

Effect of Homeopathy on Pain Intensity and Quality Of Life of Students With Primary Dysmenorrhea: A Randomized Controlled Trial

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Abstract

Background: Observational studies indicate a positive association between homeopathy and pain relief and quality of life improvement in women with dysmenorrhea. However, there are no interventional studies in this area.

Objectives: To evaluate an association between homeopathy and pain relief and quality of life improvement in a double-blind placebo-controlled randomized trial with 2 parallel arms.

Methods: Fifty-four students with primary dysmenorrhea residing at the dormitories of the Tabriz University of Medical Sciences, Iran, who had moderate or severe menstrual pain, were randomized to receive either homeopathic remedy or placebo. The homeopath and participants were blinded to treatment assignment. Primary outcomes were pain intensity and quality of life assessed using a 10-cm visual analog scale and short-form 36 (SF-36), respectively, and the secondary outcome was number of analgesic pills used.

Results: Each group comprised 27 students; eventually, 26 in the homeopathic and 21 in the placebo group were followed up. There was no significant difference between the groups for either pain intensity (adjusted difference: -0.44; 95% CI: -1.43 to 0.54) or any other outcomes. Compared with the baseline scores, statistically significant improvements were observed in pain intensity ($P = 0.021$) and physical health ($P = 0.020$) scores only in the homeopathic group; and in the mental health score in both groups ($P = 0.014$ in the homeopathy group and $P = 0.010$ in the placebo group).

Conclusions: This study could not show any significant effect of homeopathy on primary dysmenorrhea in comparison with placebo. Considering the possible effect of the homeopath and the homeopathic remedies prescribed on the results of such interventions, further studies are needed to help us arrive at a conclusion.

Keywords: Dysmenorrhea, Homeopathy, Quality of Life, Menstruation Disturbances, Complementary Therapies, Pain

1. Background

Dysmenorrhea is the most common gynecological disorder in young women (1, 2) that can affect their lives substantially. Almost 50% of all women experience dysmenorrhea, and in 15%, the pain is severe enough to limit their daily activities and cause absenteeism from school or work (3-6). The highest prevalence of dysmenorrhea is reported in girls, ranging from 20% to 90%, as assessed using various assessment methods (7-10).

Dysmenorrhea cannot be easily treated with conventional therapies (8). Non-steroidal anti-inflammatory drugs, the most common drugs used for its treatment, may cause some severe gastrointestinal side effects (11, 12) and are contraindicated for or intolerable by some women (13). Therefore, many women seek alternative therapies to cope with the condition (14, 15). Most women self-medicate with over-the-counter drugs (9, 10), whereas some use herbs or

supplements (16).

Homeopathy is used in many regions worldwide, especially in high-income countries (17, 18). It is recognized as 1 of the top 5 complementary medicines (19). Many patients accept it as a safe and acceptable alternative medicine that can be used alongside conventional medicine (17).

Some reviews (17, 20-24) indicate that homeopathic remedies are effective in treating some gynecological diseases such as hemorrhage, cysts, vaginal discharge, disturbances during labor and delivery, and some side effects of cancer treatment. These reviews however emphasized that owing to the poor quality of the trials, the strength of evidence is low and there is a need for trials with a more precise methodology to confirm the results.

We conducted an extensive literature search but found no randomized trial and only 1 observational study published in 2009 (25) that assessed the effect of homeopathy

on primary dysmenorrhea. The authors of this one study stated that homeopathy is often used for treating primary dysmenorrhea with no empirical research about its effects. They conducted a prospective study with no control group and reported that women under homeopathic treatment for dysmenorrhea had a significant improvement.

2. Objectives

Considering the common use of homeopathy for managing dysmenorrhea but lack of sufficient evidence about its effectiveness, the present randomized controlled trial aimed to examine the effect of homeopathy on pain intensity and quality of life in women with primary dysmenorrhea.

3. Methods

This double-blind placebo-controlled randomized trial with 2 parallel arms was conducted on students residing in 3 dormitories of the Tabriz University of Medical Sciences, Tabriz, Iran, from December 2013 to April 2014.

Inclusion criteria were having regular menstrual periods, having moderate or severe primary dysmenorrhea (pain score of 4 to 9 on a 10-cm visual analog scale [VAS]) in the recent cycles, having no prior experience of homeopathy, being single, and age 18 to 27 years. Those with a history of any chronic diseases or allergy, smokers, or those using oral contraceptive pills or corticosteroids or having a history of their use in previous 6 months were excluded from the study.

The study was approved scientifically by the Deputy of Research, Tabriz University of Medical Sciences, and ethically by the regional ethics committee at the university. The trial was registered in the Iranian registry of clinical trials before starting participant recruitment (registration code: IRCT201207063706N14). Written informed consent was obtained from all participants before their recruitment into the study.

3.1. Outcomes

Primary outcomes were menstrual pain intensity score and quality of life. The secondary outcome included number of analgesic pills (gelofen) taken for menstrual pain relief.

The menstrual pain intensity (VAS score) and the number of analgesic pills taken were assessed prospectively for 2 cycles before and 2 cycles after the intervention. A diary was given to each participant to record both menstrual pain intensity and number of the analgesic pills taken, once a day during the 2 days before and the 3 days after the

start of menstrual bleeding at each cycle. The VAS is a validated scale with a length of 10 cm starting from 0 (no pain) on the left and ending with 10 (the maximum imaginable pain) on the right. This measure is widely used for pain assessment, and its validity and reliability has been approved with a test-retest reliability score of 0,94 among literate patients (26). The mean of the 2 highest pain intensities was considered as the menstrual pain intensity of that cycle for each participant. Each participant was given 20 capsules of gelofen 400 mg, twice (at the recruitment visit and after the first visit by the homeopath), and was instructed to use them only for menstrual pain relief, if needed, and to not use any other pain relievers for menstrual pain relief.

Quality of life was examined on the 8th to the 12th day of menstrual cycle just before and at the second cycle after initiation of the intervention. The short-form health survey (SF-36) was used to examine the quality of life; it is of the most common tool available in this field and the reliability and validity of its Iranian version has been confirmed. The questionnaire includes 36 items, 8 scales, and 2 (physical and mental health) components, with a score ranging from 0 to 100, where 100 indicate the highest situation (27, 28).

3.2. Enrolment and Randomization

Participants were selected using purposive sampling among students from all 3 female dormitories of the Tabriz University of Medical Sciences. In these dormitories reside about 2000 non-native female students from different parts, mostly north-west, of the country and from all medical sciences disciplines at various levels from associate diplomas to PhDs. To enroll the participants, the researcher met the students at their own rooms in the dormitories and after explaining the purpose of the study, asked them "Do you suffer from painful menstruation?" Those with a positive answer to the question and were volunteering to participate in the study filled out a checklist containing the eligibility criteria of the study. In total, 60 eligible students who signed the written informed consent were enrolled into the study; they filled out the demographic part of the questionnaire and were given the pre-intervention diaries to record their menstrual pain intensity score and the number of analgesic pills, if taken, for menstrual pain relief for the following 2 cycles.

From the 8th to 12th days of the third cycle, the diaries were collected from the participants. Six participants were excluded because of non-compliance with diary completion. The remaining 54 participants were referred to a homeopath for consultation and, thereafter, were randomly allocated to receive either homeopathic treatment or placebo at an allocation ratio of 1:1 (Figure 1).

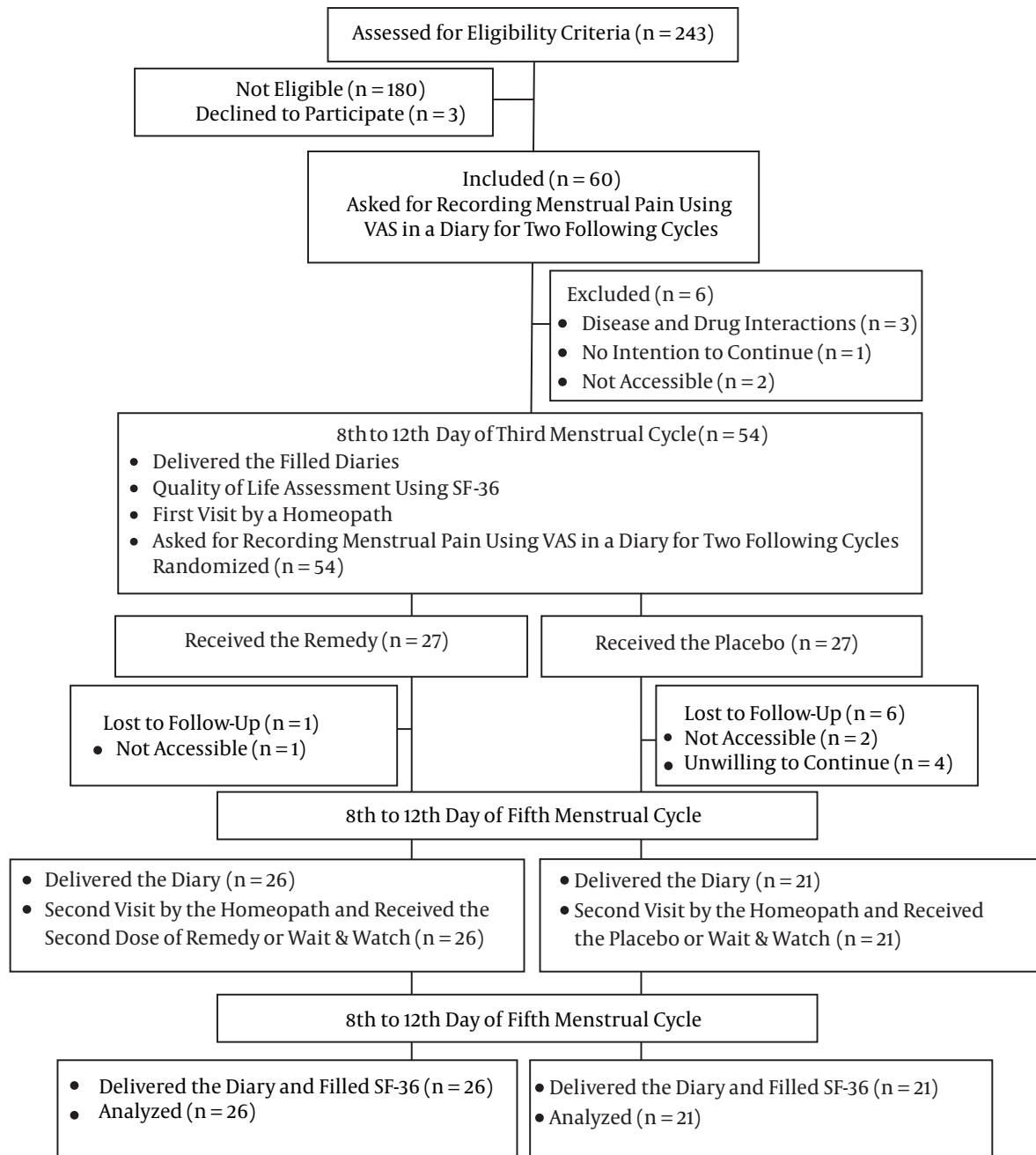


Figure 1. Flow Diagram of the Study

Remedies prescribed for each participant are presented in Appendix 1.

An independent person, who was not involved in participant recruitment and data collection, determined the allocation sequence using a computer program considering block randomization with randomly unequal block

sizes of 4 and 6. Sequentially numbered opaque, sealed envelopes were used for allocation concealment. Each envelope contained a piece of paper with the type of intervention written on it.

3.3. Intervention

A physician who had 6 years' experience in homeopathy visited all participants during their 8th to 12th days of menstrual cycle twice with a 1-month interval. At the first visit, he counseled the participants and prescribed each one a remedy according to principles of classical homeopathy. At the second visit, he counseled the participants and prescribed a remedy for those who needed it; others received a homeopathic placebo pill (lactose pills identical to the remedy). The homeopathic prescription was individualized (Appendix 1).

An associate researcher opened a numbered envelop for each participant immediately after the first visit at the homeopath's private office based on the sequence determined at the enrolling visit. She gave the prescribed remedy (water containing the remedy or placebo [only water] to the participants and asked them to drink it under her supervision. This exercise was repeated at the second visit. Therefore, this assistant researcher was the only person who was aware of the group each person assigned to (she was however not aware of the remedy or homeopathic placebo given). The homeopath, participants, and data analyzer were blinded to group assignment.

3.4. Sample Size and Data Analysis

Considering a mean value of 6.0 and a standard deviation (SD) of 2.3 for menstrual pain intensity based on the results of a study carried out in the same setting (29), $\alpha = 0.05$, $\beta = 0.20$, and 10% possible drop out, the sample size was calculated to be 27 for each group to detect at least 20% reduction in the mean of pain intensity due to the intervention ($m_2 = 4.8$ with $sd_2 = 2.3$ [same as the baseline] for SD). This sample size is enough to detect at least 10% improvement in the mean components of quality of life due to the intervention with a power of 90%.

There were some missing values in the post-intervention SF-36 questionnaire of 6 participants. For 4, values were imputed using the method explained in the SF-36 scoring, and the other 2 (1 from each group) were excluded due to many missing values. Normality of distribution for pain intensity, quality of life scores, and the number of the analgesic pills taken by study groups was checked using the Kolmogorov-Smirnov (K-S) test; all except the number of analgesic pills taken were normally distributed. As change in the number of analgesic pills taken during the intervention was distributed normally, we used the change number for comparing the groups in terms of this outcome. We used repeated measures analysis of variance (ANOVA) or analysis of covariance (ANCOVA), adjusted for the baseline values after controlling for assumptions, for post-intervention comparisons. We

also used dependent-samples t-test or Wilcoxon signed-rank test for within-group pre- and post-intervention comparisons. All analyses were conducted using SPSS ver. 16.0 and 2-sided p-values were reported; p-values less than 0.05 were considered statistically significant.

4. Results

Of the 54 students studied, 6 from placebo and 1 from the homeopathy group were lost to follow-up. The remaining 47 received the planned interventions and provided all necessary information (Figure 2). No side events were reported by any of the participants.

There was no significant difference between the groups in any of the baseline characteristics (Tables 1 and 2), except in the physical health score which was lower in the homeopathy group (70.4 vs. 74.1, $P = 0.027$; Table 2). The mean (SD) age of the participants was 22.3 (2.1) and their mean (SD) age at menarche was 13.0 (1.1) years (Table 1). During the 2 pre-intervention cycles, the mean (SD) pain intensity score was 5.8 (2.2), mental health score was 63.3 (17.0), and the number of analgesic pills taken during each cycle was 1.3 (1.3) (Table 2).

The most frequent prescribed drugs were Phos, Nat-M, and Puls. Most participants received no drug at the second visit and the wait-and-watch approach was used. For 8 of 26 (31%) participants in the homeopathy and in 9 of 21 (43%) participants in the placebo group, some drug was prescribed at the second visit. In the homeopathy group, the homeopath changed the drug in 5 and the potency of the drug in 3 participants, whereas in the placebo group, the figures were 2 and 7, respectively (Appendix 1).

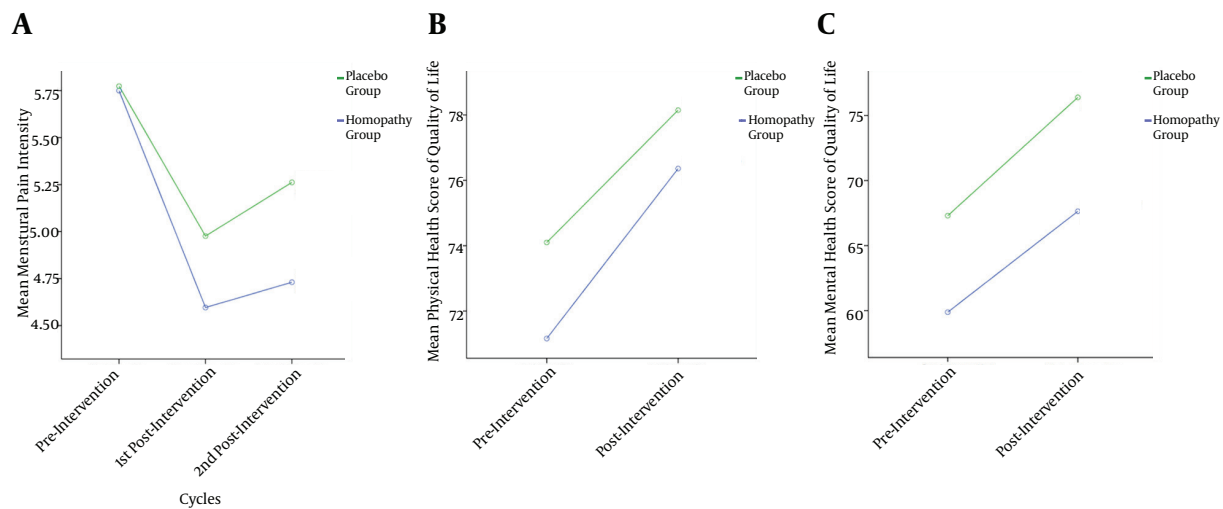
There was no significant difference between the remedy and placebo groups regarding the pain intensity score (adjusted difference: -0.44 [-1.43 to 0.54]), physical health (0.5 [-6.5 to 7.5], and mental health (-4.6 [-12.7 to 3.5]; Table 2)

Intra-group comparison showed statistically significant improvement in all primary outcomes, i.e. pain intensity, physical health, and mental health post-intervention when compared with pre-intervention in the homeopathy group ($P = 0.021$, $P = 0.020$, $P = 0.014$, respectively), but only in mental health in the placebo group ($P = 0.010$; Table 2).

There were no significant differences in both inter- and intra-group comparisons in terms of the number of analgesic pills taken at each cycle.

5. Discussion

The present study indicates that homeopathy when compared with placebo could not significantly decrease

Figure 2. Comparison of the Study Groups in Terms of the Primary Outcomes

A, mean menstrual pain intensity; B, mean physical health score for quality of life; C, mean mental health score for quality of life.

the menstrual pain intensity and the need for analgesics, and was not able to significantly improve the quality of life of the study participants. However, when compared with the pre-intervention values, the pain intensity and physical health component of the quality of life improved only in the homeopathy group, although the mental health component of the quality of life improved in the both groups.

To the best of our knowledge, this is the first randomized controlled trial to examine the effect of homeopathy on pain intensity and quality of life in women with primary dysmenorrhea. The study results regarding the decrease in the pain and improvement in the quality of life after receiving homeopathy (compared to pre-intervention) are consistent with the results of the only study published in this area conducted on women with dysmenorrhea (25), which was a prospective observational study with no control group.

However, some clinical trials conducted on patients with other conditions indicate a significant positive effect of homeopathy on pain relief in patients with fibromyalgia (30); on quality of life improvement in women with premenstrual syndrome (31); and on survival in breast cancer patients (32). The inconsistency of the results may be related to the relatively low sample size in the present study, difference in pain mechanisms and pain type in different conditions, and as mentioned in some reviews (17, 33, 34), the low quality and high risk of bias in the trials.

There was an improvement in the mental health component of quality of life in both homeopathy and placebo groups when compared with the pre-intervention period.

This might be due to lifestyle improvement in the both groups. The homeopath, who was not aware of the participants' assignment, gave some suggestions for promoting lifestyle to all participants. In this study, we did not assess lifestyle and its assessment in future trials may allow better judgment in this area.

The strengths of the study included having a placebo-controlled group to maintain blinding of the participants, the homeopath, and the person involved in data collection, as such a blinding prevents performance and detection biases. Another strength is the use of data from 2 consecutive menstrual cycles (pre-intervention), as this might prevent high attrition; however, there was a relatively high drop out of participants in the placebo group, which might have affected the study results. One of the study limitations is the relatively low sample size, which can limit detection of smaller probable effect size. Because the present trial included only 1 homeopath, it may be hard to generalize the results to homeopathy as a whole. Considering the limitations of this study and the few previously conducted studies (35), more trials with a rigorous design, with more participants, and contribution of more homeopaths are needed to arrive at definite conclusions on this issue.

5.1. Conclusions

This study could not indicate a significant effect of homeopathy in decreasing the pain intensity and improving the quality of life in comparison with a placebo group in students with primary dysmenorrhea. However, it showed a significant decrease in pain intensity and im-

Table 1. Baseline Characteristics of the Participants by Study Groups

| Characteristics | Homeopathy (n = 26) | Placebo (n = 21) | P Value |
|--|---------------------|------------------|----------------------|
| Age, years, mean (SD) | 22.3 (2.1) | 22.4 (2.3) | 0.860 ^a |
| Duration of university education, years, mean (SD) | 3.4 (1.3) | 3.2 (1.8) | 0.649a |
| Education level, No. (%) | | | 0.668 ^b |
| Bachelor of science | 20 (77) | 15 (71) | |
| Higher | 6 (23) | 6 (29) | |
| Name of the dormitory, No. (%) | | | 0.926 ^b |
| Kosar | 8 (31) | 8 (38) | |
| Fajr | 13 (50) | 9 (43) | |
| Qods | 5 (19) | 4 (19) | |
| Age at menarche, years, mean (SD) | 13.0 (0.9) | 12.9 (1.3) | 0.676 ^b |
| Menstrual pain intensity (VAS 0-10), No. (%) | | | 0.970 ^b |
| Moderate (4 - 6) | 11 (42) | 9 (43) | |
| Severe (7+) | 15 (58) | 12 (57) | |
| Onset of dysmenorrhea, No. (%) | | | 0.305 ^b |
| One or 2 days before starting menstruation | 10 (38) | 4 (19.0) | |
| A few hours before menstruation | 7 (27) | 9 (43) | |
| After starting menstruation | 9 (35) | 8 (38) | |
| Use of analgesics for dysmenorrhea, No. (%) | | | > 0.999 ^b |
| Yes | 20 (77) | 16 (76) | |
| No | 6 (23) | 5 (24) | |
| | (n = 20) | (n = 16) | |
| Type of analgesic used, No. (%) | | | 0.389 ^b |
| Only gelofen/ibuprofen | 8 (42) | 8 (50) | |
| Only mefenamic acid | 1 (5) | 0 (0) | |
| Diclofenac or acetaminophen | 0 (0) | 2 (12.5) | |
| Combination of drugs | 10 (53) | 6 (37.5) | |
| Satisfaction from the analgesic used, No. (%) | | | 0.557 ^b |
| Dissatisfied | 0 (0) | 0 (0) | |
| A little satisfied | 4 (20) | 1 (6) | |
| Relatively satisfied | 4 (20) | 6 (37.5) | |
| Satisfied | 9 (45) | 6 (37.5) | |
| Very satisfied | 3 (15) | 3 (19) | |

Abbreviations: SD, standard deviation; VAS, visual analog scale.

^aUsing independent-sample t-test.

^bUsing Chi-square test.

provement in quality of life after homeopathic treatment when compared with the pre-intervention status.

Supplementary Material

Supplementary material(s) is available [here](#).

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Table 2. Comparison of the Study Groups for Primary and Secondary Outcomes

| Outcomes | Homeopathy (n = 26), Mean (SD) | Placebo (n = 21), Mean (SD) | Comparison of Homeopathy With Placebo | | Intra-group Comparison (P Value) ^a | |
|--|--------------------------------|-----------------------------|---------------------------------------|--------------------|---|---------|
| | | | MD (95% CI) | P Value | Homeopathy | Placebo |
| Primary outcomes | | | | | | |
| Pain intensity (VAS 0-10) | | | | | 0.021 | 0.648 |
| Baseline | 5.8 (2.2) | 5.8 (1.7) | 0.27 ^b (-0.61 to 1.15) | 0.542 | | |
| First cycle post-intervention | 4.6 (2.6) | 5.0 (2.6) | -0.44 ^c (-1.43 to 0.54) | 0.371 | | |
| Second cycle post-intervention | 4.7 (2.5) | 5.2 (2.4) | | | | |
| Quality of life components (SF-36) | | | | | | |
| Physical health (0-100) | | | | | 0.020 | 0.199 |
| Baseline | 70.4 (11.2) | 74.1 (7.8) | -3.8 ^b (-9.4 to 1.8) | 0.027 | | |
| Post-intervention | 77.1 (11.2) | 78.2 (12.1) | 0.5 ^c (-6.5 to 7.5) | 0.887 | | |
| Mental health (0-100) | | | | | 0.014 | 0.010 |
| Baseline | 59.6 (17.9) | 67.9 (15.1) | -8.2 ^b (-18.1 to 1.6) | 0.299 | | |
| Post-intervention | 66.0 (18.7) | 75.7 (12.1) | -4.6 ^c (-12.7 to 3.5) | 0.259 | | |
| Secondary outcome | Median (25-75 percentile) | | | | | |
| Number of gelofen pills taken at each cycle | | | | 0.791 | 0.729 | |
| Baseline | 1 (0-2) | 1 (0-1.5) | - | 0.665 ^d | | |
| First cycle post-intervention | 1 (0-2) | 1 (0-2) | -0.2 (-0.5 to 0.4) ^e | 0.948 | | |
| Second cycle post-intervention | 1 (0-2) | 1 (0-1.5) | | | | |

Abbreviations: VAS, visual analogue scale; Baseline values are the average values of the 2 cycles pre-intervention; there was 1 missing value from each group for the postintervention score of quality of life components.

^aAdjusted difference using repeated measures ANOVA, adjusted for the baseline values; Wilks' lambda showed no significant effect of time (P = 0.419) and time × group (P = 0.875).

^bUnadjusted mean difference using an independent-sample t-test.

^cAdjusted difference using ANCOVA, adjusted for the baseline values

^dMann-Whitney U test.

^eMean difference in change in the number of gelofen pills taken by using repeated measures ANOVA; Wilks' lambda showed no significant effect of time (P = 0.962) and time × group (P = 0.653).

Footnotes

Authors' Contribution: Study concept and design: Mohammad Alizadeh Charandabi, Mohammad Hossein Biglu, and Khatereh Yousefi Rad; analysis and interpretation of data: Mohammad Alizadeh Charandabi and Khatereh Yousefi Rad; drafting of the manuscript: Khatereh Yousefi Rad; critical revision of the manuscript for important intellectual content: Mohammad Alizadeh Charandabi and Mohammad Hossein Biglu; statistical analysis: Mohammad Alizadeh Charandabi and Khatereh Yousefi Rad.

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