

## The Effectiveness of Rosemary and Mefenamic Acid Capsules on the Quality of Life of Students with Primary Dysmenorrhea

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### Abstract

**Introduction:** Dysmenorrhea is one of the main factors affecting the quality. This study was conducted with the aim to compare the effect of rosemary and mefenamic acid capsules on the quality of life of students with primary dysmenorrhea.

**Methods:** This double-blind clinical trial study was conducted on 82 students with primary dysmenorrhea at the Faculty of Medicine of Islamic Azad University of Mashhad in 2018. Students with moderate dysmenorrhea after controlling two menstrual cycles by easy sampling method and using PASS software were randomly assigned to rosemary and mefenamic acid groups using double blocks. Quality of life was assessed using the SF-36 questionnaire before and after the intervention at the end of menstrual bleeding. They consumed rosemary and mefenamic acid capsules every 8 hours for the first 3 days in intervention cycles.

**Results:** The mean score of physical health before the intervention in the Rosemary and Mefenamic groups was  $293.12 \pm 58.87$  and  $301.16 \pm 53.09$ , respectively. The mean score of physical health in the first cycle after the intervention increased by  $300.07 \pm 62.43$  and  $66.11 \pm 306.00$  and in the second cycle after the intervention increased by  $63.90 \pm 306.54$  and  $64.14 \pm 308.63$ . The mean score of mental health before the intervention in the rosemary and mefenamic acid groups was  $233.81 \pm 87.46$  and  $245.07 \pm 79.32$ , respectively. The mean score of mental health in the first cycle after the intervention increased by  $283.90 \pm 58.48$  and  $282.98 \pm 65.63$  and in the second cycle after the intervention increased by  $80.61 \pm 261.13$  and  $86.67 \pm 258.94$ .

**Conclusion:** Consumption of rosemary and mefenamic acid capsules improves the quality of life by increasing physical and mental health scores.

**Key words:** Quality of life, Rosemary, Mefenamic acid, Dysmenorrhea

## Introduction

Primary dysmenorrhea is menstrual pain without pelvic pathology (1). Pain caused by primary dysmenorrhea usually begins a few hours before or at the same time as menstrual bleeding and might last 48-72 hours. This pain is similar to labor pain and usually concentrates in the suprapubic region, and some women experience pain in the groin, back pain, nausea and vomiting, and diarrhea (1,2). The cause of primary dysmenorrhea is an increase in the production or an unbalanced amount of prostaglandins secreted from the endometrium during menstruation, which lead to an increase in basal tone and an increase in active pressure. Increasing uterine contractions contribute to pain by decreasing uterine blood flow and increasing the sensitivity of peripheral nerves (1).

The prevalence of primary dysmenorrhea is reported to be 50-90% in different societies and 74-84.4% in Iran (3). The prevalence of primary dysmenorrhea in medical students of Kurdistan in 2018 was reported as 75.33% (4). In the study which evaluated the prevalence of menstrual disorders in Mashhad and Sabzevar in 2017, the prevalence of dysmenorrhea was reported as 68.8% and was the most common disorder (5). Although primary dysmenorrhea does not threat women's lives, it has a negative effect on the performance and quality of life of women who want to have an active and regular life. Several studies have shown the negative effect of dysmenorrhea on the quality of life among female teenage and students (6,7).

Quality of life is a kind of individual's feeling of well-being that is caused by satisfaction or no satisfaction with different aspects of life which are important for a person. The quality of life is an active, dynamic and multifaceted flow of perceptions, attitudes and behavioral changes, and it results from the various experiences in a person's life (8). Pain reduction methods can improve the quality of life (9) because unrelieved pain has negative physical and psychological consequences, and no pain reduction hinders a satisfactory quality of life (10).

Non-steroidal anti-inflammatory drugs, oral contraceptives, food treatments (1), local heat, thiamine consumption, acupuncture, fish oil supplements and vitamin D, E (11) have also been suggested to treat dysmenorrhea. The most common side effects of nonsteroidal anti-inflammatory drugs include mild digestive disorders in the form of nausea, vomiting, and diarrhea. Other side effects include kidney disorders, stomach ulcers, dizziness, tinnitus, headache, insomnia, depression, allergic reactions, blood complications and liver complications (12). Moreover, due to the fewer side effects of herbal medicines and the society's attention to traditional medicine, many women with primary dysmenorrhea use effective herbs in this field. The results of Ameri et al.'s study showed that 73.3% of Iranian women use medicinal plants (13).

Shoja et al.(2010) in the study on female students living in the dormitory of Golestan University of Medical Sciences and in Attaran Golestani, through a questionnaire, found that a total of 29 herbal and food combinations are used by the affected people for this purpose, and the most used are related to peppermint, cumin, rock candy hot tea, echium, thyme, licorice, fennel, chamomile, yarrow, jujube, marshmallow, chamomile, ginger, Fumaria

officinalis, chamomile, oregano leaves, fenugreek seeds, dill seeds, Parsley seed, fennel seed, Teucrium polium, Nigella Sativa, Cyamophila astragalicola and forty plants sweat (14).

Rosemary with the scientific name Rosemary Officinalis and the Persian name Aklil Kohi is from the mint family (15). Its therapeutic properties include antispasmodic, analgesic, antifatulent, diuretic (15,16), breast diseases anti-cancer and anti-depressant (17), anti-inflammatory and antioxidant (15,17), treatment of menopause, reduction of menstrual bleeding (18), general weakness and fatigue (19). Its main compounds are camphene, limonene, cineol, linalool and ribinol (15). New studies have shown that camphene and borneol have a prostaglandin regulating effect in the body and also relieves pain, inflammation and swelling and regulates blood pressure (20).

The daily use of rosemary approved by the German Commission E is 4 to 6 grams of this plant (21), and the recommended dose based on its antispasmodic properties is 3 to 5 grams daily (22). No harmful and dangerous side effects have been identified by consuming the correct doses, but in case of consumption of high doses of rosemary leaves, it leads to deep coma, spasms, vomiting, inflammation of the digestive system, and kidney irritation (21). In the study of Fernandez et al. (2008), which prospectively investigated the effect of rosemary essential oil as an anti-hypertensive agent in people suffering from low blood pressure and its effect on the quality of life, showed that oral consumption of rosemary has the greatest effect on people's physical activities; the quality of life questionnaire (SF-36) was used and the mental factors, energy, emotional role and mental health improved, and as a result increased the quality of life of the patients (23).

Considering that people suffering from primary dysmenorrhea are mostly young women who live in a sensitive and active period of life, and dysmenorrhea can be one of the factors disrupting the quality of life and social activities of young women, and considering the high tendency of women to use herbal medicines to reduce dysmenorrhea and the importance of quality of life, this study was conducted with aim to compare the effect of rosemary and mefenamic acid capsules on the quality of life of students with primary dysmenorrhea.

## Materials and Methods

This double-blind clinical trial study was conducted on students suffering from primary dysmenorrhea at the Faculty of Medicine of Islamic Azad University of Mashhad. The study was performed after registration in the Iranian Registry Clinical Trial Center with code of IRCT20160622028586N2 and the ethics code of IR.MUMS.REC.1397.36. Since no similar study was found in the searches, the sample size was determined with 95% confidence and 80% power and 33 subjects were determined for each group, that considering 25% dropout, 45 samples were considered in each group. Finally, a total of 82 samples were analyzed.

Inclusion criteria were unmarried girls up to 25 years old, regular menstruation, pain before or at the same time as menstrual bleeding, menstrual pain for 3 days or less, pain score for the first three days of menstrual bleeding based on the visual analogue scale for pain in each control cycle of 40 to 70 mm, the normal amount of menstrual bleeding. Exclusion criteria were the use of oral contraceptive pills, the use of tobacco and alcohol-containing beverages,

sensitivity to rosemary, history of liver and kidney diseases, hyperthyroid, hypothyroid, diabetes, coagulation disorders, and depression.

After examining the eligible subjects to enter the study, the researcher obtained written consent to participate in the study. Questionnaires included individual characteristics, menstrual status, determination of pain intensity based on visual pain scale (VAS), and quality of life (SF-36) that were given to the subjects and necessary information was given to the questionnaires.

The visual pain scale (VAS) questionnaire ranged from 0 to 100 points, which is a standard, valid and reliable scale for evaluating pain. This scale includes a divided line of 100 mm, the left side of which (zero) indicates no pain and the right side (100) indicates the most severe pain. A score of 10-30 indicates mild pain, 40-70 moderate pain, and 80-100 severe pain. This tool has been validated in most countries of the world as well as in Iran (24).

The quality of life questionnaire (SF-36) is a standard questionnaire that has been used in previous studies in Iran and its validity and reliability have been determined in previous studies. This questionnaire has 36 questions and consists of eight scales that include physical functioning, role limitations due to physical health, role limitations due to emotional health, energy/fatigue, emotional well-being, social functioning, pain, and general health. The questions were scored based on the scoring system of zero to 100, and the score of each dimension is obtained by summing the scores of the questions related to each dimension and dividing the resulting number by the number of related questions. Physical health is obtained from the sum of the subscales of physical functioning, role limitation due to physical health, pain, general health, and mental health from the sum of the subscales of role limitation due to emotional health, energy/fatigue, emotional well-being, and social functioning (12). The reliability and validity of this questionnaire has been confirmed as a general health-related quality of life tool in Iran (25).

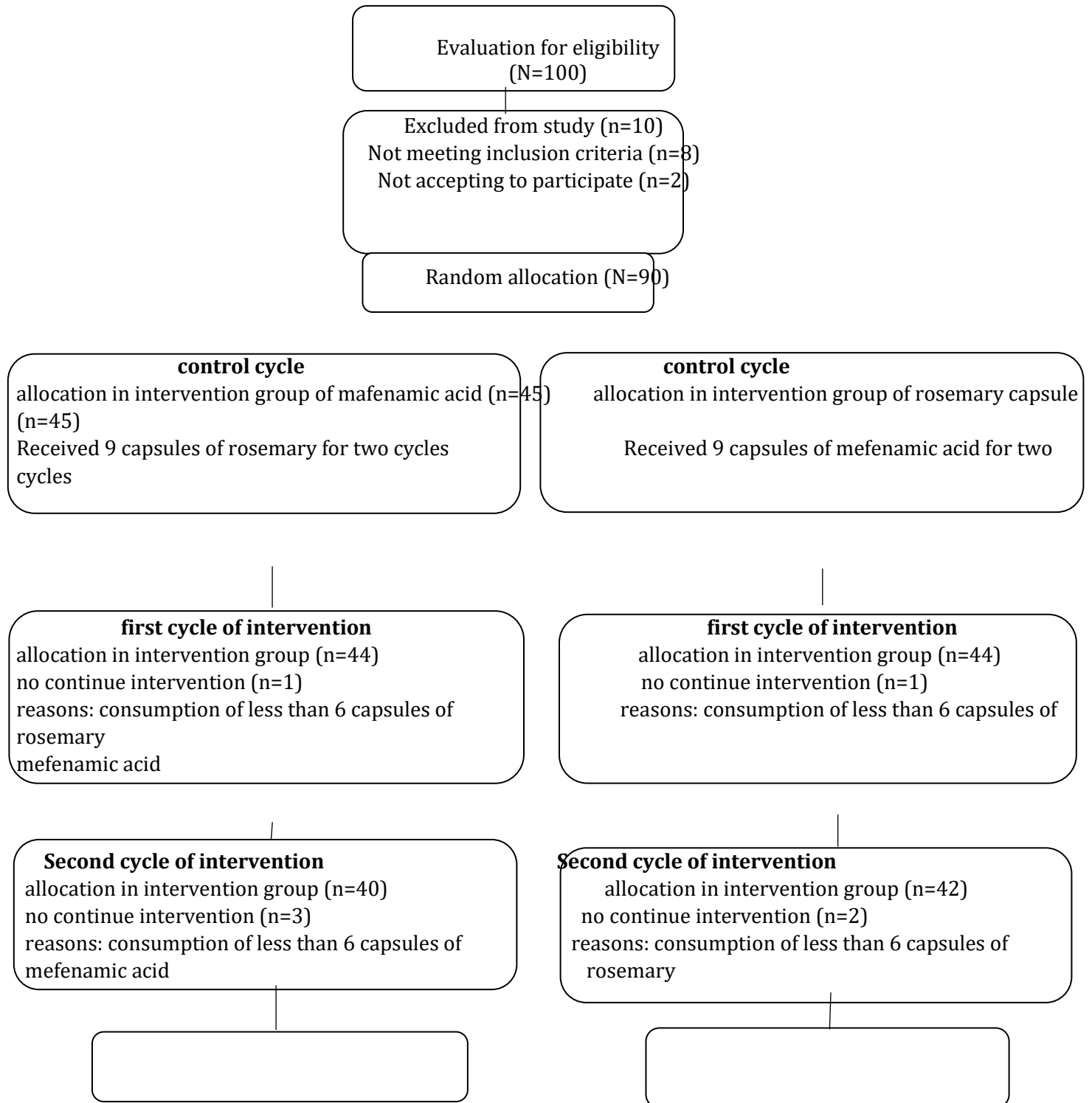
The pharmacist consultant prepared alcoholic extract of rosemary through drying 1000 grams of the flowering head of the rosemary plant from a farm in Shandiz region with herbarium code 13209 in the shade, then cleaned and powdered it. The resulting powders were extracted using 70% alcohol by percolation method. The extract was concentrated by the Rotary evaporator and turned into a powder using a freeze-drying device (26). At the end, 220 grams of dry extract was prepared from 1 kilogram of rosemary, which was mixed with 30 grams of lactose, then 250 mg of extract (equivalent to 1 gram of rosemary powder) was prepared in each capsules similar to the mefenamic capsule.

The participants were included in the study by easy sampling method. After explaining how to complete, the researcher gave the questionnaires to the subjects, which were specified for each person with a number. In the first and second cycles before the intervention, the participants completed and delivered the pain intensity and quality of life questionnaires. Then, the researcher randomly assigned the subjects to two groups of A and B using PASS software in double blocks. For blinding, the pharmacist consultant prepared the rosemary extract in capsules similar to mefenamic acid capsules and then provided the capsules to the

researcher in cans marked with the letters A and B. If the subjects were placed in group A, drug A and if they were placed in group B, drug B was available to them.

The participants in both groups orally received 3 mefenamic acid or rosemary capsules 250 mg daily in the cans marked with letters A and B during the first three days of menstruation in two intervention cycles. Then, they completed the questionnaires and delivered them to the researcher.

Data were analyzed using SPSS statistical software (version 24). The normality of the quantitative variables was determined using the Kolmogorov-Smirnov test. Normal variables were analyzed with independent t-tests and analysis of variance with repeated measures, and if not normal with Mann-Whitney and Friedman tests.  $P < 0.05$  was considered statistically significant.



**Figure 1: Distribution of research units in the two groups**

## Results

In this study, data obtained from 82 subjects in two groups of rosemary capsules (n=42) and mefenamic acid (n=40) were analyzed.

The two groups were homogeneous in terms of individual characteristics and menstrual status, including age, body mass index, age of onset of menstruation, age of onset of dysmenorrhea, interval between menstruations, and duration of menstrual bleeding; there were no statistically significant differences between the two groups in this regard ( $p < 0.05$ ) (Table 1).

**Table 1- Comparison of individual characteristics and menstrual status in the studied groups**

Variable	Rosemary group Mean±SD N=42	Mefenamic acid group Mean±SD N=40	Mann-Whitney test result
Age (years)	21.64±0.26	22.32±0.31	z=1.81 p= 0.07
BMI (kg/m <sup>2</sup> )	22.0±0.32	21.58±0.29	z=0.89 p=0.37
age of onset of menstruation (years)	13.26±0.18	13.15±0.23	z= 0.35 p= 0.72
age of onset of dysmenorrhea (years)	15.28±0.32	14.80±0.25	z= 1.08 p= 0.27
Interval between menstruations (day)	28.04±2.88	28.44±2.72	z=1.38 p= 0.16
duration of menstrual bleeding (day)	6.34±0.96	6.27±1.00	z= 0.15 p= 0.87

There was statistically significant difference in the mean intensity of menstrual pain in the first and second cycles of the intervention compared to the mean of the two cycles before the intervention in the rosemary capsule group and the mefenamic acid group ( $P < 0.001$ ), but there was no statistical difference between the two groups ( $P > 0.05$ ) (Table 2).



**Table 2- Comparison of mean intensity of menstrual pain in the studied groups**

Variable	Rosemary group Mean±SD N=42	Mefenamic acid group Mean±SD N=40	Covariance test result
Mean intensity of menstrual pain in two cycles before the intervention	40.39±11.41	46.75±13.32	
Mean intensity of menstrual pain in two intervention cycles	23.57±12.78	28.29±17.21	F=0/13    P =0/7
<b>Paired t-test result</b>	T=9/9    P<0.001	T= 9/1 P<0.001	

Comparison of quality of life dimensions before the intervention did not show a significant statistical difference between the two groups ( $p<0.05$ ).

Comparison of the differences in quality of life dimensions including physical functioning, role limitation due to physical health, role limitation due to emotional health, energy/fatigue, emotional well-being, social functioning, pain, and general health in the rosemary and mefenamic acid groups showed no statistically significant difference between the two groups in the first and second cycles after the intervention compared to before the intervention. There was ( $p>0.05$ ) (Table 3).

**Table 3- Comparison of the mean of the difference in quality of life dimensions in rosemary and mefenamic acid groups in the first and second cycles of the intervention compared to before the intervention**

variable	Mean±SD The average of two cycles before the intervention			Mean±SD First cycle compare to before intervention			Mean±SD Second cycle compared to before intervention		
	Mefenamic acid	rosemary	pvalue	Mefenamic acid	rosemary	pvalue	Mefenamic acid	rosemary	pvalue
Physical functioning	88.91±7.03	89.44±9.50	Z=.88 p=0.37	0.87±9.74	0.75±9.69	Z=0.35 p=0.72	1.85±9.25	1.98 ± 9.52	Z=0.45 p=0.64
role limitation due to physical health	75.62±29.81	73.51±31.50	Z=0.39 p=0.69	-3/75±34.1	-2.08±27.87	Z=1.96 p=0.84	-4.30±34.10	0.29 ± 31.29	Z=0.40 p=0.68
role limitation due to emotional health	56.29±40.74	53.96±40.29	Z=0.29 p=0.76	30.78±45.56	37.30±38.57	Z=0.68 p=0.49	5.39±42.17	9.12 ± 37.75	Z=0.36 p=0.71
energy/fatigue	58.00±17.85	56.48±18.57	T=0.37 p= 0.70	1.62±13.15	4.82±14.93	T=1.02 p= 0.30	3.37±15.80	5.65±14.05	T=0.69 p= 0.49



emotional well-being	64.50 ±17.55	63.04 ±18.40	T=0.36 p= 0.71	2.40±11.65	2.50±14.26	T=0.35 p= 0.97	2.00±12.68	6.47±14.25	T=1.49 p= 0.13
social functioning	66.28±18.55	60.31±24.07	Z=-0.89 p=0.37	3.09±17.62	5.45±15.44	Z=0.29 p=0.76	3.09±19.46	6.05±15.55	Z=0.57 p=0.56
pain	64.68±21.57	64.45±19.76	T=0.05 p= 0.95	6.56±18.21	3.16±18.65	T=0.83 p= 0.40	8.12±25.59	5.66±16.13	T=0.52 p= 0.60
general health	71.93±15.07	65.71±17.37	T=1.72 p= 0.08	1.18±13.85	5.11±15.28	T=1.21 p= 0.22	2.06±11.95	5.47±15.21	T=1.12 p= 0.26

The mean of physical health, which includes the sum of the subscales of physical functioning, role limitation due to physical health, pain, general health, and mental health, which includes the sum of the subscales of role limitation due to emotional health, energy/fatigue, emotional well-being, and social functioning before the intervention did not show significant difference between the two groups ( $p>0.05$ ). Comparison of the mean of physical and mental health in the first and second cycles of the intervention did not show significant difference between rosemary and mefenamic acid groups ( $p>0.05$ ) (Table 4).

**Table 4: Comparison of the mean of physical and mental health in the first and second cycles of the intervention compared to before the intervention**

	mental health		Physical health		
	rosemary	mefenamic acid	rosemary	mefenamic acid	
Mean of two cycles before intervention	233.81±87.46	245.07±79.32	293.12±58.87	301.16±53.09	T=0.61 p= 0.54
Mean of first cycle of intervention	283.90±58.48	282.98±65.63	300.07±62.43	306.00±66.11	T=0.67 p= 0.94
Mean of second cycle of intervention	261.13±80.61	258.94±86.67	306.54±63.90	308.63±64.14	T=0.11 p= 0.90

The mean of physical and mental health scores increased in the mefenamic acid and rosemary groups after the intervention compared to before the intervention (Figure 2,3).

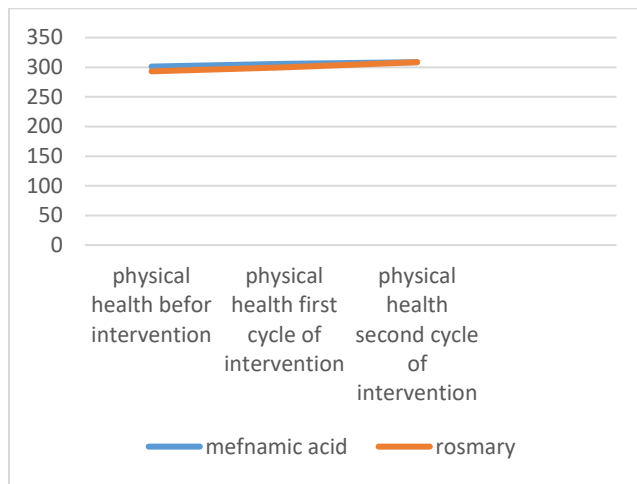


Figure : Mean scores of physical health after intervention compared to before intervention

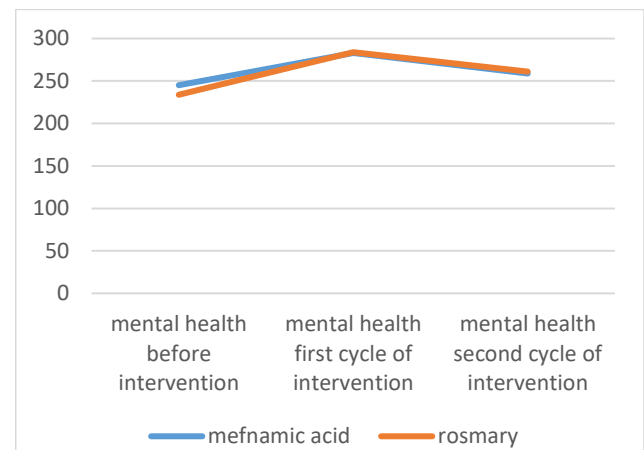


Figure 3: Mean scores of mental health after intervention compared to before intervention

## Discussion

The present study was conducted with aim to compare the effects of rosemary and mefenamic acid capsules on the quality of life of students with primary dysmenorrhea. The results of this study showed that the intensity of menstrual pain after the intervention compared to before the intervention had significant difference in the rosemary group, but it did not show a statistically significant difference between the rosemary and mefenamic acid groups. The results of this study showed that rosemary capsules like mefenamic acid capsules could reduce menstrual pain. Therefore, according to the side effects of mefenamic acid, rosemary can be a suitable alternative to reduce menstrual pain. However, the results of the study by Davari et al. (2014) that investigated the effect of aromatherapy with rosemary and valerian in primary dysmenorrhea showed that the pain intensity in the rosemary group was significantly reduced compared to the mefenamic acid group (27).

The results of the present study showed that the use of rosemary and mefenamic acid capsules improved the physical and mental health of students, but it did not show a statistically significant difference between the two groups. Pain which is not alleviated has

negative physical and psychological consequences. Failure to reduce pain prevents satisfactory quality of life (28). Physical health includes subscales of physical functioning, role limitation due to physical health, pain, and general health. Physical health improved in the rosemary group after the intervention compared to before the intervention due to pain reduction regarding to the analgesic properties of rosemary which contains diterpenes including carnocel and carcinoic acid which acts as a strong anti-inflammatory and antioxidant (15). Reducing pain improves people's physical functioning.

The results of the present study are consistent with the study of Solhi et al. (2013) which investigated the beneficial effect of *Rosemarinus officinalis* plant in the treatment of opium withdrawal syndrome in drug addiction programs. In their study, 300 mg of rosemary was used daily in the form of dried leaves in 4 capsules. After consuming rosemary, the results showed that skeletal pain, which is one of the side effects of addiction withdrawal, has decreased in comparison with the control group, which is due to the anti-inflammatory compounds of rosemary (29). The results the study by Navid et al. (2022) showed that Ginger and vitamin E supplements have a positive effect on pain and quality of life among women with primary dysmenorrhea aged 25 to 40 years, and their quality of life increased with pain reduction (30).

Mental health includes the subscales of social functioning, role limitation due to emotional health, energy/fatigue, and emotional well-being. Mental health did not show a statistically significant difference between the rosemary and mefenamic acid groups. Rosemary is considered a stimulant. This plant is very strong in eliminating general weakness and fatigue, stomach tonic and energizing (31). The results of the study by Jacob and colleagues (2012) on the short-term effects of rosemary and black pepper on maintaining concentration, energy and fatigue in low-energy adults showed that the consumption of 1.7 grams of rosemary in the form of a single dose has reduced the mental fatigue of people compared to the consumption of black pepper, but there is no significant difference with the control group, which is probably due to the single dose and amount of rosemary, which needs more research (32).

Considering that the most common method of treating dysmenorrhea is the use of non-steroidal anti-inflammatory drugs such as mefenamic acid, which decrease pain by reducing uterine contractions, but have the side effects such as headache, dizziness, anorexia, nausea, vomiting, gastrointestinal bleeding and kidney disorders (26), therefore, since in this study, the students who consumed rosemary did not report any side effects and the physical and mental health did not show a significant difference between the two groups of rosemary and mefenamic acid, rosemary can be a suitable alternative to mefenamic acid to reduce pain and increase the physical and mental health of women with dysmenorrhea and increase the quality of life of women during menstruation.

In the current study, the quality of life tool was used, which is a valid tool, but because the quality of life is a subjective concept which is self-reported, therefore the accuracy of the answers given by individuals and some factors affecting the intensity of pain such as mental characteristics and personality differences to determine the intensity of pain is one of the limitations of this research.

## Conclusion

The quality of life and efforts to improve it will play a significant role in the health of individuals' personal and social lives. Since dysmenorrhea causes widespread social, economic, physical and psychological problems, therefore, improving the quality of life of women with dysmenorrhea is of special importance. Therefore, due to the great desire of women to use herbal medicines, rosemary can be a suitable alternative due to its analgesic properties, energizing and less side effects than chemical medicines. Pain reduction methods can improve the quality of life.

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