# Effects of acupuncture on heart rate variability in adult tinnitus patients

Submission date	<b>Recruitment status</b> No longer recruiting	[X] Prospectively registered		
25/06/2012		☐ Protocol		
Registration date	Overall study status Completed	Statistical analysis plan		
03/09/2012		[X] Results		
Last Edited	Condition category	Individual participant data		
04/02/2019	Ear, Nose and Throat			

#### Plain English summary of protocol

Current plain English summary as of 04/02/2019:

Background and study aims

Tinnitus is the term for hearing sounds that come from inside your body rather than from an outside source, often described as "ringing in the ears". Severe tinnitus is associated with anxiety and depression. Hand acupuncture is a system of acupuncture in which the hand is considered to be a representation of the entire body and stimulation of specific points on the hand with needles or lasers is used to obtain effects in distant areas of the body. The aim of this study is to evaluate the effect of acupuncture on ANS reactivity in patients with chronic tinnitus.

Who can participate?
Patients aged 18-65 with tinnitus

What does the study involve?

Participants are randomly allocated to be treated with deep acupuncture or shallow acupuncture. Treatment is conducted over a period of 3 weeks, at a frequency of two sessions per week. No additional treatment is allowed. Tinnitus severity and adverse events are assessed in both groups.

What are the possible benefits and risks of participating?

It is possible that acupuncture will help improve tinnitus symptoms but we cannot say this for certain until we have completed this and further studies. Adverse events may include discomfort or bruising at the sites of needle insertion, nausea, or feeling faint.

Where is the study run from?

Beijing Hospital of Traditional Chinese Medicine affiliated to Capital Medical University (China)

When is the study starting and how long is it expected to run for? October 2012 to October 2013

Who is funding the study?

Beijing health system high-level health technology talent cultivation plan (China)

Who is the main contact? Dr Cunzhi Liu

Previous plain English summary:

Background and study aims

Tinnitus is the term for hearing sounds that come from inside your body rather than from an outside source, often described as "ringing in the ears". Severe tinnitus is associated with anxiety and depression. Hand acupuncture is a system of acupuncture in which the hand is considered to be a representation of the entire body and stimulation of specific points on the hand with needles or lasers is used to obtain effects in distant areas of the body. The aim of this study is to test whether acupuncture can be used to treat tinnitus by comparing the effect of needle and laser acupuncture in adult tinnitus patients.

Who can participate?
Patients aged 18-65 with tinnitus

What does the study involve?

Participants are randomly allocated to be treated with acupuncture using either needles or lasers. Treatment is conducted over a period of 3 weeks, at a frequency of two sessions per week. No additional treatment is allowed. Tinnitus severity and adverse events are assessed in both groups.

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Who is the main contact? Dr Cunzhi Liu

## Contact information

Type(s)

Scientific

Contact name

Dr Cunzhi Liu

Contact details

23 Meishuguanhou Street Dongcheng District Beijing

## Additional identifiers

**EudraCT/CTIS** number

IRAS number

ClinicalTrials.gov number

**Secondary identifying numbers** N/A

# Study information

#### Scientific Title

Current scientific title as of 04/02/2019:

Effects of deep acupuncture versus shallow acupuncture on heart rate variability in adult tinnitus patients: an exploratory study

#### Previous scientific title:

Effects of hand acupuncture and shallow acupuncture on heart rate variability in adult tinnitus patients: a randomized controlled trial

#### **Study objectives**

Current study hypothesis as of 04/02/2019:

This study is aimed to compare the effect of deep acupuncture versus shallow acupuncture on heart rate variability in adult tinnitus patients.

## Previous study hypothesis:

This study is aimed to compare the effect of hand acupuncture and shallow acupuncture on heart rate variability in adult tinnitus patients.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Beijing Hospital of Traditional Chinese Medicine & Capital Medical University, 28/02/2012

## Study design

Randomised 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

**Tinnitus** 

#### **Interventions**

Current interventions as of 04/02/2019:

30 tinnitus patients are randomized to receive deep acupuncture or shallow acupuncture for 3 weeks (twice per week).

Patients are stimulated by 5 main acupoints: Baihui (Du-20), Shenting (Du-24), Tinghui (GB-2), Waiguan (SJ-5), Zulinqi (GB-41). The acupoints are stimulated by the true needles or the laserneedles for 20 minutes per session.

#### Previous interventions:

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#### Intervention Type

Other

#### Phase

Not Applicable

#### Primary outcome measure

Heart rate variability (HRV), measured before and after the first acupuncture session, as well as 3 weeks after the whole acupuncture treatment.

#### Secondary outcome measures

- 1. Change of tinnitus severity according to the tinnitus questionnaire of Tinnitus Handicap Inventory (THI):
- 1.1. F: Functional subscale (11 factors)
- 1.2. E: Emotional subscale (9 factors)
- 1.3. C: Catastrophic subscale (5 factors)

Each question of the THI can be answered by the patient with either often (2 points), sometimes (1 point) or never (0 points) with a maximum total score of 100 indicating most severe suffering from tinnitus. The assessment was before and after the first acupuncture session, as well as 3 weeks after the whole acupuncture treatment.

2. Participants also reported adverse events they experienced, including discomfort or bruising at the sites of needle insertion, nausea, or feeling faint after each treatment.

#### Overall study start date

03/10/2012

#### Completion date

06/10/2013

# **Eligibility**

#### Key inclusion criteria

- 1. Typical conditions of unilateral or bilateral tinnitus
- 2. Age 18-65 years, either sex
- 3. Tinnitus duration of more than 3 months
- 4. Not receive any treatment last 1 month
- 5. Normal language and intelligence ability to answer and fill in the questionnaire
- 6. Correct understanding of acupuncture, and good compliance to the research observation and evaluation
- 7. Written and informed consent

#### Participant type(s)

Patient

#### Age group

Adult

#### Lower age limit

18 Years

#### Upper age limit

65 Years

#### Sex

Both

#### Target number of participants

30

#### Key exclusion criteria

- 1. Objectivity tinnitus
- 2. Acute or intermittent tinnitus, history of Meniere disease or tinnitus induced by middle ear /inner ear/small pons Angle tumor
- 3. Underlying disease or history: otitis media, tympanic membrane perforation, eustachian tube function obstacle
- 4. Acoustic neuroma, Intracranial damage, inner ear disease or use of any ototoxic drugs
- 5. Severe dysfunction of heart, kidneys or liver
- 6. The serious original disease of hematopoietic system or endocrine system
- 7. Serious aphasia, depression syndrome or mental disease

#### Date of first enrolment

03/10/2012

## Date of final enrolment

06/10/2013

## Locations

#### Countries of recruitment

China

Study participating centre 23 Meishuguanhou Street

Beijing China 100010

# Sponsor information

## Organisation

Beijing Municipal Health Bureau (China)

#### Sponsor details

70 Zaolinqian Sreet Xuanwu District Beijing China 100053

#### Sponsor type

Government

#### 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**

## Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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?
Basic results		04/02/2019	04/02/2019	No	No