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# The Effect of Topical *Rosa damascena* (Rose) Oil on Pregnancy-Related Low Back Pain: A Randomized Controlled Clinical Trial

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**Abstract**

The study aimed to assess the efficacy of topical rose oil in women with pregnancy-related low back pain. A randomized controlled clinical trial was conducted on 120 women with pregnancy-related low back pain. Patients were allocated to 3 parallel groups to receive topical rose oil (in the carrier of almond oil), placebo (carrier oil), or no intervention. All groups were followed for 4 weeks. All participants were evaluated by Visual Analog Scale and the Roland-Morris Disability Questionnaires to assess the pain intensity and its impact on daily activities before and after the intervention. Significant decrease in pain intensity compared to carrier oil or no intervention was observed. The rose oil also improves the functional ability of these patients in contrast with no intervention, while its effect on function is not significant compared to carrier oil. Rose oil reduced pregnancy-related low back pain intensity without any significant adverse effect.

**Keywords**

complementary and alternative medicine, Persian medicine, low back pain, pregnancy, rose oil

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One of the common complications during pregnancy (50% to 60%) is low back pain (LBP). It causes substantial distress and disruption of function; interferes with sleep, work, and capacity to carry out daily activities; and is often considered as a normal part of pregnancy. Serious pain is seen in 25% of LBP pregnant women, while a further 8% have severe disability.[1-3]

The high prevalence of back pain during pregnancy and its complications such as poor sleep, fatigue, and absence from work due to this pain has become a serious concern.[4,5] In addition to lifestyle modifications such as good posture, the use of chemical drugs with lesser side effects is commonly recommended for pain treatment.[5] However, there is not enough studies about the use of these drugs in pregnant women.[6]

Many researchers have focused on the nonpharmacologic methods for pregnancy-related LBP.[7,8] Wang et al found in a study that the majority of pregnant women who participated in their survey (61.7%) accept complementary and alternative medicine as a treatment for LBP during pregnancy.[9] Transcutaneous electrical nerve stimulation, exercise, acupuncture, chiropractic treatment, and the use of protective support are among complementary and alternative medicine methods used by pregnant women for managing their LBP.[10-15]

Traditional Persian medicine suggests a package of lifestyle modification and topical herbal oils to reduce pain and fatigue during pregnancy.[16] Rose (*Rosa damascene*) oil is among the most popular topical formulations used for this purpose in traditional Persian medicine, which is produced by trapping essential oil of flowers in a fixed oil (like almond oil).[17,18] It has shown analgesic and anti-inflammatory effects in previous studies on animal models.[19,20] The purpose of the present study was to evaluate the efficacy of rose oil in patients with pregnancy-related LBP in comparison with its

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carrier oil (almond oil) and no intervention in a randomized controlled trial.

## Materials and Methods

### Trial Design

This trial follows a single-center randomized controlled design, with 3 parallel arms from July 2014 to June 2015.

### Participants

Women between 18 and 35 years with uncomplicated pregnancies (12-33 gestational weeks of pregnancy) who visited the Prenatal Care Unit of the Department of Obstetrics and Gynecology, Faculty of Medicine, Tehran University of Medical Sciences, for standard prenatal care diagnosed with pregnancy-related LBP were recruited to the study. A total of 120 pregnant women with pregnancy-related LBP agreed to participate in this study. Participants had reported LBP (having pain score $\geq$3 by a VAS) during routine and prenatal care. They had no lumbar pathology before pregnancy. Those with a pain caused by nonmusculoskeletal factors (eg, urinary tract infection, obstetric complication) were excluded from the study. Other inclusion criteria were (*a*) having no injuries and skin disease in the lumbar, (*b*) no use of alcohol and analgesic drug, (*c*) no use of other complementary and alternative therapies, (*d*) no history of infertility and abortion, (*e*) no history of high-risk pregnancy, (*f*) no history of surgery in the lower back, and (*g*) no history of cigarette smoking. Patient's dissatisfaction, intake of analgesics, moderate or severe allergies to essential oil, and pregnancy urges were parameters considered as exclusion criteria.

### Randomization and Blindness

A total of 120 patients with pregnancy-related LBP were randomized to 1 of 3 groups: rose oil (essential oil of *Rosa damascena* in a carrier of almond oil; n = 40), carrier (almond) oil (placebo; n = 40), and control (n = 40), who received no intervention.

Both rose oil and almond oil were packed in similar bottles with the same shape, size, and color, and the bottles were coded based on randomized sequences. Almond oil bottle caps were dipped in the essence of rose to replicate the smell.

### Interventions

Pregnant women were allocated to 3 groups to receive rose oil (+carrier oil), or carrier (almond) oil, or no intervention. The pregnant women in the first 2 groups were prescribed 7 drops of oils topically for 100 $cm^2$ of the painful part of skin without massage, 2 times daily for 4 weeks. All subjects received standard prenatal care. Patients recorded drug usage and possible side effects in a diary given to them. The control group did not receive intervention.

### Preparation of Rose Oil

Rose dried petals were purchased from a local herbal store of Tehran, and a voucher specimen (*Rosa damascena* Mill, No. PMP-507) was deposited in the herbarium of the Faculty of Pharmacy. The rose oil was prepared according to prescriptions in Persian medicine manuscripts. For this purpose, 500 g of *Rosa damascena* petals were soaked in 1 kg of almond oil and was exposed to sunlight for 1 week. After 1 week, the oil was filtered and 500 g of fresh petals was added again. This procedure was repeated 7 times.[17] The final product was packaged in airtight, light-resistant containers. The almond oil used as carrier and placebo were purchased from Barij-Essence Company (Kashan, Iran), which were produced according the cold compression method as described previously.

**Table 1.** Chemical Composition of the Almond Oil From Rose Oil.

| No. | Compound[a] | RI[b] | Percentage |
|---|---|---|---|
| 1 | Hexanal | 807 | 1.11 |
| 2 | *n*-Hexanol | 872 | 0.17 |
| 3 | 2-Heptanone | 895 | 0.24 |
| 4 | Heptanal | 909 | 0.16 |
| 5 | 2*E*-Heptenal | 966 | 8 |
| 6 | Benzaldehyde | 975 | 0.5 |
| 7 | 1-Octen-3-ol | 986 | 0.28 |
| 8 | Octanona | 997 | 0.13 |
| 9 | 2*E*,4*E*-Heptadienal | 1008 | 1.95 |
| 10 | *n*-Octanal | 1011 | 0.09 |
| 11 | *cis*-Rosepoxide | 1116 | 0.11 |
| 12 | Benzene ethanol | 1127 | 8.71 |
| 13 | *trans*-Roseepoxide | 1133 | 0.06 |
| 14 | Veratrole | 1158 | 0.09 |
| 15 | 2*Z*-Nonen-1-al | 1170 | 0.06 |
| 16 | Benzyl acetate | 1175 | 0.19 |
| 17 | Terpinene-4-ol | 1190 | 0.1 |
| 18 | Cryptone | 1199 | 0.12 |
| 19 | $\alpha$-Terpineol | 1206 | 0.13 |
| 20 | 2*E*,4*E*-Nonadienal | 1228 | 0.04 |
| 21 | Nerol | 1234 | 10.28 |
| 22 | Citronellol | 1237 | 25.12 |
| 23 | Neral | 1249 | 1.28 |
| 24 | Geraniol | 1262 | 23.54 |
| 25 | *Z*-Phenyl ethyl acetate | 1268 | 4.63 |
| 26 | 2*E*-Decenal | 1273 | 0.22 |
| 27 | Geranial | 1279 | 2.03 |
| 28 | Thymol | 1303 | 0.41 |
| 29 | 2*E*,4*Z*-Decadienal | 1306 | 0.55 |
| 30 | Eugenol | 1366 | 2.25 |
| 31 | Geranyl acetate | 1384 | 0.06 |
| 32 | Methyl eugenol | 1414 | 1.16 |
| 33 | Diethyl phthalate | 1603 | 0.41 |
| 34 | *n*-Nonadecane | 1900 | 0.06 |
| 35 | *Total identified* | | 94.24 |
| 36 | Monoterpene hydrocarbons | MH | 3.86 |
| 37 | Oxygenated monoterpenes | MO | 60.03 |
| 38 | Sesquiterpene hydrocarbons | SH | 0.00 |
| 39 | Oxygenated sesquiterpenes | SO | 0.00 |
| 40 | *Total other* | Other | 30.35 |

[a]The names of the components are in order of their elution from the BPX5 column.
[b]Retention Index (RI) on BPX5 with reference to *n*-alkanes injected after the oil under the same chromatographic conditions.

### Standardization of Rose Oil

The rose oil was standardized according to essential oil. For this purpose, 100 mL of oil was mixed with 100 mL of distilled water and the essential oil was extracted by hydrodistillation using Clevenger apparatus for 5 hours. Prior to analysis, the obtained essential oils were dried using anhydrous sodium sulfate and stored at low temperature (+4°C)

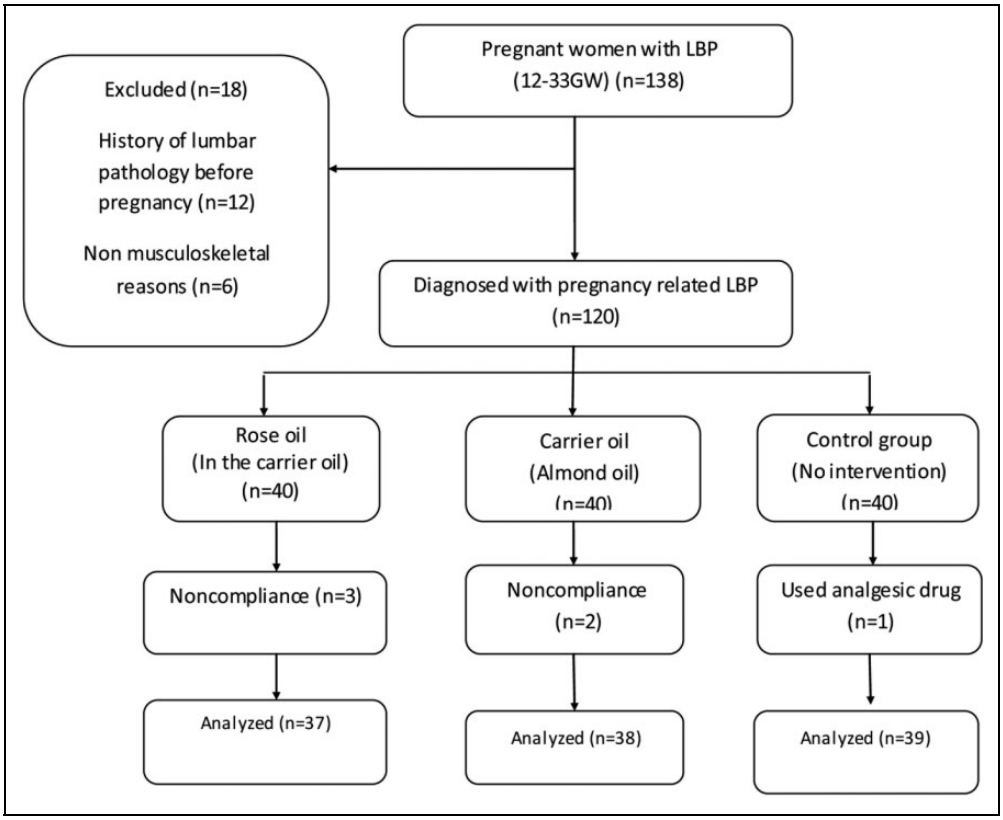


**Figure 1.** Flow diagram of study participants.

**Table 2.** Patient Characteristics in the 3 Study Groups (n = 114).

| Variables | Rose Oil (+ Carrier Oil) (N = 37), Mean ± SE or n (%) | Carrier Oil (Almond Oil) (N = 38), Mean ± SE or n (%) | Control (No Intervention) (N = 39), Mean ± SE or n (%) | *P* value |
|---|---|---|---|---|
| Maternal age (years) | 27.7 ± 0.8 | 27.9 ± 0.7 | 28.3 ± 0.6 | .852 |
| Body mass index (kg/m$^2$) | 26.5 ± 0.5 | 27.2 ± 0.9 | 27.2 ± 0.8 | .771 |
| Education | | | | .139 |
| Nonuniversity | 21 (56.8) | 14 (36.8) | 22 (56.4) | |
| University | 16 (43.2) | 24 (63.2) | 17 (43.6) | |
| Occupation | | | | .089 |
| Nonemployed | 37 (100) | 34 (89.5) | 34 (87.2) | |
| Employed | 0 | 4 (10.5) | 5 (12.8) | |
| Mode of pervious delivery | | | | .617 |
| No delivery | 20 (54.1) | 20 (52.6) | 22 (56.4) | |
| Vaginal | 8 (21.6) | 12 (31.6) | 7 (17.9) | |
| Cesarean | 9 (24.3) | 6 (15.8) | 10 (25.6) | |
| Gravid | 1.8 ± 0.2 | 1.7 ± 0.1 | 1.8 ± 0.2 | .963 |
| Parity | 0.6 ± 0.1 | 0.5 ± 0.1 | 0.5 ± 0.1 | .772 |
| Abortion | 0.2 ± 0.08 | 0.2 ± 0.08 | 0.4 ± 0.1 | .275 |
| Gestational age (weeks) | 22.1 ± 1.2 | 21.3 ± 1.1 | 24.2 ± 0.8 | .11 |
| Beginning of back pain (weeks) | 12.9 ± 1.3 | 13.1 ± 1.2 | 14 ± 1.2 | .823 |
| Resting (hours) | 12.9 ± 0.5 | 12.3 ± 0.6 | 12.2 ± 0.7 | .623 |
| Weight gain (kg) | 4.4 ± 0.9 | 4.3 ± 0.5 | 4.3 ± 0.4 | .95 |
| Pain in previous pregnancy | | | | .726 |
| No delivery | 19 (41.4) | 19 (50) | 23 (59) | |
| Negative | 9 (24.3) | 12 (31.6) | 11 (28.2) | |
| Positive | 9 (24.3) | 7 (18.4) | 5 (12.8) | |

in amber vials. The essential oil was analyzed using an Agilent 6890 gas chromatograph with BPX5 column (30 m × 0.25 mm, ft 0.25 μm); carrier gas, helium; split ratio, 1:25; and using mass detector. The column temperature was programmed at 50°C for 5 minutes and heated at the rate of 3°C/min until 240°C, then raised to 300°C at a rate of 15°C/min and then kept constant for 3 minutes. The mass spectra was regulated to 70 eV ionization energy. Retention indices were calculated using retention times of *n*-alkanes. The essential oil components were identified based on the NIST and Wiley mass spectral library.[21]

### Evaluation

Each participant completed a baseline questionnaire including demographic information and Visual Analogue Scale (VAS) form (scale from 0, no pain, to 10, the worst pain imaginable) for pain intensity and the Iranian version of the Roland-Morris Disability Questionnaires (RMDQ) to determine the physical disability and the impact of LBP on daily activities.[22] The minimum score was 0, and the maximum score was 24.

In total, 20 common skin side effects following topical medications usage on Common Terminology Criteria for Adverse Events v4.0 were recorded, and the physician evaluated them during follow-up of patients. Response to treatment and local side effects were evaluated in the first week, second week, and 2 weeks after discontinuation of treatment.[23] The control group underwent a routine prenatal care. The severity of the pain and disability were reassessed by the participants in the second week and 2 weeks after discontinuation of treatment using the VAS and RMDQ instruments in the intervention groups. After 4 weeks, the data of 114 participants (rose oil: n = 37; almond oil: n = 38; control: n = 39) who completed the study were analyzed. Six cases were not entered in the final analysis. This was because 5 patients discontinued the treatment for 4 weeks and 1 patient in the control group used an analgesic drug.

### Statistical Analysis

Data are represented by mean and standard error (SE) for numerical variables and frequency and percentage for categorical variables. Analysis of covariance tests were applied to compare the VAS and RMDQ scores by adjusting for baseline values. Bonferroni multiple comparison tests were used to compare the study groups two by two. A $P$ value less than .05 was considered statistically significant.

## Results

### Chemical Composition of Essential Oil

The hydrodistillation of rose oil yielded pink colored oil (yield: 0.10% W/V). Thirty-four constituents were identified in essential oil representing 94.24% of the total essential oil (Table 1). The volatile oil contained 60.03% oxygenated monoterpenes, 3.86% monoterpene hydrocarbons, 3.5% phenyl propanoids, 0.00% sesquiterpene hydrocarbons, 0.00% oxygenated sesquiterpenes, and 30.35% of other compounds. The most abundant components were citronellol (25.12%), geraniol (23.54%), and nerol (10.28%) (Table 1).

### Clinical Results

From a total of 138 subjects present for the pre-enrollment appointment, 120 were enrolled into the study and 114 subjects completed the 4-week study period (Figure 1). There were no significant differences between demographic characteristics in the 3 groups (Table 2).

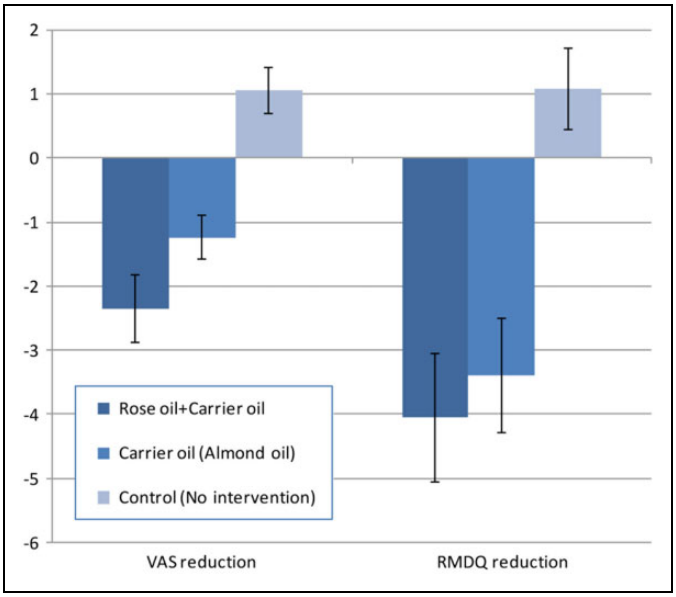


**Figure 2.** Reductions in means of Visual Analogue Scale and functional ability according to Roland-Morris Disability Questionnaires score in study groups.

The pain intensity based on VAS score decreased significantly in the rose oil and carrier oil groups (5.86 vs 3.51, $P < .001$; 5.18 vs 3.95, $P < .001$, respectively) while there was a significant increase in the control (no intervention) group (5.05 vs 6.10, $P < .001$; Figure 2). The mean reduction in VAS score of the rose oil group was significantly more than both carrier oil and no intervention groups ($P = .001$, $P < .001$, respectively; Table 3).

The effect of the both oils on the functional ability was also significant. The RMDQ scores of the rose and almond oil groups decreased significantly (9.97 vs 6.2571, $P < .001$; 8.15 vs 4.76, $P < .001$, respectively), although it increased in the control group (6.00 vs 7.07, $P = .002$; Figure 2). The mean RMDQ score in the rose oil group decreased by 0.66 points more than the carrier oil group. This difference was not significant ($P = .864$). However, the reduction in RMDQ scores in both rose oil and carrier oil groups were significantly more than in the no intervention group (Table 3).

During the study, the application of oils on pregnant women did not cause any adverse effects. Only mild allergic rhinitis was reported in one of the participants in the rose oil group.

## Discussion

The results showed that topical administration of rose oil (in a carrier of almond oil) in pregnant women with LBP causes a significant decrease in pain intensity compared to carrier oil or no intervention. The rose oil also improves the functional ability of these patients in contrast with no intervention, while its effect on function is not significant compared to carrier oil.

**Table 3.** Differences in Mean Reductions of Visual Analogue Scale (VAS) and Roland-Morris Disability Questionnaires (RDMQ) Scores in Study Groups.

| | Pairwise Comparisons | | | Confidence Interval | | | |
|---|---|---|---|---|---|---|---|
| | A | B | Mean Difference (A − B) ± SE | Lower Bound | Upper Bound | *P* Value, Pairwise (Bonferroni) | *P* Value (ANOVA) |
| VAS score reduction | Rose oil (+carrier) | Carrier oil | −1.11 ± 0.30 | −1.85 | −0.38 | .001 | |
| | Rose oil (+carrier) | No intervention | −3.40 ± 0.30 | −4.13 | −2.67 | <.001 | <.001 |
| | Carrier oil | No intervention | −2.29 ± 0.30 | −3.01 | −1.56 | <.001 | |
| RMDQ score reduction | Rose oil (+carrier) | Carrier oil | −0.66 ± 0.62 | −2.16 | 0.84 | .864 | |
| | Rose oil (+carrier) | No intervention | −5.13 ± 0.61 | −6.62 | −3.64 | <.001 | <.001 |
| | Carrier oil | No intervention | −4.47 ± 0.61 | −5.95 | −2.99 | <.001 | |

Numerous studies have examined alternative methods such as exercise programs and acupuncture for the treatment of pregnancy-related LBP. The use of complementary and alternative medicine is accepted among patients and physicians more than ever. Kashanian et al[12] evaluated the effect of exercise on back pain during pregnancy. In their study, the severity of back pain increased in the control group but decreased in the study group after 2 months. In a study by Keskin et al, the efficacy of transcutaneous electrical nerve stimulation, exercise, and acetaminophen was examined for the treatment of pregnancy-related LBP.[10] During the study period, pain increased in the control group, but decreased in the exercise group, as well as the acetaminophen and transcutaneous electrical nerve stimulation groups. In another study in Melbourne, which included 115 pregnant women, pain severity decreased significantly over a 3-week study period by a support garment.[11]

The use of topical formulations is common in traditional Persian medicine.[24,25] Pain relief is a frequent indication for these preparations.[26,27] Rose oil is one of the most popular topical preparations recommended in traditional Persian medicine for the management of pregnancy-related LBP. In this preparation the lypophilic constituents, especially essential oil from *Rosa damascena,* are trapped in a fixed oil (almond oil). Sadeghi et al[28] reported that massage therapy with rose oil in 25 volunteers with primary dysmenorrhea had a significant effect on pain reduction. In this study, pain severity decreased significantly after 2 weeks in both the rose and almond oil groups, but increased in the control group. In addition, Kim et al[29] used the essential oil of a mixture of aroma plants including *Rosa damascena* in the base of almond and jojoba oil on 63 female nurses who were suffering from dysmenorrhea. The authors reported that abdominal massage with this oil decreased menstrual pain with no significant side effects.

The exact mechanism of rose oil for pain relief is not clear, but possible mechanisms involve stimulating the olfactory system and reduction of sympathetic activity, increase in parasympathetic activity, and release of endorphin by *Rosa damascena* essential oil, which resulted in an increase in pain threshold.[30-34] Although Hongratanaworakit[35] has reported similar effects with dermal absorption of rose oil without olfactory stimulation, he has demonstrated that rose oil molecules enter the blood stream by dermal absorption.[28]

Beside decrease in LBP of rose oil group a smaller size reduction was observed in placebo (carrier oil) group. This reduction can be due to the fact that sweet almond oil is not a real inert placebo. It has shown anti-inflammatory and analgesic properties in previous studies.[36] The observed increase in pain of patients of "no intervention" group also seems to be due to the natural course of the condition. Previous studies have shown that pregnancy-related LBP increases along with increasing in gestational age.[37]

This study had some limitations: the first is the short duration of the study. Although a serious side effect was not reported in this study, the 4-week duration of the trial limited the scope of the study. The long-term effects of the oils were not evaluated, including their impact on pain and activity over the entire period of pregnancy, delivery, postpartum back pain, and recovery. The results of the study may also be limited by the small sample size.

This treatment has preferences proportion other than methods of complementary and alternative medicine. In previous studies that examined exercise programs, compliance by participants was poor. This method was more accepted by patients may be because there was no need for patients to visit health centers.

In conclusion, since the use of rose oil has reduced pain and increased functional ability LBP in pregnant women without any serious adverse events as well as considering its feasibility to apply and its low price, it could be considered as a safe and efficacious remedy for the management of this disorder.

## Authors' Note

The study protocol was registered in the Iranian Registry of Clinical Trials, Registration Number: IRCT2014091419150N1.

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## Author Contributions

SB, FN, and SM designed the study. MSH, SB, and SM acquired data. ZSH, FM, and MSY analyzed the data. SM, MSH, FN, and RR wrote the article. All authors read and approved the final draft of the article.

## Declaration of Conflicting Interests

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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## Ethical Approval

Ethical permission was received from the Local Ethics Committee of the University (Registration Number 8821309005-128051).

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