Audio Neuromodulation to Treat Adult Insomnia: An Observational Study

Professor Jonathan M Sackier[(a)], Dr. Nigel D Guest[(b)], Ethan Dsouza[(c)]

Introduction

Insomnia affects 31% of adults,[1] incidence rates varying by population[2,3], profession[4], age, co-morbidities and other factors[5].

Characteristics vary[6], with major impacts on daily functioning, mental and physical health[7].

Standard therapies include sleep hygiene[8], CBT[9], and medication[10] but provide inconsistent benefits. Neuromodulation—including rTMS and tDCS—has yielded variable results.[11]

We designed a pilot study of an audio neuromodulation device to ascertain if sleep quality could be improved.

Pittsburgh Sleep Quality Index (PSQI)

A validated instrument assessing sleep quality over the past month.

Score range:

0 (good sleep) to 21 (severe sleep difficulties).
A score >5 typically indicates poor sleep quality.

Comprises 7 components:

1. Subjective sleep quality
2. Sleep latency
3. Sleep duration
4. Sleep efficiency
5. Sleep disturbances
6. Use of sleep medication
7. Daytime dysfunction

Methods

A non-prescription audio neuromodulator (**SleepEngine™**, Cambridge Sleep Sciences Ltd., 115B Innovation Drive, Oxfordshire, OX14 4RZ, UK) previously showed positive results in adults self-reporting insomnia.[12] (Figure 1)

The device emits rhythmic pulsed sounds hypothesised to promote better sleep, sequenced for 6 – 8 hours and masked by white soundscapes such as rain or ocean waves.

To assess its effect under monitored conditions, a prospective observational study was conducted after ethical review.

Figure 1: SleepEngine™ technology in the configuration used in this trial

One British NHS General Practitioner (NDG) recruited 20 participants (16 females, 4 males; mean age 51.19, range 22–67) reporting over six months of insomnia, unresponsive to other measures.

Scan the QR code to hear the SleepSound and Soundscapes

Exclusion criteria included BMI >35, sleep apnoea, systemic neurologic disease, chronic pain, depression, anti-psychotic medication use, recreational drug use, or any disease likely to impair sleep.

No new sleep-related interventions could be introduced during the study.

After a one-week baseline, participants used the device nightly with the sound profile in the same format for 12 weeks, followed by 8 weeks washout after device withdrawal.

The primary endpoint was the Pittsburgh Sleep Quality Index (PSQI) at weeks 0, 12, and 20. PSQI scores range from 0–21, with higher scores indicating worse sleep[13].

Secondary outcomes included sleep diaries, a patient-reported sleep score (1 = poor, 5 = excellent) and qualitative feedback.

Results

There were no adverse events, and no significant differences were seen between sex, age or other characteristics. Baseline mean PSQI was 11.15 (range 4–16) and declined significantly over time.

Between baseline and end of treatment, there was a statistically significant reduction to a mean of 7.21 (range 2 - 13, mean difference paired t-test; $p = 0.0000204$).

A further significant improvement was observed between end of treatment and end of washout to a mean of 5.84 (range 2 – 10, $p = 0.0371$), and the overall reduction from week 0 to 20 was highly significant ($p = 0.000000124$). (Figure 2)

From baseline to week 16, Wilcoxon signed-rank test revealed a statistically significant reduction in time to fall asleep ($p = 0.00053$) from 0.96 (0.23 – 3.5) to 0.58 (0.1 – 1.39) hours.

Nighttime awakenings showed a non-significant trend toward reduction during the same period from median 2.07 (range 0.57 – 6.43) vs. 1.72 (0 – 6.57) respectively; $p = 0.056$.

Participants experienced a significant reduction in time spent awake during the 12-week study period (paired t-test) decreasing from 1.18 hours (range 0.11 – 4.14) to 0.33 hours (0.01 – 2.14), respectively; $p = 0.00039$ (Figure 3)

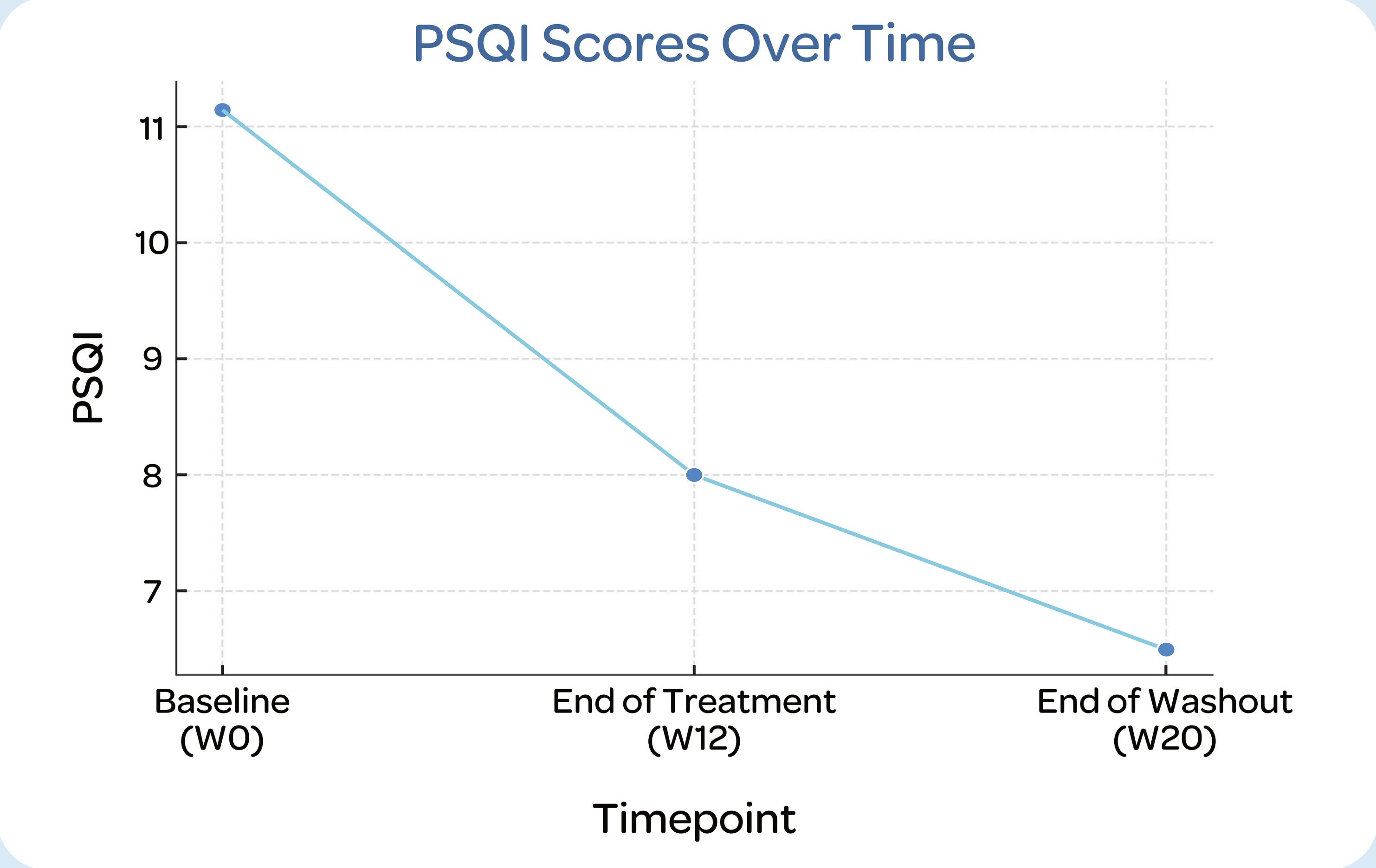

Figure 2: PSQI decrease over time

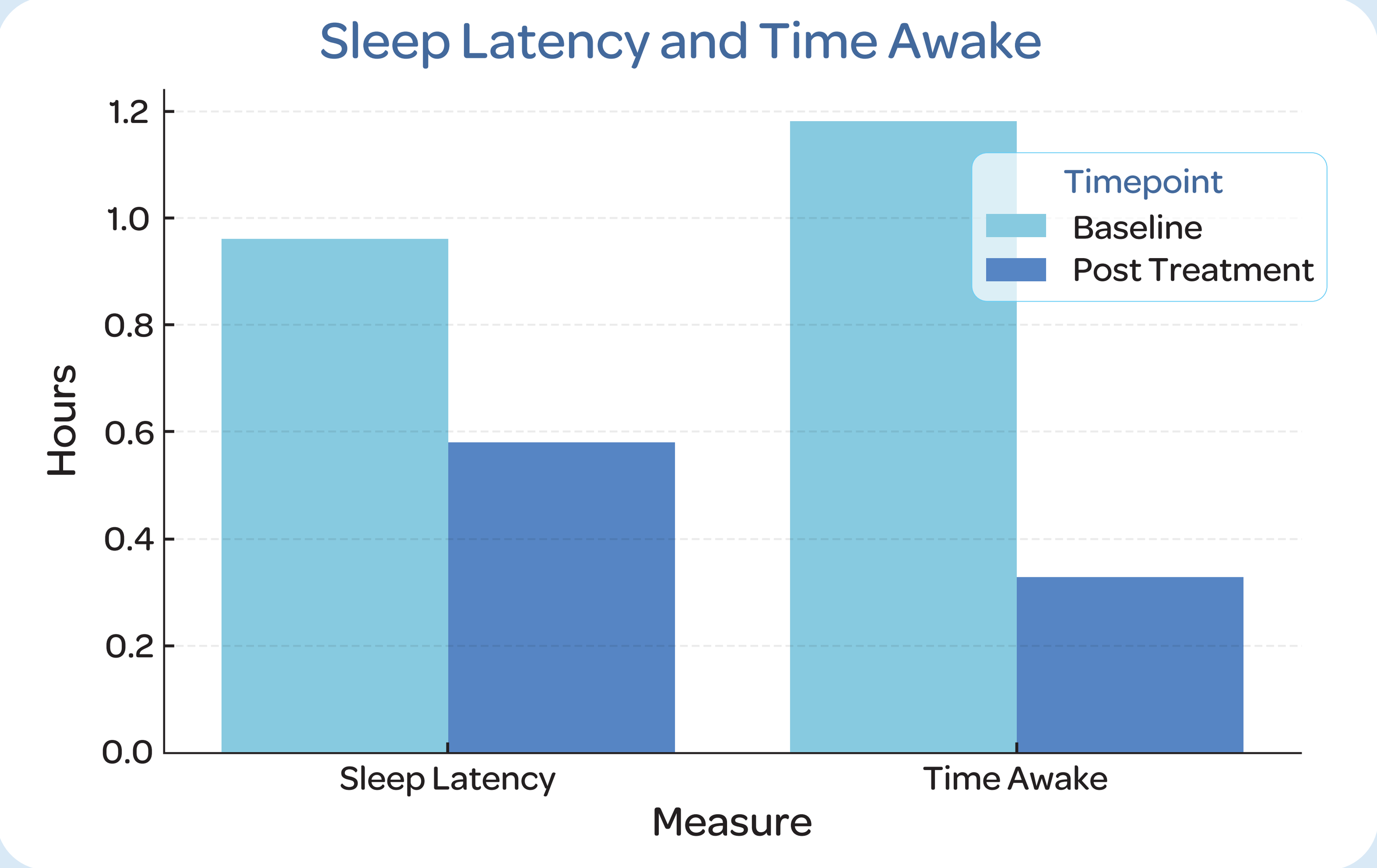

Figure 3: Sleep latency and time awake changes over time

PSQI Scores

Timepoint	Mean PSQI	p-value
Baseline (Week 0)	11.5	-
End of Treatment (Week 12)	7.24	p = 0.0000204
End of Washout (Week 20)	5.84	p = 0.0371
Total Change	**-5.31**	**p = 0.000000124**

Patient-reported qualitative sleep scores improved significantly from baseline to end of week 12 from median 2.64 (1.0 – 3.85) to 3.86 (2.86 – 5.0) respectively; $p = 0.00016$, (paired t-test).

Sleep Diary Outcomes

- **Sleep Latency:** 0.96 → 0.58 hrs ($p = 0.00053$)
- **Time Awake:** 1.18 → 0.33 hrs ($p = 0.00039$)
- **Awakenings:** 2.07 → 1.72 ($p = 0.056$, trend)
- **Self-Rated Sleep Score:** 2.64 → 3.86 ($p = 0.00016$)

Conclusions

Twelve weeks use of the **SleepEngine™** audio neuromodulator significantly improved subjective and objective sleep measures, sustained after eight weeks washout. No safety concerns arose and users were highly satisfied and keen to continue to use the device post-study.

Comments cited ease of use, comfort and noticeable improvements in sleep quality and alertness. The technology has now been embedded into a pillow such that a bed partner is not impacted. (Figure 4)

Larger randomised studies in a variety of sleep-disturbed states are contemplated with integration into primary care protocols.

Figure 4: SleepEngine™ inside a pillow

For more information

Email: jonathanav8r@gmail.com

Acknowledgement & Conflicts

This study was supported by a grant from **Cambridge Sleep Sciences** and **Medilink Midlands.**

NDG received support to complete the trial.

JMS purchased stock in the company and has received compensation for trial design, attending conference and other activities.

Scan to download poster

References

1. Aviva. Aviva Health Check UK report: Autumn 2016. Based on a survey of 2,235 nationally representative UK adults. London: Aviva; 2017. Available from: Aviva_Wellbeing_Report_FINAL_SECURED_Dec17.pdf
2. Benjafield A, Kuniyoshi FS, Malhotra A, Maurer L, Morin C, Martin J, et al. Americas prevalence of insomnia disorder in adults: Estimation using currently available data. Sleep. 2024 May;47(Suppl 1):A173–4. doi:10.1093/sleep/zsae067.0404
3. Chalet FX, Albanese E, Egea Santaolalla C, Ellis JG, Ferini-Strambi L, Heidbreder A, et al. Epidemiology and burden of chronic insomnia disorder in Europe: An analysis of the 2020 National Health and Wellness Survey. J Med Econ. 2024;27(1):1309–20. doi:10.1080/13696998.2024.2407631
4. Hsu NM, Stahlman SL, Fan MT, Wells NY. Incidence and management of chronic insomnia, active component, U.S. Armed Forces, 2012 to 2021. Med Surv Monthly Rep (MSMR). 2023 Jan 1;30(1). Available from: https://staging-mobile.health.mil/sitecore/content/MHSHome/News/Articles/2023/01/01/Chronic-Insomnia-MSMR-Vol30
5. Lemola S, Richter D. Insomnia symptoms in adulthood: Prevalence and incidence over 25 years. Sleep Med. 2023;108:1–8.
6. Porcheret K, Hopstock LA, Nilsen KB. Prevalence of insomnia in a general adult population cohort using different diagnostic criteria: The seventh survey of the Tromsø study 2015–2016. Sleep Med. 2024 Jul;119:289–95. doi:10.1016/j.sleep.2024.05.002. Epub 2024 May 3. PMID:38718598
7. Ishak WW, Bagot K, Thomas S, Magakian N, Bedwani D, Larson D, et al. Quality of life in patients suffering from insomnia. Innov Clin Neurosci. 2012 Oct;9(10):13–26. PMCID: PMC3508958. PMID:23198273
8. Irish LA, Kline CE, Gunn HE, Buysse DJ, Hall MH. The role of sleep hygiene in promoting public health: A review of empirical evidence. Sleep Med Rev. 2015 Aug;22:23–36. doi:10.1016/j.smrv.2014.10.001
9. Trauer JM, Qian MY, Doyle JS, Rajaratnam SMW, Cunnington D. Cognitive behavioral therapy for chronic insomnia: A systematic review and meta-analysis. Ann Intern Med. 2015 Aug 4;163(3):191–204. doi:10.7326/M14-2841
10. Sateia MJ, Buysse DJ, Krystal AD, Neubauer DN, Heald JL. Clinical practice guideline for the pharmacologic treatment of chronic insomnia in adults: An American Academy of Sleep Medicine clinical practice guideline. J Clin Sleep Med. 2017 Feb 15;13(2):307–49. doi:10.5664/jcsm.6470
11. Krone LB, Fehér KD, Rivero T, Omlin X. Brain stimulation techniques as novel treatment options for insomnia: A systematic review. J Sleep Res. 2023 May 18;32(6):e13927. doi:10.1111/jsr.13927. PMCID: PMC10909439. PMID: 37202368
12. Cambridge Sleep Sciences Ltd. Data on file.
13. Buysse DJ, Reynolds CF, Monk TH, Berman SR, Kupfer DJ. The Pittsburgh Sleep Quality Index: A new instrument for psychiatric practice and research. Psychiatry Res. 1989 May;28(2):193–213. doi:10.1016/0165-1781(89)90047-4. PMID:2748771

(a) Private Practice, London, UK; (b) Timperley NHS General Practice, UK; (c) City of London School, UK