

Effectiveness of aromatherapy versus standard care on physiological and psychological symptoms in pregnant women: a systematic review protocol

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ABSTRACT

Objective: This review aims to evaluate the effectiveness of aromatherapy versus standard care on common physiological and psychological symptoms in low-risk pregnant women.

Introduction: Women report common symptoms that result from anatomical and physiological changes significant for fetal development and maternal-fetal protection during pregnancy. Aromatherapy is an integrative and complementary practice of ancient origin that works through the administration of essential oils. The practice is used to promote physical and psychological well-being.

Inclusion criteria: This systematic review will include studies on healthy pregnant women before labor who received aromatherapy as antenatal care for common physiological and psychological symptoms. Randomized clinical trials, quasi-experimental studies, cohort, and case-control studies will be included. This review will exclude studies that focus on women in labor unless data relating to pregnant women can be separated.

Methods: The searches will be carried out on the following databases: MEDLINE, Scopus, CINAHL, Web of Science, CENTRAL, PsycINFO, LILACS, BDNF, CUIDEN, and MOSAICO in Portuguese, English, and Spanish, with no date limit. The searches for unpublished studies will be carried out on the following repositories: ProQuest Dissertations and Theses, Brazilian Digital Library of Theses and Dissertations, British Library EThOS, and the Canadian Theses and Dissertation Portal. The JBI approach will be used for study selection, critical evaluation, data extraction, and synthesis.

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Keywords: antenatal care; aromatherapy; essential oils; pregnancy; pregnant women

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Introduction

Gestational development causes anatomical and physiological changes in women, which are essential for maternal-fetal development and protection, and women report symptoms in pregnancy resulting from this physiological gestational process.¹ During the first trimester, women commonly experience symptoms, such as nausea, vomiting, sialorrhea, fatigue, increased daytime urinary frequency, and breast tenderness, related to hormonal

regulation and systems adaptation. Symptoms are typically related to gastrointestinal system adaptations and increased uterine volume during the second and third trimesters. The most frequently reported symptoms in the later stages of pregnancy are heartburn, constipation, hemorrhoids, flatulence, edema, varicose veins, backache, tiredness, and Braxton Hicks contractions.^{1,2}

Approximately 85% of pregnant women consider common pregnancy symptoms significant complaints to be discussed in prenatal care with their physician or midwife. Prevalence of nausea is reported by 88% of pregnant women, while vomiting affects around 40% of women in the first trimester.³ Symptoms of vaginal bleeding, pelvic pain, or low back pain are also frequently reported from

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the beginning of pregnancy, with a prevalence that can vary between 20% and 65%.⁴

In addition to the reported physiological symptoms, gestational changes can affect women's mental health, especially regarding changes in self-image, social relationships, and the individual construction of the concept of motherhood. The symptoms of psychological origin can be considered relatively common, with 15% to 25% of women reporting significant depression, anxiety, or stress.^{1,5}

Many professionals who attend antenatal care disregard the physiological and psychological complaints of pregnant women or even promote intense medicalization of the symptoms. This is particularly common in developing countries. Between 1982 and 2008, the scientific literature reports an average increase of 62.5% in the prescription of drugs during the first trimester of pregnancy.⁶ The Complementary and Integrative Health Practices (CIHPs) emerged as a set of therapies based on natural principles aiming to reduce medicalization and other common interventions performed in conventional medicine during pregnancy care. The main CIHPs used to treat physiological and psychological symptoms during pregnancy are acupuncture, acupressure, moxibustion, yoga, herbal therapy, and aromatherapy.^{7,8}

Aromatherapy is a CIHP of ancient origin that involves the administration of essential oils or aromatic substances to promote physical and emotional well-being.^{7,8} The therapy systemically promotes relaxation because the molecules of the essences act on the limbic system. This system is directly connected to parts of the brain that influence functions such as heart rate, blood pressure, breathing, memory, and stress.⁸ In a more in-depth neuroendocrine evaluation, certain aromatic oils can decrease cortisol levels and increase the amount of serotonin present in the body—a mechanism responsible for promoting relaxation.⁸ Each essential oil has hundreds of chemical compounds with specific properties, resulting in different effects depending on the essence. There are oils more focused on relaxation of the system, with a better indication for treating psychological symptoms. At the same time, other essences have a more significant stimulating effect, promoting the health and physiological well-being of the person.⁹

There are several ways to administer essential oils, and the literature on routes of administration is

diverse. Many essential oils cannot be applied directly to the skin; thus, therapists usually apply them through baths, direct inhalation, or diluting them with vegetable oils and applying them during a massage.⁸⁻¹⁰ There is still no robust evidence on the safe use of aromatherapy in pregnant women; therefore, it should be administered cautiously, with a preference for the inhalation route or application to the skin in a well-diluted form. The direct intake of essential oils is not recommended.¹⁰

Aromatherapy has been considered an essential health intervention that strengthens the field of nursing and midwifery.⁷⁻⁹ In Brazil, midwives, and nurse-midwives have been adopting aromatherapy and other CIHPs in the care practiced at daily birthing centers. These centers are characterized by comprehensive care, using naturopathies, and a reduction in excessive medicalization.¹¹ Although research on the effectiveness of aromatherapy in maternal care has advanced, there is a lack of information synthesis to support available evidence-based practice. Some studies¹²⁻¹⁴ have shown that aromatherapy can be used during pregnancy to treat several pregnancy symptoms, which may vary according to the treatment's purpose.

A peppermint function randomized controlled trial (RCT)¹² conducted in a health center in Tehran, included 56 pregnant women of gestational age between six and 20 weeks and reporting mild to moderate nausea and vomiting. The results revealed that it was impossible to identify a significant difference when comparing essential oils and a placebo (sweet almond oil). In contrast, another RCT¹³ evaluated the effectiveness of lemon among 100 pregnant women in an Iranian health center and identified a significant reduction in the intensity of nausea and vomiting. This effect was mainly on the second and fourth day of the intervention when the women presented a reduction equal to or greater than 1 point on the 24-hour Pregnancy Unique Quantification of Emesis scale.¹⁴ Corroborating these findings, an RCT¹⁵ involving 60 pregnant Iranian women evaluated the use of essential mint oil on nausea and demonstrated a downward trend for women who used the essential oil. In contrast, those who used saline as a placebo showed an upward trend in nausea intensity.

Aromatherapy can also be indicated for other common physiological symptoms in pregnancy, based on some essential oils' antimicrobial,

analgesic, and antihistamine properties. Complaints such as headaches, urinary tract infections, allergies, hemorrhoids, insomnia, and edema can be managed through aromatherapy, using German chamomile and Immortelle essential oils. These are internationally recognized for their potent anti-inflammatory and healing properties, which can be used for the complementary treatment of mild symptoms, and in conjunction with the pharmacological treatment of more severe clinical conditions, like cystitis and allergies.^{9,11,12}

With the development of pregnancy, it is common for anxiety levels to increase and even manifest as depressive symptoms, and several studies^{5,8,9} have investigated the effectiveness of aromatherapy on pregnant women's psychological complaints. Likewise, a broad meta-analysis¹⁶ that evaluated 32 trials on aromatherapy in treating anxiety, regardless of the cause, showed that the use of different essential oils could significantly relieve general anxiety in adults. To date, the results on the use of aromatherapy in pregnant women have been quite promising from a psychological point of view, mainly related to the positive association with reducing symptoms such as stress and anxiety.

However, the conventional treatment for most of these gestational complaints occurs through pharmacological interventions. Therefore, conventional treatments will be considered as comparators with aromatherapy in this review.^{2,3,10} The excessive use of medications such as analgesics, antiemetics, and anxiolytics contributes to the medicalization of pregnancy and childbirth. Many of the interventions that have been used to support maternal and neonatal health, when misused, have resulted in more harm than benefit, such as the extensive use of routine cesarean section.¹⁷ There are many contraindications regarding the use of specific medications during pregnancy and, from this perspective, aromatherapy has advantages because it does not require invasive action and has no predicted side effects.^{1,8}

A preliminary search of PROSPERO, MEDLINE, the Cochrane Database of Systematic Reviews, *JB**Evidence Synthesis*, Campbell Collaboration, Carpha Database, and Epistemonikos platforms was conducted and identified two systematic reviews^{18,19} and two meta-analyses.^{20,21} However, these only investigated the effectiveness of aromatherapy in relieving pain and reducing anxiety in the intrapartum period. Another systematic review²² evaluated

the effectiveness of aromatherapy on postnatal conditions, such as healing of perineal trauma, breast-feeding, and psychological complaints. Therefore, no published or in-progress systematic reviews on the effectiveness of aromatherapy versus standard care on physiological and psychological symptoms in pregnant women were found.

Thus, there is a gap in the literature, with no synthesis of scientific evidence on all indications of essential oils and their implications for practice in antenatal care. The results of this systematic review protocol are likely to have implications for the field of midwifery. They will improve the care of pregnant women by synthesizing scientific evidence on physiological and psychological symptoms during pregnancy, identifying the potential effectiveness of aromatherapy on these symptoms, and the positive and negative aspects of its use.

Review questions

- i. What is the effectiveness of aromatherapy versus standard care in treating common physiological and psychological symptoms and complaints in low-risk pregnant women in all gestational trimesters?
- ii. What are the key findings related to the administration of aromatherapy during low-risk pregnancy with regards to the most used essential oils, most appropriate routes of administration, and main indications for use.
- iii. What are the main side effects or benefits of aromatherapy versus conventional care in treating common physiological and psychological symptoms in low-risk pregnant women during the whole pregnancy?

Inclusion criteria

Participants

This review will consider studies that include women with an uncomplicated early and late pregnancy. This is defined as single pregnancy of primigravida or multigravida women, with a healthy fetus and mother, without known comorbidities or risks beyond what is considered usual for a pregnancy.

This review will exclude studies that focus on women in labor unless data relating to pregnant women can be separated. In this context, pregnant women will only be included from the point of pregnancy diagnosis until the commencement of labor or cesarean surgery.

Intervention

This review will consider studies that evaluate the use of aromatherapy, with any essential oil, in any dosage, duration, or route of administration to relieve gestational symptoms and complaints. Consideration will be given to essential oils used in aromatherapy (eg, lavender, rose, salvia, geranium, frankincense, chamomile, orange, peppermint, jasmine, tangerine, and ylang-ylang).

Comparators

This review will consider studies that compare aromatherapy to any other intervention to treat physiological or psychological symptoms in pregnancy. Possible comparators may vary depending on the type of outcome studied. Comparators are considered the usual care provided in institutions where drug therapy (eg, painkillers, anxiolytics, or antiemetics), placebos (eg, water or saline), or other integrative and complementary practices (eg, acupuncture, acupressure, or moxibustion) are generally used. The choice of different types of comparators aims to expand the possibility of locating primary studies that evaluate the effectiveness of aromatherapy instead of other forms of treatment used for common physiological or psychological symptoms in pregnancy.

Outcomes

The primary outcomes of interest in this review are: physiological symptoms in pregnancy, such as gastrointestinal symptoms (heartburn, constipation, diarrhea), eating disorders (loss of appetite, nausea, vomiting), obstetric complaints (need to induce labor, Braxton Hicks contractions), sleep disorders (insomnia, drowsiness), or general complaints (backache, fatigue, edema, varicose veins, vertigo). These symptoms can be measured by counting the frequency, duration, and severity as well as through validated scales such as the Visual Analog Scale, the Pittsburgh Sleep Quality Index,²³ or the Pregnancy Unique Quantification of Emesis and Nausea Questionnaire.¹⁵

Secondary outcomes of interest are related to psychological symptoms, including mood, anxiety, stress, depression, and anguish. Such factors can be measured using validated and reliable instruments, such as the 21-item Depression, Anxiety and Stress Scale²⁴ and the State-Trait Anxiety Inventory.²⁵

This review also considers the time needed to treat symptoms with aromatherapy, adverse events using aromatherapy, and women's satisfaction with aromatherapy treatment. Studies do not need to measure all the variables cited or use only validated scales, but they must include at least one of the outcomes and categorize these variables quantitatively to be considered by this review.

Types of studies

This review will consider both experimental and quasi-experimental study designs, including RCTs, non-RCTs, before and after studies, and interrupted time-series studies. Analytical observational studies, including prospective and retrospective cohort studies and case-control studies, will also be considered for inclusion.

Methods

The proposed systematic review will be conducted using JBI methodology for systematic reviews of effectiveness.²⁶ The proposed review has been registered with PROSPERO (CRD42020218730).

Search strategy

The search strategy will aim to locate published and unpublished studies. Initially, a limited search was carried out in MEDLINE (PubMed) and CINAHL (EBSCO) to identify articles on the topic. The text words in the titles and abstracts of relevant articles and the index terms used to describe the articles were used to develop a complete search strategy. This strategy was applied to MEDLINE (PubMed), as shown in Appendix I. The reference lists of all potential articles selected for critical evaluation will be checked to identify additional relevant studies. Studies published in Portuguese, English, and Spanish will be included, and there will be no time limit.

The databases to be searched for published studies will include MEDLINE (via PubMed), Scopus, CINAHL (EBSCO), Web of Science, Cochrane Controlled Register of Trials (CENTRAL), PsycINFO (APA PsycNET), LILACS, BDENF, and MOSAICO. A detailed search strategy for MEDLINE (PubMed) is available in Appendix I. The search for unpublished studies and gray literature will be carried out through repositories such as ProQuest Dissertations and Theses, Brazilian Digital Library of Theses and

Dissertations, British Library EThOS, and the Canadian Theses and Dissertation Portal.

Duplications between the article and its original thesis/dissertation will be counted as one record. Gray literature will be accessed to check specific article items, but only published articles will be incorporated into the data collection and analysis process.

Study selection

Following the search, all identified citations will be collated and uploaded into EndNote v.X7 (Clarivate Analytics, PA, USA) and duplicates removed. Titles and abstracts will be analyzed by an independent reviewer (VM), who will evaluate the records according to the inclusion criteria defined in this protocol. Potentially relevant studies will be retrieved in full, and the citation details will be imported into the JBI System for the Unified Management, Assessment and Review of Information (JBI SUMARI; JBI, Adelaide, Australia).²⁷

The full text of selected citations will be assessed in detail against the inclusion criteria by two reviewers (VM and AC). Reasons for exclusion of full-text studies that do not meet the inclusion criteria will be recorded and reported in the systematic review. Any disagreements that arise at each stage of the study selection process will be resolved with a second reviewer (MR). The search, selection, and inclusion process results will be fully described in the final systematic review and presented in a Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) flow diagram.²⁸

Assessment of methodological quality

Two independent reviewers (VM and AC) will critically appraise eligible studies for methodological quality in the review using standardized critical appraisal instruments from JBI for RCTs, quasi-experimental studies, cohort studies, and case-control studies.²⁶ Authors of papers will be contacted to request missing or additional data for clarification, where required. Any disagreements between the reviewers will be resolved through discussion or with a third reviewer (MR). The risk of individual bias in the studies will be assessed using methodological instruments. All studies, regardless of the results of their methodological quality, will be reported in a table, accompanied by a narrative synthesis of the individual findings. This assessment will be taken

into account during the sensitivity analysis and in determining whether to conduct a meta-analysis of data.

Specific questions regarding performance bias in masking participants or those who performed the intervention will not be considered an indicator of low methodological quality, given the impossibility of the blind use of aromatherapy to compare other available treatments. Due to the limited amount of research expected on the topic, none of the studies will be excluded regardless of methodological quality or level of risk of bias. All studies will undergo data extraction and synthesis. To minimize the impact of individual study bias on the overall quality of the review, the degree to which the critical assessment results can affect data analysis will be explicitly mentioned. There will also be a narrative synthesis regarding the risk of individual bias and possible impacts on the systematic review.

Data extraction

Data will be extracted from studies included in the review by two reviewers (VM, AC) using the standardized JBI data extraction tool.²⁷ The data extracted will include specific details about the country, setting, participant characteristics, description of intervention and comparator groups, sample (essential oil used, administration route, dosage or dilution, time of use, follow-up period, standard care, and how outcomes were measured), outcomes measured, and main results. Any disagreements that arise will be resolved through discussion with a third reviewer (MR).

Data synthesis

Based on the analyzed outcomes, where possible, the synthesis of data on the effectiveness of aromatherapy will be pooled with statistical meta-analysis using JBI SUMARI.²⁷ Effect sizes will be expressed with final weighted or standardized mean differences. For post-intervention outcomes, continuous data and 95% confidence intervals will be calculated for the analysis. Heterogeneity will be assessed statistically using the standard χ^2 and I^2 tests. The appropriate insertion model, random or fixed effects, will be selected based on the recommendations of Tufanaru *et al.*²⁶ Sensitivity analyses will be carried out to test the decisions made on the effectiveness of aromatherapy concerning the outcomes. A funnel plot will be generated using RevMan v.5

(Copenhagen: The Nordic Cochrane Centre, Cochrane) to assess publication bias if 10 or more studies are included in a meta-analysis.²⁹ Statistical tests for funnel plot asymmetry (Egger test, Begg test, Harbord test) will be performed where appropriate. Where statistical pooling is not possible, the findings will be presented narratively, including tables and figures, to enhance data presentation.

The main essential oils, the indications for use, and the administration routes for aromatherapy in pregnant women will be synthesized using a summary table, with the findings based on the review results. Side effects and benefits reported on the use of aromatherapy will be presented in specific subsections, and will include a discussion of these results.

Assessing certainty in the findings

The Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach for grading the certainty of evidence will be followed,³⁰ and a Summary of Findings (SoF) will be created using the GRADEPro GDT software (McMaster University, ON, Canada). The SoF will present the following information, where appropriate: absolute risk for treatment and control, relative risk estimates, ranking of the quality of evidence based on the study limitations (risk of bias), inconsistency, inaccuracy, and publication bias. If sufficient data are available, outcomes reported in the SoF will include physiological and psychological symptoms (such as heartburn, constipation, diarrhea, loss of appetite, nausea, vomiting, backache, fatigue, edema, varicose veins, vertigo, need to induce labor, Braxton Hicks contractions, insomnia, drowsiness, mood, anxiety, stress, depression, and anguish). Any adverse events resulting from aromatherapy will also be reported.

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Appendix I: Search strategy

MEDLINE (PubMed)

Search conducted on December 3, 2020.

Search	Query	Records retrieved
#1	"Pregnancy"[MeSH Terms] OR "Pregnant Women"[MeSH Terms] OR "Prenatal Care"[MeSH Terms] OR "Pregnancy"[Title/Abstract] OR "Pregnant Women"[Title/Abstract] OR "Prenatal Care"[Title/Abstract] OR "Antenatal Care"[Title/Abstract] OR "pregnan*" [Title/Abstract]	1,030,100
#2	"Aromatherapy"[MeSH Terms] OR "oils, volatile"[MeSH Terms] OR ("oils, volatile/administration and dosage"[MeSH Terms] OR "oils, volatile/therapeutic use"[MeSH Terms]) OR ("Aromatherapy"[Title/Abstract] OR "Aroma Therapy"[Title/Abstract] OR "oils volatile"[Title/Abstract])	15,735
#3	#1 AND #2	188
Limited to English, Portuguese, and Spanish.		