

Protocol/ Patient Information

Research Project

Evaluation of the Effectiveness of the Synaptic Adaptation Method in the Treatment of Tinnitus

Dear Sir/Madam,

We propose your voluntary participation in a scientific project concerning the evaluation of the effectiveness of tinnitus therapy using the Synaptic Adaptation method. The main goal of the conducted research is to analyze the effects of rehabilitation in patients with tinnitus caused by sudden hearing loss.

The Synaptic Adaptation Therapy is an innovative method of treating tinnitus, developed to reduce tinnitus by using a stimulation device designed to adapt hyperactive synapses caused by altered auditory conditions.

The study procedure will include the following steps:

1. Initial visit, including:

- a) Interview, questionnaire completion, detailed hearing tests (pure-tone audiometry, high-frequency audiometry, impedance audiometry);
- b) Tests for tinnitus (tinnitus characteristics, horizontal fiber activity test, model body hyperactivity test, ABR - neurodiagnostics);
- c) Audiological consultation.

2. Follow-up visits.

Study description

Pure-tone and high-frequency audiometry

A standard hearing sensitivity test in the range from 125 Hz to 20,000 Hz. The test is non-invasive and consists of the patient indicating when they hear a sound in the headphones.

Impedance audiometry

An objective test evaluating middle ear function (pressure, tympanic membrane compliance, stapedial reflex). The test is non-invasive and does not require patient cooperation.

Tinnitus characteristics

A test aimed at determining the frequency range of sudden hearing loss. The test is non-invasive and consists of the patient indicating a sound that masks their own tinnitus (sound provided through headphones).

Horizontal fiber activity test, model body hyperactivity test

These tests assess the functioning of nerve fibers in auditory cortex areas and model body areas. The tests are non-invasive and consist of the patient indicating a sound that masks their tinnitus (sound provided through headphones). Duration: 15 minutes.

ABR - neurodiagnostics

An objective test enabling the assessment of higher auditory pathways and synaptic function in the auditory nerve. It involves recording brainstem responses to a series of click-type stimuli. The test is non-invasive and does not require patient cooperation. Duration: 30 minutes.

Audiological consultation

Includes a detailed interview with the patient and a discussion of the test results and the mechanism of tinnitus generation. The Synaptic Adaptation Therapy method and the expected outcomes will be explained. The patient will receive all necessary information about using the device, dietary recommendations (in written or oral form). The initial visit will last up to 2.5 hours.

Using the Synaptic Adaptation Therapy requires follow-up visits with the study provider, i.e., Kinetic Center for Modern Audiology, ul. Wspólna 1 lok. 5, 85-184 Bydgoszcz. Therefore, the Organizer undertakes to ensure the availability of specialists without any additional costs for the patient, except for the travel cost. Follow-up visits will last up to 1 hour.

Risks

There are no reports that the tests and devices used in the project cause any permanent adverse effects in the subjects. Sound stimulation may cause headaches in a small number of patients.

Voluntary participation in the study

Participation in the study is entirely voluntary. You may refuse to participate or withdraw at any time without giving a reason.

Potential benefits

You have the right to receive information about your hearing condition obtained during the study. Using the stimulation device may help reduce tinnitus. In the future, general benefits from the study may also apply to other patients.

Confidentiality

Test results and other medical data are protected by medical confidentiality. Only staff directly involved in the study will have access to the information obtained. Medical data will be processed confidentially (with personal data protection). You have the right to information about your study and data storage rules.