An Exploratory Clinical Study on fMRI-Based Evaluation of Intervention Targets for Auricular Acupuncture Therapy

INFORMED CONSENT FORM

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INFORMED CONSENT FORM

Dear Participant,

We invite you to participate in the clinical study titled "An Exploratory Clinical Study on fMRI-Based Evaluation of Intervention Targets for Auricular Acupuncture Therapy" It is estimated that 32 subjects will voluntarily participate in this study. The study will last for 3months.

Why is this study being conducted?

Auricular Vagus Nerve Stimulation (aVNS) regulates central nervous system function and influences neural activity in the brain by stimulating the vagus nerve branch in the concha region, showing broad application prospects in the field of neuropsychiatric diseases in recent years. However, current research on how aVNS modulates the functional connectivity of specific brain networks—especially neural networks closely related to cognition and emotion regulation, such as those involving the insula and medial prefrontal cortex—remains insufficient.This study aimed to investigate the effects of auricular vagus nerve stimulation (aVNS) on functional connectivity between the insula and the medial prefrontal cortex (mPFC) in healthy subjects using resting-state functional magnetic resonance imaging (rs-fMRI).By establishing a baseline for the neurophysiological effects of aVNS in the healthy brain, this study sought to elucidate the core regulatory mechanisms related to cognitive function and emotional disorders. These findings provide a crucial theoretical reference and evaluative framework for subsequent clinical translation in patients with conditions such as insomnia and depression..

Who will be invited to participate in this study?

Inclusion criteria for the study population:

（1）Age 18–30 years;

（2）Basically normal diet and sleep;

（3）No history of mental illness;

（4）No MRI contraindications (e.g., metal implants or pacemakers) or claustrophobia；

（5）Willing to participate in this study and sign the informed consent form.

Exclusion criteria:

（1）Presence of auricular skin lesions or allergy to adhesive ear patches;

（2）Currently receiving regular acupuncture treatment;

（3）History of bleeding disorders or anticoagulant use (increased bleeding risk);

（4）Previous history of syncope during acupuncture.

What do I need to do if I participate in the study?

1、You need to sign the informed consent form.

2、Screening Period

All participants will undergo an on-site assessment by a physician. This evaluation will include inquiries regarding their height, weight, diet, sleep patterns, and mental status, in addition to a physical examination of the external ear.

3、Grouping:

The 32 successfully enrolled subjects will be randomly divided into 2 groups in a 1:1 ratio, with 16 subjects in each group. The experimental group (16 people) will undergo fMRI examination and receive real auricular acupuncture treatment (Dingshi Brand Disposable Sterile Press Needle with release paper, Medical Device Registration No.: Su Xie Zhu Zhun 20212200040, specification 0.20×1.3 mm). The control group (16 people) will

undergo fMRI examination and receive sham auricular acupuncture treatment (sterile press needles without tips).

4、Treatment Period

The ECG patch operation was divided into three stages: from the start of auricular press needle treatment to the end of the second resting-state fMRI scan.. We will collect resting-state functional magnetic resonance imaging (rs-fMRI) data.

Next, we will perform auricular acupuncture treatment on you. Auricular press needle acupoints: Heart, Kidney, Shenmen, Subcortex.

Experimental Group:

①Before the application, the participants rested for 5 min, followed by baseline fMRI examination (including T1-weighted and T2-weighted images).

②After the examination, auricular press needles were inserted. The physician's hands and local acupoint areas were routinely disinfected. The experimental group used Dingshi brand disposable sterile press needles (with release paper, Medical Device Registration No.: Su Xie Zhu Zhun 20212200040, specification 0.20×1.3 mm). Disposable, sterile press needles without tips were used in the control group. The needle body was inserted at the aforementioned points, the release paper was removed, and the adhesive tape was gently pressed to ensure tight adhesion. Both ears were treated at each time-point.

③After application, each acupoint was pressed 20 times. Pressing all eight points twice took approximately 2 min to complete. Rest for 10 min. A second pressing session was performed for 2 min. Rest for 10 min. A third pressing session was performed for 2 min, and the press needles were removed. (Total duration: approximately 26 min).

④Immediately an fMRI examination (T2-weighted images only) was performed to observe changes in brain regions..

Control Group:

The sham auricular acupuncture control group was identical to the experimental group in terms of acupoint locations, auricular acupuncture procedure, and fMRI scanning protocol. The sole exception was that the sham group received a needle-free, auricular press needles.

The intervention involved applying auricular press needles (a type of intradermal embedding needle) to specific acupoints.

What are the risks of participating in the study?

The potential risks associated with participation in this study include local pain, bleeding, redness, or swelling at the auricular acupuncture site. Should you experience any discomfort, new symptoms, or any other unexpected events during the study period—whether or not they are believed to be related to the study—please notify the study physician promptly. Your condition will be assessed, and appropriate medical care will be provided.

What are the benefits of participating in the study?

Direct Benefit: No direct benefit for health.

The societal benefit of this study lies in its use of resting-state functional magnetic resonance imaging (rs-fMRI) to elucidate the brain functional changes related to auricular acupuncture targets in a healthy cohort. This work thereby establishes a vital theoretical reference and an objective evaluation basis for informing and

advancing subsequent translational clinical research in patient populations, including those with insomnia and depression.

Do I need to pay any fees for participating in the study?

The study sponsors will cover the expenses for the auricular acupuncture interventions and fMRI scans required by the research protocol. Any medical costs related to co-existing disorders or resulting from a change in treatment strategy due to non-response are the responsibility of the participant.

To compensate for any inconvenience caused by your participation in this study, a transportation subsidy of 200 RMB per session will be provided via electronic transfer.

Is my personal information confidential?

Your medical records related to this study will be retained at the hospital. The principal investigator, relevant regulatory authorities, and the Institutional Ethics Committee will have access to these records for verification and oversight purposes. Any publication or report of the study findings will be presented in an aggregated manner, ensuring that your personal identity remains confidential. Every effort will be made to safeguard the privacy of your personal medical information in accordance with applicable laws and regulations.

Am I required to participate in the study?

Participation in this study is entirely voluntary. You may refuse to participate or withdraw from the study at any time during the research process. This will not affect the treatment you receive from your doctor.

If you decide to withdraw from the study, please contact your doctor. You can inquire about information related to this study and research progress at any time. If you have questions related to this study, or if you experience any discomfort or injury during the research process, you can contact Teng Zhimei at 17712746909.

If you have any questions regarding your rights, you may contact during working hours on national statutory working days:

Clinical Research Ethics Committee of Taizhou People's Hospital

Telephone: 0523-86361059

SUBJECT SIGNATURE PAGE

Subject's Statement of Informed Consent

I have read this informed consent form, and I have had the opportunity to ask questions, all of which have been answered.

I understand that participation in this study is voluntary.

I may choose not to participate in this study or may withdraw at any time by notifying the investigator without facing discrimination or reprisal, and my medical treatment and rights will not be affected.

If I require other treatments, if I do not follow the research plan, if a study-related injury occurs, or for any other reason, the research physician may terminate my further participation in this study.

I will receive a copy of this signed "Informed Consent Form."

Subject's Signature:_____ Contact Telephone (Mobile):_____

Date:_____ _Year_____Month _____Day

Guardian's Signature (Relationship to Subject):_____ (if applicable)

Contact Telephone (Mobile): _____

Date:_____ _Year_____Month_____Day

Impartial Witness Signature: _____ (if applicable)）

Contact Telephone (Mobile): _____

Date:_____ _Year_____Month _____Day

Investigator's Statement of Disclosure

I have accurately presented this document to the subject, who has accurately read this informed consent form, and I confirm that the subject has had the opportunity to ask questions. I confirm that his/her consent is given voluntarily.

Investigator's Signature: _____

Contact Telephone (Mobile): _____

Date: _____ _Year_____Month_____Day