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Efficacy and safety of acupuncture for chronic dizziness

Submission date
25/03/2013

Recruitment status
No longer recruiting

Registration date
25/06/2013

Overall study status
Completed

Last Edited
20/02/2019

Condition category
Signs and Symptoms

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Dizziness is one of the most challenging symptoms in medicine. The annual prevalence of dizziness in the adult population is 22.9% as reported in Germany. Over 66 % of dizzy patients experience psychological distress, often resulting in a vicious cycle of fear, avoiding movements that might make them feel dizzy, and increased handicap, slowing down recovery even further. Research shows that no medication in current use has well-established cure or is suitable for long-term use. Non-traditional remedies should be considered and scientifically studied. Acupuncture, which is one of the main treatment methods of traditional Chinese medicine (TCM), has been used for both prevention and treatment of dizziness for over three thousand years. Many studies have investigated the benefits and success of acupuncture in easing symptoms for various diseases. Thus, the purpose of this study is to determine how good acupuncture is in patients with chronic dizziness.

Who can participate?
Participants (both male and female) should be aged 18-75 years. Any patient with chronic dizziness, diagnosed by physicians and then referred to acupuncture department, is eligible for the study.

What does the study involve?
Two hundred patients are randomly assigned to one of the two study groups, group A (treatment group) receives acupuncture therapy or group B (control group) receives sham-acupuncture therapy. Patients in group A receive acupuncture on Baihui, Yintang, Taiyang, Wangu, Tinggong, Fengchi, Hegu, Fenglong and Taichong. Group B will receive shallow needle insertion that does not penetrate below the skin (minimal or superficial needling) at non-acupoints. The acupuncturist has an acupuncture license (Chinese medicine practitioner license) from the Ministry of Health of the Peoples Republic of China and takes an educational course to ensure that they strictly follow the study method and are familiar with conducting the study.

What are the possible benefits and risks of participating?
One of the most important benefits is finding out effective and safe treatment for patients with dizziness, especially those who do not respond to medical therapy or those who suffer from side-effects of drug therapy. The risks of taking part are minimal. Acupuncture is a very safe

treatment when given by properly trained clinicians. Occasionally acupuncture can make people feel nauseous or faint or have blood clot beneath the skin. Participants are warned of these potential side-effects before consenting to have acupuncture.

Where is the study run from?
The study is carried out at the Acupuncture Department of Beijing Hospital of Traditional Chinese Medicine affiliated to Capital Medical University in Beijing, China.

When is the study starting and how long is it expected to run for?
We started recruiting participants into the study in February 2012, with enrolment continuing until December 2015.

Who is funding the study?
Beijing Health System (China) - High Level Health Technology Talent Cultivation Plan ref: 2011-3-055

Who is the main contact?
Dr Liu Cun-zhi
lcz623780@126.com

Contact information

Type(s)
Scientific

Contact name
Dr Cunzhi Liu

Contact details
23 Meishuguanhou Street, Dongcheng District
Beijing
China
100010

Additional identifiers

Protocol serial number
20113055

Study information

Scientific Title
Efficacy and safety of acupuncture for chronic dizziness: a randomized controlled clinical trial

Study objectives
There has been relatively little evidence in randomized controlled clinical trials on acupuncture to treat chronic dizziness. This trial is to evaluate the efficacy of acupuncture in chronic dizziness patients in comparison to sham-acupuncture.

On 16/09/2013, the target number of participants was changed from 80 to 100.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethical Committee of the Beijing Hospital of Traditional Chinese Medicine, 22/03/2013, ref: 201316

Study design
Randomized blinded controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic dizziness

Interventions
The 80 chronic dizziness sufferers are randomly allocated to two different groups:
1. Treatment group: At least two acupuncture sessions per week for 4 weeks.
2. Control group: At least two sham-acupuncture sessions per week for 4 weeks.
Each acupuncture session lasts for 30 min.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Vertigo Symptom Scale (VSS) to assess the frequency of dizziness-related symptom;
2. Dizziness Handicap Inventory (DHI) to evaluate the functional, emotional and physical impact of dizziness on patients daily life.

The outcome measures above will be assessed at baseline (before treatment initiation), 4 weeks later of the first acupuncture, and 8 weeks later of the first acupuncture.

Key secondary outcome(s))
1. Short Form-36 quality-of-life questionnaire to evaluate a persons health perception in daily life at baseline (before treatment initiation), 4 weeks later of the first acupuncture, and 8 weeks later of the first acupuncture.
2. Hospital Anxiety and Depression Scale to assess non-somatic symptoms of anxiety and depression at baseline (before treatment initiation), 4 weeks later of the first acupuncture, and 8 weeks later of the first acupuncture.
3. Perceived Credibility of acupuncture is evaluated by The Treatment Credibility Scale (TCS) after a 4-week acupuncture session. It is a 5-item questionnaire ranging from 1 (not at all) to 5 (very confident); items are averaged to provide a single treatment credibility score, with high scores reflecting high treatment credibility.

4. To evaluate the adequacy of blinding, we will ask participants to rate how certain they are that they have received traditional acupuncture or new method of acupuncture on a 7-point scale (1 very sure, 7 very uncertain) after 4 weeks of treatment.
Participants will also report adverse events they experience, including discomfort or bruising at the sites of needle insertion, nausea, or feeling faint after each treatment.

Completion date
31/12/2015

Eligibility

Key inclusion criteria
Current inclusion criteria as of 16/09/2013:
1. Vertigo of unknown cause
2. Dizziness of unknown cause
3. Meniere's disease
4. Psychogenic dizziness
5. Age 18 to 75 years, either sex

Previous inclusion criteria:
1. Vertigo of unknown cause
2. Dizziness of unknown cause
3. Meniere's disease
4. Cervicogenic dizziness
6. Vestibular imbalance or disorder
8. Otologic disorder
9. Psychogenic dizziness
10. Age 18 to 75 years, either sex
11. Written and informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Labyrinthitis
2. Benign positional vertigo
3. Vestibular neuronitis
4. Duration of dizziness less than 2 months the past 2 years

5. Serious comorbid conditions (for example, life-threatening condition or progressive central disorder)
6. Patients who cannot communicate reliably with the investigator or who are not likely to cope with the requirements of the trial

Date of first enrolment
28/02/2013

Date of final enrolment
31/12/2015

Locations

Countries of recruitment
China

Study participating centre
23 Meishuguanhou Street, Dongcheng District
Beijing
China
100010

Sponsor information

Organisation
Beijing Municipal Health Bureau (China)

ROR
https://ror.org/0374a5s68

Funder(s)

Funder type
Government

Funder Name
Beijing Health System (China) - High Level Health Technology Talent Cultivation Plan ref: 2011-3-055

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	13/12/2013		Yes	No
Basic results		15/02/2019	20/02/2019	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes