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Non-pharmaceutical interventions for depressive symptoms in patients with breast cancer: protocol for a systematic review and network meta-analysis

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ABSTRACT

Introduction Patients with breast cancer often suffer from depressive symptoms throughout various stages of cancer, significantly impacting their quality of life and treatment outcomes. Non-pharmaceutical interventions such as psychotherapy, mind–body therapies and physical exercise have shown effectiveness in addressing cancer-related depression. However, the efficacy and safety of different non-pharmacological interventions remain a topic of debate. Therefore, to provide an objective assessment and comparison of the impact of different non-pharmaceutical interventions on depression, we will conduct a network meta-analysis (NMA) to explore the effects of different non-pharmaceutical interventions on reducing depressive symptoms among patients with breast cancer.

Methods and analysis We will search nine Chinese and English-language databases, from database inception to 31 July 2023, for randomised controlled trials published in Chinese or English. The English-language databases are PubMed, Medline, Embase, Web of Science and Cochrane Central Register of Controlled Trials, and the Chinese databases are CBM, CNKI, VIP and Wanfang. Two independent researchers will perform information extraction from eligible articles. The primary outcome will be the changes in depressive symptoms, while the secondary outcome will include adverse events. STATA V.15.0 will be used to conduct paired meta-analysis and NMA. Grading of Recommendations Assessment, Development and Evaluation will be used to assess the quality of evidence, and the Cochrane tool for assessing the risks of bias in randomised trials V.2 will be used for risk of bias assessment.

Ethics and dissemination The study does not require ethical approval as it will analyse data from existing studies. It is expected that the results of the study will be published in peer-reviewed journals and presented at relevant conferences.

PROSPERO registration number CRD42023450494.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The study will search nine databases to provide a comprehensive review.
⇒ The Grading of Recommendations Assessment, Development and Evaluation approach will be used to assess the quality of evidence.
⇒ Heterogeneity and sensitivity analyses will be conducted using subgroup analyses to ensure the stability of results.
⇒ The review will not encompass oral non-pharmacological treatments such as natural medicine supplements, herbal remedies and dietary therapies.
⇒ Data will only be retrieved from publications in Chinese or English, potentially limiting the available data or introducing language bias.

INTRODUCTION

Female breast cancer ranked as the second most common type of cancer globally, accounting for 11.6% of all cancer cases in 2022.[1] Additionally, it was the fourth leading cause of cancer-related deaths worldwide, contributing to 6.9% of all cancer mortalities.[1] Due to population growth and ageing, the incidence of breast cancer is predicted to rise to about 3 million new cases and 1 million deaths per year by 2040.[2] Depressive symptoms have become a significant mental health issue among patients with breast cancer, and have become a crucial concern in both clinical practice and public health.[3] Patients with breast cancer are at a higher risk of developing depressive symptoms following diagnosis and treatment compared with patients with non-breast cancer, and there may be some biological link between major depressive disorder and breast cancer.[4 5] A systematic evaluation and meta-analysis of studies on the prevalence of depression in patients with breast cancer worldwide revealed a global prevalence rate of 32.2%.[6] The prevalence of depressive symptoms in breast cancer survivors was reported to be as high as 66.1%.[7] In addition, advancing age may increase the risk of depression in women with breast cancer.[8] The presence of depressive symptoms in patients with breast cancer may harm their

treatment adherence, ultimately reducing their quality of life and overall survival.[9] Research indicates that depression can persist for over 5 years after diagnosis, adding to the long-term burden on breast cancer survivors.[10]

Pharmaceutical interventions are commonly used to alleviate depressive symptoms. However, selecting the appropriate medications requires careful consideration of potential drug interactions and side effects, especially when used alongside cancer treatments.[11] Non-pharmaceutical interventions are essential in the treatment process. Pairwise meta-analyses are often employed to assess different treatment methods for cancer-related depression. Psychotherapy, such as cognitive–behavioural therapy (CBT), mindfulness and music, has shown effectiveness in addressing depression among cancer survivors.[12–14] Mind–body therapies like yoga, acupuncture and tai chi have been demonstrated to be valuable in treating cancer-related depression.[15–17] Studies indicate that mindfulness can reduce depressive symptoms in patients with breast cancer, while acupuncture is recognised as an effective non-pharmaceutical therapy for managing depression.[18 19] Additionally, physical interventions such as exercise and massage can help improve depression in cancer survivors.[20 21] The studies have shown that exercise is effective in reducing levels of clinical depressive symptoms in patients with breast cancer.[22 23]

Various non-pharmaceutical interventions have been used to help patients with cancer with depressive symptoms, but there is limited comparative evidence on their effectiveness. However, some meta-analyses have focused on how different non-pharmaceutical interventions impact depressive symptoms in patients with breast cancer. It is noteworthy that they have largely concentrated on observing changes in depressive symptoms in patients following a single non-pharmaceutical therapy treatment. There is still a lack of comprehensive and more robust evidence-based medicine to compare the effectiveness of different types of interventions.[24 25] This uncertainty regarding the optimal interventions complicates clinical decision-making, highlighting the need to evaluate and compare these interventions for the management of depression in patients with breast cancer.

Network meta-analysis (NMA), also known as multiple treatment comparison meta-analysis, is a statistical technique that combines direct and indirect evidence from treatment networks. It can rank treatment regimens from multiple trials in a network according to their effectiveness.[26–28] Under these circumstances, NMA will be used for a more comprehensive understanding of the relative effectiveness of various non-pharmaceutical interventions by comparing multiple treatments across trials in the absence of direct head-to-head comparisons. This approach establishes a treatment hierarchy, enhances decision-making and investigates treatment effect modifiers, which provides insights into the differential effectiveness of interventions across subgroups and promotes the personalisation of treatment recommendations. Overall, NMA offers advantages such as including indirect comparisons, establishing treatment hierarchy, increasing precision and examining treatment moderators.[26] These benefits collectively contribute to a more informed and comprehensive understanding of the relative effectiveness of various non-pharmaceutical interventions for managing breast cancer-related depression.

This study aims to conduct a systematic review and NMA to compare the effectiveness and safety of non-pharmaceutical interventions in managing depression among patients with breast cancer. The findings of this study will provide a structured evaluation of interventions, assisting patients, physicians and policymakers in making well-informed decisions. The primary objective is to offer reliable evidence on the clinical utility of non-pharmaceutical interventions for managing depression in patients with breast cancer.

METHODS AND ANALYSIS

Study registration

This systematic review protocol has been registered on PROSPERO with the registration number CRD42023450494. The protocol has been prepared under the guidance of the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) Protocols guidelines.[29] The results of this study will be presented following the PRISMA-NMA reporting guidelines.[30] Work on the review is scheduled to begin on 1 December 2023 and end on 1 December 2024.

Selection of different types of studies

The review will include only randomised controlled trials, including parallel designs or cross-over designs, reported in English or Chinese. Full-text published journal papers, unpublished clinical trials with online results in English or Chinese, and clinical trials conducted in any healthcare setting are eligible. Abstracts, editorials, clinical observations, case studies, cohort studies, non-randomised trials, case–control studies, and cross-sectional and retrospective studies will not be included. We will conduct a comprehensive review of any relevant previous systematic reviews and meta-analyses to ensure that all relevant references are included in the analysis.

Types of participants

The study will involve participants aged 18 years or older who have been diagnosed with breast cancer (stages 0–IV) and experiencing depressive symptoms or have been diagnosed with depression at any stage of the disease. Diagnoses will be based on the criteria outlined in the Diagnostic and Statistical Manual of Mental Disorders (any version) or the International Classification of Diseases (any version). Alternatively, participants with depressive symptoms will be identified through validated screening measures scoring above the threshold value, such as the Beck Depression Inventory (BDI), the Hospital Anxiety and Depression Scale (HADS), or the

Center for Epidemiologic Studies-Depression Scale (CES-D), among others. Patients who are receiving or have completed radiotherapy or chemotherapy or surgery and patients with breast cancer who have never received radiotherapy or chemotherapy or surgery will be included. Studies focusing on metastatic breast cancer or multiple cancer types will usually be excluded unless they provide information on subgroups of breast cancer. There are no restrictions on race, nationality or education.

Types of interventions

The following non-pharmaceutical interventions, which include CBT and non-oral treatments of complementary medicine based on the National Center for Complementary and Integrative Health definition,[31] will be included as primary treatments: (1) psychological: CBT, mindfulness, meditation, social support and music therapy; (2) physical: massage, tuina, exercise (including aerobic, resistance, walking, increasing physical activity interventions, etc); (3) mind–body therapies: acupuncture, electroacupuncture, auricular acupuncture, yoga, tai chi, qigong. Studies in which single or multiple complementary medical intervention(s) are used will be considered.

Types of control group

Appropriate non-pharmaceutical treatments, other than interventions, such as usual care, waiting control, placebo, sham acupuncture and health education.

Types of outcomes

The primary outcomes will be the changes in depressive symptoms, which are measured with scales, including BDI, HADS, CES-D, Profile of Mood States, Hamilton Depression Rating Scale, Self-Rating Depression Scale, BDI-Short Form, BDI-II, Zung Self-Rating Depression Scaleand Patient Health Questionnaire-9.

The secondary outcome will include adverse events, regardless of their severity, which will help assess the safety of the non-pharmacological interventions by analysing the incidence of adverse events.

Information sources and search strategy

We will search for all publications in English or Chinese from database inception to 31 July 2023. The English-language databases are PubMed, Medline, Embase, Web of Science and Cochrane Central Register of Controlled Trials, and the Chinese literature databases are CBM, CNKI, VIP and Wanfang. The search keywords include 'CAM', 'breast cancer', 'depression', 'acupuncture', 'electroacupuncture', 'auricular acupuncture', 'cognitive behavioral therapy', 'mind-body therapies', 'music therapy', 'mindfulness', 'meditation', 'tuina', 'massage', 'yoga', 'tai chi', 'qigong', 'physical exercise', 'resistance training', 'walking', 'social support' and 'randomized controlled trial'. The final search formulae are based on searching for the subject words, subordinate words and free words. Table 1 shows the specific search strategies for Web of Science. Detailed search strategies for the other databases are provided in online supplemental file 1.

Study selection and data extraction

Two researchers (PY and LL) will independently screen the literature, extract the data and cross-check. Any disagreements will be resolved through discussion or with the help of a third party. Initially, researchers will

Table 1 Search strategy for the Web of Science database

Number	Search items
1	TS=(Breast neoplasms OR Breast cancer OR Breast Tumor OR Mammary cancer OR Breast Carcinoma)
2	TS=(Depression OR Depressive)
3	TS=(Complementary Therapies OR Complementary Medicine OR Alternative Medicine OR Alternative Therapies OR Integrative Medicine)
4	TS=(Acupuncture OR Electroacupuncture OR Auricular acupuncture)
5	TS=(Cognitive Behavioral Therapy)
6	TS=(Mindfulness OR Meditation)
7	TS=(Music)
8	TS=(Tuina OR Massage)
9	TS=(Mind-body therapies)
10	TS=(Yoga)
11	TS=(Tai ji OR Tai Chi OR Qigong)
12	TS=(Exercise Therapy OR Physical Exercise OR Aerobic Exercise OR Resistance Training OR Walking)
13	TS=(Social support)
14	TS=(Randomized Controlled Trial OR Controlled Clinical Trial OR Randomized OR Placebo OR Clinical Trials As Topic OR Randomly OR Trial)
15	#3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13
16	#1 AND #2 AND #14 AND #15

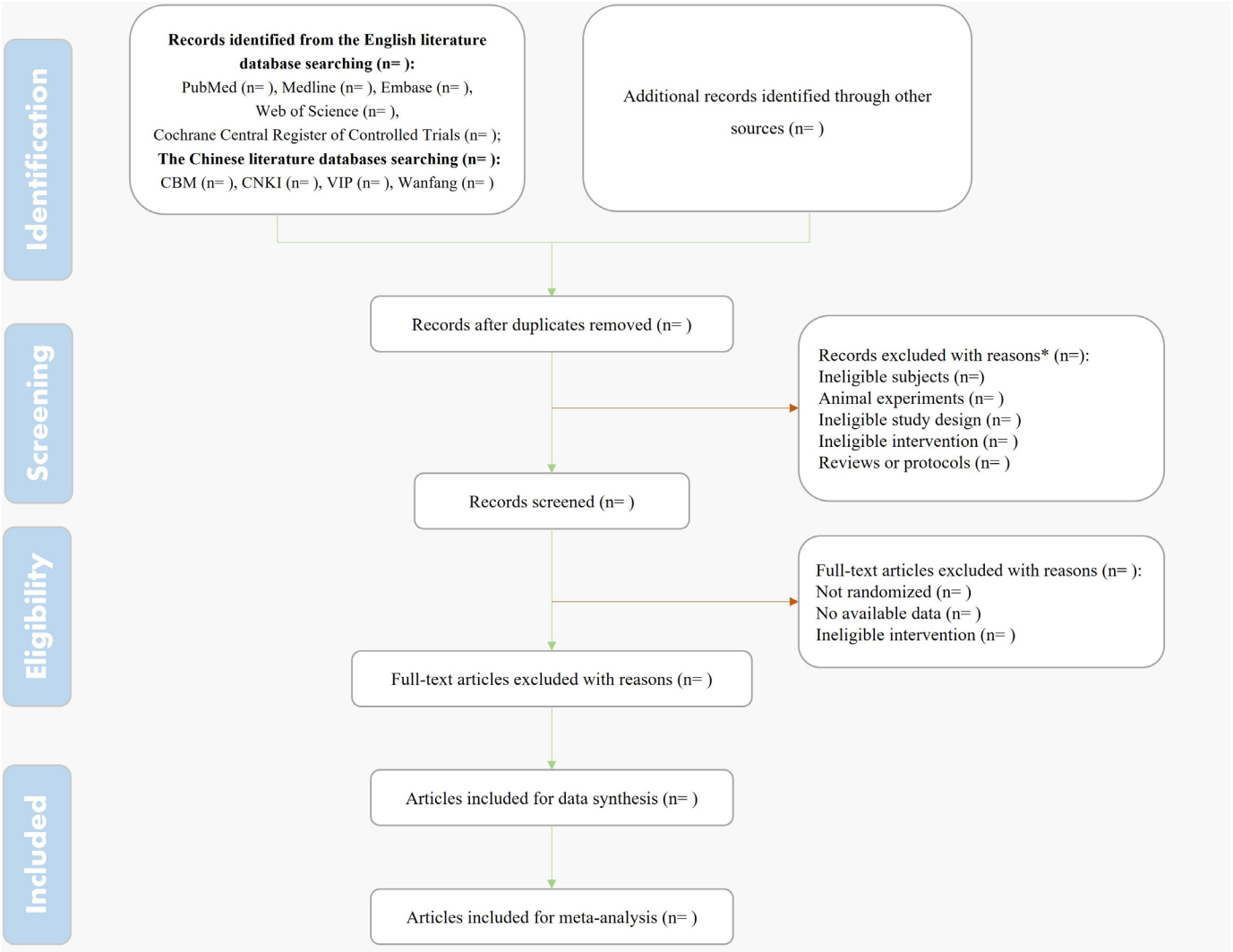

FIGURE 1 Flow chart of the selection process

* The reasons for records excluded: abstracts, editorials, clinical observations, case studies, cohort studies, non-randomized trials, case-control studies, and investigations that do not qualify as experimental (including cross-sectional and retrospective studies) are also excluded. Studies involving multiple cancer types will usually be excluded, except for studies that include information on subgroups of breast cancer.

Figure 1 Flow chart of the study selection process. *The reasons for records' exclusion: abstracts, editorials, clinical observations, case studies, cohort studies, non-randomised trials, case–control studies and investigations that do not qualify as experimental (including cross-sectional and retrospective studies). Studies involving multiple cancer types will usually be excluded, except for studies that include information on subgroups of breast cancer.

review the article titles, followed by reading abstracts and full texts to determine inclusion. If necessary, the authors of the original studies will be contacted by email or telephone. All studies will be managed using EndNote V.X9. The selection process is shown in figure 1.

A structured data abstraction form will be completed to better understand the study characteristics, including details such as first author, year of publication and study country. Participant characteristics such as the treatment received for breast cancer (radiotherapy/chemotherapy/surgery), age, sample size, intervention measures (duration, frequency) and type of study design will also be recorded. Primary and secondary outcomes related to the safety and efficacy of the interventions will be extracted from the included studies. Data will be extracted from relevant scales at the beginning and end of follow-up, or from the difference between means, depending on the data presentation format in the primary study.

Quality assessment

The risk of bias in the included studies will be independently assessed by two evaluators (YD and NG) using the method recommended by the Cochrane Handbook. A third evaluator (QJ) will resolve any differences. The Cochrane tool for assessing the risks of bias in randomised trials V.2, which was revised by the Cochrane Methodology Group in 2019, will be used to assess the risks of bias.[32] The quality of the study will be evaluated in the following five areas: (1) bias in the randomisation process, (2) deviation from established interventions, (3) bias in missing

outcome data, (4) bias in outcome measurement and (5) selective reporting of bias in results.

Pairwise meta-analysis

For the continuous variables, standardised mean differences (SMDs) or weighted mean differences with 95% CIs will be used. SMD will be used because it is anticipated that different instruments will be used for the same outcome variables. An OR will be used if studies report an outcome as dichotomous data.

Network meta-analysis

If there are sufficient data available to compare the effectiveness of different interventions and controls, the NMA will be conducted on both direct and indirect evidence in a Bayesian framework using STATA V.15.0 software. Network diagrams will be constructed using STATA software to visually represent the comparative relationships between different interventions. The surface under the cumulative ranking curve (SUCRA) probability values will be used to rank the examined treatments, with SUCRA values of 100% and 0% assigned to the best and worst treatments, respectively.[33] In addition, comparative cluster analysis will be used to compare the non-pharmaceutical intervention effects between different outcomes.

Subgroup analysis and sensitivity analysis

Possible sources of heterogeneity and inconsistency will be investigated by subgroup analysis and meta-regression studies. Subgroup analyses will be performed according to different types of non-pharmaceutical interventions and different cancer stages. Heterogeneity between trials will be estimated using the I^2 statistic and p values. The I^2 scores ranging from 0% to 40% may not be considered significant, while scores between 30% and 60% could indicate moderate heterogeneity. Scores between 50% and 90% may suggest substantial heterogeneity, with scores between 75% and 100% indicating considerable heterogeneity.[34] Clinical and methodological heterogeneity will be assessed by careful examination of participant characteristics, interventions, outcome measures, methods and fit comparisons between fixed-effects and random-effects models. If an inconsistency is found within the network, the local inconsistency for each intranetwork cycle will be assessed using cycle-specific methods to generate an inconsistency factor with an associated 95% CI.[35] If potential causes of this inconsistency are identified, participants who have received, are receiving or have never received chemotherapy/radiotherapy or surgery are considered as covariates in the meta-regression analysis. If the cause of the inconsistency cannot be determined, NMA will not be performed.[36]

Missing data

The study will use the data imputation method to address missing data, with the information-missing OR for dichotomous outcomes and informative missingness difference of means for continuous outcomes being calculated under the missing-at-random assumption.[37] If continuous outcomes are not reported as means with associated SDs, imputation methods will be used to estimate effect measures.[38] Study authors will be contacted for additional information if needed.

Assessment of publication bias

To assess publication bias and the impact of smaller studies in pairwise comparisons, funnel plots and Egger's test will be used. Additionally, we will assess the asymmetry on comparison-adjusted funnel plots to investigate any potential associations between study size and study effect.

Quality of evidence

The quality of evidence for the main outcome will be assessed using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) framework. According to the GRADE rating scale, the quality of the evidence will be classified as 'high', 'moderate', 'low' and 'very low'. Then, conclusions will be drawn from the NMA using the minimal contextualisation framework of the GRADE approach. The framework describes the quality of evidence in terms of study limitations, imprecision, inconsistency, indirectness and publication bias.[39]

Patient and public involvement

None.

ETHICS AND DISSEMINATION

The study does not require ethical approval as it will analyse data from existing studies.

Any amendments to the protocol will be indicated in the PROSPERO registration record (CRD42023450494) and will be transparently documented when the results are reported.

It is expected that the results of the study will be published in peer-reviewed journals and presented at relevant conferences.

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Contributors PY, LL and NG contributed equally to this article as co-first authors. Y-IC, PY and QJ contributed to the design of the study. The manuscript was drafted by PY, QJ and LL. YH and LL participated in the design of the search strategy and data extraction dataset. YD and NG will be responsible for data extraction and quality assessment. Y-IC and PY will monitor each procedure of the review and be responsible for quality control. All the authors participated in the reading, discussion and revision of the manuscript, and all approved of the protocol for publication.

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Competing interests None declared.

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