

# Acupuncture therapy of “regulating spirit and soothing liver” for treating insomnia in patients with breast cancer

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|--|---|---|
| <b>Submission date</b><br>04/01/2023   | <b>Recruitment status</b><br>Recruiting                       | <input type="checkbox"/> Prospectively registered               |
|  |   | <input type="checkbox"/> Protocol                               |
| <b>Registration date</b><br>07/03/2023 | <b>Overall study status</b><br>Ongoing                        | <input type="checkbox"/> Statistical analysis plan              |
|  |   | <input type="checkbox"/> Results                                |
| <b>Last Edited</b><br>13/12/2024       | <b>Condition category</b><br>Mental and Behavioural Disorders | <input type="checkbox"/> Individual participant data            |
|  |   | <input checked="" type="checkbox"/> Record updated in last year |

## Plain English summary of protocol

### Background and study aims

Cancer patients often suffer from insomnia, which is a risk factor for cancer progression, and the influence of insomnia on different cancer varies. It is imperative to pay attention to and treat insomnia in patients with different types of cancer. Breast cancer patients have a high incidence of insomnia, which is often accompanied by anxiety, depression, and fatigue. These symptoms fit the pathogenesis of "liver depression" and "weakened body resistance" in traditional Chinese medicine theory. Based on the effective treatment of common insomnia with acupuncture, it is feasible to explore the efficacy and safety of acupuncture treatment of insomnia in patients with breast cancer. Dr De'an Zhou, a National Celebrated Traditional Chinese Medicine Expert, invented the acupuncture therapy of "regulating spirit", which can effectively improve insomnia. On this basis, and in consideration of the pathogenesis of "liver depression" and "a deficiency of Qi [low energy] and blood" in breast cancer, the research team proposed the acupuncture therapy of "regulating spirit and soothing liver", which focuses on four acupoints from the liver meridian, gallbladder meridian, spleen meridian and stomach meridian in the therapy of "regulating spirit". The new therapy can regulate the "spirit of mind and brain" and "the Qi of the liver and spleen", and will treat insomnia in patients with breast cancer effectively. The purpose of this study is to evaluate the effects and safety of the acupuncture therapy of "regulating spirit and soothing liver" on insomnia in patients with breast cancer.

### Who can participate?

Breast cancer patients with insomnia

### What does the study involve?

Participants recruited into this study will be randomly divided into 2 groups according to a 1:1 ratio. Group A will receive normal acupuncture therapy and Group B will receive shallow acupuncture therapy as a control group. The treatment of both groups will be conducted over a period of 4 weeks, at a frequency of 3 sessions per week. The therapeutic effect is graded using a sleep scale.

What are the possible benefits and risks of participating?

Patients who participate in this trial will receive professional sleep assessment, corrective sleep concepts and acupuncture therapy for free, but the participants in the control group may benefit from less efficacy. The team may also provide extra treatment after the trial ends. Patients who participate in this trial may experience temporary sourness, numbness, downforce, distension or a sense of soreness during acupuncture treatment and minor bleeding or local bluish skin after acupuncture. The most serious side effect is fainting, but it is rare during clinical appointments.

Where is the study run from?

Outpatient Department of the Oncology and Psychosomatic Medicine Departments in Beijing Hospital of Traditional Chinese Medicine, Capital Medical University in Beijing (China)

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

January 2022 to December 2025

Who is funding the study?

Beijing Municipal Health Commission (China)

Who is the main contact?

Dr Tingting Ma, tingtingntyy@163.com (China)

## Contact information

### Type(s)

Principal Investigator

### Contact name

Dr Tingting Ma

### Contact details

Oncology Department  
Beijing Hospital of Traditional Chinese Medicine  
No.23, Back Street of Gallery  
Dongcheng District  
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100010  
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## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

### ClinicalTrials.gov number

Nil known

## Secondary identifying numbers

2022-4-2234

# Study information

## Scientific Title

Randomized controlled study on acupuncture therapy of “regulating spirit and soothing liver” for insomnia patients with breast cancer

## Study objectives

Acupuncture therapy of “regulating spirit and soothing liver” for treating insomnia in patients with breast cancer

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approved 30/09/2022, Medical Ethics Committee of Beijing Hospital of Traditional Chinese Medicine affiliated with the Capital Medical University (No. 23, Art Museum Back Street, Dongcheng District, Beijing, China; +86 01087906734; bjzyyllwyh@163.com), ref: 2022BL02-059-02

## Study design

Randomized controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

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

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

Insomnia treatment in patients with breast cancer

## Interventions

Current interventions as of 13/12/2023:

Participants will receive acupuncture therapy for “regulating spirit and soothing liver” for 8 weeks.

Time points are as follows:

Visit 1: Screening

Visit 2: Treatment initiation, participants will receive acupuncture for 8 weeks

Visit 3: 8 weeks after first acupuncture, treatment finish and follow-up

Visit 4: 1 month after first acupuncture, follow-up

Visit 5: 3 months after first acupuncture, follow-up

Patients who meet the inclusion criteria are randomized to one of two treatment groups:

Group A (receive normal acupuncture at selected acupoints)

Group B (receive shallow acupuncture at selected acupoints)

1. Selected acupoints:

GV20(Baihui)

GV24(Shenting)

EX-HN1(Sishencong)

GB15(Benshen)

Ht7(Shenmen)

Pc6(Neiguan)

Sp6(Sanyinjiao)

St36(Zusanli)

Sp10(Xuehai)

GB34(Yanglingquan)

LR3(Taichong)

2. Normal acupuncture therapy:

GV20, GV24, EX-HN1, GB15: The needle tip is inserted 8-15 mm at a 20°angle to the scalp.

Sp6, St36, Sp10, GB34: The needle tip is inserted 40 mm at a 90°angle to the skin.

Ht7, Pc6, LR3: The needle tip is inserted 20-25 mm at a 20°angle to the skin.

Each acupoint is used in neutral supplementation and draining methods and retained for 30 minutes.

3. Shallow acupuncture therapy:

The blunt needle on a cotton pad is stuck on the same acupoints as the treatment group and retained for 30 minutes.

4. Treatment will be conducted over a period of 8 weeks, at a frequency of 3 sessions/per week.

Previous interventions:

Participants will receive acupuncture therapy for “regulating spirit and soothing liver” for 4 weeks.

Time points are as follows:

Visit 1: Screening

Visit 2: Treatment initiation, participants will receive acupuncture for 4 weeks

Visit 3: 4 weeks after first acupuncture, treatment finish and follow-up

Visit 4: 1 month after first acupuncture, follow-up

Visit 5: 3 months after first acupuncture, follow-up

Patients who meet the inclusion criteria are randomized to one of four treatment groups:

Group A (receive normal acupuncture at selected acupoints)

Group B (receive shallow acupuncture at selected acupoints)

1. Selected acupoints:

GV20(Baihui)

GV24(Shenting)

EX-HN1(Sishencong)  
GB15(Benshen)  
Ht7(Shenmen)  
Pc6(Neiguan)  
Sp6(Sanyinjiao)  
St36(Zusanli)  
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Each acupoint is used in neutral supplementation and draining methods and retained for 30 minutes.

**3. Shallow acupuncture therapy:**

The blunt needle on a cotton pad is stuck on the same acupoints as the treatment group and retained for 30 minutes.

4. Treatment will be conducted over a period of 4 weeks, at a frequency of 3 sessions/per week.

**Intervention Type**

Other

**Primary outcome measure**

Current primary outcome measure as of 13/12/2023:

Therapeutic effect measured using the Pittsburgh sleep Scale (PSQI) at baseline (before treatment initiation), 2, 4, 6 and 8 weeks after the first acupuncture, and 1 and 3 months after the last acupuncture session

Previous primary outcome measure:

Therapeutic effect measured using the Pittsburgh sleep Scale (PSQI) at baseline (before treatment initiation), 2 and 4 weeks after the first acupuncture, and 1 and 3 months after the last acupuncture session

**Secondary outcome measures**

Current secondary outcome measures as of 13/12/2023:

Outcome measures are assessed at baseline (before treatment initiation), 2 and 4 weeks after the first acupuncture, and 1 and 3 months after the last acupuncture session unless otherwise stated:

1. Level of anxiety measured using the Generalized Anxiety Disorder (GAD-7) questionnaire
2. Level of anxiety measured using the Patient Health Questionnaire (PHQ9)
3. Serum 5-HT concentration measured using Enzyme-linked immunosorbent assay (ELISA)
4. Temporary sleeping medication use measured using a Temporary Sleeping Medication Record Form
5. Level liver depression measured using TCM Liver Depression Symptom Assessment Table
6. Adverse events, including discomfort or bruising at the sites of needle insertion, nausea, or feeling faint, measured using participants reporting up to the 6-week acupuncture session

Previous secondary outcome measures:

Outcome measures are assessed at baseline (before treatment initiation), 2 and 4 weeks after the first acupuncture, and 1 and 3 months after the last acupuncture session unless otherwise stated:

1. Level of anxiety measured using the Generalized Anxiety Disorder (GAD-7) questionnaire
2. Level of anxiety measured using the Patient Health Questionnaire (PHQ9)
3. Quality of life measured using the Functional Assessment of Cancer Therapy-Breast Cancer (FACT-B) questionnaire
4. Serum 5-HT concentration measured using Enzyme-linked immunosorbent assay (ELISA)
5. Temporary sleeping medication use measured using a Temporary Sleeping Medication Record Form
6. Level liver depression measured using TCM Liver Depression Symptom Assessment Table
7. Adverse events, including discomfort or bruising at the sites of needle insertion, nausea, or feeling faint, measured using participants reporting up to the 6-week acupuncture session

**Overall study start date**

01/01/2022

**Completion date**

31/12/2025

## Eligibility

**Key inclusion criteria**

1. Aged between 18 and 60 years old and female
2. Confirm the diagnosis of breast cancer and meet the diagnostic criteria for insomnia in DSM-V
3. PSQI score  $\geq 10$
4. Individuals who do not have a language disorder or mental retardation and can answer and finish the questionnaire smoothly
5. Signed informed consent form and volunteered to participate in this study
6. Individuals who have a correct understanding of acupuncture studies and have good compliance with the observation and evaluation of researchers

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

60 Years

**Sex**

Female

**Target number of participants**

70

### **Key exclusion criteria**

1. Individuals who have epilepsy, diabetes, cardiovascular disease, renal failure, hypertension, metabolic diseases and other major diseases
2. Individuals who have depression, anxiety, schizophrenia and other serious mental disorders with irregular drug use
3. History of sleep apnea syndrome, restless legs syndrome and other sleep disorders
4. Lactating women, pregnant women or women of childbearing age who are planning to become pregnant in a short time
5. Alcoholics and/or psychoactive drug users, drug abusers and dependents
6. Individuals who are afraid or unable to get acupuncture
7. Individuals who take medication or other interventions to sleep regularly for a long time
8. Surgery is scheduled within 1 month

### **Date of first enrolment**

01/03/2023

### **Date of final enrolment**

31/08/2025

## **Locations**

### **Countries of recruitment**

China

### **Study participating centre**

**Beijing Hospital of Traditional Chinese Medicine affiliated to Capital Medical University**

23 Meishuguanhou Street

Dongcheng District

Beijing

China

100010

## **Sponsor information**

### **Organisation**

Beijing Hospital of Traditional Chinese Medicine

### **Sponsor details**

Affiliated with Capital Medical University

No. 23 Art Museum Back Street

Dongcheng District

Beijing

China

100010  
+86 01087906734  
kycggyx126@126.com

**Sponsor type**

Hospital/treatment centre

**Website**

<https://www.bjzhongyi.com/>

**ROR**

<https://ror.org/057vq6e26>

## **Funder(s)**

**Funder type**

Government

**Funder Name**

Beijing Municipal Health Commission

**Alternative Name(s)**

, Beijing Municipal Bureau of Health, Commission municipale de la Santé de Beijing, BMHB

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Local government

**Location**

China

## **Results and Publications**

**Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal

**Intention to publish date**

31/12/2026

**Individual participant data (IPD) sharing plan**

The datasets generated during the current study will be available upon request from Dr Tingting Ma, [tingtingnty@163.com](mailto:tingtingnty@163.com).

The estimated date of availability is after 30/06/2025.



**IPD sharing plan summary**

Available on request

**Study outputs**

| Output type                 | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|-----------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Other files</a> |         |              | 20/02/2023 | No             | No              |
| <a href="#">Other files</a> |         |              | 20/02/2023 | No             | No              |