

Trigeminal Nerve Stimulation for ADHD

Table S1. Secondary Efficacy Measures with Significant Effects for Double-Blind Active vs. Sham Trigeminal Nerve Stimulation (TNS)

Measure	Effect	F	df	p
ADHD-RS-Inattentive Subscale	Group	<1	1/228	.55
	Time	34.30	1/228	<.0001
	Time2	23.20	1/228	<.0001
	Group*Time	5.35	1/228	.02
ADHD-RS-Hyperactive/Impulsive Subscale	Group	<1	1/228	.62
	Time	29.28	1/228	<.0001
	Time2	23.02	1/228	<.0001
	Group*Time	7.83	1/228	.007
Conners Global Index-Parent Report	Group	.01	1/209	.91
	Time	13.03	1/209	.0004
	Time2	7.45	1/209	.007
	Group*Time	<1	1/209	.36
CSHQ-Bedtime Resistance	Group	<1	1/205	.51
	Time	6.12	1/205	.01
	Time2	2.75	1/205	.10
	Group*Time	<1	1/205	.50
CSHQ-Sleep Anxiety	Group	<1	1/202	.33
	Time	11.48	1/202	.0008
	Time2	5.81	1/202	.02
	Group*Time	<1	1/202	.94
CSHQ-Total Sleep Problems	Group	2.04	1/183	.16
	Time	14.36	1/183	.0002
	Time2	6.18	1/183	.01
	Group*Time	1.48	1/183	.23
MASC-Parent Report	Group	.25	1/53	.62
	Time	3.58	1/53	.06
	Group*Time	2.90	1/53	.09

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Note: boldface type indicates significance at $p < .05$. Italics indicate trend level effects at $p < .10$. ADHD-RS = ADHD Rating Scale;

CSHQ = Children's Sleep Health Questionnaire; MASC = Manifest Anxiety Scale for Children.

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Table S2. Summary of F-Values for Treatment Effects on Resting State Electroencephalography (EEG) Spectral Power

Frequency Band	Electrode	Group	Time	Group*Time
Delta	F3	<1	<1	1.13
	F4	<1	2.5	5.9*
	Fz	<1	<1	2.9
	C3	<1	<1	1
	C4	<1	1.1	1.1
	Cz	<1	<1	1
	P3	<1	<1	<1
	P4	<1	<1	1.3
	Pz	<1	<1	<1
Theta	F3	<1	<1	1
	F4	<1	2.6	6.2*
	Fz	<1	1.1	2.9
	C3	<1	<1	<1
	C4	<1	<1	<1
	Cz	<1	<1	<1
	P3	<1	1.1	<1
	P4	<1	<1	<1
	Pz	<1	<1	<1
Beta 1/2	F3	<1, <1	<1, <1	<1, <1
	F4	<1, <1	2.4, 1.2	5.2*, 6.0*
	Fz	<1, <1	<1, <1	3.3, 3.3
	C3	<1, 1.5	1.5, 1.9	<1, <1
	C4	<1, <1	<1, <1	<1, <1
	Cz	<1, 1	<1, <1	<1, <1
	P3	<1, 1	2.6, 2.2	<1, <1
	P4	<1, <1	<1, <1	<1, <1
	Pz	<1, 1.7	<1, <1	<1, <1
Gamma 1, 2	F3	<1, <1	<1, <1	<1, <1
	F4	<1, <1	1.4, 1.2	7.1**, 6.5**
	Fz	<1, <1	<1, <1	4*, 3.8
	C3	1.2, <1	1.1, <1	1.2
	C4	<1, <1	<1, <1	1, <1

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Cz	1.6, 1.9	<1, <1	1.2, 1.1
P3	2, 2.2	1.3, <1	<1, <1
P4	<1, <1	<1, <1	1.6, 1
Pz	3.5, 3.7	<1, <1	<1, <1

Note: For all analyses, degrees of freedom = 1, 47-70. No significant effects were found in the alpha band. Italics indicate trend level effects at $p < 0.10$. Beta 1 = 13-16 Hz (hertz); Beta 2 = 17-25 Hz; C = central; Delta = 1-3 hertz (Hz); F = frontal; Gamma 1 = 30-40 Hz; Gamma 2 = 40-50 Hz; P = Parietal; Theta = 4-7 Hz;
* $p < .05$; ** $p < .01$.

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Table S3. Correlations Between Resting-state Electroencephalography (EEG) Power and Attention-Deficit/Hyperactivity Disorder (ADHD) Behaviors

<i>Electrode</i>	<i>Frequency Band</i>	Correlation with Visit 4 ADHD-RS Scores		
		Inattentive	Hyperactive/Impulsive	Total
F4	Delta	-0.266	-0.319	-0.35*
F4	Theta	-0.252	-0.38*	-0.38*
F4	Beta 1	-0.254	-0.34*	-0.36*
F4	Beta 2	-0.261	-0.36*	-0.37*
F4	Gamma 1	-0.229	-0.31	-0.33
F4	Gamma 2	-0.218	-0.30	-0.31
Fz	Gamma 1	-0.183	-0.41*	-0.37*

Note: * $p < .05$.

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Table S4. Spontaneously Reported Adverse Events (AEs)

Adverse Event	Participants Reporting [n (%)]	
	Active (n=32)	Sham (n=30)
Anxiety		1 (3)
Bronchitis	1 (3)	
Headache	3 (9)	1 (3)
Itching	1 (3)	
Lightheaded	1 (3)	
Mouth pain		1 (3)
Nausea	1 (3)	
Nightmares		1 (3)
Poor appetite	1 (3)	
Rash	1 (3)	
Rhinitis	2 (6)	2 (6)
Skin whitening/discoloration	1 (3)	1 (3)
Stomachache	2 (6)	1 (3)
Tooth pain	1 (3)	
Upper Respiratory Infection	3 (9)	3 (10)
Vomiting	1 (3)	
Wrist sprain		1 (3)

Note: All AE's were mild to moderate in clinical significance. There were no Serious Adverse Events (SAEs).