INPLASY PROTOCOL

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Corresponding author:
Chenxiao Ye

202011111511262@zcmu.edu.cn

Author Affiliation:
The First Clinical College of Zhejiang Chinese Medical University.

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Conflicts of interest:
None declared.

Effectiveness and safety of acupuncture for anxiety and depression induced by breast cancer: A protocol for systematic review and meta-analysis

Ye, CX[1]; Wu, CH[2]; Chen, HT[3]; Guo, Y[4].

Review question / Objective: **Is acupuncture as a complementary/ alternative therapy effective and safe for the treatment of breast cancer combined with anxiety and depression?**

Condition being studied: **Breast cancer is currently one of the most researched topics in the world. Due to advances in medical treatment and active participation in adjuvant therapy, the survival rate of patients with breast cancer has significantly improved and is relatively higher than that of patients with other types of cancer. However, various complications are inevitable, including fatigue, sleep disorders, and depression and anxiety. Among them, anxiety, depression and other mood disorder problems seriously affect the quality of life of breast cancer patients and even cause suicide. Emerging evidence revealed that acupuncture, a therapy originated from Traditional Chinese Medicine, could effectively relief depression and anxiety. Acupuncture appears to be safe with few minor and self-limiting side effects noticed in most trials. Nevertheless, the efficacy and safety of acupuncture on depression and anxiety induced by breast-cancer still remains uncertain. Herein, we evaluated the efficacy and safety of acupuncture as an adjunct/alternative therapy for breast cancer with anxiety and depression by conducting a systematic review and meta-analysis.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 07 July 2022 and was last updated on 07 July 2022 (registration number INPLASY202270036).

INTRODUCTION

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METHODS

Participant or population: Patients diagnosed with anxiety and depression induced by breast cancer emotional disorder will be included.

Intervention: The interventions considered have to involve needle insertion at acupuncture points, and had to be described as acupuncture. Acupuncture therapy used alone or as add-on to conventional drug will be included in this study. Acupuncture includes needle acupuncture, ear acupuncture, electroacupuncture, scalp acupuncture, warm acupuncture. However, other methods of stimulating acupuncture points without needle insertion (such as moxibustion, laser stimulation, massage or transcutaneous electrical nerve stimulation), will be excluded.

Comparator: For control groups, sham or placebo acupuncture intervention such as non-penetrating, sham needle or superficial needling at non-acupuncture points will be considered. Besides, no treatment, waiting list, conventional medication, psychotherapy, physical therapy, and other active treatment methods will be also considered. Notably, studies comparing the efficacy of different forms of acupuncture and different acupuncture points will be excluded. Combination treatment modalities that cannot assess the efficacy of acupuncture will also be excluded.

Study designs to be included: Only randomized controlled trials (RCTs) or controlled clinical trials (CCTs) comparing acupuncture to either placebo or sham, no treatment, conventional therapies or Chinese herbal medicine for patients with anxiety and depression induced by breast cancer will be involved. Case report, cross-sectional studies, comments, cohort studies, animal experiments and reviews will be excluded.

Eligibility criteria: Inclusion criteria: (1) RCTs involving acupuncture against another treatment or placebo/sham in patients with anxiety and depression induced by breast cancer; or studies that in the term of 'randomization' was mentioned. (2) Participants must be diagnosed with breast cancer. No restrictions on age, nationally, and race. (3) The intervention was acupuncture, electro-acupuncture or warm acupuncture and was compared with the control group. (4) The study does not require patients to be diagnosed with anxiety or depression, only to evaluate the change of anxiety or depression level after acupuncture. It means that an assessment of anxiety or depression is required in RCTs or CCTs. Exclusion criteria: (1) Incorrect randomization methods and other designs (such as in vivo, in vitro, case report and non-RCTs). (2) Studies comparing between different types of acupuncture therapies, such as only compared different manipulation forms or acupoint-selection methods of acupuncture, will be excluded.

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(3) Duplicate literature and incomplete data will not be considered.

Information sources: From inception up to June 30, 2022, the PubMed, Excerpt Medical Database (EMBASE), Web of Science(WoS), the Cochrane Library, Chinese Biomedical Database (CBM), China National Knowledge Infrastructure (CNKI), VIP Database and Wanfang Database.

Main outcome(s): The primary outcomes assessment will be carried out by the Hamilton Anxiety (HAMA) scale and the Hamilton Depression (HAMD) scale. The secondary outcomes will be included the Self-Rating Depression Scale (SDS), the Self-Rating Anxiety Scale (SAS), the quality of life based on measurement with a validated scale, such as the Short Form 36 Health Survey (SF-36), and the rate of adverse effects (AEs).

Quality assessment / Risk of bias analysis: Two authors (Chenxiao Ye and Changhong Wu) will independently assess the risk of bias with the Cochrane Collaboration's tool for risk of bias assessment for all included studies. Additionally, we will grade the quality of the evidence based on the Grades Profiler as the Grading of Recommendation, Assessment, Development, and Evaluation (GRADE) system. The assessments will be classified into three levels: low risk, high risk and unclear risk.

Strategy of data synthesis: Synthesis will be completed with clinical data by using RevMan software (V.5.3). The I2 test will be used to assess the statistical heterogeneity. If I2 is >50%, the heterogeneity across studies will be statistically significant and the random effects model will be used. Otherwise, we will choose a fixed effect model. If there is considerable heterogeneity, we will carry out subgroup analysis to identify the sources of heterogeneity.

Subgroup analysis: Planned subgroup analyses will be performed in: age, duration of disease, different stimulation methods of acupuncture, control group, different assessment scales for anxiety or depression, anxiety or depression and so on. If the study finds the substantial heterogeneity, we will carry out subgroup analysis or sensitivity analysis to identify the cause, otherwise we will give a descriptive report.

Sensitivity analysis: We will perform sensitivity analyses to verify robustness of results. It includes the impact of methodological quality, study design, and sample size.

Country(ies) involved: China.

Keywords: acupuncture, anxiety, depression, meta-analysis, protocol, breast cancer.

Contributions of each author:

Author 1 - Chenxiao Ye.
Email: 202011111511262@zcmu.edu.cn
Author 2 - Changhong Wu.
Email: 202111111511322@zcmu.edu.cn
Author 3 - Haitao Chen.
Email: chenht2756@zjcc.org.cn
Author 4 - Yong Guo.
Email: guoyong1047@zcmu.edu.cn

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