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Moxibustion alongside standard anti-HIV treatment compared with simulated moxibustion: a feasibility and safety study

Submission date
09/11/2026

Recruitment status
Recruiting

Registration date
18/11/2026

Overall study status
Ongoing

Last Edited
09/11/2026

Condition category
Infections and Infestations

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Public, Scientific, Principal investigator

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Study information

Scientific Title
Evaluation of the efficacy and adherence of moxibustion in people living with HIV: a randomized feasibility trial

Acronym
MOXHIV

Study objectives
Primary objective: This study aims to evaluate the efficacy and adherence of moxibustion therapy delivered along with standard ART, and to determine whether the existing procedures can support a future full scale randomized controlled trial.
Feasibility questions: This study will focus on answering the following questions, including whether the target population can be successfully recruited and randomized; whether true moxibustion and sham moxibustion can be implemented as per protocol; whether trial participants can maintain good adherence and follow-up retention; whether blinding can be maintained; and whether safety monitoring and outcome data collection procedures are executable.
Exploratory questions: Whether ART combined with moxibustion can improve immune-related laboratory indicators etc., without making confirmatory efficacy claims.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 05/11/2026, Medical Ethics Committee of Yunnan Infectious Disease Hospital (20 meters northwest of the intersection of Chunhui Road and Lingjiaotang Road, Wuhua District, Kunming, 650106, China; +86 871-68728017; K68728017@163.com), ref: 2026046

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
HIV infection (HIV/AIDS)

Interventions
This is a two-arm, parallel-group, randomised, sham-controlled pilot trial. Sixty adults living with HIV will be randomly allocated 1:1 using a computer-generated sequence (allocation concealed via sequentially numbered, opaque, sealed envelopes) to one of two groups, with both groups continuing their standard antiretroviral therapy (ART) throughout.
Intervention group: ART plus real moxibustion (mild-warming moxibustion), delivered with self-adhesive Baixiao moxibustion devices to the acupoints Zusanli (ST36), Shenque (RN8), and

Guanyuan (CV4), 20–30 minutes per point per session (bilateral), five times per week (at least three), for 12 consecutive weeks. Treatment will be delivered either by trained personnel in a clinic or by the participants themselves at home after standardised training, depending on the implementation model assigned by each site (not chosen by participants); in the self-administration model, participants will keep treatment logs and provide photographs/videos to confirm treatment completion.
Control group: ART plus sham (placebo) moxibustion using an identical-appearing device from the same manufacturer, in which a heat-insulating sheet markedly reduces the heat delivered while the moxa still burns and produces smoke. The sham procedure matches the real procedure in treatment schedule, session duration, environment, and participant–provider contact.
Participants and outcome assessors will be blinded to group allocation. After randomisation, participants will be followed every 2 weeks to Week 24; exploratory clinical outcomes (CD4+ /CD8+ counts and ratio, immunoglobulins A/G/M, fatigue, quality of life, BMI) will be assessed at baseline and every 6 weeks to Week 24, and adverse events will be recorded throughout.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Proportion of planned intervention sessions completed during the 12-week intervention period measured using the number of sessions completed divided by the total number of sessions planned at week 12 after randomization

Key secondary outcome(s)
1. CD4 T-cell count measured using flow cytometry at baseline, Week 12 and Week 24 using the laboratory method specified by the participating centres; week 12 is the main assessment time point and week 24 is a follow-up assessment

2. Quality of life measured using WHOQOL-HIV-BREF at baseline, week 6, week 12, week 18 and week 24

Completion date
30/11/2027

Eligibility

Key inclusion criteria
1. Adults who meet the diagnostic criteria for HIV infection in the Chinese Guidelines for the Diagnosis and Treatment of HIV/AIDS (2024 edition) (Shen 2024). Participants must meet at least one of the following three criteria:
1.1. A positive HIV antibody screening test and a positive supplementary HIV test (a positive confirmatory antibody test, or a positive qualitative HIV nucleic acid test, or a quantitative HIV nucleic acid result of >1,000 copies/mL); or
1.2. An epidemiological history or clinical manifestations associated with AIDS, together with two positive results on HIV nucleic acid tests; or
1.3. A positive HIV virus isolation test and the most recent laboratory CD4 cell count must be <350 cells/μL
2. Adults with HIV infection and are receiving standard antiretroviral treatment (ART) in accordance with the Chinese Guidelines for the Diagnosis and Treatment of HIV/AIDS (2024 edition) (Shen 2024). Standard ART consists of two nucleoside reverse transcriptase inhibitors (NRTIs) plus a drug from a third class, preferably an integrase strand transfer inhibitor (INSTI); an

approved combination regimen/ single-tablet regimen may also be used. (The treatment goal is sustained virological suppression.) And the participants must be adults who have received ART for at least 12 months, with a stable ART drug plan over the past 6–12 months
3. Aged 18–70 years
4. Have a permanent or long-term residence in the area served by the study site and be able to complete follow-up
5. Have provided written informed consent, understand and accept random allocation, be willing to adhere to the intervention protocol, and agree to attend the scheduled reassessments

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
70 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Intellectual or language impairment that prevents the individual from understanding the study or completing the questionnaires
2. Hospitalization within the past 3 months for an HIV-related opportunistic infection, progression of a malignancy, a serious acute complication, or a major change in the ART regimen due to any acute situation
3. Use of medications or treatments that may affect immune function or the study outcomes substantially, within the past month, such as systemic glucocorticoids, immunosuppressants, or immunomodulators
4. Has previously received or self-administered any similar treatments related to this study, including acupuncture, moxibustion, or cupping
5. Pregnancy, breastfeeding, or plans to become pregnant during the study
6. A clinically significant non-HIV-related autoimmune or immune system disease, such as rheumatoid arthritis, systemic lupus erythematosus, another non-HIV-related condition that may substantially affect immune function or outcomes
7. An active respiratory condition that may be aggravated by moxibustion or smoke exposure, including uncontrolled asthma, clinically significant chronic cough, or pneumonia at enrolment
8. Skin lesions, skin disease, sensory impairment, or other local conditions in the target moxibustion area that may increase the risk of burns, affect safety assessment, or interfere with intervention implementation
9. Impaired wound healing or reduced skin sensation that may increase the risk of moxibustion-related skin injury
10. Allergy or hypersensitivity to the heat of moxibustion or substances in moxa smoke, or a tendency to develop potential scars after moxibustion

11. Currently participating in another clinical trial or has participated in another clinical trial within the past 3 months
12. Participants who are currently undergoing an ART regimen adjusting, experiencing virological failure, or having confirmed ART resistance
13. Any other condition that, in the investigator’s judgement, makes participation in the study inappropriate, including circumstances that may reduce retention or complicate enrolment (e.g., highly unstable work schedule)

Date of first enrolment
01/11/2026

Date of final enrolment
31/05/2027

Locations

Countries of recruitment
China

Sponsor information

Organisation
Hospital of Chengdu University of Traditional Chinese Medicine

Funder(s)

Funder type

Funder Name
State Administration of Traditional Chinese Medicine of the People's Republic of China

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available