

The Effect of Emotional Freedom Technique on Fatigue among Women with Multiple Sclerosis: A Randomized Controlled Trial

Abstract

Background: This study aimed to investigate the effect of Emotional Freedom Technique (EFT) on the severity of fatigue among women with Multiple Sclerosis (MS). **Materials and Methods:** This was a single-blind, randomized controlled trial study conducted on 50 women with MS in Isfahan, Iran. Sampling was performed using simple sampling method, then the participants were randomly divided into two groups of case and sham using the minimization method. The EFT intervention was performed on the case group, 2 sessions per week for a 4-weeks period. In the sham group, with the same psychological part of the EFT technique like case group, mild tapping was applied on false points for the same period of time. Fatigue severity score was obtained using the Fatigue Severity Scale (FSS) before and immediately and 4 weeks after the intervention in the two groups. Data analysis was conducted using descriptive and inferential statistical methods. **Results:** The results of the independent *t*-test indicated that the mean (SD) score of fatigue severity before the intervention was not significantly different between the case and sham groups 5.48 (0.75) and (5.39 (0.71) with ($p = 0.67$). However, this difference was significant immediately [(3.05 (0.89) and 5.15 (0.94)] and 4 weeks after the intervention 3.10 (0.81) and 5.59 (0.57) ($p < 0.001$). **Conclusions:** It seems that EFT is effective in diminishing fatigue among patients with MS and is recommended as a convenient and safe non-medicament strategy for self-management of fatigue among these patients, and can be used at the bedside by nurses.

Keywords: *Acupuncture points, complementary therapies, fatigue, multiple sclerosis*

Introduction

Multiple Sclerosis (MS) is a chronic inflammatory demyelinating, and neurodegenerative disease with unpredictable course in young adults^[1]; however, it is often observed between the ages of 20 and 50 years, and its incidence rate is three times higher among women compared to men.^[2] As a progressive heterogeneous disease, MS causes a variety of symptoms including fatigue, muscle weakness, imbalance, sensory impairment, etc.^[3] Among the symptoms of MS, fatigue is the most common with an incidence of 55 to 90 percent, and is described as the worst symptom by 69% of the patients.^[4] It seems that the fatigue experienced by patients with MS is distinct from the fatigue seen in healthy individuals or those with other diseases, and clearly carries a major physical and psychological burden, especially when completing everyday tasks.^[5] The common medical treatments to

control MS fatigue include amantadine, modafinil, and pemoline. However, in the National of Institute for health and Care Excellence (NICE) guidelines, there is a clear recommendation of not offering this or other drugs for which scientific evidence is lacking to treat MS-related fatigue.^[6] The effectiveness of non-pharmaceutical and rehabilitation measures has been proven in the treatment of fatigue among patients with MS. These effects include improving physical and mental functions of patients, and hence, controlling of their fatigue.^[7]

Patients with MS usually use complementary and alternative treatments to cure MS or its symptoms. Cross-sectional studies indicate that 37 to 100 percent of the patients use these treatments.^[8] Investigations on MS fatigue management have shown that non-pharmacological interventions are considered as the first step in fatigue management, and patients with MS must apply these interventions in their daily

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schedule in order for these interventions to be sustainable and effective.^[9] The Emotional Freedom Technique (EFT) is one of the alternative therapies, a kind of Energy Psychology (EP) based on acupuncture in which the fingers are used to provide tapping, massage, or pressure instead of a needle.^[10] This method is also called needleless acupuncture. Magnetic Resonance Imaging (MRI) studies show that stimulation of acupuncture points affects the regulation of the limbic system activity, and creates relaxation by the releasing of serotonin, Gamma-Amino Butyric Acid (GABA) in the amygdala, and beta-endorphin.^[11] Energy psychologists believe that Chi (life energy) flows along the pathways of the meridians that are in contact with the internal organs of the body, and organ dysfunction is due to a recession of energy flow along these energy channels, and physical and mental health can be achieved by removing the obstruction and establishing the energy flow. EFT is the stimulation of the energy flow through tapping on the endpoints of the meridians.^[12]

This technique can be applied in a variety of mental and physical problems. In addition, it can be used with other methods, with the capability to combine with common medicine, hypnosis, and etc., and improve their results.^[13] EFT is used as a clinical intervention in nursing care, training, and research, and is an effective method for nurses to improve a variety of physical and emotional problems of their patients.^[14] Searching on various websites indicated that no study had been carried out regarding the effects of this method on fatigue in various diseases or on the symptoms of MS; however, case reports of EFT effects on chronic fatigue and MS symptoms like fatigue reported by the users of this technique as well as doctors are available on the eftuniverse.com website. The present study was the first controlled clinical trial investigation of the effect of this technique on fatigue severity in patients with MS. In the study by Baker *et al.*,^[15] EFT was used to eliminate the complications of Tamoxifen intake among the patients with breast cancer, which also resulted in the reduction of fatigue among these patients which persisted in the 12-week follow-up. Moreover, in the study by Bougea, EFT had a positive effect on the energy of patients with Tension-Type Headache (TTH) in the energy-fatigue dimension of Quality of Life (QOL).^[11] This technique is highly flexible, and as self-help tool to one's self or family members, it does not require the prescription of a physician, and can be taught individually or in groups and safely administered one-on-one, in group settings, online, or even in the field during large-scale disasters. EFT is safely delivered to people of all ages.^[16] The prevalence of MS is increasing, especially among women. Moreover, it has negative consequences, in particular the loss of quality of life associated with fatigue. Furthermore, the EFT technique as benefits like being easy to learn, the possibility of being performed by the patients themselves everywhere, its non-invasive nature relative to acupuncture, its patient empowerment regarding self-management of symptoms, and its lack of complication, Due to the abovementioned facts and the difference in treatment sessions in previous studies, a

clinical trial with a sham group was required on patients with MS and this study was performed with the aim to evaluate the effect of this technique on fatigue severity among these patients.

Materials and Methods

The current research was a randomized, single-blind, clinical trial performed on 50 women with MS referred to the MS Clinic of Ayatollah Kashani Hospital in Isfahan, Iran, from June to October 2017. The data collected in this study was registered in the Iranian Registry of Clinical Trials with the code IRCT20140422017387N6. The number of the subjects required to conduct the research was calculated at 30 individuals in each group using the sample size formula and based on a similar study and comparison of means, with 95% confidence interval and power of 80% (equal to 1.96 and 0.84). During the intervention, 1, 1, 1, and 7 individuals were excluded from the study due to performing plasmapheresis, recurrence of the disease, use of herbal remedies, and unwillingness to continue their cooperation, respectively [Figure 1].

The study inclusion criteria were as women with MS, aged 18-50 years, with a minimum of 6-month time since diagnosis, having fatigue severity score equal to or greater than 4 based on Fatigue Severity Scale (FSS), an Expanded Disability Status Scale (EDSS) score of equal to or less than 4.5 (assessed by a neurologist), lack of any disease other than MS, lack of menstruation, lack of pregnancy, lack of use of other complementary and alternative therapies in the last 6 months, lack of addiction to drugs and psychotropic drugs, and lack of injury and wound in the desired acupuncture points. In addition, the exclusion criteria included the reluctance to continue to collaborate in the study, the use of other complementary therapies, like acupuncture, yoga, meditation, and etc., during the intervention, absence from more than two consecutive sessions in the study, pregnancy, and recurrence of disease or hospitalization during the study.

In the first step, sampling was performed using simple non-random sampling method based on the inclusion criteria, then the informed consent form was completed by the subjects and the questionnaire was completed by the questioner in the absence of the researcher. In the next step, the participants were randomly assigned by minimization method to the two groups of case and sham by the minimization method using MiniPy software (GNU GPL v3, <http://minimpy.sourceforge.net>). In the process of randomization, it is probable that the treatment groups develop significant differences in some prognostic factors, especially when the sample size is relatively small (<200). If these factors have important effects on the primary or secondary outcomes of the study, any important difference in the levels of these factors invalidate the trial results and necessitate complicated statistical analysis. This software is a powerful program in group matching.^[17] For blinding, the patients were unaware of their treatment group

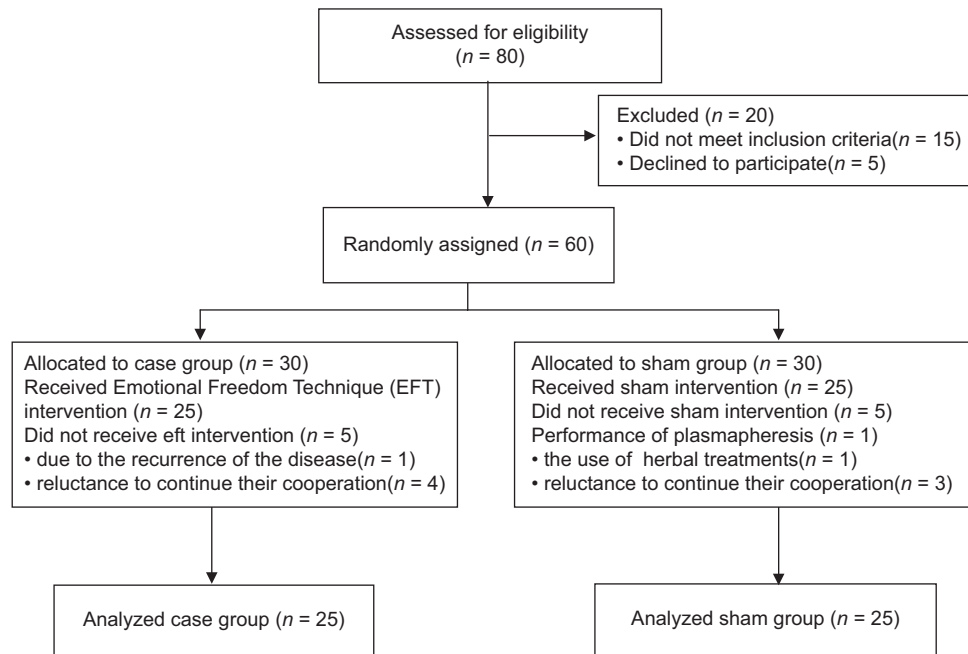


Figure 1: CONSORT flow of participant through the study

and the name of the technique used. The tool exploited in the study was a three-part questionnaire. The first part was a demographic information form consisting of 4 questions on age, education level, occupation, and marital status. The second part was related to the condition of the disease, and consisted of 2 questions on the length of suffering from MS and type of clinical pattern of MS. The third part consisted of the 9-item standard Fatigue Severity Scale (FSS). Each item was scored based on a scale ranging from 1 to 7. The total score was obtained by dividing the sum of scores by 9. The scores equal to or higher than 4 and scores less than 4 indicated fatigue and lack of fatigue, respectively. The FSS is a valid tool designed by Krupp (1998) in order to measure the severity of fatigue among individuals with MS and lupus.^[18] The reliability and validity of the FSS scale was standardized by Shahvaraghi *et al.*^[19] This tool has been used in several studies to measure fatigue severity in Iran.^[7,20] In the current study, the reliability of the FSS scale was obtained using Cronbach's alpha coefficient ($\alpha = 0.81$).

The researcher performed the intervention after learning EFT under the supervision of an expert. The EFT intervention for the case group was performed individually by the researcher in a calm room with adequate lighting and temperature, free of environmental stimuli, in the supine position on the bed, twice a week, 30 minutes each time, during 4 weeks (a total of 8 sessions). This technique, based on Gary Craig's basic EFT guideline, consisted of 4 steps. In the setup stage, the patient expressed the statement "Although I feel tired, I completely and deeply accept my body and myself;" repeated this sentence three times, and at the same time, the researcher rotationally massaged the sore spot (ST14 point in acupuncture) at a radius of 5 cm. In the recall step, the 13 acupuncture points, including head (DU20), eyebrows (BL2),

the side of eye (GB1), under the eyes (ST1), under the nose (GV26), chin (CV24), the lower border of the clavicle (KD27), armpit (SP21), the margin between the thumb and the outer corner of the nail (LU11), the index finger (LI 1), the middle finger (PC9), the little finger (HT9), and the karate point (SI 3) were tapped 10 times by the researcher using the fingertips of the index finger and middle finger. At the same time, the patient repeated the statement "I'm tired" with a focus on fatigue. In the 9-gamut step, the researcher tapped the gamut spot (TH3 point of acupuncture located on the back of the hand between the ring finger and the little finger on the metacarpal bone). Simultaneously, the patient performed the 9 brain stimulation actions of closing the eyes, opening the eyes, looking down and right, looking down and left, rotating the eyes clockwise, rotating the eyes counterclockwise, whispering a desired song for 2 seconds, counting numbers from 1 to 5, and whispering the desired song again for 2 seconds. In the last step, the second step was repeated by the researcher. Performing these four steps is called an EFT round. These rounds were repeated for 30 minutes.

In the sham group, the patients laid on a bed in the supine position in a quiet room with suitable lighting and temperature, without any environmental stimuli, and the researcher smoothly tapped the false points, including biparietal, the outer margin of the chin, the sides, the top of the nails, and the forearm, using the tips of the middle finger and forefinger. The researcher asked the patients to repeat the setup and recall statements of the problem (as in the case group) simultaneously with the taps. This procedure was also performed for 30 minutes twice a week for 4 weeks (8 sessions in total).

In order to guarantee the homogeneity of the subjects, the subjects were notified not to use this technique at home until the end of the study. The questionnaire was completed before, and immediately and 4 weeks after the study by the questioner in the absence of the researcher among both the case and sham groups. The interviewer was unaware of the intervention for the study subjects in order to prevent information bias. The collected data were analyzed using descriptive statistical tests including mean and Standard Deviation (SD) as well as inferential tests including Mann-Whitney, Chi-square, Fisher's exact test, independent *t*-test, and repeated measures analysis of variance (ANOVA) in SPSS software (version 18.0, SPSS Inc., Chicago, IL, USA).

Ethical considerations

The researcher conducted the study after introducing herself, explaining the objectives of the study and the study method to the participants, and obtaining written informed consent forms from all subjects. The subjects were insured of the confidentiality of their information and anonymity. They were informed that they could leave the study at any stage. This study was conducted with the ethical code IR.MUI.Research.rec.1396.3.017. After the intervention the technique was completely taught to both groups in one session, and the technique files were presented to both groups on a DVD.

Results

The two groups were not significantly different in terms of demographic characteristics, type of pattern of disease, and duration of MS ($p > 0.05$) [Table 1]. The independent *t*-test showed that the mean fatigue severity score did not differ significantly between the two groups before the intervention; however, this difference was significant immediately and 4 weeks after the intervention ($p < 0.05$) [Table 2]. In addition, in order to compare the mean score of fatigue severity among the subjects before and immediately and 4 weeks after the intervention, repeated measures ANOVA was used separately in each group. Based on the results of this test, the difference in mean of the three stages were statistically significant [Table 2].

Therefore, using the Least Significant Difference (LSD) test, these three stages were compared two by two. The results of this test indicated that in the case group, between the times immediately after and 4 weeks after the intervention, the mean fatigue severity score decreased significantly compared to before the intervention ($p < 0.05$). However, 4 weeks after the intervention, the mean changes were not significant in comparison to immediately after the intervention ($p > 0.05$). In the sham group, immediately after the intervention as well as 4 weeks after the intervention, the mean changes were not significant relative to before the intervention ($p > 0.05$). However, there was a significant change between the times immediately after and

4 weeks after the intervention, and the severity of fatigue increased in the follow-up phase ($p < 0.05$) [Table 3].

Discussion

The overall purpose of this study was to determine the effect of EFT on fatigue severity among women with MS. No article with this title was found on all sites with emphasis on 1995 (the year of the discovery of this method) until 2017. It was also not found on eftuniverse.com, where all articles are available. This study was the first controlled clinical trial regarding the effect of this technique on fatigue in patient with MS. The results of the study revealed that EFT reduced fatigue in the case group compared to the sham group. Moreover, in the case group, there was a significant difference in the severity of fatigue before and after the implementation of the technique, and this reduction continued until 4 weeks later. The results of the present study were in line with the study by Baker and Hoffman on the effect of EFT on Hormone Therapy (HT) complications among women with breast cancer. They also reported that after 3 weeks of intervention with a 3-hour session per week, fatigue reduced among the patient.^[15] Furthermore, in the study by Bougea on individuals with TTH along with other symptoms, fatigue and energy of the patients decreased and increased, respectively, and the QOL of the patients improved, which was consistent with the results of the present study indicating the positive effect of this technique on the reduction of fatigue.^[11]

A meta-analysis study examined 6 experimental studies with an active control group, including diaphragmatic breathing or pressure on sham points. The goal of these studies was to separate the psychology section of this technique (which is also used in several other treatment approaches) from the pressure therapy (tapping therapy). The results of these studies indicated that there was a significant difference between the case and control groups, and tapping therapy was an active and effective component of EFT and it was not a placebo.^[21] In the current study, the psychology section of EFT included cognitive components which were common between the two groups of case and sham and the only difference was the tapping on the false points. The results revealed that the active and superior part of the EFT was its somatic section or tapping therapy, which confirmed the results of this meta-analysis study.

The number of EFT sessions delivered ranges from one to eight. Numerous scientific studies of the use of EFT on depression, anxiety, and other psychological problems have shown that those who use EFT can recover quickly and often within a few sessions.^[16] Due to the lack of a study on the measurement of the effect of the EFT on fatigue in patients with MS, various studies examining the effect of mind and body therapies on fatigue among patients with MS, including acupuncture and acupressure based on stimulation of energy flow in the body, were assessed. Since EFT is based on the principles of acupuncture, studies have shown that pressing

Table 1: Comparison of demographic characteristics and clinical data of the participants in the two groups

Variable	Case group (n=25) Mean (SD)	Sham* group (n=25) Mean (SD)	p
Age (years)	36.44 (8.52)	36.00 (8.38)	0.85
Duration of MS** (years)	9.28 (5.67)	7.74 (5.53)	0.34
Level of Education	n (%)	n (%)	0.08
Under diploma	4 (16)	8 (32)	
Diploma	11 (44)	12 (48)	
Collegiate	10 (40)	5 (20)	
Marital status			0.73
Married	20 (80)	19 (76)	
Single	5 (20)	6 (24)	
Occupational status			0.42
Housewife	20 (80)	23 (92)	
Employed	5 (20)	2 (8)	
Pattern of disease			0.23
Relapsing-remitting	22 (88)	25 (100)	
Secondary progressive	3 (12)	0 (0)	

*Sham is “a treatment or procedure that is performed as a control and that is similar to, but omits a key therapeutic element of the treatment or procedure under investigation”. **Multiple sclerosis

Table 2: Comparison of the mean fatigue intensity score at different time periods in the two groups

Time	Case group Mean (SD)	Sham* group Mean (SD)	Statistical test		Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
			t	p			Lower	Upper
Immediately after the intervention	3.05 (0.89)	5.15 (0.94)	-8.08	<0.001	-2.09	0.25	-2.61	-1.57
Four weeks after the intervention	3.10 (0.81)	5.59 (0.57)	-12.54	<0.001	-2.49	0.19	-2.89	-2.09
Repeated measures ANOVA								
F	160.70	7.42						
p	<0.001	0.002						

*Sham is “a treatment or procedure that is performed as a control and that is similar to, but omits a key therapeutic element of the treatment or procedure under investigation”

Table 3: Paired comparison of mean fatigue intensity scores at different time periods using LSD* follow-up test in the two groups

Groups	Time		
	Before and immediately after p	Before and 4 weeks after p	Immediately and 4 weeks after p
Case	<0.001	<0.001	0.66
Sham**	0.053	0.057	0.002

*LSD: Least significant difference, ** Sham is “a treatment or procedure that is performed as a control and that is similar to, but omits a key therapeutic element of the treatment or procedure under investigation”

acupuncture points can be as effective as acupuncture, and EFT is called the “needleless acupuncture”,^[17] the results of those studies have been compared to those of the present study.

According to statistics, acupuncture is one of the most common types of complementary medicine used by patients with MS, and pain and fatigue are the most common symptoms improved by this treatment. In addition, in the study by Tajik et al.,^[22]

performing acupuncture once every 2 weeks for 6 months significantly reduced fatigue among patients with MS. The results of the investigation by Foroughipour on the effect of amantadine and acupuncture on fatigue among patients with MS showed that among patients in whom fatigue had not decreased with amantadine, 12 sessions of acupuncture significantly decreased fatigue.^[23] In the study by Bastani, acupuncture was implemented for 4 weeks in patients with MS, which resulted in a significant decrease in fatigue compared to the placebo group.^[24]

Given the consistency of the results of this study with other studies based on energy balance and achieving positive results through stimulation of energy flow in the body, and the chronic nature of MS and its associated symptoms, including fatigue, an easy and safe way is required to manage fatigue. In comparison with acupuncture, acupressure, and other complementary and alternative medicine, EFT does not require specialized training and it is easy to learn and apply in all places. In addition, due to its non-invasive nature and achieving of the desired results in less time in comparison to acupuncture, and lack of observation of a complication so far, it can be used by the patients as a method to help themselves.

While drugs used to treat fatigue in patients with MS such as amantadine, modafinil, and pemoline have side effects, and are not tolerated by some patients.^[6]

Individual differences and the commute to the hospital to participate in the study were among the limitations of this study, which could affect the severity of fatigue in patients and their response. In general, since fatigue is a mental symptom of MS, and several factors are involved in it, more extensive studies with larger sample sizes and greater blindness are required in this regard. Furthermore, since this study was the first clinical trial on fatigue in patients with MS, further studies on this symptom as well as comparison with other methods with focus on these patients are required. Due to the time limitation in this study, further studies with longer follow-up are needed to evaluate the longevity of this treatment.

Conclusion

According to the results of this study, it can be concluded that the EFT may be effective in decreasing fatigue among patients with MS, and can be used as a non-medical, easy, and safe method for fatigue management among these patients. Moreover, it is recommended as a nursing intervention to help diminish fatigue in patients with MS and increase energy at the bedside.

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Conflicts of interest

Nothing to declare.

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