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Acupuncture for treatment of primary insomnia

Submission date	Recruitment status	[X] Prospectively registered
18/03/2015	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
07/04/2015	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
17/12/2020	Mental and Behavioural Disorders	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Primary insomnia is commonly defined as a state of being disturbed during daytime activities due to poor sleep quality. Studies have demonstrated increased levels of arousal (hyperarousal) in primary insomnia during both night and daytime. Acupuncture is one of the most common treatments for insomnia in China. According to traditional Chinese medicine, acupuncture is considered to be beneficial to restore the normal sleep-wake cycle. Nevertheless, the evidence and mechanism are not clear. The aim of the study is to assess the effects of acupuncture for sleep and hyperarousal in patients with primary insomnia.

Who can participate?
Patients with a definite diagnosis of primary insomnia and hyperarousal state can participate in this study.

What does the study involve?
The participants will be randomly allocated to one of two groups: the intervention group or the control group. Participants in the intervention group will receive acupuncture therapy three times a week for 4 weeks. Participants in the control group will receive sham acupuncture therapy three times a week for 4 weeks. They will complete some questionnaires and examinations at the start of the study, at regular intervals and at follow up to find out about any changes in sleep quality, hyperarousal and fatigue.

What are the possible benefits and risks of participating?
The participants will receive free acupuncture for 4 weeks and a series of free examinations. Their sleep quality could be improved and the hyperarousal state could be inhibited. They could feel improvement both in their sleep and daytime functioning. The results of the study may help to provide evidence that acupuncture is effective for primary insomnia and to understand the mechanism .The risks may lie in the weak effectiveness of the sham acupuncture for improving sleep quality. Occasionally acupuncture may cause local hematoma (swelling) or dizziness. All adverse events would be mild.

Where is the study run from?
The study is run from Beijing Hospital of Traditional Chinese Medicine (China).

When is study starting and how long is it expected to run for?
From June 2015 to July 2017.

Who is funding the study?
Beijing Municipal Science & Technology Commission (China).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Z141107002514066

Study information

Scientific Title
Acupuncture for treatment of primary insomnia: a randomized, single-blinded, sham-controlled trial

Acronym
ATPI

Study objectives

Primary insomnia is a disorder of 24-h hyperarousal. It is expressed in terms of physiologic, cognitive and cortical activation. Based on the hyperarousal hypothesis, the purpose of the trial is to assess the therapeutic effects of acupuncture for sleep and hyperarousal in patients with primary insomnia. We aim to demonstrate the hypothesis that the effect of acupuncture on insomnia is based on inhibiting the hyperarousal state.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethical Committee of the Beijing TCM Hospital, 05/01/2015, REC ref: 2014BL-056-02

Study design
Single-centre randomized single-blinded 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 below to request a patient information sheet

Health condition(s) or problem(s) studied
Primary insomnia (named as Insomnia Disorder in DSM-V)

Interventions
The 88 eligible participants will be randomly allocated to two different groups:

Intervention Group: Participants in the intervention group will receive acupuncture therapy three times a week for 4 weeks. Acupuncture will be applied to Baihui (DU-20), Shenting (DU-24), Benshen (GB-13), Sishencong (EX-HN1), Sanyinjiao (SP-6), neiguan (PC6), and Shenmen (HT-7) using stainless steel needles (0.32× 40 mm, HuaTuo, China). Baihui (Du-20), Shenting (DU-24), Benshen (GB-13), and Sishencong (EX-HN1) are punctured at a depth of 10 mm obliquely. Sanyinjiao (SP-6) was punctured 10mm straightly, while Neiguan (PC6) and Shenmen (HT-7) was inserted 5mm perpendicularly. All the acupoints are inserted without hand-manipulating of the needle. Needle manipulation will be applied to achieve “De Qi”. Needles retention will be 30 minutes.

Control Group: Participants in the control group will receive sham acupuncture therapy three times a week for 4 weeks. Sham acupuncture was conducted by needling the acupoints of Binao (LI-14), Shousanli (LI-10), Yangchi ((SJ4), Waiguan (SJ5), Fengshi (GB31), Futu (ST32) and Liangqiu

(GB-31). According to lecture review and clinical experiences, the acupoints are mainly used for local disease and have no therapeutic effect for insomnia. Stainless steel needles of the same specifications as the intervention group were inserted superficially at the acupoints and kept for 30 minutes. Manual stimulation and De qi were avoided.

All acupuncture treatment complies with the Standards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA) revised in 2010.

Intervention Type
Other

Primary outcome measure
1. Sleep quality assessment: Pittsburgh Sleep Quality Index (PSQI)
2. Hyperarousal level assessment (HAS)
Assessment time of the outcome measures above will be: baseline, 2 and 4 weeks during the treatment, and 8 weeks after the treatment.

Secondary outcome measures
1. Fatigue Scale-14 (FS-14)
Assessment time: the baseline, 2 and 4 weeks during the treatment, and 8 weeks after the treatment.
2. Polysomnography (PSG)
3. Heart rate variability (HRV)
4. Morning salivary cortisol level
The outcome measures above will be assessed at baseline and the first week after treatment.

Overall study start date
01/06/2015

Completion date
30/06/2017

Eligibility

Key inclusion criteria
1. Meeting the primary insomnia criteria of DSM-IV-TR
2. Patients with insomnia persistent for 3 months or longer before the start of the observation period
3. Score of 8 or above on the PSQI, 33 or above on the HAS
4. Having not yet received any psychoactive medications
5. No problem with communication and intelligence
6. Either gender aged 18-65 years
7. Signed the written informed consent form for the clinical trial

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
88 subjects, 44 patients for each group

Key exclusion criteria
1. Patients who had epilepsy, diabetes mellitus, cardiovascular disease, kidney failure, hypertension, metabolic diseases, benign prostatic hyperplasia
2. Patients who had depression, anxiety ,schizophrenia and other severe mental disorders
3. Patients who had other sleep disorders, or discovered any other sleep disorder on PSG at the baseline, like sleep apnea, restless legs syndrome
4. Pregnancy, breastfeeding, or woman of childbearing age not on a proper method of birth control
5. Patients who had acupuncture for insomnia treatment in the past month
6. Patients who had taken alcohol and/or mentally active drug, drug abuse and dependence
7. Patients who fear or can’t accept the acupuncture therapy

Date of first enrolment
01/06/2015

Date of final enrolment
30/01/2017

Locations

Countries of recruitment
China

Study participating centre
Beijing Hospital of Traditional Chinese Medicine, Capital Medical University
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Sponsor information

Organisation
Beijing Scientific Committee

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Sponsor type
Government

ROR
https://ror.org/034k14f91

Funder(s)

Funder type
Government

Funder Name
Beijing Scientific Committee

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date
30/06/2015

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	08/03/2016	17/12/2020	Yes	No