Wearable Auricular Neurostimulation Reduces Anxiety and Improves Sleep in First Responders

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Introduction

First responders face chronic exposure to occupational stress and trauma, driving nervous system dysregulation that can manifest as psychological and physiological dysregulation, including PTSD, burnout, anxiety, and disturbed sleep[1]. Epidemiological data report significant sleep disturbance in the majority of first responders (58–93% across studies) and clinically significant anxiety symptoms in up to 28% of personnel, rates that markedly exceed those observed in civilian cohorts[2]. A survey of 575 law enforcement officers found 74.5% had personally experienced a traumatic event on the job, and those with trauma exposure were significantly more likely to report having thought about suicide (27.2% vs. 7.7%)[3]. Traditional wellness programs (peer support, debriefing, counseling) have limited reach and don't directly target the underlying neurophysiology, and invasive VNS approaches face adoption barriers[3]. Scalable, non-pharmacologic interventions that can be deployed in real-world settings are needed to support stress resilience and overall well-being. Spark Biomedical has developed a non-invasive, portable, easy-to-use device that delivers **transcutaneous auricular neurostimulation (tAN)**, which targets auricular vagal pathways to improve autonomic regulation and stress recovery.

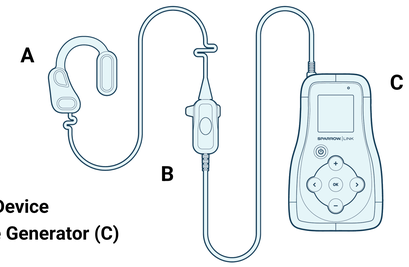
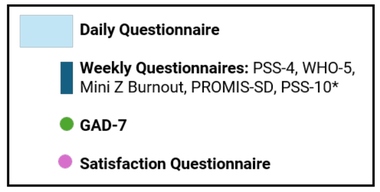


Fig 1. Sparrow Link tAN Device
Earpiece (A), Cable (B), and Pulse Generator (C)

Methods

This open-label decentralized clinical study evaluates daily use of a wearable tAN device in U.S. active-duty first responders over 56 days. This report presents preliminary data from the first 12 participants. Participants were recruited, consented, trained on device use, and completed all study procedures using online platforms. Following baseline assessments, participants self-administered **one daily tAN session of 1–2 hours on Days 1–28**, recommended post-shift prior to sleep. After Day 28, participants discontinued daily tAN sessions and entered a **passive follow-up phase through Day 56**. Beginning on Day 0, participants completed the following validated patient-reported outcomes at weekly timepoints: **Perceived Stress Scale (PSS-4 and PSS-10), WHO-5 Well-Being Index, Mini-Z Burnout, PROMIS Sleep Disturbance (PROMIS-SD), and Generalized Anxiety Disorder-7 (GAD-7).** Longitudinal changes from baseline were assessed to evaluate the feasibility and effectiveness of tAN in a real-world operational population.



*PSS-10 replaced the PSS-4 on Days 0, 28, and 56

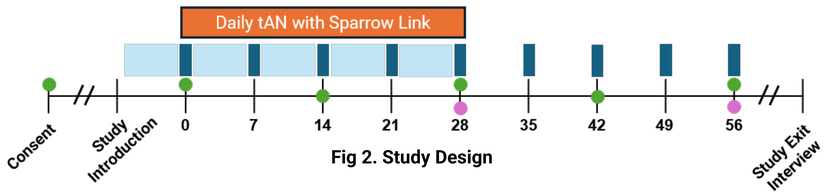


Fig 2. Study Design

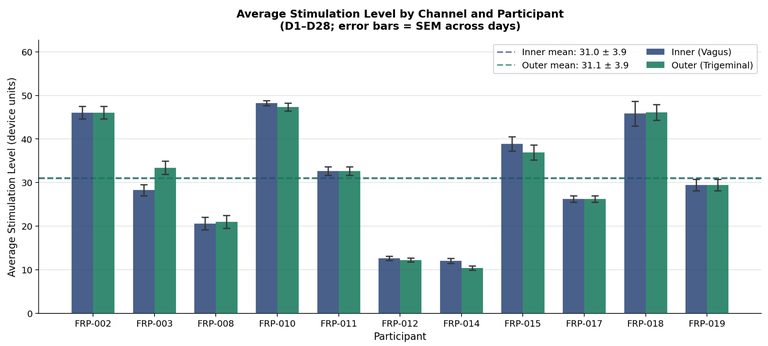


Fig 3. Average stimulation Intensity. Average stimulation intensity delivered via the inner (vagus) and outer (trigeminal) channels for each participant across the 28-day active treatment period (Days 1–28), in device units. Error bars represent ±1 SEM across days. Dashed lines show the group mean ± SEM for each channel (Inner: 31.0 ± 3.9; Outer: 31.1 ± 3.9; n=11), which are nearly identical between channels.

Preliminary Results (n=12)

Data from 12 first responders demonstrated consistent improvements across anxiety, sleep, stress, well-being, and burnout outcomes following four weeks of daily tAN therapy.
Row A: Individual trajectories with group mean +/- SEM. **Row B**: per-participant Day 0->28 change vs. MCID. **Row C**: Day 0 vs. Day 28 group means +/- SEM with paired t-test significance (*** p<0.001, ** p<0.01, * p<0.05, ns = not significant). **Row D**: Day 28 vs. Day 56 persistence, same test.

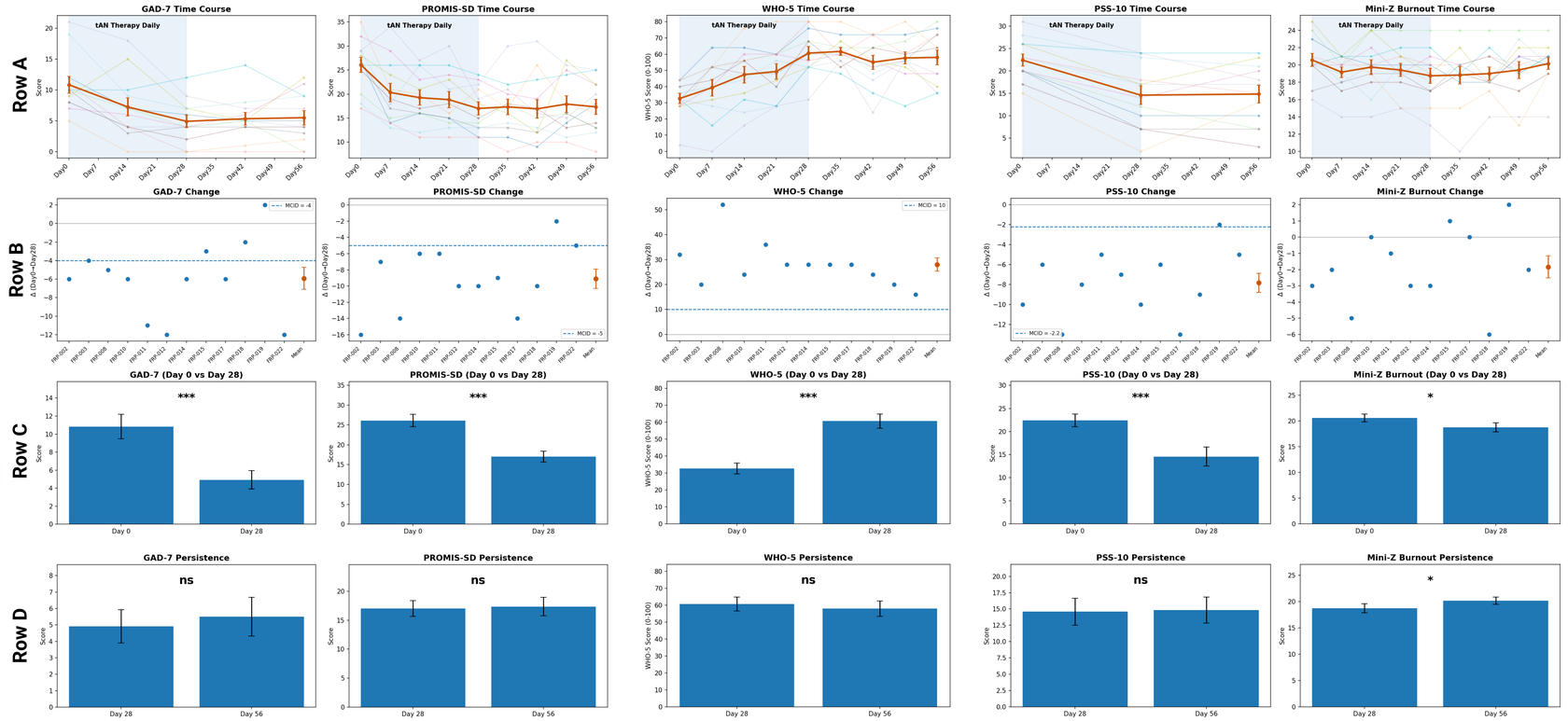


Fig 4. Effects of tAN on anxiety. Anxiety scores decreased significantly from Day 0 to Day 28 (p<0.001), with most participants exceeding the 4-point MCID. Gains were maintained through the 28-day, no-treatment follow-up (Day 28 vs. 56, ns).

Fig 5. Effects of tAN on sleep disturbances. Sleep disturbance improved significantly from Day 0 to Day 28 (p<0.001). This improvement held steady through Day 56 with no significant rebound (ns).

Fig 6. Effects of tAN on well-being. Well-being scores increased significantly from Day 0 to Day 28 (p<0.001). Gains were sustained through the follow-up period, with no significant decline by Day 56 (ns).

Fig 7. Effects of tAN on perceived stress. Perceived stress decreased significantly from Day 0 to Day 28 (p<0.001), and the reduction was maintained through Day 56 (ns).

Fig 8. Effects of tAN on burnout. Burnout showed a smaller but still significant decrease from Day 0 to Day 28 (p<0.05) relative to the other measures. Unlike the other four outcomes, burnout partially rebounded toward baseline during the no-treatment follow-up (Day 28 vs. 56, p<0.05).

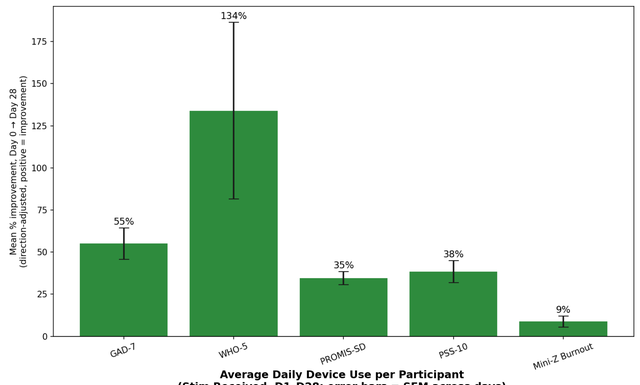


Fig 9. Mean percent improvement by outcome measure (n=12).

Direction-adjusted mean percent change ± SEM from Day 0 to Day 28 (treatment period) for each of the five outcome measures (positive = improvement in all cases). WHO-5's wide error bars reflect one participant's outlier baseline (near-zero score), which inflates the mean percent change; the median percent improvement (~78%) may better represent the central tendency of this measure.

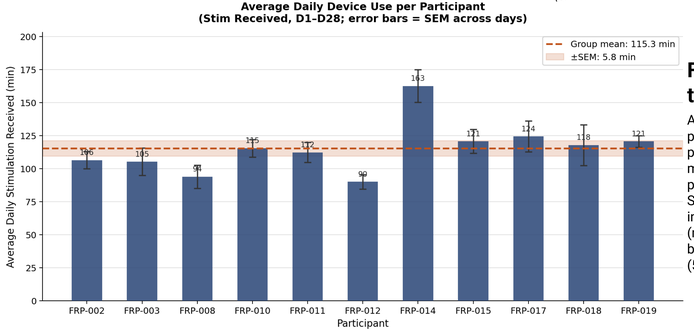


Fig 10. Average amount of tAN daily

Average daily stimulation dose received per participant across the 28-day active treatment period (Days 1–28), calculated as mean daily minutes of stimulation received per participant, with error bars representing ±1 SEM across days. Numbers above bars indicate each participant's mean daily use (min). The dashed orange line and shaded band show the group mean (115.3 min) ± SEM (5.8 min) across participants (n=12)

Discussion

GAD-7 scores decreased significantly from Day 0 to Day 28 (p<0.001), with 58% achieving remission (score <5). Sleep disturbance (PROMIS-SD) also improved significantly over the same period (p<0.001), with 83% of participants shifting from a mild-to-moderate impairment band to none-to-slight by Day 28. These findings support the feasibility of daily wearable auricular neurostimulation (tAN) and suggest preliminary benefit for anxiety and sleep in first responders. The rapid onset and durability of improvement are consistent with tAN's proposed mechanism of autonomic/vagal modulation. These results support further evaluation in controlled trials and highlight the potential for scalable neuromodulation approaches to enhance resilience and operational readiness in high-stress populations.

References

1. Ugwu, L. E., & Idemudia, E. S. (2024). Burnout and Post-traumatic Stress Disorders in Police Officers: Systematic Review and Meta-analysis. *Journal of Police and Criminal Psychology*. https://doi.org/10.1007/s11896-024-09713-7
2. Jones S, Nagel C, McSweeney J, Curran G. Prevalence and correlates of psychiatric symptoms among first responders in a Southern State. *Arch Psychiatr Nurs*. 2018;32(6):828-835. doi:10.1016/j.apnu.2018.06.007
3. Fleischmann, M. H., Strode, P., Broussard, B., & Compton, M. T. (2018). Law enforcement officers' perceptions of and responses to traumatic events: A survey of officers completing Crisis Intervention Team training. *Policing and Society*, 28(2), 149–156. https://doi.org/10.1080/10439463.2016.1234469