



## The effect of foot reflexology on constipation and quality of life in patients with multiple sclerosis. A randomized controlled trial



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### ABSTRACT

**Background:** Constipation is a major problem in most patients with multiple sclerosis (MS). The aim of this study was to investigate the effect of foot reflexology on constipation and quality of life in patients with MS.

**Methods:** This study was a randomized controlled trial, in which 63 patients with MS referred to Arak MS Society, Iran were participated (from May to Dec. 2018). In this study participants were selected according to inclusion criteria and randomly divided into intervention (n = 33) and control (n = 30) groups. In the intervention group, foot reflexology was applied twice a week for 6 weeks (each session lasted about 30–40 min). Data were collected using demographic questionnaire, Constipation Assessment Scale (CAS) and Short Form (SF) 36 Quality of Life (QOL) questionnaire. Finally, the data were analyzed using SPSS Ver. 16 and descriptive and inferential statistical tests.

**Results:** The results of the study showed that severity of constipation and QOL score were not significant between the two groups before intervention ( $p > 0.05$ ), but; after intervention, severity of constipation significantly decreased in the reflexology group ( $p < 0.05$ ). Nevertheless, after intervention, the QOL was improved in the reflexology group compared to the control group but was not significant ( $p > 0.05$ ).

**Conclusion:** The results of this study showed that foot reflexology, as an effective intervention can be useful in management of constipation in patients with MS. Therefore, this intervention can be applied as a safe method for the decrease of constipation in MS patients.

### 1. Introduction

MS is a chronic autoimmune disease associated with central nervous system inflammation and leads to progressive degeneration in the neuroaxonal system.<sup>1</sup> More than two million people in worldwide suffered from MS. MS are main responsible of non-traumatic and irreversible neuropathy in young peoples.<sup>2</sup> Bladder and bowel dysfunction have been reported as the third symptoms of all problems associated with MS.<sup>3</sup> The prevalence of intestinal disorders in patients with MS (constipation, fecal incontinence or both) is between 50 % and 80 %, approximately.<sup>4,5</sup> Motility disorders are frequently in patients with MS and have negative effects on quality of life.<sup>6,7</sup> Constipation is a common chronic gastrointestinal disorder characterized with bloating, agitation, abdominal pain, hard or lumpy stools, and a sense of incomplete evacuation, defective emptying, and the evacuation less than 3 times a week.<sup>8</sup> Constipation, due to severe restrictions in daily activities, leads

to a sharp decline in the quality of life of these patients.<sup>9,10</sup> Approximately 85 % of people with constipation need to expensive medical interventions.<sup>11</sup> Current treatments for constipation are including fiber intake, use of concomitant medication, laxatives, gastrokinetic agent, prosecretory agents, bile acid transporter inhibitors, biofeedback and probiotics. Some of which are effective in the management of constipation. However, not all patients respond to treatment and there is concern about drugs side effects.<sup>12,13</sup> Now day, complementary medicine has a special place among peoples and the use of it is growing.<sup>14</sup> Reflexology is a form of complementary technique by creating slight pressure on specific reflex points on the foot, hand and ear.<sup>15,16</sup> When an area was stimulated by reflexology, the cells, muscles and nerves respond to it, and lead to reducing stress, accelerating of blood flow, reducing tension, relaxing the mental state, increasing immunity, and improving the sense of well-being.<sup>17</sup> Reflexology is a non-invasive and safe intervention and can reduce pain, anxiety, depression and fatigue,

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improves sleep quality, QOL and immunity functions.<sup>18,19</sup> It also has a positive effect on constipation.<sup>20</sup> Endorphins are endogenous opioid neuropeptide hormones in humans. They are produced from central nervous system and the pituitary gland and released as a response to reflexology.<sup>21</sup> Complementary therapies such as reflexology may be helpful in management of MS complications.<sup>22</sup> Yadav et al. in 2014 concluded there was not sufficient data to reject or support the theory of reflexology can improve the intestinal functions in MS patients.<sup>23</sup> Due to negative effects of constipation on quality of life in patients with MS, the aim of this study was to investigate the effect of foot reflexology on constipation and quality of life in patients with MS.

## 2. Materials & methods

This study was a double-blind, randomized, controlled trial in which 63 patients with MS referred to Arak MS Society affiliated to Arak University of Medical Sciences, Arak, Iran were participated (from May to Dec. 2018).

### 2.1. Study design and selection of patients

In this study, 63 patients were participated. Before intervention, the study protocol and objectives was explained to the patients and informed consent form was obtained. Then, patients randomly using computer program assigned into intervention (n = 33) and control (n = 30) groups according to inclusion criteria (Fig. 1).

The main inclusion criteria were included: age between 18–50 years, Expanded Disability Status Scale (EDSS) less than or equal to 4

verified by a neurologist, confirmation of constipation according to Rome IV criteria, non-use of other complementary therapy methods, having a recommended diet as taught at Arak MS Society. The main exclusion criteria were included: lower limb vascular diseases, skin disorders and lower limb damage, opiate addiction, use of hypnotic and antipyretic, antidepressant and analgesics medications during the study, a history of obstructive diseases of the gastrointestinal tract, inflammatory digestive diseases and irritable bowel syndrome, history of hypothyroidism, hyperparathyroidism, hypopituitarism.

At the beginning of the study, participants were asked about exercises, mobility status, diet and fluids intake. Responses indicated that none of the participants had a specific exercise programs. Also, patients in both groups listed their past 3-month diet. During the study, participants were asked not to change their diet, fluids intake and exercises, and report it to the researchers if any new change was creating to their daily programs. If any of the above cases were changed in each patient, he/she was excluded.

### 2.2. Ethical considerations

This study was approved by Ethics Committee of Arak University of Medical Sciences (ethical approval No.: IR.ARAKMU.REC.1397.038). Also was registered at the Iranian Registry of Clinical Trials (RCT code No.: IRCT20180103038211N5). All patients voluntarily participated in the study. The purpose and process of study were described to potential participants, their families, nurses and authorities of MS Society of Arak.

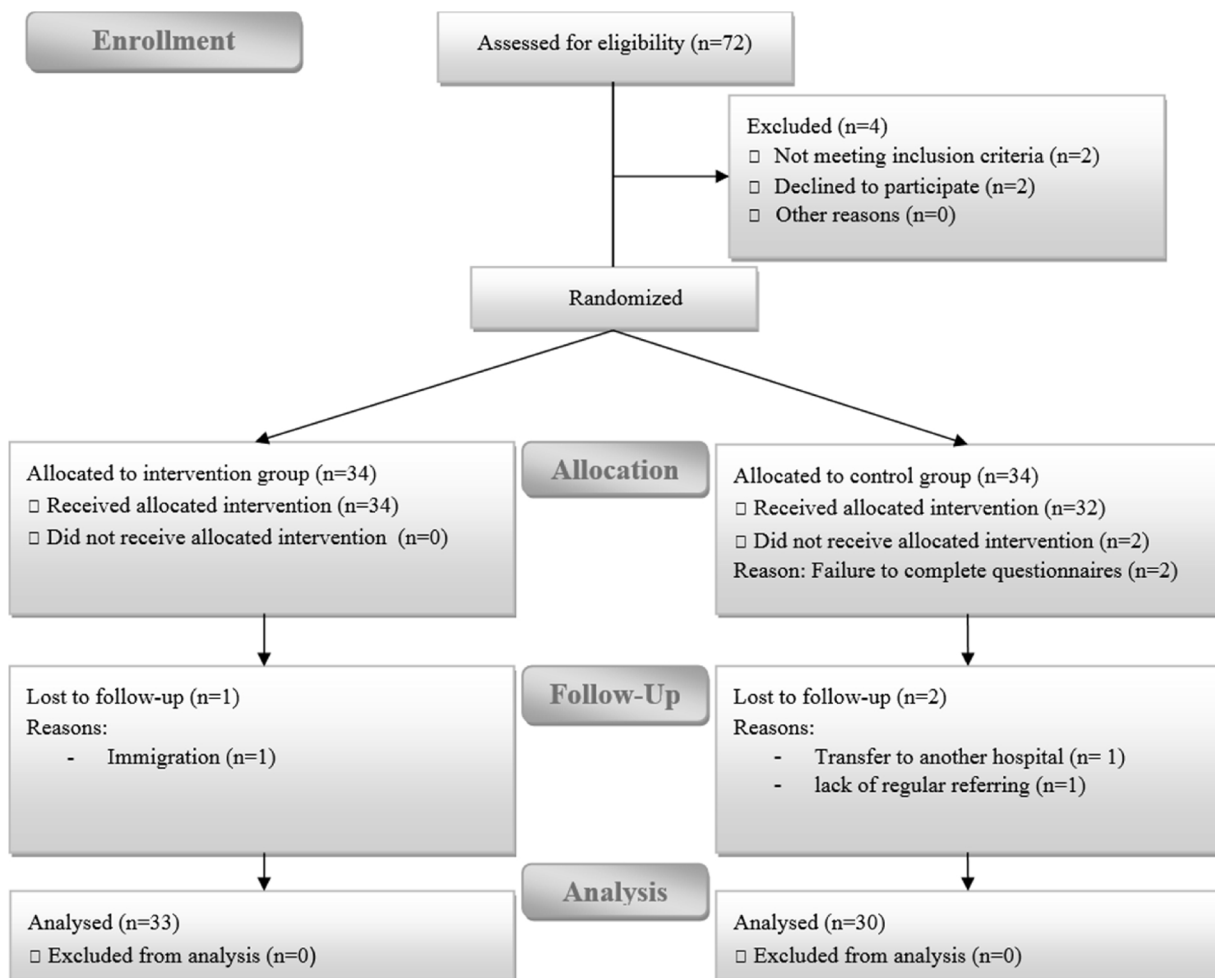


Fig. 1. Process of study.

### 2.3. Instruments

In the first step of study, demographic questionnaire CAS, and SF36 QOL questionnaire completed by all patients.

CAS is a scale consist of eight-item that was planned for nurses to evaluate the presence and severity of constipation. The score was calculated based on the 5-point (0–4) likert scale. Score 0–8 indicates least problems related to constipation; 9–16 indicates some problems related to constipation; 17–24 indicates severe constipation; and 25–32 indicates very severe constipation. A useful coefficient for assessing internal consistency is Cronbach's alpha in Ismail Poor et al. study and its value was 0.86. For repeatability of the test, the test-retest method was used and the stability of the tool was confirmed with a correlation coefficient  $r = 0.999$ .<sup>24</sup> Ghaffari et al. in their study with a time interval of about 24 h, Pearson correlation coefficient was  $r = 0.84$ , which indicates the reliability of the tool.<sup>25</sup>

The SF36 quality of life questionnaire has 36 questions in eight section that includes physical function, role disorder due to physical problems, role disorder due to emotional problems, energy/fatigue, emotional well-being, social function, physical pain, and general health. The validity and reliability of the Persian version were 0.4 and the Cronbach's alpha coefficient are between 0.77 and 0.90.<sup>26</sup>

### 2.4. Reflexology intervention

In current study, the Rwo Shur method of reflexology was used. This method is combination of thumb sliding and pressure techniques. In the Rwo Shur method, soft pressure was applied on the corresponding reflex points.<sup>27</sup> Reflexology was done by third author of manuscript (trained and certified in the Shahid Beheshti University of Medical Sciences in Tehran, Iran) with slow speed, regular rhythm and depths of one to three mm<sup>28</sup> for each patient in a separate room (patient and reflexologist were alone in the room) in MS Society of Arak. The room had standard light and humidity, and there was no other stimulus.

In the intervention group, foot reflexology was done twice a week for 6 weeks (each session lasted about 30–40 min for each foot).

Reflexology was done using with a lubricant fluid (natural sunflower oil) to reduce friction on the feet. At first, general massage was done on right foot for 5 min and then reflexology by performing specific movements of two hands on related area to gastrointestinal system was done for 10 min' (stomach, liver, small intestine, large intestine and solar plexus). After this step, reflexology was performed with the same technique on the left foot. For patients in the control group foot surface massage without pressure was applied to simulate the interventions similar to the intervention group. All patients in this study received standard MS therapeutic protocols. Patients were reminded did not take

any anti-constipation medication throughout the study.

### 2.5. Statistical analysis

Finally, the data were analyzed using SPSS 16. Descriptive analysis was used for qualitative variables and data presented by frequency and percentage. Quantitative variables analyzed by Chi-Square and Fischer exact test and data presented by mean and standard deviation (Mean  $\pm$  SD). Independent *t*-test and paired *t*-test were used for comparison of quantitative variables between two groups. The Kolmogorov-Smirnov test was used to check the normality of data. The significance level was considered 0.05.

## 3. Results

The patients' demographic data and test parameters are summarized in Table 1. The mean age and BMI were similar in the two groups. Also, the two groups were approximately analogous in terms of diet type, liquid intake and mobility at baseline. There was no statistically significant difference in the demographic characteristics, severity of constipation, distribution intervals and quality of life before the intervention between the groups (Table 1).

The results showed, after the intervention, the CAS scores were statistically significant in the foot reflexology group compared to the control group ( $p = 0.001$ ). Also, the mean intervals of stool defecation in the patients before the intervention in the foot reflexology group was 4.18 days and in the control group was 4.27 days. After 6 weeks, in the reflexology group intervals of stool defecation was 2.48 days and in the control group was 4.17 days. The mean change in the frequency of defecation was significantly different after the intervention, in the foot reflexology group in compared with control group ( $p = 0.001$ ) (Table 2).

Table 3 demonstrates the differences of the quality of life before and after the intervention and the results of the comparison between two groups. After the intervention, the quality of life scores in the foot reflexology group was slightly improved compared to the control group. But, there was not significant difference in the all aspects of quality of life in before and after intervention in two group (Table 3).

## 4. Discussion

This study evaluated the effect of foot reflexology on constipation and quality of life in patients with MS. The result of study showed foot reflexology had positive effect on management of constipation in patients with MS.

According to inclusion criteria, patients with MS who had

**Table 1**  
Demographic characteristics of participants ( $n = 63$ ).

Variable	Intervention ( $n = 33$ )	Control ( $n = 30$ )	p-value
	Mean $\pm$ SD	Mean $\pm$ SD	
Age	34.52 $\pm$ 8.36	32.12 $\pm$ 7.67	0.84*
BMI <sup>1</sup>	24.27 $\pm$ 7.49	22.38 $\pm$ 7.51	0.85*
	n (%)	n (%)	
Sex			0.99**
	Male	2 (6.1)	
	Female	31 (93.9)	
Level of educational			0.85***
	Primary degree	5 (16.7)	
	High School degree	12 (40)	
	Academic degree	13 (43.3)	
Marital status			0.28***
	Married	18 (60)	
	Single/Divorced	12 (40)	
Working status			0.57**
	Unemployed	25 (83.3)	
	Free work	3 (10)	
	Employee	2 (6.7)	

1 = Body Mass Index: is measure of body fat based on height (m) and weight (kg). Mass  $\text{kg} / \text{Height}^2_{\text{m}^2}$ .

\**t*-test, \*\*Fisher's exact test, \*\*\*Chi square.

**Table 2**  
Comparing mean scores of CAS and Stool frequency between two groups.

Variable	Time	Group		p-value*
		Reflexology group Mean $\pm$ SD	Control group Mean $\pm$ SD	
CAS <sup>1</sup>	Before intervention	14.39 $\pm$ 3.81	14.8 $\pm$ 4.62	0.93**
	After intervention	6.39 $\pm$ 3.51	14.97 $\pm$ 4.92	0.0001**
	p-value	0.0001*	0.20*	
Stool frequency	Before intervention	4.81 $\pm$ 0.91	4.27 $\pm$ 1.01	0.80**
	After intervention	2.48 $\pm$ 1.06	4.17 $\pm$ 1.17	0.0001**
	p-value	0.0001*	0.31*	

1 = Constipation Assessment Scale: is a guidance to assessment of constipation.  
\*independent *t*-test, \*\* paired *t*-test.

constipation were participated in this study. The mean score of constipation on the first day before the intervention in reflexology and control groups was moderate (score 9–16 from the CAS), and two groups did not significant differences in severity of constipation. Comparison scores in reflexology and control groups after reflexology showed significant difference in severity of constipation ( $P = 0.001$ , Table2). The results of the study showed that reflexology could decrease the severity of constipation in MS patients. Our founding was similar to the results of Elbasan et al., study. They evaluated the effect of reflexology on constipation in patients with cerebral palsy.<sup>29</sup>

Our results were also comparable to the results of Woodward. He reported foot reflexology can decrease the female idiopathic constipation.<sup>13</sup> Özkan et al., in their study, showed reflexology can improve the constipation in children with cerebral palsy.<sup>30</sup> Bishop et al., showed positive effect of reflexology in chronic constipation in children.<sup>31</sup> Researcher report that reflexology can activate the self-healing process in the body, improves the flow of blood circulation and energy, relaxes the person and maintains homeostasis.<sup>32</sup>

Mean scores of quality of life in two study groups before the intervention were not statistically significant. In other word, there was not statistical significant difference in quality of life items after reflexology compared to control group. Miller reported reflexology in MS patients

did not change quality of life significantly.<sup>33</sup> His findings were similar to result of our study.

Also Dikmen et al., showed Reflexology improved quality of life, but its changes were not statistically significant.<sup>34</sup> The results of the present study were almost in contrast with the results of several studies.<sup>14,35</sup> Researchers' believe Therapeutic responses to reflexology was differ from person to person, because body systems differ from one to another.<sup>21</sup> However, this can be attributed to type, area and, depth of reflexology, number of reflexology sessions and associated illnesses. According to the results of various studies, reflexology can induce relaxation in a person.<sup>30,35</sup> In this study, it was found that patients' quality of life was improved some aspects of quality of life, especially in physical functioning and pain, although its changes were not significant.

#### 4.1. Limitations

In this study, we do not plan long-term follow-up study and consequently the long-term effects of reflexology were unidentified. Also, our results were obtained from small size of the sample, and cannot be representative of the whole society.

**Table 3**  
Comparing mean scores of QOL items between two groups.

Items	Time	Group		p-value*
		Intervention Mean $\pm$ SD	Control Mean $\pm$ SD	
Physical function	Before intervention	59.09 $\pm$ 27.82	55.5 $\pm$ 29.37	0.62**
	After intervention	70.15 $\pm$ 27.71	56 $\pm$ 28.65	0.06**
	p-value	0.12*	0.86*	
Role disorder due to physical problems	Before intervention	45.45 $\pm$ 42.13	42.33 $\pm$ 41.16	0.77**
	After intervention	56.06 $\pm$ 39.54	41.5 $\pm$ 40.19	0.15**
	p-value	0.27*	0.98*	
Physical pain	Before intervention	57.8 $\pm$ 23.51	59.25 $\pm$ 20.47	0.98**
	After intervention	66.36 $\pm$ 19.69	58.41 $\pm$ 21.04	0.08**
	p-value	0.17*	0.91*	
Role disorder due to emotional problems	Before intervention	38.38 $\pm$ 39.19	42.22 $\pm$ 39.08	0.69**
	After intervention	48.48 $\pm$ 37.35	42.22 $\pm$ 39.08	0.48**
	p-value	0.35*	0.97*	
Energy/fatigue	Before intervention	51.06 $\pm$ 20.79	50.62 $\pm$ 18.71	0.93**
	After intervention	53.48 $\pm$ 23.86	50.62 $\pm$ 18.71	0.71**
	p-value	0.91*	0.81*	
Emotional well-being	Before intervention	53.69 $\pm$ 22.58	54.63 $\pm$ 20.47	0.95**
	After intervention	58.12 $\pm$ 20.91	54.56 $\pm$ 20.50	0.44**
	p-value	0.50*	0.72*	
Social function	Before intervention	67.04 $\pm$ 22.92	63.33 $\pm$ 21.75	0.45**
	After intervention	70.45 $\pm$ 23.34	63 $\pm$ 22.83	0.19**
	p-value	0.62*	0.80*	
General health	Before intervention	55.56 $\pm$ 19.77	57.16 $\pm$ 20.07	0.86**
	After intervention	59.69 $\pm$ 20.11	55.83 $\pm$ 19.69	0.38**
	p-value	0.44*	0.69*	

\*independent *t*-test, \*\* paired *t*-test.

## 5. Conclusion

Reflexology had positive effect on the constipation in patients with MS. This study showed reflexology improves constipation in patients with MS. This method is effective as a simple, safe and non-pharmacological method in patients with MS. However, further studies needed to determine the effect of foot reflexology in reducing symptoms in MS patients.

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## Declaration of Competing Interest

The authors have no financial or nonfinancial conflicts of interest.

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