White Paper

Effectiveness of transcranial direct current stimulation (tDCS) in depression care

Highlights

Transcranial direct current stimulation (tDCS) has emerged as a valuable clinical tool for healthcare professionals in managing depression, with A-level evidence in international guidelines.

In a study published in Nature Medicine, 57.5% of patients achieved remission from a home-based tDCS treatment course, without serious side effects.

The treatment can be prescribed by healthcare professionals as an additive form of treatment to antidepressants or as a standalone solution for patients who are looking for an alternative to medication.

Major Depressive Disorder (MDD) is one of the most common and disabling psychiatric conditions, affecting millions worldwide. Traditional forms of treatment, such as antidepressants and psychotherapy, can be effective for many patients, but a significant number continue to experience persistent symptoms. Moreover, not all patients are able to take antidepressants, and the availability of psychotherapy is scarce in many countries. Against this background, transcranial direct current stimulation (tDCS) offers a promising non-invasive solution for healthcare professionals treating MDD patients.

The therapeutic effect of tDCS is based on the modulation of neuronal activity, particularly in the dorsolateral prefrontal cortex (DLPFC), as well as the induction of neuroplasticity. This helps to restore balance in the brain activity associated with mood regulation, which has been shown to relieve symptoms of depression.

Treatment with tDCS is fast becoming a part of the current care guidelines and clinical routines. The European evidence-based guidelines on non-invasive brain stimulation techniques for depression have given an A-level recommendation for tDCS (1). This endorsement underscores the growing consensus that tDCS is a viable option for treating MDD. This white paper explores the effectiveness of **Sooma tDCS™** depression treatment, as supported by recent clinical evidence and international guidelines.

Sooma

Nature Medicine study

The latest advancements in tDCS technology allow for convenient home-based treatment. A clinical trial published in Nature Medicine demonstrated significant improvements in the depressive symptoms of MDD patients with home-based tDCS care, with 57.5% of patients achieving remission compared to 29.4% in the placebo group (P = 0.002) (2).

The trial protocol involved a 10-week home-based tDCS treatment course with 174 patients enrolled from the United States and the United Kingdom. Patients underwent regular stimulation sessions 5 times per week for the first 3 weeks and 3 times per week for the subsequent weeks. Significant clinical benefit was observed as early as 4 weeks into the treatment. Safety outcomes were favorable, with no serious adverse events reported. The most commonly reported side effects included skin sensations, such as itching or tingling, redness of the skin, or irritation in the stimulation area. These symptoms were all transient and resolved without intervention. The drop-out rate in the study was also notably low, indicating good tolerability and adherence to the treatment.

Additionally, the study highlighted the suitability of tDCS as an effective form of treatment in both standalone

use as well as use in conjunction with antidepressants. This versatility makes tDCS an attractive option for a wide range of patients, whether they are looking for an alternative to medication or an enhancement to their current treatment regimen.

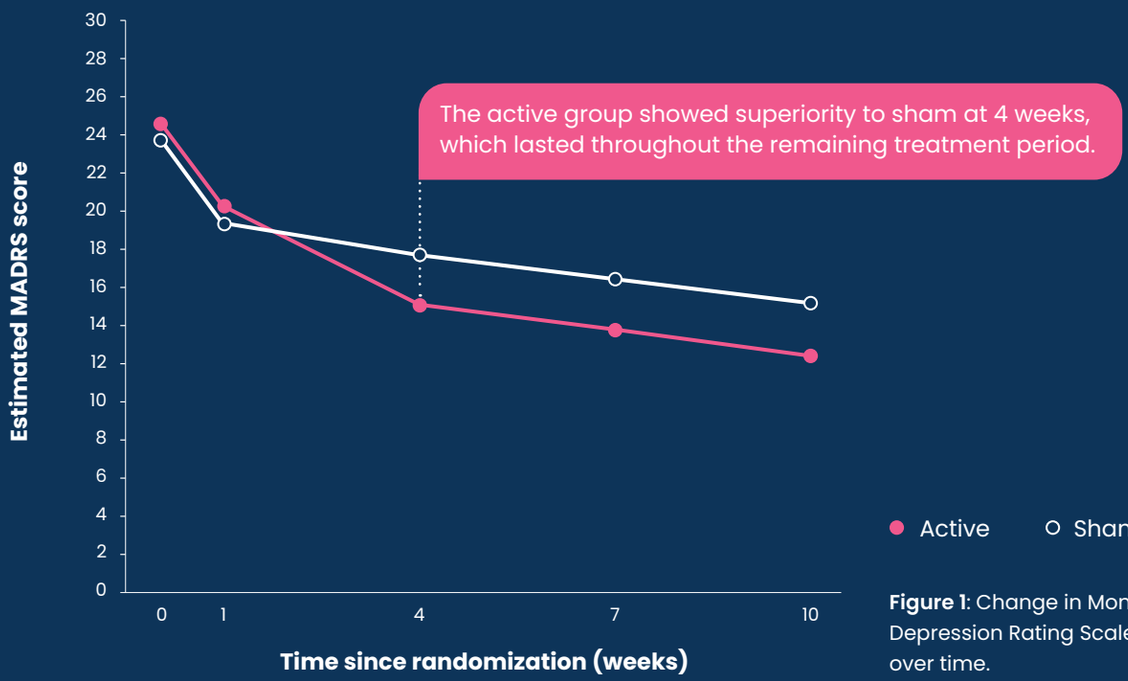

Figure 1: Change in Montgomery-Åsberg Depression Rating Scale (MADRS) ratings over time.

Results from clinical routine

Sooma real-world data

The real-life effectiveness and tolerability of Sooma tDCS depression treatment were evaluated in a cohort of 462 MDD patients from seven countries, who received treatment as part of routine clinical practice (3). Data from 410 patients were analysed after completing the treatment course. The course followed a standardized stimulation protocol in which a 2 mA current was used 5 times per week in 30-minute sessions for 2–3 weeks, with maintenance sessions administered as needed. Depression severity was assessed using validated scales. The results indicated that 55% of patients achieved a clinical response (defined as >50% reduction from the baseline), with 20% achieving remission. Notably, no serious adverse effects were reported, with the most common side effects being mild and transient, such as itching of the skin and headaches.

Most patients experienced significant improvement in their depression severity, with the majority being in remission (20%) or presenting with only mild symptoms (60%) after treatment. This was a notable shift from the baseline severity, where approximately 52% of patients had moderate depression and 38% had severe depression. Furthermore, patients receiving tDCS as monotherapy showed better outcomes, with higher response (68%) and remission rates (35%).

This finding highlights the potential of tDCS as a viable standalone treatment for MDD, particularly for patients who do not respond to antidepressants or prefer non-pharmacological options. Patients receiving concurrent antipsychotic, benzodiazepine, or mood-stabilizing medication had 50% response and 14% remission rates, but the data showed that their outcomes became even better with longer treatment schedules..

The study provides valuable real-world evidence of the clinical benefits of tDCS, especially when compared to traditional antidepressant treatments. The study was conducted in a clinical setting similar to the STAR*D trial (4), the largest clinical trial evaluating optimized antidepressant medication treatment strategies for real-world MDD patients. Both studies recruited comparable patients from routine clinical practice. A re-analysis of the STAR*D trial (5) reported a response rate of 41% at 7–8 weeks for patients in the first-line antidepressant medication treatment, while Sooma tDCS showed superior outcomes both in a more challenging patient population and in half the time. Additionally, tDCS had a lower discontinuation rate (3% vs. 7.5% in STAR*D) and no serious adverse events, making it a safer and more effective treatment option for MDD.

Conventional treatment	tDCS treatment
Response rate 41%	Response rate 55%
4% of patients had a serious adverse event	No serious effects
Up to 27% suffered from intolerable side-effects	No discontinuation due to intolerance

sooma

Effective, safe, and accessible treatment

As the studies presented have demonstrated, tDCS stands out as an excellent treatment option for patients who have failed their first antidepressant trial or who either cannot or do not wish to use medication. With its safety profile and efficacy, tDCS can offer both an alternative or a complementary approach to traditional pharmacological treatments. The low discontinuation rate and absence of serious and systemic side effects further support it as a sustainable long-term treatment solution for MDD.

At the same time, while some patients are able to benefit from the treatment after just a few weeks, research has increasingly highlighted the importance of sufficient treatment duration to allow slower responding patients to see improvement as well. Importantly, recent meta-analyses have shown that the benefits of tDCS treatment are sustained even after treatment has ended (6).

Additionally, the ability for patients to self-administer tDCS at home has significant cost-saving potential by reducing the need for specialized facilities and the presence of highly trained staff. This home-based approach also enables wider and more equal access to care, as tDCS can also be administered remotely from local health centers without the logistical barriers associated with more complex treatments. Most importantly, though the treatment can be administered at home, tDCS is always prescribed by a healthcare professional to ensure that patients are receiving the most optimal treatment for their symptoms.

In sum, Sooma tDCS™ depression treatment is a comprehensive, safe, and effective treatment option for individuals struggling with depression. With the growing body of evidence supporting its use, tDCS represents an essential addition to the options available for managing MDD. Furthermore, home-based administration offers a patient-friendly solution that both ensures treatment adherence and comfort while maintaining clinical effectiveness.

For more information on Sooma tDCS depression treatment, please visit our website or contact our clinical team to learn how the treatment could benefit you or your patients.

Read the full
Lõokene study

Read the full
Nature Medicine study

References

1. Fregni F, El-Hagrassy MM, Pacheco-Barrios K, Carvalho S, et al. Evidence-Based Guidelines and Secondary Meta-Analysis for the Use of Transcranial Direct Current Stimulation in Neurological and Psychiatric Disorders. Int J Neuropsychopharmacol. 2021 Apr 21;24(4):256-313. https://doi.org/10.1093/ijnp/pyaa051

2. Woodham RD, Selvaraj S, Lajmi N, et al. Home-based transcranial direct current stimulation treatment for major depressive disorder: a fully remote phase 2 randomized sham-controlled trial. Nat Med. 2024 Oct 21. 3. Lõokene M, Markov N, Nikander M, et al. Reduction of symptoms in patients with major depressive disorder after transcranial direct current stimulation treatment: A real-world study. Journal of Affective Disorders Reports, Volume 8, 2022. https://doi.org/10.1016/j.jadr.2022.100347

4. Rush AJ, Trivedi MH, Wisniewski SR, et al. Acute and longer-term outcomes in depressed outpatients requiring one or several treatment steps: a STAR*D report. Am J Psychiatry. 2006 Nov;163(11):1905-17. https://doi.org/10.1176/ajp.2006.163.11.1905

5. Pigott HE, Kim T, Xu C, et al. What are the treatment remission, response and extent of improvement rates after up to four trials of antidepressant therapies in real-world depressed patients? A reanalysis of the STAR*D study's patient-level data with fidelity to the original research protocol. BMJ Open. 2023 Jul 25;13(7). https://doi.org/10.1136/bmjopen-2022-063095

6. Nikolin S, Moffa A, Razza L, et al. Time-course of the tDCS antidepressant effect: An individual participant data meta-analysis. Prog Neuropsychopharmacol Biol Psychiatry. 2023 Jul 13;125. https://doi.org/10.1016/j.pnpbp.2023.110752

sooma

Sooma Oy is a Finnish medical device company developing accessible therapy solutions for routine care.

Sooma tDCS medical devices are manufactured in Finland in accordance with the international ISO 13485 quality management system for medical devices.

www.soomamedical.com, sales@soomamedical.com,
tel. +358 10 328 9811, Atomitie 5 C, 00370 Helsinki, Finland

MD CE 0598

MK113 EN

Prodaja i podrška za Hrvatsku

REHA FIT d.o.o.
damir.rovis@rehafit.hr
098274116

rehafit