trials (IRCT) with a registration code of IRCT20130721014086N13.

3. Results

The total number of samples assessed for eligibility was 150, of whom 60 patients who had the inclusion criteria were included in the study and were randomly allocated to the control and intervention groups. One patient in the control group died and was excluded from the study, and finally, the analysis was performed on 59 HD patients with RLS (Figure 1).

3.1 Demographic characteristics of the respondents

The mean age of the subjects in the intervention group was 55.33(10.97) (ranging from 40 to 60 years), the mean number of children was 3(1.50), and the mean history of dialysis was 56(32.47). In this study, most of the patients were married (86.7% in the intervention group and 79.3% in the control group). The independent t-test did not show a significant difference between the two groups in terms of variables, and the variables were identical (Table 2).

Table 2. Demographic characteristics of the intervention and control groups[†]

Variables	Intervention group (n=30)	Control group (n=29)	*p*-value
Age (year)	55.33(10.97)	51.27(11.32)	0.16*
Number of children	3(1.50)	2.89(2.02)	0.82*
History of dialysis (month)	56.93(32.47)	48.20(37.49)	0.34*
Gender			
Female	11 (36.7%)	12 (41.4%)	0.45**
Male	19 (63.3%)	17 (58.6%)	
Marital status			
Single	4 (13.3%)	6 (20.7%)	0.34**
Married	26 (86.7%)	23 (79.3%)	
Having children			
Yes	26 (86.7%)	23 (79.3%)	0.34**
No	4 (13.3%)	6 (20.7%)	
Occupation			
Occupied	17 (56.7%)	18 (62.1%)	0.43**
Retired	13 (43.3%)	11 (37.9%)	
Education			
Undergraduate	19 (63.3%)	17 (58.6%)	0.45**
Diploma	11 (36.7%)	12 (41.4%)	

Notes.
[†] Data are presented as f(%), except age, the number of children and history of dialysis, which are presented as mean(SD).
* Obtained from Independent *t*-test.
** Obtained from Fisher Exact test.

3.2 The difference in RLS score between groups

As shown in Table 3, the independent t-test showed no significant difference in the severity of RLS between the intervention group (24.33(4.46)) and the control group (23.44(3.18)) at baseline (t=0.87, df=57, 95% CI:-1.14 to 2.91, *p*>0.05). However, at the end of the study, this test showed a significant difference in the severity of RLS between the intervention group (12.90(4.58)) and the control group (22.27(4.19)) (t=-8.18, df=57, 95% CI:-11.66 to -7.08, *p*<0.0001).

3.3 The difference in RLS scores within groups

The paired t-test showed a significant difference in the severity of RLS before the intervention (24.33(4.46)) and after one month of mindfulness (12.90(4.58)) in the intervention group (t=12.99, df=29, 95% CI:9.63 to 13.23, *p*<0.0001). By contrast, no significant difference was observed in the severity of RLS before the intervention (23.44(3.18)) and after one month of mindfulness (22.27(4.19)) in the control group (t=1.52, df=28, 95% CI:-0.4 to 2.74, *p*=0.13) (Table 3).

3.4 The effect of MBSR on RLS after controlling the confounding factors

According to the results of covariance analysis, the mean severity of RLS in the intervention group was significantly lower than in the control group (F=85.69, Adjusted R:0.6, *p*<0.0001) (Table 3). Adjusting the analyses for the participants' general characteristics, no significant difference in age (*p*=0.3) and dialysis history (*p*=0.16) was observed.

For effect size estimates between groups, Cohen's d=2.13 showed that the effectiveness of the intervention was very large.

Table 3. Comparison of pre-test and post-test of the severity of RlS between two groups [a]

Variables		Intervention group n= 30	Control group n= 29	*P* [b]	*P* [d]
Severity of RLS	Before	24.33 (4.46)	23.44 (3.18)	0.38	0.0001[e]
	After	12.90 (4.58)	22.27 (4.19)	0.0001	
	P [c]	0.0001	0.13		

[a] Data are presented as Mean(SD); [b] Obtained from Paired t-test; [c] Obtained from Independent t-test; [d] Obtained from ANCOVA; [e] Adjusted R Squared = 0.60

4. Discussion

This study aimed to investigate the effect of MBSR on RLS severity in HD patients. The findings indicated that a mindfulness-based stress reduction program was effective in reducing the severity of RLS. MBSR could be effective by increasing the capacity to accept thoughts and emotions and modulating and reducing negative and dysfunctional thoughts (Jalali et al., 2017). In addition, mindfulness helps people to identify situations that lead to discomfort and pain, gain a better understanding of themselves, and learn coping strategies in dealing with these situations (Mohammed et al., 2018) and, consequently increasing the indicators of well-being and psychological health (Jalali et al., 2017). The result of this study is congruent with a previous study by Bablas et al. (2016) that examined the effect of MBSR on women with RLS admitted to a sleep clinic. It was found that MBSR effectively reduced the severity of RLS and its consequences, such as anxiety and depression, and showed improvement in the quality of life and the quality of sleep (Bablas et al., 2016).

Effective mechanisms of mindfulness include coping/encountering, cognitive change, self-management, relaxation, and acceptance; all of which can reduce the severity of pain and discomfort (Khoo et al., 2019). Various studies have measured the effect of effective mechanisms in mindfulness intervention on RLS and kidney patients separately. Mousavi et al., for instance, revealed that progressive muscle relaxation effectively reduces pain intensity and RLS symptoms (Mousavi et al., 2016). Furthermore, Innes et al. (2013) also indicated that yoga significantly increased sleep quality and mood and reduced the prevalence of insomnia and hypertension in middle-aged women with RLS.

Mindfulness practice through various pathways affects pain (Zeidan et al., 2011). First, manipulating attention in meditation practices might impress both sensory and affective components of pain perception. Second, mindfulness reduces the reactivity to distressing thoughts and feelings that accompany and strengthen pain perception. Third, mindfulness reduces psychologic symptoms such as comorbid anxiety and depression and finally increases parasympathetic activity, which can promote deep muscle relaxation that may reduce pain (Omidi & Zargar, 2014). Therefore, it seems that mindfulness mechanisms can affect the severity of RLS. Research has also shown that MBSR training, combined with relaxation and mental meditation through breathing and thinking, is associated with a variety of health outcomes, such as the relief of pain, stress, anxiety, and depression (Sobhani et al., 2019). Vøllestad et al. (2011) argued that MBSR had an effect on anxiety disorders and other disorders whose symptoms were similar to anxiety disorders and reduced these symptoms. Cho et al. (2017) also indicated that MBSR is an effective program for controlling stress in HD patients. Furthermore, Haghshenas et al. (2019) showed that MBSR significantly reduced anxiety and depression in HD patients. Therefore, since RLS is a psychiatric disorder with symptoms and consequences such as pain, stress, anxiety, and depression, it seems that MBSR can have an important effect on RLS in HD patients by reducing psychological problems such as stress, anxiety, and depression and, thus, leads to pain reduction.

In a previous study, cognitive therapy was introduced as an effective method for reducing the symptoms of depression, anxiety, and stress in renal patients undergoing HD (Khoshkhatti et al., 2020). However, studies have revealed that the effect of MBSR treatment in reducing the stress of HD patients has been more than cognitive-behavioral interventions (Khoshkhatti et al., 2020) and commitment-based psychotherapy (Yasaie Sokeh et al., 2017). Therefore, because of its focus on the present time and acceptance as well as being conducted in groups, MBSR treatment seems to be more effective in reducing the severity of RLS, which indeed requires further studies and comparison in these patients.

According to studies, the duration of each mindfulness training session and the exercises and tasks which should be performed at home are the factors increasing the effect of mindfulness programs on RLS (Haghshenas et al., 2019). Therefore, this factor was also considered in the present study. The researchers also tried to follow up on the exercises and tasks through weekly phone calls (if needed) and text messages. Additionally, we tried to adjust the time according to the content so that it could be most effective.

5. Implications and limitations

MBSR can be included as an alternative treatment in nursing interventions for hemodialysis patients with RLS. Teaching and learning the techniques and components of mindfulness help nurses provide holistic care by considering the psychological aspects of RLS for patients. Nurses

in general or hemodialysis nurses could implement MBSR to help RLS patients reduce their pain, agitation, and other related symptoms of RLS.

The present study has been successful in investigating the effect of MBSR on reducing the severity of RLS in HD patients; however, some limitations are warranted. One of the limitations of this study was the lack of blinding the study so that participants might receive information from other sources or the interaction of patients with each other, which were not within the control of the researchers. Also, limited controls of the confounding factors of RLS, such as stress and anxiety, should be considered in future studies.

6. Conclusion

This preliminary study showed that the implementation of the MBSR program significantly reduced the severity of RLS in HD patients. MBSR has the potential to be a complementary healthcare program for patients with RLS. Accordingly, it may be recommended for health professionals to add MBSR to their interventions. Further research can evaluate the use and continuity of the effectiveness of this treatment as a complementary treatment in patients. It is suggested that more follow-ups be performed in future studies to evaluate the long-term effects of this intervention. Moreover, it is recommended that more research be conducted to compare the effects of other psychological therapies with MBSR on the severity of RLS in patients.

Acknowledgment

Author contribution

All authors contributed to the study's conception and design. Material preparation and data collection were performed by ZD and MA. The analysis and final draft of the manuscript were written by MA.

Conflict of interest

No potential conflicts of interest.

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