ISRCTN — Basic Results Summary (final, registry-ready)

Study status
Completed

Date of last data collection
30 December 2024

Background

Transcutaneous tibial nerve stimulation (TTNS) is an established non-invasive therapy for overactive bladder, yet its autonomic mechanisms remain incompletely understood. This exploratory physiological study evaluated the acute effects of TTNS on autonomic nervous system activity in healthy volunteers using heart rate variability (HRV) metrics.

Methods

Open-label, prospective, single-arm exploratory study in healthy adults. Participants underwent three consecutive 10-minute phases: baseline rest, continuous submotor TTNS applied via surface electrodes over the left tibial nerve, and post-stimulation recovery. HRV was recorded using a validated chest-strap sensor and analyzed with standard software. Time-domain, frequency-domain, and composite autonomic indices were assessed in standardized 5-minute windows. Non-parametric repeated-measures tests with correction for multiple comparisons were applied.

Results

Twenty participants completed the study. During TTNS, parasympathetic-related indices (e.g., SDNN, RMSSD, parasympathetic composite indices) increased, while sympathetic and stress-related indices decreased compared with baseline ($p<0.05$). Some parameters showed partial persistence into the post-stimulation phase, though sustained effects were attenuated after conservative correction. Exploratory analyses indicated that younger age was associated with greater parasympathetic responsiveness.

Conclusions

Acute TTNS induces a shift toward parasympathetic predominance with sympathetic suppression in healthy individuals, supporting a biologically plausible autonomic mechanism relevant to bladder neuromodulation. Results are consistent with an ongoing peer-reviewed manuscript currently under journal evaluation.

Publications
Manuscript under peer review: *Acute Effects of Transcutaneous Tibial Nerve Stimulation on Autonomic Nervous System Activity in Healthy Volunteers: An Exploratory Study* (Neurourology and Urodynamics).

Perfecto. A continuación tienes **el Basic Results Summary EXACTO**, estructurado **en los 4 apartados que pide ISRCTN**, **sin interpretación**, **en formato tabular**, y **compatible con ICMJE**.
Esto lo puedes **copiar y pegar tal cual** en el formulario o enviarlo por email a ISRCTN.

BASIC RESULTS SUMMARY — ISRCTN17718049

1. Participant Flow

Study Stage	Number of Participants
Assessed for eligibility	22
Enrolled	20
Received intervention (TTNS)	20
Completed study protocol	20
Included in analysis	20
Withdrawals / losses to follow-up	0

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2. Baseline Characteristics

Characteristic	Value
Number of participants	20
Age, years (median [range])	31 [19–68]
Sex	11 women (55%), 9 men (45%)
BMI, kg/m^2 (median [range])	26.0 [18.0–33.2]

Characteristic	Value
BMI category	Normal 45%, Overweight 35%, Obese 20%
Smoking status	Current smokers: 3 (15%)
Physical activity level	Active 65%, Sedentary 35%
Relevant comorbidities	2 participants (10%), minor
Medication use affecting ANS	1 participant (5%)

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3. Outcome Measures

Primary Outcome Measure

Acute change in autonomic nervous system activity assessed by heart rate variability (HRV) parameters during TTNS compared with baseline.

Outcome	Baseline (mean ± SD)	During TTNS (mean ± SD)	Post-stimulation (mean ± SD)
SDNN (ms)	42.6 ± 17.6	56.6 ± 29.3	56.3 ± 28.9
RMSSD (ms)	45.3 ± 27.6	61.9 ± 47.0	61.8 ± 43.5
PNS index	−0.03 ± 1.22	0.59 ± 1.64	0.53 ± 1.48
SNS index	0.36 ± 1.08	−0.10 ± 1.02	−0.08 ± 0.94
Stress index	10.8 ± 4.0	9.0 ± 4.4	8.8 ± 4.5

Analysis population: All enrolled participants (n = 20).

Secondary Outcome Measures

Exploratory associations between autonomic response magnitude and demographic variables.

Variable	Association with autonomic response
Age	Negative correlation
BMI	Positive trend
Physical activity level	No clear association

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4. Adverse Events

Adverse Event	Number of Participants Affected
Serious adverse events	0
Non-serious adverse events	0

Statement:
There were no adverse events associated with this study.