

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

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ABSTRACT

Background & aim: Dysmenorrhea is one of the main factors affecting the quality of life. This study aimed to determine the impact of rosemary and mefenamic acid capsules on the quality of life of students with primary dysmenorrhea.

Methods: This double-blind clinical trial study was performed on 82 students with primary dysmenorrhea from June to September 2018 at the Faculty of Medicine of the Islamic Azad University of Mashhad. Students with moderate dysmenorrhea, after controlling two menstrual cycles by the convenience sampling method and using PASS software, were randomly assigned to the rosemary and mefenamic acid groups using double blocks. They consumed rosemary and mefenamic acid capsules every 8 hours for the first 3 days of intervention cycles. The SF-36 questionnaire was used to assess quality of life before and after the intervention at the end of menstrual bleeding. The data were analyzed using SPSS 24 and descriptive and interpretive statistical tests.

Results: The mean score of physical health in the first cycle after the intervention increased by 300.07 ± 62.43 and 306.00 ± 66.11 and in the second cycle after the intervention increased by 306.54 ± 63.90 and 308.63 ± 64.14 ($P=0.94$). The mean score of mental health in the first cycle after the intervention increased by 283.90 ± 58.48 and 282.98 ± 65.63 and in the second cycle after the intervention increased by 261.13 ± 80.61 and 258.94 ± 86.67 ($P=0.90$).

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

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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 leads to an increase in basal tone and an increase in active pressure. Increasing uterine contractions contribute to pain by decreasing uterine blood flow and

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increasing the sensitivity of peripheral nerves (1).

It is reported that the prevalence of primary dysmenorrhea was 50-90% in different societies and 74-84.4% in Iran (3). The prevalence of primary dysmenorrhea among medical students in Kurdistan in 2018 was reported at 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 at 68.8% and was the most common disorder (5). Although primary dysmenorrhea does not threaten women's lives, it negatively affects the performance and quality of life of women who want to have an active and regular life. Several studies have reported the negative effect of dysmenorrhea on the quality of life among female teenagers 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 and 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, headaches, insomnia, depression, allergic reactions, blood complications, and liver complications (12). Moreover, due to the fewer side effects of herbal medicines and society's attention to traditional medicine, many women with primary dysmenorrhea use effective herbs in this field. The research by Ameri et al. (2019) indicated that 73.3% of Iranian women use medicinal plants (13).

Shoja et al. (2010) in a 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 were used by the affected people for this purpose, and the most used are related to peppermint, cumin, rock candy hot tea, echium amoenum, 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 and anti-depressant (17), anti-inflammatory and antioxidant (15,17), anti-breast cancer (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 on the body and also relieve pain, inflammation, and swelling and regulate 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 or dangerous side effects have been identified by consuming the correct doses, but in the case of high doses of rosemary leaves, it leads to deep coma, spasms, vomiting, inflammation of the digestive system, and kidney irritation (21).

Fernandez et al. (2008) investigated the impact of rosemary essential oil on individuals with low blood pressure and its influence on quality of life. The findings revealed that oral rosemary consumption had the greatest effect on physical activity. The researchers utilized the SF-36 quality of life questionnaire to assess improvements in mental factors, energy, emotional role, and mental health. Consequently, the participants reported an overall enhancement in their quality of life (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 that may disrupt the quality of life and social activities of young women, and taking into account the high tendency of women to use herbal medicines to reduce dysmenorrhea and the importance of quality of life, this study was performed with to compare the effectiveness of rosemary and mefenamic acid capsules on the quality of life of students with primary dysmenorrhea.

Materials and Methods

This double-blind clinical trial was conducted on students suffering from primary dysmenorrhea at the Faculty of Medicine of Islamic Azad University of Mashhad from June to September 2018. The study was performed after registration at the Iranian Registry of Clinical Trials under the code of IRCT20160622028586N2 and the ethics code of IR.MUMS.REC.1397.36. Since no similar study was found in the literature search, the sample size was determined with 95% confidence and 80% power, and 33 subjects were estimated for each group. Considering 25% dropout, 45 sample were considered in each group. Finally, a total of 82 sample were analyzed (Figure 1).

The 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, and a 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, hyperthyroidism, hypothyroidism, diabetes, coagulation disorders, and depression.

Tools for data collection included demographic characteristics questionnaire, questionnaire for menstrual status-related data, visual analogue scale (VAS), and 36-Item Short Form Health Surve(SF-36) to measure quality of life that were given to the subjects, and necessary information was provided to help them to respond to the questionnaires.

The demographic questionnaire consisted of 3 parts. The first part of personal and social information has 11 questions about information such as weight, height, BMI, economic status, and the second part of lifestyle information has 5 questions about diet and the amount of rest. The third part has information about menstrual history and has 10 questions about Menstrual age, number of days of dysmenorrhea, amount of bleeding, drug use during menstruation.

The visual analogue scale (VAS) 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 in the world as well as in Iran (24).

The quality of life questionnaire (SF-36) is a standard questionnaire that previous research in Iran has used 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 have been confirmed as a general health-related quality of life tool in Iran (25). In this study we determine the reliability, by

test-retest was used with 30 day intervals on 20 subjects ($r = 0.75$). Completing the questionnaires using the self-report method took about 10 minutes.

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

After examining the eligible subjects to enter the study, written informed consent signed by the participants in the study. At first, the participants were selected by the convenience sampling method. After explaining how to complete them, 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 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 given to them.

The participants in both groups orally received three 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 analysis was done by SPSS statistical software (version 24). The Kolmogorov-Smirnov test was employed to examine the normality of the quantitative variables. 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.

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 similar regarding 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; no statistically significant differences were found between the two groups in this regard ($P < 0.05$) (Table 1).

Table 1. Individual characteristics and menstrual status in the two 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 ²)	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 no statistical difference was observed between the two groups ($P = 0.07$) (Table 2).

Table 2. The 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	F= 0.13 P= 0.07
Mean intensity of menstrual pain in two intervention cycles	23.57±12.78	28.29±17.21	
Paired t-test result	T=9.9 P<0.001	T= 9.1 P<0.001	

Table 3. Mean of difference in quality of life dimensions in rosemary and mefenamic acid groups in the first and second cycles of the intervention compared to preintervention phase

variable	Mean±SD The average of two cycles before the intervention			Mean±SD First cycle compared to before intervention			Mean±SD Second cycle compared to before intervention		
	Mefenamic acid	Rosemary	P-Value	Mefenamic acid	Rosemary	P-Value	Mefenamic acid	Rosemary	P-Value
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

variable	Mean±SD The average of two cycles before the intervention			Mean±SD First cycle compared to before intervention			Mean±SD Second cycle compared to before intervention		
	Mefenamic acid	Rosemary	P-Value	Mefenamic acid	Rosemary	P-Value	Mefenamic acid	Rosemary	P-Value
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 two groups were not significantly different regarding quality of life dimensions before the intervention ($P>0.05$).

The 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).

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 indicate a significant difference between the two groups ($P>0.05$). A comparison of the mean of physical and mental health in the first and second cycles of the intervention did not show significant differences between the rosemary and mefenamic acid groups ($P>0.05$) (Table 4).

Table 4. Mean of physical and mental health in the first and second cycles of the intervention compared to before the intervention

variable	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

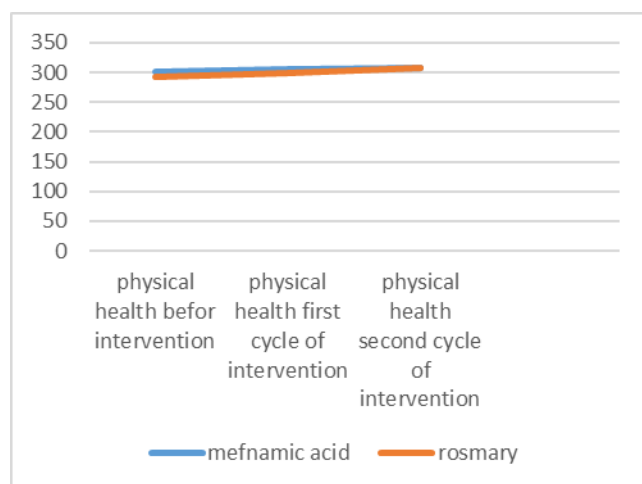


Figure 2. Mean scores of physical health after intervention compared to before intervention

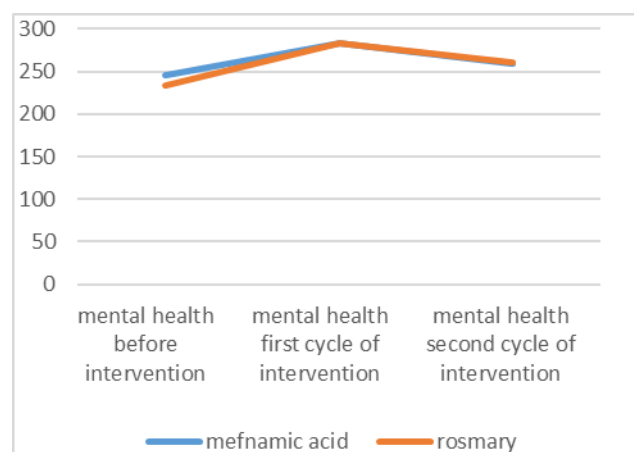


Figure 3. Mean scores of mental health after intervention compared to before intervention

The mean of physical and mental health scores increased in the mefenamic acid and rosemary

groups after the intervention compared to before the intervention (Figures 2 and3).

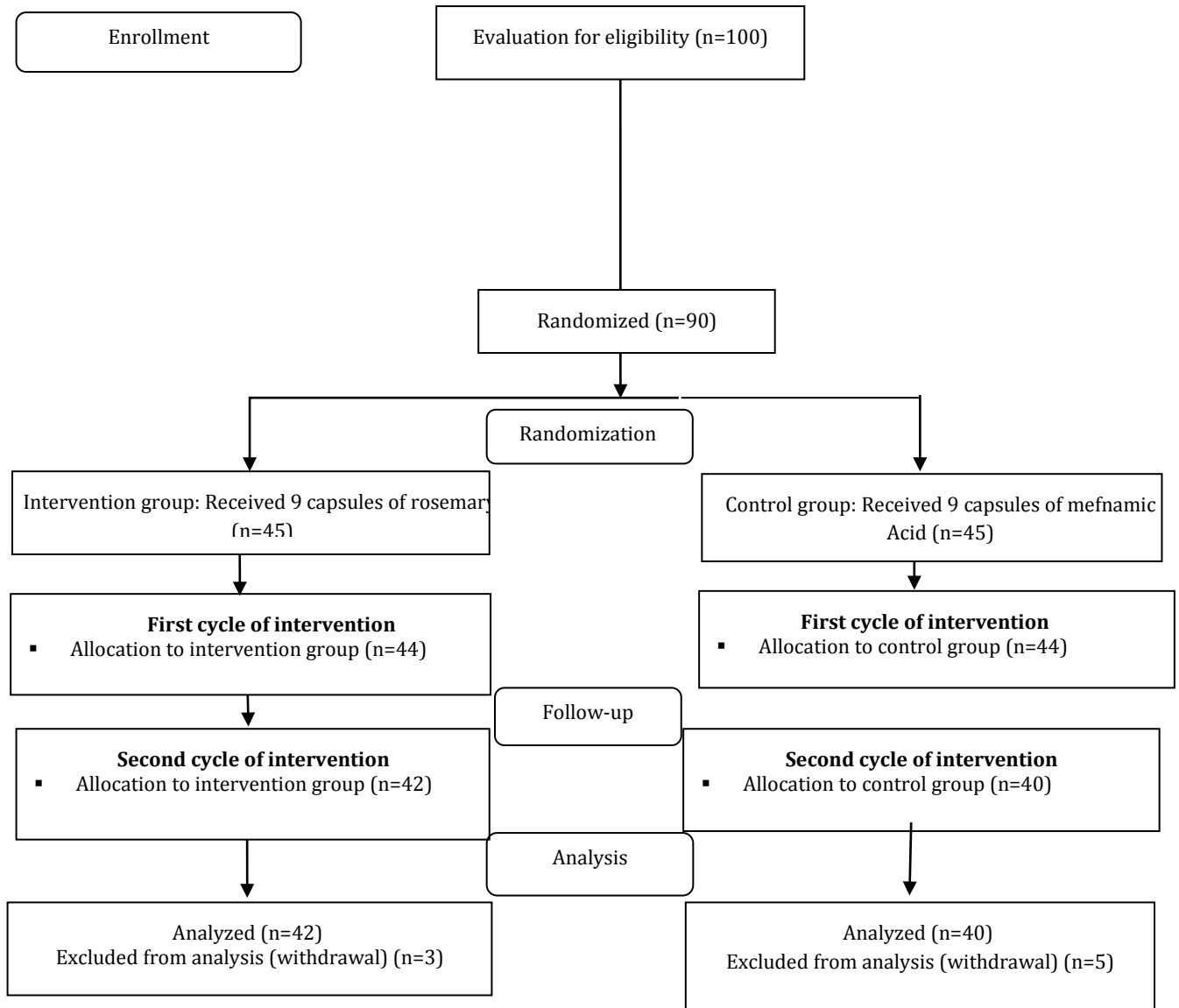


Figure 1. The CONSORT flow diagram of intervention in the two groups

Discussion

The current study aimed to compare the effectiveness of rosemary and mefenamic acid capsules on the quality of life of students with primary dysmenorrhea. The results revealed that the intensity of menstrual pain after the intervention compared to before the intervention had a significant difference in the rosemary group, but it did not show a statistically significant difference between the rosemary and mefenamic acid groups. In addition, 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 research by Davari et al. (2014) that investigated the impact of aromatherapy with rosemary and valerian in primary dysmenorrhea revealed that the pain intensity significantly decreased in the rosemary group compared to the mefenamic acid group (27).

According to the findings of the current research, the use of rosemary and mefenamic acid capsules improved the physical and mental health of students, but no significant difference was found between the two groups. Pain that is not alleviated has negative physical and psychological consequences. Failure to reduce pain prevents a 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 the analgesic properties of rosemary, which contains diterpenes including carnosol and carnoic acid, which act as strong anti-inflammatory and antioxidant agents(15). Reducing pain improves people's physical functioning.

The findings of the current research are consistent with the study of Solhi et al. (2013), which examined the beneficial effect of the *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. Skeletal pain, which is one of the side

effects of addiction withdrawal, decreased after consuming rosemary, which is due to the anti-inflammatory compounds of rosemary (29). The research by Naveed et al. (2022) revealed that ginger and vitamin E supplements positively affected 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 herb is an energizing stomach tonic and is particularly effective in alleviating general weakness and fatigue (31). Lindheimer et al. (2012), in their study 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 side effects such as headache, dizziness, anorexia, nausea, vomiting, gastrointestinal bleeding, and kidney disorders (26), therefore, since in this study, the students consuming rosemary reported no side effects and the physical and mental health was not significantly different between the rosemary and mefenamic acid groups, 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 that is self-reported, the accuracy of the answers given by individuals and the factors that affect the

intensity of pain, including mental characteristics and personality differences is one of the limitations of this research. Considering that it is possible to prepare non-edible products such as rosemary oil from rosemary, it is suggested to conduct other researches on the effect of rosemary oil on reducing the pain of dysmenorrhea and subsequently increasing the quality of life.

Conclusion

Improving the quality of life has a significant role in the health of individual's 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 fewer side effects than chemical medicines. Pain reduction methods can improve the quality of life.

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Conflicts of interest

The authors declared no conflicts of interest.

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