

ESP

Evidence Synthesis Program

Aromatherapy and Essential Oils: A Map of the Evidence

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The review team developed the report's scope, study questions, and methodology in consultation with the Operational Partners (*ie*, topic nominators), the ESP Coordinating Center, and the technical expert panel (TEP). Broad expertise and perspectives were sought. Divergent and conflicting opinions are common and perceived as healthy scientific discourse. Therefore, in the end, study questions, design, methodologic approaches, and/or conclusions do not necessarily represent the views of individual technical and content experts.

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Operational Partners

Operational partners are system-level stakeholders who have requested the report to inform decision-making. They recommend TEP members; assure VA relevance; help develop and approve final project scope and timeframe for completion; provide feedback on draft report; and provide consultation on strategies for report dissemination.

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Technical Expert Panel (TEP)

To ensure robust, scientifically relevant work, the TEP guides topic refinement; provides input on key questions and eligibility criteria, advising on substantive issues or possibly overlooked areas of research; assures VA relevance; and provides feedback on work in progress.

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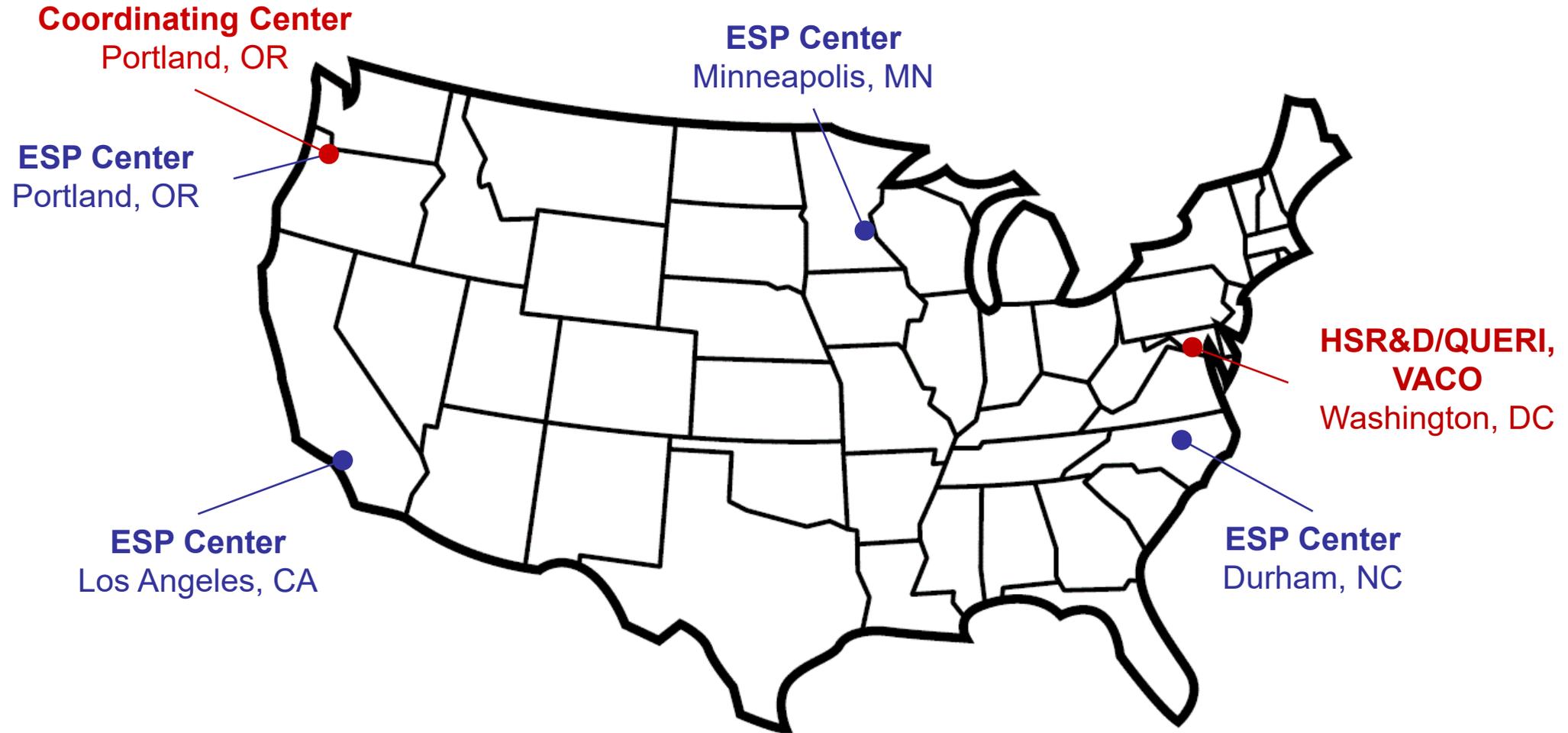
This report is based on research conducted by the Evidence Synthesis Program (ESP) Center located at the **Portland VA Health Care System, Portland, OR**, funded by the Department of Veterans Affairs, Veterans Health Administration, Health Services Research and Development. The findings and conclusions in this document are those of the author(s) who are responsible for its contents; the findings and conclusions do not necessarily represent the views of the Department of Veterans Affairs or the United States government. Therefore, no statement in this article should be construed as an official position of the Department of Veterans Affairs. No investigators have any affiliations or financial involvement (eg, employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties) that conflict with material presented in the report.

- Established in 2007
- Provides tailored, timely, and accurate evidence syntheses of VA-relevant, Veteran-focused healthcare topics. These reports help:
 - Develop clinical policies informed by evidence;
 - Implement effective services and support VA clinical practice guidelines and performance measures; and
 - Set the direction for future research to address gaps in clinical knowledge.
- Four ESP Centers across the US:
 - Directors are VA clinicians, recognized leaders in the field of evidence synthesis, and have close ties to the AHRQ Evidence-based Practice Center Program and Cochrane Collaboration
- ESP Coordinating Center in Portland:
 - Manages national program operations and interfaces with stakeholders
 - Produces rapid products to inform more urgent policy and program decisions

To ensure responsiveness to the needs of decision-makers, the program is governed by a Steering Committee comprised of health system leadership and researchers.

The program solicits nominations for review topics several times a year via the [program website](#).

ESP Center locations



- The IHCC is charged with developing and implementing CIH strategies in clinical activities, education, and research across the system.
- Its **two major functions** are to:
 - identify and remove barriers to providing CIH across the VHA system.
 - serve as a resource for clinical practices and education for both veterans and clinicians.



- CIH Directive – **SIGNED BY USH 5/19/2017**
http://vaww.va.gov/vhapublications/ViewPublication.asp?pub_ID=5401
- **LIST I: evidence of promising or potential benefit**
 - evidence of promising or potential benefit
 - vetted by IHCC Advisory Group
 - VA must provide a mechanism to offer these approaches either within VA facility or in the community
- **LIST II: generally considered safe**
 - General recognition of safety requires common knowledge, throughout the expert scientific community (both internal and external to VHA) knowledgeable about the safety of CIH approaches and the impact on Veterans' physical and mental well-being, that there is a reasonable certainty that the approach is not harmful under the conditions of its intended use.
 - Optional for inclusion in VA facility, depending on capability (staff/space) at sites

CIH Therapies approved to date

- Acupuncture
- Tai chi
- Yoga
- Meditation
- Massage therapy
- Guided imagery
- Hypnosis
- Biofeedback

Chiropractic included already by specific Congressional mandate

Whole Health
is an approach
to health care that
empowers and equips
people to take charge
of their health and well-being,
and live their life to the fullest.

Whole Health System



Aromatherapy and Essential Oils: A Map of the Evidence

September 2019

Full-length report available on ESP website:

<http://www.hsrd.research.va.gov/publications/esp/reports.cfm>

Poll question 1

In which settings do you use aromatherapy or topically applied essential oils in practice? Select all that apply:

- Palliative or hospice care
- Burn or wound care center
- Psychiatric or addiction services
- Cancer care, sleep center, or other outpatient setting
- None of the above

Poll question 2

In which settings do you use aromatherapy or topically applied essential oils in practice [continued]? Select all that apply:

- Emergency Department or intensive care unit
- Medical or surgical ward
- Perioperative area
- Waiting area
- None of the above

Essential Oils

- Essential oils (EOs) are part of a tradition of herbal medicine dating back thousands of years.
- EOs are volatile oils that contain the “essence” of a aromatic plants’ fragrance.
- There are various topical EO applications that are purported to be beneficial apart from their aromatic qualities (e.g., as antiseptics).
- The chemical components of some EOs have also been shown to inhibit microbial and fungal growth.

Aromatherapy

- The therapeutic inhalation of EOs, considered to have physiological and/or psychological benefits.
- Aromatherapy using EOs is thought to mediate emotional responses by affecting the neuroendocrine system and autonomic nervous systems.

Key question: What evidence is available that examines the effectiveness of aromatherapy or essential oils for health-related indications?

- In which health conditions/target populations have they been studied?
- Which formulations have been studied?
- What is the effect of the intervention in each health condition studied?
- What is the level of confidence in the evidence for that effect?

Pros

- Provide a broad (high-altitude) overview of the evidence on an intervention across diverse health conditions/target populations
- Can be useful for finding promising areas for treatment and prioritizing further research
- Based on methods established for systematic reviews (comprehensive literature search, assessment for risk of bias)

Cons

- Based on existing systematic reviews; evidence from recent trials not represented
- Broad brushstrokes about potential benefits; do not characterize magnitude of treatment effects
- Cannot be definitive in determining absence of evidence

PICOTS – scope parameters

Population	Included: Adults (18+) receiving an EO intervention for a targeted health condition or risk group. Excluded: Children and adolescents; healthy/non-elderly volunteers.
Interventions	Include: EO preparations that are inhaled or topically applied; massage with EO is included as an inhaled modality. Exclude: <ul style="list-style-type: none">• EO preparations that are ingested, consumed, or absorbed through oral and mucosal membranes.• EO preparations that combine EO with another drug or active ingredient.
Comparators	Inhaled-only EO interventions: No limits EO-massage interventions: Must include a massage-only comparator arm (using an inert/carrier oil)
Outcomes	<ul style="list-style-type: none">• Psychological symptoms• Physical outcomes• Global outcomes including quality of life, activities of daily living, mobility, social functioning, employment• Harms
Timing	Any duration of treatment and follow-up.
Study design	Included: Systematic reviews and meta-analyses that include randomized or non-randomized controlled trials. Excluded: Non-systematic reviews, reviews of reviews, and primary studies.

Literature search and data sources

- Search strategy developed by a research librarian and peer reviewed by a 2nd research librarian
- Multiple databases searched through February 2019
- Suggestions from technical experts about potentially relevant reports
- Reviewed bibliographies for additional studies
- Search yield was dual-reviewed for potentially relevant publications

- **Study selection**
 - Systematic reviews (SRs)/meta-analyses that included randomized controlled trials (RCTs) of aromatherapy or topical EOs
 - Study populations defined by specific health indications, risk factors, or targeted settings (e.g., healthcare waiting spaces)
- **Criteria for potentially eligible SRs**
 - 1) Provided a reproducible search strategy and inclusion criteria
 - 2) Conducted a comprehensive search (at least 2 electronic databases)
 - 3) Assessed potential risk of bias of included trials
- **Selection of SRs for evidence maps**
 - We selected a single SR to represent each population
 - If multiple SRs included for a population: selection based on recentness of search strategy, methodological quality, size of the evidence (scope), and applicability

Data abstraction

- Characteristics of the populations studied, EO interventions, number of studies, sample size, and findings.
- 6 categories of outcome data: psychological symptoms, nausea/vomiting, pain and other physical outcomes, global outcomes (e.g. functional status, quality of life), sleep quality, and adverse effects.

Risk of bias assessment

- To qualify for inclusion in our evidence map, SRs had to have assessed the methodological quality of clinical trials using a standardized instrument.
- We took the adjudications conducted by SR authors at face value, and used their ratings in assessing the overall body of evidence.

Effects of the intervention

We classified the evidence of effectiveness into 4 categories:

- 1) **No effect:** a preponderance of null or negative findings.
- 2) **Unclear:**
 - Mixed findings for a single outcome with no preponderance of either benefit or negative effects, or
 - The number of studies, sample sizes, and/or the methodological quality of the studies were insufficient to form a conclusion about effectiveness.
- 3) **Potential positive effect:**
 - Mixed findings for a single outcome that include some evidence of benefit, or
 - Multiple outcomes within the same category with at least 1 clear finding of benefit.
- 4) **Positive effect:**
 - Numerous studies with a preponderance of positive findings, or
 - A large, methodologically sound trial showing a positive effect.

Assessing level of confidence

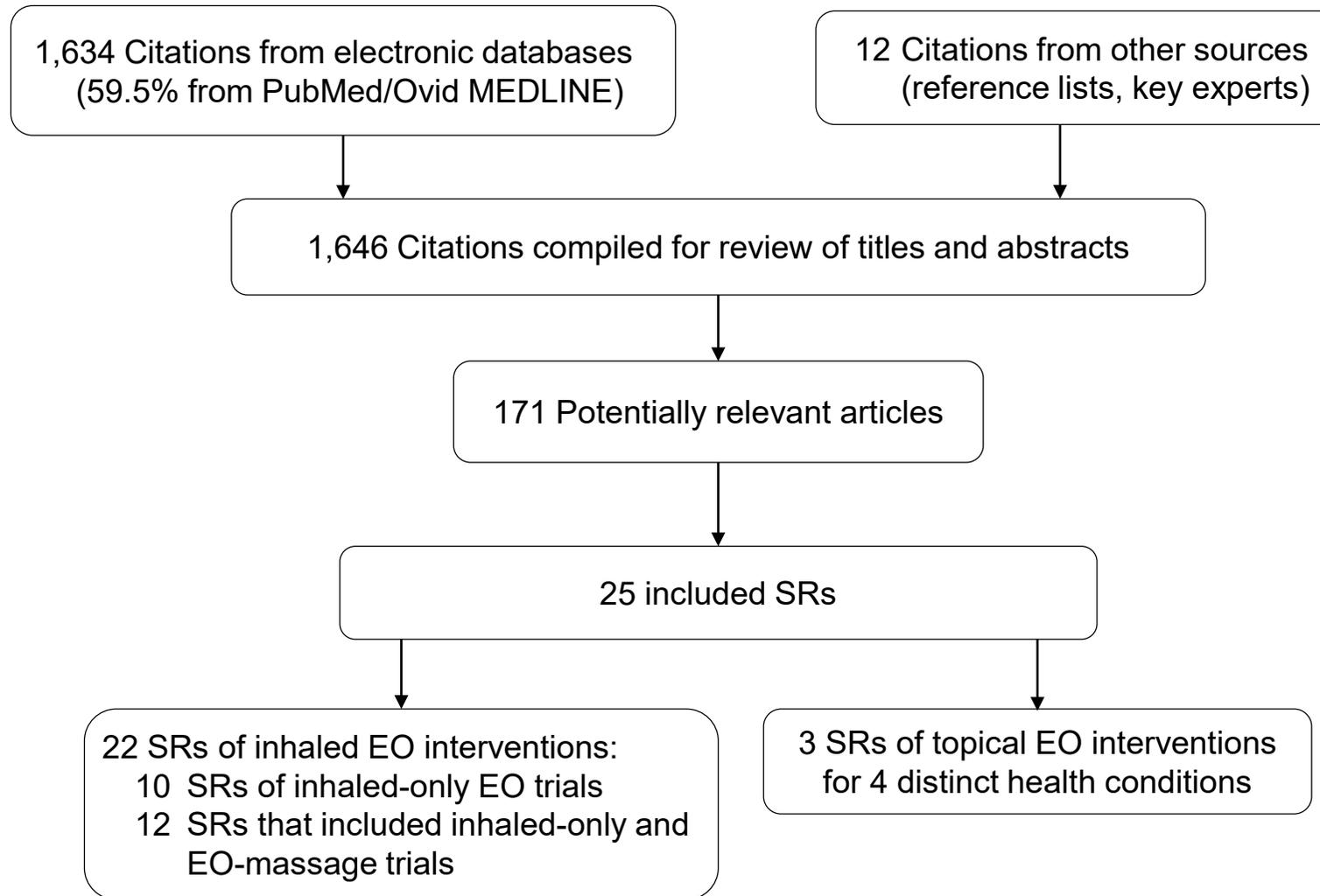
Domain: range of points	Description
Sample Size: 1 to 3	1: N ≤ 100 2: N = 100-500 3: N = 500+
Consistency: -1 or 0	0 = No major flaw, -1 = Serious inconsistency
Directness: -1 to 0	0 = No major flaw -1 = Limited applicability
Overall ROB/study quality: -1 or 0	0 = Unclear or low ROB -1 = High ROB (poor quality)

The sum of points from each domain was used to classify level of confidence into 4 categories:

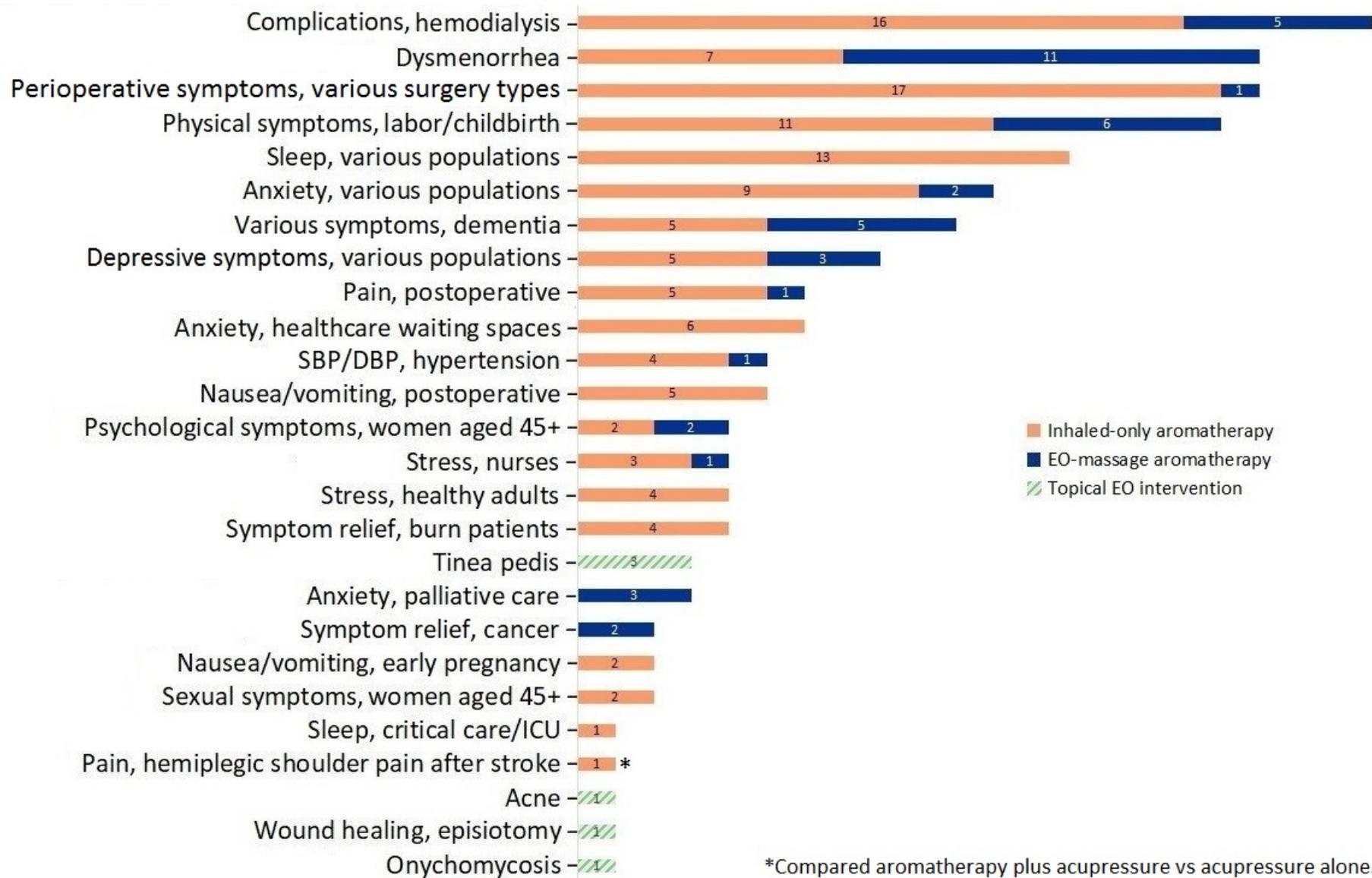
- (3) High: Consistent findings from larger studies with low risk of bias.
- (2) Moderate: Larger studies that may have limitations in study quality, applicability, or consistency of findings.
- (1) Low: Small sample size, or major deficiencies in the body of evidence.
- (≤0) Insufficient: The body of evidence has unacceptable deficiencies.

For the evidence maps, we grouped together Unclear effect with Insufficient confidence.

Results – literature flow



RESULTS - Number of trials for targeted health conditions/ populations, by treatment modality

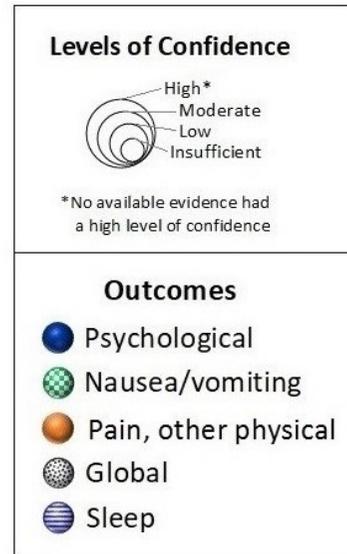


*Compared aromatherapy plus acupressure vs acupressure alone.

Results - Evidence Map

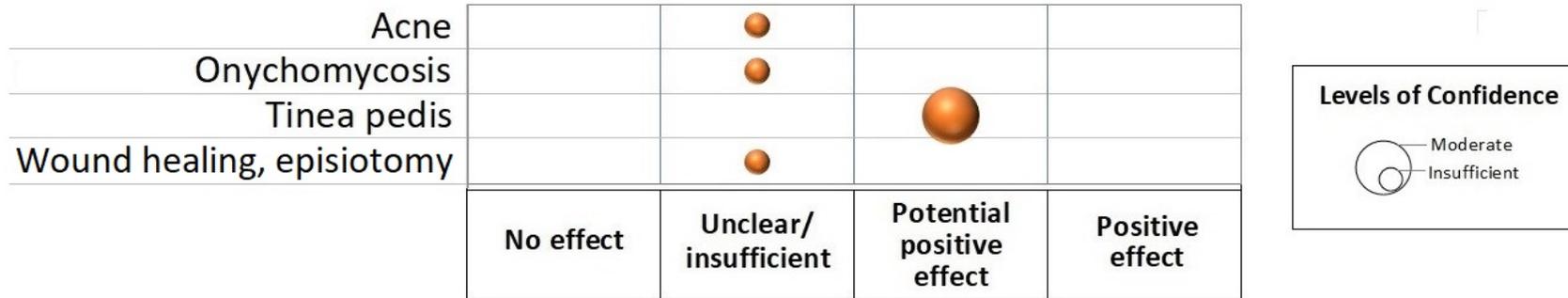
Map of the evidence from systematic reviews of inhaled essential oils for targeted health conditions/populations

Anxiety, healthcare waiting spaces		●		
Anxiety, palliative care	●			
Anxiety, various populations		●		
Complications, hemodialysis		● ●	● ●	
Depressive symptoms, various populations		●		
Dysmenorrhea				●
Nausea/vomiting, postoperative			●	
Nausea/vomiting, early pregnancy		● ●		
Pain, hemiplegic shoulder pain after stroke		●		
Pain, postoperative		●		
Perioperative symptoms, various surgery types		● ●	● ●	
Physical symptoms, labor/childbirth			● ●	
Psychological symptoms, women aged 45+		●		
SBP/DBP, hypertension			●	
Sexual symptoms, women aged 45+		●		
Sleep, critical care/ICU			●	
Sleep, various populations			●	
Stress, healthy adults			●	
Stress, nurses		●		
Symptom relief, burn patients		● ● ●		
Symptom relief, cancer		● ● ●		
Various symptoms, dementia		● ●		
	No effect	Unclear/ insufficient	Potential positive effect	Positive effect



- Method of application varied widely
- SRs of aromatherapy frequently included trials of aromatherapy-massage, which may involve direct dermal exposure through the addition of EO to massage lotion or oil, or may be diffused in the room during massage.
- **Dysmenorrhea** - beneficial for pain (moderate-confidence evidence)
- **Pain in labor/childbirth** - potential benefit for (moderate-confidence evidence)
- **Hypertension** - potential benefit for BP reduction (low-confidence evidence)
- **Sleep quality** – potential positive effects in various populations (low-confidence evidence)
- **Anxiety in palliative care** – no effect (moderate-confidence evidence)
- **Nausea/vomiting** – unclear effectiveness

Map of the evidence from systematic reviews of topically applied essential oils for targeted health conditions



Note: Only physical outcomes were reported, and no evidence reached a high level of confidence

- There is moderate-confidence evidence of the potential effectiveness of tea tree oil for tinea pedis.
- The effectiveness of topical EOs is unclear for onychomycosis, acne, and episiotomy wound healing.

- The level of confidence for the majority of outcomes and health conditions was low or insufficient. Few trials/small combined sample sizes and methodological limitations in trials were the most common contributing factors.
- Many trials failed to report quantitative measures, used inadequate placebos, or lacked standardized procedures.
 - Aromatherapy may not lend itself well to standardization in the trial setting, because usual practice involves a great degree of personalization of dosage, dilution, and scent.
- Systematic review-level limitations
 - Several SRs did not report effect sizes or p-values, stating only the presence or absence of a treatment effect, and whether the finding of difference was statistically significant.
 - We relied on the reporting of the systematic reviews; therefore, it is possible that primary trials included in these SRs reported more detailed analyses, but this would not have been reflected in our report.

- Based on existing systematic reviews; did not search for more recently published trials.
- Not definitive in identifying absence of evidence. Existing evidence from aromatherapy/EO trials is not represented in the evidence map if:
 - no prior SR has reviewed them, or
 - a SR was conducted, but did not meet our minimum quality criteria.
- We relied on the assessments of study quality made by the authors of the systematic reviews.
- Our measure for level of confidence in the evidence is approximate; not equivalent to the more rigorous standards for determining strength of evidence.

- The evidence map highlights many potential areas for future research
- The interventions and health conditions for which there was evidence of a “potential positive effect”
- The comparative effectiveness of different, standardized aromatherapeutic approaches should be examined
- Future studies should capture potential adverse effects data, and the safety of aromatherapy should be examined in patients with comorbidities, particularly those of the respiratory tract.
- The use of a non-EO fragrance comparator to EO aromatherapy would improve blinding and allow better comparison of effects and harms.

Aromatherapy

There is moderate confidence that aromatherapy is effective for pain in dysmenorrhea (menstrual cramps).

We found *potential* positive effects (with low to moderate confidence in the evidence) of aromatherapy for:

- Pain in labor/childbirth
- Blood pressure reduction in those with hypertension
- Stress, depression, and sleep in patients on hemodialysis
- Stress in healthy adults
- Anxiety in perioperative patients undergoing various types of surgery
- Sleep quality in various populations

Topical EOs

There is moderate confidence in the *potentially* positive effect of tea tree oil for tinea pedis.

If you have further questions, please feel free to contact:

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Full-length report and cyberseminar available on ESP website:

<http://www.hsrd.research.va.gov/publications/esp/>

- Aromatherapy is on the list of OPTIONAL CIH approaches that are Generally Considered Safe when delivered as intended by an appropriately trained or credentialed practitioner or instructor, and may be made available to enrolled Veterans, within the limits of VA medical facilities. These optional, List 2, approaches are not considered a required part of the standard medical benefits package.
- It is key that facilities know that aromatherapy *is not to be used for treatment*. Joint Commission released a statement regarding the use of essential oils and that they are not to be used for treatment, otherwise they would have to follow joint commission medication management guidelines.
- Current recommendation in VA is that aromatherapy is provided with local policies and procedures and only for wellbeing, not for treatment of specific conditions. So more for relaxation and healing environments.
- Similar to any CIH approach, providers should have completed training in aromatherapy , ideally as an aromatherapist, in order to deliver this aromatherapy safely.
- Beth Abele, RN from Chillicothe has developed an internal aromatherapy training which she has been offering locally.
 - Course Overview: *This level 1 Aromatherapist certification class consists of 14 hours of hands on learning. This certification class is for current health professionals (Massage Therapists, Nurses, Recreation Therapists, Physicians, etc.) who have already taken Anatomy & Physiology from an accredited institution. After this course participants will have a well-rounded foundation of knowledge of the practices and philosophies of integrating holistic aromatherapy into their practice. Including evidence-based studies, introduction to the history of Aromatherapy, profiles of 25 essential oils, essential oil effects, quality, and blending.*
- Some sites use aromatabs to avoid potential issues with diffusers
- IHCC has been compiling facility examples of policies and SOPs related to aromatherapy and housing them on our internal VA facing IHCC SharePoint: <https://dvagov.sharepoint.com/sites/VHAOPCC/sitePages/IHCC-home.aspx>
 - If you have items you would like to have posted related to aromatherapy please email IHCC Team at: vhaopcctintegrativehealth@va.gov
- IHCC will be forming an Aromatherapy listserv that folks can join who are interested in connecting with others who have completed aromatherapy training or are implementing at their facilities. Email Lana Frankenfield to be added to the list once the listserv is created. Lana.frankenfield@va.gov
- Additional questions can be sent to the IHCC Team at: vhaopcctintegrativehealth@va.gov