

# ARC synaptic adaptation therapy: A new treatment for tinnitus

<b>Submission date</b> 05/03/2017	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 30/03/2017	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 07/05/2025	<b>Condition category</b> Ear, Nose and Throat	<input type="checkbox"/> Individual participant data

## 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

### **Study website**

<http://kinetic-ct.com/en/current-clinical-trial/>

## **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**

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

GP practice

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use the contact details to request a patient information sheet

**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 measure**

Tinnitus reduction is measured by using a tinnitus patient questionnaire at baseline and 4 months

### **Secondary outcome measures**

There are no secondary outcome measures

### **Overall study start date**

06/06/2016

### **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 ( $>100 \mu\text{g/l}$ )
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

**Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

60 Years

**Sex**

Both

**Target number of participants**

38

**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

**Sponsor details**

Żurawia 43

Warsaw

Poland

00-680

+48 669 300 003

office@bioacoustic.tech

**Sponsor type**

Industry

**Website**

www.bioaoustic.tech

# Funder(s)

## Funder type

Industry

## Funder Name

Bioacoustic LTD Poland

# Results and Publications

## Publication and dissemination plan

Planned publication in a peer-reviewed high-impact journal

## Intention to publish date

03/05/2017

## 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?
<a href="#">Basic results</a>		07/05/2025	07/05/2025	No	No
<a href="#">Participant information sheet</a>			07/05/2025	No	Yes
<a href="#">Statistical Analysis Plan</a>			07/05/2025	No	No