Research Paper: (a) The Effect of Foot Reflexology Massage on the Sleep Quality of Elderly Women With Restless Leg Syndrome

Amine Abbasi Fakhravari¹ 💿, Farideh Bastani¹* 💿, Hamid Haghani² 💿

- 1. Department of Nursing, School of Nursing and Midwifery, Iran University of Medical Sciences, Tehran, Iran.
- 2. Department of Biostatistics, School of Public Health, Iran University of Medical Sciences, Tehran, Iran.



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ABSTRACT

Background: Restless Leg Syndrome (RLS) is a common disorder in the elderly, especially older women, which causes sleep disorders and endangers the elderly with increase in the risk of falling, memory disturbances, and eventually, poor quality of life. Today, non-pharmacological approaches, including reflexology massage, are considered along with pharmaceutical methods for improving sleep quality. This study aims to examine the effect of foot reflexology massage on the sleep quality of the elderly women with RLS.

Methods: The was a non-randomized clinical trial with a control group (quasi-experimental design) conducted on 67 elderly women with RLS resident in nursing homes located in Fars Province of Iran. Samples were selected using convenience sampling method. By tossing a coin, some elderlies were selected and allocated in the control and test groups. Foot reflexology intervention comprised eight 20-minute sessions (10 min for each foot) for 4 weeks. Pittsburgh Sleep Quality Index (PSQI) and a demographic questionnaire were used for collecting data which were administered before and after the intervention. The collected data were analyzed in SPSS V. 16 using descriptive statistics and inferential statistics such as Independent t test, paired t test, Fisher exact test, and Chi-squared test at a significance level of P<0.05.

Results: The Mean±SD ages of the participants in test and control group were 71.43 ± 6.25 and 72.6 ± 4.67 years, respectively and both groups were matched in terms of age (P=0.389). There was no significant difference in sleep quality of the control group before and after the intervention (P=0.013 or 0.13), while in the test group the difference was statistically significant (P<0.001). In addition, the difference in RLS pain scores before and after the intervention was significantly lower in the test group compared to the control group (P<0.001).

Conclusion: Foot reflexology massage had a positive effect on the sleep quality of the elderly women with RLS. Caregivers and nurses of the elderly are recommended to learn and use this easy and almost cost-free intervention for their patients.

* Corresponding Author:

Farideh Bastani, PhD. Address: Department of Nursing, School of Nursing and Midwifery, Iran University of Medical Sciences, Tehran, Iran. Tel: +98 (21) 43651820 E-mail: bastani.f@iums.ac.ir

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Highlights

- Foot reflexology massage improves sleep quality of the elderly women with restless legs syndrome.
- Elderly often suffer from many physical complications including restless legs syndrome.
- Foot reflexology can be used as a safe and non-medicinal intervention in older women with restless legs syndrome.

Plain Language Summary

This paper reports the effect of foot reflexology massage on sleep quality of the elderly women with Restless Legs Syndrome (RLS). This syndrome causes unpleasant or uncomfortable sensations in the legs and an irresistible urge to move them. It is a common neurological movement disorder that its prevalence increases with age. Women are twice as likely to develop RLS. Symptoms commonly occur in the late afternoon or evening hours, and are often most severe at night when an older adults are resting or lying in bed. On the other hand, sleep quality changes as a function of normal aging, both in terms of decreased duration and consolidation, and it plays a critical role in promoting good health.

Unfortunately, sleep quality is usually worse at night in older adults with RLS. Because of the effects of RLS on the life of older adults, treatment plan to relieve RLS symptoms is important. Leg massage is an easy and relaxing treatment that could ease RLS symptoms. Reflexology as a foot massage involves application of pressure to the feet with specific thumb, finger, and hand techniques without the use of oil or lotion. The results showed that the foot reflexology massage had a positive effect on the sleep quality of the elderly women with RLS. It is recommended that formal and informal caregivers learn and apply this easy technique of foot massage for their elderly care receivers.

1. Background



ging is a global phenomenon. The population of people aged 60 or over is estimated to reach 2 billion in the world (22% of the total population) by 2050 (World Health Organization 2017). In Iran, the population of over 60 years

of age reached from 7.27% in 2006 to 8.26% in 2011 (Statistical Center of Iran 2011). Old age is a sensitive period of life, and attention to the needs and problems of these people is essential (Brunner 2010). One of the most common problems of older people is Restless Leg Syndrome (RLS). In this disorder, the person feels unpleasant sensations in his/her lower limbs that causes an urge to move the legs to relieve the sensations (Goldman & Schafer 2016).

According to The International Restless Legs Syndrome Study Group (IRLSSG), the criteria for the diagnosis of this syndrome include an urge to move the lower limbs repeatedly; transient relieve of unpleasant sensations by movement; and initiation or worsening of the unpleasant sensations during periods of rest, inactivity, evening, or night (International Restless Legs Syndrome Study Group 2012). Various studies have reported different rates of prevalence for this syndrome in the elderly (11.9% to 29.7%). These studies have shown that RLS is more common in women than men, and the prevalence of this syndrome increases with older ages (Celle et al. 2010; Chavoshi et al. 2015; Çurgunlu et al. 2012; Shin et al. 2013). According to Fereshtehnejad et al. (2017) study, this disorder is common in Iranian elderly people three times more than young people.

One of the most important adverse effects of RLS is sleep disorders. In a study in Iran, the prevalence of this syndrome in subjects with sleep disorders was reported 4.62 times higher than those without sleep disorder (Habibzadeh, Lazari & Ghanei Gheshlagh 2013). One study reported that RLS severity had positive relationship with impairment of sleep quality (Gade et al. 2013). RLS by negatively affecting the quality of sleep, reduces the person's quality of life (Kocabicak et al. 2014).

Sleep disorders reduce the quality of life; increases the risk of falling, cost of treatment, and most importantly, the mortality rate in the elderly (Kocabicak et al. 2014; Cuellar, Rogers & Hisghman 2007). Therefore, attention to the sleep quality of the elderly, especially those resident in nursing homes, is important, because they have

a poorer sleep quality compared to the elderly living at home (Beyrami et al. 2014).

With regard to the polypharmacy phenomenon and its adverse effects in the elderly, using non-pharmacological methods to improve their sleep quality can be very valuable. In addition, many elderly people are not optimistic about the safety of drugs and prefer to use complementary therapies (Cuellar, Rogers & Hisghman 2007). One of the most popular complementary therapies is massage therapy. This treatment is a favorite of the elderly and is usually used as a home remedy (Cuellar, Rogers & Hisghman 2007). One of the widely-used massage therapies is reflexology, which is a holistic treatment. It is based on the notion that there are certain points on the hands and feet that pressing them affects internal organs of the body (Saiidi et al. 2015).

The mechanism of this treatment is stimulating the nervous system and the transfer of sensory stimuli to the brain which can increase the secretion of dopamine (Khojandi et al. 2015). There are several studies on foot reflexology massage. In a systematic review, it was suggested that foot reflexology is a useful nursing intervention to relieve fatigue and promote sleep (Lee et al. 2011). In a randomized controlled trial conducted in Taiwan to examine the effectiveness of foot reflexology to improve sleep quality in postpartum women, it was observed that women in the test group had better sleep quality than those in the control group (Li et al. 2011). There are also some similar studies in Iran. For example, in a study conducted in Tabriz, it was found out that foot reflexology can affect the sleep quality of the elderly (Seyedrasooli et al. 2013). A study on the effects of reflexology on sleep disorder in menopausal women conducted in Tuyserkan City, Iran reported the effectiveness of reflexology in improving sleep disorder.

There are limited number of studies on the elderly people. Older people have different problems and issues, and the special needs of this group should be taken into consideration. In this regard, this study aims to investigate the effect of foot reflexology on the sleep quality of the elderly women with RLS.

2. Materials and Methods

Study design

This study is a quasi-experimental clinical trial. The study population consisted of the elderly women with RLS resident in four nursing homes affiliated to Welfare Organization in Shiraz City, Iran.

Study samples

By tossing a coin, two nursing homes were selected as the control groups and two as the test groups. Then convenience sampling method was applied. In this regard, by using the "standard tool for screening RLS", the older women with this disorder were identified and their syndrome severity was measured using the "standard tool for screening severity of RLS" and registered (International Restless Legs Syndrome Study Group 2012). Seventy subjects who had all four criteria for syndrome and their syndrome severity was 11 or above were selected as study samples. The sampling was conducted from January to April 2017.

The sample size was obtained as 35 in each group by considering 5% significance level, 80% test power, and assuming that the effect of foot reflexology on the sleep quality of elderly women with RLS is at least d=3 in comparison with the control group in order to be statistically significant. The probability of drop-out was considered, too. In a similar study, the standard deviation of sleep quality in the test and control groups were reported as 5.3 and 3.1, respectively (Nasiri et al. 2015).

Inclusion and exclusion criteria

The inclusion criteria were as follows: Having sleep disorder for more than a year (A total score of 6 or more based on the Pittsburgh sleep quality index); reporting symptoms of RLS for more than a year according to the elderly; having RLS severity above 11 based on international restless legs scale; Lacking history of taking foot reflexology for treatment of RLS or sleep disorder; Lacking any cognitive impairment, addiction, mental illness; and having a healthy foot.

The exclusion criteria were as follows: Experiencing wound, infection or complicated leg problems during intervention; developing peripheral neuropathy or vascular disorders in the lower limbs or coagulation problem during the study; taking drugs that worsen the syndrome (e.g. tricyclic antidepressants, selective serotonin reuptake inhibitors, antiemetics, anticonvulsants, antidepressants, dopamine antagonists); losing interest to participate in the intervention, even for one session; and unwilling to continue the clinical trial. It should be noted that out of 35 participants in each group, no dropout was observed in the test group, but in the control group, three samples dropped out of the study in posttest phase because of death, hip fracture, and unwilling-ness to continue the trial.

Data collection tools

For collecting data from the participants, Pittsburgh Sleep Quality Index (PSQI) and a demographic form (collecting age, education, marital status, number of children, economic status, length of stay in the nursing home, chronic diseases and history of drug use) were used. PSQI is a self-rated questionnaire with 18 items which assesses sleep quality by measuring seven components: subjective sleep quality (obtained by dividing the length of quality sleep over the total time spent in bed), sleep latency, sleep duration, habitual sleep efficiency, sleep disorders (measured by the persons' awakening at night), use of sleeping medications, and daytime dysfunction (defined by the problems the person experiences during the day which is caused by sleep disturbances) over the last month. The scores of these subscales are added to obtain a total score ranging from 0 to 21. A total score of 6 or more indicates a poor quality sleep. Those older women entered our study who had a poor quality of sleep.

PSQI was designed by Buysse et al. (1989) at Pittsburgh Psychiatric Institute. It is a self-report questionnaire and can be completed within 5 minutes. It is the most appropriate tool for measuring the quality of sleep in the elderly people (Beyrami et al. 2014). Psychometric properties of PSQI were evaluated by Farrahi et al. (2009) in Iran. Its Cronbach alpha coefficient was reported as 0.77, which indicates the acceptable psychometric properties of the tool. In the study of Ghanei et al. (2011), the validity of the PSQI was also determined by content validity and its reliability by test-retest method (r=0.94). In the study of Beyrami et al. (2014), the Cronbach alpha coefficient was reported as 0.86. We used PSQI before and after the intervention.

Study procedure

After obtaining written and verbal informed consent, demographic data collection form was completed by the participants. Before the intervention, pretest was administered by using the PSQI tool. Intervention included eight 20-minute sessions (two sessions per week for 4 weeks). Because PSQI assesses the sleep quality in the last month, the intervention period was considered 4 weeks. According to some studies, the duration of the massage do not affect the results (Seyedrasooli et al. 2013; Li et al. 2011).

Based on the researcher's experiences and similar studies, the duration of massage for each foot was set for 10 minutes and the time of performing massage, due to the intensification of symptoms in the afternoon, was considered around 3-7 PM. Every older woman received a massage on their own comfortable bed in a quiet place. First, a general massage was performed on the sole of the foot with a neutral lotion (Vaseline) for 5 minutes, and then pineal gland point on the outside of the big toe was massaged for 5 minutes. Massage was performed at a slow speed with a regular rhythm and with a depth that is tolerable to the patient. The post-test was administered in the fifth week after the end of the intervention and the results were analyzed. The intervention process was carried out by the researcher.

Data analysis

Data were analyzed using descriptive statisfics such as mean and standard deviation, and inferential statistics such as the Independent t test, paired t test and Chi-squared test in SPSS V. 16. The significant level was set at 0.05 (P<0.05).

3. Results

The Mean±SD ages of the participants in the test and control group were 71.43 ± 6.25 and 72.6 ± 4.67 years, respectively and both groups were matched in terms of age (P=0.389). Other demographic characteristics of the participants (level of education, marital status, number of children, financial status, length of stay in the nursing home, diagnosed chronic diseases, prescribed medication use due to illnesses) are presented in Table 1.

According to the paired t test results shown in Table 2, In the test group, the mean scores of sleep quality before and after the intervention were significantly different and after the intervention, the mean sleep quality score decreased, which indicates improvement in sleep quality of the elderly (P<0.001). The mean sleep quality score in the control group did not significantly change after the intervention (P=0.013 or 0.13). According to the Independent t test results in Table 2, there was no significant difference between two groups before and after the intervention with regard to the mean scores of sleep quality (P=0.085), but after the intervention, the difference was significant (P<0.001).

In order to investigate the effect of foot reflexology on the sleep quality, the difference in sleep quality score in both test and control groups after the intervention was compared to the difference reported before the intervention by using the Independent t test. The results indicated that the difference between two groups was statistically significant (P<0.001) and after the interven-

Table 1. Demographic variables and their P

		Groups		
Variables	Characteristics	Test	Control	Р
		No. (%)	No. (%)	_
Educational level	Illiterate	20 (62.5)	25 (71.4)	0.563
	Middle school degree	6 (18.8)	7 (20)	
	High school diploma	4 (12.5)	3 (8.6)	
	Academic degree	2 (6.2)		
	Married	4 (12.5)	4 (11.4)	0.346
Marital status	Single	9 (28.1)	13 (37.1)	
	Widowed	16 (50)	18 (51.4)	
	Divorced	3 (9.4)	-	
Number of children	0	8 (34.8)	5 (22.7)	0.488
	1 - 2	8 (34.8)	4 (18.2)	
	3 or more	7 (30.4)	13 (59.1)	
Financial status		45 (46 0)	14 (40)	0.627
	High	15 (46.9)	14 (40)	
	Moderate	17 (53.1)	21 (60)	
	<1	2 (6.2)		
Length of stay in the nursing home, y	1	11 (34.4)	10 (28.8)	0.538
	2	8 (25)	10 (28.8)	
	>2	11 (34.4)	15 (42.9)	
	0	3 (9.4)	5 (14.3)	
Diagnosed chronic diseases	1	14 (43.8)	11 (31.4)	0.577
	>1	15 (46.9)	19 (54.3)	
	Use	1 (3.1)	1 (2.9)	
	1 drug	6 (18.8)	7 (20)	0.965
	2 drugs	9 (28.1)	7 (20)	
Prescribed medication	3 drugs	5 (15.6)	8 (22.9)	
	4 drugs	5 (15.6)	6 (17.1)	
	5 drugs and more	6 (18.8)	6 (17.1)	

Client- Centered Nursing Care

	Groups			
Activity (Time of Intervention)	Test	Control	Independent t-test Results	
	Mean ± SD		_	
Before the intervention			T = -1.751	
	16.87 ± 1.89	16.05 ± 1.87	df = 64	
			P = 0.085	
		16.62 ± 1.87	T = 13.146	
After the intervention	9.32 ± 2.68		df = 64	
			P < 0.001	
	T = 12.717	T = -2.921		
Paired t test results	df = 30	df = 34		
	P < 0.001	P = 0.013		
Difference in pair secre			T = -13.43	
Difference in pain score before and after the	7.54 ± 3.30	-0.57 ± 1.28	df = 64	
intervention			P < 0.001	
			Client- Centered Nursing Care	

Table 2. Comparing the Mean±SD scores of sleep quality and pain difference of the elderly women in both groups before and after the intervention

tion, sleep quality improved in the test group. Hence, it can be said that foot reflexology affect the sleep quality of older women with RLS.

4. Discussion

Results of this study revealed that foot reflexology has significant effect on the sleep quality of women with RLS and improved their sleep quality. This effect can be explained by the effect of reflexology on the nervous system that by transferring sensory stimuli to the brain can increase the secretion of dopamine. Because RLS is caused by dopamine secretion disturbance (Goldman & Schafer 2016), foot reflexology can improve the symptoms of RLS by regulating dopamine secretion (Shahgholian et al. 2016). Because the severity of symptoms in this syndrome is directly related to the quality of sleep, it can be inferred that foot reflexology, by reducing the symptoms of the syndrome has improved the sleep quality of the elderly studied in the present study.

Results of this study is consistent with a study that examined the effectiveness of foot reflexology and back massage on optimizing the sleep quality and reducing the fatigue of patients undergoing hemodialysis. The study results reported that foot reflexology and back massage improved the sleep quality (Unal & Akpinar 2016). Our results are also in agreement with the results of Li et al. (2011) who examined the effectiveness of foot reflexology in improving sleep quality in Taiwanese women after child delivery.

Their study concluded that foot reflexology in the postnatal period could significantly improve the quality of sleep in these women. The results of Asltoghiri and Ghodsi (2012) study are also consistent with our results. They reported that reflexology was effective in improving the sleep disorders in menopausal women. In the study of Seyedrasooli et al. (2013), it was also reported that foot reflexology can influence sleep quality in the elderly.

Several studies on the effect of foot reflexology have been conducted to improve the health status and quality of life of people around the world. Academic studies have examined the effects of this type of massage on various diseases and age groups. This type of massage has had a positive effect on pain, fatigue, insomnia, anxiety and depression in some patient groups such as patients under hemodialysis, patients with cancer, patients with chronic heart failure and postpartum women (Ray & Natha 2017; Tarrasch et al. 2017; Mei et al. 2017; Unal & Akpinar 2016).

Studies have shown that this type of massage also affects the severity of RLS symptoms in patients under hemodialysis and reduces their symptoms (Shahgholian et al. 2016). In the present study, this mediating effect of foot reflexology on the severity of RLS symptoms can be accepted as a presumption. While, the hypothesis of our study states that "foot reflexology affects the sleep quality of elderly women with RLS". On the other hand, based on a systematic review, studies conducted on the effect of reflexology on the patients with diabetes, premenstrual syndrome, cancer, multiple sclerosis, and dementia have not presented acceptable results (Ernst, Posadzki & Lee 2011).

The quality of sleep varies in different persons. This difference can be due to individual and even gender differences of the elderly, as well as biological and nutritional factors, and even tensions on their everyday activities which can show the quality of sleep more undesirable than its actual level. This factor was controlled to some extent by having a control group. Another limitation of this study was the quasi-experimental design of the study and non-randomized selection and allocation of the subjects in the test and control groups which obviously affects the generalizable of the results. Quasi-experimental study is a research that is usually conducted in real conditions. In these conditions, it is not possible to control all the empirical and clinical variables and just some of them can be controlled. Moreover, like any experimental research, there was no possibility of blindness to reduce the biases of intervention and evaluation of the outcomes.

Overall, the findings of this study supported the hypothesis of the research that foot reflexology is effective on improving the sleep quality of the elderly women with RLS. Therefore, caregivers and nurses of the elderly are recommended to learn and use foot reflexology as a non-invasive and non-pharmacological approach that is easy to administer and almost cost-free. In this study, no complications due to foot reflexology was observed. Reflexology, with regard to its beneficial effects, is of particular interest to treatment staff, especially nurses. These interventions reduces the use of sleeping pills, while protecting the elderly from the phenomenon of polypharmacy. Therefore, the present study may be important in introducing a "nursing care with no medication use" to improve the quality of sleep in the elderly with RLS. It is suggested that this type of intervention be used in health centers. Obviously, this objective can be achieved only through proper planning by relevant authorities and nursing managers.

Ethical Considerations

Compliance with ethical guidelines

This study was approved by the Ethics Committee of Iran University of Medical Sciences (Code No.: IR.IUMS.REC 1395.9411580005). All participants signed the informed consent form before entering the study. In addition, this trial has been registered in Iranian Registry of Clinical Trials website (code: IRCT2017032733154N1).

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Authors contributions

Farideh Bastani, conceived and designed the work, acquired research funding, supervised the conduct of the study, the intervention and data collection. Amine Abbasi Farkhravari undertook recruitment of patients and managed data collection and the intervention. Hamid Haghani provided statistical advice on sampling method and analyzed the data. Amine Abbasi Farkhravari drafted the manuscript, and all authors contributed substantially to its revision.

Conflict of interest

The authors declare that there is no conflict of interest.

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