TREATS EXPLANATORY STATEMENT

Note: The primary purpose of the TREATS Critique Checklist is to promote complete reporting of the aromatic and essential oil components of all types of studies. Thorough reporting facilitates study replication and progression of programs of research. The TREATS Explanatory Statement document is designed to provide some basic elaboration for the critique items in the tool. It is by no means exhaustive in examples.

Explanation and Elaboration for Item in TREATS

TREATS Section 1: Essential oil questions The scope of the TREATS project is to address clear identification of which essential oil(s) were used and is not intended to redefine or replace formally recognized industry standards and Pharmacopoeias that offer clarity and historical grounding regarding essential oils.
Please refer to the ISO (International Organization for Standardization) and AFNOR (Association Française de Normalisation [AFNOR, English: French Standardization Association]) https://www.afnor.org/en/ and the *European Pharmacopoeia* regarding essential oil https://pheur.edqm.eu/home definitions and to Heinrich et al., 2022 for more about herbal extractions and methods.[1]

1	**Essential Oil (EO) Name**
	Essential oil (EO) name, including full binomial, also known as the botanical or scientific name, provided in Latin which provides identification of genus, species, and chemotype if applicable – noted by chemotype (ct) or variant (var.). Chemotypes indicate the EO differs intraspecies in chemical components, possibly resulting in different therapeutic properties. Binomial names can be abbreviated. Using the common name e.g., lavender, for an essential oil does not give adequate information. Chemical properties of EOs vary with species, and chemotype, resulting in varied therapeutic properties, e.g., lavender - *Lavandula angustifolia* may be effective for relaxation while *Lavandula latifoli*a is more stimulating. The classification for botanicals is established by the International Code of Botanical Nomenclature. Kingdom (plant) is the largest unit of the hierarchy for example: Kingdom, Division, Subdivision, Class, Order, Family, etc.
	Examples "This experiment used two kinds of aroma stimulation: lavender *(Lavandula angustifolia).*"[2] "The essential oils of four chemotypes of *Thymus vulgaris* L. (Lamiaceae) were analyzed for their composition and antibacterial activity to assess their different properties. GC-MS and GC-FID analyses revealed that the essentials oils can be classified into the chemotypes thymol (41.0% thymol), geraniol (26.4% geraniol), linalool (72.5% linalool) and 4-thujanol/terpinen-4-ol (42.2% *cis*- and 7.3% *trans*-sabinene hydrate, 6.5 % terpinen-4-ol)."[3]

"Plants of *Matricaria recutita* L. were collected in the wild at Montesinho Natural Park, during the flowering stage (July-August). Plants of *Lavandula angustifolia* Mill were collected in the gardens and greenhouses of Agrarian School of Bragança, between June and July."[4]

"We carried out a multi-centre double-blind parallel group placebo-controlled randomized trial comparing the effects of an essential oil of *M. officinalis* L. (synonyms: melissa, lemon balm) selected on the basis of traditional use, as well as chemical and pharmacological profiles consistent with reducing agitation (e.g., serotonergic, ion channel and y-aminobutyric acid receptor activities) versus medication in the treatment of agitation in people with Alzheimer's disease."[2]

2 **Production Method**

Production method influences the final composition of the EO or aromatic product used in aromatherapy. Production methods include steam distillation, carbon dioxide extraction, solvent extraction, and cold-pressed extraction such as extracting essential oils from citrus peel. The EO/ aromatic product will have different chemical components, depending on the production method.

Since there is no universally accepted definition of aromatherapy that limits the type of material that can be used to only essential oils, guidelines for describing extracts in the literature may be found in Heinrich et al., 2022.[1]

Examples
"Essential oil was obtained from these chips by steam distillation."[5]

Bergamot (*Citrus bergamia*) EO, most commonly obtained via cold expression contains chemical properties rendering it phototoxic to the skin, whereas distilled bergamot does not.

3 **Plant Part**

Plant part from which the essential oil is extracted is documented. Some plants produce more than one type of essential oil, e.g., EOs from the *Citrus aurantium* plant can be obtained from the fruit peel (bitter orange), leaf/twig (petitgrain), and blossoms (neroli), all with different chemical properties.

Example
"Neroli oil is extracted from the *Citrus aurantium* L. blossoms, commonly named bitter orange, which is a tree belonging to the Rutaceae family."[6]

4 **Cultivation Method**

Providing details about cultivation methods (including post-harvesting practices) such as sustainable farming or wild harvesting methods for the plants which produced the EOs allows for greater understanding of the materials being used. Harvesting and drying practices may be considered. Due to varied cultivation methods and locations for growing (i.e., mountains, sea level), plants' essential oils may have varying chemical components which may impact replication of studies.

Example
"Plants of *Lavandula angustifolia* Mill were collected in the gardens and greenhouses of Agrarian School of Bragança, between June and July."[7]

"The data obtained clearly revealed the presence of chemical variety within the accessions of *G. hederacea* and indicated the chemical compositions were different between harvesting periods. From the point of view of commercial cultivation and based on the different chemical compositions of the flowering and vegetative shoots of *G. hederacea*, the most suitable harvesting time for polyphenolic compounds is the flowering phase, while for essential oils, it is the vegetative phase."[8]

"The study was conducted in western Himalayan conditions to assess the essential oil content and composition of two Lavandula species viz., lavender (Lavandula angustifolia Mill.), and lavandin (Lavandula × intermedia Emeric ex Loisel), at four different drying duration (0 h, 24 h, 48 h and 72 h after the harvest). The higher growth attributes viz., plant height (71.7 cm), ear length (8.8 cm), number of spikes (18.1), and number of flowers per ear (47.5) were higher in lavandin, while the number of branches (17.1) was higher in lavender. Essential oil content (%) and moisture reduction (%) were significantly higher at 72 h than at 0 h. The major components of lavender and lavandin essential oil were linalool (33.6–40.5%), linalyl acetate (10.8–13.6%), lavandulyl acetate (2.8–14.5%), and linalyl propionate (5.3–14.1%) in both the Lavandula species. There was a decreasing trend in linalool and an increasing trend in linalyl acetate content in lavandin, with an increase in drying duration up to 72 h; while in lavender, no regular trend was observed in linalool and linalyl acetate content."[7]

5 **Country of Origin**

Country of origin, or geographical location within a country, where the EO plant material was grown and harvested is identified. EOs produced from the same plant species grown in different countries can have different chemical composition and quality due to climate, elevation, soil type, genetic factors, and others.[9]

Examples
"Plants of *Matricaria recutita* L. were collected in the wild at Montesinho Natural Park, during the flowering stage (July-August)."[10]

"We used Japanese cedar from Kitayama (Kyoto, Japan) as the experimental material."[5]

6 **Source**

Source documentation supports determination of where the EO is manufactured. The source differs from where the EO is distributed. The manufacturer of the EO is clearly stated. A distributor will place their own marketing and label on the product.

Example
"The peppermint and lavender essential oils, with 100% concentrations, were purchased from Zardband Pharmaceuticals Company (Yasouj, Iran). The plants had been harvested from the pastures of Yasouj, Iran."[11]

"Melissa essential oil was obtained from a commercial supplier (Baldwin's, London, England) that was able to guarantee the authenticity and purity of the source through the original suppliers."[12]

7 **Batch or Lot Number**

Batch or lot number is a unique number provided by the supplier that will allow the EO to be traced back through its journey from plant to bottle and provide authenticity to the EO. The batch number can support the replication of the study. Note: This section is specific to EOs purchased from suppliers and does not pertain to researchers who distill their own plant material in the lab.

Examples

"BEO (Lot: LF1481211) was produced from original Italian bergamot fruits and obtained via Laboratoire Sanoflore (Renens, Switzerland)." BEO stands for Bergamot essential oil.[12]

"Plants of *Matricaria recutita* L. were collected in the wild at Montesinho Natural Park, during the flowering stage (July-August). Plants of *Lavandula angustifolia* Mill were collected in the gardens and greenhouses of Agrarian School of Bragança... The extraction of essential oils by hydro distillation was performed using a Clevenger apparatus, for 3 h, according to the European Pharmacopoeia [14], with yield determination (v/fresh weight). The essential oils were stored at -20°C in the dark. From each essential oil, a small amount was used for the GC and GC-MS analyses and the remainder was used to prepare the mixtures for further use in the aromatherapy assays."[4]

8 **Identification of Plant Chemical Constituents of EO**

Identification of plant chemical constituents of EO allows comparison between studies of the same EO. Major or complete EO constituent percentages (chemical analysis) should be listed in the study or as an attached link. Chemical analysis most often used is gas chromatography and mass spectrometry (GC-MS)*, which identifies the quality of the essential oil being studied. GC-MS also screens for any adulterations.

*Unlike herbal extracts, the narrower focus of aromatherapy in choices of active materials allows greater simplicity in definition of validation of sources and supply chains so that GC techniques will be used in all but some notable exceptions such as bergapten, vanillin, piperine, gingerol, which require LC (liquid chromatography) techniques, for example. For more about analysis methods in herbal extracts see Heinrich et al., 2022.[1]

Example

"BEO (Bergamot essential oil)* was characterized at the laboratory of Sanoflore using a Hewlett Packard GC-MS instrument with combined mass spectrometric and flame ionization detectors… Helium was chosen as vector gas and applied with a pressure of 23 psi. This measurement revealed the tested brand of BEO to be composed of 45.45% limonene, 23.10% linalyl acetate, 8.05% γ-terpinene, 7.25% β-pinene, 6.50% linalool, 1.35% α-pinene, and 0.35% geranial (a huge variety of unidentified minor compounds constitute the remaining 7.95%)."[13]

*NOTE: The above study uses BEO via inhalation only. For studies using essential oils such as bergamot that have bergapten and have potential phototoxic implications, HPLC (High-performance Liquid Chromatography) is recommended per ISO standards (https://www.iso.org/obp/ui/en/#iso:std:iso:7358:ed-2:v1:en)

TREATS Section 2a: Topical Application (If inhalation application only, skip this section)

1 **Dilution of EO (if applicable)**

Dilution of EO is provided by listing the volume or weight per volume and includes the name of the diluent, such as, but not limited to the following examples:

a. A 3% dilution of *Lavandula angustifolia* EO and cold-pressed sweet almond oil
b. Lavender was used at a dilution of 1 ml per 100 ml almond oil (v/v)
c. If the volume is reported as drops (gtts) per volume (ml or ounce) – **partial credit is given (**dropper sizes vary greatly making it difficult to duplicate the research with the accurate volume of EO used)

This is important because of safety and the ability to replicate the study. This information is provided by listing the volume or weight per volume and including the name of the diluent.

Example
"A nursing staff member then massaged 1 ml of either the lavender or control oil into both forearms for one minute each, giving a total of 2 mls per session. Since lavender plasma levels peak after 20 minutes, and are barely detectable after 90 minutes, participants were observed for 30 minutes before and 60 minutes after application."[14]

2 **Dose of EO**

Dose refers to the specified amount of essential oil given at one time, such as, but not limited to the following examples:

a. 5 mls lavender essential oil, 2% almond oil dilution
b. 0.25ml dose of the 1% EO infused cream
c. If the dose is reported as drops (gtt) per volume (ml or ounce) - **partial credit is given**

This is important because research criteria should be clearly defined to ensure safety within the study. Accurate dosage allows the study to be replicated and verified.

Example
"A nursing staff member then massaged 1 ml of either the lavender or control oil into both forearms for one minute each, giving a total of 2 mls per session. Since lavender plasma levels peak after 20 minutes, and are barely detectable after 90 minutes, participants were observed for 30 minutes before and 60 minutes after application."[14]

3	**Body surface area EO contacts**
	This is for safety purposes, and to help replicate the study, and how body parts may respond to treatment. Following are examples: a. 10 ml of a 2% v/v blend of lavender EO in sweet almond oil was applied to the entire surface of the back, neck, and shoulders b. 2 ml of a 1% v/v blend of rose EO in jojoba oil was applied to the forehead and temples of the face
	Example "A nursing staff member then massaged 1 ml of either the lavender or control oil into both forearms for one minute each, giving a total of 2 mls per session. Since lavender plasma levels peak after 20 minutes, and are barely detectable after 90 minutes, participants were observed for 30 minutes before and 60 minutes after application."[14]
4	**Frequency of EO**
	The frequency of the EO dose is provided. How often? Once a day, twice a day, every so many hours? Dosage regimen is frequency plus duration. This ensures safety and quality replication of study.
	Example "To capture any cumulative effects, each of the two experimental conditions comprised three exposures over a one-week period with a four-day washout period between them. Treatments were administered at times when nursing staff reported that the selected physically agitated behaviour was most likely to be present, excluding times of personal nursing care."[14]
5	**Duration of EO**
	The duration of the EO treatment is described. How many days, weeks, or months? How long were participants studied? Dosage regimen is frequency plus duration. This is important for the safety and reproducibility of the study.
	Example "To capture any cumulative effects, each of the two experimental conditions comprised three exposures over a one-week period with a four-day washout period between them. Treatments were administered at times when nursing staff reported that the selected physically agitated behaviour was most likely to be present, excluding times of personal nursing care."[14] "The complete treatment of the two groups consisted of 14 sessions (once a week) of 30 minutes each. The levels of stress and anxiety of the participants were assessed before and after treatment, in the two groups."[4]
6	**Description of control or placebo**

This is important for identifying other factors within the study, safety, and control measures. Following are examples:

a. Usual treatment (no control intervention)
b. Carrier oil (jojoba, almond oil, etc.)
c. Another essential oil
d. A specific fragrance
e. An "attention control" (non-equivalent alternative activity)

Example
"" Aroma group" received a treatment with a mixture of the two essential oils (*Lavandula angustifolia* Mill and *Matricaria recutita* L; 60:40 v/v) using sweet almond oil as vector and Effleurage massage, while for "control group" only Effleurage massage with sweet almond oil, an odorless oil, was applied. The complete treatment of the two groups consisted of 14 sessions (once a week) of 30 minutes each. The levels of stress and anxiety of the participants were assessed before and after treatment, in the two groups."[4]

7 **Carrier(s) name, including full binomial**

Carrier(s) including the name and binomial (Latin) is provided. If a diffuser is used, the type of water is provided. **Partial credit** is given if the common name is used without the binomial name. While carrier oils are not necessary for inhalation purposes, they are used to dilute the essential oil in some situations. N/A is used if no carrier is used. Following are examples:

a. Almond oil: *Prunus amygdalus* var. *dulcis*
b. Jojoba oil: *Simmondsia chinensis*

This is important for understanding other variables that may affect outcomes, as well as contributing to reproducibility.

Example
"'Aroma group' received a treatment with a mixture of the two essential oils (*Lavandula angustifolia* Mill and *Matricaria recutita* L; 60:40 v/v) using sweet almond oil as vector and Effleurage massage, while for "control group" only Effleurage massage with sweet almond oil, an odorless oil, was applied. The complete treatment of the two groups consisted of 14 sessions (once a week) of 30 minutes each. The levels of stress and anxiety of the participants were assessed before and after treatment, in the two groups."[4]

While the referenced article above does identify the carrier, it did not include the carrier Latin binomial, e.g., *Prunus amygdalus* var. *dulcis or Simmondsia chinensis*.

8 **Source of carrier or delivery system**

Manufacturing differs among distributors. Was the manufacturer of the carrier oil clearly stated? A distributor will place their own marketing and label on the product. A supplier may be a warehouse that holds carrier oils on behalf of the distributor to sell, such as large marketplace companies. Examples (false names used to create examples):

a. John Doe's Almond Oil Factory (manufacturer)
b. The Essential Oil Warehouse (supplier)
c. Happy Farm Aromatherapy Company (distributor)

This is important for understanding the quality of material used, reproducibility, and safety.

Example:

"Jojoba *(Simmondsia chinensis);* Country of origin*:* United States; Lot number JC371216JD; Plant parts utilized: seeds; Method of extraction: expeller pressed; Quality testing: various testing; Testing conducted by: Jojoba Valley, Israel; Distributed by: The Jojoba Company."[15]

TREATS Section 2b: Inhalation – Complete only if inhalation delivery method used

1 **Mode of inhalation**

(e.g., direct-personal inhaler, aroma stick, sniff stick, cotton ball, patch. Indirect-ambient, diffusion) Following are examples:

a. Direct (personal inhaler, aroma stick, sniff stick, cotton ball, patch)
b. Indirect (ambient, diffusion)

This is important to identify the way in which EO was administered and allows for quality replication.

Example
" All subjects in the experimental (IPA) group received inhalation therapy using a commercially available 70% IPA pad. All subjects were instructed to remove the IPA pad from the protective covering, fold the IPA pad in half, and take 3 deep inhalations from the pad."[15] "Airflow from the diffuser was set at 1.3m per minute and placed near the subject's nostrils using the diffuser's 30cm long circular cylinder."[10]

2 **Dose of EO**

Total Dosage of EO given to participants is provided. Total volume is specified: (e.g., mls, %, drops (gtt) per volume (ml or oz.)? For direct inhalation, the approximate distance of the inhaler device from the nose is described; for diffusion, the approximate distance of the diffuser from the participant, and the room size is provided **Partial credit is given if identified by drops (gtts) and not milliliters (mls). Partial credit is given if the distance is not specified.** Examples are not limited to the following:

a. 0.25 ml *Lavandula angustifolia* placed in a personal inhaler stick and held 3 inches from the nares for 5 seconds (Full credit- due to dose, distance, and duration listed)
b. 0.5 ml *Lavandula angustifolia* placed on 2x2 felt pad attached to shirt collar (Partial credit due to measurement difficult to replicate)
c. 2 drops of *Lavandula angustifolia* were placed on the cotton ball; the patient was instructed to gently move back and forth approximately 6 inches from the nose (Partial credit due to drops listed)

Dose refers to the specified amount of essential oil given at one time to understand safety and to allow for consistent reproducibility in future studies. To help understand the inhaled concentration of the EO, the distance from the participant to the device (length) is included. For indirect diffusion, the room size (length, width, and height) is also included to determine the environmental concentration of the EO.

Example
"In the RWB setup, bergamot essential oil (BEO) was applied by giving 400ul of BEO into the 400ml tank of the [*diffusor*], dispersing it in the air together with the water. This dosage of BEO was determined on the basis of previous preliminary test results."[13]

3 **Frequency of EO**

Is the frequency of the dose provided? How often? Once a day, twice a day, or every so many hours? Dosage regimen is frequency plus duration. This ensures safety and quality replication of study.

Example
"The complete treatment of the two groups consisted of fourteen sessions (once a week) of thirty minutes each."[4]

4 **Duration of EO**

The duration of the treatment is described. How many days, weeks, or months? How long were participants studied? Dosage regimen is frequency plus duration. Ensuring accurate reporting allows for quality replication of study.

Example
"In the aromatherapy groups using peppermint and lavender essential oils, three drops of each essential oil were smeared on a napkin, which was attached to a collar for 20min at 9:00pm. The same procedure was applied for the control group using three drops of aromatic distilled water. The duration of the intervention was seven nights…."[11]

5 **Description of control or placebo**

Is the control or placebo provided? If yes, what intervention is used (e.g., no control intervention, carrier oil, another essential oil, specific fragrance, "attention control")? Examples are not limited to the following:

a. Usual treatment (no control intervention)
b. Carrier oil (jojoba, almond oil, etc.)
c. Another essential oil
d. A specific fragrance
e. Distilled water
f. An "attention control" (non-equivalent alternative activity)

Understanding the specific type of placebo is important to identify other contributing factors within the study and gain a better understanding of control measures used.

Example
"For this study, we used 100% pure bergamot essential oil made in Italy, diluted to 2%. The placebo was a synthetic essential oil (Shunyi Chemical Co., Ltd., Taiwan) with a similar scent to the bergamot essential oil..."[16]

6 **Carrier(s) name, including full binomial *Mark N/A if no carrier used**

Are carrier(s) including the name and binomial (Latin) provided (e.g., almond oil: *Prunus amygdalus* var. *dulcis,* jojoba oil: *Simmondsia chinensis,* diffuser and type of water)? **Partial credit** is given if the common name is used without the binomial name. While carrier oils are not necessary for inhalation purposes, they are used to dilute the essential oil in some situations. **N/A is used if no carrier is used**. Examples are not limited to the following:

a. Almond oil: *Prunus amygdalus* var. *dulcis*
b. Jojoba oil: *Simmondsia chinensis*
c. 120 mls distilled water placed in a diffuser

Understanding the non-aromatic components that impact outcomes is essential to validating the outcome of a study.

Example
"Ten percent (by weight) Melissa oil (active treatment) or sunflower oil (placebo) was combined with the base lotion (containing *Prunus dulcis* oil, glycerine, stearic acid, cetearyl alcohol, and tocopheryl acetate)."[12]

7 Source of carrier or delivery system

What source of carrier or delivery system is used (e.g., manufacturer, supplier, distributor)? This could be a diffuser, patch, or aroma stick. The manufacturer or other details of purchase for the carrier or delivery system are provided.

This is important as there can be variations in the type of delivery system used. The specific type of delivery system impacts the outcome and can skew results if variations are not identified.

	Example "Aromatherapy was administered via inhaling, utilizing an electric ultrasonic cool mist diffuser (Zaq Dew Litemist Aromatherapy Essential Oil Diffuser), with a capacity to hold 80ml of water, measuring 7.1 x 4.2 in., and with 12 W of power."[17]
TREATS Section 3: Aromatherapy Intervention	
1	**A clear description is necessary for reliability, fidelity, and the consistency of protocols.**
	Reliability allows for a protocol to be reproducible. Fidelity is an important measure of reliability to validate the research study. Was the research conducted as planned? Does the clear description support adherence to the protocols?
	Example There is no comprehensive study or systematic review that uses the same guidelines for researchers or clinicians due to the variety of essential oils, doses, and duration of course.[18–20] Many studies combine aromatherapy and massage and may lack methodological consistency with studies using EOs only.[21–24] Some studies report clear protocols, especially when there are protocol violations.[25]
2	**The rationale for Essential Oil**
	Rationale determines whether the intervention is appropriate in the age/demographics of the population and whether the EO or EO blend is appropriate to support the research study hypothesis.
	Example Many studies don't provide a strong rationale for clinical use.[26] "For many commonly treated symptoms or side effects, there is no clear rationale for why the effects of aromatherapy would differ importantly by condition."[27] Some studies use isopropyl alcohol as an 'aromatic vapor' without a rationale.[28,29] While there are studies that have determined good rationales.[25,30–32]
3	**Is there a theoretical conceptual framework provided?**
	This is important in all research; however, it is rarely included in aromatherapy research. Examples of frameworks: Whole System Health; Comfort Theory (Katherine Kolcaba)[33] ; and Chaos Theory (Margaret Wheatly).
	Example Braden uses the conceptual framework of Nightingale,[20] while the Comfort Theory[33] only appears in two aromatherapy studies.[34,35]
4	**Was a qualified Aromatherapist consulted: Registered Aromatherapist, Certified Aromatherapist, Qualified Aromatherapist, or the name of the aromatherapy school or education provided?**
	There are no internationally agreed-upon standards for aromatherapy educational curricula to define an aromatherapist. The Aromatherapy Registration Council (ARC), a U.S. organization that sponsors international voluntary aromatherapy examinations, requires a minimum of 200 hours of aromatherapy education that meets specific criteria. Those who successfully demonstrate a core body of aromatherapy

knowledge by passing the ARC examination hold the title of Registered Aromatherapist (RA). Other aromatherapy organizations and schools hold similar standards as a minimum to award titles such as certified aromatherapist or qualified aromatherapist. We use the term "qualified aromatherapist" broadly to include aromatherapists with core knowledge of essential oil chemistry, safety, and application of aromatherapy with humans for physical and emotional conditions and overall well-being. (Supplementary material 1)

Example
*Most studies and systematic reviews do not mention whether an aromatherapist was included in the study rationale and design. Two studies included aromatherapist researchers.[25,30] One study recommends having an aromatherapist researcher with relevant training for EO accuracy and safety.[30] Another SR found only five studies where a qualified aromatherapist delivered the aromatherapy (AT).[22] Most clinicians and medical providers "don't commonly receive AT training on EO use and safety."[36]

5 **Safety Considerations**

It is crucial to understand methods of indirect, direct, and topical delivery and application; to assess a participant for past allergic reactions or sensitivities to EOs or fragrance; to acknowledge if one might be pregnant or nursing and if this is included in the rationale for exclusion (if excluded); to identify EO safety measures specific to infants and children if they were included as study participants; to be aware of contraindications related to EOs and health conditions/
Medications (e.g., asthma, seizures, hypertension, dementia); and discussion of cleansing method for diffuser if it was used in the study.

Example
Study participants had skin patch tests[30] ; study subjects were excluded if unable to tolerate lavender aroma[37] ; and subjects were excluded if allergic to the essential oil or anosmic.[20]

6 **Report of allergic and adverse reactions to the EO or control during the trial or comment that no adverse reactions are reported**

In addition to screening for past adverse reactions or sensitivities to EOs and fragrances, and excluding a participant if they answered yes, it is crucial to report any adverse reaction or sensitivity, especially if the participant had no known sensitivities to an EO or chemical constituent. Examples: report how many participants had a reaction, what type of reaction, what actions were taken to address the reaction.

Example
In a systematic review of adverse reactions, 14 reports did not provide details of clinical outcomes.[38] Also noted, adverse reactions in clinical trials have failed to be reported.[22,38] Some studies do a skin patch test[30] but not many studies screen for past adverse reactions to EO or sensitivities to fragrance. Studies report adverse reactions, but do not state what actions were taken to address the reaction.[31]

7 **Safety consideration of EO storage and shelf life during the trial**

Was the EO and control stored away from participants; was EO protected from light and heat; was the EO storage location identified (e.g., refrigerator, locked cabinet); were participants instructed how to

store the EO or use trial materials? Was information given about the shelf life of the EO? Was the EO distillation date given to show the EO was within the shelf life window and not expired?

Example
Many studies didn't report how the essential oil and control were stored from participants and didn't identify a storage location such as a refrigerator or locked cabinet. Oftentimes, researchers and/or study participants were instructed how to use the trial materials.[25,32]

TREATS Section 4a: Olfactory function questions (Asked prior to allocation of treatment to help understand if participants have loss of smell or strong aversions to smells that may impact their participation in the study)

1 **Anosmia**

Olfactory ability of participants is evaluated prior to allocation to treatment groups. Were participants asked if they currently experience loss of smell? Anosmia is not necessarily a reason for exclusion; however, consideration is important, especially if the design relies on people's response to the aroma of the oils.

Example
"We performed the olfactory function test on all subjects to assure that none had anosmia. Briefly, subjects were given two sets of three bottles—two held distilled water; the third contained essential oils (lavender or orange)— and were asked to choose the one that differed from the other two. To be eligible for the study, subjects had to choose the correct response in both trials."[10]

2 **Previous use of Eos**

Participants were asked about their previous use of essential oils, and their preference or aversion to the oils used in the study. The discovery of an aversion to the EO(s) being used in the trial may exclude participants from the study, especially if the aversion is linked to adverse effects like sneezing, headache, or eye irritation.

Example
"We also conducted a structured interview to assess prior experiences with aromatherapy."[39]

TREATS Section 4b: Olfactory bias questions if practical in an experimental setting (Asked as part of the trial. If not asked, the researcher may explain why they excluded these steps. Give partial credit if mentioned in the limitations section)

1 **Olfactory testing**

	To avoid olfactory interference with the aromatics used in the study, the authors should state whether these considerations were included in their study protocols: a. Participants asked to not wear scents on their skin like perfumes or lotions on the day(s) of the aromatic intervention. b. Were clients asked if they were experiencing any congestion or allergies on the day of testing? c. Were the participants around other participants when being tested, or were they tested in individual cubicles/ rooms? d. If the aromatics were presented in a way which could affect the residual aroma in the testing area (e.g., cotton ball, tester strip, diffuser into the room), how were the aromas removed prior to the admittance of other test subjects? e. Was the room free of other odors?
	Example "Testing cubicles measured 2.4m long_1.8m wide_ 2.4m high and were maintained at a temperature of between 18 and 22*8*C throughout the testing sessions. The doors were kept closed except for participant access. Three identical cubicles were used, and testing took place on three different days of the week (Monday, Wednesday and Friday) to avoid cross contamination of aromas."[40]
2	**Odor recognition testing**
	Participants should be asked if they recognized the aroma of the EO. Odor recognition may bias people's expectations of how an aroma should affect them, and familiar aromas are more likely to have emotional links due to past experiences than unfamiliar aromas, which may bias outcomes. It is unlikely to affect outcomes much, but until more research shows that recognition of odors does not impact outcomes, particularly psychological outcomes, it is better to ask the question than leave it un-asked.
	Example "On completion of each series, subjects rated the odor's pleasantness, familiarity, and intensity using a 1–10 scale."[39]
3	**Participants' expectations stated**
	Participants' expectations were addressed. Participants were asked how they thought the aroma of the EO would affect them, particularly if they recognized it (e.g., "I expected Lavender to be relaxing"). If the odor was recognized, this was acknowledged under limitations. Studies by Jaén and Dalton (1996),[41] show that expectation can influence participants' responses to aroma.
	Example "We also conducted a structured interview to assess prior experiences with aromatherapy. Questions elicited participants' evaluation of and previous experience with aromatherapy, and their expectancies about the extent to which their own psychological and physiological responses would be influenced by odors."[41]
4	**Odor preference bias**

	Odor preference bias was addressed. Participants were asked whether they liked or disliked the aroma of the treatment and control aromas. Biases were acknowledged under limitations. Liking a smell or disliking it can affect a person's physiological responses to an aroma.[39,42–44]
	Example "Affective reactions to the odor stimuli were measured with the "Mehrdimensionale Befindlichkeitsfragebogen" (MDBF questionnaire... The dependent variables were mood, alertness, and calmness. In addition, subjective ratings of odor pleasantness and intensity were assessed on 100-mm visual analog scales."[45]
5	**Perceived aroma intensity**
	Perceived aroma intensity was addressed. Examples (not limited to): Participants were asked if they found the aroma too strong or too weak. Reports should show that researchers addressed the issue of aroma intensity, as odors perceived as too strong may be evaluated as unpleasant, and thus impact psychological responses to the aroma. This was evaluated in a study by Heuberger et al. (2006) and shown to be relevant.[46] Possibility of olfactory fatigue was controlled for (experience of losing sensitivity to odors after prolonged exposure). It is important to consider olfactory fatigue in extended use of aroma for therapy, as it can lead to the aroma being perceived as less pleasant over time.[47]
	Example "During each odor presentation interval (15 × 1 min intervals) participants were asked to rate the odor on multiple dimensions, including the perceived intensity, irritancy and annoyance using the general Labeled Magnitude Scale (gLMS) scale."[41]
6	**An adverse effect from olfaction testing**
	Any adverse effects experienced by participants or observed by researchers during the olfactory testing were reported. A statement saying "No adverse events observed" should also be included to show it was part of the design. Examples of adverse effects might be (not limited to): Irritating or non-irritating responses such as sneezing, watery eyes, excess salivation (potential trigeminal nerve response); headache; nausea.

OPTIONAL Scoring:

**Please transfer points from each section in the table below. Add points to obtain the total.

*FOR N/A—when NA is used to describe the non-applicability of something within this tool, that should be taken out of the calculation and the total number changed (e.g., 16/29 if NA used for 2B: 6 Carrier(s) name and using the INHALATION only pathway).

Section (Points)	Total section points INHALATION	Total section points TOPICAL	Total section points Topical AND Inhalation
Section 1 (8)	/8	/8	/8
Section 2 (7-15)	/7	/8	/15
Section 3 (7)	/7	/7	/7
Section 4a (2)	/2	/2	/2
Section 4b (6)	/6	/6	/6
Total (30-38) Poor, Fair, Good	/30	/31	/38

0-10 = Poor; 11-20 = Fair; 21-38 = Good

(These ratings serve as guidance. Additional comments & conclusions are necessary to qualify these ratings. For example: "16/30—Fair quality for aromatherapy practice in this study with acknowledgment of best practice observed for essential oil reporting and safety. No mention of how olfactory bias or function was accounted for."

ADDITIONAL REVIEWER COMMENTS:

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