INPLASY PROTOCOL

To cite: Qin et al. Effectiveness and safety of massage in the treatment of anxiety and depression in patients with cancer: protocol for systematic review and meta-analysis. Inplasy protocol 202060101.

10.37766/inplasy2020.6.0101

Received: 27 June 2020

Published: 27 June 2020

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Support: Grant number: 81860877, 816608.

Review Stage at time of this submission: The review has not yet started.

Conflicts of interest: No.

Effectiveness and safety of massage in the treatment of anxiety and depression in patients with cancer: protocol for systematic review and meta-analysis

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Review question / Objective: This study comprehensively searched the literature to further systematically evaluate the efficacy and safety of massage in the treatment of anxiety and in patients with cancer, with a view to clinically treating anxiety and depression in patients with cancer, alleviating its related clinical symptoms and preventing its further development, and providing the latest evidence-based medical evidence.

Condition being studied: Cancer is one of the most common causes of death worldwide. It accounted for 7.6 million deaths (around 13% of all deaths) in 2008, and deaths from cancer internationally are projected to rise to over 11 million in 2030, according to the World Health Organization (WHO). Conventional treatment for cancer, such as surgery, chemotherapy, radiotherapy, and endocrine therapy, aiming at curing the disease or prolonging life, produces considerable beneficial medical outcomes. However, these treatments cannot eradicate the diseases and are often accompanied by adverse effects. It is acknowledged that most cancer patients suffer from both the disease itself and symptoms induced by conventional treatment, such as fatigue, anxiety, depression, nausea, and pain. Numerous patients report feeling abandoned and isolated following cessation of active treatment, which could exacerbate symptoms such as depression and anxiety. Massage is a Chinese nursing intervention that can effectively relieve anxiety and depression in patients with cancer. The treatment is safe and has no obvious adverse reactions.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 27 June 2020 and was last updated on 27 June 2020 (registration number INPLASY202060101).

INTRODUCTION

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METHODS

Search strategy: 8 electronic databases including PubMed, Web of Science, the Cochrane Database, EMBASE, China Knowledge Network (CNKI), Wanfang Data Knowledge Service Platform, VIP Chinese Science and Technology Periodical Database (VIP) and China Biomedical Literature (CBM) Database .The retrieval time was from the time the database was built to June 1, 2020. The search uses the keyword search. Chinese search terms include cancer, Malignant tumor, tumor,

Massage, tuina,anxiety, depression, random. English search terms include "Neoplasms" and "depression" and "anxiety" and "Massage or Massage Therapy". This study does not limit the

scope of language retrieval. In addition, we manually searched other literature, as well as unpublished research and conference materials. If the test report data is unknown or lacking, we will contact the author by email.

Participant or population: All cases included in the trial were patients with cancer and met the clinical diagnostic criteria of the International Continence Society for "cancer," without age and race restrictions.

Intervention: The treatment group was mainly massage therapy. The comparison group consisted of those receiving routine care or any intervention other than massage therapy.

Comparator: All cases included in the trial were patients with cancer and met the clinical diagnostic criteria of the International Continence Society for "cancer," without age and race restrictions.

Study designs to be included: A randomized controlled trial(RCT) study on massage treatment of cancer, published in any language.

Eligibility criteria: Types of study:All randomized controlled trials (RCTs) study on massage treatment of cancer.Others such as case reports, animal experiments, non-RCTs, or RCT protocol will be excluded.

Information sources: 8 electronic databases including PubMed, Web of Science, the Cochrane Database, EMBASE, China Knowledge Network (CNKI), Wanfang Data Knowledge Service Platform, VIP Chinese Science and Technology Periodical Database (VIP) and China Biomedical Literature (CBM) Database.

Main outcome(s): State Subscale of the State Anxiety Inven-tory (SAI); Center for Epidemiological Studies Depression (CES-D) Scale.

Additional outcome(s): Quality of Life Questionnaire Core 30 (QLQ-C30) from European Organization for Research on Treatment of Cancer (EORTC); Adverse events.

Data management: Two reviewers independently screened the literature, extracted the data, and cross-checked. If there were differences, they would discuss or listen to a third party to resolve them. The extracted data mainly include: ? basic characteristics: author, year of publication, sample size, age, gender, intervention measures, course of treatment, outcome indicators, follow-up, etc. ? methodological characteristics: random allocation method, random scheme concealment, blind method, etc.

Quality assessment / Risk of bias analysis:

Two reviewers performed rigorous methodological quality evaluation of the included studies with reference to the Cochrane Collaboration Bias Risk Assessment Tool for the extracted methodological features.

Strategy of data synthesis: Meta analysis was performed using RevMan5.3 provided by the Cochrane collaboration network. Relative risk (RR) was used for the two categorical variables, and mean difference (MD) was used for the continuous variables. Both were expressed with 95% confidence intervals (CI). The heterogeneity test between the results of the included studies was performed using the l2 test. The I² value reflects the proportion of the total variation in the effect size due to the existence of heterogeneity. I² ? 50%, indicating that heterogeneity is more obvious. If there is no obvious heterogeneity between the research results (I² <50%), the fixed effect model is used to merge them; if there is significant heterogeneity (I2?50%), the source of the heterogeneity is analyzed first, which may lead to heterogeneity Factors for subgroup analysis. If statistical heterogeneity exists in each subgroup without clinical heterogeneity, a random effects model is used for analysis. If the heterogeneity is too large and the results cannot be combined,

a descriptive analysis is used and a sensitivity analysis is performed if necessary.

Subgroup analysis: Subgroup analysis will be handled according to the differences in massage methods, patient conditions, and control.

Sensibility analysis: Sensitivity analyses will be performed to verify the robustness of the review conclusions. The impacts of study design, methodo- logical quality, and missing data will be evaluated. Sensitivity analyses were planned by studies considered being at low risk of bias.

Country(ies) involved: China.

Keywords: Massage; Cancer; Depression; Anxiety; meta-analysis; systematic review.

Contributions of each author:

Author 1 - Siyu Qin - Author 1 drafted the manuscript.

Author 2 - Yuanyi Xiao - The author provided statistical expertise.

Author 3 - Lin Jiao - Give funding and guidance.