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Effectiveness Of Aromatherapy In Healthcare Professionals During The Covid-19 Pandemic: Systematic Review Protocol Of Randomized Clinical Trials

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Abstract:
Background*: Aromatherapy is an integrative and complementary practice that uses volatile concentrates extracted from plants, called Essential Oils, which are natural, complex and highly volatile chemical compounds, characterized by a strong aroma and produced as secondary metabolites of aromatic plants and have been associated with better health outcomes, such as reduced blood pressure, anxiety and stress. In this context, this protocol aims to identify the effectiveness of the use of aromatherapy in health professionals in combating Covid-19.*
Materials and Methods*: Systematic review protocol prepared according to the Cochrane methodology. Protocol published in Prospero (CRD42024508246) and its writing followed the PRISMA checklist guidelines. The PUBMED, EMBASE, COCHRANE and LILACS databases will be consulted until December 2023 using the health descriptors "Aromatherapy", "Health Personnel" and "COVID-19". Randomized clinical trials that reported metrics associated with sleep quality, quality of life and anxiety and used aromatherapy will be included. Reviewers will independently screen eligible articles; extract data and assess risk of bias using the RoB 2.0 tool. Meta-analysis will be contemplated with random-effects models and the Mantel-Haenszel method. Associations will be reported as relative risks (RR) and their 95% confidence intervals (CI). Review Manager (RevMan) software will be used for the analyses. The quality of evidence will be assessed according to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) framework.*
Results*: The COVID-19 pandemic has affected many healthcare professionals who have been on the front lines in healthcare institutions. Identifying the effectiveness of aromatherapy is necessary to assist these professionals who have a high work demand.*
Conclusion: *Knowledge about the effectiveness of the use of aromatherapy represented by the assessment of sleep quality, quality of life and anxiety during the Covid-19 pandemic will encourage new complementary studies on the subject, in addition to providing subsidies and data to assist in the creation and development of periodic monitoring programs for the health of workers working in health institutions.*
Key Word: *Aromatherapy; COVID-19; Nursing; Systematic Review*

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I. Introduction

Complementary and alternative health therapies are defined as any system of medicine, practice or product that is not part of conventional medical care.1

This definition may include Aromatherapy. The term "complementary" is used when the practice is associated with traditional Western medicine, complementing the treatment, while the term "alternative" is applied when the therapy completely replaces conventional treatment [1-2].

In Brazil, in 2006, the Ministry of Health approved the National Policy for Integrative and Complementary Practices (PNPIC) in the Unified Health System (SUS), covering the areas of homeopathy, medicinal plants and phytotherapy, traditional Chinese medicine/acupuncture, anthroposophic medicine and social thermalism/crenotherapy, which promoted the institutionalization of these practices in the Brazilian health system [3].

Among the objectives of the PNPIC are the incorporation of PICs into the SUS, with an approach focused on the prevention of diseases and health promotion, with an emphasis on primary health care, providing continued, humanized and comprehensive health care; contributing to the system's resolvability and expanding population access to practices, ensuring quality, efficiency and safety in their use; and encouragement of social participation, promoting the involvement of users, managers and workers in the various scenarios for implementing health policies [4].From March 2017 to March 2018, 24 other therapies were included, including aromatherapy, which is characterized as an approach that uses essential oils to promote and improve health, well-being and hygiene [5].

Aromatherapy is a PIC that uses volatile concentrates extracted from plants, called Essential Oils (EOs), which are natural, complex and highly volatile chemical compounds, characterized by a strong aroma and produced as secondary metabolites of aromatic plants[6].

EOs are substances with unique properties due to the chemical characteristic of being composed of numerous substances, which gives them the particularity of not being able to be replaced by another synthetic one, despite the olfactory similarity. Synthetic products are called "essences" and act in a restricted way in the body due to the fact that they have a specific chemical composition, while EO act more broadly [6].

In the health field, a quantitative, exploratory-descriptive and correlational study with a quasi-experimental design aimed at investigating the effectiveness of the use of aromatherapy with lavender essential oils in undergraduate nursing course teachers identified that blood pressure showed an effective reduction in some aromatherapy sessions. It was observed that stress had a greater reduction when compared to anxiety, and the group that used ylang-ylang had a greater reduction in anxiety than the lavender group [7].

Regarding its association with Covid-19, a review that aimed to summarize what is in the recent literature on the use of Aromatherapy as an Integrative and Complementary Practice (ICP) in the control of anxiety resulting from Covid-19 identified that there are no studies using Aromatherapy to prevent and/or cure anxiety caused by the Covid-19 pandemic. However, there are records of the anxiolytic potential of essential oils, which improve the patient's well-being. Lavender essential oil (Lavandula angustifolia Mill.) is the most described for use in Aromatherapy, with anxiolytic potential[8].

The pandemic caused a major shock to the health system and to professionals on the front lines, both due to the increased demand on health services that proved to be incompatible with the existing capacity in some locations, leading to lack of assistance to the population and repression of the flow of routine demand; as well as due to the high demand received by health professionals, resulting from the infection, mental and social stress [9].

In view of the above, it is understood that the COVID-19 pandemic has been affecting the lives of many Brazilians and, mainly, of health professionals who are on the front lines in public and private institutions, fighting something new, unknown and for which there is still no scientifically proven prevention or effective treatment strategy. This gives rise to the interest in evaluating the quality of life and the impact on the health of healthcare professionals in dealing with the new Coronavirus in Brazil.

II. Material And Methods

This is a protocol for a systematic bibliographic review study that will be carried out in accordance with the Cochrane methodology[10] with the aim of identifying the effectiveness of the use of aromatherapy in health professionals who worked to combat the Coronavirus. This systematic review has its protocol submitted to the PROSPERO® database (PROSPERO 2024 CRD42024508246)[11] and its writing followed the PRISMA checklist standards [12].

Procedure methodology

Eligibility Criteria: The systematic review will evaluate the use of aromatherapy administered to healthcare professionals working on the frontline of COVID-19. Randomized controlled studies will be included in which healthcare professionals (all classes and categories) are randomly distributed into two groups: intervention group or control group, following the "PICO" methodology described below. Population: Healthcare professionals working (who worked) on the frontline of COVID-19. Intervention: Use of aromatherapy at any frequency or protocol. Comparator: No use of aromatherapy and/or use of placebo. Outcomes: metrics associated with sleep quality, quality of life and anxiety measured using validated instruments.

Inclusion and exclusion criteria: Randomized clinical trials (RCTs) that report metrics associated with sleep quality, quality of life and anxiety using validated instruments that used aromatherapy in at least one session. The exclusion criteria will be: observational studies, no randomization between groups, no control group in the study and/or intervention.

Search strategy: The electronic databases National Center for Biotechnology Information (NCBI/PubMed), Embase, Cochrane Library, and Latin American and Caribbean Literature on Health Sciences (LILACS) will be searched through December 2023. Information on ongoing clinical trials will be retrieved through the clinical

trials website of the National Institute of Health (http://clinicaltrials.gov) and through the Brazilian Registry of Clinical Trials-ReBEC (http://www.ensaiosclinicos.gov.br/).

The basic search strategy will be developed for PubMed and modified as necessary for other databases. Health descriptors available in Health Sciences Descriptors (DECs) and Medical Subject Heading (MeSH) were used. The descriptors used will include "Aromatherapy", "Health Personnel", and "COVID-19". There will be no language restrictions, but only human studies will be selected. References of the selected articles, including pertinent review articles, will be reviewed to identify all relevant studies. Grey literature will be screened by manually searching for references to clinical trials. Authors will be contacted if necessary to obtain information not available in the manuscript.

Study selection and data extraction: For this review, two investigators (JGAF and MRKR) will independently review the titles and abstracts for eligibility. Disagreements regarding article selection will be resolved by consensus or discussion with a third investigator (NOF). A study selection flowchart will be created according to the PRISMA guidelines. Two investigators (JGAF and MRKR) will independently extract relevant data from each full-text article using a standardized form based on the Cochrane Handbook 10 with the following information: study characteristics (study setting; design; randomization method; follow-up time; patient age); participants; interventions; control; inclusion criteria; exclusion criteria; clinical outcomes (types of outcomes measured – i.e., dichotomous or continuous) and their scales used for analysis. The selection will be compared for accuracy, and any discrepancies will be resolved by consensus or discussion with another investigator (NOF).

Risk of Bias Assessment in Randomized Clinical Trials: Two investigators (RCR and MRKR) will independently assess the risk of bias of each eligible RCT. Discrepancies will be resolved by consensus or discussion with another researcher (NOF). The RoB 2.0 tool – Risk of bias in randomized clinical trials will be used. The following items will be assessed: Bias in the randomization process (selection bias); Deviations from the intended intervention (selection bias); Bias due to missing data (detection and performance bias); Bias in measuring outcomes (attrition bias); Bias in reporting outcomes (information bias). For each RCT, each item will be described and presented as low risk of bias, some concerns or high risk of bias according to the classification obtained[13].

Statistical analysis: This systematic review will include meta-analysis and, in this case, random-effects models and the Mantel-Haenszel method will be used. Associations will be reported as relative risks (RR) and their 95% confidence intervals (CI). Heterogeneity will be tested with the Cochrane $\chi 2$ test, and the degree of heterogeneity will be quantified with the I2 statistic and its 95% CI. An I2 value between 30% and 60% will be described as moderate heterogeneity. Publication bias will be assessed with funnel plots and formally tested with the Egger test. For variability in results between studies, the I2 statistic and the P value obtained from the Cochrane chi-square test will be used. The Review Manager (RevMan) software will be used for all analyses (version 5.3; Nordic Cochrane Centre, Cochrane)[14].

Assessment of the quality of evidence: The assessment of the quality of evidence will be carried out using the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) System for the outcomes with the greatest impact [15].

III. Expected Results And Conclusion

Knowing the effectiveness of aromatherapy in healthcare professionals in terms of outcomes related to metrics associated with sleep quality, quality of life and anxiety, and its strength of evidence, is essential because even with the end of the pandemic declared, it is necessary to provide data based on scientific evidence to assist in the development of proposals and programs aimed at psychosocial care and the promotion of mental health among healthcare workers.

Knowing the effectiveness of aromatherapy during the COVID-19 pandemic encourages additional studies on the subject and provides support and data to assist in the creation and development of periodic monitoring programs for the health of workers working in healthcare institutions.

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