This file includes answers to all items of WHO Trial Registration Data Set.

ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: May 23, 2017

ClinicalTrials.gov ID: NCT03015766

Study Identification

Unique Protocol ID:	YN2015MS25
Brief Title:	Auricular Acupressure for Hemodialysis Patients With Insomnia (AAHDIN)
Official Title:	Auricular Acupressure for Hemodialysis Patients With Insomnia: Study Protocol for a Multi-centre Double-blind, Randomized Controlled Trial
Secondary IDs:	

Study Status

Record Verification:	May 2017
Overall Status:	Recruiting
Study Start:	May 1, 2017 [Actual]
Primary Completion:	October 1, 2018 [Anticipated]
Study Completion:	June 1, 2019 [Anticipated]

Sponsor/Collaborators

Sponsor:	Guangdong Provincial Hospital of Traditional Chinese Medicine
Responsible Party:	Principal Investigator Investigator: Qizhan Lin [qlin] Official Title: Professor Affiliation: Guangdong Provincial Hospital of Traditional Chinese Medicine
Collaborators:	

Oversight

U.S. FDA-regulated Drug:	No
U.S. FDA-regulated Device:	No
U.S. FDA IND/IDE:	No
Human Subjects Review:	Board Status: Approved Approval Number: B2016-137-01 Board Name: Institutional Ethics Committee Board Affiliation: Guangdong Provincial Hospital of Traditional Chinese Medicine Phone: +86-20-81887233 Email: szyllwyh@163.com Address:

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Data Monitoring:	No
Plan to Share IPD:	Yes IPD including the demographic information, PSQI scores and drug use at baseline and 8,12,16,20 week from baseline of all participants will be shared. The data will be availbale at ResMan® Clinical Trial Management Public Platform, with the link http://www.medresman.org/uc/index.aspx
FDA Regulated Intervention:	No

Study Description

Brief Summary:	Auricular acupressure therapy (AAT) has been applied in MHD patients with insomnia in recent years and yielded favorable results. However, the effect and safety of AAT for insomnia in MHD population still lacks high quality evidence. A randomized controlled clinical trial is planned to evaluate the effect and safety of AAT in MHD patients with insomnia.
Detailed Description:	Insomnia, a worldwide health problem, is much more frequently complained in maintenance hemodialysis (MHD) patients and impairs their quality of life and long term outcome. Hypnotic sedative agents are often reluctantly prescribed with doses mounting up. Patients are concerned about drug dependence and drug-related adverse effects. As a non-drug therapy, auricular acupressure therapy (AAT) is attractive to both patients and practitioners and is widely used to treat many conditions in China. The investigators had been applying AAT for MHD patients with insomnia in recent years and yielded favorable results. However, the effect and safety of AAT for insomnia in MHD population still lacks high quality evidence. Therefore, the investigators aimed to perform a randomized controlled clinical trial in MHD patients with insomnia to evaluate the effect and safety of AAT.

Conditions

Conditions:	Insomnia Chronic
Keywords:	insomnia hemodialysis auricular acupressure randomized controlled trial

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	N/A
Interventional Study Model:	Parallel Assignment
Number of Arms:	2
Masking:	Participant, Care Provider, Outcomes Assessor
Allocation:	Randomized
Enrollment:	112 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Auricular acupressure therapy Participants in the treatment group will received AAT on five active acupoints including Acup.1. Shen Men (Spiritual Gate, TF4), Acup.2. Jiao Gan (Sympathetic autonomic, AH6a), Acup.3. Xin (Heart, CO15), Acup.4. Pi Zhi Xia (Subcortex, AT4), Acup.5. Nei Fen Mi (Endocrine, CO18)	auricular acupressure therapy Auricular acupressure, is a therapeutic method in which specific acupoints on the ear are stimulated to treat various disorders of the body. This practice is based on the theory that there are specific points on the auricle which correspond to major organs or systems of the body; and therapeutic effect on the corresponding target organ or system can be exerted by manipulating auricular acupoints. Auricular acupressure applies stimulation through pressure on specific acupoints by the imbedded beads, usually Semen Vaccaria (Wang Bu Liu Xing) or stainless steel beads. This therapeutic method is non-invasive and can be self-manipulated by the recipients at times required. Other Names: • auricular acupressure • ear acupressure
Sham Comparator: sham auricular acupressure therapy Participants in the control group (SAA group) will receive auricular acupressure on five Helix points (HX 5–9), which were clearly remote from the inner ear area. These points have no evidence for insomnia management.	sham auricular acupressure therapy The intervention is the same as that in the experimental group only when the points are five Helix points (HX 5-9). These points are clearly remote from the inner ear area and have no evidence for insomnia treatment. Other Names: • sham AAT

Outcome Measures

Primary Outcome Measure:

1. clinical response rate
   Response is defined as a reduction of Pittsburgh sleep quality index (PSQI) global score by 3 points and more according to literature review

   [Time Frame: at 8 weeks from baseline]

Secondary Outcome Measure:

2. change of PSQI scores at the end of treatment
   PSQI scores will include PSQI global score, and scores of each domain (i.e. sleep duration, sleep disturbance, sleep latency, day dysfunction, sleep efficiency, overall sleep quality and sleep medication).

   [Time Frame: change from baseline PSQI scores at 8 weeks]

3. change of PSQI scores at the first followup
   PSQI scores will include PSQI global score, and scores of each domain (i.e. sleep duration, sleep disturbance, sleep latency, day dysfunction, sleep efficiency, overall sleep quality and sleep medication).

   [Time Frame: change from baseline PSQI scores at 12 weeks]

4. change of PSQI scores at the second followup
   PSQI scores will include PSQI global score, and scores of each domain (i.e. sleep duration, sleep disturbance, sleep latency, day dysfunction, sleep efficiency, overall sleep quality and sleep medication).

   [Time Frame: change from baseline PSQI scores at 16 weeks]

5. change of PSQI scores at the third followup
   PSQI scores will include PSQI global score, and scores of each domain (i.e. sleep duration, sleep disturbance, sleep latency, day dysfunction, sleep efficiency, overall sleep quality and sleep medication).

   [Time Frame: change from baseline PSQI scores at 20 weeks]

6. weekly dose of hypnotics
   If participants required hypnotic agents during the study because of unbearable sleep disorders, they will be allowed to take hypnotics initiating from the minimum dose and encouraged to complete the trial. The weekly dose of hypnotic agents will be recorded.

   [Time Frame: Day 0 (baseline), at 8 weeks (the end of treatment), at 12 weeks (the first followup),at 16 weeks (the second followup) and at 20 weeks (the third followup)]

7. adverse events
   Adverse events throughout the treatment and follow-up periods, regardless of its relevance to the interventions, will be documented and dealt with by appropriate measures.

   [Time Frame: through study completion, an average of 20 weeks]

Eligibility

Minimum Age:	18 Years
Maximum Age:	75 Years
Sex:	All
Gender Based:	
Accepts Healthy Volunteers:	No

Criteria: Inclusion Criteria:

- Aged 18~75 years
- On regular dialysis (2 - 3 sessions weekly, 4 hours each session, total weekly dialysis hours ≥ 10 hours) for more than 3 months (but less than 10 years)
- Insomnia according to The Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5)
- Global score of PSQI > 7
- Informed consent.

Exclusion Criteria:

- Presence of co-morbidities including cancer, congestive heart failure, connective tissue disease and hematologic diseases;
- Inadequately dialyzed, indicating by urea clearance index (KT/V) < 1.20;
- Presence of severe physical symptoms such as bone pain, itchy skin, sleep apnea and restless legs which are obviously causative for insomnia; and weary condition caused by severe anemia (hemoglobin<60g/L) or malnutrition (serum albumin<30g/L).
- Infections of external ears or malformed ears.

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References

Citations: [Study Results] Zou C, Yang L, Wu Y, Su G, Chen S, Guo X, Wu X, Liu X, Lin Q. Auricular acupressure on specific points for hemodialysis patients with insomnia: a pilot randomized controlled trial. PLoS One. 2015 Apr 15;10(4):e0122724. doi: 10.1371/journal.pone.0122724. eCollection 2015. PubMed 25874938

[Study Results] Wu Y, Zou C, Liu X, Wu X, Lin Q. Auricular acupressure helps improve sleep quality for severe insomnia in maintenance hemodialysis patients: a pilot study. J Altern Complement Med. 2014 May;20(5):356-63. doi: 10.1089/acm.2013.0319. Epub 2014 Feb 26. PubMed 24571603

Links: URL: http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0122724
Description previously finished pilot RCT

URL: http://online.liebertpub.com/doi/abs/10.1089/acm.2013.0319
Description observational study on auricular acupressure

Study Data/Documents: