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The Effect of Aromatherapy Using Lavendar on Nausea, Vomiting, and Anxiety during Pregnancy: A Quasi Experimental Study

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ABSTRACT

Background & aim: The treatment of nausea and vomiting in pregnancy (NVP) includes both pharmacological and non-pharmacological approaches. There is evidence of adverse effects of medications during pregnancy, however, results confirming the effectiveness of non-pharmacological methods such as aromatherapy remains inconclusive. So, this study aimed to determine the effect of lavender aromatherapy on nausea, vomiting, and anxiety during pregnancy.

Methods: This non-randomized, single-blind, two-group quasi-experimental study included pregnant women (n=66) with a gestational age of 6-16 weeks. Sampling was convenience and study was conducted in one training and treatment center in Tehran, Iran between 2015 and 2016. Eligible participants were assigned to either the lavender (intervention) or seasame oil (placebo) group every other day during the recruitment period. The intervention group inhaled four drops of 10% lavender oil twice daily for 7 days. Participants completed the Rhodes Index of Nausea, Vomiting, and Retching (RINVR) every night before sleeping for seven days. Additionally, state anxiety was measured both before, and on completion of day 7 of the intervention period using the state anxiety scale.

Results: The overall mean of RINVR scores (6.91±3.58 and 9.58±4.31, P=0.008), and state anxiety scores (36.21±5.68 and 40.27±7.02, P=0.012) were lower in the lavender group than those of the placebo group. The severity of state anxiety (P=0.027 and NVP P=0.032) in the lavender group were lower compare to placebo group.

Conclusion: Care providers could promote the use of lavender aromatherapy during pregnancy for the amelioration of NVP and anxiety.

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Introduction

Nausea and vomiting in pregnancy (NVP) is a common condition. It is stimated that the prevalence of nausea during pregnancy is between 50-80%, whilst the prevalence of vomiting and retching during pregnancy is approximately 50% (1). NVP can significantly

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reduce one's quality of life and have negative effects upon daily activities, marital life, parenting roles, work life, and social functioning whilst also accounting for 33% of all cases of work-related sickness absence during pregnancy (2-3). NVP can also impose a great economic burden on both individuals and society due to the loss of productivity and rising healthcare costs it creates (4). Such findings point to the need for effective evidence-based interventions in this context.

Despite its high prevalence and associated social and economic burden, a wholly effective treatment for NVP has yet to be established (5). Moreover, the teratogenic effects of medications previously used for the management of NVP have led to caution in the prescription of medications, particularly during the first trimester of pregnancy (4). Indeed, pregnant people generally prefer non-pharmacological interventions due to concerns about their side effects on the fetus (1). As such, alternate interventions and a thorough examination of their effectiveness are required.

Complementary and alternative medicine (CAM) is often preferred as a natural and safe alternative to alleviate pregnancy symptoms in general (6). The use of CAM during pregnancy ranges from 20% to 60%, with aromatherapy being one of the most popular (7). Indeed, aromatherapy is one of the fastest growing therapies in the world today (8). Yet there is a paucity of high-quality evidence for the use of aromatherapy in pregnancy, particularly about NVP, and findings remain inconclusive in many cases.

Lavender oil is the most commonly used oil in pregnancy (9), and is considered safe for use during pregnancy (10–14). Indeed, an in-vitro safety assessment demonstrated no detrimental effects using both low and high lavender concentrations in a widely used placental cell model (14). The key constituents of Lavandula angustifolia, the most commonly used species of lavender, are linalyl acetate and linalool (7). Linalool and linalyl acetate in lavender works by stimulating the parasympathetic system, linalyl acetate has narcotic properties and linalool can act as a sedative (11). Such effects show promise for the alleviation of NVP, and one pilot randomized controlled trial (RCT) has already demonstrated that a combination of both peppermint and lavender oil can reduce the mean score of nausea and vomiting, along with fatigue, and promote an increase in energy levels during pregnancy (11). Nevertheless, there remains a paucity of available studies in this area and thus there is a need for further research to reach a definitive conclusion regarding the effect of lavender as an aromatherapy agent on NVP.

Alongside NVP, it is well-established that anxiety is one of the most prevalent conditions affecting almost one-third of pregnancies (15). This is concerning as evidence suggests that anxiety may also increase the risk of preterm birth and low birth weight infants (15). Some research has thus far focused on the effects of aromatherapy using lavender oil on anxiety levels during pregnancy (12,13). Yet, none have examined the effect of lavender oil on both anxiety and NVP together. Some studies have suggested that anxiety plays a role in the incidence of nausea and vomiting (16). Moreover, some researchers have reported an association between anxiety and NVP (17–19). Whilst the use of mint oil has been found to positively reduce NVP, without affecting state anxiety (20), a Cochrane review has demonstrated little conclusive evidence regarding the overall efficacy of aromatherapy in alleviating NVP (4). Considering the above, further research is required to provide conclusive recommendations on the use of aromatherapy, particularly with the use of lavender oil and its effect on both nausea, vomiting, and anxiety in pregnancy. The aim of this study was therefore to determine the effect of lavender aromatherapy on nausea, vomiting, and anxiety in pregnancy.

Materials and Methods

A non-randomized, single-blind, quasi-experimental study was conducted with two parallel groups of lavender oil (intervention) and placebo. It was recorded in the Iranian Registry of Clinical Trials Center with the code IRCT201306082324N12 on 09/23/2014 (URL of registry: https://en.irct.ir/trial/1967). This study was conducted between June, 2015 and January, 2016 at the Baharloo hospital, a training and treatment center affiliated with Tehran University of Medical Sciences (TUMS),

Iran. Participants included those pregnant and with a gestational age of between 6 and 16 weeks who were experiencing mild to moderate symptoms of nausea and vomiting.

Based on a previous study where the Rhodes Index of Nausea, Vomiting, and Retching (RINVR) was used on day three of the intervention period (11), and the mean (SD) of the placebo (n=23) (6.37) and the intervention group (n=18) (6.08) as used to calculate differences among the two groups, a sample of 33 participants in each group was estimated. The study with this sample size had a power of 90% at a 5% significance level. However, considering 10% drop out, a sample of 36 participants per group was estimated.

$$n = \frac{(Z_{1-\alpha/2} + Z_{1-\beta})^2 (S_1^2 + S_2^2)}{(\mu_1 - \mu_2)^2}$$

$$= \frac{10.5 \times (6.37^2 + 6.08^2)}{(23.01 - 17.98)^2} = 33$$

$$n_c = \frac{33}{1 - 0.1} = 36$$

In a convenience sampling, of the total number of participants screened for eligibility (n=83), 72 met the inclusion criteria and were assigned to either the lavender (n=36) or placebo group (n=36). To prevent participants contacting each other, they were allocated to either the intervention or placebo group on alternate days. Aroma bottles were dispensed to participants by a research assistant who was unaware of the research objectives. The research assistant was blinded to the two groups.

Recruitment commenced after ethical approval was granted by the Research Ethics Committee of TUMS. Subsequently, the researcher explained the objectives and procedure of the study to potential participants who met the inclusion criteria, who were then encouraged to ask any questions about the research before providing their informed consent. Written informed consent, was obtained from those who were willing to participate in the study.

The socio-demographic characteristics questionnaire prepared through a literature review, consisted: age, gestational age, BMI (body mass index), gravidity, economic and occupational status, and level of education of participants.

The RINVR consists of eight items rated on a five-point Likert scale to measure nausea and vomiting. The total score of this index ranges from zero to 32. A score of zero indicates an absence of symptoms, other scores range from 1-8, 9-16, and 17-32, each indicating mild, moderate, and severe symptoms respectively. It has been validated in a separate study assessing complications, such as NVP (21). The reliability of the Persian version of the RINVR was confirmed based on Cronbach's alpha coefficient test (α=0.80) (22). However, in the present study, the Cronbach's alpha coefficient of the RINVR has been calculated as 0.89.

The state anxiety scale used and prepared by Spielberger consists of 20 self-report statements, with each item ranging from 1-4 (23). The total score ranges from 20 (the lowest level of anxiety) to 80 (the highest level of anxiety) (24). Scores are categorized as follows; mild anxiety, 20-39; moderate anxiety, 40-59; and severe anxiety, 60-80. The reliability of the Persian version of this tool was confirmed based on a Cronbach's alpha coefficient of 0.90 (25). However, the Cronbach's alpha coefficient for this tool was found to be 0.89 in the present study. The reliability of both the Spielberger and RINVR scales was assessed with a two-week test-retest design with 15 pregnant people who were not included in the main study.

Participants met the inclusion criteria if they were aged between 20-34 years old and currently pregnant with a singleton planned pregnancy. Participants were also eligible if they reported experiencing mild to moderate NVP and had a state anxiety score of <60. Participants were excluded if they had following: A diagnosis of a physical or psychological disorder; exposure to stressful events <3 months; allergies to herbs; olfactory disorders; antiemetic or anti-anxiety drug (herbal or chemical drugs) usage <24-hours; and a lack of self-reporting on the use of sedative medications. Participants were also excluded during the seven-day intervention period if they experienced a crisis or stressful event; were unwilling to continue participating in the study; did not comply with inhalation

instructions for two consecutive or non-consecutive days; were using other antiemetic or anti-anxiety drugs or any other complementary medications that could potentially reduce NVP or anxiety during the study.

The instructed frequency and duration of inhalation during this aromatherapy intervention were guided by Ghani's previous study (11). As it was considered inappropriate for participants to use an oil burner at home, dripping a higher percentage of lavender (10%) onto cotton for inhalation was suggested as an appropriate and comparable alternative by an aromatherapy specialist.

Participants were advised to stop aromatherapy if they experienced any of the following allergic reactions: runny nose, skin rash, itching, headache, burning eyes, and/or abdominal pain. They also received seven copies of the RINVR to complete after oil inhalation every night for a period of seven days. To ensure regular inhalation, a daily record checklist was also provided. Participants were asked to submit their completed Rhodes nausea-vomiting index to the research team after the seven-day intervention period. They were also asked to complete the state anxiety scale both before and after the intervention period. The RINVR and the state anxiety scale were completed through self-reporting. The RINVR typically required around 3-5 minutes, while the state anxiety scale took about 5-10 minutes to complete.

On the first day of the intervention period, participants completed a socio-demographic data questionnaire, the RINVR, and a state anxiety scale. All participants also received routine training on how to relieve NVP, such as avoiding certain foods, odors, activities, or situations that may exacerbate NVP (11). NVP was considered to be a primary outcome, and state anxiety was considered to be a secondary outcome.

Participants in the lavender group inhaled lavender oil whilst participants in the placebo group inhaled sesame oil. Inhalation occurred twice a day (once before afternoon rest and again just before nighttime sleep) for seven days. For each inhalation participants extracted four drops of the bottle's contents onto a piece of cotton and then inhaled this for 20 minutes at a distance of 20 cm from their nose.

Identical glass containers (aroma bottles) were pre-coded by the pharmacist using the letters A and B. Assignment remained blind to the research team. A research assistant, who was also unaware of the research objectives, assigned bottles to participants. Nevertheless, we considered that participants would be able to ascertain the bottle's content once inhaled. Thus, only the assessor was truly blinded to each group's assignment.

The lavender oil (lavender group) and the sesame oil used as a placebo (placebo group) were both provided by Kashan Barij Essence Pharmaceutical Company (Kashan, Iran). This lavender oil was extracted from the flowering aerial parts of the lavender plant (Lavandula angustifolia) and then diluted with odorless sesame oil at a ratio of 10%. The sesame oil used as a placebo was procured as a harmless oil used during pregnancy (26,27).

Descriptive statistics were used to interpret the sample characteristics. The normal distribution of quantitative data was evaluated using the Kolmogorov-Smirnov test. The Chi-square and Fisher's exact test were also used to compare qualitative variables. In addition, both paired and independent sample t-tests were used to determine differences in quantitative data both within and between the groups. Furthermore, a repeated measures analysis of variance (ANOVA) was employed to compare the mean RINVR scores both within and between the groups during the seven-day intervention period. The mean RINVR score was compared two-by-two over time using the Bonferroni test. To examine comparisons between the two groups, the Greenhouse-Geisser test was also used where there was no assumption of sphericity. SPSS version 16 was used for all data analyses. A P-value of <0.05 was considered statistically significant.

Results

In total, 66 of the 72 recruited participants completed this study (33 participants in each group). Three participants were excluded from the study because they were inhaling the oils irregularly and outside of the timeframes prescribed (one in the lavender group and two in the placebo group). A further three participants were removed due to their use of antiemetic and/or anti-anxiety drugs (one from

the placebo group and two participants from the lavender group) (Figure 1).

There was no statistically significant difference between the two groups regarding socio-demographic data. The 47% of the participants were primigravida (Table 1).

Prior to the intervention, there were no statistically significant differences between the two groups regarding the mean RINVR scores (P= 0.914) (Tables 2 and 4). The independent sample t-test conducted on scores taken on the seventh day of the intervention period revealed that the overall mean RINVR score of the lavender group was lower than the overall mean RINVR score of the placebo group (6.91±3.58 and 9.58±4.31, respectively) (P=0.008). This result is similar to those reported when comparing the severity of NVP between the two groups (P=0.032) (Table 3).

Results from the Bonferroni test demonstrated no statistically significant difference in the mean RINVR scores of the lavender (intervention) and placebo groups over the time (P=0.117). Yet a statistically significant decreasing trend was observed in both groups over the time (P=0.001 and P=0.004, respectively) (Table 2 and Figure 2).

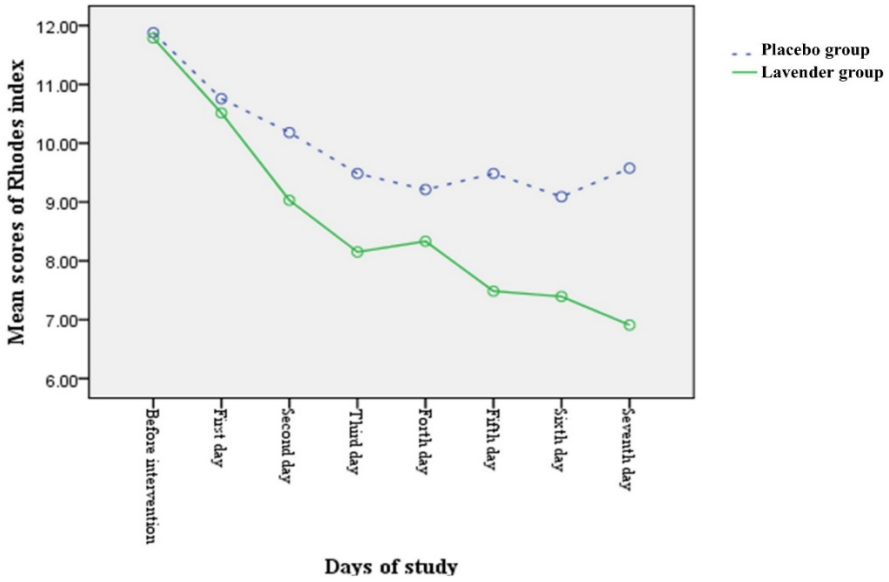

Figure 2. The mean RINVR scores in the two groups

Table 1. Socio-demographic data in the two groups

Characteristics	Lavender group (N=33)	Placebo group (N=33)	Test results	
Age (year)	27.79±3.58	28.24±3.91	*P=0.624	t=0.492
Gestational age (weeks)	10.58±2.73	10.64±2.34	*P= 0.907	t=0.117
BMI (kg/m2)	24.80±2.99	25.50±3.81	*P=0.430	t=0.480
Gravidity			**P=0.787	F=1.305
Primigravida	16(48.5)	15(45.5)		
Gravida 2	11(33.3)	9(27.2)		
Gravida 3	3(9.1)	6(18.2)		
Gravida 4	3(9.1)	3(9.1)		
Economic status			***P =0.725	χ^2=0.686

Good	8(24.2)	6(18.2)	
Medium	21(63.6)	21(63.6)	
Poor	4(12.2)	6(18.2)	
Occupational status			
Housekeeper	32(97)	30(90.9)	**P=0.613 F=1.060
Employed	1(3)	3(9.1)	
Level of education			
<High school	9(27.2)	7(21.2)	***P=0.839 χ2=0.350
High school	19(57.6)	21(63.6)	
University	5(15.2)	5(15.2)	

Data presented as mean ± Standard Deviation or number (percentage). BMI: Body Mass Index
* Independent sample t-test, ** Fisher's exact test, *** Chi-square test.

Table 2. Comparison of the mean RINVR scores

Time	Lavender group (N=33)	Placebo group (N=33)
Before intervention	11.78±3.89	11.76±5.00
First day	10.52±3.89	10.76±5.00
Second day	9.03±3.87	10.18±4.29
Third day	8.15±3.77	9.48±5.68
Fourth day	8.33±4.61	9.21±5.16
Fifth day	7.48±4.61	9.48±4.27
Sixth day	7.39±3.77	9.09±4.46
Seventh day	**6.91±3.58**	**9.58±4.31**
*P-value	**0.001**	**0.004**
Test result	****P= 0.117**	**F=2.524**

Data presented as mean ± Standard Deviation.
*Repeated measures analysis of variance (within group test), **Greenhouse-Geisser test (between groups test)

Table 3. Severity of nausea and vomiting on the seventh day of intervention

Severity	Lavender group (N=33)	Placebo group (N=33)	Test results
No symptoms	1(3)	0(0)	*P= 0.032 F=6.989
Mild	23(69.7)	14(42.5)	
Moderate	9(27.3)	18(54.5)	
Severe	0(0)	1(3)	

Data presented as number (percentage).
The score of severity of nausea and vomiting: no symptoms; 0, mild; 1-8, moderate; 9-16, severe; 17-32. *Fisher's exact test.

On intervention day 7, the mean score of state anxiety in the lavender group was markedly lower than the mean score of state anxiety in the placebo group (36.21±5.68 and 40.27±7.02, respectively, P=0.012) (Table 4). This result was also similar when comparing the severity of state anxiety between the two groups (P=0.027) (Table 5). The paired t-test equally revealed that the mean score of state anxiety had also distinctly decreased in both groups (Table 4).

Table 4. Comparison of the mean score of state anxiety

Time	Lavender group (N=33)	Placebo group (N=33)	Test results
Before intervention	43.42±6.37	43.36±6.26	*P= 0.969 t=-0.39
7th day after intervention	36.21±5.68	40.27±7.02	*P= 0.012 t=-2.58
Test results			**P<0.001 t=10/98 **P<0.001 t=5/69

Data presented as mean ± Standard Deviation. * Independent sample t-test. ** Paired t-test

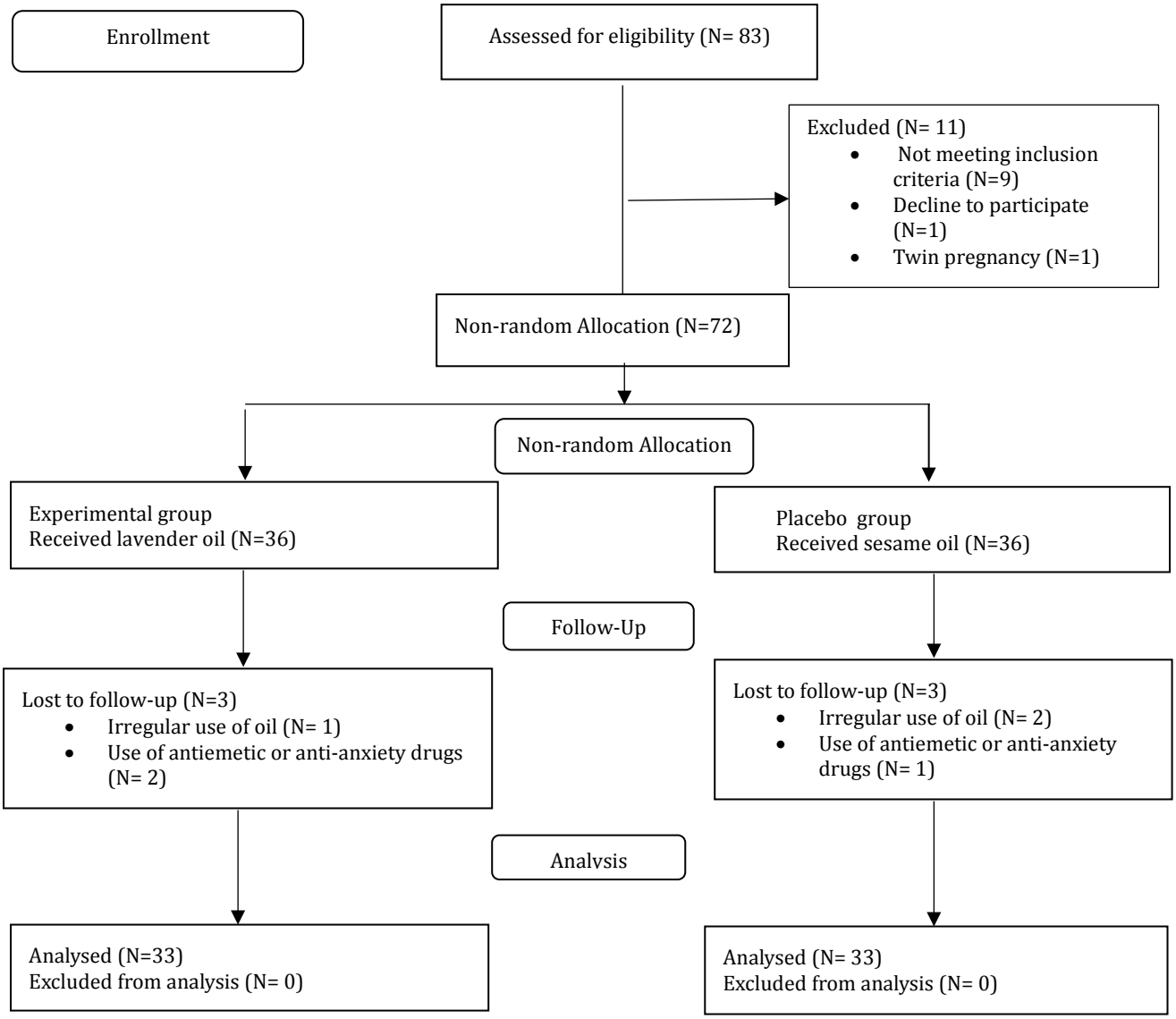

Figure 1. CONSORT Flowchart of the study

Table 5. Severity of state anxiety on the seventh day of intervention

Time	Lavender group (N=33)	Placebo group (N=33)	Test results
Mild	21(63.6)	12(36.4)	*P= 0.027 χ^2=4.909
Moderate	12(36.4)	21(63.6)	

Data presented as number (percentage). The score of severity of anxiety: mild; 20-39, moderate; 40-59. *Chi-square test.

Discussion

This study investigated the effect of aromatherapy using lavender oil and sesame oil as a placebo on nausea, vomiting, and anxiety between the 6th and 16th weeks of pregnancy over a period of seven days. The mean score of nausea and vomiting were compared between the two groups (Intervention and placebo). A

statistically significant difference was only identified between the two groups in terms of the total RINVR score at the end of the intervention period whereby on the seventh day, the mean RINVR score was statistically, significantly lower in the lavender group than in the placebo group. State anxiety was also compared between the two groups on the seventh day of the intervention period, and our statistical analysis demonstrated that both severity and the mean score of state anxiety were markedly lower in the lavender group than they were in the placebo group.

This study contributes to the limited number of valid studies conducted thus far on the effects of aromatherapy using lavender oil on NVP. Ghani et al. (2013) previously investigated the impact of a lavender and peppermint oil combination on NVP at 8-16 weeks gestation. In their pilot study, between one and four drops of peppermint and lavender oil 2%, respectively were added to a large spoon of water in an oil burner in a closed room. Participants were subsequently asked to breathe deeply in the room saturated with this aroma for 20 minutes, twice a day. After three days, the total RINVR score was significantly reduced compared to scores in the pre-intervention phase. Nevertheless, despite this reduction, the severity of NVP remained high (11). Conversely in the present study, the severity of NVP on the seventh day of the intervention period was either mild (69.7%) or moderate (27.3%), and none of our participants had severe NVP. A key strength of our study is that the lavender aroma was studied in isolation whereas when aromas are mixed such as in this earlier pilot study (11), the impact of the intervention cannot be attributed to any one particular aroma. This also has implications for any future research.

In our sample, the mean total RINVR score decreased in both the lavender and placebo groups during seven days of the intervention period. This decline in the placebo group may be attributed to placebo effects. For example, in the reporting of clinical trials it has been speculated that placebo treatments exert their effects through psychological and mental factors (28). In this sense, one's belief in the efficacy of treatment can positively affect the sensory experience of treatment. Considering the above it will be important not to overclaim the effects of placebos in this context, particularly where they are not statistically significant.

Lavender oil is the most studied aromatic oil in the amelioration of anxiety and depression in obstetrics (7). Yet few studies have examined the effect of lavender oil on anxiety in pregnancy. In two randomized controlled trials it was reported that lavender oil was one of the three oils (lavender, petitgrain, and bergamot) used in the third trimester of pregnancy (12,13). Yet Igarashi et al. (2010) reported that aromatherapy was evidenced to have no statistically significant effects on state anxiety between the 32nd and 36th weeks of pregnancy (13). In another trial conducted by Igrashi et al. (2012), five minutes of inhaling an essential oil with high linalool and linalyl acetate content was also evidenced to have little to no effect in improving scores related to tension and anxiety (12). Our results differ in that the positive effect of lavender oil on state anxiety we have found is promising. The reason for this contradictory finding may be related to differences in gestational age and the frequency with which aromatherapy had been administered. Yet often, earlier studies in this field have included small sample sizes and the type of oil used by participants is not reported. Thus, the conclusions of these earlier studies remain unreliable, whilst ours may be more reliable due to our larger sample size and detailed reporting. Overall, few studies have investigated the use of essential oils for the treatment of NVP and anxiety in pregnancy, and the use of different oils can affect results, for example where the positive effects of aromatherapy are observed in relation to NVP, but not state anxiety (20). As such, further studies are also required to investigate the effect of different aromatic essential oils on the alleviation of NVP.

Lavender oil is an aromatic herbal extract with carminative (a smooth muscle relaxant), sedative, and antidepressant properties (29). Its anticholinergic, antihistaminic, and anti-inflammatory activities resemble those of antiemetic drugs (30). Linalool and linalyl acetate, the main chemical constituents of lavender (31) are known to depress the

central nervous system and induce sedative effects, and marked narcotic-like activities (29). Lavender inhibits the hypothalamic-pituitary-adrenal axis and reduces the secretion of corticotropin-releasing hormone. It also reduces the secretion of adrenocorticotropic hormones from the pituitary gland, decreases the release of cortisol, increases the secretion of serotonin from the adrenal gland, and thus leads to anxiety alleviation (32). Accordingly, we hypothesize that lavender oil used in aromatherapy would have a statistically significant positive effect on NVP and state anxiety. Whilst we only identified a statistically significant difference between the two groups in terms of the total RINVR score at the end of the intervention period (7 days), future studies could usefully measure these effects over longer time periods.

The primary effect of aromatherapy is the stimulation of olfactory receptor cells in the nasal epithelium and the transmission of neural signals to the brain, limbic system, and thalamus to achieve both mental and physical balance through the release of endorphins and serotonins (33). Aromatherapy can directly affect the limbic system by bypassing oral intake and protecting against adverse reactions during pregnancy (7). There are no known adverse effects or complications associated with this type of aromatherapy during pregnancy, whether by inhaling or applying essential oils topically (11,34–36). Indeed, we observed no adverse effects in our sample. This suggests that lavender oil may be used effectively and safely as a low-cost intervention for the management of nausea, vomiting, and anxiety during pregnancy.

Whilst this study has been conducted rigorously, it has not been possible to blind the participants as to which group they were in due to the nature of aromatherapy (e.g., participants having prior recognition of lavender scent). Moreover, the research team had no control over participants' psychological state during the intervention period. Whilst these are limitations, they could not be mitigated. A key strength of this study was that we were able to test the effectiveness of a single oil (lavender oil) on both NVP and state anxiety on a large sample size. Future studies may usefully compare the effects of different essential oils delivered via aromatherapy over longer time periods in this context.

Conclusion

Drawing from the results presented here, aromatherapy with lavender oil resulted in a statistically significant positive effect on day seven of the intervention period. So, it can be considered safe and effective in reducing nausea, vomiting, and anxiety during pregnancy. Increasing the duration of this intervention may enable further positive effects to emerge. Due to the simplicity, safety and cost-effectiveness of using aromas in this context, care providers could promote the use of lavender aromatherapy during pregnancy for the amelioration of NVP and anxiety.

Declarations

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Conflicts of interest

The authors declared no conflicts of interest.

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Ethical approval

The study protocol was written in accordance with declaration of Helsinki and was approved by the Research Ethics Committee of TUMS, Tehran, Iran. Informed consent was obtained from all subjects. Participants were ensured of the

confidentiality of their information, and they were informed of their right to leave the study at any time without consequence and without giving a reason. All data were kept in a secured and locked personal file which was only accessed by the research team.

Code of Ethics

IR.TUMS.REC. 2478/130/92.

Use of Artificial Intelligence (AI)

No AI was used in all part of this research.

Authors' contribution

AA conceptualization, methodology, investigation, resources, validation, formal analysis, writing, original draft. MK conceptualization, methodology, investigation, resources, supervision, formal analysis, writing – review, and editing. SP writing, editing and interpretation. RB conceptualization, methodology, formulating and supplying the aromatherapy oils used in the study. AM formal analysis and SHJ conceptualization and critical appraisal. All authors read and approved the final manuscript and agreed to be accountable for all aspects of the work.

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