ISRCTN12913513 https://doi.org/10.1186/ISRCTN12913513

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

Submission date
04/01/2023

Recruitment status
No longer recruiting

Registration date
07/03/2023

Overall study status
Completed

Last Edited
13/12/2024

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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
Beijing
China
100010
+86 (010)87906735
tingtingntyy@163.com

Additional identifiers

Protocol serial number
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; bjzyyyllwyh@163.com), ref: 2022BL02-059-02

Primary study design
Interventional

Study design
Randomized controlled trial

Study type(s)
Treatment

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)
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 4 weeks, at a frequency of 3 sessions/per week.

Intervention Type
Other

Primary outcome(s)
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

Key secondary outcome(s)
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

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≥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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
60 Years

Sex
Female

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

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

Individual participant data (IPD) sharing plan

The datasets generated during the current study will be available upon request from Dr Tingting Ma, tingtingntyy@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?
Other files			20/02/2023	No	No
Other files			20/02/2023	No	No