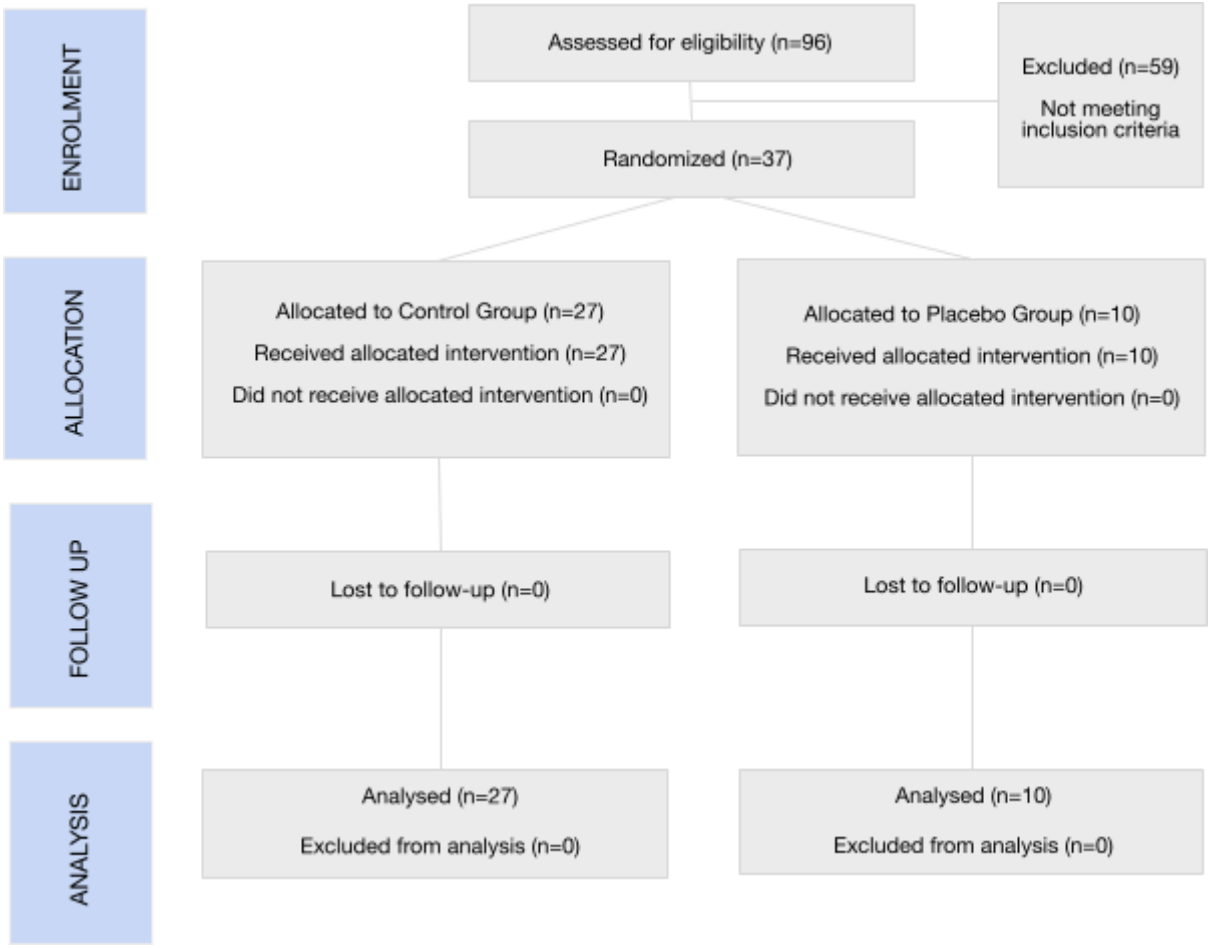
ARC synaptic adaptation therapy study design and participant flow



Characteristics of enrolled participants*

Characteristics	Control group (n=27)	Placebo (n=10)
Number of participants	27 (72.97%)	10 (27.03%)
Sex: male	8 (21.6%)	7 (18.9%)
Sex: female	19 (51.4%)	3 (8.1%)
Age (years)	29.7 (5.6)	34.5 (9.0)
Tinnitus duration:		
<6 months	11 (40.7%)	1 (10.0%)
1–2 years	15 (55.6%)	7 (70.0%)
2–5 years	0 (0.0%)	1 (10.0%)
>5 years	1 (3.7%)	1 (10.0%)
Mean hearing loss (dB HL)	45	37
Tinnitus heard:		
in right ear	1 (3.7%)	3 (30.0%)
in left ear	1 (3.7%)	2 (20.0%)
center	25 (92.6%)	5 (50.0%)
Right-handed	27 (100%)	10 (100%)
HDL - LDL cholesterol (mg/dL)	Range HDL: 85 / LDL: 100	
Level of BDNF protein (ng/mL)		
Min.	18.3	
Max.	31.4	
Tonal Tinnitus	22 (81.48%)	7 (70.00%)
Wide-band Tinnitus	5 (18.52%)	3 (30.00%)
Serotonin level (ng/mL):		
Min.	80	
Max.	280	

* Data are means (SD) or numbers (%).

Mean hearing loss is the average of hearing thresholds across frequencies of 8,10,11,12,14,16,18,20 kHz for both ears, dB HL.

Summary results from tinnitus patients questionnaire after 4 months of acoustic stimulation*

Question	Control Group (n=27)	Placebo (n=10)
How bothersome was your tinnitus before the therapy? (0-10)	7.85 (1.23)	7.4 (1.58)
How bothersome was your tinnitus after the therapy? (0-10)	2.15 (1.66)	7.2 (1.62)
By what percentage was your tinnitus reduced? (0-100%)	64.8% (18.7%)	0.0 (0.0%)
How many hours per day did you wear the device?	6.67 (1.36)	6.3 (1.34)

* Data are means (SD) or numbers (%).

Distribution of tinnitus reduction percentages by groups

Tinnitus reduction (%)	Control group (n=27)	Placebo (n=10)
0%	0 participants	10 participants
10–30%	3 participants	0 participants
40–60%	8 participants	0 participants
70–80%	12 participants	0 participants
90%-100%	4 participants	0 participants

Safety data recorded throughout the study

Number of device related mild adverse events (AEs) at sound stimulation		
	Sound stimulation (n=37)	
	Total number of events	Ongoing
Increased of worsening tinnitus	0	0
Glossodynia	0	0
Salivary hypersecretion	0	0
Dizziness	0	0
Headache	0	0
Dry throat	0	0
Number of adverse events (AEs) by relatedness to device at sound stimulation		
Possibly device related	0	0
Probably device related	0	0
Causal relationship	0	0