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# A study of a traditional Chinese herbal formula combined with standard medication for treating a specific type of rheumatoid arthritis

**Submission date**
22/09/2025

**Recruitment status**
Recruiting

**Registration date**
24/09/2025

**Overall study status**
Ongoing

**Last Edited**
23/09/2025

**Condition category**
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

## Plain English summary of protocol

Background and study aims
Rheumatoid arthritis (RA) is a long-term condition that causes pain, swelling, and stiffness in the joints. For many people with RA, the condition also affects their mood, leading to anxiety and depression. This can create a difficult cycle: emotional distress can make RA symptoms worse, and in turn, the pain and disability from RA can worsen feelings of anxiety and depression.

Currently, when people with RA also have anxiety or depression, they are often given separate antidepressant medicines. However, these medicines can have side effects that are difficult for patients to tolerate. This study is testing a new approach based on traditional Chinese medicine principles. We want to find out if a specially formulated herbal medicine, called Wenyang Jieyu granules, can improve both joint symptoms and mood when it is taken together with the standard RA drug, methotrexate. The aim is to find a treatment that can help manage both the physical and emotional aspects of rheumatoid arthritis more effectively.

Who can participate?
This study is for adults aged between 18 and 70 years who have been diagnosed with rheumatoid arthritis. Participants must also be experiencing symptoms of anxiety or depression and have mild to moderate disease activity. The study team will check some other health criteria to ensure it is safe for a person to take part.

What does the study involve?
Participants who join the study will be randomly assigned (like flipping a coin) to one of two groups for a 12-week treatment period. One group will receive the active Wenyang Jieyu granules plus the standard drug, methotrexate. The other group will receive a placebo (a dummy treatment that looks the same but has no active ingredients) plus methotrexate. This is a 'double-blind' study, which means neither the participants nor their doctors will know who is receiving the active herbal medicine until the study is over. This helps to ensure the results are unbiased.

What are the possible benefits and risks of participating?
Taking part in the study may lead to an improvement in arthritis symptoms and mood. The information we get from this study will also help researchers and doctors understand better ways to treat RA in the future. However, there are also possible risks. The study drugs can have side effects, which the study team will monitor very carefully. Participating in the study also requires a time commitment for visits to the hospital.

Where is the study run from?
The research is being carried out at the Beijing University of Chinese Medicine Fangshan Hospital in Beijing, China.

When is the study starting and how long is it expected to run for?
January 2024 to December 2026.

Who is funding the study?
This research is funded by the Beijing Municipal Health Commission through the Capital's Funds for Health Improvement and Research program (China)

Who is the main contact?
Wei Shufeng, weifeng19711009@126.com

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# Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
2024-2- 7073

# Study information

### Scientific Title
Double blind randomized controlled trial of WenyangJieyu decoction combined with methotrexate in the treatment of rheumatoid arthritis with cold dampness obstruction and depression

### Acronym
WYJY-RA

### Study objectives
The primary aim is to evaluate the clinical efficacy of Wenyang Jieyu Decoction combined with methotrexate in treating rheumatoid arthritis (RA) of the cold-dampness obstruction with depression pattern. The study will also observe changes in indicators such as anxiety, depression, and quality of life, in order to clarify the therapeutic advantages of Wenyang Jieyu Decoction for treating RA complicated with anxiety and depression.

### Ethics approval required
Ethics approval required

### Ethics approval(s)
1. Approved 22/01/2024, Beijing University of Chinese Medicine Fangshan Hospital Ethics Committee (No. 4, Baojian Road, Chengguan, Fangshan District, Beijing, 102400, China; +86 10-89325950; fszykjk2017@sina.com), ref: FZYLK-2024-002

2. Approved 12/12/2024, Beijing University of Chinese Medicine Fangshan Hospital Ethics Committee (No. 4, Baojian Road, Chengguan, Fangshan District, Beijing, 102400, China; +86 10-89325950; fszykjk2017@sina.com), ref: FZYLK-2024-043

### Study design
Single-center interventional double-blinded randomized controlled trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Treatment, Safety, Efficacy

## Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

## Health condition(s) or problem(s) studied
Rheumatoid arthritis with cold dampness obstruction and depression

## Interventions
Intervention group: Participants will receive Wenyang Jieyu granules (1 dose daily, dissolved in water and taken in two divided doses) in combination with methotrexate tablets (10 mg, taken orally once a week).

Control group: Participants will receive a placebo matching the Wenyang Jieyu granules (1 dose daily, dissolved in water and taken in two divided doses) in combination with methotrexate tablets (10 mg, taken orally once a week).
The treatment period for both groups will be 12 weeks.

A random allocation sequence will be generated using SAS statistical software with a 1:1 allocation ratio. The sequence will be implemented using sequentially numbered, sealed envelopes.
A third party will assign participants to either group A or group B according to the random numbers, and the allocation will be concealed from the investigators responsible for patient recruitment. The randomization code, including the initial seed and block size, as well as the corresponding treatments for groups A and B, will be documented. This documentation will be kept securely by the hospital's Scientific Research Department and can be reproduced if necessary.

## Intervention Type
Drug

## Pharmaceutical study type(s)
Pharmacodynamic

## Phase
Not Applicable

## Drug/device/biological/vaccine name(s)
Wenyang Jieyu granules; methotrexate tablets; placebo matching Wenyang Jieyu granules

## Primary outcome measure
ACR20 response measured using the American College of Rheumatology (ACR) 20 criteria at 12 weeks of treatment.

## Secondary outcome measures

1. Disease Activity Score (DAS28) measured using the DAS28 assessment at weeks 0, 4, 8, and 12.
2. Proportion of participants achieving ACR50 response measured using the American College of Rheumatology (ACR) 50 criteria at weeks 0, 4, 8, and 12.
3. Proportion of participants achieving ACR70 response measured using the American College of Rheumatology (ACR) 70 criteria at weeks 0, 4, 8, and 12.
4. Overall response rate of Traditional Chinese Medicine (TCM) syndromes measured using TCM syndrome scoring criteria at weeks 0, 4, 8, and 12.
5. Patient-reported outcomes measured using the Patient-Reported Outcome (PRO) scale for RA at weeks 0, 4, 8, and 12.
6. Disability index measured using the Health Assessment Questionnaire (HAQ) at weeks 0, 4, 8, and 12.
7. Anxiety symptoms measured using the 14-item Hamilton Anxiety Scale (HAMA-14) at weeks 0, 4, 8, and 12.
8. Depression symptoms measured using the 24-item Hamilton Depression Scale (HAMD-24) at weeks 0, 4, 8, and 12.
9. Joint inflammation and damage measured using the 7-joint ultrasound score (US7) at weeks 0, 4, 8, and 12.

### Overall study start date
01/01/2024

### Completion date
30/12/2026

## Eligibility

### Key inclusion criteria
1. Voluntarily participate and sign the informed consent form after understanding the full trial process.
2. Meet the 2010 ACR/EULAR diagnostic criteria for Rheumatoid Arthritis (RA).
3. Meet the Traditional Chinese Medicine (TCM) pattern differentiation of cold-dampness obstruction with depression.
4. Meet the diagnostic criteria for an anxiety and/or depressive state.
5. Aged between 18 and 70 years, inclusive, any gender.
6. Males or females with no plans for childbirth; or are peri- or post-menopausal women.
7. Patients with mild to moderate disease activity, defined as a DAS28-ESR score > 2.6 and ≤ 5.1.
8. No severe systemic involvement, such as severe pericardial effusion, interstitial lung disease, renal tubular acidosis, atrophic gastritis, or autoimmune liver disease.
9. Have not participated in any other drug trials within 1 month prior to enrollment.

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Upper age limit
70 Years

### Sex
Both

### Target number of participants
72

### Key exclusion criteria
1. Pregnant, planning to become pregnant, or breastfeeding women.
2. Patients with active liver disease or abnormal liver function, defined as Alanine Aminotransferase (ALT) or Aspartate Aminotransferase (AST) levels > 1.5 times the upper limit of normal (ULN).
3. Impaired renal function, defined as serum creatinine above the upper limit of normal.
4. Peripheral white blood cell count < $3.0\times10^9$/L, confirmed anemia (hemoglobin < 80g/L), platelet count < $80\times10^9$/L, or have other hematological disorders.
5. History of intolerance or significant adverse reaction to methotrexate, OR an inadequate response to a prior course of treatment with methotrexate at a dose of ≥10 mg/week for at least 12 weeks.
6. Patients with acute or chronic infectious diseases.
7. Patients with severe arrhythmia found on electrocardiogram (ECG).
8. Patients with a current or a history of malignancy.
9. Patients with a psychiatric disorder, a history of alcohol abuse, OR a history of drug abuse.
10. A confirmed diagnosis of another connective tissue disease, OR failure to achieve disease control within the 3 months prior to enrollment despite receiving guideline-recommended standard therapy with immunosuppressants or biologic agents.

### Date of first enrolment
01/08/2024

### Date of final enrolment
30/09/2026

## Locations

### Countries of recruitment
China

### Study participating centre
**Beijing University of Chinese Medicine Fangshan Hospital**
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## Sponsor information

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Beijing Municipal Health Commission

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### Sponsor type
Government

### Website
https://wjw.beijing.gov.cn

### ROR
https://ror.org/0374a5s68

## Funder(s)

### Funder type
Government

### Funder Name
Capital's Funds for Health Improvement and Research program

## Results and Publications

### Publication and dissemination plan
Planed publication in a peer-reviewed journal

### Intention to publish date
30/12/2027

### Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as a supplement to the results publication.

### IPD sharing plan summary
Published as a supplement to the results publication