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ARC synaptic adaptation therapy: A new treatment for tinnitus

Submission date 05/03/2017	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [X] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/03/2017	**Overall study status** Completed	
Last Edited 07/05/2025	**Condition category** Ear, Nose and Throat	

Plain English summary of protocol

Background and study aims

Tinnitus (or “ringing in the ears”) describes hearing noises from inside the body. It is often described as hearing ringing, buzzing, humming, grinding, hissing or whistling in the ears. Tinnitus can come and go and can get better over time. However, tinnitus can be more severe, causing depression or insomnia (problems falling asleep) and hearing loss. Hearing loss is also associated with the loss of auditory (hearing) hair cells. It is not very clear what can cause sudden tinnitus and it could be related to the changes in the nervous system (the brain) more than it is to just hearing. There is growing evidence that when damage occurs quickly (such as sudden hearing loss), it can impact the brain's functioning (working). Therefore, when the loss of auditory hair cells is sudden, this can mean that the nervous system does not change the amount of neurons (connections to the brain) that are working in that area. This could be why tinnitus occurs more with sudden hearing loss as opposed to slow hearing loss, where the auditory hair cells are less stimulated over time. Using a brain retraining therapy could help reduce the symptoms of tinnitus. Synaptic Adaptation Stability (ARC therapy) is a device that an artificial environment that slowly makes inner auditory hair cells less stimulated by decreasing acoustic stimulation (sounds created by the device). This mimics progressive (slow-forming) hearing loss. The aim of this study is to examine the influence of hearing loss on tinnitus occurrence and to see how well ARC therapy is at reduce tinnitus symptoms.

Who can participate?

Adults aged 18 to 60 who suffer from permanent tinnitus.

What does the study involve?

Participants are allocated to one of two groups. Participants are given a hearing aid that sits in their ear canal (like a headphone) that they wear daily for eight to ten hours for four months. Those in the first group receive a placebo stimulation (a dummy stimulation). This remains constant throughout the study. Those in the second group begin with the same stimulation as the first group but this decreases in intensity and in signal over time. Participants are assessed for their tinnitus symptoms prior to the study and after the study (four months).

What are the possible benefits and risks of participating?

Participants may benefit from improvement in their emotional stress and improvement in their

mood. There are no notable risks with participating, however, participants could get headaches from wearing the headphones for too long so they are recommended to get rest between wearing the headphones.

Where is the study run from?
Kinetic Center of Advance Audiology LTD (Poland)

When is the study starting and how long is it expected to run for?
June 2016 to December 2016

Who is funding the study?
Bioacoustic LTD (Poland)

Who is the main contact?
Mr Adam Pabiś

Contact information

Type(s)
Scientific

Contact name
Mr Adam Pabiś

Contact details
Kinetic Centrum Nowoczesnej Audiologii
ul. Paderewski 159
Rembertów
Warsaw
Poland
02-681
+48 733 149 666
adampabis@kinetic-cna.pl

Additional identifiers

Protocol serial number
7010426856

Study information

Scientific Title
ARC synaptic stabilization: Synaptic adaptation therapy as a new treatment for tinnitus trial

Acronym
ARC

Study objectives
1. Tinnitus can be effectively reduced by acoustic treatment strategy that involves long-lasting stimulation that is reduced progressively in frequency and intensity in time

2. Tinnitus is caused by sudden hearing loss that can be manifested from 4 to 20 kHz in frequency were cochlear have less vestibular fibers and this can cause fast acting deprivation of outer hair cell caused by oxidative stress, lipids dysregulation, ischemia by testosterone or estrogen fast decrease
3. If patients have the right diagnosis tinnitus plasticity model and it will have better BDNF neurotrophins level environment therefore tinnitus can be reduced due to reducing stimulation over time (progressive hearing loss environment simulation) that is fit to the tinnitus model

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 9/04/2016, Nicolaus Copernicus University [Uniwersytet Mikołaja Kopernika w Toruniu] Medical College Bioethics Committee (Ul. M. Skłodowskiej-Curie 9, 85-094 Bydgoszcz, Poland; +48 (052) 585-35-63; no email), ref: KB 336/2016

Study design
Double-blind single centre randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Tinnitus

Interventions
Participants are randomly allocated to either the control group or the intervention group (this is done using a coin toss). Participants are given a synaptic adapter (tone generator) with a stimulation range that covers the range of sudden hearing loss and its intensity confirmed by pre-existing hearing and neurobiological studies. The device is non non-invasive ear canal headphone. The device is worn daily for eight to ten hours.

Control group: Those in the control group receive the placebo stimulation. They wear the same setting with a consistent tone, duration and frequency (Hz). The stimulation remains constant during the same time.

Intervention group: Participants start at the same tone, duration and frequency (Hz) stimulation as the placebo group but the signal consistently decreases over time (i.e. the interval between sequences increases each week) and the intensity in dB which dropped by three each week (reversal of gradual hearing loss).

The device is worn for 4 months (109 days). Participants are assessed for their reduction in tinnitus at baseline and after the intervention period (after 4 months).

Intervention Type
Device

Phase

Not Specified

Drug/device/biological/vaccine name(s)
ARC synaptic adaptation therapy

Primary outcome(s)
Tinnitus reduction is measured by using a tinnitus patient questionnaire at baseline and 4 months

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
10/12/2016

Eligibility

Key inclusion criteria
1. Both women and men
2. Age between 18 and 60 years of age
3. Must be right-handed
4. Must suffer from permanent tinnitus
5. Tinnitus must not last longer than for 2 years
6. Only two persons with tinnitus lasting for more than 2 years may participate in the trial
7. Tinnitus may be tone or wide-band one
8. Tinnitus heard in head or ear
9. Movement or sight may modulate tinnitus
11. Have a high level of serotonin tested in the laboratory in serum or blood plasma (>100 µg/l)
12. Small difference in the HDL- LDL cholesterol units of the patient; it should be at the level of 1: 1 or very similar (high level of BDNF protein)
14. Hearing loss in the range between 10 kHz and 20 kHz
15. Tinnitus occurs due to the model of increased synapse activity (Tinnitus does not require macroscopic tonotopic map reorganization)
16. Follows the recommendation referring to the diet and physical activity which notified to it before the clinical trial
17. Auditory canals must not be obstructed during the therapy, no inflammation of the middle ear before commencing of the treatment and during its course
18. Average loss of hearing of the patient noted on audiogram does not exceed the level of 70 dB for a single frequency
19. Apart from the gradual loss of hearing the patient had to experience also the sudden loss of hearing visible in the background of dead outer hair cells in the range from 10 to 20 kHz
20. Does not work in the noise
21. Does not suffer from depression, anxieties, sleep disorders

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Adult

Lower age limit
18 years

Upper age limit
60 years

Sex
All

Total final enrolment
37

Key exclusion criteria
1. Suffers from hearing loss that starts already in the range of from 125 Hz to 10 kHz in one or both ears
2. Suffers from a chronic disease, such as diabetes, kidney failure, cancer
3. Tinnitus is pulsed or not continued
4. Model of nervous system plasticity, increased synchronization, which assumes that the nervous system of the patient underwent the neurons migration process or the reorganization of the auditory cortex, which additionally leads to auditory oversensitivity
5. Auditory Hyperacusis (a negative symptom of hidden hearing loss in the scope of proper hearing or increased synchronization model)
6. The hearing loss exceeds 70 dB of the single frequency
7. In audiogram, the patient manifests a dead zone of the inner ear (destroyed external and internal hair cells)
8. Partially or deaf in one or both ears
9. The auditory canal of the patient obstructed due to cerumen or inflammation of the middle ear
10. Serotonin level of the patient is lower than required.
11. Manifests metabolic disorders, which cannot be adjusted with diet and physical activity (hyperlipidemia), congenital heart disease, in spite of following the diet and physical activities there is a big difference between HDL and LDL cholesterol and high level of triglycerides
12. Works in noise
13. Suffers from depression, anxieties, sleep disorders
14. Does not want to follow the diet and physical activities

Date of first enrolment
24/04/2016

Date of final enrolment
29/07/2016

Locations

Countries of recruitment
Poland

Study participating centre
Kinetic Center of Advance Audiology LTD
Street Wspólna 1
Bydgoszcz
Poland
85-184

Sponsor information

Organisation
Bioacoustic LTD

Funder(s)

Funder type
Industry

Funder Name
Bioacoustic LTD Poland

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Artur Bogacz (arturbogacz@kinetic-cna.pl)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		07/05/2025	07/05/2025	No	No
Participant information sheet	Participant information sheet		07/05/2025	No	Yes
Participant information sheet		11/11/2025	11/11/2025	No	Yes
Statistical Analysis Plan	Study website		07/05/2025	No	No
Study website		11/11/2025	11/11/2025	No	Yes