ISRCTN53183053 https://doi.org/10.1186/ISRCTN53183053

Randomized, double-blind, placebo-controlled, multicenter clinical study of Xiaoyao Mixture for the treatment of mild to moderate depression

Submission date
28/03/2024

Recruitment status
No longer recruiting

Registration date
11/04/2024

Overall study status
Completed

Last Edited
12/11/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Depression is a common mental health condition affecting millions of people worldwide. Traditional Chinese Medicine (TCM) has been used for centuries to treat various conditions, including depression. This study aims to evaluate the efficacy and safety of a TCM formula known as Xiaoyao Mixture in treating mild to moderate depression. Our goal is to provide clinical evidence that supports the use of this TCM approach in treating depression.

Who can participate?
Individuals aged 16 to 65 years, of any gender, who have been diagnosed with mild to moderate depression according to the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) and have a specific score on the Hamilton Depression Rating Scale (HAMD-17) can participate. These participants should also meet the TCM diagnosis for liver stagnation and spleen deficiency syndrome. Participants should be willing to sign an informed consent form and agree to participate in all required visits and treatment checks.

What does the study involve?
Participants will be randomly assigned to either the treatment group or the placebo group. The treatment group will receive Xiaoyao Mixture orally, twice a day, while the placebo group will receive a placebo with the same schedule. The trial includes several visits for assessment and monitoring, during which participants will undergo various health checks and evaluations, including blood and urine tests.

What are the possible benefits and risks of participating?
Participants may not directly benefit from participating in the study. However, the results may help improve the understanding and treatment of depression, benefiting future patients. As with any medication, there may be risks of side effects. Potential risks will be explained in detail prior to participation, and participants are free to withdraw from the study at any time.

Where is the study run from?
The study is being conducted at several sites in China, including Jinan University, Guangzhou, Guangdong Province.

When is the study starting and how long is it expected to run for?
November 2022 to November 2025

Who is funding the study?
The study is funded by a grant from Lunan Hope Pharmaceutical Co., Ltd. (China)

Who is the main contact?
Dr xuan ZHOU, xuetcm@gmail.com
Prof. Jia-xu Chen, chenjiaxu@hotmail.com

Contact information

Type(s)
Principal investigator

Contact name
Prof jia-xu Chen

ORCID ID
https://orcid.org/0000-0002-5570-6233

Contact details
No.601, West Huangpu Avenue
Guangzhou
China
510632
+86 20 8522 1323
chenjiaxu@hotmail.com

Type(s)
Public, Scientific

Contact name
Dr xuan ZHOU

ORCID ID
https://orcid.org/0000-0002-5501-4579

Contact details
No.601, West Huangpu Avenue
Guangzhou
China
510632
+86 20 8522 1323
zhoux2019@jnu.edu.cn

Additional identifiers

Protocol serial number
ChiCTR2300074953

Study information

Scientific Title
Randomized controlled study on the treatment of mild to moderate depression with Xiaoyao Mixture

Study objectives
Xiaoyao Mixture is effective in treating mild to moderate depression compared to a placebo

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 04/11/2022, IRB of Jinan University (No.613, West Huangpu Avenue, Guangzhou, 510632, China; +86 20 8522 0250; oykyc@jnu.edu.cn), ref: JNUKY-2022-100

Study design
Multicenter interventional double-blinded randomized controlled trial

Primary study design
Interventional

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Mild to moderate depression

Interventions
This study is a prospective, multi-center, double-blinded, randomized controlled trial (RCT) with two parallel arms: XYM group and placebo group. The trial will recruit 72 patients with MMD from 4 hospitals in China, who will be randomly assigned in a 1:1 ratio to receive either XYM (Xiaoyao Mixture), an oral solution, at a dosage of 30 millilitres, two times per day or placebo for 6 weeks.

Randomization will be performed using a central, concealed, web-based system, with stratification by site. An independent statistician will generate the allocation sequence. Participants, researchers, and outcome assessors will be blinded to the group assignments. Unblinding will occur only after the trial's conclusion or in case of emergency.

Intervention Type
Supplement

Primary outcome(s)

Depression severity measured using Hamilton Depression Rating Scale at baseline, Week 1, Week 2, Week 4 and Week 6.

Key secondary outcome(s))
1. Anxiety levels measured using Hamilton Anxiety Rating Scale at Week 1, Week 2, Week 4, and Week 6.
2. Anhedonia assessed with Dimensional Anhedonia Rating Scale at Week 1, Week 2, Week 4, and Week 6.
3. Pleasure experience measured using Temporal Experience of Pleasure Scale at Week 1, Week 2, Week 4, and Week 6.
4. Quality of life satisfaction gauged with Quality of Life Enjoyment and Satisfaction Questionnaire-Short Form at Week 1, Week 2, Week 4, and Week 6.
5. Somatic symptoms measured using Patient Health Questionnaire-15 at Week 6.
6. Sleep quality assessed with Pittsburgh Sleep Quality Index at Week 6.
7. Global functioning evaluated with Clinical Global Impression scale at Week 1, Week 2, Week 4, and Week 6.
8. Traditional Chinese Medicine syndrome evaluated with Liver Depression and Spleen Deficiency Syndrome score at Week 1, Week 2, Week 4, and Week 6.

Completion date
07/11/2025

Eligibility

Key inclusion criteria
1. Meet the diagnostic criteria for depression in the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) with a HAMD-17 score between 7 and 24 points.
2. Meet the diagnosis criteria for liver depression and spleen deficiency syndrome;
3. Patients aged 16-65 years, regardless of gender;
4. Patients are voluntary, have informed consent, and have good compliance.

Participant type(s)
Healthy volunteer, Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
16 years

Upper age limit
65 years

Sex
All

Total final enrolment
72

Key exclusion criteria
1. Patients with bipolar depression, refractory depression, or suicidal tendency (item 3 score of HAMD scale > 2 points);
2. Patients with other mental disorders such as organic mental disorders, schizophrenia, depression disorders caused by psychoactive substances and non-addictive substances;
3. Patients with severe organ lesions such as heart, liver and kidney, hematological diseases or tumors;
4. Patients who have received systematic treatment within 2 weeks before enrollment;
5. Pregnant or lactating women, or those who require fertility during the trial;
6. Patients who are participating in other clinical trials or have participated in other drug clinical trials within 3 months before screening;
7. Patients with a known or suspected allergy to the investigational drugs and excipients, or hypersensitivity constitution (defined as allergy to at least 2 drugs);
8. Patients who used fluoxetine within 4 weeks before enrollment;
9. Other situations that the researchers consider unsuitable for participating in this trial.

Date of first enrolment
01/11/2023

Date of final enrolment
31/12/2024

Locations

Countries of recruitment
China

Study participating centre
Guangdong Province Hospital of Traditional Chinese Medicine
No.111 Dade Road, Yuexiu District
Guangzhou
China
510120

Study participating centre
Guangzhou Overseas Chinese Hospital
No.613, West Huangpu Avenue
Guangzhou
China
510632

Study participating centre

Beijing Hospital of Traditional Chinese Medicine
No.23 Meishuguanhoujie Street, Dongcheng District
Beijing
China
100010

Study participating centre
Ganzhou City people's hospital
No. 16 Meiguan Avenue, Zhanggong District
Ganzhou
China
341000

Sponsor information

Organisation
Jinan University

ROR
https://ror.org/04bgbsx11

Funder(s)

Funder type
Industry

Funder Name
Lunan Hope Pharmaceutical Co., Ltd.

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Protocol file	11/04/2024	No	No