Transcranial Electric Stimulation (tES) in Warfighters with Moderate-to-Severe Insomnia

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Sleep. Neuroscience. Technology.

Key Takeaway #1:

tES worn 30-min before bed elicited a therapeutic effect on insomnia symptoms compared to baseline, however the effects were not frequency-specific.

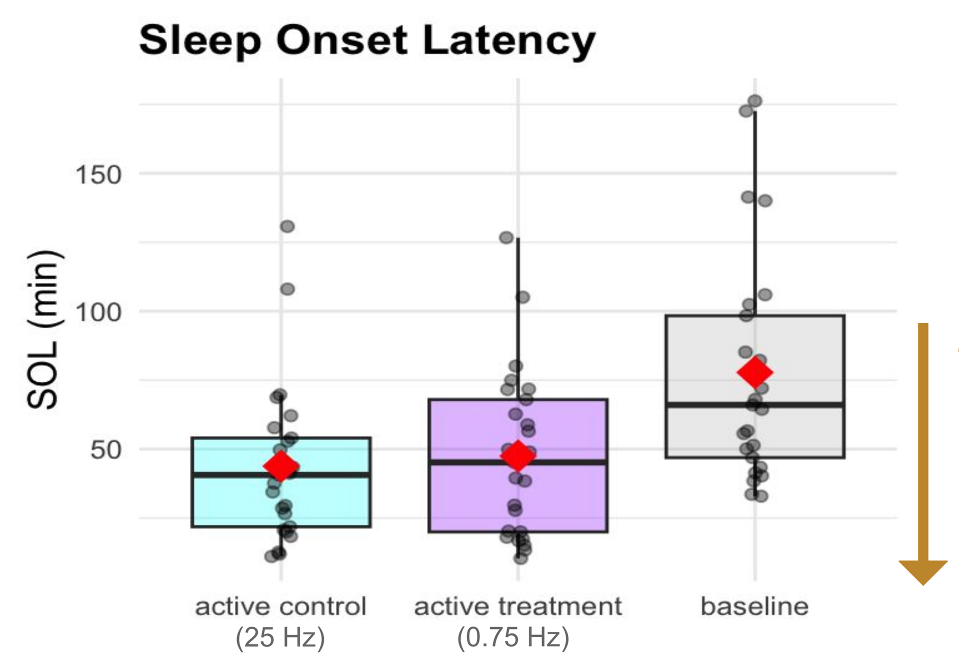

Sleep Onset Latency
SOL (min)
150
100
50
active control (25 Hz)
active treatment (0.75 Hz)
baseline

Figure 1. Median + IQR (box plot) and mean (red diamond) sleep onset latency for N=25 participants.

therapeutic effect (participants fell asleep faster while wearing the headset)

Introduction

- Insomnia is prevalent in the military, especially when returning home from deployment [1]
- Sleep medications can be limited by side effects and recurring costs [2]
- TES shows promise as a safe, non-invasive alternative to improve sleep quality, possibly by enhancing frontal slow wave activity before bed [3]

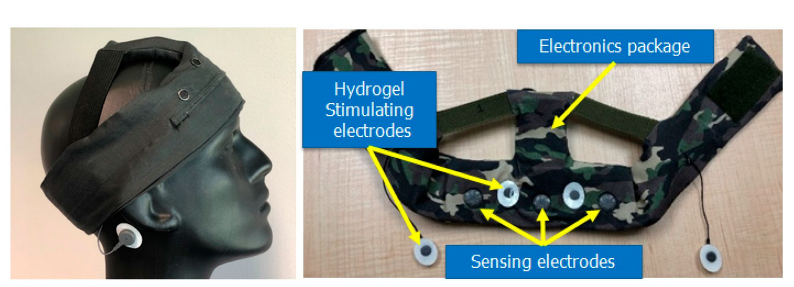

Electronics package
Hydrogel Stimulating electrodes
Sensing electrodes

Figure 2. Teledyne's PeakSleep tES headset has 3 frontal EEG electrodes and 2 stimulating electrodes [3]

We aimed to validate the efficacy of Teledyne Scientific's PeakSleep active stimulation headset to reduce insomnia in a military cohort.

Methods

Table 1. Metrics of Interest

Metric:	Calculation:
Sleep Onset Latency (SOL)	sleep start - latest bedtime
Insomnia Severity Index (ISI)	aggregate score (self report)
Wake After Sleep Onset (WASO)	wake between sleep start & stop
Frontal Slow Wave Activity	Δ Fpz delta power

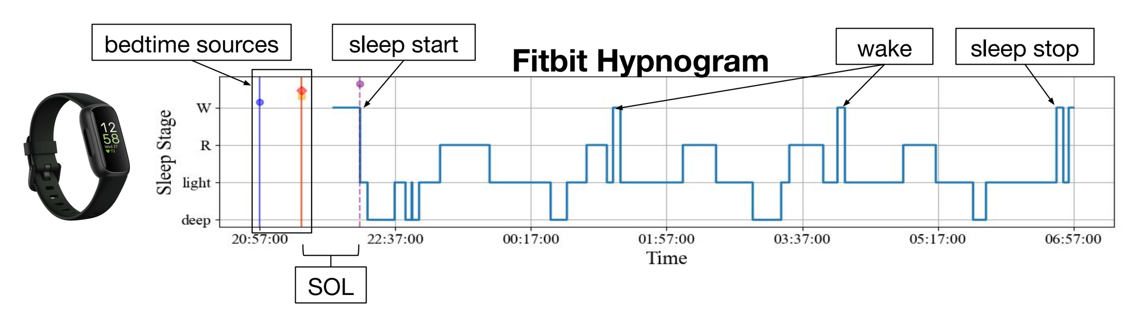

bedtime sources
sleep start
Fitbit Hypnogram
wake
sleep stop
Sleep Stage
W
R
light
deep
20:57:00
22:37:00
00:17:00
01:57:00
03:37:00
05:17:00
06:57:00
Time
SOL

Figure 3. Hypnogram in the Fitbit Inspire 3 used to calculate SOL and WASO.

Study design:

- Double-blind, randomized, crossover, phase II clinical trial in military personnel with moderate-to-severe insomnia (ISI ≥ 15; SOL ≥ 30 min.)

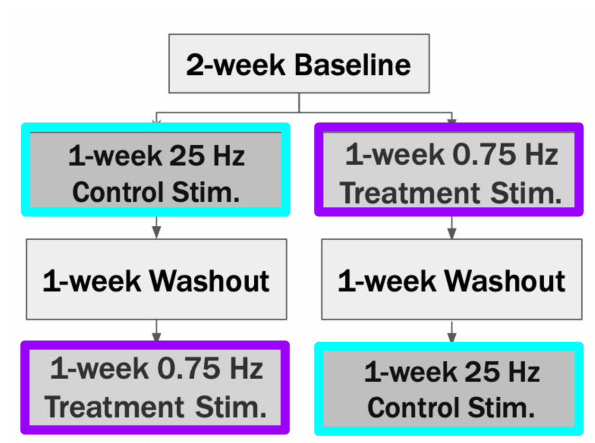

2-week Baseline
1-week 25 Hz Control Stim.
1-week 0.75 Hz Treatment Stim.
1-week Washout
1-week Washout
1-week 0.75 Hz Treatment Stim.
1-week 25 Hz Control Stim.

Figure 4. Data collection flow diagram of the ~5-week paradigm, participants counter-balanced by stimulation order.

Stimulation:

- Headset worn immediately before trying to fall asleep
- 30 min: 60s EEG baseline → 100 trials (8s ON + 10s OFF)
- Amplitude scaled by real-time measure of skin impedance

Results

- N = 25 participants completed the full 5-week paradigm and had at least 3 nights of viable data in baseline and stimulation sessions (age 43 +/- 12 years, 13 females, 13 reported using sleep medication prior to participation)

Table 2. Summary of Outcomes

Characteristic	active control N = 25[1]	active treatment N = 25[1]	baseline N = 25[1]	p-value[2]
SOL (min)	44 (±29)	47 (±30)	78 (±42)	0.002
ISI	16 (±6)	16 (±5)	20 (±3)	0.014
WASO (min)	37 (±13)	35 (±12)	37 (±10)	0.9
TST (min)	405 (±73)	394 (±61)	397 (±53)	0.8
Awakenings	19.9 (±6.1)	19.4 (±5.1)	20.4 (±5.2)	0.9
Light Sleep %	0.57 (±0.06)	0.57 (±0.06)	0.58 (±0.05)	0.9
Deep Sleep %	0.15 (±0.04)	0.16 (±0.03)	0.15 (±0.03)	>0.9
REM Sleep %	0.19 (±0.05)	0.18 (±0.06)	0.18 (±0.04)	0.7
Resting HR (bpm)	67 (±10)	70 (±10)	68 (±7)	0.4
PHQ-9	8 (±5)	8 (±4)	9 (±5)	0.8

[1] Mean (±SD)
[2] Kruskal-Wallis rank sum test

Table 2. SOL and ISI dropped in both active treatment and active control conditions, as compared to baseline

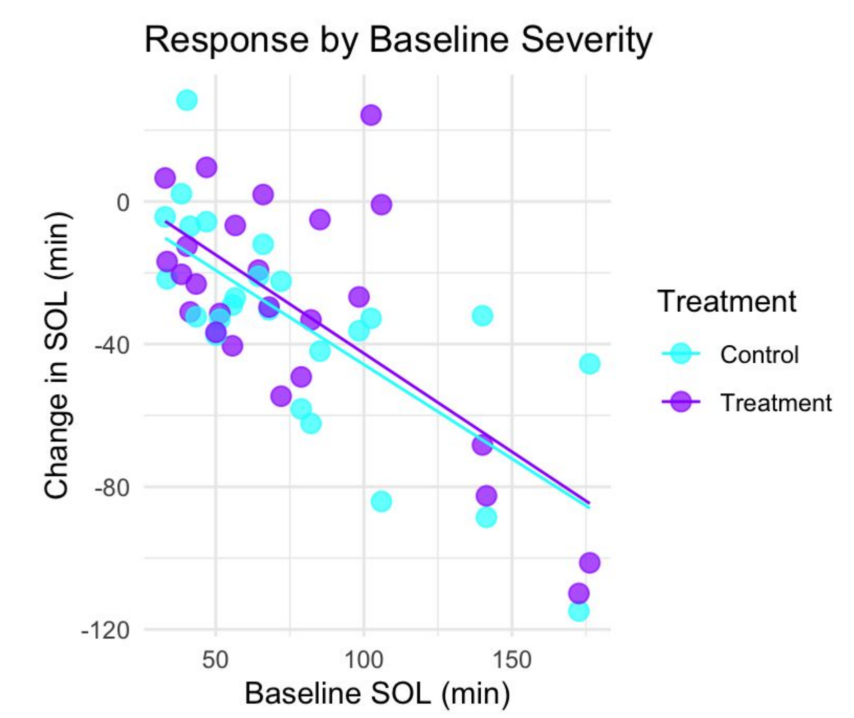

Response by Baseline Severity
Change in SOL (min)
0
-40
-80
-120
50
100
150
Baseline SOL (min)
Treatment
Control
Treatment

Figure 5. Subjects with severe insomnia (high SOL) had greatest change in SOL, regardless of stim type (cyan: 25 Hz vs purple: 0.75 Hz). Active Control Pearson's R value = -0.723 ($p < 0.001$). Active Treatment Pearson's R value = -0.694 ($p = 0.001$).

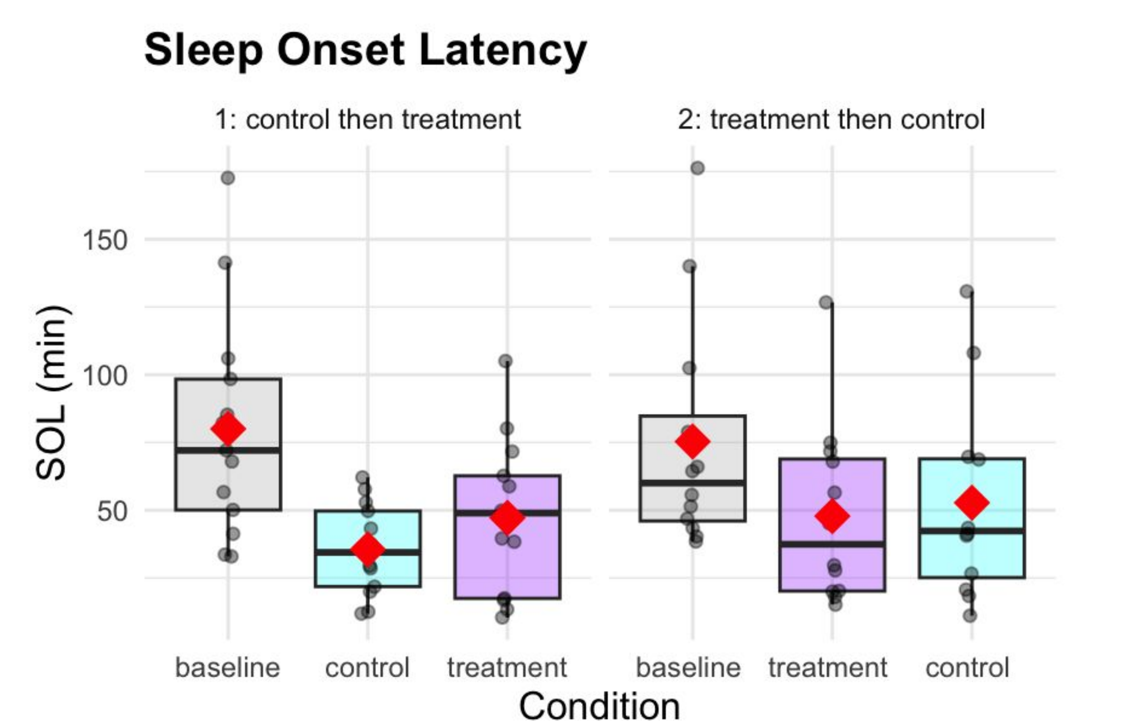

Sleep Onset Latency
1: control then treatment
2: treatment then control
SOL (min)
150
100
50
baseline
control
treatment
baseline
treatment
control
Condition

Figure 6. Both Order 1 (25 Hz control → 0.75 Hz treatment) and Order 2 (0.75 Hz treatment → 25 Hz control) showed reductions in SOL compared to baseline.

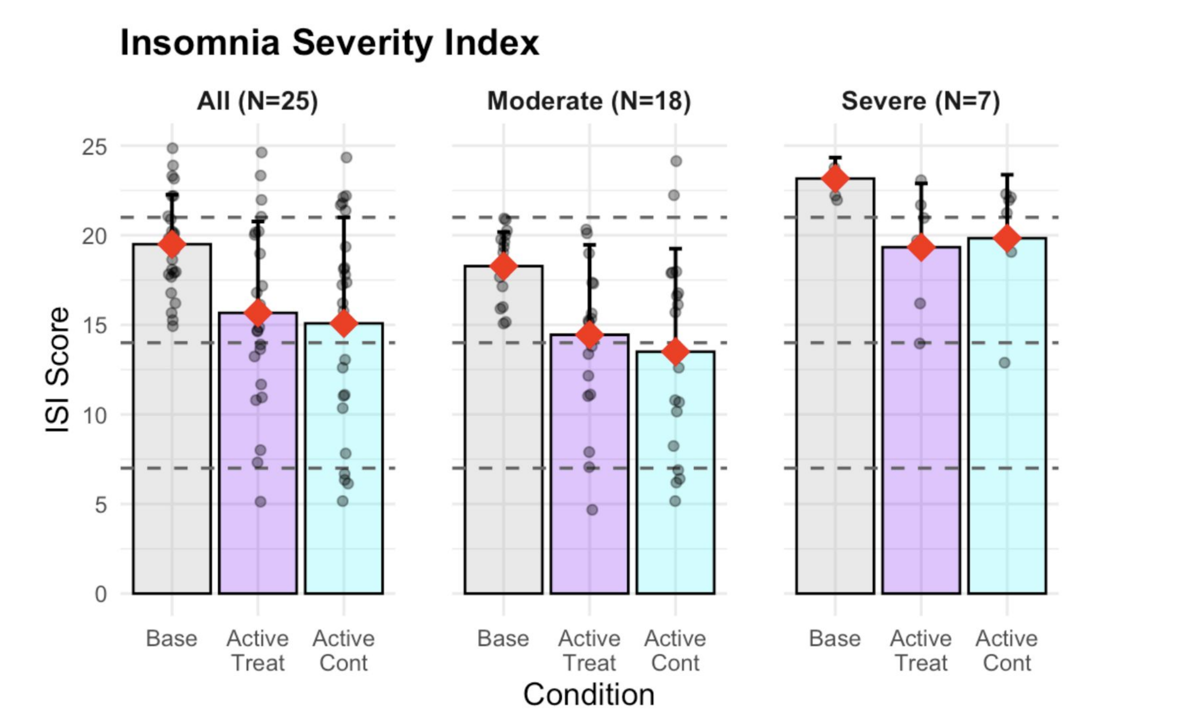

Insomnia Severity Index
All (N=25)
Moderate (N=18)
Severe (N=7)
ISI Score
25
20
15
10
5
0
Base
Active Treat
Active Cont
Condition

Figure 7. Mean +/- SD ISI aggregate score dropped from 20 +/- 3 at baseline to 16 +/- 6 in active control and 16 +/-5 in active treatment (i.e., right on the border of "subthreshold" insomnia levels).

Discussion

- This work is impactful where sleep interventions could enhance operational readiness
- Participants showed improved SOL and ISI while wearing the PeakSleep headset, regardless of stimulation frequency, compared to pre-treatment baseline
- Wearables are limited in their ability to accurately determine sleep start
- This study is limited by not having a true sham to control for the placebo effect

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References: [1] CH Good et al., "Sleep in the United States Military", *Neuropsychopharm. Reviews,* 2019. [2]Lie J., Tu K., Shen D., Wong B., "Pharmacological Treatment of Insomnia", *P&T,* 2015. [3] Simons S. et al., "A study on the effect of a wearable device using 0.75 Hz tES on sleep onset insomnia", *Front. Neurosci.* 2024.