Scientific Research Publishing

Open Journal of Psychiatry, 2025, 15(2), 109-121
https://www.scirp.org/journal/ojpsych
ISSN Online: 2161-7333
ISSN Print: 2161-7325

Transcranial Direct Current Stimulation (tDCS) Used at Home for People with a Diagnosis of Depression: Sleep Quality Outcomes

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How to cite this paper: da Silva, K.M., Griffiths, C., Banazadeh, A. and Mu, M. (2025) Transcranial Direct Current Stimulation (tDCS) Used at Home for People with a Diagnosis of Depression: Sleep Quality Outcomes. *Open Journal of Psychiatry*, **15**, 109-121.
https://doi.org/10.4236/ojpsych.2025.152010

Received: March 19, 2025
Accepted: April 15, 2025
Published: April 18, 2025

Abstract

Background: There is a high prevalence of sleep quality problems and insomnia in people with depression. Insomnia is a common, distressing, and impairing sleep disorder and is linked to poor mental and physical health. Research evidence indicates that transcranial direct current stimulation (tDCS) can reduce symptoms of insomnia and improve sleep quality. Flow FL-100 is a tDCS device self-administered at home. Purpose/aim: To investigate the impact of up to 10 weeks of Flow Neuroscience AB FL-100 tDCS use on sleep quality in people with depression, using the Montgomery-Åsberg Depression Rating Scale Self (MADRS-S) sleep quality question. Methods: A retrospective analysis of MADRS-S self-report data collected between 2020 and 2024. Results: 6229 datasets of people who received tDCS and who self-reported insomnia were analysed. The MADRS-S sleep quality remission rates in people who adhered to the tDCS protocol were 36.1% at one week, 43.1% at two weeks, 50.2% at three weeks, 59.3% at six weeks and 63.2% at ten weeks. Conclusion: The results show that tDCS may improve sleep quality in those with depression and insomnia. Due to problems with existing insomnia treatment options, it is important to be able to offer additional evidence-based insomnia treatments. Appropriately designed and powered randomised controlled trials (RCTs) and testing of feasibility in healthcare settings are warranted.

Keywords

Insomnia, Depression, Transcranial Direct Current Stimulation (tDCS), Sleep

1. Introduction

Insomnia is persistent difficulty with getting to sleep, maintaining sleep, and/or

poor quality sleep, which occurs despite adequate opportunity and circumstances for sleep; with symptoms that include fatigue, depressed mood, irritability, general malaise, and cognitive impairment (NICE, 2025). Insomnia can lead to impaired daytime functioning including longer reaction times, poorer cognitive performance, and an increased risk of costly injuries/accidents and workplace mistakes [1]. Insomnia is associated with poorer physical health, such as increased obesity, chronic obstructive pulmonary disease, cancer, high blood pressure, heart failure, and chronic pain [2] [3]. Sleep deprivation increases the risk of mortality by 13% and leads to a loss of approximately 200,000 workdays a year in the UK, equivalent to £40 billion in lost productivity annually [4]. The links between insomnia and mental distress have been well-established [2]; insomnia is a risk factor for depression and vice versa [5]. The general adult population prevalence of insomnia is around 30% [6].

Clinical guidelines for insomnia treatment recommends sleep hygiene, cognitive behavioural therapy for insomnia (CBT-I), sleep medication (hypnotic) or a referral to a 'sleep clinic' [7] (NICE, 2022). However, due to long waiting lists for CBT-I, a lack of availability of specialist referrals and pressure from patients to prescribe, insomnia treatment is dominated by sleep medication prescription or patients using "over-the-counter" and unapproved products [8]-[10]. Eighty percent of people report experiencing negative side effects from sleep medication (e.g., drowsiness, difficulty concentrating, impaired memory, headaches, nausea, and drug dependence) [11]. In 2022, there were more than 12 million prescriptions to treat insomnia, costing the UK's National Health Service (NHS) £72 million [7] (NICE, 2022). The effect sizes for CBT-I and prescribed medications are small to moderate, and a need for a stepped-care model with more treatment options has been raised [12]. The high prevalence of insomnia [13], coupled with its reoccurring nature [14], indicates the need for an effective treatment with fast action and few side effects that can be used by patients at home at times of need and that reduce NHS demands and the economic costs of insomnia [15].

Transcranial direct current stimulation (tDCS), a type of non-invasive brain stimulation (NIBS), uses mild electrical currents to modulate brain activity and treat neurological and mental disorders. tDCS devices are easy to use, have relatively low cost and can be used at home while maintaining an excellent safety and tolerability profile [16] [17]. tDCS treatment does not have the side effects of medication [16]; the most reported side effect is a mild headache lasting less than an hour [18]. There is evidence for the use of tDCS in the treatment of depression [18]-[20], anxiety [21] [22], tinnitus [23] and pain [24]. The tDCS protocol of bi-directional via anode (which increases cortical arousal) and cathode (which decreases cortical arousal) over left and right dorsolateral prefrontal cortex (DLPFC), F3 and F4 electrodes on a standard electroencephalogram (EEG) positioning, respectively, with stimulation at 2 mA, has been found to be safe and well-tolerated, with mild temporary physical sensations and few minor side effects [18].

There is evidence for the use of NIBS for insomnia [25]. Anodal stimulation

reduced total sleep time compared to cathodal stimulation, supporting the idea that increased levels of arousal in the DLPFC plays a major role in the pathophysiology of insomnia; conversely, the therapeutic impact of tDCS lies in cathodal stimulation which decreases arousal and hence elicits sleep-promoting brain wave activity [8]. Total sleep time (TST) was found to increase after a single tDCS session in 19 healthy people [8] and tDCS was found to improve sleep continuity and quality in 32 healthy student-athletes on three self-report measures of sleep and insomnia after two nights of 20-minute stimulation [26]. Following one night's sleep of those in a sleep deprivation experimental condition, 23 healthy participants showed a significant improvement in the ability to maintain wakefulness after a single 30-minute tDCS bi-frontal F4 + F3 session [27]. tDCS may have a positive impact on sleep quality, it was found to change the complexity of rapid eye movement (REM) sleep in 19 users with depression [28]. These studies had several limitations, including small participant numbers, applying only one or two tDCS sessions, and the inclusion of participants with healthy sleep patterns.

In interviews after tDCS treatment for depression, patients reported improvements in sleep initiation, duration, and quality, and reduction in wakefulness after sleep onset (WASO) [29]-[31] (Baukaite *et al.*, 2024; Griffiths *et al.*, 2024a; Griffiths *et al.*, 2024b). An randomised controlled trial (RCT) of 20 daily tDCS sessions with 90 users with major depressive disorder and insomnia found that the Pittsburgh Sleep Quality Inventory (PSQI; [32]) total score and all PSQI sub-divisions, except for 'sleep duration and sleep efficiency', significantly improved after tDCS use [33]. Using the same protocol, 53 users with chronic insomnia and no psychiatric comorbidities achieved a 22% remission and a response (50% reduction in the PSQI) of 27% at four weeks [34]. An RCT with 100 participants with moderate to severe stress levels found significantly improved sleep quality after five 20-minute daily tDCS sessions [35] (Dos Reis *et al.*, 2024).

In summary, there is evidence that the bi-directional anode and cathode tDCS improves sleep quality and insomnia, with some understanding of its underlying mechanisms on sleep architecture, in both healthy participants and people with depression. Treatment with CBT-I and medication is not effective for some people, and some cannot or do not wish to try them, so there is a need for alternative low-cost, effective, and safe treatment options that empower patient choice. This large-scale retrospective data analysis study investigated the impact of Flow FL-100 tDCS on the sleep quality of those self-reporting depression and insomnia. This study addresses the question of what the impact of tDCS on sleep symptoms is as measured by the sleep quality question of the Montgomery-Åsberg Depression Rating Scale Self (MADRS-S) scale [36]. The study compares the change in sleep quality over a period of ten weeks of tDCS in people with depression.

2. Methods

2.1. Design

The study was a retrospective analysis of data collected by Flow Neuroscience AB

between 2020 and 2024. Flow Neuroscience AB meet their legal obligations to comply with UK and EU GDPR. All those providing data gave permission to do so to Flow Neuroscience AB.

All users are provided with Flow Neuroscience AB's privacy policy https://api.flowneuroscience.com/app/sign_up/privacy/en/.

Analysis was conducted on data from an anonymised database provided by Flow Neuroscience AB to University of Northampton, UK.

2.2. Approval

Approval was gained from the owners of the Flow Neuroscience AB data. The study was undertaken in accordance with the Declaration of Helsinki. The study was approved by the Research Ethics Committee at the Faculty of Arts, Science and Technology, University of Northampton. Ethics approval reference is FREC2425005.

2.3. Participants

The inclusion criteria to participate were individuals who were ≥18 years old with a MADR-S total score of 13 or over, *i.e.* meeting a threshold of having a diagnosis of depression. The exclusion criteria were defined by Flow Neuroscience AB based on regulation approvals: medical reasons preventing wearing the devices (e.g., epilepsy, heart disease, an open wound in the area of the pad contact point on the forehead, a neurological or neuropsychiatric condition, recent or planned major surgical procedure, defect or implant), pregnancy (or suspected pregnancy), bipolar disorder or current suicidal ideation (thoughts about ending one's own life).

2.4. Measures

A self-rating version of the original clinician-rated Montgomery-Åsberg Depression Rating Scale Self (MADRS-S) [36] was used. It has 9 items, each one scored between 0 (minimum) and 6 (maximum). The person is asked to assess how he or she has felt during the previous 3 days. The scores for all 9 items are added, and cutoff scores for the MADRS-S are defined for the level of depression (total score of 0 - 12 = minimal depression, 13 - 19 = mild depression, 20 - 34 = moderate depression, ≥35 = severe depression). Remission is a MADRS-S score change from 13 or over (have depression) to 12 or less (cut-off for depression). The MADRS-S scale has acceptable psychometric properties (validity, reliability, and sensitivity to change) [37].

MADRS-S was completed at baseline (prior to start) and then every week over the course of tDCS use. Analysis was conducted on the scores specific to the MADRS-S sleep question (question 3 on MADRS-S): "Here you should indicate how well you sleep, how long you sleep, and how good your sleep has been for the past 3 nights. Your assessment should reflect how you have actually slept, regardless of whether you have used sleeping pills. If you have slept more than usual, you should mark the scale at zero (0)."

0. I have no sleeping problems, and get as much sleep as I need. I have no difficulty in falling asleep.

2. I have some sleeping problems. Sometimes it is hard to get off to sleep, or I sleep more lightly or restlessly than usual.

4. I sleep at least 2 hours a night less than usual. I wake often during the night, even if nothing has disturbed me.

6. I sleep very badly, no more than 2 - 3 hours a night Insomnia is defined as answering 4 or 6 and not having insomnia as answering 0 or 2.

2.5. Intervention

Flow Neuroscience FL-100 is a BSI UKCA certificated and Conformite Européenne (CE) marked Class IIa medical device (UKCA 776047). Flow can be purchased directly by anyone over the age of 18 via the manufacturer's website in the European Union and other European countries.

The tDCS treatment consisted of five tDCS sessions of 2 mA current for 30 minutes per week over three weeks, and a further two sessions weekly, for seven weeks. The tDCS device is a headset placed over the forehead with two pre-positioned soft-padded foam electrodes, each 23 cm^2. The anode was positioned over the left dorsolateral prefrontal cortex (DLPFC) (F3 on the international 10/20 EEG system) and the cathode over the right DLPFC (F4). In the treatment protocol, the user remains awake and self-administers at home or other convenient place.

The Flow Neuroscience AB mobile phone software app is used to set up and control the Bluetooth-connected Flow FL-100 tDCS headset via the user's smartphone. Written instructions are provided, and the Flow Neuroscience AB website offers information, usage training, and email support.

2.6. Data Processing

All weekly data from MADRS-S (sleep item Q3 and total), Flow stimulations (counts), and user metadata (age, sex, diagnoses) were merged. MADRS-S entries with a completion time of 14 seconds or less were excluded to minimize invalid responses. Weeks were truncated at 10. This final, filtered dataset was then used for all analyses described in this paper.

2.7. Adherence Definitions

Adherence to the protocol was achieved when the users completed the following number of stimulations:

- Week 1, 2 and 3 adherence: 4 or 5 stimulations per week
- Week 6 adherence: 4 or 5 stimulations in Weeks 1 to 3 and 2 stimulations in Weeks 4 to 6
- Week 10 adherence: 4 or 5 stimulations in Weeks 1 - 3 and 2 stimulations in Weeks 4 to 10.

3. Results

3.1. Baseline Insomnia Prevalence

Out of 20197 users, 6229 had insomnia (30.8%). Out of those with insomnia who reported their sex, 43.9% were male and 56.1% were female. Users with self-reported diagnoses of anxiety, bipolar disorder or post-traumatic stress disorder (PTSD) had higher rates of insomnia than average (Table 1).

Table 1. Baseline insomnia by sex and self-reported diagnoses.

Group	n	n insomnia	% Insomnia
Females	6859	2239	32.6
Males	6265	1749	27.9
Missing sex data	7073	2241	31.7
Anxiety	3036	1051	33.1
Bipolar disorder	424	141	33.3
PTSD	1173	498	42.5

3.2. Adherence and Sleep Improvement

Table 2 shows the improvements in sleep in those users who adhered to the protocol. A course of 1 week of Flow tDCS treatment (4 - 5 times) resulted in 36.1% remission. A course of 2 weeks of Flow tDCS (4 - 5 times for 2 weeks) resulted in 43.1% remission. A course of 3 weeks of Flow tDCS (4 - 5 times for 3 weeks) resulted in 50.2% remission. A course of 6 weeks of Flow tDCS (4 - 5 times for 3 weeks and 2 times for 3 weeks) resulted in 59.3% remission. A course of 10 weeks of Flow tDCS (4 - 5 times for 3 weeks and 2 times for 7 weeks) resulted in 63.2% remission.

Table 2. Adherence and Sleep Improvement by weeks of treatment.

Duration	Adherence definition	Number adherent	Number improved	Percentage remission
1-week	4 or 5 stimulations	4299	1551	36.1%
2-week	4 or 5 stimulations per week	3276	1412	43.1%
3-week	4 or 5 stimulations per week	2434	1223	50.2%
6-week	4 or 5 stim in weeks 1 - 3, then 2 or 3 stimulations in Weeks 4 - 6	1161	689	59.3%
10-week	4 or 5 stim in weeks 1 - 3, then 2 or 3 stimulations in Weeks 4 - 10	555	351	63.2%

In the 6 week use data, in users who partially complied with the protocol (1 - 3 stimulations per week in first 3 weeks and 1 - 2 stimulations in next 3 weeks), the remission rate of insomnia symptoms was 9.2% (119 out of 1288). Only 2.5% of users (21 out of 825) who received no stimulation or up to one stimulation per week for six weeks experienced insomnia remission.

3.3. Sleep and Depression

Table 3 shows a moderate correlation between question 3 (sleep) and the total MADRS-S score from baseline to week 10 of the treatment, suggesting a moderate positive link between sleep disturbance and overall depression severity.

Table 3. Pearson correlations between sleep question and total MADRS-S.

Time	n	Pearson r	95% CI	p-value
Baseline	20197	0.47	(0.45 - 0.48)	<0.001
Week 1	15739	0.53	(0.52 - 0.54)	<0.001
Week 2	14242	0.56	(0.55 - 0.57)	<0.001
Week 3	12065	0.60	(0.59 - 0.62)	<0.001
Week 6	8092	0.63	(0.61 - 0.64)	<0.001
Week 10	6019	0.62	(0.61 - 0.64)	<0.001

Analysis of the 8092 patients' data from week 6, found that 2569 patients (31.7%) were in remission, out of which only 41 (1.6%) still had insomnia. Conversely, 5523 patients (68.3%) were not in remission, of which 1109 (20%) still had insomnia. For all 1150 patients who were still experiencing insomnia at week 6, 96% also reported depression. These observations indicate that insomnia could be a leading contributing factor to depression.

4. Discussion

Flow FL-100 tDCS was found to reduce the symptoms of insomnia for users with self-reported depression and insomnia. These results provide additional evidence that tDCS can be effective in reducing symptoms of insomnia [29]-[31] [33]-[35] [38]. In line with research evidence, this study found that sleep disturbances are positively linked to overall depression severity [2] [5].

There were higher rates of remission for those who adhered to the protocol of tDCS use, and low rates of remission were seen for those who did not use or used tDCS very little. This indicates a dose (amount) response link. Longer length of use provided greater remission rates indicating a cumulative effect of tDCS on insomnia symptoms, and this cumulative treatment effect has also been found when tDCS is used as treatment for depression [19] [39]. This finding provides evidence for recommendations as to amount and length of tDCS use.

This study's results suggest that tDCS works relatively quickly, as 36.1% remission in insomnia is observed after one week and 4 - 5 sessions. This is aligned with other studies, which reported positive results after a single or two tDCS sessions [8] [9] [26]-[38]. Therefore, tDCS could be considered as a treatment when a relatively quick relief of insomnia symptoms is required. Hypnotic medications used for insomnia treatment may act quickly if they provide symptom relief [40]; however, side effects (e.g. sedation, psychomotor impairment) and risk of dependency must be considered [41] [42].

Our results showed that when patients reached remission for depression, only 1.6% of them were still experiencing insomnia; however, 20% of patients who did not reach remission for depression continued to experience insomnia. The link between depression and insomnia is well documented and emphasises the importance of seeking to address sleep problems to reduce depression [2] [5]. Future studies could investigate tDCS as an insomnia treatment where insomnia occurs without the presence of depression.

This study found that Flow FL100 delivered tDCS can be used by patients at home and data can be collected. GP primary care services are well-placed to deliver tDCS insomnia treatment as they seek to understand a patient's individual circumstances and provide individualised support and treatment. GP primary care services have successfully offered tDCS for depression [19] [43].

High rates of insomnia seen for those with a self-reported diagnosis of post-traumatic stress disorder (PTSD) in this study's data reflects PTSD insomnia prevalence data. In a meta-analysis of the prevalence of insomnia combined with post-traumatic stress symptoms (PTSS) (n = 573,665) the authors concluded that the prevalence of insomnia in PTSD/PTSS was 63% and highlight the importance of screening and managing insomnia in PTSD patients [44]. NICE PTSD guidance states that interventions which specifically target sleep problems should be provided [45]. This highlights the potential value of tDCS as a treatment for insomnia in PTSD.

Future studies investigating the impact of tDCS on sleep, especially those that rely on sleep tracking data collection, should allow sufficient time before treatment start to accurately assess baseline sleep patterns. Future studies should seek to have an extended follow-up data collection period, to help determine longer term effects of tDCS and if 'top up' treatments might be useful or required to sustain any benefits. Future studies should consider and where appropriate incorporate the latest findings in circadian research and investigate if specific timing of the tDCS use might yield better remission rates [46] [47]. It would be valuable to investigate the impact of tDCS combined with hypnotic medication and/or CBT-I, and how tDCS can fit within standard clinical guidelines as a standalone or complementary treatment.

5. Limitations

There were several limitations of the study. The use of Flow FL100 tDCS was "open-label" and adjunct to any existing other treatments or therapies. All data was self-reported. Sex data had a high percentage of missing data. We relied on a single insomnia item (MADRS-S question 3). Future studies should incorporate standardized insomnia assessments (e.g., ISI, PSQI) to validate these findings.

6. Conclusions

This study is the first to report that higher adherence to the tDCS protocol and longer length of use provide greater insomnia remission rates. There was a high

correlation between sleep disturbance and overall depression severity. tDCS can be used for a relatively quick resolution of insomnia. It is important to provide patients with various effective treatment options for insomnia, focusing on personalised strategies [42]. While tDCS treatment may have reduced the symptoms of insomnia for some, it is unclear why some patients did not respond. Research is needed to understand individual differences in response, particularly regarding the mechanisms of tDCS action.

Flow tDCS can be purchased and used independently in several countries; however, its cost is prohibitive for many, and awareness and availability within healthcare systems are low. Improving access through free universal healthcare systems like the UK's NHS would help address treatment inequality, especially for those who have not benefited from medication and/or psychotherapy. Primary care general practices are well-placed to prescribe tDCS treatment as most people first seek help for insomnia through a GP, and many patients are treated by their GP for long-term or recurrent insomnia. Appropriately designed and powered RCTs and feasibility testing in healthcare settings are warranted.

Funding

Funding was provided by Flow Neuroscience AB, but study design, analysis, interpretation, and reporting was independent of Flow Neuroscience AB's involvement.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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