A randomized controlled clinical trial evaluating quality of life when using a simple acupressure protocol in women with primary dysmenorrhea

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Abstract

Objective: To evaluate a simple acupressure protocol in LIV3 and LI4 acupoints in women with primary dysmenorrhea.

Methods: This paper reports a randomized, single blinded clinical trial. 90 young women with dysmenorrhea were recruited to three groups to receive 20 minutes acupressure every day in either LIV3 or LI4, or placebo points. Acupressure was timed five days before menstruation for three successive menstrual cycles. On menstruation, each participant completed the Wong Baker faces pain scale, and the quality of life short form -12 (QOL SF-12).

Results: Intensity and duration of pain between the three groups in the second and third cycles during the intervention ($p<0.05$) differed significantly. Significant differences were seen in all domains of QOL except for mental health ($p=0.4$), general health ($p=0.7$) and mental subscale component ($p=0.12$) in the second cycle, and mental health ($p=0.9$), and mental subscale component ($p=0.14$) in the third cycle.

Conclusion: Performing the simple acupressure protocol is an effective method to decrease the intensity and duration of dysmenorrhea, and improve the QOL.

Key words: Dysmenorrhea, acupressure, quality of life

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Introduction

Primary dysmenorrhea describes painful menstrual bleeding where there is no other associated disease in the pelvic (1). In young women, there is an 88% prevalence worldwide of primary dysmenorrheal and painful menstruation(2). Symptoms start at the onset of menstruation, and typically include pain which radiating from the lower abdomen to the inner thighs(3). Dysmenorrhea may disturb activities of daily living for as much as 1-3 days per month. Dysmenorrhea and its associated symptoms may have an economic burden on society since the condition can cause women to lose some workdays per month (4). Primary dysmenorrhea leads to recurrent absence from work, anxiety, and it is reported that quality of life is affected (5, 6).

During menstruation, excessive prostaglandin release causes excessive uterine contraction, uterine hypoxia and ischemia which results in primary dysmenorrhea. Pharmacologic medications aimed at alleviating menstrual pain and relaxing the uterine muscles include non steroidal anti inflammatory drugs ($NSAID_S$) and oral contraceptive pills (OCP). Side effects of these medications include nausea, breast tenderness, metrorrhagia, visual and auditory hallucinations (7). About, 20-25% of women have reported that their menstrual pain is not controlled by taking NSAIDs alone (8).

Acupuncture, electro acupuncture and moxibusion are traditional treatments in Chinese medicine. Acupoints stimulation improves Qi and blood flow, restores harmony to the body, and improves balance in the body by modulating physiologic interactions and transmitting impulses to the brain and other organs located at the line of nerves and meridians. Acupoint stimulation in Chinese medicine has been described as effective in managing primary dysmenorrhea. According to the Chinese medical theory, primary dysmenorrhea is the stagnation or deficiency of energy in the uterus, and it is cured by changing the energy flow and blood flow; and regulating the performance of internal organs, especially the spleen, liver, and kidney (9-11).

According to Chinese medical theory, dysmenorrhea is divided into two categories: excess and deficiency syndromes. The symptoms of excess syndrome include lower abdominal pain before menstruation; diffuse pain across the back, menses of a purple colour with blood clots, a purplish tongue, deep pulse, swelling of the breast, and anxiety. Acupoints associated with the excess syndrome are LIV_3, LI_4, SP_{10}, SP_8, and $B_{23;}$ it is easy to access acupoints of LIV_3 and LI_4, for

treatment with acupressure. The symptoms of the deficiency syndrome include abdominal pain during or after menstruation, pale colour menses with small volume, and cold hands and feet. Acupoints used in deficiency syndrome are B_{20}, B_{23}, and SP6 (12, 13). The criterion of excess syndrome is identical to the western medical definition of primary dysmenorrhea (abdominal pain before or during menstruation). Previous studies have reported that primary dysmenorrhea is alleviated by applying pressure on pressure on acupoints of CV_6, CV_4, SP_6, SP_{10}, and LIV_3(14).

Complementary and alternative therapies including acupressure are increasingly offered as part of holistic nursing care (15).Considering the high prevalence of primary dysmenorrhea among young women and its adverse effects on their QOL, trying to reduce this problem is an important clinical nursing task in primary care to promote health and self-care in young women. Acupressure may provide a means to improve young women's dysmenorrhea, improve their self care and hence their wellbeing (16). A previous study by the authors had tested quality of life and severity of dysmenorrhea by using acupressure at LIV3 acupoint compared placebo point (11, 17-19). The findings indicated that effective acupressure in LIV3 acupoint than the placebo could improve quality of life and severity of dysmenorrhea. The authors concluded that there was a need to study effective acupoints in the excess syndrome of dysmenorrhea and compare LIV3 and LI4 acupoints. Thus, the present study aimed to determine the impact of acupressure in the LIV_3, LI_4, and the placebo points on the QOL of young women with primary dysmenorrhea.

Materials and methods

Participants

Young female students with primary dysmenorrhea were recruited to a randomized single blind controlled clinical trial; students were living in accommodation in the Hormozgan University of Medical Science, Iran from 2015-2016. Inclusion criteria are given in Table 1.

Simple randomized sampling and allocation of the groups to the intervention groups was undertaken. For this purpose, we used the table of random numbers to allocate participants to the study groups. Researchers invited all occupants of two dormitories in Hormozgan University to participate in the study; volunteers were screened against the inclusion criteria and those

participants who were eligible to enter the study identified. Participants were assured that participation is voluntary and that their information would remain confidential. 90 participants were accepted onto the study after giving written consent. This process is shown in Figure 1.They was randomly divided into three groups of $LIV_{3,}$ LI_4, and the placebo group using the table of random numbers. Participants were blinded to their allocation to the intervention and placebo groups. They were in separate blocks in accommodation of Hormozgan University of medical sciences. They were requested to not search for information about acupressure and only ask the researchers if they required further information about the study protocol and outcomes.

Sample size

The sample size of this study was determined by the primary hypothesis. That is, the difference between Wong-Baker faces pain scale scores after acupressure on LIV3, LI4 and the mean score after the placebo. The effect size was estimated from pilot data for the LIV3 and LI4 acupressure compared with that for a control group. Using a significance level of 0.05, a power of 80%, and a sample size of 30 per group (90 in total) was needed to test this hypothesis.

Intervention

First cycle (control cycle): The pain intensity was measured using the Wong-Baker faces pain scale, and the duration of pain was assessed by participants' replies. The QOL SF_{12} questionnaire was also completed by participants. Participants were trained about acupressure on the related acupoints.

Second cycle: Participants were laid down firstly in the supine position (to avoid hypotension and dizziness). Windows and doors were locked to ensure privacy and to avoid external stimuli. The LIV_3 point (or third hepatic acupoint) is one of the hepatic meridians located at the point of bones junction. The LI_4 point (HUGO) is located at the dorsal surface of the hand between the thumb and the index finger, at the middle of the second metacarpus bone. The placebo point is located between the third and the fourth toes which are not in the meridian line (Figure 2).

Applying pressure for 20 minutes on the above mentioned points was started at between three to seven days before menstruation (for average five days) on the right foot (according to Chinese medicine, the vital energy of women is stronger in the right foot) between 19.00-21.00. This

process was repeated daily until the bleeding started. The points were pressed for two minutes in a harmonic manner (one minute in a clockwise direction and one minute in a counter clockwise direction). After that, pressure was stopped for two minutes and the researcher manipulated the point so that the meridian remained stimulated. Applying pressure continued until the participant felt a mild pain in the point, the pressing was stopped, and the amount of colour change in the nail was adopted as a marker to show participants how much pressure they should apply themselves in the next menstrual cycle. The researcher also trained participants to apply pressure on the points of LIV_3 or LI_4, or placebo according to which group they had been randomly assigned to. As menstrual bleeding started, participants were asked to complete SF_{12} questionnaire, as well as the intensity and duration of pain questionnaire.

Third cycle: Based on the education offered to the participants during the previous cycles, each participant was able to do acupressure by herself. The procedure was performed in the sitting position, so that any chance of hypotension could be avoided. As bleeding started, the questionnaires were completed by each participant.

Participants received a motivational telephone call encouraging participants to complete the questionnaires, reminding them of the times of the interventions and follow-up visits.

Measures

1- Wong-Baker faces pain scale: this scale is used to measure the pain in people aged three years old and more. The scale is graded with even numbers (0,2,4,6,8 and10) including six smiles where the zero smiley indicates no pain, the second smiley indicates 'hurts a little bit', fourth means 'hurts a little more', sixth represents even more pain, eighth indicates 'hurts a whole lot', and the tenth shows 'hurts worst'. This scale is frequently used to measure pain and its validity and reliability are approved (20, 21).

2- SF_{12}: This questionnaire was used to evaluate quality of life, which includes 12 questions about eight domains: vitality, physical functioning, bodily pain, general health perceptions, physical role functioning, emotional role functioning, social role functioning, mental health. Scoring uses the RAND system from zero to 100. The score of each domain is obtained by aggregating the question scores in every domain and dividing the resulting number by the

number of questions in the same domain. A higher score indicates better quality of life (22). The validity and reliability of the questionnaire are approved (23).

3. Socio-demographic details: number of years of formal education of each participant is considered as the socio-economic index in Iran. Therefore, we used formal education as an index to evaluate socio-economic status(24).

4. BMI: was measured by weigh (kg)/Height^2 (m).

Statistical methods

Data are provided as mean± SD for quantitative variables, and n (%) for qualitative variables. Comparison between groups was done using ANOVA. Data were analyzed using Statistical Package for the Social Sciences 21.0 (SPSS Inc., Chicago, IL, USA). A significance level of $p<0.05$ was considered acceptable.

Results

Sample characteristic

In total, 90 participants completed the intervention over three menstrual cycles. Table 2 shows that no significant difference between groups in age, BMI, and education ($p>0.05$).

Intensity and duration of pain

The severity of dysmenorrhea was similar in all three study groups at the first cycle (control) (Table 2) ($p=0.17$); but by the second and third cycles there was a significant difference between three groups in pain intensity ($p<0.05$).The results in Table 3 show that the pain intensity in the placebo group was more than LIV3 and LI4 groups by the second and third cycles.

No significant difference was detected between the three groups in terms of pain duration at the first cycle ($p=0.16$) (Table 2). After the intervention, a significant difference between three groups in the second and third cycle in pain duration ($p<0.05$) (Table 4) was detected. The results of Table 4 show that the pain duration in the placebo group were more than LIV3 and LI4 groups by the second and third cycles.

Quality of life

According to the results presented in Table 2, no significant differences between the three groups in terms of QOL scores of all domains at the first cycle ($p>0.05$) were observed.

In the second cycle, a significant difference between the three groups in all domains of QOL, except for general health perceptions ($p=0.4$), mental health ($p=0.7$), mental subscale factor ($p=0.12$) (Table 5) was detected. The finding of Table 5 showed that the all domains of QOL in the placebo group were worse than LIV3 and LI4 groups by the second and third cycles.

A significant difference between three groups in all domains of QOL, except for mental health ($p=0.9$), and mental subscale component ($p=0.14$) were observed in the third cycle.

Discussion

This is the first study which evaluates the effect of acupressure in two separate acupoints (LIV_3 and LI_4) compared with a placebo on QOL in women with dysmenorrhea. Our results show that the severity of dysmenorrhea is significantly decreased in both acupressure groups (LIV_3 and LI_4) by the second and third cycles compared to the placebo group. In the previous study by Bazarganipour et al. (2011), the pain intensity was also relieved in the LIV_3 group in comparison to the control group by the second, third, and forth cycles ($p<0.001$)(25). While, Kafaei-Atrian et al (2013) found that there is no significant difference between LIV3 and the placebo group in term of pain intensity in the third cycle. To address these issues, in our study, the acupressure protocol was started 3-7 days before menstruation (20 minutes per day) (26). In Kafaei-Atrian et al's study, acupressure was started by the onset of menstruation (less than 16 minutes per day) when pain had commenced. In addition, in our study, the first intervention (second) cycle was done by researchers to ensure the correct performance of acupuncture by participants, while in the study of Kafaei-Atrian et al (2013); the intervention was done by subjects themselves from the first cycle.

Compared to the control group, the pain duration was significantly decreased in the acupressure groups in the second and third cycles. Comparing the pain duration between intervention and control groups shows that applying pressure in the acupressure group during three cycles results in a decreased number of people with maximum pain duration ($\geq$ 1 day), and an increased number of people with minimum pain duration (1-5 hours). In other words, the pain duration is significantly decreased in the two acupressure groups. Although, we can see a decrease in placebo group as well, the degree of pain relief is overall lower. This finding is similar to the study of Bazarganipour et al. (2011) in which the pain duration decreased in LIV_3group by the second, third, and the forth cycles in comparison to the control group (25). It would be important to note that although the above mentioned outcomes decreased in the control group in the second and third cycles, this was not clinically significant and could be attributed to the placebo effect. The effectiveness of combined alternative methods such as acupressure is well known, and in many of related studies, it is tried to nullify the impact of these factors by considering a placebo group because of the positive changes which tend to occur in the placebo group (27-29). In our study, this caused the intensity and duration of pain to be significant also in the placebo group

over three cycles. Harmon et al (2000) suggested that there is no appropriate method available to control related research (acupressure and acupuncture studies), and considering the placebo group has its disadvantages. On the one hand, patient should be unable to distinguish placebo from real acupressure (patient should feel the pressure); on the other hand, pseudo-acupressure may have its impact (30).

Research has already shown that stimulating acupoints can influence the neurological condition of the brain in such a way that acupressure facilitates the release of endorphins, and endorphins in turn stimulate the opioid receptors and consequently pain transmitter impulses are inhibited resulted in pain relief (14). The possible explanation for the impact of acupressure on dysmenorrhea would be spinal control mechanism, i.e., somatic stimulation acting as an obstacle to the transition of pain stimulus, and activates the release of opioids.

The score of all physical domains of QOL was better in acupressure groups compared to the placebo group in the second and third cycle, which is probably due to the physical health improvement and the pain relief in acupressure groups. Moreover, all domains of QOL except for general health, mental health, and mental subscales component scored better in acupressure groups compared to the placebo group in the second and third cycle. Bazarganipour et al also reported that, there was a better QOL score of all domains of SF_{36} in Liv_3 acupressure groups after three cycles of intervention compared to the control group (31). Given that pain can affect physical health, mental, psychological and emotional status, and social performance as well, we suggest that one reason for QOL improvement in this study would be that a diminution in intensity and duration of pain has desirable effects on quality of life.

The strength of this study included telephone follow-up to motivate the participants during each consecutive menstrual cycle, including the application of pressure in the placebo group to measure the placebo effect which goes some way to addressing previous criticisms with measuring the placebo effect in acupuncture studies; and applying pressure before menstruation onset to prevent pain.

Considering that primary dysmenorrhea is so common among young women, with adverse effects on their QOL, trying to reduce this problem is an important reproductive health special duty. Therefore acupressure to improve primary dysmenorrhea could be an important means to

deliver holistic reproductive health care and enhance self care in young women (32) .We advocate acupressure for self-care of primary dysmenorrhea at LIV3and LI4 acupoints, because pressure at these points is not difficult for young women to learn and practice.

Limitations

There are some limitations in our study. We used oral, written, and practical training to help subjects identify the location of acupoints and learn the pressing technique. The ability of individuals to understand and apply the training may differ and comprehension is not controllable by the researcher. The Wong-Baker scale was used to express the pain intensity. Mental and psychological differences will have affected the experience and expression of pain intensity by individuals. Lastly, in the blinding process, participants were in separated by accommodation blocks and were requested to not communicate with other students about the trial or try to find out about acupressure from media sources. We trusted the participants to adhere to these guidelines but their adherence was not controllable by the researcher.

Conclusion

The results of this study show that applying acupressure on $LIV_3$and LI_4 acupoints improves the intensity and duration of pain and QOL in women with primary dysmenorrhea. By training women with primary dysmenorrhea to use this method, they may be encouraged to use this method instead of pharmacological treatment, and thereby improve their self-care and enhance wellbeing.

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Figure 1: flow chart of study

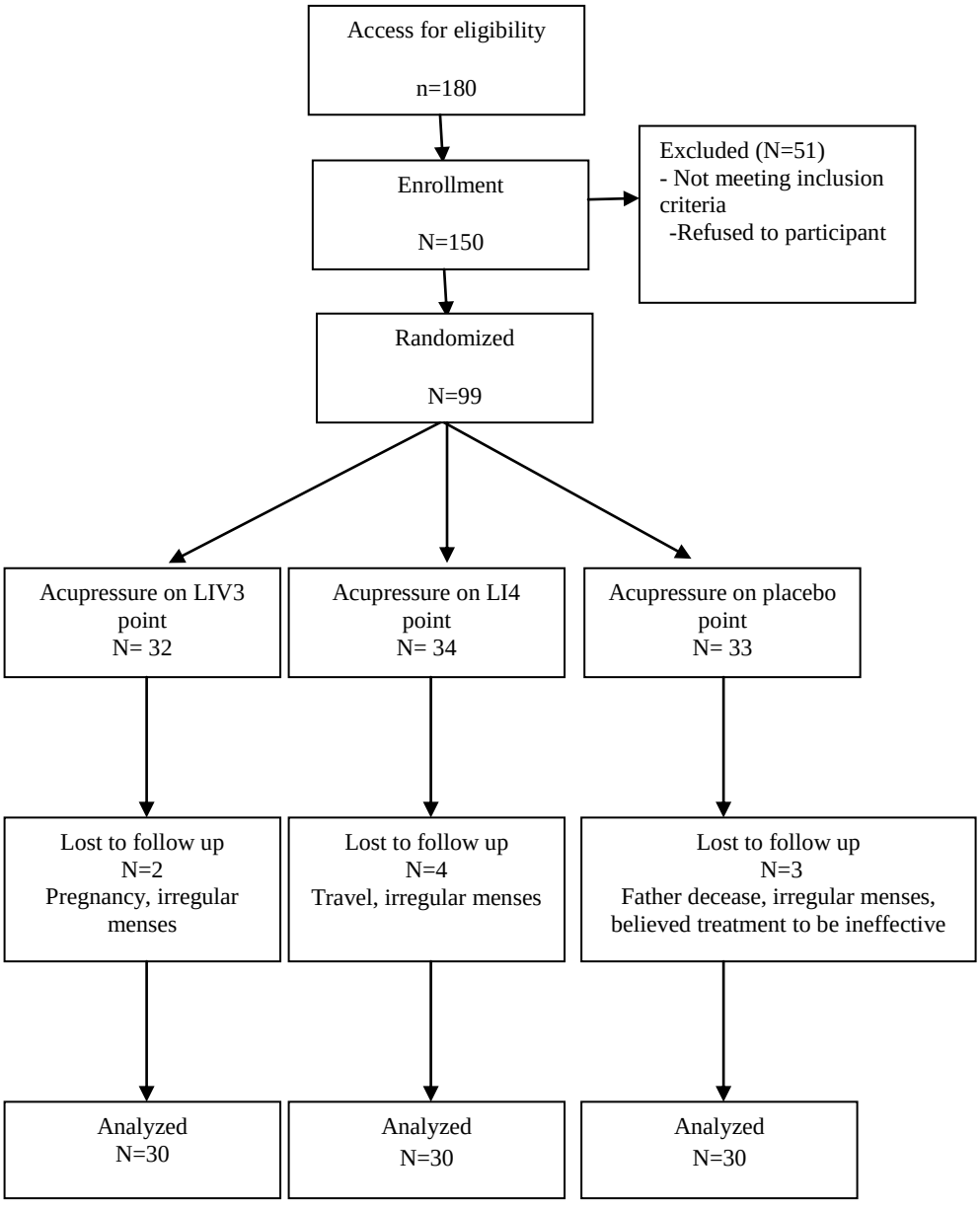

Table 1: inclusion criteria

being18-21 years old
being single
Having regular menstrual periods of 3-8 days duration and a cycle of 21-35 days
A pain score of 4-10 according to the Wong-Baker faces pain scale
The presence of excess syndrome signs (fixed and heavy pain 1-2 days before menstruation, breast and stomach swelling, menses of dark colour with blood clots, purplish tongue, deep pulse and diffused pain to the back)
No genital disease; at least two hours passing after the last meal
absence of pain in all days of bleeding
absence of moderate to severe complications specially moderate to severe depression(based on HADS questionnaire)
no usage of oral or other contraceptives or drugs which disturb the ovulation cycle, analgesics, prostaglandin synthesis inhibitors) four days before acupressure is started
lack of any abdominal/pelvic surgery
absence of tobacco consumption; not being alcohol consumer; absence of medical disease(cardio-vascular disease, nephropathy, respiratory disorders, diabetes, asthma, hypo/hyperthyroidism)
absence of any speaking, visual, and auditory problems
absence of any severe psychological stress during the last six months(loss of relatives, etc)
Absence of any lesion, varices, or inflammatory skin disease at the location of applying pressure.

Figure 2: location of acupressure points

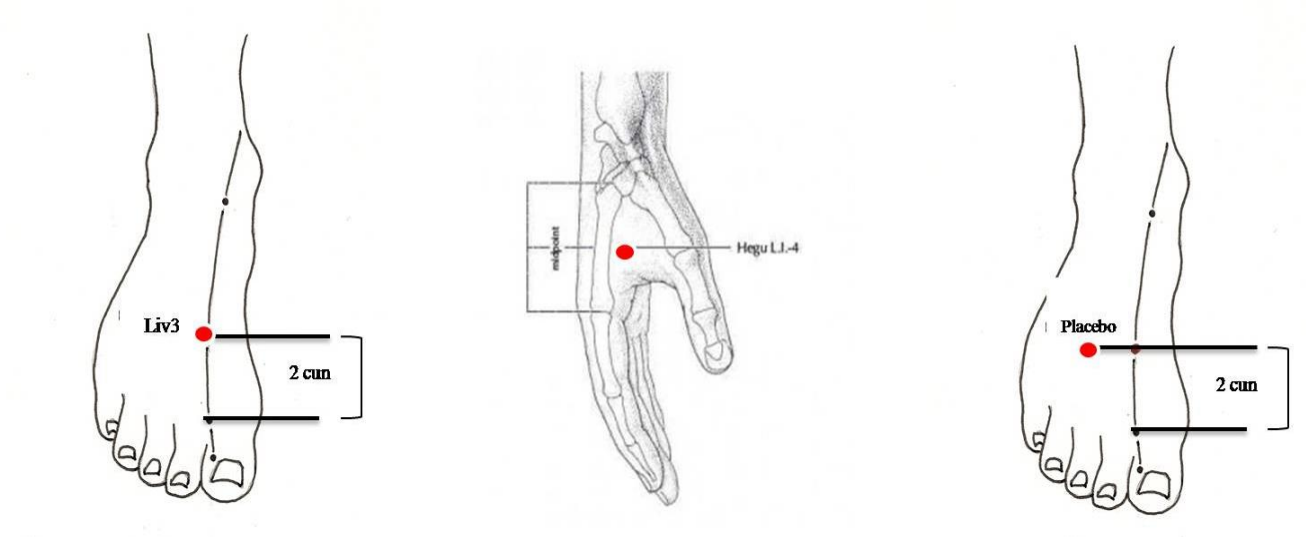

Table 2: Demographic and baseline characterizes of participants

Variable		Group			P value
		placebo	Liv_3	LI_4	
Age (years)**		21.76±1.73	22±1.71	21.55±1.66	0.09
Education (years)**		15.66±0.75	15.84±0.54	15.13±0.81	0.85
BMI**		19.33±0.41	20.47±2.56	20.72±2.69	0.06
Pain intensity**		5.26±1.22	5.53±1.81	5.57±1.68	0.17
Pain duration*	1-5 h	7(23.3)	17(56.7)	6(20)	0.16
	6-10h	4(13.3)	8(26.6)	5(16.7)	
	≥1 days	19(63.3)	15(51.7)	19(63.3)	
SF_{12} domains**	PF	69.16±23.37	65.83±31.13	70.83±27.91	0.79
	RP	58.75±22.54	62.50±22.50	65.83±22.24	0.47
	RE	64.58±23.69	65±23.76	57.50±25.34	0.40
	VE	60.83±19.34	70.83±14.80	61.66±3.92	0.07
	SF	41.66±21.10	32.33±19.62	38.33±23.42	0.08
	BP	55±22.16	57±16.08	58.33±24.85	0.09
	GH	62.50±26.86	75±14.68	68.33±25.37	0.11
	MH	53.75±8.77	51.66±7.86	54.58±2.50	0.54
	MSC	55.20±8.81	52.70±6.75	53.52±7.84	0.4
	PSC	61.35±16.98	69.58±12.52	65.83±16.18	0.12
	Total score	58.21±3.35	54.01±31.12	57.24±4.14	0.18

**Mean±SD; * n (%)

physical functioning (PF), role limitations due to physical problems (RP), bodily pain (BP), general health perception (GH), social functioning (SF), role limitations due to emotional problems (RE), vitality (VT), and mental health (MH), mental subscale component (MSC), physical subscale component(PSC).

Table 3: Dysmenorrhea severity in the second and third menstrual cycles in three groups.

Variable	Group			P value*
	Placebo	Liv_3	LI_4	
Second cycle**	5±1.94	3.86±1.56	3.76±1.77	<0.001
Third cycle**	3.73±2.21	3.24±1.88	3.26±1.81	0.001

*ANOVA

**Mean±SD

Table 4: dysmenorrhea duration in the second and third menstrual cycles in three groups

Duration of dysmenorrhea		Group			P value*
		placebo	Liv_3	LI_4	
Second Cycle**	1-5 h	10(33.3)	21(70)	18(60)	0.009
	6-10 h	7(23.3)	5(16.7)	5(16.7)	
	≥1 days	13(43.3)	4(13.3)	7(23.3)	
Third Cycle**	1-5 h	15(51.7)	22(73.3)	18(60)	0.008
	6-10 h	7(24.1)	3(10)	9(30)	
	≥1 days	7(24.1)	5(16.7)	3(10)	

*kruskal walis test

**n (%)

Table 5: quality of life subscales in the second & third menstrual cycles between three groups.

Quality of life subscales		Group			P value*
		placebo	Liv_3	LI_4	
Second Cycle **	PF	66.83±22.44	68.10±28.26	67.50±27.18	0.08
	RF	58.87±13.81	65.83±21.25	66.25±22.77	0.01
	RE	67.58±14.32	71.55±20.56	70±27.54	0.008
	VE	67.50±13.37	72.66±14.28	75.83±27.60	0.007
	SF	22.50±21.12	42.50±16.28	41.66±23.05	0.002
	BP	60.33±15.99	65.86±19.46	61.66±24.33	0.03
	GH	70±24.03	76.72±16.27	75±18.56	0.4
	MH	51.25±8.27	53.33±6.51	52.50±17.79	0.7
	PSC	51.15±14.71	56.13±10.31	56.97±8.80	0.02
	MSC	48.92±8.06	54.09±5.41	52.66±7.68	0.12
	Total score	50.32±13.29	52.12±3.29	51.87±1.12	0.37
Third Cycle*	PF	66.5±27.88	78.79±17.14	75.83±24.10	0.001
	RP	66.25±22.77	75.87±13.81	75.83±21.25	0.01
	RE	74.16±26.12	78.87±20.07	75.50±23.11	<0.001
	VE	58.33±24.85	70.83±14	68.10±17.54	0.03
	SF	41.66±18.25	45±16.36	44.16±28.37	<0.001
	BP	68.33±29.60	72.50±23.98	73.27±14.83	0.02
	GH	66.66±23.97	75±14.68	78.17±20.46	0.03
	MH	51.29±9.05	52.66±7.86	52.50±16.21	0.9
	PSC	64±18.51	82.29±10.91	80.28±11.54	<0.001

	MSC	52.29±8.26	55.81±6.77	53.91±6.30	0.14
	Total score	58.12±0.98	61.23±1.12	65.31±13.89	0.35

*ANOVA

**Mean ± SD

physical functioning (PF), role limitations due to physical problems (RP), bodily pain (BP), general health perception (GH), social functioning (SF), role limitations due to emotional problems (RE), vitality (VT), and mental health (MH), mental subscale component (MSC), physical subscale component(PSC).