

# Comparing the Effect of Ginger-Lavender, Ginger and Mefenamic Acid Capsules on the Severity of Primary Dysmenorrhea among University Students: A Triple-Blind Clinical Trial

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ARTICLE INFO	ABSTRACT
<p><i>Article type:</i> Original article</p>	<p><b>Background &amp; aim:</b> Primary dysmenorrhea is one of the most common complaints in women. This study compared the effect of ginger-lavender, ginger and mefenamic acid capsules on the severity of primary dysmenorrhea among female university students.</p>
<p><i>Article History:</i> Received: 25-Jan-2022 Accepted: 07-Oct-2022</p>	<p><b>Methods:</b> This randomized, triple-blind clinical trial was performed in 2020 on 90 female students with primary dysmenorrhea, who lived in dormitories of Shahid Beheshti University of Medical Sciences, Tehran, Iran and randomly assigned to three groups. During the first three days of menstruation, the students received ginger-lavender (250 mg ginger and 50 mg lavender extract), ginger (250 mg), and mefenamic acid (250 mg) in two consecutive cycles, which were prescribed four times daily for three days from the onset of menstruation. A menstrual status questionnaire, verbal multidimensional scoring system, and visual analog scale were used to measure pain duration and intensity before and two cycles after intervention. Data were analyzed using two-way (intragroup) and one-way (intergroup) repeated measures ANOVA.</p>
<p><i>Key words:</i> Dysmenorrhea Ginger Lavender Mefenamic Acid</p>	<p><b>Results:</b> Ginger- lavender, ginger and mefenamic acid significantly reduced the severity and duration of primary dysmenorrhea (P 0.05). This decrease was greater in the ginger-lavender group than in the other two groups. Also, the mean score of pain in the ginger-lavender group was 1.04 and 1.53 units lower than the ginger and mefenamic acid groups, respectively. The mean pain score in the ginger group was 0.49 units lower than that the mefenamic acid group.</p> <p><b>Conclusion:</b> Ginger-lavender significantly reduced the duration and severity of menstrual pain and was more effective than only ginger and mefenamic acid.</p>

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## Introduction

Primary dysmenorrhea is the most common complaint experienced by many women (1). This common gynecological disorder is divided into two types of primary and secondary dysmenorrhea. Primary dysmenorrhea is painful menstruation in the absence of confirmed pelvic disease. In secondary dysmenorrhea is associated with a pelvic pathology that causes the painful menstrual cramps.(2). Dysmenorrhea may be associated with systemic symptoms such as headache, dizziness, nausea, vomiting, diarrhea, fever, and fatigue (3). Low menarche age, the duration of menstrual bleeding, high levels of stress, smoking, and alcohol use can increase the incidence of dysmenorrhea and anxiety (4, 5). One possible cause of primary dysmenorrhea is the overproduction of prostaglandins in the endometrium. In general, women with the highest endometrial concentrations of PGF<sub>2</sub>α and PGE<sub>2</sub> are more likely to experience dysmenorrhea (6).

Alternative therapies, including tocolytics, vitamins, dietary supplements, acupuncture, acupressure, behavioral therapy, and sedation, has been suggested to improve the symptoms of dysmenorrhea (7-9). Of course, it is worth noting that acupuncture does not have the same effect on all people and, in some cases, is ineffective and can have side effects such as pain, bleeding, and bruising at the site of the needle, infectious diseases such as hepatitis and AIDS, and injuries to lung tissue (10). Excessive consumption of dietary supplements and vitamins also leads to side effects such as gout, dehydration, and decreased bone mass (11). Since chemical drugs for the treatment of dysmenorrhea have side effects such as liver and kidney damage; so the use of herbal remedies is preferred (12).

Ginger is one of the herbs which has been recommended for pain relief in cases of dysmenorrhea. Ginger, with its scientific name (*Zingiber officinale*), is from the ginger family. It is obtained from a yellow plant with purple veins. The part used by this plant is its swollen underground stem called the rhizome (13). The effects of fresh ginger are due to gingerol, which is a phenolic compound, and the effects of dried ginger are due to the shoagol

substance, which is an anhydrous form of gingerol (14). Ginger has a wide range of treatments for diarrhea, constipation, muscle aches, diabetes, high blood pressure, and vomiting. Its anti-inflammatory, analgesic, and antispasmodic properties have also been proven (15). A review study conducted by Terry et al. (2011) using *Zingiber officinale* to relieve pain showed that daily consumption of 750-2000 mg of ginger in the first 3-4 days of the menstrual cycle had a significant effect on reducing pain and symptoms of dysmenorrhea (16). In the review studies of Lakhan et al. (2015) and Akso et al. (2016), the positive effect of plants of the ginger family, including ginger, on the severity of dysmenorrhea has also been reported(17). Gupta et al. (2013) conducted a quasi-experimental study (ginger-exercise) and (exercise) on the severity of dysmenorrhea among students in Chandigarh, India. In the 60-day follow-up, the pain intensity in the group (ginger and exercise) significantly reduced compared to the exercise group alone( $p < 0.01$ ) (18). Despite its medicinal properties, overdosing can lead to side effects such as diarrhea, heartburn, and mild gastrointestinal disorders (9).

Lavender with its scientific name (*Lavandula Angustifolia*) is from the genus Mint (19); this plant can be grown in Iran (20). One of the most important ingredients of lavender is linalool (21), which has analgesic properties. Lavender inhibits synthesis (22) and reduces nitric oxide, and it has powerful antioxidant effects (23). The effectiveness of lavender has been confirmed to reduce labor anxiety (24). Massage with the extract of this plant can reduce labor pain (25). *Lavandula angustifolia* is a sign of the oily extract and polyphenols of lavender, which have anti-inflammatory and analgesic effects (26). Also, the effects of lavender in reducing the symptoms of dysmenorrhea and reducing the symptoms of mild to moderate depression were shown in the study of Dehkordi in 2014 (27). Moreover, Serap et al. (2010) conducted a quasi-experimental study on the effect of massage on dysmenorrhea in Turkish students with primary dysmenorrhea at Ataturk University in Turkey. There was a significant reduction in the level and severity of primary dysmenorrhea in the lavender massage group ( $p < 0.01$ ) (28). The oily

extract of this plant in a laboratory environment can have toxic-cellular (cytotoxic) effects on skin cells (29). Even though ginger is anti-inflammatory and effective in the treatment of dysmenorrhea, the two plants were combined because lavender is a sedative and pain reliever, and the benefits of mixing these two plants are greater. No known side effects or drug interactions with ginger have been mentioned. Thus, this study was conducted to compare the effects of "Ginger-Lavender," "Ginger," and "Mefenamic Acid" capsules on the severity of primary dysmenorrhea in the female students living in the selected dormitories at Shahid Beheshti University of Medical Sciences, Tehran, Iran.

### Materials and Methods

This study was a triple-blind clinical trial with the IRCT registration number of IRCT20200525047565N. It was done on 90 female students living in certain dormitories at Shahid Beheshti University of Medical Sciences with permission from the ethics committee of (Shahid Beheshti University of Medical Sciences) (IR.SBMU.PHARMACY.REC.1398.239).

The sample size was calculated using the data of a related study (1), with an error of the first type of 5% ( $\alpha = 0.05$ ) and a power of 90% ( $1 - \beta = 0.90$ ). So in each group 27 sample were estimated, which with estimating the probability of drop-out 30 additional sample were considered for each group and a total of 90 people included in the trial. Due to the three groups of the study, the analysis of the variance table was used to determine the sample size. To use this table, the number of groups in this study ( $r = 3$ ) and the quantity  $\Delta / \sigma$ ,  $\sigma$  was the standard deviation and  $\Delta$  was equal to the difference between the maximum and minimum mean pain intensity, this quantity was co

Inclusion criteria included students with primary dysmenorrhea, having pain intensity according to VSA ranging from moderate to severe, having cycles with regular intervals of 21 to 38 days, duration of 3-7 days, and no specific underlying and gynecological diseases. To collect data, at first, the objectives of the research and the method of conducting the study were explained to the students living in the dormitories of Shahid Beheshti University of Medical Sciences, and written consent was

Exclusion criteria included not using the drug or mefenamic acid supplement correctly and taking any herbal medicine during the study.

To collect data, a demographic and menstrual status questionnaire, a verbal multidimensional scoring system, visual analog scale and also a drug side effect checklist were used. Content and face validity were used to confirm the validity of these tools. The reliability of menstrual status questionnaires was evaluated using test-re-test ( $r = 0.89$ ). Visual analog scale (VAS) was also used to determine the severity of the pain, which is widely used in studies and is a reliable tool for measuring pain intensity (2).

Preparation of fresh rhizomes of ginger and fresh leaves of lavender was carried out by a pharmacist at the Shahid Beheshti University of Traditional Medicine. The rhizomes were then cut into slices in the dry sun and pulverized in the machine. In the case of lavender, clean flowers of the lavender plant were prepared from the market, powdered, and then extracted, and the extract was 50 mg, which is equivalent to 250 mg of powder, which was added in capsules containing 250 mg of "ginger". Finally, a 300 mg capsule of "Ginger-Lavender" (250 mg of ginger and 50 mg of lavender extract) and a 250 mg capsule of "Ginger" were prepared. "Mefenamic acid" (250 mg) capsules were also provided by Amin Company.

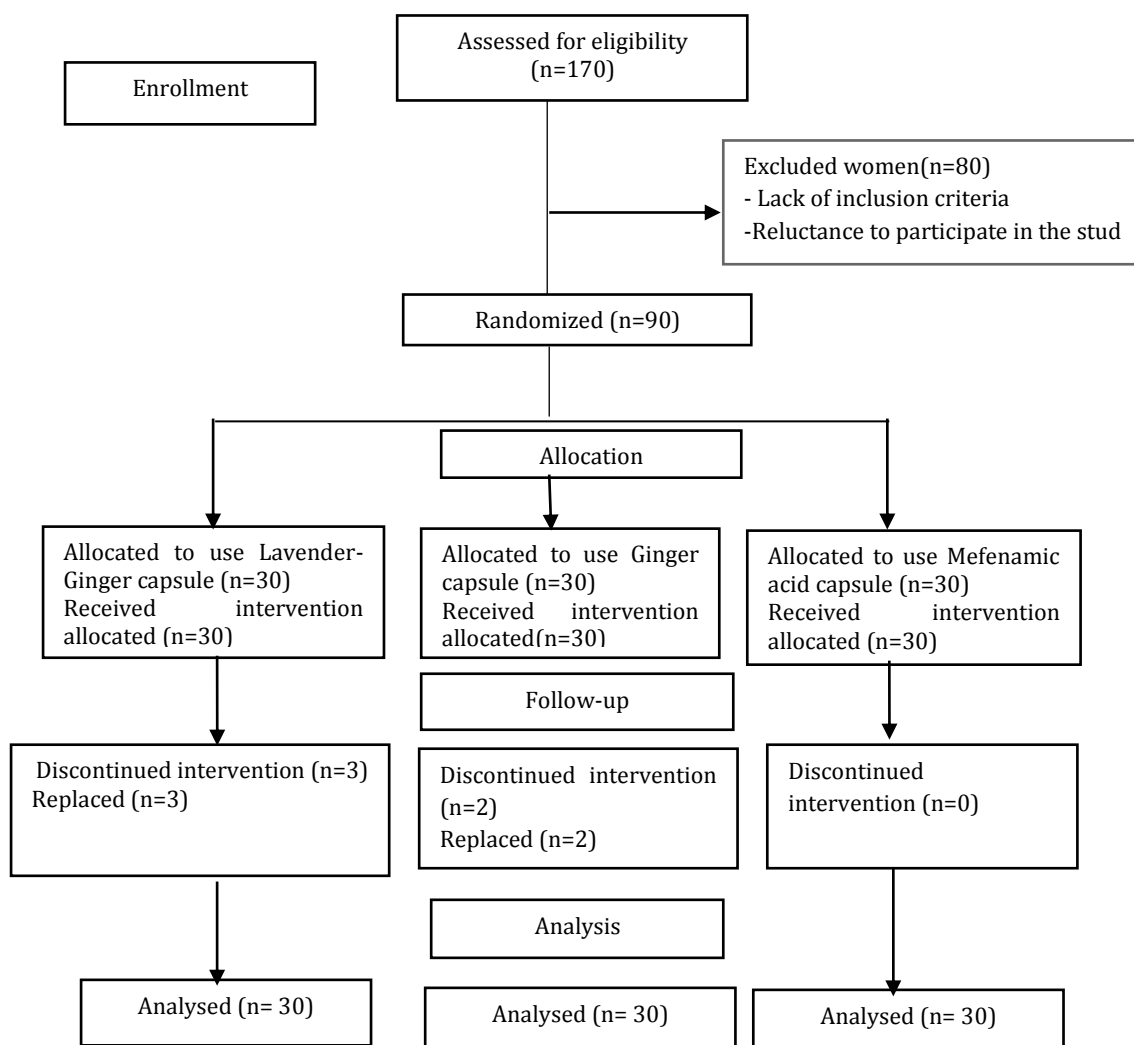
To blind the "Ginger-Lavender" and "Ginger" capsules in terms of shape, appearance, and color, they were prepared very similarly to the "Mefenamic Acid" capsule and packaged and coded by the pharmacist in similar capsules and cans, so the researcher, the statistical consultant, and the participants were not aware of the type of drug, so the present study was conducted in a third-blind manner.

The sampling method in this study was first based on convenience sampling of the eligible individuals and then randomly assigning them to three groups. The participants included students living in the dormitories of Shahid Beheshti University of Medical Sciences, Tehran, Iran.

obtained from them. Eligible individuals were randomly divided into three groups (Ginger-Lavender, Ginger, and Mefenamic acid Capsules) into separate blocks (moderate to severe dysmenorrhea) based on Excel software. One

"Ginger-Lavender" capsule with 300 mg of ginger and 50 mg of lavender extract, one 250 mg capsule of "Ginger" and one 250 mg capsule of "Mefenamic acid" were taken every 6 hours during menstruation until the end of the third day of menstruation. Severe pain in the first three days of bleeding when the person felt the

most pain was marked on the VSA and finally the average score during the three days was calculated and compared with the baseline. Participants were asked to complete questionnaires before using additional housing if it was required.



**Figure 1.** The CONSORT flow diagram of intervention in the three groups

Data analysis was performed using SPSS statistical software version 24. At first, the mean and standard deviation of pain intensity before and after the intervention were calculated in three groups; then, to compare the mean scores before and after the intervention, ANOVA, Two-way repeated measures ANOVA were used, and

to compare the scores of each group with itself, the one-way repeated measures ANOVA used. The significance level was considered ( $p < 0.05$ ).

## Results

During the course of study, one student in the "Mefenamic acid" group withdrawn from the study due to stomachache when using

mefenamic acid capsules, and two other students in the "Ginger" group due to gastrointestinal problems such as gastric reflux and constipation. They were excluded from the study (Figure 1). Among the three groups

studied, there were no significant differences in terms of mean age, menstruation initiation, menstruation initiation age, and body mass index (Table 1).

**Table 1.** Demographic characteristics of participants

Variables	Ginger	Ginger-lavender	Mefenamic acid	P-Value
Age	0.12±24.40*	2.31±23.6	0.043±23.30	8***
Age of onset of menstruation	0.431±9.312*	0.141±3.013	33.1±3.313	0.36***
Age of painful menstruation	08.1±30.14	10.1±40/14	67.1±50.14	0.42***
BMI	78.10±83.22*	17/20±39.23	76.10±29.23	0.45***

\* Significant level P< 0.05 \*\* Mean ±standard deviation \*\*\* ANOVA test

The results of one-way and two-way repeated measures ANOVA tests showed no significant difference in the duration of pain before the intervention (P<0.07), but in the first and second cycles after the intervention, there was a significant difference between the three groups (P<0.004). Also, within the group, there was a significant difference in the duration of pain (hour) between the three groups of "Ginger-Lavender", "Ginger," and "Mefenamic acid" capsules (P<0.001) (Table 2). The Bonferroni test results for the comparison of the mean difference in duration of pain showed a

significant difference between the cycle before the intervention and the first cycle after the intervention. Also, the comparison of the two cycles was different between the cycle before the intervention and the second cycle after the intervention. In addition, the results of the first and second cycles after the intervention due to the mean difference were different in the "Ginger-Lavender" group (P<0.001). Also, a significant difference was observed in the "Ginger" group before and after the first cycle, before and after the second cycle, and after the first and second cycles after the intervention).

**Table 2.** Comparison of pain duration (hours) in the three groups of "Ginger-Lavender", "Ginger" and "Mefenamic acid"

Groups	Before intervention	The first cycle after the intervention	The second cycle after the intervention	P-Value
<b>Ginger-lavender</b>				
Mean	2.30	0.70	0.66	0.001
standard deviation	0.66	0.46	0.47	
<b>Ginger</b>				
Mean	2.16	0.90	1.13	0.001
standard deviation	0.79	0.57	0.57	
<b>Mefenamic acid</b>				
Mean	1.86	1.2	1.13	0.001
standard deviation	0.86	0.76	0.73	
P-Value	0.33**	0.004*		

\*Two-way repeated measures ANOVA (between groups) \*\*ANOVA

\*\*\* One-way repeated measures ANOVA (within groups)

**Table 3.** Comparison of pain duration (hour) through cycles in the three groups of "Ginger-Lavender", "Ginger" and "Mefenamic acid"

Cycles	Ginger-Lavender			Ginger			Mefenamic acid		
	Mean difference	standard deviation	The result of Bonferroni test*	Mean difference	standard deviation	The result of Bonferroni test*	Mean difference	standard deviation	The result of Bonferroni test*
<b>Before</b>									
first	0.66	0.11	0.00	0.72	0.10	0.01	0.33	0.10	0.00
second	0.73	0.11	0.00	0.80	0.10	0.00	0.16	0.11	0.00
<b>After</b>									
First	-	-	-	-	-	-	-	-	-
second	0.60	0.48	0.00	0.64	0.03	0.00	0.06	0.04	0.02

\*Bonferroni test

There was a significant difference in the Mefenamic acid group in all three cycles ( $P < 0.002$ ) (Table 3).

Comparing the three groups using one-way and two-way repeated measure ANOVA, no

significant difference was observed in pain intensity before the intervention ( $p < 0.06$ ), while in the first and second cycles after the intervention, there was a significant difference between the three groups ( $P < 0.00$ ).

**Table 4.** Comparison of pain intensity in three groups of "Ginger-Lavender", "Ginger" and "Mefenamic acid"

Groups	Before intervention	The first cycle after the intervention	The second cycle after the intervention	P-Value
<b>Ginger-lavender</b>				
Mean	5.75	3.37	2.45	0.001
standard deviation	1.22	1.13	0.73	
<b>ginger</b>				
Mean	6.31	2.52	1.70	0.001
standard deviation	1.24	0.92	0.69	
<b>Mefenamic acid</b>				
Mean	5.53	4.06	2.55	0.001
standard deviation	1.22	1.04	0.87	
P-Value	0.06**		0.001*	

\*Two-way repeated measures ANOVA (between groups) \*\*ANOVA \*\*\*One-way repeated measures ANOVA (within groups)

**Table 5.** Comparison of average pain intensity through cycles in the three groups of "Ginger-Lavender", "Ginger" and "Mefenamic acid"

Cycles	Ginger-Lavender			Ginger			Mefenamic acid		
	Mean difference	standard deviation	The result of Bonferroni test*	Mean difference	standard deviation	The result of Bonferroni test*	Mean difference	standard deviation	The result of Bonferroni test*
<b>Before</b>									
first	1.46	0.19	0.00	3.78	0.16	0.00	2.38	0.16	0.00
second	2.97	0.14	0.00	4.61	0.15	0.00	3.30	0.23	0.00
<b>After</b>									
first	-	-	-	-	-	-	-	-	-
second	0.92	0.13	0.00	0.82	0.12	0.00	1.51	0.18	0.00

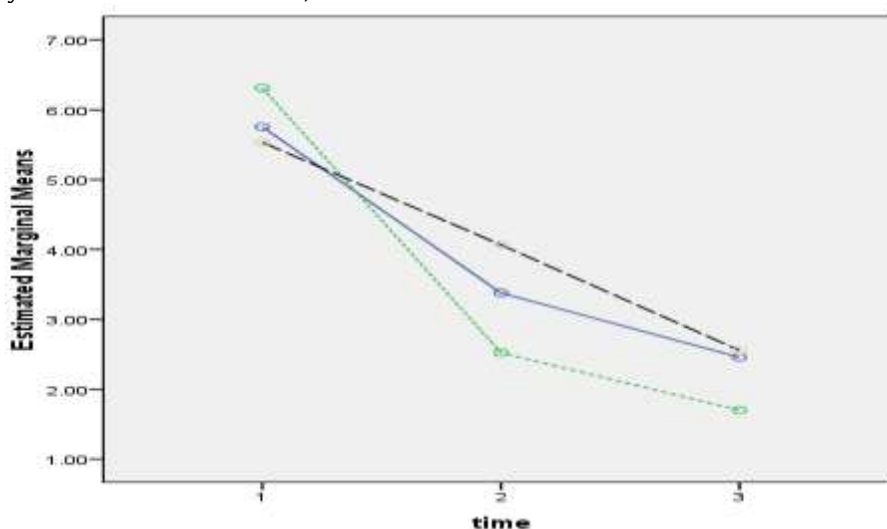
\*Bonferroni test

Also, in the intergroup and intragroup comparison, there was a significant difference between the three groups of "Ginger-lavender," "Ginger" and "Mefenamic acid" in terms of pain intensity ( $P > 0.00$ ) (Table 4). Also, according to the results of the Bonferroni test in the "Ginger-Lavender" group, there was a significant difference in terms of comparison of the average pain intensity in three cycles ( $P < 0.00$ ) (Table 5).

In the "Ginger" group that compared the cycle, significant differences were observed before and after the first cycle, before and after the second cycle after the intervention, and between

the first and second cycles after the intervention ( $P < 0.00$ ). Comparison of the difference between the mean pain intensity before the intervention

cycle and the two cycles after, in the three groups, the results of the Tukey test showed the mean pain score was lower in the "Ginger-lavender" group compared to the "Mefenamic acid" (1.53) and "Ginger" (1.04) groups. The mean pain score in the "Ginger" group was 0.49 units less than "Mefenamic acid" (Table 6).



**Figure 2.** The average severity of dysmenorrhea in the three groups of "Ginger-Lavender", "Ginger" and "Mefenamic acid"

**Table 6.** Comparison of the difference between the mean pain intensity in the pre-intervention cycle and the two post-intervention cycles in the three groups

Groups	Mean difference	The standard error	P-Value	95% confidence interval	
				Lower bound	Upper bound
<b>Mefenamic acid</b>					
Ginger	-0.49	0.15	0.003*	-0.81	-0.17
Ginger-lavender	-1.53	0.17	0.001*	-1.85	-1.20
<b>Ginger</b>					
Ginger-lavender	-1.04	0.16	0.004*	-1.36	-0.72

\*Tukey test

### Discussion

The present study showed that the use of the "Ginger-Lavender" combination capsule can relieve the pain caused by primary dysmenorrhea and reduce the duration and

severity of pain. Therefore, it can be said that consumption of the "Ginger-Lavender" compound probably improves the severity of dysmenorrhea. The overproduction of endometrial prostaglandins is one of the causes of primary dysmenorrhea, so reducing its

production can be effective in treating primary dysmenorrhea (32). One of the characteristics of inflammation is increased oxidation of arachidonic acid and the production of prostaglandins and leukotrienes. Many studies have shown that ginger has components with anti-inflammatory properties. Some studies have shown that ginger has components with anti-inflammatory properties. The inhibitory effects of ginger on prostaglandin biosynthesis were first discovered in 1970 (33). In the study conducted by Rahnema (2011) reported a significant decrease in the severity and duration of menstrual pain was observed in the ginger group compared to the control group (34). The results of their study are consistent with the present study.

Ginger inhibits the synthesis of prostaglandins by inhibiting cyclooxygenases 1 and 2. The extract of this plant also inhibits the production of leukotrienes by inhibiting 5 lipoxygenases (33). In the present study, there were no statistically significant differences in terms of demographic and obstetric characteristics, pain intensity, and duration of pain before the intervention. Also, the intensity and duration of pain in the "Ginger-Lavender" capsule group were significantly reduced compared to before the intervention and in comparison, with the "Ginger" and "Mefenamic acid" groups. Pak Niat and colleagues (2019) conducted a study entitled "The results of their study showed that ginger has a great effect on reducing the severity of primary dysmenorrhea (35), therefore their finding is consistent with the results of the present study.

Shogaol in ginger has analgesic effects by inhibiting the release of prostaglandin. It appears that Shogaol interferes with inflammation by producing the arachidonic acid cascade, leading to the inhibition of cyclooxygenase and inhibition of prostaglandin release (36). Saadatnejad et al. (2015) showed that the physical symptoms of primary dysmenorrhea were significantly reduced after consuming ginger (37). The study by Ebrahimi et al. (2019), showed that the severity and duration of primary dysmenorrhea were lower in the intervention groups than in the control group. The ginger rhizome has antispasmodic properties that can be used to prevent muscle

spasms by relaxing uterine muscles (38). Azizi (2020) similarly reported that massage with 2% ginger oil had an effect on reducing the active phase of labor pain in primiparous women. (39).

Skold and colleagues (2008) conducted a study, "which showed that linalool acetate in lavender can stimulate the parasympathetic system. Therefore, this plant has sedative, analgesic, and anti-contraction effects. Linalool acetate has narcotic properties, and linalool has sedative properties (40). The study conducted by Umezu et al. (2012) to evaluate the analgesic effects of lavender oil and identify its active ingredients on gamma-aminobutyric acid receptors showed that linalool may play an important role due to the importance of these receptors in reducing anxiety. Lavender oil affects these receptors and exerts anti-anxiety effects (41). The effects of lavender in various forms, including aromatherapy, inhalation, and its extract taken orally as an anti-anxiety drug, have also been confirmed in reducing the symptoms of primary dysmenorrhea (42). The study by Davari et al. (2014) showed that the effect of lavender is the same as mefenamic acid in terms of reducing the severity and duration of menstrual pain (43). The results of the present study are not consistent with their study because in the present study, the combined capsule "Ginger-Lavender" was more effective in reducing pain and duration of primary dysmenorrhea than the capsule "Mefenamic acid".

The study of Fasanghari (2023) showed that lavender oil is more effective than paraffin oil and only massage in reducing the pain of students with primary dysmenorrhea. The essential oil of lavender can be used as a reference in alternative and complementary medicine for the management and treatment of primary dysmenorrhea (44).

In the study of Biranvand (2015) it was reported that the mean intensity of menstrual pain in the intervention group decreased two months after the intervention compared to the placebo group. The results of their study are consistent with the results of the present study (43). (3) The anti-inflammatory effects of ginger are mediated by inhibiting the production of prostaglandins and leukotrienes. Gingerols and shogaols, which are the active ingredients of ginger, inhibit cyclooxygenases 3 and 2 and



prevent the synthesis of leukotriene and the production of proinflammatory cytokines in vitro (45). In lavender, the analgesic effects of linalool are inhibited by naloxone, an opioid receptor antagonist (46).

Due to the lack of side effects of the combined capsule of "Ginger-Lavender" plants, as well as the availability of these plants, the effectiveness of this combination compared to "Ginger" alone and the chemical drug "Mefenamic acid" and the use of plants in the treatment of many diseases, are accepted all over the world. To further investigate and use the properties of the two plants "lavender and Ginger" orally and simultaneously, the combination of these two plants was selected to reduce the severity of dysmenorrhea. On the other hand, due to the many side effects of common chemical drugs and their high costs, treatments with fewer side effects that are easier to use and cheaper are always more popular. It is recommended to conduct further studies with larger number of sample in the future to achieve more accurate results.

## Conclusion

The "ginger-lavender" combination capsule can be effective and satisfying as a safe, cost-effective, and side-effect-free method of reducing the duration and severity of primary dysmenorrhea.

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## Conflicts of interest

The authors declared no conflicts of interest.

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