The Effect of Short-Term Transcutaneous Electrical Stimulation of Auricular Vagus Nerve on Parameters of Heart Rate Variability: Randomised Controlled Trial

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This clinical trial is registered with the ClinicalTrials database under a unique identifier: **NCT05680337**

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Non-invasive vagus nerve stimulation acutely improves spontaneous cardiac baroreflex sensitivity in healthy young men: A randomized placebo-controlled trial

Diego Antonino [1], André L Teixeira [1], Paulo M Maia-Lopes [1], Mayara C Souza [1], Jeann L Sabino-Carvalho [1], Aaron R Murray [2], Jim Deuchars [2], Lauro C Vianna [3]

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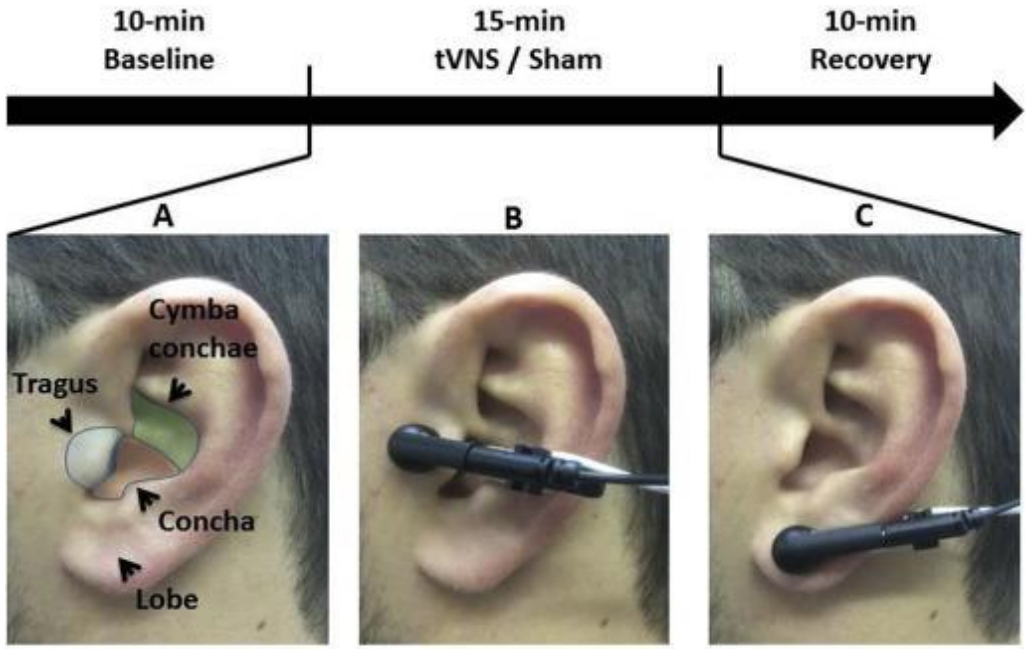
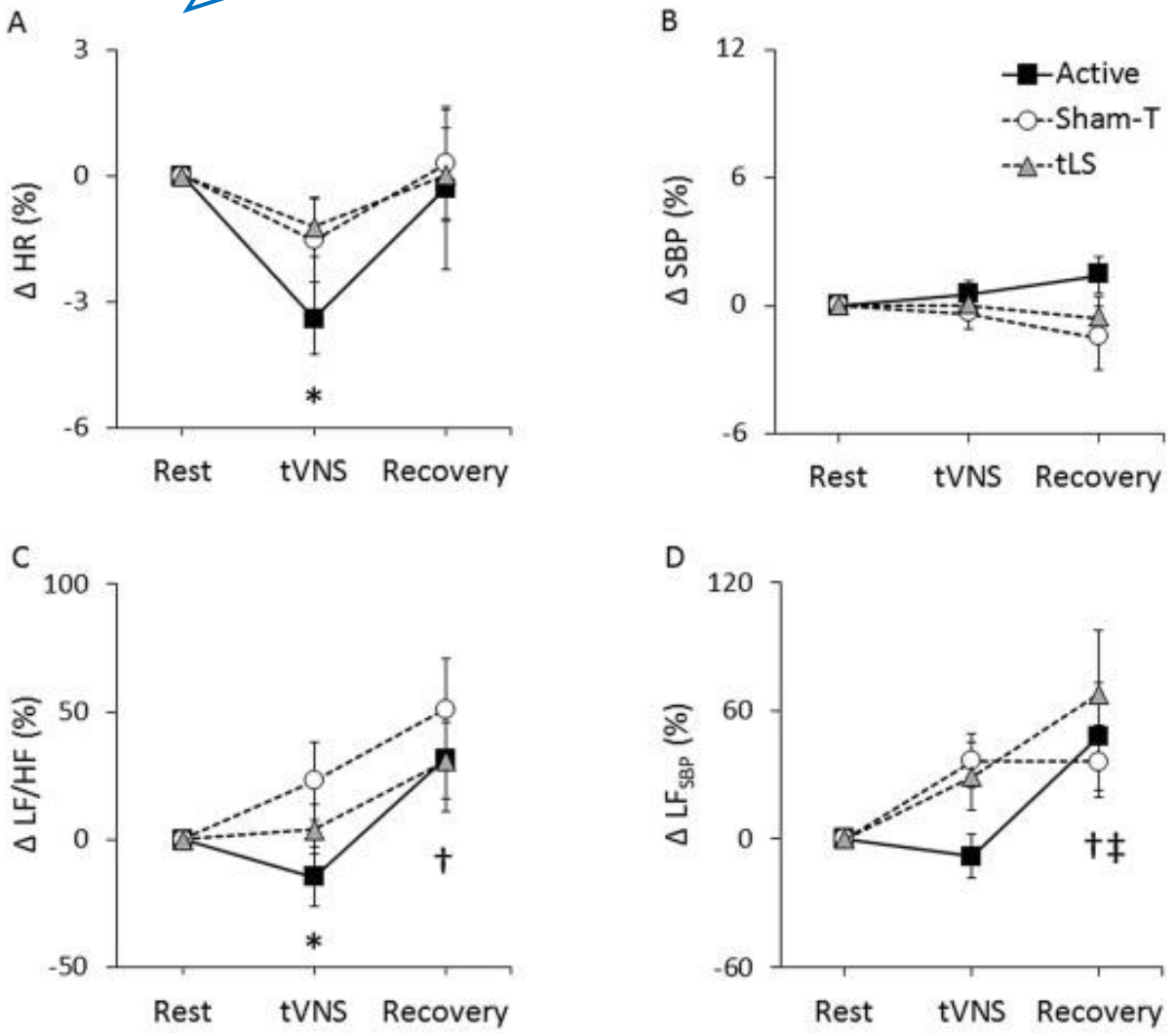


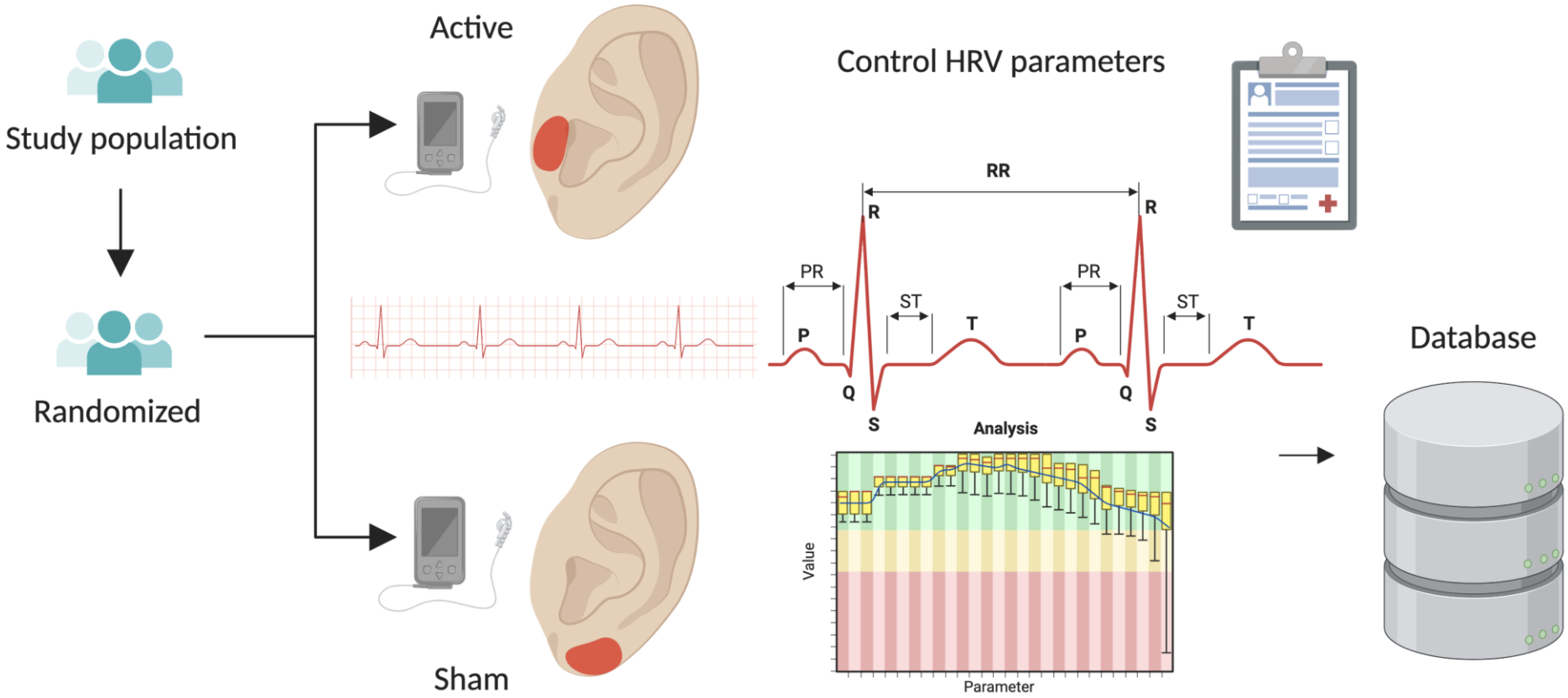
tVNS acutely improves cBRS and autonomic modulation in healthy young men



Badran et al. (2018) Heart rate	ΔHR during stimulation	9 waveforms (1, 10, 25 Hz) × (100, 200, 500 μs PW), on/off cycle NR Left tragus	2x sensory threshold (at 100 μs PW: 9.28 ± 2.56 mA, at 200 μs PW: 5.32 ± 1.60 mA, at 500 μs PW: 3 ± 0.93 mA), custom clip electrodes	Sham: At 100 μs PW: 6.57 ± 1.83 mA. At 200 μs PW: 3.64 ± 1.26 mA. At 500 μs PW: 1.97 ± 0.71 mA. diff location (earlobe)
Afanasiev et al. (2016) Coronary Insufficiency and LV dysfunction	Heart rate and 6 min walk distance	Frequency NR, PW NR, on/off cycle NR Side NR concha	Titration method NR (mean 0.05–0.15 mA), electrode NR	Placebo: same location (concha)
Tobaldini et al. (2019) Orthostatic stress	ΔHR, LF/HF, systolic arterial BP variance, RR interval pattern, respiratory rate	25 Hz, 200 ms PW (reported 200 ms in methods and 200 us in discussion), on/off cycle NR, phase NR Left cymba concha	First sensory (1–6 mA), NEMOS ball contact electrodes	Placebo: No stimulation, same location.
Fisher et al. (2018) Hypertension	Percentage decrease in median systolic blood pressure (SBP)	25 Hz, 15 ms PW, 1 s duration (gated to exhalation), biphasic Left cymba concha and beneath antihelix	Strong sensory (mA NR), stimulator NR, surface electrodes	Placebo: no current, same location
Stowell et al. (2019) Hypertension	Arterial blood pressure	2, 10, 25, or 100 Hz. 300 μs PW, 1 s on/off Left cymba concha	Strong sensory (mA NR) Urostim device, custom-built ergonomic electrodes	Placebo: no current, same location
Zamotrinsky et al. (2001) coronary artery disease	HR, BP, LV diastolic function, LV filling	3 Hz, 1,500 μs PW, on/off cycle NR Bilateral cavum concha	Titration method NR (0.2–1.25 mA), acupuncture needles	No intervention
Antonino et al. (2017) Baroreflex sensitivity	cBRS from systolic blood pressure and RR interval HRV (LF/HF)	30 Hz, 200 μs PW, on/off cycle NR Bilateral tragus	Sensory threshold (10–50 mA device range), ear clip electrodes	1 Placebo 1 Sham: same waveform (mA NR), diff location (bilateral earlobe)
Bretherton et al. (2019) HRV and baroreflex sensitivity	cBRS and HRV	30 Hz, 200 μs PW, on/off cycle NR Side NR inner & outer tragus	Sensory threshold (2–4 mA), custom TENS electrodes	Placebo: same location (inner and outer tragus)
Clancy et al. (2014) HRV and sympathetic activity	HRV (LF/HF)	30 Hz, 200 μs PW, continuous, Side NR inner and outer tragus	Sensory threshold (10–50 mA device range), V-TENS Plus with modified surface electrodes	Placebo: no current, same location
De Couck et al. (2017) HRV	ECG with HRV	25 Hz, 250 μs PW, on/off cycle NR Bilateral cymba concha	Strong sensory (mean ~0.7 mA), NEMOS ball contact electrodes	Placebo: no current, same location
Borges et al. (2019) Cardiac vagal activity	HRV	25 Hz, PW of 200–300 μs, 30 s on/off Left cymba concha	Set stimulation (1 mA) and strong sensory stimulation (2.5 ± 0.93 mA), NEMOS ball contact electrodes	Sham: same set stimulation, different strong sensory stimulation (2.76 ± 1.01 mA), diff location (earlobe)

In other studies, the results were not so unequivocal

The purpose of our study was to study the effect of short-term noninvasive stimulation of the auricular branch of the vagus nerve on heart-rate variability (HRV) parameters

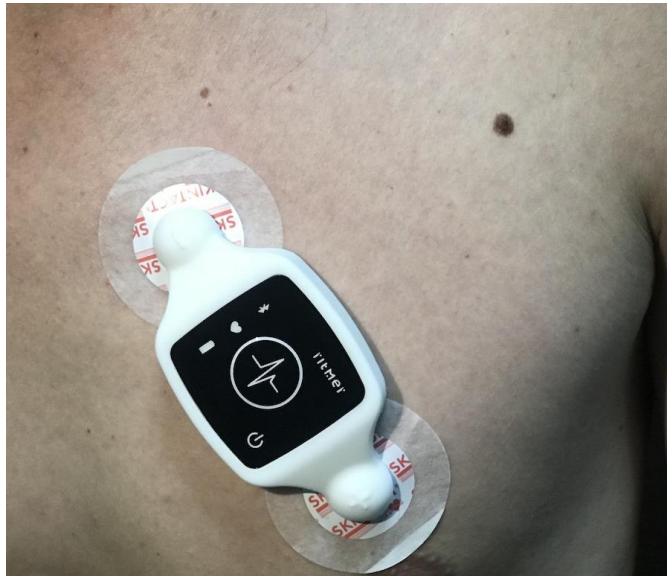


Patients were randomized into two groups according to the 1:1 scheme. Active tVNS was performed attached to the tragus of the left ear. Sham tVNS - was performed attached to the earlobe of the left ear. The stimulation frequency was 20 Hz with a pulse duration of 200 microseconds.

The research algorithm included four five-minute time intervals for recording biological signals:
(1) initially at rest,
(2) during the first 5 minutes of stimulation,
(3) during the next 5 minutes of stimulation,
(4) after the end of stimulation.

HRV parameters evaluated in this study included the standard temporal and spectral characteristics of HRV

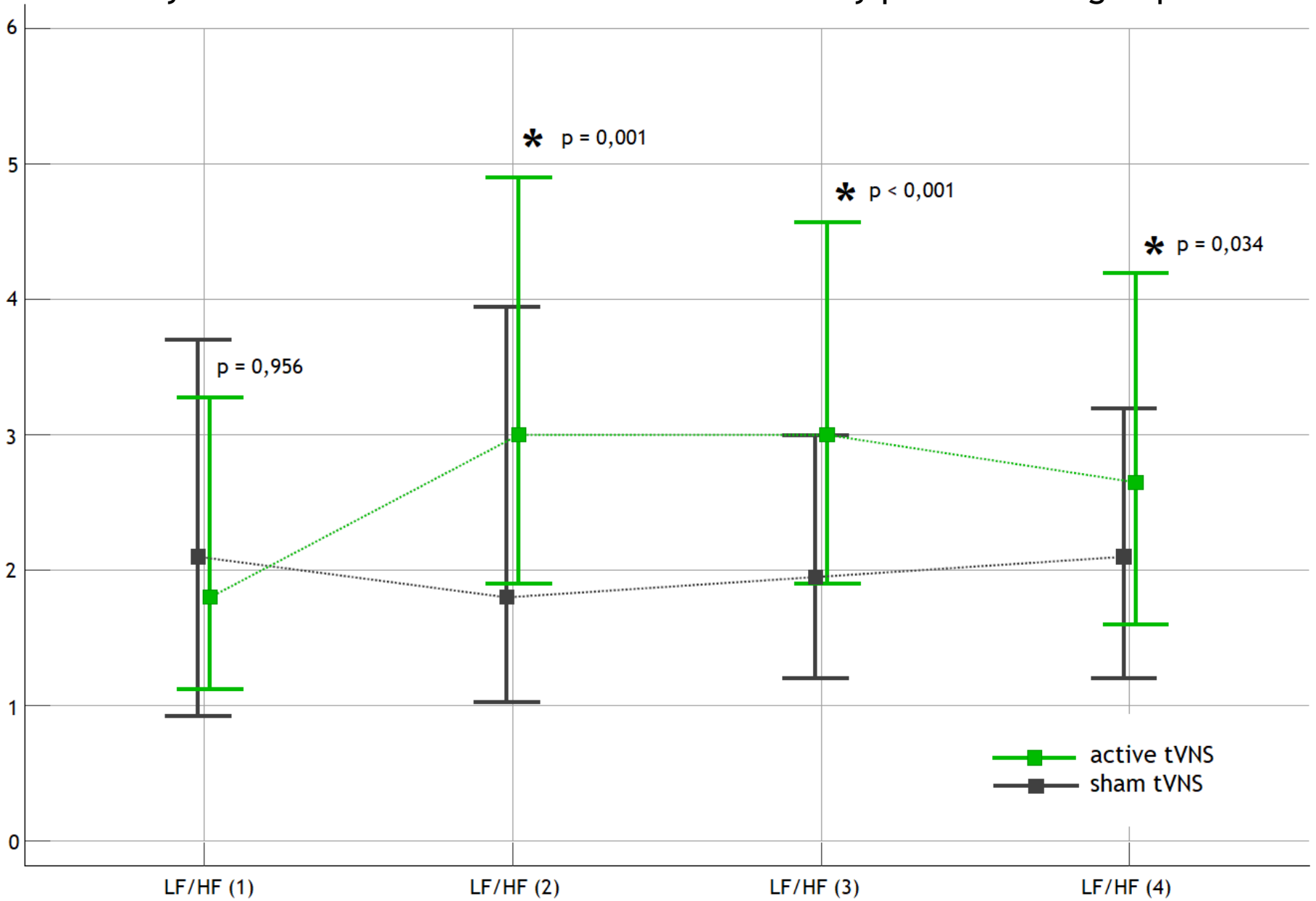
A single-channel ECG recorder ‘Ritmer M1’ with automatic calculation of HRV parameters in the web application ‘Ritmer’ was used to record biological signals



HRV parameters that showed statistically significant differences at different study points in the groups

Parameters	Active tVNS n=68	Sham tVNS n=71	p
during the first 5 minutes of stimulation			
HF мс$^2_2$	66 (35;173)	114 (58;227)	0,022*
LF/HF$_2$	3 (1,9;4,9)	1,8 (1;4)	0,001*
during the next 5 minutes of stimulation			
HF мс$^2_3$	82 (27;216)	125 (48;341)	0,028*
LF мс$^2_3$	199 (64;390)	290 (125;611)	0,048*
LF/HF$_3$	3 (1,9;4,6)	1,9 (1,2;3)	<0,001*
after the end of stimulation			
pNN50$_4$	0,8 (0; 5,2)	2 (0,3;9,6)	0,044*
IC1$_4$	0,55 (0,3;0,95)	0,7 (0,5;1,1)	0,045*
IC2$_4$	10,7 (5,6;19,5)	6,4 (4,3;10,6)	0,002*
HF%$_4$	8,5 (5;15,5)	13 (9;19)	0,002*
HF мс$^2_4$	81 (32;216)	115 (52;253)	0,033*
LF/HF$_4$	2,6 (1,6;4,2)	2,1 (1,2;3,1)	0,034*

Dynamics of the LF/HF ratio at different study points in the groups



Conclusion

In our study, during of low-frequency electrical stimulation of the auricular branch of the vagus nerve, the active group showed a decrease in the level of indices reflecting the activity of the parasympathetic nervous system, while in the sham stimulation group no statistically significant dynamics was observed

Thus, the obtained results allow us to conclude that HRV parameters can be considered as a biomarkers of ANS modulation during percutaneous vagus nerve stimulation. Percutaneous vagus nerve stimulation causes rapid but transient changes in HRV parameters, which confirms its role as a tool for modulation of autonomic balance