ORIGINAL RESEARCH ARTICLE

The effect of Su Jok therapy on dysmenorrhea: A randomized placebo controlled study

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Abstract

Women can experience varying degrees of pain associated with menstruation during each cycle. They use both non-pharmacological and pharmacological methods to reduce menstrual pain. One of the non-pharmacological methods for reducing pain is the acupuncture-based Su Jok therapy. This study aims to determine the effect of Su Jok application in reducing menstrual pain The study was conducted as a single-blind, randomized, placebo-controlled trial with nursing students. In the study, pain levels in both groups decreased significantly after the intervention. There was no significant difference between the groups' mean pain scores.. When the change from the first to the last measurements was examined, there was no statistically significant difference between the groups, although the reduction in the experimental group was greater than in the control group. As a result of the study, both correct-point and sham-point applications reduced pain. *(Afr J Reprod Health 2025; 29 [12]: 148-158).*

Keywords: Dysmenorrhea; Non-pharmacological methods; Pain; Su Jok therapy

Résumé

Les femmes peuvent éprouver des douleurs menstruelles de gravité variable, également connues sous le nom de dysménorrhée. Pour soulager cette douleur, elles ont recours à des méthodes pharmacologiques et non pharmacologiques. La thérapie Su Jok, une technique basée sur l'acupuncture, fait partie des approches non pharmacologiques. Cette étude visait à évaluer l'efficacité de la thérapie Su Jok dans la réduction des douleurs menstruelles. Un essai contrôlé randomisé en simple aveugle a été mené auprès d'étudiantes en soins infirmiers. Les niveaux de douleur dans les deux groupes ont diminué de manière significative après l'intervention. Toutefois, aucune différence statistiquement significative n'a été observée entre les scores moyens de douleur des deux groupes. Bien que la réduction de la douleur ait été plus importante dans le groupe expérimental, la différence entre les mesures initiales et finales n'était pas statistiquement significative. Les résultats suggèrent que les applications de la thérapie Su Jok, qu'elles soient réalisées sur les points corrects ou sur des points simulés, peuvent toutes deux contribuer à la réduction de la douleur. *(Afr J Reprod Health 2025; 29 [12]: 148-158).*

Mots-clés: Dysménorrhée ; Méthodes non pharmacologiques ; Douleur menstruelle ; Thérapie Su Jok

Introduction

Dysmenorrhea is a condition that directly affects women's daily lives and quality of life. Women resort to different methods to reduce this pain, which is experienced at varying degrees from mild to severe In addition to pharmacological methods, various approaches, including hot application, aromatherapy, acupuncture, and acupressure, can be applied. Studies have reported that acupuncture and acupuncture-based practices are effective in reducing menstrual pain caused by dysmenorrhea Su Jok has also been reported to be effective for different types of pain in various parts of the body. In this study, the effect of Su Jok therapy on dysmenorrhea was compared with that of a sham point.

Pain is one of the most common problems during menstruation.[1-3] Dysmenorrhea is a Greek term for "painful monthly bleeding" and can be classified as primary and secondary dysmenorrhea.[4] Primary dysmenorrhea is lower abdominal pain that occurs during the menstrual cycle and is not associated with other diseases or pathologies, while secondary dysmenorrhea refers to menstrual pain caused by anatomical or obvious pelvic pathology such as endometriosis.[5-7] In dysmenorrhea, the pain is cramping and colicky, and is frequently experienced as abdominal and low back pain.[1,2] As a result of a study conducted by Karabulutlu[3] with

nursing students, it was determined that 86.4% of the students experienced dysmenorrhea, and 88.6% reported abdominal pain.

Studies have noted that women affected by menstrual pain may miss work or school due to this pain, which can have significant social and economic impacts.[8-10,4,7] Various pharmacological and non-pharmacological methods are widely used in pain management. Among pharmacological treatments, the most commonly used are nonsteroidal anti-inflammatory drugs (NSAIDs), hormonal contraceptives, and analgesics to reduce menstrual pain. Long-term use of pharmacological drugs can cause side effects such as nausea, indigestion, diarrhea, and fatigue, and may also affect the gastrointestinal, hematological, renal, and central nervous systems.[11,12] Non-pharmacological methods are used to improve the quality of life of women and to relieve pain, and their use has been increasing in recent years.[13,14] Methods such as exercise, yoga, connective tissue manipulation, massage, aromatherapy, topical heat, Transcutaneous Electrical Nerve Stimulation (TENS), acupuncture, acupressure, and reflexology are used in the management of dysmenorrhea.[14] The application of non-pharmacological methods, either alone or in combination with pharmacological methods, is effective in reducing the severity of pain. These methods are applied not to replace pharmacological interventions, but to assist them and to reduce drug use.[15-17]

One of the non-pharmacological methods is Su Jok therapy. It was discovered and developed by Prof. Park Jae Woo, a scientist who worked at Seoul University in Korea, and is accepted and applied in countries such as South Korea, Russia, India, and the United States.[18,19] Su Jok means 'hand-foot' in Korean and is applied by using the hands and feet.[8,19] It is similar to reflexology and acupuncture-based acupressure applications, and is based on the concept of energy flow and meridians. It involves the use of the representations of the human body on the hands and feet, i.e., the points where the limbs and organs correspond to these areas. It is reported that there are receptor sites on the hands and feet that are reflexively connected to various parts of the body. When pain occurs in an organ in the body, signals are sent to the corresponding area on the hands and feet according to the principle of the compliance system.[20-22] When pressure is applied to the relevant point, electrochemical nerve impulses are activated, the stimulus is perceived by the peripheral nervous system, and a neural response is generated. This message is transmitted by afferent neurons to a ganglion in the central nervous system. The message passing through the ganglion is transmitted to specific organs and glands by efferent neurons, and a physiological response is generated.[23] Thus, the flow of blocked energy is restored and the secretion of substances necessary for treatment is promoted. When the energy flow is balanced, improvement in symptoms is observed.[20,21] In the application, the point corresponding to the affected organ on the hands and feet is initially determined. This point is stimulated by massaging with various materials (blunt, round-tipped objects; sticks specially made for this application; magnets; or plant seeds). It is a non-invasive technique that has no side effects.[19] Numerous studies have shown that Su Jok application has positive effects in reducing pain.[24-26]

Dysmenorrhea is a problem that women experience every month, negatively affecting their comfort, quality of life, work productivity, and social life. For this reason, identifying and using methods that reduce pain and have no side effects can improve women's comfort during this period. This study aims to determine the effect of Su Jok application in reducing menstrual pain.

Methods

Design

The study was designed as a single-blind, randomized, placebo-controlled trial.

Participants

The study was conducted at a foundation university in Türkiye between March and June 2024. The study population consisted of female students enrolled at the university, and the sample included those who met the research criteria and agreed to participate. Female students aged 18 years or older, with regular menstrual cycles (21–35 days), and who had experienced abdominal pain in the last three cycles were included. Students with any

health problems that could affect the menstrual cycle, such as ovarian cysts, and those using hormonal medications were excluded from the study. Cohen's d power analysis was used to determine the sample size. According to the reference article[27], in order to achieve over 95% power for the study, 16 participants (8 in each group) were required at a significance level of 5% and an effect size of 3.04 (df = 6; t = 1.943).

Students who met the inclusion criteria were recruited, and the study was conducted with those who agreed to participate. Students who met the criteria were identified, and a participant pool was created. Simple randomization was then performed. In total, 60 students who met the research criteria and volunteered to participate were recruited.

The randomization table was created using https://www.calculatorsoup.com, and the students were divided into two groups: experimental (n = 30) and placebo control (n = 30). After three months of implementation and follow-up, a total of 34 students completed the intervention and submitted their data. A total of 26 students left the study due to various reasons, including heavy workload, forgetting to perform the intervention, and losing interest (n = 23), or taking analgesics (n =3).

Data collection methods and tools

Data were collected by the researcher using the Information Form and the Visual Analog Scale (VAS).

Information Form: The form prepared by the researchers included information about the participants' age, marital status, menstrual cycle frequency and duration, duration of pain, pain intensity and type, and the practices used to reduce pain.

Visual Analog Scale (VAS): The VAS is a scale assessed by individuals marking a point on a horizontal or vertical line of 10 cm or 100 mm, with one end indicating no pain (0 points) and the other end indicating unbearable pain (10/100 points). It is used in various patient populations to assess the severity of acute pain, especially to evaluate the effectiveness of treatment or intervention.[2,28] Figure 1

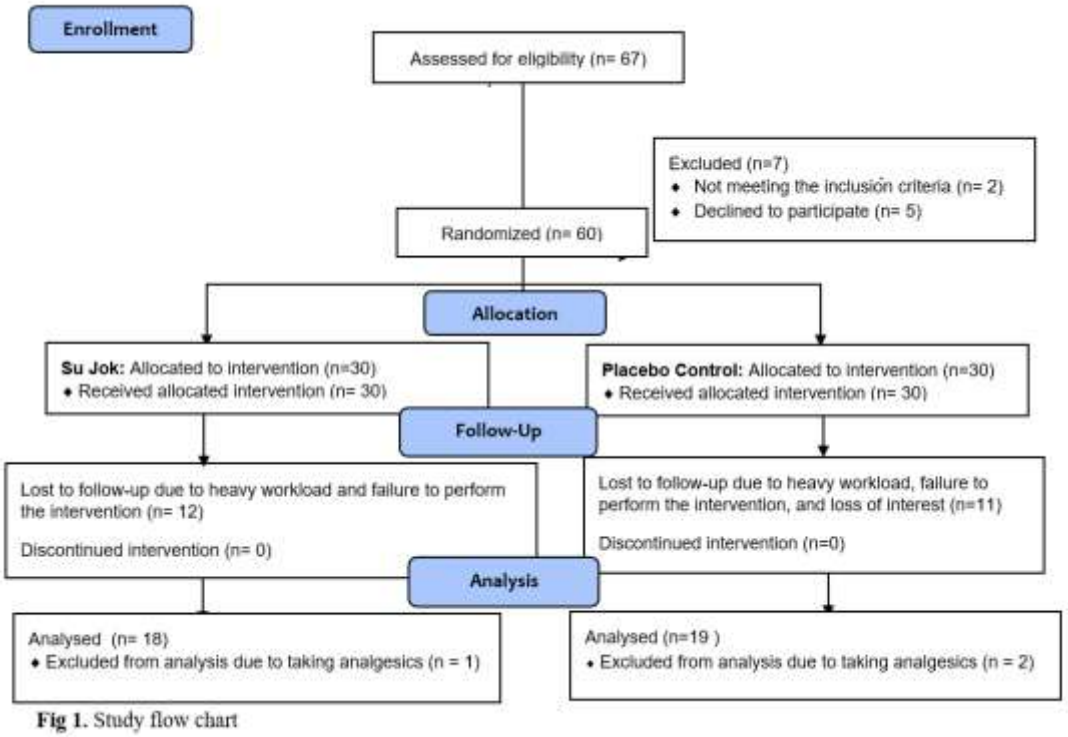

Fig 1. Study flow chart

Figure 1: Study flow chart

Interventions

Initially, female students in the study population were evaluated according to the research criteria, and groups were formed by identifying eligible participants. The study was conducted according to CONSORT guidelines. At the beginning of the study, all students were instructed not to take analgesics or use any non-pharmacological methods during the intervention period The application point was determined based on the designated area specified by Woo in his book.[18-19]

Participants in the experimental group (Su Jok group) were first asked by the researcher to complete the Information Form. In the study, the seed therapy method—one of the Su Jok application techniques—was used, and black pepper seeds were applied, with preference given to application on the hands for ease of use. Each participant was individually instructed on the application area on their hands, the application method and steps, and how to evaluate their pain using the VAS. For the application, three black pepper seeds were fixed between the 3rd and 4th fingers of the hand using Betafix. The seeds were kept in this position for four hours and massaged with pressure for 10–15 seconds every hour. When the participants began to experience abdominal pain associated with the menstrual cycle, they evaluated their pain using the VAS and then performed the intervention themselves. During the intervention, the participants recorded their pain intensity every hour and at the end of the massage session. After the four-hour application period, the seeds were removed. The intervention was performed on the first day of the menstrual cycle. The interventions were repeated with the same group of participants for three menstrual cycles.

Participants in the placebo control group were first asked by the researcher to complete the Information Form. Similar to the experimental group, black pepper seeds were used, but the application was performed on a different projection point on the hand, rather than the area designated for Su Jok application. Each participant was individually instructed on the application area on their hands, the application method and steps, and how to evaluate their pain using the VAS. For the application, three black pepper seeds were fixed with Betafix between the 2nd and 3rd fingers of the hand, designated as the placebo area. The seeds were kept in this position for four hours, and massage was applied with pressure for 10–15 seconds every hour. When the students began to experience abdominal pain associated with the menstrual cycle, they contacted the researcher, evaluated their pain using the VAS, and then performed the intervention themselves. During the intervention, the participants recorded their pain intensity every hour and at the end of the massage session. Betafix and the seeds were discarded after four hours of the intervention. The intervention was performed on the first day that pain was experienced during the menstrual cycle. The interventions were repeated with the same group of participants for three menstrual cycles. Figure 2

Figure 2: Sham point, Su jok point, Application, Application bag

Ethical issues

Before the study was conducted, ethical approval was obtained from Fenerbahçe University Ethics Committee (Number: 14.2024fbu). The students who were invited to the study were informed about the purpose of the study. All the stages of the study were carried out in accordance with the ethical standards established in the Declaration of Helsinki.

Statistical analysis

In this study, the data were analyzed using IBM SPSS Statistics version 22. Normality tests (skewness and kurtosis), descriptive statistics (mean, standard deviation, minimum, maximum, number–percentage distributions), Pearson chi-square test, Independent Samples t-test, Repeated Measures Analysis of Variance (ANOVA), and Bonferroni correction (for post-hoc testing) were used in the analysis of the data. Statistical significance was determined using an alpha value of 0.05 and a 95% confidence interval.

Results

The study included 60 participants, and data were obtained from 34 participants after three months of implementation and follow-up.

Table 1: Baseline characteristics of participants

Characteristics	**Su Jok group (n=17)**	**Placebo-control group (n=17)**			**Total (N=34)**
	x±SD	**x±SD**	**x^2/t**	**p**	**x±SD**
Age	23.82 ± 5.02	20.17±1.62	13.349	**0.001**	22±4.11
Menstruation Cycle frequency (day)	26.52±4.40	28.82±5.04	0.286	0.596	27.67±4.80
Menstruation duration (day)	5.82+1.77	5.88±1.40	1.118	0.298	5.85±1.57
Age at onset of menstruation	13.05±0.74	13.05±0.74	0.000	1.000	13.05±073
Marital status	**n (%)**	**n (%)**			
Single	16 (94.1%)	17 (100%)	1.030	0.310	33 (97.1%)
Married	1 (5.9%)	-			1(2.9%)
Other symptoms in addition to abdominal pain					
Nausea-vomiting	13 (76.5%)	9 (52.9%)	5.927	0.313	22 (64.7%)
Dizziness	-	2 (11.8%)			2 (5.9%)
Headache	-	2 (11.8%)			2(5.9%)
Fever	-	1 (5.9%)			1(2.9%)
Low back pain	1 (5.9%)	1 (5.9%)			2(5.9%)
Weakness	-	2 (11.8%)			2 (5.9%)
None	3 (17.6%)	-			3(8.1%)
Pain intensity					
Mild	-	1 (5.9%)	2.902	0.407	1 (2.9%)
Moderate	2 (11.8%)	5 (29.4%)			7 (20.6%)
Severe	11 (64.7%)	8 (47.1%)			19 (55.9)
Too intense to bear	4 (23.5%)	3 (17.6%)			7 (20.6)
Pain pattern					
Cramping	12 (70.6%)	13 (76.5%)	2.840	0.242	25 (73.5%)
Penetrating	1 (5.9%)	3 (17.6%)			4 (11.8%)
Stabbing pain	4 (23.5%)	1 (17.6%)			5(14.7%)
Non-pharmacological interventions for pain					
Hot application	7 (41.2%)	8 (47.1%)	4.067	0.772	15(44.1%)
Massage	1 (5.9%)	1 (5.9%)			2 (5.9%)
Hot drink	1(5.9%)	3 (17.6%)			4 (11.8)
Shower	1(5.9%)	1 (5.9%)			2 (5.9%)
Moving	1 (5.9%)	-			1 (2.9%)
None	6 (35.3%)	4 (23.5%)			10(29.40)
Family history of dysmenorrhea					
Yes	9 (52.9%)	10 (58.8%)	0.119	0.730	19 (55.9%)
No	8 (47.1)	7 (41.2%)			15 (44.1%)

t: Independent groups t test x^2: Pearson Chi-square test

Table 2: Comparison of VAS measurements between the groups across cycles

	Su Jok group (n=17)	**Placebo-control group (n=17)**	**Tests and Significance Between group**
Cycle 1	x±SD	x±SD	
1st measurement	6.94±1.51	6.23±1.75	p = 0.218 t = 1.255
2nd measurement	5.35±1.93	5.52±1.62	p = 0.775 t = – 0.288
3rd measurement	4.35±2.08	4.35±1.86	p = 1 t = 0.000
4th measurement	3.47±2.15	3.70±2.05	p = 0.747 t = – 0.326
5th measurement	3.00±2.03	2.94±2.22	p = 0.936 t = 0.081
Tests and Significance Within group	**p=0.001** F= 13.686 (4-5 p > 0.05) (Other measurements p < 0.05)* **d = 2.202 (1st-5th)**	**p=0.001** F= 8.788 (1-2, 2-3, 2-4, 3-4 p > 0.05) (Other measurements p < 0.05)* **d = 1.645 (1st-5th)**	
Cycle 2			
1st measurement	6.58±1.22	6.52±2.50	p=0.931 t = 0.087
2nd measurement	5.41±1.76	5.76±2.68	p=0.654 t = –0.453
3rd measurement	4.58±2.03	5.17±2.15	p=0.419 t = –0.818
4th measurement	3.29±2.33	4.35±2.78	p=0.239 t = – 1.201
5th measurement	2.82±2.24	3.70±2.93	p=0.332 t = – 0.986
Tests and Significance Within group p	**p=0.001** F = 9.464 (1-2 p > 0.05 4-5 p > 0.05) (Other measurements p < 0.05) * **d = 2.08 (1st-5th)**	**p=0.012** F = 4.929 (1-2, 2-3, 3-4, p > 0.05) (Other measurements p < 0.05)* **d = 1.03 (1st-5th)**	
Cycle 3			
1st measurement	6.52±2.06	5.76±2.16	p = 0.300 t = 1.054
2nd measurement	5.29±2.22	4.94±1.78	p=0.614 t = 0.510
3rd measurement	5.11±2.71	4.70±1.64	p=0.597 t = 0.535
4th measurement	3.94±2.22	4.11±2.23	p=0.819 t = – 0.231
5th measurement	3.41±2.42	3.11±2.36	p=0.723 t = 0.358
Tests and Significance Within group p	**p=0.001** F = 9.721 (1-3, 2-3, 4-5 p > 0.05) (Other measurements p < 0.05)* **d = 1.383 (1st-5th)**	**p=0.025** F = 3.986 (1-5,2-5, 3-5 4-5 p < 0.05) (Other measurements p>0.05)* **d = 1.171 (1st-5th)**	

F: Repeated measures ANOVA t: Independent groups t test * Bonferroni correction
d=Cohen's d effect size: Small 0.2; Medium 0.5; Large 0.8; Very large 1.3

Table 3: Comparison of the differences between the first and fifth VAS measurements of the groups across cycles

	Su Jok group (n=17)	**Placebo-control Group (n=17)**	**Tests and Significance Between group**
Cycle 1	3.94±2.38	3.29±2.36	p=0.433 t = 0.794
Cycle 2	3.70±2.39	2.88±2.28	p=0.313 t = 1.026
Cycle 3	3.11±2.11	2.64±3.06	p = 0.877 t =-0.156

t: Independent groups t-test

The mean age of the participants was 22 ± 4.1 years, and the mean menstrual cycle length was 27.67 ± 4.80 days. The majority were single, and 55.9% had no family history of dysmenorrhea. In addition to abdominal pain, 64.7% of the participants reported nausea and vomiting, and their pain was severe (55.9%) and cramping in nature (73.5%). It was observed that 44.1% preferred the use of heat therapy to reduce their pain. Other characteristics of the participants were similar across the groups, except for their mean age (Table 1).

When the mean VAS scores for the first measurement of the first cycle were examined, they were 6.94 ± 1.51 for the experimental group and 6.23 ± 1.75 for the control group. There was no statistically significant difference between the groups in the initial measurements, indicating that the pain scores of the groups were similar. The mean VAS scores for the fifth measurement were found to be 3.00 ± 2.03 for the experimental group and 2.94 ± 2.22 for the control group. There was no significant difference between the mean VAS scores of the groups across all measurements. When comparing the within-group mean VAS scores, it was observed that the scores of both groups decreased over time. The mean VAS scores of the first and fifth measurements decreased significantly in both groups ($p < 0.05$).

In the first measurement of the second cycle, the mean VAS scores were 6.58 ± 1.22 for the experimental group and 6.52 ± 2.50 for the control group, with no significant difference between the groups. The mean VAS scores for the fifth measurement were found to be 3.00 ± 2.03 for the experimental group and 2.94 ± 2.22 for the control group. There was no significant difference between the mean VAS scores of the groups across all measurements. When comparing the within-group mean VAS scores, it was observed that the scores of both groups decreased over time. The mean VAS scores of the first and fifth measurements decreased significantly in both groups ($p < 0.05$).

During the first measurement of the third cycle, the mean VAS scores were 6.52 ± 2.06 for the experimental group and 5.76 ± 2.16 for the control group, with no statistically significant difference between the groups. In the fifth measurement, the mean VAS scores were 3.41 ± 2.42 for the experimental group and 3.11 ± 2.36 for the control group. Across all measurements, there was no significant difference in the mean VAS scores between the groups. However, within-group comparisons revealed that the mean VAS scores decreased significantly over time in both groups. The reductions in mean VAS scores between the first and fifth measurements were statistically significant in both the experimental and control groups ($p < 0.05$). The calculated effect sizes, based on the first and fifth measurements across cycles with significant changes, indicated large and very large effects (Table 2).

Although the difference between the first and fifth VAS scores was not statistically significant between the groups, the change observed in the Su Jok group was greater than that in the placebo control group. This difference was numerically greater but did not reach statistical significance ($p > 0.05$) (Table 3).

Discussion

In this randomized, placebo-controlled experimental study, Su Jok therapy was applied to the experimental group for the reduction of menstrual pain over three menstrual cycles, while

the placebo control group received a sham Su Jok application. The demographic characteristics, menstrual-related features, and pain characteristics of the participants were similar across the groups. Similarly, the mean pain scores in the first cycle were comparable between the groups. This indicates that participants in both the control and intervention groups experienced similar moderate pain levels. The average age at menarche, menstrual cycle frequency and duration, and pain characteristics of the participants were consistent with those reported in the literature.[30-33]

Based on five measurements of pain intensity across three menstrual cycles, no statistically significant difference was found between the mean pain scores of the intervention and control groups. However, both the Su Jok group and the placebo control group showed significant reductions in pain scores from the first to the fifth measurement Across the three cycles, this pattern remained consistent, with both groups demonstrating significant decreases in pain between the first and fifth measurements. Both Su Jok therapy and the sham point placebo application were associated with pain reduction. However, when comparing the magnitude of change between the first and fifth measurements, no statistically significant difference was found between the groups, although the reduction in the Su Jok group was greater. In other words, the decrease in pain was more pronounced in the Su Jok group compared to the placebo control group.

Non-pharmacological interventions such as transcutaneous electrical nerve stimulation (TENS), heat therapy, aromatherapy, cognitive behavioral therapy, hypnotherapy, acupuncture, auricular acupressure, and physiotherapy have been shown to reduce pain perception in studies targeting menstrual pain relief.[34-37] In a meta-analysis conducted by Chen *et al.*,[38] the effects of acupuncture-related interventions on primary dysmenorrhea were evaluated, identifying moxibustion, massotherapy, acupoint patching, acupuncture, and heat-sensitive moxibustion as the most effective methods. "Additionally, auricular point therapy, electropuncture, acupuncture, point embedding, and massage therapy have also been found effective in reducing pain.[38]

A meta-analysis conducted by Cao *et al.*[39] investigated the effects of auricular acupoint therapy on dysmenorrhea and concluded that it was more effective than nonsteroidal anti-inflammatory drugs and placebo. Another study examining the effects of acupressure and ice massage on dysmenorrhea demonstrated that both interventions reduced pain, with ice massage being more effective. [32] Liu *et al.*[30] reported that moxibustion was effective in reducing pain in their study on dysmenorrhea. Zhao et al.[40] also found that two different acupuncture points reduced pain in dysmenorrhea patients.

Su Jok, similar to acupuncture, acupressure, and reflexology, involves stimulation of biologically active points on the meridians of the body, aiming to promote the healthy flow of life energy, Chi.[21,24,41] These methods work by applying pressure to acupuncture points, which are considered key to restoring energy balance in the body.[42] However, black pepper seeds were used in this study, as it is argued that seeds, which give life to plants, contain a great energy, making them a life-giving source that is in constant exchange with the external environment.[18,19] It is hypothesized that Su Jok may have been effective due to the energy of the seeds and its ability to clear energy blockages. In addition, according to the Gate Control Theory, the stimulation of the skin may also have contributed to a reduction in pain perception.[43,44]

Wang *et al.*[45] conducted a study on patients with dysmenorrhea, applying both real and sham acupuncture, and performed brain imaging using functional magnetic resonance imaging (fMRI). The study showed that twirling acupuncture at both real and sham acupoints resulted in different patterns of brain activity in pain-related brain areas, suggesting that acupuncture acts via multiple neural mechanisms. Short-term analgesic effects of acupuncture were also identified.[45] Sun *et al.*[46] conducted a meta-analysis on the placebo effects of sham acupuncture on dysmenorrhea, and a strong placebo response was found. In another study, Alp Yılmaz and Başer[47]examined the effects of reflexology, a non-pharmacological method, on dysmenorrhea and found that both reflexology and placebo foot massage were effective in reducing

pain. The results of our study are consistent with the literature.[45-47]

In previous studies, Su Jok was found to be an effective method for reducing pain in various conditions, including abdominal, arm, back, extremity, head, hip, neck, scapula, shoulder, chronic migraine, periarthritis, tension headache, pelvic, and chest pain.[48-54] In a study by Iskandar *et al*.[55] involving 25 women, it was reported that Su Jok was effective in reducing labor pain. Salsabila *et al*.[56] conducted a quasi-experimental study on the effects of Su Jok on dysmenorrhea with 44 participants, showing a significant difference in pain scores between the intervention and control groups, and concluded that Su Jok was effective in reducing pain. Apart from Salsabila *et al*.[56] study, there are no other studies in the literature specifically examining the effect of Su Jok on dysmenorrhea. This study is the first to examine the effect of Su Jok on dysmenorrhea in a randomized placebo-controlled trial design.

Conclusion

The results of this study suggest that Su Jok is effective in reducing pain and could be a practical method for alleviating dysmenorrhea. These methods can easily be applied by women to reduce dysmenorrhea, and their use is recommended.

Contribution of authors

Elmalı Şimşek H.: Writing – Original Draft, Visualization, Resources, Methodology, Investigation, Data Curation, Conceptualization, Formal Analysis, Writing – Review & Editing.

Conflict of interests

The author declares that they have no competing interests, and the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Clinical Trial Number: NCT06896851 (https://clinicaltrials.gov/study/NCT06896851?term=NCT06896851&rank=1).

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