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ADMINISTRATIVE INFORMATION

Support - No.
Review Stage at time of this submission - Preliminary searches.
Conflicts of interest - None declared.
INPLASY registration number: INPLASY2025100031

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 9 October 2025 and was last updated on 9 October 2025.

INTRODUCTION

Review question / Objective Given the substantial global public health burden of adult depression, there exists an urgent and critical need to formulate optimal or alternative treatment modalities grounded in the highest-quality available evidence. This study examined the association between Traditional Chinese Medicine (TCM) interventions and clinical efficacy in adult depression, while systematically evaluating the strength of evidence underpinning these associations.

Condition being studied Depression, a prevalent mood disorder, has emerged as a significant global public health concern. Epidemiological data indicate that approximately 322 million individuals worldwide are affected by depression, with a notable 18.4% increase in prevalence from 2005 to 2015. Projections suggest that by 2030, depression will surpass other conditions to become the leading cause of global disease burden. This "silent epidemic" not only severely

impairs patients' quality of life and social functioning but also contributes to high rates of recurrence and disability, exacerbating both individual suffering and societal costs. Current management of depression primarily relies on antidepressant medications and psychological therapies, yet these approaches face substantial limitations. Antidepressants, while effective in alleviating symptoms, typically require weeks to exert clinical effects and are associated with notable adverse reactions, such as sexual dysfunction and weight gain.

METHODS

Search strategy We conducted electronic searches across several databases: PubMed, MEDLINE, Scopus, Web of Science, Cochrane, Embase, China National Knowledge Infrastructure, Science and Technology Journal Database, and Wanfang from the establishment of the database to May 31, 2025, for meta-analyses investigating the association between Traditional Chinese Medicine (TCM) and clinical efficacy in adult

depression. Medical subject heading (MeSH) terms and keywords used in the search included "depression", "Traditional Chinese Medicine (TCM)", and "meta-analysis" or "systematic review". A Manual searches were also performed, and the authors of the original publications were contacted via email for additional data or clarification when necessary; however, most did not respond and were subsequently excluded.

Participant or population The study population comprises patients with depression, depressive disorder, post-stroke depression, postpartum depression, pain-related depression, perimenopausal depression, or cancer-related depression.

Intervention The interventions involve the use of Traditional Chinese Medicine (TCM) as an adjunct or in combination with conventional Western medicine and pharmacotherapy. TCM interventions may include Chinese herbal decoctions, herbal formulas, Chinese Patent Medicines, acupuncture, acupoint needling, traditional Chinese music therapy based on the Five Elements theory, or Baduanjin (Eight Pieces of Brocade) exercises. The comparator group consists solely of conventional Western medical treatments without TCM adjuncts.

Comparator Conventional Western medicine and pharmacotherapy.

Study designs to be included To be eligible for inclusion, articles must meet the following criteria: The study population comprises patients with depression, depressive disorder, post-stroke depression, postpartum depression, pain-related depression, perimenopausal depression, or cancer-related depression. The interventions involve the use of Traditional Chinese Medicine (TCM) as an adjunct or in combination with conventional Western medicine and pharmacotherapy. TCM interventions may include Chinese herbal decoctions, herbal formulas, Chinese Patent Medicines, acupuncture, acupoint needling, traditional Chinese music the.

Eligibility criteria Comprises patients with depression, depressive disorder, post-stroke depression, postpartum depression, pain-related depression, perimenopausal depression, or cancer-related depression. The interventions involve the use of Traditional Chinese Medicine (TCM) as an adjunct or in combination with conventional Western medicine and pharmacotherapy. TCM interventions may include Chinese herbal decoctions, herbal

formulas, Chinese Patent Medicines, acupuncture, acupoint needling, traditional Chinese music therapy based on the Five Elements theory, or Baduanjin (Eight Pieces of Brocade) exercises. The comparator group consists solely of conventional Western medical treatments without TCM adjuncts. The reported outcomes must include at least one of the following: total effective rate (TER) or the Hamilton Depression Rating Scale (HAMD) score. The study type must be a systematic review and meta-analysis of randomized controlled trials (RCTs) (with no restrictions on the size of the studies). There are no language, nationality, or ethnicity restrictions on the published articles. If an article presents multiple meta-analyses, all meta-analyses will be included and assessed separately according to the inclusion criteria. For multiple systematic reviews of the same TCM intervention in the same population with the same outcome, the following criteria will be applied: If the primary studies are completely overlapping, the highest-quality review will be selected. If the primary studies partially overlap or do not overlap, the meta-analysis with the largest number of trials and the most recent publication date will be chosen.

Information sources We conducted electronic searches across several databases: PubMed, MEDLINE, Scopus, Web of Science, Cochrane, Embase, China National Knowledge Infrastructure, Science and Technology Journal Database, and Wanfang from the establishment of the database to May 31, 2025, for meta-analyses investigating the association between Traditional Chinese Medicine (TCM) and clinical efficacy in adult depression. Medical subject heading (MeSH) terms and keywords used in the search included "depression", "Traditional Chinese Medicine (TCM)", and "meta-analysis" or "systematic review". A Manual searches were also performed, and the authors of the original publications were contacted via email for additional data or clarification when necessary; however, most did not respond and were subsequently excluded.

Main outcome(s) The reported outcomes must include at least one of the following: total effective rate (TER) or the Hamilton Depression Rating Scale (HAMD) score.

Quality assessment / Risk of bias analysis Assessment of Methodological Quality and Evidence Quality for Included Studies
Two reviewers (NF, SW) independently used the AMSTAR 2 to evaluate the methodological quality of the included systematic reviews (SRs) and meta-analyses (MAs). This tool comprises 16 core items, covering key domains such as the clarity of

research questions and inclusion criteria, the comprehensiveness of literature search strategies (e.g., whether grey literature was included), the reproducibility of study selection and data extraction, the assessment of bias risk in included studies, the testing of publication bias, heterogeneity analysis, and the validation of conclusion robustness. Ultimately, methodological quality was stratified into four levels: "High", "Moderate", "Low", and "Critically Low".

Concurrently, the Ioannidis evidence strength grading criteria were applied to categorize the evidence strength for the efficacy of traditional Chinese medicine (TCM) interventions. This framework is grounded in five core elements: st.

Strategy of data synthesis To ensure methodological rigor and statistical reliability in the comprehensive analysis, this study employed a two-stage strategy: in the first stage, given the diversity of Traditional Chinese Medicine (TCM) interventions (e.g., herbal medicines, acupuncture) and the inherent between-study heterogeneity (e.g., baseline characteristics of study populations, intervention protocols) and within-study heterogeneity (e.g., randomization methods, blinding implementation) in the included meta-analyses (MAs) or MAs attached to systematic reviews (SRs), the DerSimonian and Laird (D-L) random-effects model was used to re-model each eligible MA or SR-attached MA, aiming to correct for the impact of heteroscedasticity on effect size estimation. This stage specifically involved two key operations: first, extraction of primary effect sizes, where original effect sizes were retrieved from the included SRs/MAs—for dichotomous outcomes (e.g., total effective rate [TER]), pooled odds ratios (ORs) or risk ratios (RRs) were ext.

Subgroup analysis No.

Sensitivity analysis No.

Country(ies) involved China.

Keywords Umbrella Review; Adult Depression; TCM Interventions; Clinical Efficacy; Evidence Grading.

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