

INPLASY2025110053
doi: 10.37766/inplasy2025.11.0053
Received: 18 November 2025
Published: 18 November 2025

Yu, YJ; Zhu, LH; Guo, WC.

Corresponding author:
yongjiang Yu

s15301471@outlook.com

Author Affiliation:
Yibin First People's Hospital West
District General Hospital.

ADMINISTRATIVE INFORMATION

Support - This study is supported by institutional research resources; no specific external funding has been received.

Review Stage at time of this submission - Preliminary searches.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY2025110053

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 18 November 2025 and was last updated on 18 November 2025.

INTRODUCTION

Review question / Objective Using the PICOS framework: P (Participants): Patients diagnosed with breast cancer receiving radiotherapy. I (Intervention): Radiotherapy combined with Traditional Chinese Medicine (TCM), including herbal medicine, TCM decoctions, patent medicines, or integrative regimens. C (Comparator): Radiotherapy alone or radiotherapy plus conventional Western supportive care. O (Outcomes): Treatment effectiveness (tumor response, symptom improvement), radiotherapy-related toxicities, immune indicators, quality of life, and safety outcomes. S (Study design): Randomized controlled trials.
Objective:
To systematically evaluate whether combining TCM with radiotherapy improves clinical outcomes and reduces toxicity in breast cancer patients compared with radiotherapy alone.

Condition being studied Breast cancer, a malignant tumor originating from breast epithelial cells, commonly treated with surgery, chemotherapy, radiotherapy, and targeted therapy. Radiotherapy plays an essential role but may cause significant side effects. TCM is used clinically as an adjunct therapy aiming to enhance efficacy and reduce toxicity.

METHODS

Participant or population Women (or mixed populations) with clinically diagnosed breast cancer undergoing radiotherapy.

Intervention Radiotherapy combined with Traditional Chinese Medicine, including: TCM herbal decoctions
Chinese patent medicines
Injectables of TCM origin
Integrated TCM-Western medicine supportive care.

Comparator Radiotherapy alone, or radiotherapy with standard Western supportive treatment.

Study designs to be included Randomized controlled trials.

Eligibility criteria

Inclusion:

Studies including breast cancer patients treated with radiotherapy

Studies comparing radiotherapy+TCM vs. radiotherapy alone

Studies reporting at least one outcome of interest

Exclusion:

Reviews, case reports, conference abstracts without full data

Animal studies

Interventions not primarily involving TCM

Duplicate publications.

Information sources Electronic databases, manual search of references, clinical trial registries, grey literature, and contacting authors if necessary.

Main outcome(s) Clinical effectiveness rate or objective tumor response

Radiotherapy-related toxicities (e.g., skin reactions, fatigue, leukopenia)

Quality of life scores

Immunological or inflammatory biomarkers

Effect measures: Risk ratios (RR), mean differences (MD), or standardised mean differences (SMD) with 95% CI.

Quality assessment / Risk of bias analysis RCTs will be assessed using the Cochrane Risk of Bias 2.0 tool. Two authors will independently assess quality, with arbitration by a third reviewer if needed.

Strategy of data synthesis

Data will be synthesized using RevMan or R (meta package). Heterogeneity will be evaluated using I^2 statistics.

Fixed-effects model if $I^2 < 50\%$

Random-effects model if $I^2 \geq 50\%$

Subgroup analyses and sensitivity analyses will explore sources of heterogeneity. Publication bias will be assessed using funnel plots and Egger's test.

Subgroup analysis

Possible subgroups:

Type of TCM intervention

Radiotherapy modality (IMRT/3D-CRT)

Stage of breast cancer

Study design (RCT vs. cohort).

Sensitivity analysis Performed by excluding low-quality studies, changing effect models, and removing studies with extreme effect sizes to test robustness.

Country(ies) involved China.

Keywords Breast cancer; radiotherapy; traditional Chinese medicine; meta-analysis; integrative oncology.

Contributions of each author

Author 1 - yongjiang yu.

Author 2 - lihua zhu.

Author 3 - weichang guo.