

The impact of self-administered acupressure on sleep quality and fatigue among patients with migraine: A randomized controlled trial



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ABSTRACT

Background and aim: Poor sleep and fatigue are among the most common complaints of patients with migraine. These problems can lead to different negative consequences such as headaches. This study aimed to examine the impacts of self-administered acupressure on sleep quality and fatigue among patients with migraine.

Methods: This double-blind randomized controlled trial was conducted in 2016 on 76 patients who suffered from migraine without aura. Patients were conveniently selected from the neurology clinic of Valiasr (PBUH) teaching hospital and randomly allocated to either an acupressure ($n = 38$) or a sham acupressure group ($n = 38$) group. Data collection instruments were a demographic questionnaire, Pittsburg Sleep Quality Index, and Fatigue Severity Scale. Patients in the acupressure and the sham acupressure groups were trained to apply acupressure on respectively acupoints and sham points thrice weekly at bedtime for four consecutive weeks. The data were analyzed through the Chi-square, the independent-sample t , the paired-sample t , and the ANCOVA tests at the significance level of less than 0.05.

Results: After controlling sleep quality mean scores at baseline, no significant difference was found between the sleep quality of the two groups after intervention ($P > 0.05$). The mean scores of fatigue significantly decreased in both acupressure and sham acupressure groups ($P < 0.05$). However, the decrease in the acupressure group was significantly greater than in the sham acupressure group ($P < 0.05$).

Conclusion: As a noninvasive non-pharmacological therapy, acupressure can significantly reduce fatigue among patients with migraine.

1. Introduction

Migraine is a primary recurrent headache characterized by throbbing headaches which are typically unilateral and moderate to severe in intensity. Migraine headaches usually last 4–72 hours and are associated with accompanying symptoms such as nausea, photophobia, and phonophobia [1]. Overall, the prevalence of migraine is highest in both men and women aged from 25 to 55 years [2]. Migraine afflicts almost 15% of women and 6.5% of men in the United States [3]. The total prevalence of migraine in Iran is also 14% [4].

Migraine pathophysiology is still poorly known, even though its underlying mechanism is thought to be neural activation in the brain stem and subsequent release of neuropeptides which cause inflammation, vasodilation, and pain [5].

Based on the attack frequency, migraine can be considered as either episodic or chronic. In episodic migraine, the patients have fewer than 15 headache days per month. In chronic migraine, however, the patients experience 15 or more headache days per month for more than 3 months, where at least 8 of the headache days have features of migraine [1].

Migraines can also be accompanied by or go without *aura*, which is a warning sensation. Visual aura is the most common migraine aura. Other migraine auras include somatosensory, motor, and speech disturbances [6,7]. Migraine without aura (MWA) is the most common type of migraine [8].

Various stimuli, known as migraine triggers, can lead to migraine attacks in susceptible individuals. Common migraine triggers include stress, sleep disruption [9], intense emotions, menstruation, fasting,

bright sunlight, hot/cold weather, shinning [10], and fatigue [11].

Migraine has devastating effects on afflicted patients both during headache attacks and during interictal periods. It is the seventh leading cause of years of life lost due to disability [12]. Migraine attacks can severely affect afflicted persons' familial and social lives, work productivity, and quality of life [13]. The quality of life in people with migraine is affected not only by the attacks themselves, but also by problems such as sleep disturbances including low sleep quality [14]. On the other hand, sleep disturbances as mentioned above can trigger migraine attacks [9]. A study showed that the frequency of headaches among patients with migraine with low sleep quality and short sleep duration was greater than patients with migraine who did not suffer from these problems [15].

Low sleep quality among patients with migraine causes them different levels of fatigue so that fatigue is among the most common complaints of patients with migraine [16]. Fatigue is a feeling of tiredness which interferes with the activities of daily living and is not alleviated with rest [17]. The risk of chronic fatigue among patients with migraine is almost 1.5 times greater than healthy people [18]. Fatigue is associated with different negative outcomes such reduced cognitive capacity of the brain and subsequent increased rate of committing cognitive-behavioral errors [19]. In patients with migraine, fatigue can be a trigger factor for migraine attacks [11].

An optimized management of migraine encompasses education, behavioral treatments, and pharmacological therapy. The pharmacological therapy for migraine can be classified as acute or preventive treatment. While acute treatment aims to abort migraine attacks when they occur, preventive treatment aims to reduce attack frequency and

severity, and overall to prevent headaches [20].

Acute migraine medications may be specific or non-specific. Specific medications are ergotamine-containing compounds and triptans. Non-specific medications include non-steroidal anti-inflammatory drugs (NSAIDs), antiemetic agents, neuroleptics, and some steroids [20,21].

A variety of medications such as beta-adrenergic blockers, antidepressants, antiepileptics, and calcium-channel blockers are used to prevent migraine headache [21]. However, drugs not only impose a heavy financial burden on patients but also bring about different side-effects. It is expected that decreased headache frequency and/or severity would reduce the need for taking medications among people with migraine. To this end, avoiding or reducing the severity of migraine triggers such as poor sleep quality and fatigue may be of benefit. Complementary and alternative therapies, such as acupressure, appear to offer an option to achieve this goal.

The underlying principles of acupressure are the same as acupuncture, except that it is non-invasive. In acupressure, some points on meridians (known as acupoints) are pressed with parts of the body [22,23]. Traditional Chinese Medicine holds that acupressure helps open up the Qi energy flow and thereby restores the internal balance of the body [24]. Acupressure needs no sophisticated equipment and can be applied by physicians, nurses, and even patients [25].

Previous studies reported the effectiveness of acupressure in improving sleep quality among middle-aged and elderly patients with hypertension [26]. Moreover, some studies reported its positive effects on fatigue among patients with multiple sclerosis [27] and hepatocellular carcinoma [28]. However, to the best of our knowledge, its effects on sleep quality and fatigue among patients with migraine are still unknown. To narrow this gap, this study was done with the aim of examining the impacts of self-administered acupressure on sleep quality and fatigue among patients with migraine.

2. Materials and methods

2.1. Type of study

This study was designed as a double-blind two-group randomized controlled trial in 2016.

2.2. Sample of the study

In the present study, 76 patients who suffered from MWA participated. Patients were conveniently selected from the neurology clinic of Valiasr (PBUH) teaching hospital, which is affiliated to Birjand University of Medical Sciences (BUMS), Birjand, Iran. For these patients, a definitive diagnosis of MWA was established by a neurologist in accordance with the beta version of the 3rd edition of the International Classification of Headache Disorders (ICHD-3 beta) criteria (Table 1) [1]. Other inclusion criteria were initial onset of migraine at least one year before the study, age of 18–60 years, basic literacy skills, a score of more than 5 for the Pittsburgh Sleep Quality Index, no skin lesions (such as rash or wound) at acupoints, no drug addiction, and no affliction by serious mental disorders and chronic

Table 1
ICHD-3 beta diagnostic criteria for MWA.

A: At least 5 attacks fulfilling criteria B-D
B: Headache attacks lasting 4–72 h (untreated or unsuccessfully treated)
C: Headache has at least 2 of the following characteristics:
1: Pulsating quality
2: Moderate or severe pain intensity
3: Aggravation by or causing avoidance of routine physical activity (e.g., climbing stairs)
D: During headache at least one of the following:
1: nausea and/or vomiting
2: photophobia and phonophobia
E: Not attributable to another disorder [1]

illnesses such as cancer, systemic lupus erythematosus, or advanced heart failure. Moreover, pregnant women were not included and women who became pregnant during the study were excluded.

Sample size was calculated with a type I error of 0.05 and a power of 0.80 and based on the results of an earlier study which reported two means of 10.7 ± 3.3 and 6.8 ± 2.6 [29]. The calculated sample size was equal to thirteen for each group; however, it was increased to forty in order to improve study power.

During sampling process, which lasted from June to December 2016, 106 patients were approached, 26 of whom either were ineligible or refused participation. Therefore, eighty patients with MWA were recruited. Afterward, a demographics form containing items on gender, educational status, the mean number of headache attacks per month (in the last three months), marital status, and the duration of affliction by migraine and primary outcomes measures were completed by the patients.

2.3. Primary outcomes

In this study, the primary outcomes were sleep quality and fatigue. Pittsburgh Sleep Quality Index (PSQI) was used to assess sleep quality. This inventory was developed in 1989 by Buysse et al. for the assessment of sleep quality in the last month. This index contains eighteen items in seven subscales, namely subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medications, and daytime dysfunction. Item scores range from 0 to 3. Scores 0, 1, 2, 3 respectively stand for good status, relatively good status, relatively bad status, and bad status. The total score of PSQI is 0–21 with higher scores standing for poorer sleep quality. Moreover, scores 5 and more show poor sleep quality [30]. The PSQI has been translated into Persian and cross-culturally adapted; the validity and reliability of the Persian version have proved acceptable [31]. The Cronbach's alpha of the index in the present study was 0.72. Fatigue was measured by Fatigue Severity Scale (FSS). It assesses individuals' personal perceptions of their fatigue using nine items. Items can be scored from 1 (“Completely disagree”) to 7 (“Completely agree”). Total FSS score can be 9–63, with higher scores showing severer fatigue [32]. FSS has been used as a valid and reliable tool in previous Iranian-based studies on patients with migraine [33]. Its Cronbach's alpha in the present study was 0.8.

2.4. Randomization

The selected participants were then assigned into either a sham acupressure or an acupressure group through block randomization. Accordingly, a research assistant prepared eighty opaque envelopes using a block size of four and a randomization ratio of 1:1. Finally, one envelope was given to each eligible patient and the patient was allocated to either the groups based on the allocation sequence in the envelope.

2.5. Intervention

Initially, all patients completed the data collection instruments and then, they were randomly allocated to either the groups. Patients in the acupressure group were subjected to self-administered acupressure. Accordingly, the second author—who had received acupressure training from a Chinese Traditional Medicine specialist—trained patients in the acupressure group to apply self-administered acupressure on the Neiguan and the Yin Tang acupoints (Box 1) [34,35].

Patients were trained to use their thumb to respectively press the right Neiguan point, the left Neiguan point, and the Yin Tang point, each for 3 min with two-minute rest intervals in between—thirteen minutes in total. They were asked to apply such acupressure at bedtime on Saturdays, Mondays, and Wednesdays for four consecutive weeks. The participants made gentle but firm pressures on the specified

Box 1

Standard acupressure notes for the selected acupoints

Neiguan.

This point is located on the anterior aspect of the forearm between the tendons of the palmaris longus and the flexor carpi radialis, 2 B-cun proximal to the palmar wrist crease.

Note 1: With the fist clenched, the wrist supinated, and the elbow slightly flexed, the two tendons become more prominent. Neiguan is located 2 B-cun proximal to Daling.

Note 2: If the palmaris longus tendon is not present, Neiguan is medial to the flexor carpi radialis tendon.

YinTang.

This acupoint is located at the center of the glabella, on the anterior midline, between the eyebrows.

Note 1: The glabella area is located on the smooth surface of the frontal bone, directly above the root of the nose, between the superciliary arches.

Note 2: YinTang is located on the center of glabella, on the midline, and between the medial extremities of the eyebrows [34,35].

acupoints. The amount of applied pressure was dependent on the location of the acupoint and thickness of the skin, where the pressure produced a feeling of tingling, soreness, and distention.

Patients exercised the acupressure technique under the supervision of the second author until achieving mastery over it. Besides, they were provided with a CD which contained the acupressure technique video clip and a checklist which contained the time and the day of acupressure. They were asked to complete the checklist after each acupressure session. Moreover, the second author made telephone contacts with each participant at the end of each week during the study and reminded him/her of applying acupressure.

The sham acupressure group members were trained to press, using their thumb, 2.5 cm below the Neiguan points and a point 3 cm above the Yin Tang point, each for 3 min with two-minute rest intervals in between. The participants were asked to perform this technique at bedtime on Saturdays, Mondays, and Wednesdays for four successive weeks with gentle but firm pressures. The pressure level relied on the location and skin thickness of the acupoint such that the pressure produced a feeling of tingling, soreness, and distention. The participants practiced the acupressure technique under the second author's supervision until they achieved mastery. A CD containing the technique' video clip and a checklist containing the time and date of performing the technique were given to the participants. They were asked to complete the checklist after each acupressure session. Furthermore, the second author gave the participants telephone calls at the end of each week during the study and reminded them of applying the technique.

At the end of the fourth week of the study, all patients in both groups completed the data collection instruments for a second time.

2.6. Ethical considerations

This study has the ethical approval of the Ethical and Research Committee of BUMS, Birjand, Iran, (approval code: IR.BUMS.1395.11). It was also registered in the Iranian Registry of Clinical Trials (registration code: IRCT2016061117756N3). Written informed consent was obtained from the participants, and they were told that their information would be managed confidentially and used just for the purposes of the present study. Moreover, participation in the study was voluntary and withdrawal was not associated with any punishment.

2.7. Data analysis

The participants' demographic characteristics except for the mean number of headache attacks were compared with between the groups using the Chi-square and Fisher's exact tests. The mean number of headache attacks was compared between the groups using independent-sample *t*-test. The distributions of the mean scores of sleep quality and fatigue were assessed using the Kolmogorov-Smirnov test. Then, the

independent-sample *t* and the paired-sample *t* were conducted for respectively between- and within-group comparisons concerning the mean scores of fatigue. An independent-sample *t*-test indicated that there was a significant difference in the mean scores of sleep quality between the acupressure and sham acupressure groups. Thus, an ANCOVA test was applied to identify any difference in the mean scores of sleep quality between groups after intervention, thus controlling for the effect of the mean scores of sleep quality before intervention. The level of significance was set at less than 0.05.

3. Results

As shown in Fig. 1, two patients from each group were excluded from the study and final data analysis was carried out on the data retrieved from 38 patients in each group. The groups did not significantly differ from each other concerning participants' age, gender, educational status, marital status, and the duration of affliction by MWA ($P > 0.05$; Table 2). The mean number of headache attacks per month at baseline was 2.68 ± 0.66 for the acupressure group and 2.86 ± 0.93 for the sham acupressure group ($P > 0.05$).

As displayed in Table 3, before the intervention, the mean scores of sleep quality in the sham acupressure group were significantly less than the acupressure group ($P < 0.05$). After intervention, the mean scores of sleep quality in the acupressure and in the sham acupressure groups were 8.11 ± 2.84 and 9.63 ± 3.17 , respectively. ANCOVA was applied to examine differences in the mean scores of sleep quality after intervention between the two groups, controlling for the mean scores of sleep quality before intervention. The adjusted means were 10.28 ± 1.66 and 7.50 ± 1.66 for acupressure and sham acupressure groups respectively. The ANCOVA results did not reveal a statistically significant difference between adjusted means of the two groups ($P > 0.05$; Table 4).

There were no significant differences between the groups concerning the mean scores of fatigue ($P > 0.05$). Within-group comparisons in the acupressure group revealed significant decreases in the mean scores of fatigue ($P < 0.05$). Similarly, significant decreases were observed in the sham acupressure group concerning the mean scores of fatigue ($P < 0.05$; Table 5).

After the intervention, within-group comparisons indicated that the pretest-posttest mean differences of fatigue in the acupressure group were significantly greater than the sham acupressure group ($P < 0.05$; Table 5).

4. Discussion

This study aimed to examine the impacts of self-administered acupressure on sleep quality and fatigue among patients with MWA. Its findings revealed that sleep quality improved in both the acupressure and sham acupressure groups after intervention. Nevertheless, after

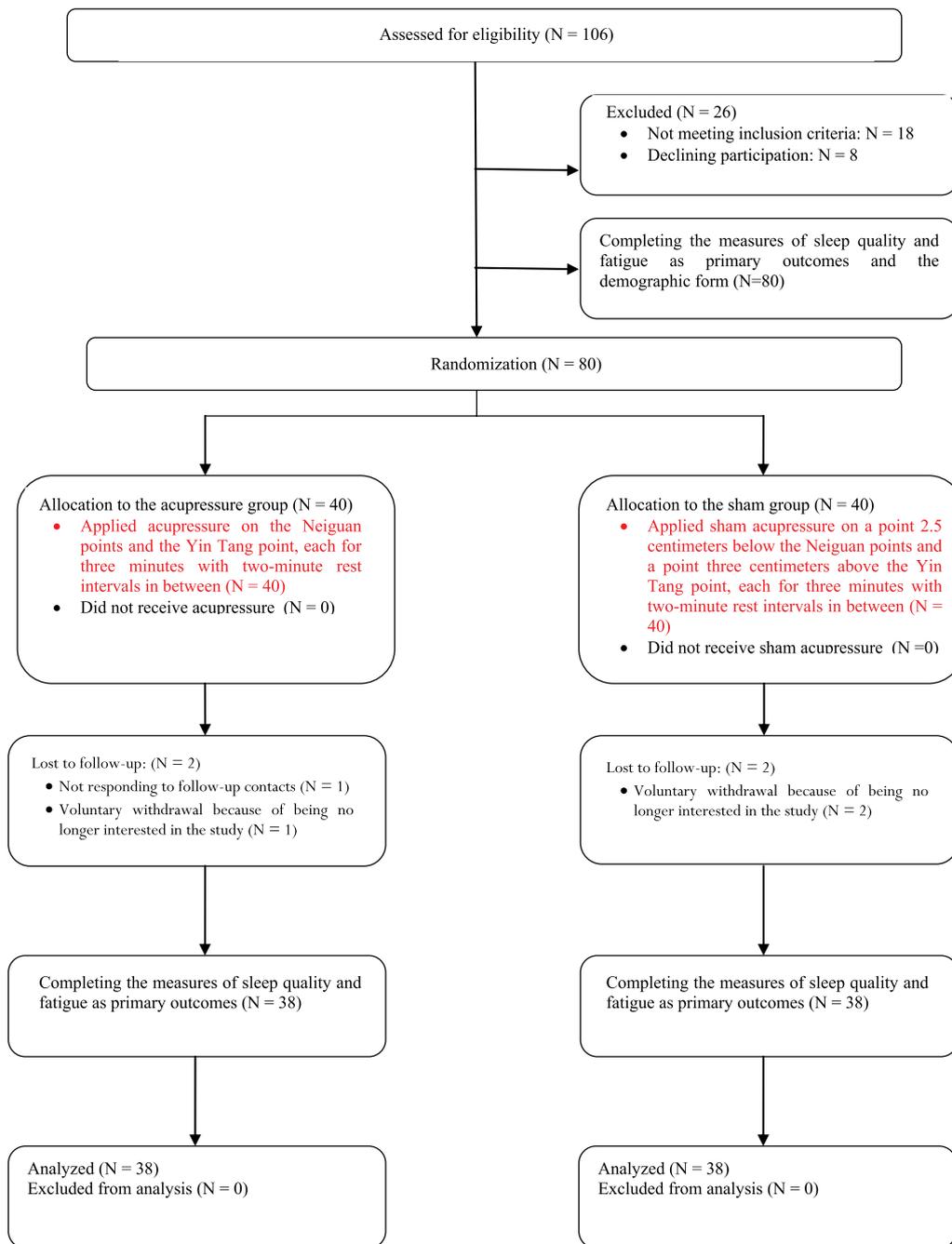


Fig. 1. The Consort diagram of the study.

controlling sleep quality mean scores at baseline, no significant difference was found between sleep quality of the two groups after intervention. In the present study, in the acupressure group, the amounts of decreases in the mean scores of fatigue were significantly greater than the sham acupressure group.

In contrast with this finding, some previous studies on other patient populations reported the positive effects of acupressure on sleep quality. For instance, a study found acupressure effective in improving sleep quality among middle-aged and elderly patients with hypertension [26]. Two other studies showed that acupressure significantly improved sleep quality among patients with chronic low back pain [36] and nursing home residents [37]. Acupoint stimulation is believed to regulate neurotransmitters and hormone functions in the body [38] and thereby, improves sleep quality [39]. As expressed in the previous sections, sleep quality of the acupressure group in the present study was

significantly worse than that of the sham acupressure group. Thus, while the performed intervention in the acupressure group improved sleep quality, it could not make a significant difference between the two groups. This finding also may be partially attributed to the improved sleep quality in the sham acupressure group after intervention, which might also have led to a narrow difference in mean scores of sleep quality between the two groups after intervention.

Similarly, some studies have reported decreases in the mean scores of sleep quality in the sham acupressure group. In a study, for instance, the mean scores of sleep quality and some of its subscales significantly decreased in both the acupressure and the sham acupressure groups [37]. Significant decreases in the mean scores of sleep quality and some of its subscales in sham acupressure groups may be due to the fact that the stimulation of non-acupoints can cause effects, depending on the location of the points [40].

Table 2
Between-group comparisons concerning participants' demographic characteristics.

Characteristics		Groups		P value
		Sham acupressure	Acupressure	
		N (%)	N (%)	
Gender	Female	14 (36.8)	16(42.1)	0.64 ^a
	Male	24(63.2)	22(57.9)	
Age (Years)	30 and less	13(34.2)	10(26.3)	0.30 ^a
	31–40	8(12.1)	12(31.6)	
	41–50	12(31.6)	7(18.4)	
Educational status	More than 50	5(13.2)	9(23.7)	0.20 ^a
	Primary and guidance school	9(23.7)	16(42.1)	
	High school and diploma University	11(28.9)	10(26.3)	
Marital status	Single	18(47.4)	12(31.6)	0.67 ^b
	Married	8(21.1)	5(13.2)	
	Divorced or widowed	25(65.8)	29(76.3)	
Duration of affliction by migraine (Years)	5 and less	5(13.2)	4(10.5)	0.88 ^a
	6–10	17(44.7)	16(42.1)	
	More than 10	11(28.9)	13(34.2)	
		10(26.3)	9(23.7)	

^a The Chi-square test.

^b The Fisher's exact test.

Table 3
Between-group comparisons concerning the mean scores of sleep quality and fatigue before intervention.

Group	Variables	
	Overall sleep quality (Mean ± SD)	Fatigue (Mean ± SD)
Acupressure	12.50 ± 3.12	42.82 ± 8.70
Sham acupressure	10.89 ± 3.32	40.42 ± 5.77
P value	0.03 ^a	0.16 ^a

^a Independent-sample *t*-test.

Table 4
Between-group comparisons concerning the mean scores of sleep quality after intervention, adjusting for pretest mean scores of sleep quality.

Group	Variable
	Overall sleep quality (Mean ± SD)
Acupressure	10.28 ± 1.66
Sham acupressure	7.50 ± 1.66
F	2.001
P value	0.16 ^a

^a ANCOVA test.

Table 5
Between-group comparisons concerning the mean scores and the pretest-posttest mean differences of fatigue.

Variable	Group	Time		P value	Mean difference (Mean ± SD)
		Before (Mean ± SD)	After (Mean ± SD)		
Fatigue	Acupressure	42.82 ± 8.70	34.76 ± 7.52	< 0.001 ^b	−8.05 ± 3.55
	Sham acupressure	40.42 ± 5.77	39.71 ± 4.95		
P value		0.16 ^a	0.001 ^a	–	< 0.001 ^a

^a Independent-sample *t*-test.

^b The paired-sample *t*-test.

The other finding of the present study was a significant decrease in the mean score of fatigue in both the acupressure and the sham acupressure groups. Of course, the amount of decrease in the acupressure group was significantly greater than the sham group. In line with this finding, previous studies reported the positive effects of acupressure on fatigue among patients with multiple sclerosis [27] and hepatocellular carcinoma [28]. This finding may be attributed to the effectiveness of acupoint stimulation in regulating the functions of the nervous and the endocrine systems [41]. Moreover, a significantly greater decrease in the mean score of sleep quality in the acupressure group in the present study might have contributed to the significantly greater decrease in fatigue mean score in this group. Besides, different types of acupoint stimulation can cause some levels of placebo effects [42].

It is noteworthy that no side-effects were reported in either group during the study period. Furthermore, the effect size using Cohen's *d* for fatigue was 0.77, which suggests a medium clinical effect [41]. Thus, it seems that the intervention performed in the acupressure group had a clinically meaningful effect on reducing fatigue among patients with MWA.

In future studies, it will be interesting to determine the effect of the acupressure on the other underlying causes of migraine such as stress and hormonal fluctuations [43,44].

Among the study limitations were convenience sampling from a single healthcare center. Future studies can assess the effects of acupressure on different acupoints among random samples of patients and healthy people. Comparing the effects of acupressure with other complementary therapies on sleep quality and fatigue can be another area

of investigation. Longitudinal studies can also be conducted to provide more credible results concerning the long-term effects of acupressure on fatigue and sleep quality among people with MWA.

5. Conclusion

As a noninvasive non-pharmacological therapy, acupressure can significantly reduce fatigue among people with migraine. Therefore, it can be used as a complementary therapy to manage fatigue in people with MWA.

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Conflicts of interest

The authors declare no conflict of interest.

Author contributions

SAV conceived of the initial idea for the study and helped to study design. MS designed the study, collected data, and performed the statistical analysis. HRB contributed to intervention design and to draft the manuscript. HRR helped to recruit the participants and to intervention design. All authors read and approved the final manuscript.

Ethical considerations

This study has the ethical approval of the Ethical and Research Committee of Birjand University of Medical Sciences, Birjand, Iran (approval code: IR.BUMS.1395.11). It was also registered in the Iranian Registry of Clinical Trials (registration code: IRCT2016061117756N3).

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Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.ctcp.2018.10.011>.

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