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Clinical trial

The effects of aromatherapy using rose oil (*Rosa damascena* Mill.) on preoperative anxiety: A prospective randomized clinical trial

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ABSTRACT

Introduction: Preoperative anxiety is a common problem before anesthesia. Pharmacologic agents or non-pharmacologic methods are widely used to reduce preoperative anxiety. The aim of our study was to investigate the effect of aromatherapy with rose oil on preoperative anxiety.

Methods: This study was a prospective, randomized, controlled trial. The patients (n = 99) were randomized as the control group (group C), the sham group (group S) and the rose oil group (group R). The State-Trait Anxiety Inventory- State Questionnaire of Spielberger (STAI-S) was used to determine anxiety levels. The first STAI-S (Q_1) was administered in the otorhinolaryngology clinic in the morning on the day of the operation. Group C received no intervention. In group S, a mixture (distilled water/ethyl alcohol) and in group R, a mixture (distilled water/ethyl alcohol/ 0.2 mL rose oil (*Rosa damascena* Mill.)) was used with the ultrasonic aroma diffuser. Aromatherapy was applied by an ultrasonic nebulizer for 15 min before patients went to the operating room for surgery in group S and group R.In the operating room, the second STAI-S (Q_2) were recorded.

Results: There was no statistical significant difference between the groups at baseline in terms of Q_1 scores, but when the second STAI- S was administered after the intervention, there was a significant difference in Q_2 scores (43.15 ± 7.55, 36.03 ± 9.60, respectively, 95% CI, 38.39–43.12, P = .004) between group C and R.

Conclusions: The application of rose oil aromatherapy by inhalation reduced the scores of preoperative anxiety of patients undergoing septorhinoplasty/rhinoplasty.

1. Introduction

Anxiety is a common problem before anesthesia and surgery. It causes psychological and physiologic effects both in adults and children. The high anxiety level of patients in the preoperative period increases the need for anesthetic medication, and additional treatment may be required for developing complications, which can change the duration and process of the surgical procedure [1,2]. Therefore, preoperative anxiety should be reduced by medication or by different methods by nurses, technicians and doctors in the surgical service and surgery team [3–5].

Pharmacologic agents such as benzodiazepines are widely used to reduce preoperative anxiety [6]. Nonpharmacologic methods such as preoperative information, music, aromatherapy, and acupuncture are also used [7–10].

Aromatherapy, which uses essential oil derived from plants, is a complementary and alternative medicine (CAM). Essential oils are often applied through skin massage or inhalation for different diseases [11]. Their use to reduce anxiety has been the subject of widespread research in recent years [12]. Preoperative anxiety reducing effects have been seen in randomized studies with essential oils obtained from plants such as Lavandula angustifolia, and Osmanthus fragrans [13,14].

Rosa damascena Mill. (RDM), also called Damask rose, has been used in complementary and alternative medicine for different purposes for thousands of years in a wide geographic area,e.g. Bulgaria, Turkey, Iran, India, China, northern African countries and Europe [15].

There are a number of studies, in particular, originating from Iran, investigating the analgesic, anti-inflamatory, and anti-septic effects of rose oil [15–17]. In addition, psychological relaxation, anti-anxiety and anti-depressant effects of RDM have been confirmed in another studies [17–20].

In the systematic review by Nayebi et al., 12 randomized clinical

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trials were identified as significant [16]. Mohebitabar and al. in their comprehensive review indicated further clinical trials with larger sample size and better design were required [17]. In additon to these reviews, in our literature review, we found no randomized studies that examined the efficacy of the RDM grown in our region, Kirsehir, Turkey, on preoperative anxiety.

The aim of this randomized controlled trial was to investigate the effect of aromatherapy with rose oil on preoperative anxiety.

2. Materials and method

2.1. Ethical considerations

This randomized clinical trial was prepared in accordance with current Helsinki guidelines. Ethical approval was obtained the Ahi Evran University Clinical Investigations Ethics Committee (Decision Number: 2017-16-192). In addition, the permission for research was obtained from the Complementary Medical department of the Republic of Turkey Ministry of Health (77979112/622.02). This Clinical trial was registered to the IRCT (IRCT20180324039145N1).

2.2. Study design and setting

This study was a prospective, randomized, controlled trial.

2.3. Inclusion and exclusion criteria

Patients who underwent septorhinoplasty/rhinoplasty surgery in Ahi Evran University Training and Research Hospital Department of Otorhinolaryngology between June 1st, 2018, and September 30th, 2018, were enrolled in the study. Patients who were American Society of Anesthesiologists (ASA) I—II risk group and aged 18–40 years were included in the study.

Patients with hypertension, cardiac dysrhythmia, chronic depression and anxiety treatment, allergy to aromatherapy oils, bronchospasm, and anosmia were excluded from the study.

2.4. Sample size and randomization

The three study groups were defined as:

1 The control group (group C): No intervention
2 The sham group (group S): mixture (distilled water/ethyl alcohol)
3 The rose oil group (group R):mixture (distilled water/ethyl alcohol/ rose oil)

The preliminary study, which included ten from each group, a total 30 patients, was planned to calculate the effect size. The Microsoft Excel random number generator function was used with blocks of 30 for randomization (1:1:1) as the group C, the group S, and the group R. The randomization table was created. Patients were randomized according to this table, respectively.

The G*Power 3.1.9.2 software package was used to calculate the sample size ($\alpha = 0.05$, Power $(1\text{-}\beta) = 0.80$, Effect size $d = 0.32$). According to the result of the preliminary study, it was determined that 33 patients should be included in each group, a total of 99 patients (Fig. 1).

Randomization was repeated for 69 patients using the Microsoft Excel random number generator function.

2.5. The essential oil

The rose oil used in group R was obtained from a distillation of fresh rose petals (RDM) grown in the Ahi Evran University Faculty of Agriculture in the region of the Kırşehir, Turkey. The mixture used in group S and group R was made in the Central Biochemistry Laboratories of Ahi Evran University. The rose oil product used in this study was specially produced for this study and is therefore not a licensed product.

The chemical compositions of the rose oil used in group R were analysed by Gas Chromatography–Mass Spectrometry (GC—MS); citranellol (26.14%), nonadecane (21.32%), heneicosane (10.33%), geraniol (5.08%), methyl eugenol (1.46%), ethanol (0.48%), and linalool (0.12%) were detected.

2.6. Questionnaire

The Turkish version of the State-Trait Anxiety Inventory- State (STAI-S) questionnaire of Spielberger was used to determine anxiety levels in the study [21,22]. The STAI-S of Spielberger is commonly used to measure state anxiety and consists of ten positive (e.g., “I feel frightened”,” I feel upset”) and ten negative (e.g., “I feel calm”,” I feel relaxed”) items. Each items is scored between 1 (never)-4 (completely). The difference between the positive and negative scores is determined and an anxiety score is calculated by adding 50 as standard. The total score can range between 20–80 (min.–max.)

2.7. Practice

Patients were approached at the otorhinolaryngology clinic on the morning of the day of surgery. A researcher gave information about the study to those patients who met the inclusion criteria. Patients who provided informed consent were thenrecruited into the study.

The heart rate (bpm) (HR_1) and mean blood pressure (mm Hg) (MAP_1) of the patients were measured. The first STAI-S questionnaire (Q_1) was administered by a researcher and responses were be recorded on the case report form.

The patients’ groups were determined by first researcher according to the randomization table in the morning of the day of surgery. Aromatherapy was implemented according to the patient's group by a nurse who had aromatherapy education and experience.

Group C received no additional intervention.

In group S, 10 mL of a mixture of 80 mL distilled water / 20 mL ethyl alcohol (the mixture was made with ethyl alcohol to dissolve the rose oil in water) were added to the ultrasonic aroma diffuser (ShenZhen GeiLiMei Tech. Co, PRC). In group R, 10 mL of a mixture of 98 mL distilled water/ethyl alcohol, and 2 mL rose oil were placed on the aroma diffuser.

Aromatherapy was applied using an ultrasonic nebulizer for 15 min before going to the operating room for surgey in group S and group R, and the patient inhaled room air during this time.

In the operating room, the second STAI-S Questionnaire (Q_2) was administered by the other researcher who was blinded to the group allocation of the patients. The preoperative heart rate (bpm) (HR_2) and mean blood pressure (mm Hg) (MAP_2) of the patients were measured and recorded.

2.8. Statistical analysis

The primary outcomes of the study are scores of STAI-S (Q_1 and Q_2) and the secondary outcomes of the study are values of MAP (MAP_1 and MAP_2) and HR (HR_1 and HR_2).

Data were analyzed using the IBM SPSS 21.0 (IBM SPSS Inc, Chicago, IL, USA) package program. Descriptive statistics (frequency, percentage, mean, standard deviation, median, inter-quartile range) are given. The Chi-square test was used for categorical variables. Normal distribution of data was analyzed using the Shapiro-Wilk test.

One-way analysis of variance (ANOVA) or the Kruskal-Wallis test was used to analyze data between groups according to data distribution. The Tukey (HSD) test was used to determine the group that was responsible for the difference in cases where a significant difference was detected in intergroup comparisons. Welch’s test was used when variance homogeny assumption was not met. The paired sample *t*-test or

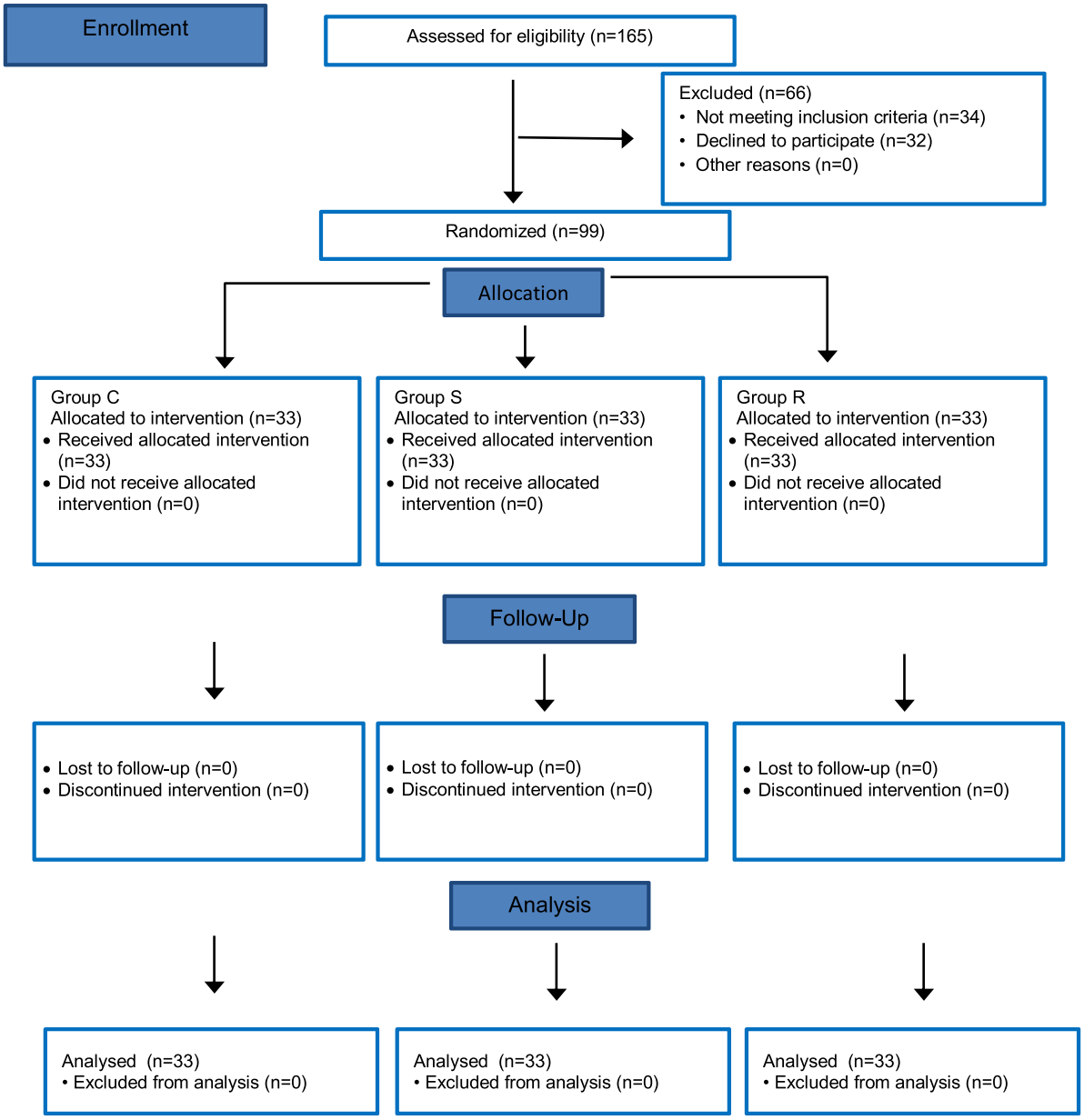

Fig. 1. CONSORT 2010 Flow Diagram.

Wilcoxon signed-ranks test was performed to evaluate the differences of MAP_1 and MAP_2, HR_1 and HR_2, Q_1 and Q_2 in each group.

$P < .05$ was accepted as statistical significance.

3. Results

Of the 165 patients screened for eligibility, 66 patients were excluded from the study (Fig. 1). The remaining 99 were then randomly allocated to one of the three groups and baseline data were compared. There were no statistical differences between the groups in terms of sex, age, and body mass index (Table 1).

There was no statistical significant difference between the groups in terms of Q_1 scores, but there was a statistical significant difference between Q_2 scores ($P = .004$) (Fig. 2). The Tukey HSD test revealed a statistical significant difference between group C and group R (Table 2).

When the change between Q_1 and Q_2 in each group was evaluated, a statistically significant increase in group C ($P = .018$), a non statistical significant increase in group S ($P = .634$), and a statistical significant decrease in group R ($P = .028$) were observed (Table 2).

The results of MAP_1 scores, MAP_2 scores, MAP_1 and MAP_2 changes are presented in Table 3. A statistically significant difference was found between MAP_2 scores ($P = .004$). Post hoc tests showed a statistically significant difference between group C and both group S and group R.

The results of HR_1 scores, HR_2 scores, HR_1 and HR_2 changes are presented in Table 4. HR_2 values were statistically significantly different ($P = .027$) (between group C and group R according to the Tukey HSD test).

4. Discussion

This research suggests that the use of rose oil administered using a diffuser may reduce preoperative anxiety scores. When the scores were compared, a significant difference was found compared with the control group, but the difference between the sham group and rose oil group was not significant.

Preoperative anxiety is a common problem and is affected by many factors. The frequency and severity of preoperative anxiety may vary

Table 1
Demographic data of the control group (C), sham group (S), and rose group (R).

		Group C (n = 33)	Group S (n = 33)	Group R (n = 33)	*P*
Sex	Female	18 (54.5%)	21 (63.6%)	19 (57.6%)	.747[a]
	Male	15 (45.5%)	12 (36.4%)	14 (42.4%)	
Age (years)		27.06 ± 5.01	26.58 ± 5.45	28.61 ± 6.61	.451[b]
		25 (23–30)	26 (22–30)	26 (24–36)	
BMI (kg. m^{-2})		24.63 ± 2.65	24.24 ± 2.24	25.47 ± 2.56	.130[c]
		24.7 (22–27.8)	23.7 (22.5–25.7)	25.2 (23.9–27.5)	

All data is presented n(%), mean ± SD and median (inter-quertile range).
[a] Pearson Chi-Square.
[b] Kruskal Wallis Test.
[c] One-Way Anova.

depending on the age and sex of the patient, size of the operation, information about surgical and anesthesia applications, and the surgical team [23]. In a study conducted by Wotman et al., lavender aromatherapy was found to be effective on preoperative anxiety [24]. In their study, however, the type of operation was not standardized, and the application of surgery to different groups by different surgeons were mentioned as limitations of the study. We standardized our study by eliminating the majority of these factors, which would affect the level of anxiety. For example, all patients included in our study were aged 18–40 years and underwent septorhinoplasty/rhinoplasty by the same surgeon. All patients were informed about the research and the informed consent forms were signed by the same investigator. Hemodynamic follow-ups of patients were performed by the same nurse in the morning of surgery and completed the Q_1 form. When patients arrived in the operating room, the Q_2 questionnaire was administered by the same surgeon. Hemodynamic follow-ups were perfomed by the same anesthesia technician. In our study, aromatherapy and other treatments were performed in the patient room in the otolaryngology clinic, unlike in these studies. Patients were brought to the operating room after application. In these studies, because the aromatherapy was performed in the operating room, the first anxiety scores were higher than the

Table 2
Comparison of questionnaire 1 (Q_1) and 2 (Q_2) scores of the control group (C), sham group (S), and rose group (R).

	Group C (n = 33)	Group S (n = 33)	Group R (n = 33)	*P*
Q_1	40.76 ± 6.68	38.88 ± 5.61	38.48 ± 8.85	.378[a]
	42 (37–44)	39 (36–43)	38 (30–46)	
Q_2	43.15 ± 7.55	39.30 ± 8.15	36.03 ± 9.60	.004[a] (C/R)
	42 (38–48)	41 (33–43)	32 (30–40)	
P	.018[b]	.634[b]	.028[b]	

All data is presented n(%), mean ± SD and median (inter-quertile range).
[a] One-Way Anova.
[b] Paired Samples Test.

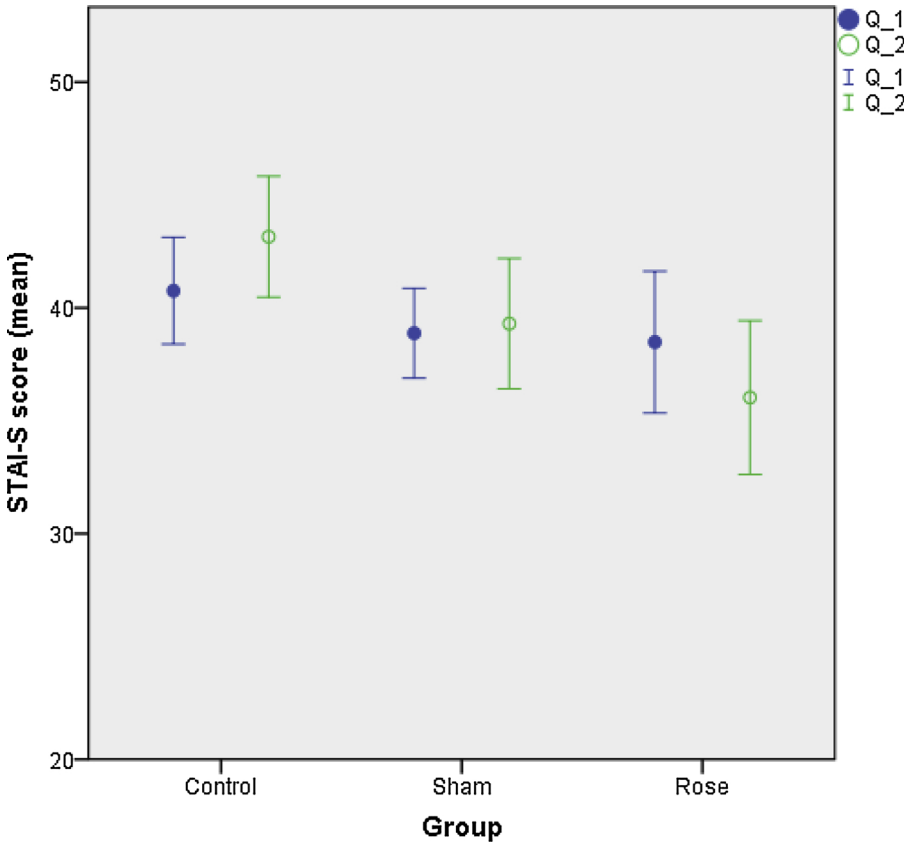

Fig. 2. Mean of Questionnaire 1(Q_1) and 2(Q_2) scores of control group (C), sham group (S), and rose group (R).

Table 3
Comparison of mean arterial pressure (MAP) 1 and 2 scores of the control group (C), sham group (S), and rose group (R).

	Group C (n = 33)	Group S (n = 33)	Group R (n = 33)	*P*
MAP_1(mmHg)	83.27 ± 7.15 87 (77–87)	84.09 ± 6.50 83 (80–92)	84.73 ± 5.38 83 (83–87)	.736[a]
MAP_2(mmHg)	92.79 ± 6.08 95 (89–97)	87.82 ± 9.69 90 (80–97)	87.70 ± 6.73 87 (83–93)	.004[b] (C/S-R)
P	< .001[c]	.017[d]	.047[c]	

All data is presented n(%), mean ± SD and median (inter-quertile range).
[a] Kruskal Wallis Test.
[b] One-Way Anova.
[c] Paired Samples Test.
[d] Wilcoxon Signed Ranks Test.

Table 4
Comparison of heart rate (HR) 1 and 2 scores of the control group (C), sham group (S), and rose group (R).

	Group C (n = 33)	Group S (n = 33)	Group R (n = 33)	*P*
HR_1 (bpm)	77.18 ± 3.86 75 (74–80)	76.76 ± 3.61 78 (74–80)	77.33 ± 4.17 80 (75–80)	.707[a]
HR_2 (bpm)	86.36 ± 10.13 85 (80–94)	81.94 ± 7.55 82 (76–85)	80.94 ± 7.69 80 (76–85)	.027[b] (C/R)
P	< .001[c]	< .001[d]	.022[d]	

All data is presented n(%), mean ± SD and median (inter-quertile range).
[a] Kruskal Wallis Test.
[b] One-Way Anova.
[c] Wilcoxon Signed Ranks Test.
[d] Paired Samples Test.

scores in our study. Therefore, in our study, the change between the anxiety scores before and after the aromatherapy is more significant, unlike these studies.

For thousands of years, plants have been used for the treatment of many diseases. This complementary medicine method, called aromatherapy, has become popular again in the last few decades all over the world. Essential oils obtained from some of these plants have been used as anxiolytics [25]. In particular, there are a number of investigations of the effects of lavender aromatherapy on preoperative anxiety [26]. We also aimed to contribute to the literature by investigating the effect of rose oil obtained from RDM in this randomized, controlled study on the same topic.

The active ingredients of rose oil obtained from RDM grown in a wide geographic area vary according to the area grown and the method of production [27]. We analyzed the active substances in our study in order to provide standardization, we used rose oil obtained by distillation from fresh RDM petals grown in Ahi Evran University Faculty of Agriculture in the region of the Kırşehir, Turkey. The amount of active substance in rose oil varies according to the region where it is grown. However, this problem, which is seen as a limitation of our research, is valid for all aromatherapy studies where no active substance standardization has been perfomed.

Despite the studies on animals and humans, the anxiolytic mechanism of RDM is not yet clear [19,28]. In another animal study, it was reported that RDM increased the effect of pentobarbital [29]. Therefore, there is a need for well-planned clinical trials on humans to examine the interactions with anesthetic drugs, particularly when investigating the effects of RDM on preoperative anxiety levels.

4.1. Limitations

Aromatherapy was used in 30–35 square-meter single rooms. However, the number of the relatives of the patient during the aromatherapy application could not be standardized. For this reason, the concentration of active substance inhaled by the patient could be affected. Another limitation of our study is that the transfer times from the patient room to the operating room and the time between Q_1 and Q_2 tests could not be standardized. A further limitation is that the ethyl alcohol added to the mixture to dissolve the rose oil in water in group S and group R may have an anxiolytic effect with additive or synergistic effects when combined with rose oil. Therefore, no statistical significance could found between group S and R.

5. Conclusions

Application of rose oil aromatherapy by inhalation reduces scores of preoperative anxiety. However, in order to show the true anxiolytic effect, more widespread clinical trials that do not contain ethyl alcohol or with other solvents and rose oil mixture are needed in this subject.

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Conflict of interest

The authors declare that they have no conflict of interest.

Ethical approval

This clinical trial was prepared in accordance with current Helsinki guidelines.

Informed consent

Informed consent was obtained from all individual participants included in the study.

Registration

Ethical approval was obtained the Ahi Evran University Clinical Investigations Ethics Committee (Decision Number: 2017-16-192). The permission for research was obtained from the Complementary Medical department of the Republic of Turkey Ministry of Health (77979112/622.02). This Clinical trial was registered to the IRCT (IRCT20180324039145N1).

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