**Informed consent**

Subject information

Program name: Clinical study on the intervention mechanism of fractal music therapy on tinnitus

Main investigator: Department of Neurology, Zhongshan Hospital, Fudan University

Sponsor: Zhongshan Hospital Affiliated to Fudan University

Dear Mr. / MS

You were invited to participate in the study, which was supported by Zhongshan Hospital Affiliated to Fudan University. Please read this informed consent form carefully and make a decision on whether to participate in this study. It's entirely up to you to participate in this study. As a subject, you must give your written consent before joining the clinical study. When your research doctor or researcher discusses the informed consent form with you, you can ask him / her to explain what you don’t understand. We encourage you to have a full discussion with your family and friends before making a decision to participate in this study. You have the right to refuse to participate in the study or withdraw from the study at any time without penalty or loss of your due rights. If you are participating in another study, please inform your research doctor or researcher. The background, purpose, process and other important information of this study are as follows: Clinical study on the intervention mechanism of fractal music therapy on tinnitus in Zhongshan Hospital Affiliated to Fudan University

**1、 Research background**

With the development of society and the acceleration of pace of life, the incidence rate of tinnitus is increasing year by year, and seriously affects the body and mind and life. Tinnitus itself is not a disease, but a symptom. It is the perception of sound from the ear or head in the absence of external sound. Its occurrence is the result of multiple factors, sometimes the precursor of a certain disease. From the medical point of view, "tinnitus treatment" is commonly used in the treatment of tinnitus, focusing on the treatment of physiological aspects of the disease, such as surgical resection of acoustic nerve tumors, including drug therapy (Tyler RS, 2012) and surgery, so as to achieve the purpose of treating tinnitus. However, in the field of audiology, "tinnitus management" is more commonly used, which tends to improve the overall situation of a certain disease outcome, physiological and psychological aspects (tunkel De, 2014), including counseling, cognitive behavioral therapy (Jiang David, 2012), acclimatization therapy, the use of acoustic stem predictor, the use of tinnitus masking device and its auxiliary devices. At present, there are two treatment principles for tinnitus: one is etiological treatment. To treat the primary disease of tinnitus. After the treatment of the primary disease, the tinnitus will exist for a long time if the cause is not clear. Second, symptomatic treatment, including: acclimatization therapy, masking therapy, music therapy, relaxation therapy and so on

The new tune developed based on fractal technology can help patients with subjective tinnitus relieve symptoms. In order to evaluate the safety and effectiveness of tinnitus sound intervention based on Fractal tone production in the treatment of tinnitus patients, this clinical validation study is carried out. Approved by the ethics committee of Zhongshan Hospital Affiliated to Fudan University, this clinical study was carried out in the Department of Otolaryngology, Zhongshan Hospital Affiliated to Fudan University and Minhang Central Hospital, Zhongshan University.

**2、 Research purpose**

This follow-up survey will be conducted in a single research center

1.  To evaluate the efficacy of WZT in the treatment of subjects with significant tinnitus (with or without hearing loss) within 6 months;

2.  Study how subjects use hearing aids and voice therapy (fractal tone or filtered noise).

**3、 Research process**

**1. How many people will participate in this study?**

About (96) people will participate in the study conducted in our hospital, and about (96) people will participate in this study in our hospital.

**2. Research steps**

If you agree to participate in this study, please sign this informed consent form.

Before you are enrolled in the study, your medical history will be inquired and recorded, and routine physical examination and audiological examination will be conducted.

After confirming that you can participate in this study, we will explain in detail the background knowledge of hearing loss and tinnitus, the relationship between them, and the general emotional connection between limbic system, autonomic nervous system and auditory cortex. This article introduces the WZT treatment plan in detail, including hearing-only hearing aids, Zen program (including fractal tone / noise) and detailed guidance and consultation. In addition, it can help you to establish a correct understanding of tinnitus, and give relaxation exercise guidance when tinnitus has shown serious negative effects, such as progressive muscle relaxation, deep breathing, etc. You will wear a voice intervention instrument under the guidance of a professional doctor, and the whole process will last for 6 months. During the wearing period, you should cooperate with the researcher to complete the corresponding listening test and questionnaire.

**3. How long will this study last?**

The duration of this study is about 6 months. The specific fitting process and follow-up time will be arranged in detail by special researchers and fitting personnel, and you will be informed in time. Follow up will be conducted in the second and sixth months after wearing.

You can opt out of the study at any time without losing any benefits you should have received. However, if you decide to withdraw from the study during the course of the study, we encourage you to consult with your doctor first. If you have a serious adverse event, or if your study doctor feels that it is not in your best interest to continue to participate in the study, he or she will decide to withdraw you from the study. The sponsor or regulator may also terminate the study during the study period. However, your withdrawal will not affect your normal medical treatment and rights and interests.

If you withdraw from the study for any reason, you may be asked about your participation in the study. You may also be required to have a laboratory test and a physical examination if the doctor considers it necessary.

**4、 Risks and benefits**

**1. What are the risks of participating in this study?**

The possible risks of participating in this study are as follows. You should discuss these risks with your research doctor, or if you like, with your doctor who visited you on a regular day.

During the study period, you may have some, all or none of these adverse events (adverse medical events after patients or clinical trial subjects accept a drug / medical device and other experimental products), risks, discomfort, inconvenience, and this study will not bring risks. However, there may be information security risks. We will try our best to protect the information provided by you from being leaked. We will try our best to protect the privacy of your personal medical data to the extent permitted by law. Some of the questions we asked you in this study may make you feel uncomfortable, you can refuse to answer such questions, and you can rest at any time during the study. You may withdraw from the study at any time during the study.

If you have any discomfort, new changes in your condition, or any unexpected situation, whether or not related to the study, your doctor should be informed in a timely manner. He / she will make a judgment and give appropriate medical treatment.

During the study period, you need to visit the hospital on time and do some examinations, which will take up some of your time and may cause you trouble or inconvenience.

**2. What are the benefits of participating in the research?**

Direct benefits: if you agree to participate in this study, you may receive direct medical benefits.

(1) You are free to participate in this clinical study period. During the study period, you will be provided with hearing test and sound intervention instrument. At the end of the study, the device was recovered.

(2). Your participation in this clinical study is entirely voluntary. During the course of the study, you can communicate with your doctor at any time. We hope you can insist on completing this clinical study. However, you have the right to withdraw from this clinical study at any time without any explanation. You will not be treated unfairly because of your withdrawal, and will not affect your normal and reasonable treatment and your rights.

(3) If you have any questions during the clinical study, please contact your responsible doctor at any time.

(4) If you have any adverse events during the study period, which are determined by experts to be related to the device, you will receive active treatment and / or corresponding economic compensation provided by the sponsor within the scope of law.

Potential benefits: This study may prevent / slow the progression of the disease. We hope that the information from this study that you participated in will benefit you or other patients with the same condition as you in the future.

**5、 Alternative treatment options**

 You may choose not to participate in this study. This study only collects your information or information, no alternative treatment.

**6、 Use of research results and confidentiality of personal information**

During the study, we will collect your medical history information, hearing test results and follow-up information. To ensure privacy, we will code some of your information, and your personal identifier (such as name, date of birth, address) will be replaced by code (unique patient number), so that no one can determine your identity. All the data were kept in the hands of the main researchers in the clinical laboratory, and were destroyed after 5 years. This information will not be used again in the future except for this study.

With the understanding and assistance of you and other subjects, the results of this project may be published in medical journals, but we will keep your research records confidential according to the legal requirements. The personal information of research subjects will be kept strictly confidential, and your personal information will not be disclosed unless required by relevant laws. If necessary, government departments, hospital ethics committee and other relevant researchers can access your information according to regulations.

**7、 Research expenses and related compensation**

**1. Drugs / devices used in the study and related inspection costs**

    During the course of the study, you will be provided with free hearing test and sound intervention instrument fitting by clinicians, as well as relevant examinations and scales including follow-up in the second and sixth months. At the end of the study, the device was recovered. The routine treatment and examination for other diseases you have at the same time will not be free of charge.

**2. Compensation / compensation after damage**

In case of injury related to the study, you can get free treatment provided by Zhongshan Hospital Affiliated to Fudan University, or compensate / compensate according to relevant laws of China.

**8、 Subjects' rights and related precautions**

**1. Your rights**

You were voluntary throughout the study. If you decide not to participate in this study, it will not affect the other treatments you should receive. If you decide to participate, you will be required to sign this written informed consent form. You have the right to withdraw from the trial at any time at any stage of the trial without being discriminated against or treated unfairly, and your corresponding medical treatment and rights and interests will not be affected.

**2. Precautions**

As a subject, you need to provide true information about your medical history and current physical condition; tell the research doctor of any discomfort you have found during the study; you should not take restricted drugs, foods, etc. that your doctor has informed you; and tell the research doctor whether you have recently participated in other studies or are currently participating in other studies.

**9、 Contact information**

If there is any important new information in the course of the study that may affect your willingness to continue to participate in the study, your doctor will inform you in time. If you have data about your own research, or you want to know the findings of this study at the end of the study. You can ask any questions about this study at any time and get the corresponding answers. Please contact us by telephone. Wu Shuai

The ethics committee has reviewed and approved the study. If you have any questions related to your own rights / interests, or you want to reflect the difficulties, dissatisfaction and concerns encountered in the process of participating in this study, or you want to provide opinions and suggestions related to this study, please contact the ethics committee of Zhongshan Hospital Affiliated to Fudan University at 021-31587871, email: ec@zs-hospital.sh.cn

Subject signature page

Informed consent statement:

I have been informed of the purpose, background, process, risks and benefits of the study. I have enough time and opportunity to ask questions and I am satisfied with the answers.

I was also told who I should contact when I have questions, want to reflect difficulties, concerns, suggestions for research, or want to get further information or help with research.

I have read this informed consent form and agree to participate in this study.

I know that I can choose not to participate in this study or withdraw from this study at any time during the study without any reason.

I already know that if my condition gets worse, or if I have a serious adverse event, or if my research doctor feels that it is not in my best interest to continue to participate in the study, he or she will decide to withdraw me from the study. Funding or regulatory agencies may terminate the study during the study without my consent. If this happens, the doctor will inform me in time, and the research doctor will discuss my other options with me.

I will get a copy of this informed consent form, which contains my and the Researcher's signatures.

Subject signature: Date:

(Note: if the subject has no capacity / limited capacity, the signature and date of the legal representative are required)

Signature of legal representative: Date:

(Note: if the subject is unable to read the informed consent, an independent witness is required to prove that the researcher has informed the subject of all the contents of the informed consent, and the independent witness shall sign and sign the date.)

Signature of independent witness: Date:

Researcher's signature: Date: