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Effects of auricular gua sha combined with auricular acupressure on sleep quality in young and middle-aged patients with insomnia

Submission date
26/03/2026

Recruitment status
No longer recruiting

Registration date
27/03/2026

Overall study status
Completed

Last Edited
31/03/2026

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
Insomnia is a common sleep problem that can make daily life difficult. Some people also experience anxiety and low mood alongside poor sleep. This study looked at whether using ear acupressure together with a technique called Gua Sha on the ear could help people sleep better. The aim was to compare this combined treatment with ear acupressure on its own.

Who can participate?
Adults aged 18 years and older with insomnia were able to take part. Participants needed to have an insomnia severity score of at least 8. People were not able to take part if they had certain health problems, were pregnant or breastfeeding, had skin problems on their ears, or were allergic to the tape used in treatment.

What does the study involve?
Participants were randomly placed into one of two groups.
One group received ear acupressure once a week for 4 weeks. Small cowherb seeds were placed on specific points on the ear, and participants pressed each point several times a day.
The second group received the same ear acupressure plus ear Gua Sha once a week for 4 weeks. Gua Sha involved gentle scraping and massage of the ear using a copper tool.
All participants were asked to return for follow-ups up to one month after the treatment period.

What are the possible benefits and risks of participating?
Participants in the combined treatment group showed improvements in sleep and reductions in anxiety and low mood compared with the group that received acupressure alone. No serious side effects were reported during the study. Some people may have mild discomfort on the ear from the treatment.

Where is the study run from?
A specialty nurse-led clinic of a tertiary hospital of traditional Chinese medicine in Suzhou, Jiangsu Province, China

When is the study starting and how long is it expected to run for?
The first participant joined the study in March 2023. The study finished in June 2024.

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Contact information

Type(s)
Public, Scientific

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Study information

Scientific Title
Effects of auricular gua sha combined with auricular acupressure on sleep quality in young and middle-aged patients with insomnia

Study objectives
This study aimed to compare the clinical effect of auricular acupressure combined with auricular gua sha compared with auricular acupressure for insomnia patients.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 07/03/2023, Ethics Committee of Soochow University (No. 1 Shizi Street, Suzhou City, Jiangsu Province, Suzhou, 215009, China; +86 5120473567; ethics@suda.edu.cn), ref: SUDA20230307H05

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Insomnia

Interventions
Group A (control group): Auricular acupressure once weekly for 4 weeks. Cowherb seeds affixed to auricular acupoints (Shenmen, Endocrine, Heart, Subcortical, with patternbased additions). Participants press each point 5 times daily, 30 seconds per point. One ear per session, alternated weekly.

Group B (intervention group): Auricular acupressure combined with auricular gua sha once weekly for 4 weeks. Auricular acupressure protocol identical to the control group. Auricular gua sha performed using a copper scraping tool, including ear microcirculation massage, ear meridian massage, and scraping along auricular regions. One ear per session, alternated weekly.

The randomisation process was performed using a random number table to generate the allocation sequence. Sequentially numbered, opaque, sealed envelopes were used to conceal the allocation until intervention assignment.

Intervention Type
Behavioural

Primary outcome(s)

1. Insomnia severity measured using the Insomnia Severity Index (ISI) at six time points: baseline (T0), weekly during the 4week intervention period (T1, T2, T3, T4), and 1 month postintervention (T5)

Key secondary outcome(s))
1. Sleep quality measured using Pittsburgh Sleep Quality Index (PSQI) at three time points: baseline (T0), after the fourth intervention (T4), and 1 month postintervention (T5)
2. Anxiety measured using Hospital Anxiety and Depression Scale – Anxiety subscale (HADSA) at six time points: baseline (T0), weekly during the 4week intervention period (T1, T2, T3, T4), and 1 month postintervention (T5)
3. Depression measured using Hospital Anxiety and Depression Scale – Depression subscale (HADSD) at six time points: baseline (T0), weekly during the 4week intervention period (T1, T2, T3, T4), and 1 month postintervention (T5)

Completion date
04/06/2024

Eligibility

Key inclusion criteria
1. In accordance with the diagnostic criteria of insomnia in the Chinese Guidelines for the Diagnosis and Treatment of Insomnia in Adults (2017 edition)
2. ISI score >=8 points
3. Age >=18 years old, regardless of gender

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
90

Key exclusion criteria
1. Those suffering from major organic diseases or mental and psychological diseases
2. Those who have recently planned to have a baby or are breastfeeding or pregnant
3. Ear skin with inflammation, eczema, ulcers, frostbite or larger scar organizers
4. People who are allergic to the tape or have other serious adverse events and are unable to complete the trial

Date of first enrolment
17/03/2023

Date of final enrolment
04/06/2024

Locations

Countries of recruitment
China

Sponsor information

Organisation
School of Nursing, Medical College of Soochow University

Funder(s)

Funder type

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files	Informed consent form in Chinese		26/03/2026	No	No
Protocol file	in Chinese		26/03/2026	No	No