INPLASY

Efficacy of Integrated Traditional Chinese and Western Medicine in the Treatment of Rheumatoid Arthritis: a systematic review and meta-analysis

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ADMINISTRATIVE INFORMATION

Support - None.

Review Stage at time of this submission - Data analysis.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 16 March 2025 and was last updated on 16 March 2025.

INTRODUCTION

Review question / Objective The objective of this meta-analysis is to explore the efficacy and safety of integrated traditional Chinese and Western medicine in the treatment of rheumatoid arthritis(Ra).

Rationale Rheumatoid arthritis (RA) is a refractory autoimmune disease that affects multiple organ systems throughout the body, clinically presenting as erosive polyarthritis. It is a common and challenging condition with a high disability rate and significant harm. If not treated promptly and effectively, the destruction of bones and joints is often irreversible, leading to loss of joint function, and in severe cases, can result in disability or even death . Currently, the treatment for rheumatoid arthritis primarily involves drug therapy, with commonly used medications including non-steroidal anti-inflammatory drugs, traditional anti-rheumatic drugs, biologics, and corticosteroids. These medications can be used alone or in combination. During treatment, patients often experience relapses, drug side effects, increased risk of infection, and high medical costs. Increasingly, studies have found that the combination of traditional Chinese medicine and Western medicine in treating rheumatoid arthritis can significantly improve patients' conditions, alleviate their suffering, and enhance their quality of life, with treatment costs being more acceptable to many families. However, there is a lack of strong support for its efficacy from multi-center, large-sample clinical trials. Therefore, this study aims to systematically evaluate the clinical efficacy and safety of integrated traditional Chinese and Western medicine (TCW)compared to Western medicine alone in the treatment of RA, in order to provide evidence-based references for its clinical application.

Condition being studied Rheumatoid arthritis (RA) is an intractable autoimmune disease that affects multiple organ systems throughout the body. Clinically, it is most often characterized by erosive polyarthritis, making it a common yet challenging condition associated with a high rate of disability

and significant health risks. Without timely and effective treatment following onset, the destruction of bones and joints is frequently irreversible, ultimately leading to the loss of joint function and, in severe cases, resulting in disability or even death.

METHODS

Search strategy Using keywords and titles such as 'rheumatoid arthritis', 'rheumatoid disease', 'rheumatism arthritis', 'integrated medicine', 'combination of Chinese traditional and Western medicine', 'integrated traditional Chinese and Western medicine', 'integration of traditional and Western medicine', and 'integrative medicine', a computer search was conducted in the China National Knowledge Infrastructure (CNKI), VIP Chinese Science and Technology Journals Full-text Database, Wanfang Database, China Biomedical Literature Database (CBM), PubMed, Embase, Cochrane Library, and a manual search in the Chinese Clinical Trials Registry to find relevant literature. The search period was from the establishment of the database until December 2024. The literature abstracts and full texts were read strictly according to the inclusion and exclusion criteria, and unqualified literature was excluded with reasons indicated. The methodological quality of the included studies was assessed according to the methods in the Cochrane Handbook for Systematic Reviews 5.1.0 for evaluating the quality of RCTs, including randomization methods, allocation concealment, blinding of patients and physicians, outcome evaluation, completeness of outcome data, selective reporting, and other sources of bias.

Participant or population Inclusion criteria(1) Literature type: Randomized controlled study (2) Subjects: The diagnostic criteria of Western medicine in the included cases refer to the new diagnostic criteria of the American College of Rheumatology and the European League of Anti-Rheumatism in 2010 for the diagnosis of RA. This criterion scores 4 parts: joint involvement, serological indicators, duration of synovitis, and acute phase reactants, and a total score of ≥6 or more can be used to diagnose RA. The diagnostic criteria of TCM are based on the syndrome differentiation criteria of the Guidelines for the Combined Diagnosis and Treatment of Rheumatoid Arthritis. (3) Interventions: The treatment group of patients with rheumatoid arthritis was treated with integrated traditional Chinese and Western medicine, and the patients with rheumatoid arthritis in the control group were treated with Western medicine alone. (4) The outcome indicators of the two groups could be extracted from the literature, and the relevant indicators and efficacy judgment criteria of rheumatoid arthritis treatment could be comprehensively evaluated. Overall efficacy: The overall efficacy of patients was determined according to the changes in clinical indicators and CRP and ESR levels before and after treatment; Clinical cure: Symptoms and signs completely disappeared, joint mobility returned to normal, and the total score of TCM syndrome decreased by ≥95%; Efficacy: Symptoms and signs are significantly improved or basically disappeared, joint mobility and function are close to normal, and the total score of TCM syndrome is reduced by 70% ~94%; Effective: Symptoms and signs were improved, joint mobility function was improved, and the total TCM pattern score was reduced by 30% ~ 69%; Ineffective: The above criteria are not met. The efficacy of rheumatoid arthritis treated with Western medicine alone is not very ideal, and the combination of traditional Chinese and Western medicine in the treatment of rheumatoid arthritis has gradually shown great advantages, but its efficacy lacks strong support from multi-center and large-sample clinical trials. In this study, we searched for randomized controlled trials (RCTs) in the treatment of rheumatoid arthritis and conducted a meta-analysis, aiming to further evaluate the clinical efficacy of the combination of traditional Chinese and Western medicine in the treatment of rheumatoid arthritis and the relevant evidence-based medical evidence, in order to provide evidence-based basis for clinicians to rationally use drugs.Exclusion Criteria:
(1) Patients enrolled in the study who have concomitant severe organ or systemic diseases, other immunological disorders, intolerance or allergy to the study medication, or communication barriers or psychiatric conditions.(2) Studies that do not clearly specify the grouping method, employ non-randomized grouping, or use an evidently flawed randomization method.(3) Studies in which the study interventions are confounded by other therapeutic measures.(4) Studies employing reciprocal control designs.(5) Studies in which both the control and treatment groups receive an integrated approach combining traditional Chinese and Western medicine.(6) Patients who do not adhere to the prescribed medication regimen or who withdraw from the study for personal reasons. (7) Patients who had received related treatments prior to enrollment, or who are pregnant or lactating.

Intervention The treatment group was treated with a combination of traditional Chinese and Western

medicine; The control group was treated with Western medicine alone.

Comparator Our objective is to compare the cure rate, improvements in ESR and CRP levels, the incidence of interstitial pneumonia, and the extent of bone and joint destruction between rheumatoid arthritis patients treated with integrated Chinese and Western medicine and those receiving Western medicine alone.

Study designs to be included Randomized controlled trial.

Eligibility criteria Rheumatoid arthritis(RA)was diagnosed according to American College of Rheumatology 1987 RA classification standard or European League Against Rheumatism 2010 RA classification standard.The diagnostic criteria of Traditional Chinese Medicine (TCM) refer to the syndrome differentiation standards outlined in the Guidelines for the Diagnosis and Treatment of Rheumatoid Arthritis with Integrated Disease and Syndrome Differentiation.

Information sources PubMed, EMBASE, Cocharne Library, CHKD-CNKI, CBM, WANFANG, VIP Databases.

Main outcome(s) The efficacy of integrated traditional Chinese and Western medicine treatment compared to conventional Western medicine treatment for rheumatoid arthritis.

Additional outcome(s) Joint pain and functional recovery status, progression of interstitial pneumonia, and other related conditions.

Data management In accordance with the research requirements, two retrieval personnel independently extracted and recorded various data using a double-blind method. The extracted data included the first author of the literature, year of publication, sample size of the experimental and control groups, gender distribution, intervention details, intervention protocol, and outcome measures, among other relevant information.The Meta-analysis was conducted using RevMan 5.3 software to assess the quality of the included studies. Low-quality studies were excluded, while medium- and high-quality studies were pooled for analysis. A forest plot was generated for descriptive analysis, and a funnel plot was drawn to evaluate publication bias. For dichotomous variables, relative risk (RR) was used as the statistical measure, with all effect sizes presented as 95% confidence intervals (CI).

Quality assessment / Risk of bias analysis According to the recommendations of evidence-based medicine research guidelines, the "Risk of Bias Assessment" tool from the Cochrane systematic review was employed to evaluate the quality of the included studies based on six criteria: randomization method, allocation concealment, blinding, completeness of outcome data, selective reporting of study results, and other sources of bias. During the statistical process, the quality assessment was categorized as follows: studies meeting five or more criteria were classified as having a low risk of bias, those meeting three to four criteria were classified as having a moderate risk of bias, and those meeting fewer than three criteria were classified as having a high risk of bias.

Strategy of data synthesis The Meta-analysis was conducted using RevMan 5.3 software to assess the quality of the included studies. Low-quality studies were excluded, while medium- and high-quality studies were pooled for analysis. A forest plot was generated for descriptive analysis, and a funnel plot was drawn to evaluate publication bias. For dichotomous variables, relative risk (RR) was used as the statistical measure, with all effect sizes presented as 95% confidence intervals (CI).

Subgroup analysis This study will conduct a subgroup analysis based on Traditional Chinese Medicine (TCM) diagnostic classifications, recovery status, improvement in inflammation, and enhancement of joint function.

Sensitivity analysis When heterogeneity is detected in the screened literature, sensitivity analysis will be conducted to identify the source of heterogeneity.

Language restriction Randomized clinical trials published in Chinese and English will be considered for inclusion.

Country(ies) involved China.

Other relevant information Hui Yang, Fenglian Ma These authors contributed equally to this work.

Keywords Integrated Traditional Chinese and Western Medicine, Rheumatoid arthritis, Meta-analysis.

Dissemination plans The findings of this study will be disseminated in the form of a published paper..

Contributions of each author

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