



The effect of yoga on the severity of symptoms of restless leg syndrome: a randomized controlled trial

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Introduction: Restless leg syndrome is a sensory motor disorder that is more common in patients with type 2 diabetes and leads to sleep disorders, lack of control of blood sugar, increased complications, and mortality. **Objective:** the present study was conducted in order to determine the effect of yoga on the severity of symptoms of restless leg disorder in patients with type 2 diabetes. **Materials and methods:** The present randomized, one way blinded clinical trial study was conducted with pre-test and post-test and control group; the statistical population included 114 patients with type 2 diabetes admitting to Tohid Medical Clinic affiliated to Kurdistan University of Medical Sciences. Patients were randomly assigned to two groups of control and intervention in blocks of four using state direct software. Required data was collected through a demographic questionnaire, a four-item questionnaire about restless leg syndrome screening, and a questionnaire of 10 standard questions about the severity of restless leg syndrome. After completing the questionnaire at the beginning of the study, the intervention group received yoga training for 8 weeks in 60-minute sessions. At each session, the intervention group subjects received training pamphlets and a home checklist for conducting and recording homework; additionally, only routine treatments were provided to the control group. At the end of the eighth week, the severity of restless leg syndrome was again measured in two groups. Collected data was analyzed using SPSS 20 and Chi-square, t-test, Independent T, and paired t test. **Results:** there turned out to be a significant difference between mean restless leg syndrome before and after yoga training in the intervention group. ($P=0.00$).

INTRODUCTION

As a chronic and non-communicable disease, diabetes mellitus has emerged as one of the major challenges of health systems throughout the world (1). According to the World Federation of Diabetes (IDF), more than 382 million people in the world have diabetes in 2013, and this rate is estimated to reach 592 million by 2035 (2). The increasing prevalence of diabetes mellitus and its complications are one of the most important causes of death in the world (3). Peripheral neuropathy is one of the most common chronic complications of diabetes; this disorder can lead to loss of quality of life in diabetic patients through inducing numbness, ulcers and ultimately amputations (4). Neuropathy is also known to be a risk factor for increasing the prevalence of restless leg syndrome in diabetic patients. The prevalence of this syndrome is 17.7 to 21% in diabetic patients (5, 6) and 7-10% in general population (7). Restless legs syndrome is a sensory motor disorder involving a

continuous movement of the legs during resting periods; it usually appearing at night and is often associated with an unpleasant feeling of numbness, pain, sagging, tingling, burning and a feeling like the movement of insects on the skin (8). International Restless Legs Syndrome Study Group (IRLSSG) outlines five essential clinical features to diagnose the syndrome in its 2012 revision: 1. Severe and uncontrollable tendency to frequent leg movements with uncomfortable and unpleasant feelings. 2. More severe manifestation of symptoms during rest periods 3. Relief of complete or partial symptoms by moving the legs 4. Exacerbation of symptoms at nights or at the end of day 5. These symptoms are not the primary signs of the disease and other medical conditions (9).

Sleep disorder is the most important complication of restless leg syndrome; it involves delayed onset of sleep, difficulty in maintaining sleep, reducing the total sleep time, not having or reduced peaceful sleep (10). Disabling symptoms are chronic deprivation of sleep, discomfort, and fatigue, leading to weakened individual performance in occupational, social, and family activities, as well as a reduction in self-care and increased complications of the disease (6, 11) Chu (2014) study shows that 49% of type 2 diabetic patients suffer from sleep disorders (12).

The purpose of the treatment of restless leg syndrome is to relieve symptoms and improve the quality of sleep (13). There is no definitive

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treatment for restless leg syndrome, and existing therapies include dopamine agonists, anticonvulsants, opiates, hypnotics, benzodiazepine, and iron supplements, which can lead to many complications in case of long-term use (14). The use of complementary and alternative medicine is another part of the treatment that, in addition to the complications and interactions of drug therapies, maintains patient autonomy, easy acceptance of treatment, and proper collaboration on the side of the patient at low cost (15).

Yoga is a branch of complementary medicine, a unique form of exercise that has a holistic view towards humans and its physical, mental, psychological and spiritual needs. Physical exercises practiced during Yoga enhance muscle strength, flexibility, maintains balance, improves hormonal function and reduces fatigue (16). This method is easy, inexpensive, without the need for equipment and has significant implications for the management and prevention of type 2 diabetes (17). Mundal's study (2018) illustrates the beneficial effects of yoga on type 2 diabetes by reducing blood glucose and lipids (18). Yoga is one of the least complicated exercises that has been shown to have a positive therapeutic effect on chronic diseases, including osteoarthritis and decreased inflammation of the joints (19, 20). Regarding the complications of drug therapies and increasing the cost of treatment for restless leg syndrome, it is essential to perform non-pharmacological interventions to improve and overcome this disorder. Performing yoga exercise does not require any special space and patients can easily learn and practice at home in form of training, which, in turn, can reduce the severity of symptoms of restless leg syndrome by reducing the need for medication. Therefore, the present study was designed to determine the effect of yoga on decreasing the symptoms of restless leg syndrome.

METHOD AND METHODS

The present pre-test and post-test clinical trial was approved by the Ethics Committee under the number of 4112/23529 and registered in the clinical trial registration system with the code of [IRCT20170815035723N2](#). The license from the university's vice president was obtained to conduct a research on type 2 diabetes patients admitting to Tohid Hospital clinic affiliated to Kurdistan University of Medical Sciences in Sanandaj, Iran, in 2017. This study was conducted on 114 subjects. Having Type 2 diabetes, non-insulin consumption, restless leg syndrome based on the diagnosis of the doctor responsible for the diabetes center and the questionnaire 4 questions of screening for restless leg syndrome, being ages 18 to 65, the ability to receive and do yoga exercises, and not having other chronic diseases and heart disease were the main inclusion criteria. Exclusion criteria included any changes in the general condition of the body during exercise, unwillingness to continuous exercise during the study, reluctance to continue to participate in the research, having a mental disorder, severe blood glucose, seizure, coma and death.

The overall number of patients in the chemotherapy center was about 200 individuals; so according to similar previous studies and using a statistical formula the size of the sample was estimated to be 114 individuals. By using advice from statistics experts, T-test, Independent T, and paired T test were practiced. The standard questionnaire contained ten questions, including severity of the syndrome, the extent of need to move the leg, the amount of relief resulting from the movement of the legs, the severity of sleep disturbance, the severity of fatigue and drowsiness, the overall syndrome severity, duration of the symptoms, average symptom severity, the effect of the symptoms on everyday life, and the severity of mood disorder. These questions were used in collecting data as well as in discussions and the conclusion.

Given that the prevalence of restless leg syndrome is reported to be about 18% in diabetic patients in various studies and 5% in general population, the patients were, using the following formula, randomly divided into two groups of intervention and control, using State Direct software, in blocks of four with a confidence of 95% and the test power of 80%:

$$n = \frac{\left(Z_{1-\frac{\alpha}{2}} + Z_{1-\beta}\right)^2 (\sigma_1^2 + \sigma_2^2)}{(\mu_1 - \mu_2)^2}$$

The minimum sample size was 51 in this study in each group, which including the sample loss, was considered to be 57 subjects.

Required data was collected using three questionnaires: 1. A demographic and clinical data collection form that includes age, sex, education, occupation, marital status, place of residence, drug use, and duration of diabetes. 2. A four-dimensional screening scale that includes four criteria for repeated movements of the leg with an unpleasant sensation, exacerbation of symptoms by rest, relief of symptoms by moving and exacerbation of symptoms at night; patients who responded to each of the four questions and had experienced it at least once a month were considered to have restless leg syndrome (14). 3. The standard question about the severity of restless leg syndrome which includes ten questions of five options, each with 0 to 4 points. The severity of the disorder is based on the points obtained: (0) no problem, (1-10) mild, (11-20) Moderate, (21-30) Severe, (31-40) Very Severe. The screening questionnaire and the severity of restless leg syndrome questionnaire have been designed and approved by the International Restless Legs Syndrome Study Group(21). Validity and reliability of both questionnaires in Iran were confirmed by Habibzadeh (2011) with Cronbach's alpha coefficients of 90% and 97% (22).

Individuals who met the inclusion criteria completed the questionnaires after entering the study group and providing their informed consent forms. The severity of the restless leg was measured individually for each participant. The intervention group received necessary training and conducted yoga exercises under the supervision of an experienced Yoga instructor and the researcher during a training session in the Diabetes Clinic of Tohid Hospital in Sanandaj. Yoga classes were conducted once a week for 8 weeks at 60-minute sessions. The yoga technique used was Hatha yoga with light asana, which included proper muscle traction, tendons, ligaments and muscles, especially in the legs and hips, torsional movements and all kinds of carpet motions, forward bending, and proper respiratory techniques with release. In each training session, 45-50 minutes was allocated to physical training and positioning (asana) and the final 10-15 minutes was allocated to muscle relaxation (Savasana). Exercises enough to cover two home sessions and educational pamphlets with a home-based checklist were provided for the participant at each session. The pamphlets included a weekly exercise plan, illustrating how the exercise was supposed to be conducted and the number and duration of each exercise that was provided by the researcher and with the advice of the yoga instructor. Home-exercises checklist includes a column for the name of the exercise, the number of iterations, the timing of each exercise, and the names of the weekdays. Participants were asked to complete the checklist in the column for the same day after finishing their exercises at home. At the start of each week, the patient checklist was evaluated by the researcher within 10 minutes, and the rate of participation and practice at the home was evaluated and their questions

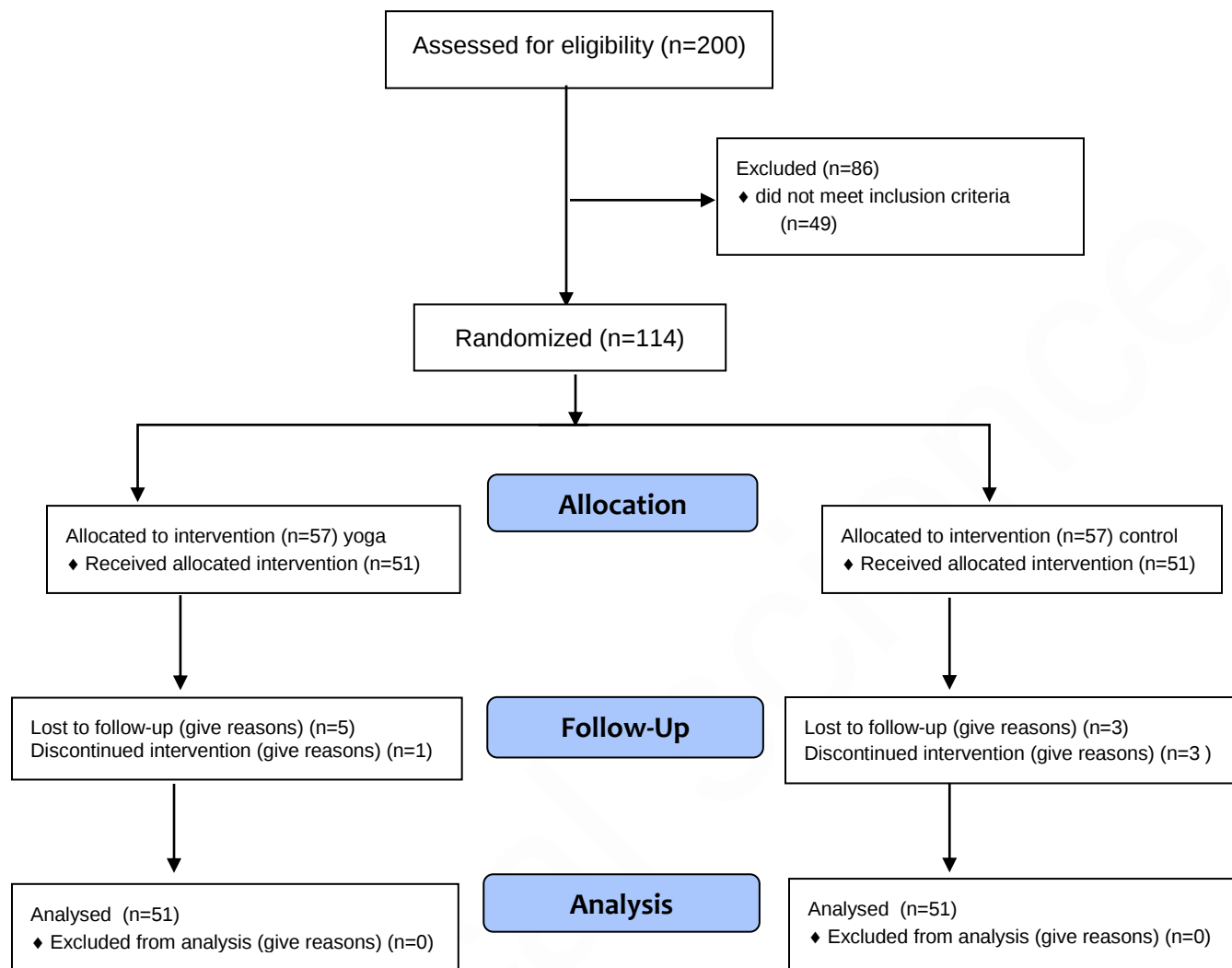


Figure 1 The Flow Diagram of Recruitment and Retention of Participants in the Study

were answered. Patients were examined by a consulting physician during eight weeks and the absence of complications was ensured. By the end of the eighth week, the severity of restless leg symptoms was measured again based on the relevant questionnaire. In order to observe ethical considerations, required training was provided for the control group about doing yoga, correct nutrition and lifestyle modification. Collected data was analyzed by SPSS 20 using Chi-square, t-test, and independent T-test.

RESULTS

Out of 200 patients admitting to the Diabetes Clinic, 114 subjects who met the inclusion criteria were selected for the present study and randomly divided in two groups of intervention and control, each with 57 individuals. 5 subjects in the intervention group were excluded from the study because of their unwillingness to continue the research; additionally, an individual was removed due to intensifying muscle aches. In the control group, one subjects withdrew due to having stroke, two subjects due to the inauguration of insulin therapy and 3 individuals due to the lack of willingness to answer the questionnaires. The study continued with 51 subjects in each group. The total number of

participants in this study was 102. Two groups were examined for demographic characteristics which included age, gender, occupation, marital status, education, place of residence and duration of diabetes. Clinical features are presented separately in Table 1. Data analysis shows that the age of participants is between 28 and 65 years, with an average of (9.311 ± 54.647) in the intervention and 52.745 ± 8.223 in the control group and there was no statistically significant difference between two groups in regard with age. The duration of the disease varied from 1 year to 20 years. Also, the number of female patients was more than male subjects and the majority of patients were married, urban, unemployed, and illiterate. The results of the study showed that most of the patients in the two groups had moderate symptoms; however, the majority of patients in the intervention group turned out to have mild symptoms after the intervention (72.8%). Before conducting the program, in the intervention group, 10 patients had mild symptoms, 34 were moderate and 7 had severe symptoms (13.7%, 66.7%, 13.7%); in regard with the control group, 10 subjects had mild symptoms, 31 were moderate and 10 had severe symptoms before the intervention (19.6%, 60.8%, 19.6%); there was no significant difference between the two groups before the intervention in regard with the severity of

Table 1 Frequency distribution of research samples based on demographic characteristics

Variable		case		control		p-value
		Number	Percent	Number	Percent	
Sex	male	5	4.9	5	4.9	1.000
	female	46	45.1	46	45.1	
Education	illiterate	33	64.7	23	51	0.291
	domain	17	33.3	22	43.1	
	Academic	1	2	3	5.9	
Marital status	Single	8	15.7	9	17.6	0.790
	Married	43	84.3	42	82.4	
Location	town	46	90.2	44	86.3	0.539
	Village	5	9.8	7	13.7	
job	workless	46	90.2	42	82.4	0.241
	Employee	1	2	5	9.8	
	self-employment	4	7.8	4	7.8	

Table 2 Comparison of severity of restless leg syndrome before and after intervention in two groups

	Before intervention						After the intervention							
	Mild		Moderate		severe		None		Mild		Moderate		severe	
	Perce	Num	Perce	Num	Perce	Num	Perce	Num	Perce	Num	Perce	Num	Perce	Num
case	19.6%	10	66.7%	34	13.7%	7	7.8%	4	72.5%	37	17.6%	9	2.0%	1
control	19.6%	10	60.8%	31	19.6%	10	0.0 %	0	21.6%	11	56.9%	29	21.6%	11
total	19.6%	20	63.7%	65	16.7%	17	3.9%	4	47.1%	48	37.3%	38	11.8%	12

Table 3 Mean and standard deviation of severity of restless leg syndrome before and after intervention in two groups

gropo	After the intervention	Before intervention	p-value
case	1.5686±0.47053	0.83725±0.42425	p= 0.00
control	2.5667±0.58435	0.57420±2.5098	p=0.258
p-value	0.00	0.361	

symptoms. After conducting the yoga exercises, subjects in the intervention group experienced significant change and the rates turned out to be something like this: 4 subjects with no symptom of restless leg syndrome, 37 subjects with mild, 9 patients were moderate and only 1 individual turned out to have severe restless leg syndrome (7.2, 72.5%, 17.6%, 2.0%). In the control group, 11 subjects had mild symptoms, 29 were moderate and 11 had severe symptoms (21.6%, 56.9%, 21.6%). There was a significant difference between two groups after the intervention in regard with the severity of symptoms ($P = 0.000$), (Table 2).

The results of independent t-test showed that there was no significant difference in the severity of restless leg syndrome between two groups before the intervention ($p = 0.361$). However, after intervention, the two groups had a significant difference in severity of restless leg syndrome ($p = 0.000$) Table 2. Also, the results of paired t-test in the control group with mean and standard deviation (0.35637 ± 5.5686) did not show a significant difference before and after the intervention ($p = 0.285$); however, the same test, with mean and standard deviation of (0.42425 ± 83725), showed a significant difference before and after the intervention ($p = 0.00$), (Table 3).

DISCUSSION

The findings of the present study indicate that yoga has positive effect on restless leg syndrome and it brings about significant reduction in severity of symptoms in type 2 diabetic patients. The results of this study are consistent with the findings of previous studies. Ines (2013) showed that doing eight weeks of yoga exercise can improve sleep quality and reduce the severity of symptoms of restless leg syndrome

significantly in patients (23). Dacosta (2013) stated that increased physical activity improves sleep quality and quality of life in type 2 diabetic patients with restless leg syndrome (24). Additionally, some studies have proven the impact of yoga on type 2 diabetes, a point which is consistent with the present research. The results of Ebrahimi's study (2017) showed that doing yoga for 12 weeks, compared to aerobic exercise, improved the sleep quality of women with type 2 diabetes significantly (25). McDermott (2014), in a study to determine the impact of yoga on reducing the risk of type 2 diabetes, showed that doing eight weeks of yoga, although not affecting insulin resistance and fasting blood glucose, reduced weight, weight index Body mass, waist circumference, blood pressure and blood lipids significantly; it, also, can improve the mental state of people by reducing the amount of anxiety, depression, and increased sense of well-being (26). Also, other studies were conducted to determine the impact of yoga exercises on improving the quality of sleep, which is consistent with some of the results of this study. Baba Hajji et al. (2014), in a study on the effect of Hatha Yoga on the quality of sleep in patients with dialysis, showed that doing Hatha Yoga exercises for two months can improve the quality of sleep in hemodialysis patients (16). The result of the study by Ines and Salafi (2012), which was conducted to determine the effect of light yoga program on sleep quality, mood and blood pressure in elderly women with restless leg syndrome, shows that doing yoga program in 90-minute sessions twice a week for eight weeks improves the quality of sleep and decreases stress, anxiety and sympathetic activity significantly (blood pressure, heart rate) in postmenopausal women with restless leg syndrome (14). Ahmadi's study (2013) was conducted to compare the effectiveness of eight weeks of aerobic training and yoga training in

improving motor and balance status, fatigue and mood in MS patients; the results of his study suggests that eight weeks of yoga can improve the movement and balance, anxiety and depression and fatigue in MS patients significantly (27).

CONCLUSION

To put it in a nutshell, the results of this study show the positive effect of yoga exercises on reducing the severity of restless leg syndrome and, thus, improving the quality of sleep and quality of life in type 2 diabetic patients with restless leg syndrome. Therefore, with timely diagnosis and using the results of this study, the progression of mild and moderate forms of the syndrome to severe and very severe stages could be prevented, and by reducing the use of therapeutic medications, patients' quality of life, including sleep and rest, would be improved. Further studies are recommended to evaluate the effect of yoga on other complications of diabetes.

Limitations

The unmatched level of home patient training, and the lack of willingness of male clients to participate in the study were some of the main limitations of the present study. Also, due to the shorter study time and the low number of yoga sessions, generalizations are limited. Therefore, in order to generalize the results of similar studies, longer studies and more educational sessions are recommended.

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Author Contributions

GM: Study conception and design, Data collection, Data analysis, Drafting of manuscript

FE: Drafting of manuscript, Critical revisions of manuscript for important, intellectual content, Statistical expertise, Obtaining funding

DR: Data analysis, Statistical expertise

MF: Study conception and design, Data collection, Data analysis, Drafting of manuscript, Critical revisions of manuscript for important, intellectual content, Statistical expertise, Obtaining funding, Administrative, technical or material support, Supervision

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Conflict of Interest

There is no conflict of interest regarding this manuscript

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