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INVESTIGATION OF THE EFFICACY OF THE RELAXATION TECHNIQUE ON PRIMARY DYSMENORRHEA AND MENSTRUAL SYMPTOMS: A RANDOMIZED CONTROLLED LONGITUDINAL TRAIL

GEVŞEME EĞİTİMİNİN PRİMER DİSMENORE VE MENSTRÜEL SEMPTOM ÜZERİNE ETKİNLİĞİN İNCELENMESİ: RANDOMİZE KONTROLLÜ BOYLAMSAL ÇALIŞMA

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ABSTRACT

Aim: The aim of this study is to examine the effectiveness of Mitchell's relaxation technique applied to young women with primary dysmenorrhea (PD) on dysmenorrhea and menstrual symptoms in long-term follow-ups.
Methods: This is a randomized-controlled intervention trial. A total of 76 students, 37 in the intervention and 39 in the control group, were included in the study. Data collection tools were a Descriptive Information Form, the Visual Analog Scale (VAS), and the Menstrual Symptom Scale (MSS). The intervention group was followed during five menstrual cycles, four of which were consecutive. During a total of three menstrual cycles, 30-minute educational video lessons were given every day on menstrual days or at least three times a week. It was determined that the groups were independent and homogeneous in terms of the specified characteristics.
Results: There was no statistically significant difference between the groups in terms of VAS and MSS scores in the first follow-up, but differences were found in the 2nd, 3rd, 4th, and 5th follow-ups ($p<0.05$). It was determined that the 2nd, 3rd, 4th, and 5th follow-up VAS and MSS scores of the intervention group were significantly lower than those of the control group.
Conclusion: Mitchell's relaxation education has positive effects on dysmenorrhea and menstrual symptoms. Women can receive this education and include it in their daily life.
Keywords: Menstrual Symptom, Mitchell Relaxation Technique, Primary Dysmenorrhea, Woman.

ÖZET

Amaç: Bu çalışmanın amacı primer dismenore (PD) şikayeti olan genç kadınlara uygulanan Laura Mitchell'in gevşeme eğitiminin uzun vadeli izlemlerde ki dismenore ve menstrüel semptom üzerine etkinliğini incelemektir.
Yöntem: Araştırma, randomize kontrollü müdahale çalışmasıdır. Araştırmanın evrenini bir devlet üniversitesinde öğrenimi sürdüren 1493, örneklemini ise araştırmaya gönüllü olarak katılmak isteyen 856 kadın öğrenci oluşturdu. Örneklem seçim kriterlerine uyan öğrenciler 2 gruba rastgele dağıtılarak; 46 öğrenci egzersiz grubuna, 46 öğrenci kontrol grubuna dâhil edildi. Araştırmada veri toplama araçları olarak; Tanıtıcı Bilgi Formu, Visual Analog Skala (VAS) ve Menstruel Semptom Ölçeği (MSÖ) kullanıldı. Egzersiz grubu 4'ü ardışık olmak üzere 5 menstruasyon siklus süresince izlendi. Toplam 3 menstrual siklus süresince adet günlerinde her gün ya da haftada en az 3 kez 30 eğitimi video ders eşliğinde devamı sağlandı. Kontrol grubuna müdahale edilmeden, deney grubunda olduğu gibi ölçüm araçları ile 5 izlemde verileri toplandı.
Bulgular: Grupların belirtilen özellikler açısından bağımsız ve homojen olduğu belirlendi. Gruplara göre 1.izlem VAS ve MSÖ puanları açısından istatistiksel olarak anlamlı farklılık olmadığı fakat 2, 3, 4 ve 5.izlem VAS ve MSÖ puanları açısından farklılık tespit edilmiştir ($p<0,05$). Deney grubundakilerin 2, 3, 4 ve 5.izlem VAS ve MSÖ puanları, kontrol grubundakilere göre anlamlı düzeyde daha düşük olduğu belirlendi.
Sonuç ve Öneriler: Laura Mitchell'in gevşeme eğitimi dismenore ve menstrüel semptom üzerine olumlu etkileri vardır. Kadınlar bu eğitimi öğrenerek günlük yaşamlarına dâhil edebilirler.
Anahtar Kelimeler: Kadın, Menstrüel Semptom, Mitchell Gevşeme Eğitimi, Primer Dismenore.

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** This study was presented as an oral summary at the 1st International 1st National Sivas Midwifery Congress.*

INTRODUCTION

Primary dysmenorrhea (PD) is defined as painful menstrual cramps that are not caused by pathology (Iacovides et al., 2015; Lee et al., 2018; Shundo et al., 2017). The pain usually begins just before or at the beginning of menstruation and lasts for 72 hours. It emerges as mild to severe cramping in the suprapubic region, spreading to the upper legs (Ganesh et al., 2017; Zurawiecka and Wronka, 2018). Systemic findings, such as nausea, vomiting, headache/vertigo, sweating, diarrhea, sleep disturbances, and syncope, are also observed (American College of Obstetricians Gynecologists 2019; Kilci et al., 2020).

The prevalence of PD varies between 70 and 95% (Uysal et al., 2016; Subasinghe et al., 2016; Lee et al., 2018). PD can negatively affect women's quality of life and hinder workplace and school attendance (Hailemeskel et al., 2016, Kaplan et al., 2022; Motahari-Tabari et al., 2017). For this reason, women often resort to the use of alternative methods for coping with PD. Various relaxation techniques are used to reduce pain in women with PD (Çelik and Apay, 2021, Zainab et al., 2021). Relaxation techniques are applied to reduce the effects of pain, stress, depression, anxiety, and mood changes on the individual and to control the body (Emarloo and Doustkam, 2015). Laura Mitchell's simple physiological relaxation training, one of these techniques, is used especially in obstetrics/gynecology, with its advantages, such as requiring less concentration, learning in a short time, and showing rapid effects (Güvey, 2019; Ferreira and Kulkarni, 2019; Murphy et al., 2014; Vaziri et al., 2015).

Ganesh et al. (2017) found that Laura Mitchell's physiological relaxation training, in which they applied 30-minute sessions twice a day in two consecutive menstrual cycles, was effective in reducing pain (Ganesh et al., 2017). Dogan et al. (2020) determined the effectiveness of this training in reducing PD in their study by applying it as 30-minute sessions once a day from the first day of the cycle to the first day of the next cycle (Doğan et al., 2020). In another study by Dogan et al. (2019), in which they examined the effectiveness of this training, they applied the sessions in consecutive cycles as 30-minute sessions until the third day of the first and second cycle (Doğan et al., 2019). In another study, the effectiveness of the training was determined by carrying out two repetitive 30-minute sessions three times a week for four weeks (El-Kosery et al., 2006). As seen in these studies in the literature, the effectiveness of Laura Mitchell's simple physiological relaxation training in short-term follow-ups in individuals with PD was examined. However, there was no study on the effectiveness of this training in long-term follow-ups. The aim of our study, which was planned in light of this information, was to examine the effectiveness of Laura Mitchell's relaxation training applied to young women with PD complaints in dysmenorrhea and menstrual symptoms in long-term follow-ups.

MATERIAL AND METHODS

Type and Time of the Study

This is a randomized controlled intervention study. It was carried out according to CONSORT guidelines (CONSORT, 2010) with students of a state university in the south of Turkey between February 6, 2021 and September 15, 2021. Students included in the study were contacted via an online survey link.

Population/Sample and Randomization

The population of the research consisted of 1,493 female students at a vocational higher school, and the sample included 856 female students who voluntarily wanted to participate in the research. Considering similar studies in the literature (Demiralp, 2018; Dogan et al., 2019), it was estimated that a total of 35 women would be needed to detect a 30-mm difference on the VAS with a significance level of 0.05 and a power value of 90%. Considering some attrition, it was decided to recruit at least 75 women, including the control group.

Numbers 1-92 were randomly distributed into two groups using computer software (https://www.randomizer.org/) to determine the group of students who met the inclusion criteria. Accordingly, 46 students were assigned to each of the intervention and control groups. During the follow-up period, six students from the intervention group and two students from the control group were excluded because they did not have 80% attendance. Since three students from the intervention group and five students from the control group could not be reached during the analysis process, their final measurements could not be made and they were not included in the analysis due to data loss. The study was completed with 37 students from the intervention group and 39 from the control group, with a total

of 76 students (Figure 1). Due to the nature of this study, it was not possible to blind the participants and researchers; however, we provided blinding during data collection and statistical analysis to reduce bias.

***Inclusion criteria*:** Students who were diagnosed with primary dysmenorrhea, had a regular menstrual cycle (28±7 days), had a VAS measurement of greater than four cm, and wanted to voluntarily participate in the study were included.

***Exclusion criteria*:** Students who had been diagnosed with systemic and psychiatric diseases, had chronic pain, had a history of pregnancy-delivery, had been breastfeeding, had undergone pelvic operation, used contraceptive or chronic medication, had an irregular cycle, and had a diagnosis of secondary dysmenorrhea were excluded from the study.

***Study termination criteria*:** The study was terminated for students who did not have 80% attendance.

Data Collection Tools

Study data were collected using an online questionnaire that included a Descriptive Information Form, the Visual Analog Scale (VAS), and the Menstrual Symptom Scale (MSS).

Descriptive Information Form: This form consists of 19 questions about the socio-demographic characteristics and menstrual symptoms of the participants.

Visual Analog Scale (VAS): The VAS was used to evaluate the pain severity of individuals during their menstruation. It is an analog linear scale with proven validity and is widely used in clinical studies to evaluate the severity of pain, especially in PD studies. It is a 100-mm-long line with the left extreme reading "no pain at all" and the right extreme reading "the worst pain I've ever felt." The score is determined by measuring the distance from the left extreme of the scale to the point marked by the patient. The reported value indicates the severity of the patient's pain (1-39=mild dysmenorrhea; 40-79=moderate dysmenorrhea; 80-100=severe dysmenorrhea) (Price et al., 1983).

Menstrual symptom scale (MSS): This scale was developed by Chesney and Tasto (1975) to evaluate menstrual symptoms and adapted into Turkish by Güvenç et al. (2014). It has 24 items and a five-point Likert-type scale (1=never, 5=always) (Chesney and Tasto, 1975, Güvenç et al., 2014).

The Procedure / Intervention and Data Collection

***Intervention group*:** Women were followed for a total of seven months during five menstrual cycles, four of which were consecutive, as stated below.

First follow-up (1st month): On the 1st day of the 1st menstruation, the 1st evaluation was performed. The data were collected with the VAS and MSS for both groups and relaxation training was initiated for the intervention group.

Second follow-up (2nd month): On the 1st day of the 2nd menstruation period, the 2nd evaluation was performed. Data were collected for both groups with the VAS and MSS, and relaxation training continued for the intervention group.

Third follow-up (3rd month): On the 1st day of the 3rd menstruation period, the 3rd evaluation was performed. Data were collected for both groups with the VAS and MSS, and relaxation training continued for the intervention group.

Fourth follow-up (4th month): On the 1st day of the 4th menstruation period, the 4th evaluation was done. Data were collected from both groups with the VAS and MSS, and relaxation training was terminated for the intervention group. They were told that they were free to continue relaxation training until the seventh menstruation. Fourteen people from the intervention group continued relaxation training for six months.

Fifth follow-up (7th month): The 5th evaluation was performed on the 1st day of the 7th menstruation period, and the data were collected with the VAS and MSS in both groups.

The intervention group was taught to practice relaxation training in online live lessons. During a total of three menstrual cycles, 30 training sessions were provided via live video lessons every day on menstrual days or at least three times a week.

***Relaxation training protocol*:** The participants were laid on a hard floor in the supine/semi-lying position with their body supported with a pillow/cushion and were told to relax and close their mouth/eyes. The researcher's voice was calm/soft. The instructions of Laura Mitchell's simple physiological relaxation training were explained to the participants by the researcher (Mitchell, 1984).

***Control group*:** The same questionnaire was applied to the students in the control group. Data from the control group were collected in five follow-ups with measurement tools, as in the intervention group, but with no intervention.

Ethical Considerations

The study was conducted in accordance with the medical research ethical principles of the Declaration of Helsinki. Ethics committee approval (date: 22.01.2021, number: 107/70) and permission from the institution where the study was conducted (date: 05.02.2021, number: 25678) were obtained. Consent of the students included in the research was obtained through the online survey used in the research. The study is registered at clinicaltrials.gov (NCT05128877).

Statistical Analysis

Study data were analyzed on the SPSS (IBM SPSS Statistics 24) software package. Frequency tables and descriptive statistics were used to interpret the findings. Independent samples t-test and repeated measures test were employed for measurements suitable for normal distribution and Mann-Whitney U and Friedman tests were used for non-normally distributed data. Continuity correction and Pearson-$\chi 2$ crosstabs were used to examine the relationship between two qualitative variables. The p-value was taken as 0.05 to show significance in all statistical calculations.

RESULTS

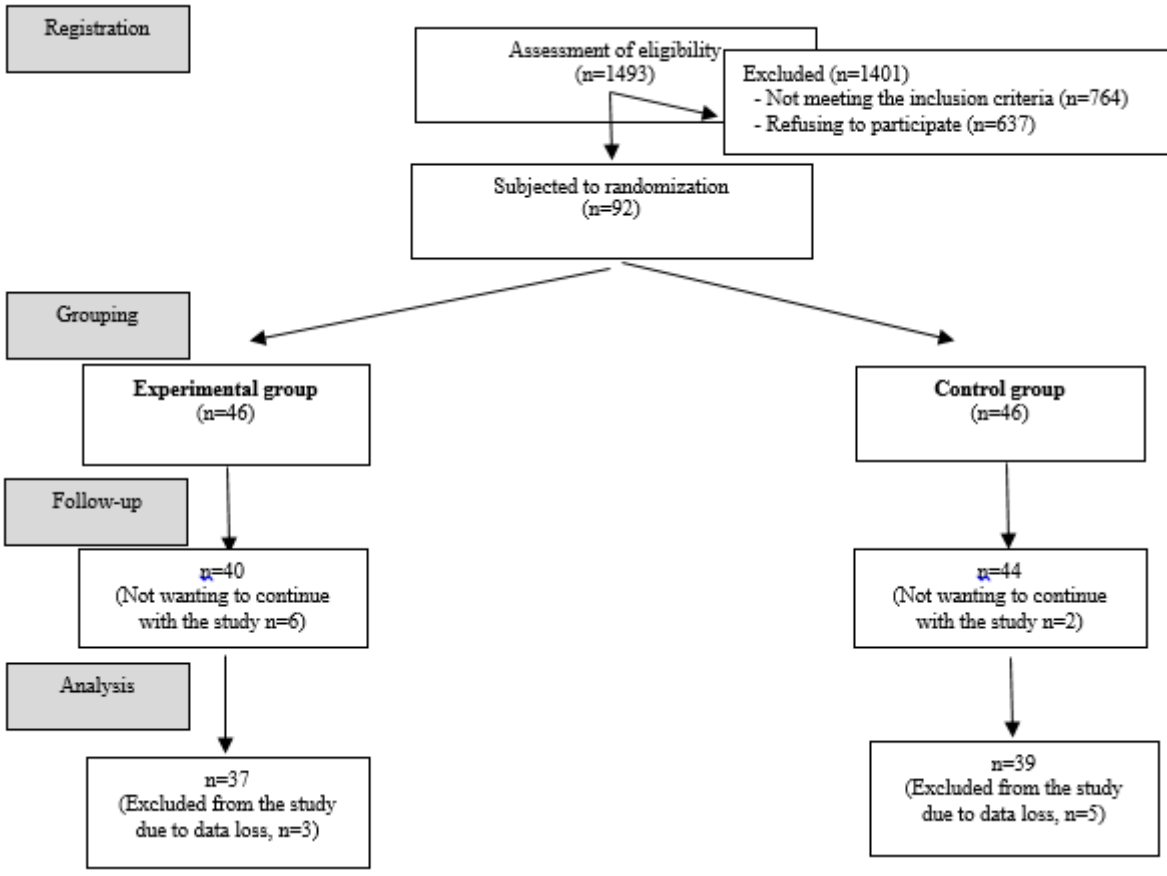

Figure 1. CONSORT Flow Chart

Table 1. Analysis of The Relationships Between Groups and Some Characteristics

Variables	Intervention group (n=37)		Control group (n=39)		Statistical analysis* Probability
	n	%	n	%	
Smoking					
No	33	89.2	32	82.1	χ^2=0.311 p=0.577
Yes	4	10.8	7	17.9	
Doing exercise					
Yes	15	40.5	19	48.7	χ^2=0.236 p=0.627
No	22	59.5	20	51.3	
Time when pain peaks					
Before menstruation	4	10.8	6	15.4	χ^2=1.669 p=0.434
On the 1st day of menstruation	27	73.0	23	59.0	
During menstruation	6	16.2	10	25.6	
Attendance to relaxation training for six month					
Yes	14	37.8	-	-	χ^2=15.659 **p=0.000**
No	23	62.2	39	100.0	

A total of 856 women were screened. After randomization, 92 were included, and 76 completed the study (Figure 1). The groups (intervention and control) were independent and homogeneous in terms of the characteristics indicated in Tables 1 and 2.

Table 2. Comparison of Some Parameters by Groups

Variables	Intervention group (n=37)		Control group(n=39)		Statistical Analysis* Probability
	$\bar{X} \pm SD$	Median[Min-Max]	$\bar{X} \pm SD$	Median[Min-Max]	
Age (year)	19.95±0.97	20.0 [19.0-22.0]	19.95±1.05	20.0 [19.0-23.0]	Z=-0.121 p=0.904
BMİ (kg/m^2)	21.46±1.40	21.5 [18.8-24.3]	21.61±2.10	21.3 [18.6-24.8]	Z=-0.052 p=0.959
Age of menarche (year)	13.05±1.20	13.0 [10.0-15.0]	13.15±1.14	13.0 [11.0-16.0]	Z=-0.027 p=0.978
Average menstrual period (days)	5.54±1.19	5.0 [3.0-9.0]	5.82±1.31	6.0 [3.0-10.0]	Z=-0.986 p=0.324

*****Mann-Whitney U test (Z-table value)*

There was no statistically significant difference between the groups in terms of VAS scores in the first follow-up (p>0.05). However, a significant difference was detected in the 2nd, 3rd, 4th, and 5th follow-ups (p<0.05). It was determined that the VAS scores of the women in the intervention group in the 2nd, 3rd, 4th, and 5th follow-ups were significantly lower than the scores of the those in the control group (Table 3).

Table 3. Comparison of VAS and MSS Scores of Groups according to Follow-Ups

Variables	Intervention group (n=37)		Control group(n=39)		Statistical Analysis* Probability
	$\bar{X} \pm SD$	Median [Min.-Max.]	$\bar{X} \pm SD$	Median [Min.-Max.]	
VAS					
Follow-up 1	67.24±8.50	68.0 [46.0-82.0]	65.49±9.21	66.0 [45.0-81.0]	t=0.863 p=0.391
Follow-up 2	46.73±7.25	45.0 [34.0-62.0]	63.31±8.65	62.0 [45.0-79.0]	Z=-6.383 **p=0.000**
Follow-up 3	39.27±9.54	37.0 [27.0-76.0]	67.10±9.97	67.0 [43.0-83.0]	Z=-6.990 **p=0.000**
Follow-up 4	35.32±9.85	35.0 [21.0-67.0]	66.49±10.27	66.0 [42.0-86.0]	Z=-7.056 **p=0.000**
Follow-up 5	54.62±17.15	57.0 [26.0-83.0]	64.31±10.19	63.0 [46.0-86.0]	Z=-2.043 **p=0.041**
Statistical analysis	χ^2=81.293		F=3.779		
Probability	**p=0.000**		p=0.407		
Difference	**[1-2, 3, 4, 5] [3-2,5] [4-2,5]**				
MSS					
Follow-up 1	71.73±12.88	73.0 [35.0-93.0]	74.90±15.05	76.0 [38.0-100.0]	t=-0.673 p=0.503
Follow-up 2	47.27±8.35	46.0 [30.0-63.0]	75.00±15.70	76.0 [40.0-111.0]	t=-9.535 **p=0.000**
Follow-up 3	43.86±7.72	43.0 [28.0-63.0]	72.87±14.76	74.0 [41.0-104.0]	t=-10.439 **p=0.000**
Follow-up 4	40.68±6.83	41.0 [26.0-58.0]	73.18±15.51	72.0 [35.0-100.0]	t=-11.560 **p=0.000**
Follow-up 5	61.41±17.90	61.0 [24.0-90.0]	73.56±14.91	76.0 [39.0-99.0]	t=-3.489 **p=0.001**
Statistical analysis	F=93.507		F=2.180		
Probability	**p=0.000**		p=0.496		
Difference	**[1-2,3,4,5] [2-4,5][3-4,5] [4-5]**				

***Independent Sample-t test (t-table value); Repeated Measures test (F-table value); Mann-Whitney U test (Z-table value); Friedman test (χ^2--table value)*

There was a significant difference between the VAS scores of the intervention group according to the follow-ups (χ2=81.293; p=0.000). Bonferroni-corrected paired comparisons were made to determine which group this difference originated from. Comparisons showed that the differences were between the 1st follow-up and the 2nd, 3rd, 4th, and 5th follow-up scores. The first follow-up VAS scores were significantly higher than the scores obtained in the 2nd, 3rd, 4th, and 5th follow-ups (Table 3). In addition, the reduction in pain level measured by the VAS in women who received the intervention decreased further over time.

There was no significant difference between the first follow-up MSS scores of the groups (p>0.05). A statistically significant difference was found between the groups in terms of their 2nd, 3rd, 4th, and 5th follow-up MSS scores (p<0.05). It was determined that the 2nd, 3rd, 4th, and 5th follow-up MSS scores of the intervention group were significantly lower than the scores of the control group (Table 3).

There was a significant difference between the MSS scores of the intervention group according to the follow-ups (F=93.507; p=0.000). Bonferroni-corrected paired comparisons were made to determine which group this difference came from, and the difference was determined between the 1st follow-up and the 2nd, 3rd, 4th, and 5th follow-up scores. The 1st follow-up MSS score was significantly higher than the 2nd, 3rd, 4th, and 5th follow-up scores (Table 3). In addition, the reduction in menstrual complaints in women who received the intervention, as measured using the MSS, further decreased over time.

There was no significant difference between the VAS and MSS scores of the control group according to the follow-ups (p>0.05).

DISCUSSION

In this study, the effectiveness of Mitchell's relaxation training in dysmenorrhea and menstrual symptoms in long-term follow-ups was examined. As a result of the study, it was determined that the women in the intervention group had significantly lower VAS and MSS scores than those in the control group.

PD is quite common in women and affects activities of daily living and quality of life (Motahari-Tabari et al., 2017). The stress response resulting from pain is under the control of the sympathetic nervous system. The parasympathetic nervous system is effective in the reverse physiological process to reduce and eliminate the stress created by pain (Ganesh et al., 2017; George et al., 2019). In the Mitchell relaxation technique applied to the intervention group in the current study, there was reciprocal

relaxation, in which a part of the body is moved from a tension field in the opposite direction, which returns the movement and leads to relaxation. With this technique, physiological arousal is reversed and the body goes into a calm state. When women gain the ability to control parasympathetic activity, they can manage pain and stress. In addition, relaxation training has an analgesic effect. It also stimulates the production of endorphins, which act as natural pain relievers for the body (George et al., 2019; Polat et al., 2009). Relaxation training is effective in reducing/eliminating the effects of pain, anxiety, stress, emotional changes, and depression in the body of the individual and controlling many bodily functions (El-Kosery et al., 2006; Doğan et al., 2019; Dogan et al., 2020; Ganesh et al., 2017; George et al., 2019,). With this technique, general well-being is achieved by closing the pain gate and reducing the severity of pain (Emarloo and Doustkam, 2015). Some studies in the literature have shown that relaxation training is effective in increasing sleep quality and reducing pain, cramps, fatigue, and blood pressure (Jose et al., 2022; Mujahid et al., 2022; Shahzadi et al., 2022). El Kosery et al. (2006), Doğan et al. (2020), and Ganesh et al. (2017) reported that using Mitchell's technique was effective in reducing dysmenorrhea in women (Doğan et al., 2019; El-Kosery et al., 2006; Ganesh et al., 2017). Similar findings were obtained in this study using Mitchell's technique. In the current study, unlike the studies in the literature, as a result of the relaxation training program applied to women in the intervention group followed for a longer period (7 months), significant improvements were found in dysmenorrhea according to VAS measurements. We think that the decrease in dysmenorrhea was due to the effects of hormonal changes on the uterine epithelial tissues or due to an increase in endorphin levels.

Overproduction of prostaglandin contributes to abnormal uterine contractions and increased intrauterine pressure, vasoconstriction of small uterine vessels leading to reduced uterine blood flow, increased sensitivity of pain receptors, uterine muscle ischemia, and eventually pelvic pain. Endometrial blood flow decreases during uterine contractions, indicating that ischemia due to hyper contractility is the primary cause of PD (Dmitrovic et al., 2012). In the literature, it has been reported that women with PD have less uterine blood circulation in Doppler ultrasonography examinations, not only on the days of bleeding but also on all days of the cycle compared to other women (Dmitrović, 2000; Dmitrovic et al., 2012). In the current study, reductions in menstrual symptoms as well as pain were observed in women in the intervention group. Dogan et al. (2019) also reported similar findings in their study (Doğan et al., 2019). We think that ischemia is eliminated with the Mitchell's technique, as a result of the removal of prostaglandins with the increase in uterine blood circulation, and thus a decrease in uterine contractions. In addition, we think that relaxation training had positive effects on women's mood and that there was a parallel decrease in menstrual symptoms with the reduction of pain.

Strengths and Limitations of the Study

The current research provided new findings on the long-term follow-up of the efficacy of the Mitchell's technique. In addition, data were collected with valid and reliable scales. Interventions and follow-ups were carried out by experts in the field.

However, our study has several limitations. In this study, the findings were based on participants' self-reports and may therefore be prone to social desirability bias. The generalization of the study only to the participants within the scope of the study can be considered another limitation of the study.

CONCLUSIONS

Mitchell's relaxation training has positive effects on dysmenorrhea and menstrual symptom. Women can receive this education and incorporate it into their daily lives. In conclusion, this technique is an effective, non-invasive, safe, inexpensive, easy-to-apply, and successful treatment method for reducing pain and tension. Mitchell's relaxation training appears to be an effective method for reducing menstrual pain severity in individuals with PD. It is recommended that all health professionals working in the field of women's health, especially midwives integrate Mitchell's relaxation training into their routine practices in obstetrics/gynecology. It is also recommended to make comparisons with different techniques and to conduct randomized studies with larger sample groups to increase the consistency of the results.

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Conflict of interest

The authors report no actual or potential conflicts of interest.

Author Contributions
Plan, design: ED, NÇ; **Material, methods and data collection:** ED, NÇ, EİI; **Data analysis and comments:** ED, NÇ; **Writing and corrections:** ED, NÇ.

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