Journal of Affective Disorders 396 (2026) 120859

Contents lists available at ScienceDirect

Journal of Affective Disorders

journal homepage: www.elsevier.com/locate/jad

Research paper

Real-world evaluation of at-home cranial electrotherapy stimulation (CES) for the management of sleep, anxiety, depression, stress, quality of life, and self-efficacy

Ksenija Maravic da Silva [a,*], Clementine Broom [b], Harvey Daly [b], Chris Griffiths [c], Andy Willis [d], Jovana Bjekic [e]

[a] Centre for Healthcare and Communities, Coventry University, United Kingdom
[b] School of Psychological, Social, and Behavioural Sciences, Coventry University, United Kingdom
[c] Northamptonshire Healthcare NHS Foundation Trust, United Kingdom
[d] Lived Experience Expert, Patient and Public Engagement and Involvement, United Kingdom
[e] Institute for Medical Research, Human Neuroscience Group, Centre for Neuroscience and Neuromodulation, University of Belgrade, Serbia

ARTICLE INFO

Keywords:
Non-invasive Brain Stimulation
Cranial Electrotherapy Stimulation
Sleep
Mental Health
Wellbeing
Naturalistic Evaluation
Community

ABSTRACT

Background: Direct-to-consumer neuromodulation technologies are transforming how sleep and mood disorders are self-managed outside clinical settings. Cranial electrotherapy stimulation (CES) is a low-intensity, portable intervention with growing accessibility but limited evidence in non-clinical populations and real-life contexts. This naturalistic cohort study investigated the effects of CES on sleep, anxiety, depression, stress, quality of life, and self-efficacy in a real-world, community-based setting.

Methods: Sixty adults agreed to use the Alpha-Stim AID CES device daily for 21 days (40–60 min/day). Validated self-report measures were completed at baseline, day 21 (end-of-treatment), and day 42 (follow-up). A subsample ($n = 27$) wore actigraphy devices to monitor objective sleep changes.

Results: By day 21, sleep quality significantly improved, with 48 % achieving insomnia remission and 50 % a reduction in daytime sleepiness. Actigraphy data corroborated subjective sleep improvements. Anxiety and depression remission rates were 72.3 % and 71.2 %, with improvements maintained three weeks post-intervention. Stress levels decreased, while self-efficacy, wellbeing, and quality of life improved, with moderate to large effect sizes. CES was rated as safe, acceptable, and easy to use: 48 % of participants preferred it over psychotherapy or medication.

Discussion: CES is a safe, self-administered intervention that benefits sleep, mental health, and quality of life. This study presents the first actigraphy evidence of CES effects on sleep in a diverse, non-clinical population. Findings support a novel framework for accessible, non-pharmacological interventions for sleep and wellbeing with sustained impact at three-week follow-up. Results have significant implications for sleep quality and mental health, especially for populations underserved by traditional healthcare.

1. Introduction

Direct-to-consumer neuromodulation technologies (i.e. sold directly to consumers) are reshaping how various conditions are managed and cognition is enhanced beyond traditional clinical environments. These portable non-invasive brain stimulation (NIBS) interventions enable individuals to self-administer brain stimulation without healthcare service prescription, reflecting a broader shift toward safe, personalised, scalable, and cost-effective mental healthcare (Wexler, 2015, 2019). Among these, cranial electrotherapy stimulation (CES) has emerged as a promising self-management tool for insomnia, anxiety, depression, and stress, conditions with significant public health burden and unmet treatment needs.

These disorders are highly prevalent and often co-occur, impairing functioning, reducing quality of life (QoL), and contributing to long-term physical and mental health consequences (Kessler et al., 2012; Palagini et al., 2022; Wittchen et al., 2011). Despite the availability of pharmacological and psychotherapeutic treatments, many individuals

* Corresponding author.
E-mail address: k.dasilva@coventry.ac.uk (K.M. da Silva).

https://doi.org/10.1016/j.jad.2025.120859
Received 23 July 2025; Received in revised form 3 October 2025; Accepted 5 December 2025
Available online 7 December 2025

are unable or unwilling to access treatment due to side effects, cost, limited availability, psychological barriers, and high non-response rates (Andrade et al., 2014; Coêlho et al., 2021; Griffiths et al., 2023; da Silva et al., 2025). This has led to a growing crisis in untreated mental health conditions and highlights an urgent need for effective, safe, and scalable alternatives that can be deployed in real-world settings (World Health Organization, 2024).

NIBS techniques, including CES, are increasingly viewed as viable adjuncts or alternatives to pharmacological and psychotherapeutic treatments, offering favourable safety profiles and minimal contraindications. CES involves the application of low-intensity pulsed electrical current via ear-clip electrodes and is associated with neurophysiological effects linked to relaxation and mood regulation (Kirsch and Nichols, 2013; Nardone et al., 2014). Although clinical studies suggest CES is well tolerated with few side effects and may reduce symptoms of anxiety and depression (Barclay and Barclay, 2014a; Ching et al., 2022a; Griffiths et al., 2023; Shekelle et al., 2018), research has largely focused on treatment-resistant or clinically diagnosed populations under controlled conditions. As such, little is known about its wider utility among the general public or its potential role in promoting mental health strategies.

The Alpha-Stim AID (Anxiety Insomnia Depression) is a CE-marked, direct-to-consumer CES device designed for use in the treatment of anxiety, depression, and insomnia. It is portable, user-directed, and marketed for self-management. Despite its increasing use, evidence regarding its real-world effectiveness, particularly outside clinical contexts and among diverse, underserved populations, remains limited. A recent randomised controlled trial (RCT) reported clinically significant depression and anxiety symptom reductions but found no superiority over sham treatment (Morriss et al., 2023). The National Institute for Health and Care Excellence (National Institute for Health and Care Excellence, 2021) has called for further research into CES, with specific attention to long-term outcomes, integration into care pathways, and its effectiveness in community settings.

The aim of this open-label cohort study was to address this evidence gap by evaluating the real-world effects of CES in a non-clinical, ethnically diverse community sample. The primary objective was to assess changes in symptoms of anxiety, depression, perceived stress, sleep quality, QoL and self-efficacy over a 21-day period of self-administered CES treatment. A secondary objective was to enhance ecological validity by combining validated self-report measures with continuous, objective sleep tracking, making this the first known study to integrate wearable sleep data with CES use in a naturalistic setting. Furthermore, this study integrates data on patient-reported outcomes, acceptability, and tolerability. This open-label approach offers practical and ecological advantages but inherently limits the ability to draw causal conclusions. By investigating Alpha-Stim AID as a self-managed intervention outside formal care pathways, this study contributes to the growing body of evidence on NIBS as a safe, scalable intervention with the potential to support early mental health intervention and sleep promotion.

2. Methods

2.1. Design

This study used a within-participant, prospective, open-label cohort design to evaluate the effects of CES in a naturalistic, community setting. No control or placebo group was included, as the study prioritised ecological validity and real-life effects over placebo comparison (Paulus et al., 2014). Participants self-administered CES daily over 21 days, with outcome measures collected at baseline, at the end of treatment (day 21), and at 21-day follow-up (day 42). A pragmatic compromise of three weeks intervention length was chosen to balance participant feasibility with sufficient time for emerging clinical effects, consistent with evidence that benefits often appear after two weeks or at least 10 sessions (Brunoni et al., 2016; Meron et al., 2015; Mutz et al., 2018), and that CES shows its greatest improvements early in treatment (Morriss et al., 2019). Similarly, follow-up was limited to three weeks post-intervention to maximise data completeness and capture the relatively immediate effects of Alpha-Stim.

2.2. Participants

Participants were recruited from the general public through community outreach and social media platforms (including Coventry University and local charities). The inclusion criteria required participants to be adults (aged 18+), residing in the UK, and able to provide informed consent. Exclusion criteria included current or recent treatment for anxiety or depression, pregnancy, presence of a pacemaker, history of seizures, or impaired capacity to consent.

A power analysis was conducted using G*Power software (Faul et al., 2007) indicated a required minimum sample size of 27 participants to detect a medium effect size (power = 0.80, $\alpha = 0.05$). To account for possible drop-out, 60 participants were recruited. Of these, 52 completed the baseline assessment and 47 completed the Day 21 assessment (a 9.6 % attrition rate). At follow-up (Day 42), 15 of the 27 participants who consented to recontact completed the final questionnaire battery (44 % attrition rate).

A subsample of 30 participants consented to wear actigraphy devices to monitor objective sleep outcomes. Of these, 25 completed both baseline and Day 21 assessments: 18 returned devices with $\geq$90 % analysable data coverage across the treatment period.

2.3. Procedure

Participants received a CE-marked Alpha-Stim-AID (Electromedical Products International Inc.) class IIa medical device and were instructed to use it unsupervised at home (0.5 Hz, 100–500 μA, 50 % duty cycle; biphasic rectangular wave) daily over 21 days for a minimum of 40 and maximum 60 min per day, as per manufacturer's instructions. It is widely used in clinical and non-clinical settings and is approved for over-the-counter use in several countries. Participants received the devices free of charge and returned them at the end of the study. Researchers had no contact with participants during the 21-day treatment phase, except to collect the device upon completion and provide a debrief letter. Participants completed study measures online at baseline, day 21, and day 42. Ethical approval was granted by Coventry University Research Ethics Committee, and all procedures adhered to the British Psychological Society's Code of Human Research Ethics. All electronic data were anonymised and stored on secure, encrypted servers with restricted access. Data handling procedures complied fully with the UK General Data Protection Regulation (GDPR) and institutional ethical guidelines.

2.4. Patient and Public Involvement (PPI)

Participant recruitment materials and study protocol were reviewed by individuals with lived experience of depression and sleep disturbances. Their feedback informed the accessibility, acceptability, and ecological alignment of study procedures. AW also reviewed the final manuscript.

2.5. Measures

Participants completed a battery of validated self-report measures at baseline, day 21, and day 42:

2.6. Sleep-related measures

Pittsburgh Sleep Quality Index (PSQI) (Buysse et al., 1989) - 19-item self-report measure of subjective sleep quality and disturbances over the past month; *Insomnia Severity Index (ISI)* (Bastien, 2001) - 7-item

brief screening tool for insomnia; *Epworth Sleepiness Scale (ESS)* (Johns, 1991) - 8-item self-report measure of general daytime sleepiness, commonly used to identify excessive sleepiness.

Objective sleep data were collected using wrist-worn actigraphy devices (Condor ActTrust2, Condor Instruments) worn continuously during the 21-day treatment period.

2.7. Mental health and wellbeing

Generalised Anxiety Disorder scale (GAD-7) (Spitzer et al., 2006) - a 7-item self-administered screening tool for assessing the severity of generalised anxiety symptoms; *Patient Health Questionnaire (PHQ-9)* for depression (Kroenke and Spitzer, 2002) - 9-item self-report scale measuring the severity of depressive symptoms; *Perceived Stress Scale (PSS)* (Cohen, 1988) - 10-item instrument assessing perceived stress in the past month; *General Self-Efficacy Scale (GSE)* (Schwarzer and Jerusalem, 1995) - includes 10 self-report items evaluating confidence in one's ability to cope with daily challenges; *EQ-5D-5L* (Herdman et al., 2011) – 5-item standardised instrument to measure health-related quality of life; *Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS)* (Tennant et al., 2007) - 14-item scale assessing positive mental health and wellbeing.

2.8. Safety, adherence, and acceptability

Participants were asked a range of questions about the times and compliance of using the device, reasons for deviations, safety and ease of use, noticeable feelings during and after the intervention, and benefits and limitations of the device.

2.9. Data analysis and statistical methods

Data were analysed using IBM SPSS v28. Descriptive statistics were computed for all variables. Assumptions of normality, homogeneity of variance, and sphericity were checked (Mauchly's test; Greenhouse–Geisser correction applied where appropriate).

Primary outcomes (anxiety, depression, stress, sleep quality, QoL, self-efficacy) were analysed using repeated measures ANOVA. Pairwise Bonferroni-adjusted post-hoc tests were used for significant effects; effect sizes reported as η^2_p. Sleep outcomes from actigraphy were analysed using repeated measures ANOVA comparing baseline to Day 21. Pearson's correlation analyses were used to explore relationships between changes in mental health scores and sleep metrics.

All tests were two-tailed with $\alpha = 0.05$. Missing data were managed via pairwise deletion. Objective sleep data preprocessing included quality checks and aggregation for nightly metrics.

3. Results

3.1. Participant characteristics

Of 60 enrolled participants, 52 completed baseline assessments (mean age 33.1 ± 12.5 years; range 18–63; 73 % female). Baseline scores indicated significant sleep disturbances (PSQI), and moderate-to-severe anxiety (GAD-7) and depression (PHQ-9) symptoms (Table 1).

Table 1
Descriptive statistics (M, SD) and repeated measures t-test results for the effects 21 days after CES treatment (n = 47).

	Baseline	Day 21	t^+	p	d
PSQI	9.77 (4.38)	5.64 (2.77)	7.615	<0.001	1.11
GAD-7	11.09 (5.44)	5.36 (4.59)	8.758	<0.001	1.28
PHQ-9	13.47 (6.82)	5.53 (4.16)	7.891	<0.001	1.15
WEMWBS	37.72 (7.89)	46.92 (9.71)	−5.138	<0.001	−1.03
PSS	22.86 (6.27)	14.82 (6.90)	7.711	<0.001	1.64
GSE	27.55 (4.14)	31.64 (2.66)	−4.193	<0.001	−0.89

$^+$ Assumptions met.

3.2. Sleep outcomes

PSQI scores improved significantly from baseline to day 21, with the proportion of participants reporting clinically significant sleep disturbances declining from 82.7 % to 53.2 %.

In the subset wearing actigraphy devices ($n = 25$), 18 provided valid data; all had severe baseline sleep issues, with 12 participants (48 %) reaching remission (ISI < 7) by day 21 (Table 2). Excessive daytime sleepiness (ESS > 7) decreased from 80 % to 40 %. Sleep onset latency and sleep efficiency (PSQI) improved significantly, corroborated by actigraphy, though no significant correlations between subjective and objective measures were found except for test-retest reliability of actigraphy sleep efficiency ($r = 0.632$, $p < .001$).

3.3. Mental health and wellbeing

GAD-7 scores declined significantly at day 21 ($F(2,28) = 24.22$, $p < .001$, $\eta^2 = 0.634$), with remission (≤7 for GAD-7) in forty participants (72.3 %), reliable improvement (a change index of ≥4 points for GAD-7) in 61.7 %, and recovery (both remission and recovery are recorded) in 46.8 %. Two participants reported a deterioration in GAD-7 scores by 1 or 2 points.

These effects persisted at day 42, $F(2,28) = 24.22$, $p < .001$, partial $\eta^2 = 0.634$. Post-hoc pairwise comparisons showed a statistically significant decrease between baseline and days 21 and 42, but not between days 21 and 42. Remission at day 42 was 73.3 %, reliable improvement 66.7 %, and recovery 60.0 %. All but two participants had no or mild symptoms of anxiety by day 42.

Similarly, PHQ-9 scores decreased significantly ($F(2,28) = 16.42$, $p < .001$, $\eta^2 = 0.540$), with 78.7 % achieving remission (≤9 for PHQ-9) at day 21 and 93.3 % at day 42. Reliable improvement (a change index of ≥6 points for PHQ-9) was 63.8 % at the end of treatment. Recovery was recorded for 22 participants (46.8 %). Two participants reported a deterioration in PHQ-9 scores by 1 or 2 points. Fifteen participants reported sustained, below threshold levels for depression three weeks after finishing the treatment, $F(2,28) = 16.42$, $p < .001$, partial $\eta^2 = 0.540$. Post-hoc pairwise comparisons showed a statistically significant decrease between baseline and days 21 and 42 but not between days 21 and 42. Remission at day 42 was 93.3 %, reliable improvement 53.3 %, and recovery 53.3 %. Only one participant reported clinically significant symptoms of depression by day 42.

Suicidal ideation (PHQ-9 item 9) decreased from 19.2 % at baseline to 8.5 % reporting thoughts at any frequency by day 21 ($p = .058$).

WEMWBS scores increased significantly from low baseline to average by day 21. Perceived stress (PSS) decreased substantially, with low-stress individuals rising from 7.4 % at baseline to 47.6 % on day 21; this was sustained 3-weeks post-intervention, $F(2,28) = 21.03$, $p < .001$, partial $\eta^2 = 0.600$). Self-efficacy (GSE) also improved significantly and remained stable post-intervention $F(2,28) = 7.24$, $p < .001$, partial $\eta^2 = 0.341$) (Table 1).

3.4. Health-related QoL

EQ-5D-5L data (Table 3) revealed significant improvements in 'usual activities' and 'anxiety/depression' dimensions, alongside increased overall health index and VAS scores (medium effect sizes), indicating enhanced QoL after CES treatment.

3.5. Safety, adherence, and acceptability

Seventy-nine percent of participants used the device at least five times weekly. Reasons for non-use included forgetfulness or absence from home. Those who used it less than 3 days a week were excluded from the study. The most common reasons were that they were worried

Table 2
Descriptive statistics (M, SD) and repeated measures t-test results for the sleep effects 21 days after CES treatment.

		Baseline	Day 21	*n*	*z*[+]	*p*	*d*
Scales	ISI	14.56 (3.62)	9.12 (5.46)	25	−3.99	<0.001*	1.69
	ESS	10.32 (3.77)	7.72 (5.36)	25	−2.26	0.024*	0.49
	PSQI sleep onset (mins)	52.7 (61.47)	29.08 (20.10)	25	−1.96	0.049*	0.44
	PSQI sleep efficacy (mins)	74.93 (17.89)	84.10 (16.83)	25	−2.00	0.046*	−0.42
Sleep tracker	Total bed time (mins)	469.44 (46.77)	459.72 (71.16)	18	−0.762	0.446	
	Total sleep time (mins)	391.94 (51.46)	397.11 (51.28)	18	−0.218	0.828	
	Sleep onset (mins)	13.65 (15.14)	11.40 (10.21)	18	−0.109	0.913	
	Sleep efficacy (%)	83.34 (8.55)	86.84 (0.05)	18	−2.199	0.028*	−0.53
	WASO	21.69 (6.86)	22.25 (9.26)	18	−0.568	0.570	
	IV60	0.84 (0.24)	0.84 (0.30)	18	−0.196	0.845	
	IS60	0.55 (0.18)	0.54 (0.17)	18	−0.588	0.557	
	CFI	0.67 (0.12)	0.66 (0.13)	18	−0.283	0.777	

[+] Some assumptions were not met; while no difference was observed between Wilcoxon Signed Ranks Test and paired samples t-test, Wilcoxon z is reported for rigour and consistency.

Table 3
Means and standard deviations within each dimension across time with corresponding mean variation, significance, and effect size.

EQ-5D-5L Dimension	Baseline	Day 21	*Z*	*p*	*d*
	M (SD)	*M (SD)*			
Mobility	1.46 (0.83)	1.33 (0.82)	−1.732	0.083	
Self-care	1.38 (0.58)	1.21 (0.51)	−1.414	0.157	
Usual activity	2.12 (1.03)	1.58 (0.72)	−2.264	0.024*	0.53
Pain/discomfort	2.12 (0.95)	2.04 (0.91)	−0.632	0.527	
Anxiety/ depression	2.79 (0.83)	2.21 (0.88)	−2.424	0.015*	0.55
Health index score	0.62 (0.20)	0.75 (0.18)	−2.289	0.022*	−0.548
EQ-VAS score	51.83 (15.18)	64.12 (18.62)	-2.580	0.010*	−0.592

* Significant at $p < .05$ level.

about their heart condition ($n = 1$), the device was causing them a headache ($n = 2$), or were anxious about the device (n = 2).

Only 36 % used the device always at the same time, although 92 % primarily used it in the afternoon or evening, whilst in bed, watching TV, playing a game or listening to the radio. All participants found the devices easy or very easy to use. Simple design interface, straightforward instructions, few buttons, small portable size, and pre-set timer were some of the advantages mentioned. One participant thought the buttons could be made easier to press; an ear clip of another one broke, but they continued using it with care.

The safety of the devices was evident from participants' responses. When asked about how they felt while using the device, the most common responses were relaxed, light-headed, dizzy, sleepy, optimistic, and amazing. One participant reported no changes, and another felt tired and uncomfortable. Surprisingly, 38 % reported no changes in their mood even if they noticed other changes, such as falling asleep faster and being more mindful of their nighttime routine (e.g. no phone around). Only two participants expressed unwillingness to reuse the device, while all would recommend it. When asked about what they liked about the devices, the most common responses were ease of use, immediate results, simplicity, size, and no side effects. 100 % of participants would recommend the device.

Notably, 48 % preferred Alpha-Stim over medication or psychotherapy; 36 % preferred psychotherapy and 16 % preferred medication.

4. Discussion

This open-label cohort study provides support for the feasibility, acceptability, and effectiveness of the Alpha-Stim AID CES device when self-administered at home by individuals from the general population experiencing anxiety, depression, stress, and sleep disturbances. It also provides preliminary evidence on the effectiveness, although the absence of a control group limits causal conclusions. Over a 21-day treatment period, participants demonstrated statistically and clinically significant improvements across multiple domains—including affective symptoms, sleep quality, wellbeing, and self-efficacy—with effects sustained at three-week follow-up.

The results align with previous evidence that CES and other non-invasive brain stimulation interventions can improve sleep quality, promote remission of insomnia, anxiety, and depression, reduce stress, and enhance self-efficacy, wellbeing, and overall quality of life (Barclay and Barclay, 2014b; Ching et al., 2022b; Griffiths et al., 2025; Khan et al., 2023; da Silva et al., 2025). Specifically, Chu et al. (Chu et al., 2024) demonstrated that a 6-week CES intervention using the Alpha-Stim AID device significantly reduced anxiety symptoms in elderly patients with generalised anxiety disorder. Our study extends these findings by providing evidence of the Alpha-Stim AID device's efficacy in improving sleep quality, promoting insomnia remission, reducing daytime sleepiness, decreasing stress levels, improving self-efficacy, and enhancing mood and quality of life in a broader population. Moreover, the findings support research in health service settings (Shekelle et al., 2018) and add to a growing body of evidence supporting the potential of CES as a scalable mental health intervention.

Notably, this study observed greater reliable improvement in GAD-7 scores than reported by Griffiths et al. (2023), suggesting Alpha-Stim AID may be particularly well suited for individuals with moderate symptoms who do not yet meet diagnostic thresholds or who are not receiving clinical treatment. Improvements in PHQ-9 scores were observed as early as day 10, indicating a faster onset of effect than typically expected (Morriss and Price, 2020). Furthermore, effects were sustained across all five scales, including general self-efficacy, which is considered a stable, trait-like construct (Schwarzer and Jerusalem, 1995), suggesting at least immediate to short-term benefits from CES use in this population. Future research should consider longer and continuous follow-up periods to assess relapse rates, the durability of treatment effects, and long-term efficacy (e.g. Yang et al., 2025). However, as indicated by the 44 % attrition rate observed at follow-up in this study, such approaches may be impractical, introduce bias, and reduce generalisability.

While the PSQI scale indicated improvement, particularly in sleep latency (dimension 2), it lacked the granularity to reveal the specific sleep pattern changes associated with CES-related mental health improvement. This limitation highlights the need for future research to continue incorporating objective sleep monitoring, such as actigraphy or wearable sleep trackers, to better understand the mechanisms by which CES influences both sleep architecture and mental health recovery. To our knowledge, this is the first study to enhance ecological validity through actigraphy; nevertheless, the modest sample size limits the generalisability of the findings, and larger cohorts will be required in future research to draw more definitive conclusions.

More broadly, our findings contribute to the evidence base

supporting wearable, home-based neuromodulation technologies as viable, non-invasive, and user-led mental health interventions. The Alpha-Stim AID, as an over-the-counter CES device, aligns with international movements toward decentralised treatment and user empowerment, mirroring trends in remotely supervised transcranial direct current stimulation (RS-tDCS). RS-tDCS has been shown to be safe and effective across several trials using structured protocols, remote monitoring, staff training, and user support (Charvet et al., 2018; Pilloni et al., 2022; Richardson et al., 2023). Moreover, studies of direct-to-consumer transcranial electric stimulation (tES) devices found that users generally adhered to the current levels (1–2 mA) and typical length of stimulation session (20 min), even if they are not externally supervised or controlled. Even among direct-to-consumer users of tES devices, evidence suggests typical parameters are generally adhered to (Antal et al., 2022; Jwa, 2015; Wexler, 2016; Wexler and Reiner, 2019), though efficacy varies widely.

Several direct-to-consumer neuromodulation devices marketed for performance enhancement, wellness or mental health purposes (e.g., Halo Sport, Thync, FeelZing) have faced criticism due to inconsistent effects or limited regulatory oversight and have since been discontinued (Garner, 2021; Wexler and Reiner, 2019). However, new or rebranded neuromodulation products have emerged (e.g. Thync device and subsequent Feelzing "Energy Patch"), and many of them are at least partially built on a direct-to-consumer sales model (e.g. Flow Neuroscience).

Consequently, there is a critical distinction to be made between healthcare-prescribed, supervised neuromodulation and self-initiated use of direct-to-consumer devices designed for independent use without the involvement of a healthcare provider. Whereas the former is embedded in clinical systems with oversight, personalised protocols, and patient monitoring, the latter often lacks mechanisms for safety, appropriateness, or efficacy assurance. The Alpha-Stim AID device falls in the latter category, as it does not include remote supervision by design. While it is registered for anxiety, depression, and insomnia, the absence of integrated medical oversight places the responsibility for appropriate use and monitoring largely on the user.

Despite this, high adherence and low attrition during the intervention stage in this study underscore the real-world practicality of Alpha-Stim AID. Participants found it easy to use, incorporated it into daily routines with minimal burden, and reported few adverse effects. Nevertheless, the absence of clinician guidance or real-time monitoring amplifies the importance of user education, appropriate labelling, and regulatory safeguards, especially as consumer demand for brain stimulation tools continues to grow (Wexler, 2019). Only data from participants who used the device at least four times per week were included in the analysis (21 % excluded). However, partial compliance, which may limit real-world feasibility, could be treated as a covariate in future studies to assess whether intervention effectiveness varies continuously with adherence or whether a minimum usage threshold is necessary to achieve significant improvements in mood and sleep (da Silva et al., 2025).

Furthermore, participants were recruited through community outreach and social media, which may have introduced self-selection bias. Voluntary participants are often more motivated, healthier at baseline, and more likely to adhere to treatments (de Souto Barreto et al., 2013; Liberman et al., 2011), potentially leading to inflated adherence rates compared with the general population. This limitation is inherent in studying non-clinical samples, and findings should therefore be interpreted with caution regarding generalisability to less motivated populations.

From a health equity perspective, wearable neuromodulation may fill important gaps. CES can be particularly valuable for those with barriers and attitudes to conventional treatments, such as stigma, waiting lists, cost, or contraindications related to pregnancy, neurodivergence, or comorbidities. Importantly, even individuals below diagnostic thresholds showed reliable symptom improvement, suggesting potential applications in prevention, early intervention, or support during transient mental distress. These characteristics make CES a promising adjunct or alternative during times of restricted service access or unmet need.

The ethical and regulatory implications of these findings also warrant consideration. While direct-to-consumer devices like Alpha-Stim AID increase accessibility, they risk fragmenting care or bypassing professional diagnosis if not integrated thoughtfully into broader treatment pathways. Moreover, the efficacy of CES remains underresearched in certain populations and symptom domains, underscoring the need for ongoing evaluation and transparent reporting through post-market surveillance and well-designed trials.

From a healthcare systems perspective, CES and other home-based neuromodulation tools could relieve pressure on overstretched services by providing low-risk, low-cost symptom relief. However, the effectiveness of Alpha-Stim CES remains uncertain. Although this study offers preliminary evidence, the lack of a control group prevents causal inference. This limitation is especially relevant in NIBS research, where placebo responses are often substantial, particularly in affective disorders (Razza et al., 2018), raising concerns about reduced statistical power. Thus, the observed effects may, at least partly, reflect expectancy or general placebo responses. Alternatives to placebo-controlled designs have been discussed (Burke et al., 2019).

Large RCTs remain the gold standard for evaluating effectiveness, but in NIBS, especially home-based applications, they face significant logistical, methodological, and ethical challenges in addressing placebo effects (Mollica et al., 2023). Here, we propose that the efficacy paradox (Walach, 2001), as well as the overall effect, nocebo responses and accelerated protocols, be investigated through platform trials spanning multiple NIBS interventions (Gold et al., 2025), alongside mechanistic studies. Such designs could include RCTs with active comparators, RCT designs with active comparators and placebo arms, or real-world data for comparative analyses between different active interventions. Platform trials, however, also have limitations that must be weighed against these advantages. Further, gender-specific effects should be examined in light of observed sexual dimorphism in anxiety responses, and cognitive outcomes, such as participants reporting "clarity of thought" and "lightness of being", should be objectively assessed in future work, alongside qualitative interviews that can illuminate user experiences and pathways to change.

Finally, given the rapid treatment response observed in some participants, it is advisable to establish baseline measures at least one week before treatment begins, particularly for sleep-related outcomes.

4.1. Lived experience–informed recommendations for adopting CES in mental health prevention

1. **Recognise the preventative potential of Alpha-Stim CES.**
   Research presents a clear, evidence-based case for Alpha-Stim CES as an effective tool for reducing anxiety, low mood, stress, and sleep difficulties, especially for individuals at low to medium, pre-clinical diagnostic thresholds. These benefits can greatly improve individuals' quality of life. The device was used safely by a non-clinical population without clinical supervision, reinforcing its role as a self-directed, preventative tool in primary and community mental health care.
2. **Align CES with long-term health system goals.**
   The use of CES supports the prevention-focused ambitions of Integrated Care System's and the NHS 10 Year Health Plan for England, resonating with its broader health improvement themes and ambitions.
3. **Promote recovery through self-efficacy.**
   From a lived experience point of view, fear of relapse and sustaining recovery are key concerns during recovery from severe mental illness. Taking ownership and responsibility for one's recovery journey is crucial, and CES provides that vital non-

pharmacological, empowering tool to help individuals maintain their wellbeing and adopt a more holistic approach to mental health.

4. **Incorporate CES into social prescribing.**
   CES can be recommended by social prescribers as a self-administered intervention, either alongside or while waiting for other therapies such as Talking Therapies. This helps keep service users engaged and actively managing symptoms.
5. **Make CES devices available in community wellbeing hubs.**
   Placing CES devices in local wellbeing hubs, especially in underserved communities where health inequalities are often most stark, would enable safe, unsupervised use by non-clinical populations.
6. **Facilitate peer-led support groups.**
   CES could foster peer support networks where individuals share experiences and combine device use with activities like group exercise or wearable tech monitoring, promoting mutual encouragement and behavioural change.
7. **Use CES alongside personalised sleep toolkits.**
   CES use for sleep improvement could be enhanced by developing "Sleep Boxes" with personalised items and routines. These kits, successfully piloted at NHFT with lived experience input, support better sleep hygiene, which is an essential factor in mental and physical health.
8. **Highlight potential to reduce suicidal ideation.**
   This study indicates that CES use reduced suicidal ideation in some participants. This is especially valuable considering most people who die by suicide are not in contact with mental health services. Any intervention that helps prevent suicidal thoughts is critically important and should be explored further
9. **Promote cultural relevance and trust.**
   It is important to collect and report ethnicity data to evaluate CES's potential in reducing stigma and overcoming distrust of mental health services, particularly in ethnic minority communities. These self-administered devices may encourage engagement where clinical interventions are less trusted.
10. **Consider accessibility and affordability.**
    Future qualitative research should explore awareness, accessibility, and affordability of CES devices, including alternative funding models such as lending libraries or community hub distribution. Understanding willingness to pay and potential barriers can inform equitable implementation.

5. Conclusion

Alpha-Stim AID CES was found to be a feasible, acceptable, and effective intervention for reducing symptoms of anxiety, depression, insomnia, and stress, while improving wellbeing, sleep quality, self-efficacy, and QoL in a non-clinical population. Improvements were observed after three weeks of the intervention and were sustained at the three-week follow-up. The results reinforce the role of CES as an early-stage intervention, especially for individuals waiting for psychotherapeutic support or for whom pharmacological approaches are not viable. By supporting symptom management outside formal health settings, CES has the potential to reduce the burden on healthcare systems and provide meaningful support for individuals across a range of mental health needs. Appropriately powered and well-controlled trials are needed to further validate these promising findings and guide the safe, ethical integration of CES into public health strategies.

CRediT authorship contribution statement

Ksenija Maravic da Silva: Writing – review & editing, Writing – original draft, Supervision, Software, Resources, Project administration, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Clementine Broom:** Writing – review & editing, Writing – original draft, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Harvey Daly:** Writing – review & editing, Writing – original draft, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Chris Griffiths:** Writing – review & editing, Writing – original draft, Conceptualization. **Andy Willis:** Writing – review & editing, Writing – original draft, Conceptualization. **Jovana Bjekic:** Writing – review & editing, Writing – original draft, Methodology, Data curation, Conceptualization.

Declaration of Generative AI and AI-assisted technologies in the writing process

During the preparation of this work, the authors used the Grammarly tool to improve language and readability for specific sentences. After using this tool, the authors reviewed and edited the content as needed and take full responsibility for the content of the publication.

Funding sources

Coventry University's pump-priming funding awarded to KDS enabled the purchase of the Electromedical Products International Inc. Alpha-Stim AID and Condor sleep tracking devices. JB receives institutional support from the Ministry of Science, Technological Development and Innovation of the Republic of Serbia (451-03-136/2025-03/200015)

Declaration of competing interest

The authors declare no conflicts of interest regarding the publication of this paper. Authors are not affiliated or in any way connected to the Alpha-Stim AID device manufacturer.

Data availability

Data available upon request from the authors:
The data that support the findings of this study are available from the corresponding author, KMDS, upon reasonable request.

Acknowledgements

Many thanks to the participants for their contribution.

References

Andrade, L.H., Alonso, J., Mneimneh, Z., Wells, J.E., Al-Hamzawi, A., Borges, G., Bromet, E., Bruffaerts, R., de Girolamo, G., de Graaf, R., Florescu, S., Gureje, O., Hinkov, H.R., Hu, C., Huang, Y., Hwang, I., Jin, R., Karam, E.G., Kovess-Masfety, V., Levinson, D., Matschinger, H., O'Neill, S., Posada-Villa, J., Sagar, R., Sampson, N.A., Sasu, C., Stein, D.J., Takeshima, T., Viana, M.C., Xavier, M., Kessler, R.C., 2014. Barriers to mental health treatment: results from the WHO World Mental Health surveys. Psychol. Med. 44, 1303–1317. https://doi.org/10.1017/S0033291713001943.

Antal, A., Luber, B., Brem, A.-K., Bikson, M., Brunoni, A.R., Cohen Kadosh, R., Dubljević, V., Fecteau, S., Ferreri, F., Flöel, A., Hallett, M., Hamilton, R.H., Herrmann, C.S., Lavidor, M., Loo, C., Lustenberger, C., Machado, S., Miniussi, C., Moliadze, V., Nitsche, M.A., Rossi, S., Rossini, P.M., Santarnecchi, E., Seeck, M., Thut, G., Turi, Z., Ugawa, Y., Venkatasubramanian, G., Wenderoth, N., Wexler, A., Ziemann, U., Paulus, W., 2022. Non-invasive brain stimulation and neuroenhancement. Clin. Neurophysiol. Pract. 7, 146–165. https://doi.org/10.1016/j.cnp.2022.05.002.

Barclay, T.H., Barclay, R.D., 2014a. A clinical trial of cranial electrotherapy stimulation for anxiety and comorbid depression. J. Affect. Disord. 164, 171–177. https://doi.org/10.1016/j.jad.2014.04.029.

Barclay, T.H., Barclay, R.D., 2014b. A clinical trial of cranial electrotherapy stimulation for anxiety and comorbid depression. J. Affect. Disord. 164, 171–177. https://doi.org/10.1016/j.jad.2014.04.029.

Bastien, C., 2001. Validation of the Insomnia Severity Index as an outcome measure for insomnia research. Sleep Med. 2, 297–307. https://doi.org/10.1016/S1389-9457(00)00065-4.

Brunoni, A.R., Moffa, A.H., Fregni, F., Palm, U., Padberg, F., Blumberger, D.M., Daskalakis, Z.J., Bennabi, D., Haffen, E., Alonzo, A., Loo, C.K., 2016. Transcranial direct current stimulation for acute major depressive episodes: meta-analysis of

individual patient data. Br. J. Psychiatry 208, 522–531. https://doi.org/10.1192/bjp.bp.115.164715.
Burke, M.J., Kaptchuk, T.J., Pascual-Leone, A., 2019. Challenges of differential placebo effects in contemporary medicine: the example of brain stimulation. Ann. Neurol. 85, 12–20. https://doi.org/10.1002/ana.25387.
Buysse, D.J., Reynolds, C.F., Monk, T.H., Berman, S.R., Kupfer, D.J., 1989. The Pittsburgh sleep quality index: a new instrument for psychiatric practice and research. Psychiatry Res. 28, 193–213. https://doi.org/10.1016/0165-1781(89)90047-4.
Charvet, L., Shaw, M., Dobbs, B., Frontario, A., Sherman, K., Bikson, M., Datta, A., Krupp, L., Zeinapour, E., Kasschau, M., 2018. Remotely supervised transcranial direct current stimulation increases the benefit of at-home cognitive training in multiple sclerosis. neuromodulation: technology at the neural. Interface 21, 383–389. https://doi.org/10.1111/ner.12583.
Ching, P.-Y., Hsu, T.-W., Chen, G.-W., Pan, C.-C., Chu, C.-S., Chou, P.-H., 2022a. Efficacy and tolerability of cranial electrotherapy stimulation in the treatment of anxiety: a systemic review and meta-analysis. Front. Psych. 13. https://doi.org/10.3389/fpsyt.2022.899040.
Ching, P.-Y., Hsu, T.-W., Chen, G.-W., Pan, C.-C., Chu, C.-S., Chou, P.-H., 2022b. Efficacy and tolerability of cranial electrotherapy stimulation in the treatment of anxiety: a systemic review and meta-analysis. Front. Psych. 13. https://doi.org/10.3389/fpsyt.2022.899040.
Chu, C.-S., Chang, C.-H., Pan, C.-C., Chiang, Y.-C., Kuo, H.-Y., Hsu, T.-W., Chen, S.-L., Chen, C.-S., 2024. Effect of cranial electrotherapy stimulation as an add-on therapy on late-life generalized anxiety disorder: an open-label study. J. Formos. Med. Assoc. 123, 781–787. https://doi.org/10.1016/j.jfma.2023.12.002.
Coêlho, B.M., Santana, G.L., Viana, M.C., Wang, Y.-P., Andrade, L.H., 2021. "I don't need any treatment" – barriers to mental health treatment in the general population of a megacity. Braz. J. Psychiatry 43, 590–598. https://doi.org/10.1590/1516-4446-2020-1448.
Cohen, S., 1988. Perceived stress in a probability sample of the United States. In: Spacapan, S., Oskamp, S. (Eds.), The Social Psychology of Health. Sage Publications, Inc, pp. 31–67.
Faul, F., Erdfelder, E., Lang, A.-G., Buchner, A., 2007. G*Power 3: A flexible statistical power analysis program for the social, behavioral, and biomedical sciences. Behav. Res. Methods 39, 175–191. https://doi.org/10.3758/BF03193146.
Garner, C., 2021. Transcranial direct current stimulation with the Halo Sport does not improve performance on a three-minute high intensity cycling test. Int. J. Exerc. Sci. 14. https://doi.org/10.70252/AXTP9971.
Gold, S.M., Mäntylä, F.-L., Donoghue, K., Brasanac, J., Freitag, M.M., König, F., Posch, M., Ramos-Quiroga, J.A., Benedetti, F., Köhler-Forsberg, O., Grootendorst, N., Hoogendijk, W., Pariante, C.M., Katz, E.R., Webb, S., Lennox, B., Furukawa, T.A., Otte, C., 2025. Transforming the evidence landscape in mental health with platform trials. Nat. Ment. Health 3, 276–285. https://doi.org/10.1038/s44220-025-00391-w.
Griffiths, C., da Silva, K., Jiang, H., Walker, K., Smart, D., Zafar, A., Deeks, S., Galvin, S., Shah, T., 2023. Alpha-Stim AID cranial electrotherapy stimulation (CES) anxiety treatment: anxiety, depression and health-related quality-of-life outcomes in primary health-care social prescribing services. Ment. Health Rev. J. https://doi.org/10.1108/MHRJ-11-2022-0068.
Griffiths, C., da Silva, K.M., Mobee-Dumi, A., Gill, A.K., Ibrahim, D., 2025. Transcranial direct current stimulation (tDCS) and online wellbeing training used at home for perinatal and maternal loss patients with a diagnosis of depression: depression, real world-functioning, and quality of life outcomes. Open J. Depression 14, 29–44. https://doi.org/10.4236/ojd.2025.142003.
Herdman, M., Gudex, C., Lloyd, A., Janssen, M.F., Kind, P., Parkin, D., Bonsel, G., Badia, X., 2011. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). Qual. Life Res. 20, 1727–1736. https://doi.org/10.1007/s11136-011-9903-x.
Johns, M.W., 1991. A new method for measuring daytime sleepiness: the epworth sleepiness scale. Sleep 14, 540–545. https://doi.org/10.1093/sleep/14.6.540.
Jwa, A., 2015. Early adopters of the magical thinking cap: a study on do-it-yourself (DIY) transcranial direct current stimulation (tDCS) user community. J. Law Biosci. 2, 292–335. https://doi.org/10.1093/jlb/lsv017.
Kessler, R.C., Petukhova, M., Sampson, N.A., Zaslavsky, A.M., Wittchen, H., 2012. Twelve-month and lifetime prevalence and lifetime morbid risk of anxiety and mood disorders in the United States. Int. J. Methods Psychiatr. Res. 21, 169–184. https://doi.org/10.1002/mpr.1359.
Khan, Z., Saif, A., Parveen, A., 2023. Effectiveness of low frequency noninvasive brain stimulation therapy for improving neuropsychological and neurophysiological functions: a systematic review. NeuroRegulation 10, 186–206. https://doi.org/10.15540/nr.10.3.186.
Kirsch, D.L., Nichols, F., 2013. Cranial electrotherapy stimulation for treatment of anxiety, depression, and insomnia. Psychiatr. Clin. N. Am. 36, 169–176. https://doi.org/10.1016/j.psc.2013.01.006.
Kroenke, K., Spitzer, R.L., 2002. The PHQ-9: a new depression diagnostic and severity measure. Psychiatr. Ann. 32, 509–515. https://doi.org/10.3928/0048-5713-20020901-06.
Liberman, J.N., Hutchins, D.S., Shrank, W.H., Slezak, J., Brennan, T.A., 2011. Adherence to medication under mandatory and voluntary mail benefit designs. Am. J. Manag. Care 17, e260–e269.
Meron, D., Hedger, N., Garner, M., Baldwin, D.S., 2015. Transcranial direct current stimulation (tDCS) in the treatment of depression: systematic review and meta-analysis of efficacy and tolerability. Neurosci. Biobehav. Rev. 57, 46–62. https://doi.org/10.1016/j.neubiorev.2015.07.012.
Mollica, A., Greben, R., Cyr, M., Olson, J.A., Burke, M.J., 2023. Placebo effects and neuromodulation: ethical considerations and recommendations. Can. J. Neurol. Sci. 50, s34–s41. https://doi.org/10.1017/cjn.2023.24.
Morriss, R., Price, L., 2020. Differential effects of cranial electrotherapy stimulation on changes in anxiety and depression symptoms over time in patients with generalized anxiety disorder. J. Affect. Disord. 277, 785–788. https://doi.org/10.1016/j.jad.2020.09.006.
Morriss, R., Xydopoulos, G., Craven, M., Price, L., Fordham, R., 2019. Clinical effectiveness and cost minimisation model of Alpha-Stim cranial electrotherapy stimulation in treatment seeking patients with moderate to severe generalised anxiety disorder. J. Affect. Disord. 253, 426–437. https://doi.org/10.1016/j.jad.2019.04.020.
Morriss, R., Patel, S., Boutry, C., Patel, P., Guo, B., Briley, P.M., Butler, D., Craven, M., Duncan, A., Griffiths, C., Higton, F., McNaughton, R., Nixon, N., Prasad, V., Sayal, K., Smart, D., Zafar, A., Kai, J., 2023. Clinical effectiveness of active Alpha-Stim AID versus sham Alpha-Stim AID in major depression in primary care in England (Alpha-Stim-D): a multicentre, parallel group, double-blind, randomised controlled trial. Lancet Psychiatry 10, 172–183. https://doi.org/10.1016/S2215-0366(23)00007-X.
Mutz, J., Edgcumbe, D.R., Brunoni, A.R., Fu, C.H.Y., 2018. Efficacy and acceptability of non-invasive brain stimulation for the treatment of adult unipolar and bipolar depression: a systematic review and meta-analysis of randomised sham-controlled trials. Neurosci. Biobehav. Rev. 92, 291–303. https://doi.org/10.1016/j.neubiorev.2018.05.015.
Nardone, R., Höller, Y., Leis, S., Höller, P., Thon, N., Thomschewski, A., Golaszewski, S., Brigo, F., Trinka, E., 2014. Invasive and non-invasive brain stimulation for treatment of neuropathic pain in patients with spinal cord injury: a review. J. Spinal Cord Med. 37, 19–31. https://doi.org/10.1179/2045772313Y.0000000140.
National Institute for Health and Care Excellence, 2021. Alpha-Stim AID for anxiety disorders [WWW Document]. Medical technologies guidance MTG56.
Palagini, L., Hertenstein, E., Riemann, D., Nissen, C., 2022. Sleep, insomnia and mental health. J. Sleep Res. 31. https://doi.org/10.1111/jsr.13628.
Paulus, J.K., Dahabreh, I.J., Balk, E.M., Avendano, E.E., Lau, J., Ip, S., 2014. Opportunities and challenges in using studies without a control group in comparative effectiveness reviews. Res. Synth. Methods 5, 152–161. https://doi.org/10.1002/jrsm.1101.
Pilloni, G., Vogel-Eyny, A., Lustberg, M., Best, P., Malik, M., Walton-Masters, L., George, A., Mirza, I., Zhovtis, L., Datta, A., Bikson, M., Krupp, L., Charvet, L., 2022. Tolerability and feasibility of at-home remotely supervised transcranial direct current stimulation (RS-tDCS): single-center evidence from 6,779 sessions. Brain Stimul. 15, 707–716. https://doi.org/10.1016/j.brs.2022.04.014.
Razza, L.B., Moffa, A.H., Moreno, M.L., Carvalho, A.F., Padberg, F., Fregni, F., Brunoni, A.R., 2018. A systematic review and meta-analysis on placebo response to repetitive transcranial magnetic stimulation for depression trials. Prog. Neuropsychopharmacol. Biol. Psychiatry 81, 105–113. https://doi.org/10.1016/j.pnpbp.2017.10.016.
Richardson, J.D., Galletta, E.E., Charvet, L., Shaw, M., 2023. Feasibility of remotely supervised transcranial direct current stimulation (RS-tDCS) for people with stroke-induced and progressive aphasia. Aphasiology 37, 1039–1063. https://doi.org/10.1080/02687038.2022.2076279.
Schwarzer, R., Jerusalem, M., 1995. Generalized self-efficacy scale. In: Weinman, J., Wrights, S., Johnson, M. (Eds.), Measures in Health Psychology: A User's Portfolio. Causal and Control Beliefs. NFER-NELSON, Windsor, pp. 35–37.
Shekelle, P.G., Cook, I.A., Miake-Lye, I.M., Booth, M.S., Beroes, J.M., Mak, S., 2018. Benefits and harms of cranial electrical stimulation for chronic painful conditions, depression, anxiety, and insomnia. Ann. Intern. Med. 168, 414. https://doi.org/10.7326/M17-1970.
da Silva, K.M., Griffiths, C., Banazadeh, A., Mu, M., 2025. Transcranial direct current stimulation (tDCS) used at home for people with a diagnosis of depression: sleep quality outcomes. Open J. Psychiatry 15, 109–121. https://doi.org/10.4236/ojpsych.2025.152010.
de Souto Barreto, P., Ferrandez, A.-M., Saliba-Serre, B., 2013. Are older adults who volunteer to participate in an exercise study fitter and healthier than nonvolunteers? The participation bias of the study population. J. Phys. Act. Health 10, 359–367.
Spitzer, R.L., Kroenke, K., Williams, J.B.W., Löwe, B., 2006. A brief measure for assessing generalized anxiety disorder. Arch. Intern. Med. 166, 1092. https://doi.org/10.1001/archinte.166.10.1092.
Tennant, R., Hiller, L., Fishwick, R., Platt, S., Joseph, S., Weich, S., Parkinson, J., Secker, J., Stewart-Brown, S., 2007. The Warwick-Edinburgh Mental Well-being Scale (WEMWBS): development and UK validation. Health Qual. Life Outcomes 5, 63. https://doi.org/10.1186/1477-7525-5-63.
Walach, H., 2001. The efficacy paradox in randomized controlled trials of CAM and elsewhere: beware of the placebo trap. J. Altern. Complement. Med. 7, 213–218. https://doi.org/10.1089/107555301300328070.
Wexler, A., 2015. A pragmatic analysis of the regulation of consumer transcranial direct current stimulation (TDCS) devices in the United States: table 1. J. Law Biosci., lsv039 https://doi.org/10.1093/jlb/lsv039.
Wexler, A., 2016. The practices of do-it-yourself brain stimulation: implications for ethical considerations and regulatory proposals. J. Med. Ethics 42, 211–215. https://doi.org/10.1136/medethics-2015-102704.
Wexler, A., 2019. Direct-to-consumer neurotechnology: a grounded appraisal. AJOB Neurosci. 10, 172–174. https://doi.org/10.1080/21507740.2019.1665138.
Wexler, A., Reiner, P.B., 2019. Oversight of direct-to-consumer neurotechnologies. Science (1979) 363, 234–235. https://doi.org/10.1126/science.aav0223.
Wittchen, H.U., Jacobi, F., Rehm, J., Gustavsson, A., Svensson, M., Jönsson, B., Olesen, J., Allgulander, C., Alonso, J., Faravelli, C., Fratiglioni, L., Jennum, P., Lieb, R., Maercker, A., van Os, J., Preisig, M., Salvador-Carulla, L., Simon, R.,

Steinhausen, H.-C., 2011. The size and burden of mental disorders and other disorders of the brain in Europe 2010. Eur. Neuropsychopharmacol. 21, 655–679. https://doi.org/10.1016/j.euroneuro.2011.07.018.
World Health Organization, 2024. Integrated operational framework for mental health, brain health and substance use. Geneva.
Yang, Y., Chen, J., Yu, M., Xiong, C., Zhang, R., Jiang, G., 2025. Comparative efficacy of multiple non-invasive brain stimulation to treat major depressive disorder in older patients: a systematic review and network meta-analysis study based on randomized controlled trials. Psychiatry Res. 344, 116340. https://doi.org/10.1016/j.psychres.2024.116340.