



Clinical evidence of transcranial direct current stimulation (tDCS) in major depressive disorder

Summary

Non-invasive Sooma tDCS™ Depression Therapy relieves depression by modulating hypoactive areas of the brain with a weak current

Real-world clinical effectiveness of Sooma Depression Therapy was assessed in 302 patients with major depressive disorder (MDD)

Treatment response was achieved in 61% of patients, and 20% of patients were in clinical remission post-treatment

Transcranial direct current stimulation (tDCS) relieves the symptoms of major depressive disorder (MDD) by modulating cortical excitability with a weak current. tDCS delivers a constant current that induces changes in neuronal excitability in a polarity-dependent manner.¹ In Sooma Depression Therapy, the positive anodal stimulation is used to increase neuronal excitability at the left dorsolateral prefrontal cortex (DLPFC), which is found to be hypoactive in depressed patients.^{2,3} The flow of current from the positive to the negative electrode influences the activity in the prefrontal cortex¹, relieving symptoms in depressed patients.⁴

tDCS can be administered as a monotherapy, or as an

adjunct treatment to enhance the effect of pharmaceutical or psychological therapy.^{5,6} The efficacy and safety of tDCS has been shown in randomized controlled studies, either as a monotherapy or as an adjunct therapy to pharmaceutical or psychosocial treatments.^{5,7-11}

A meta-analysis of ten randomized clinical trials (RCTs) with a total of 455 patients demonstrated the superiority of active tDCS to sham in response (odds ratio of 4.17) and remission (OR 2.88).¹⁰

Figure 1. Sooma tDCS consists of a light-weight, battery-powered stimulator, electrodes with conductive medium and a headcap with fixed electrode positions.

Sooma tDCS™ session: 2 mA direct current for 30 min

Acute treatment:

1 session per day,
5 days a week
for 2 to 3 weeks

Maintenance treatment:

1 session per week up to
6 months or as required



In a recent 10-week randomized double-blind placebo-controlled trial comparing tDCS with escitalopram on 245 patients, both tDCS and escitalopram were superior to placebo.¹²

tDCS has also been studied in patients with bipolar depression. In a recent randomized, double-blind trial on 59 bipolar patients, significantly higher cumulative response rates were observed for patients receiving active tDCS compared to patients receiving sham treatment (67.6% vs. 30.4%).¹³

Current research evidence supports the use of tDCS in major depressive disorder.^{14,15} The National Institute for Health and Care Excellence (NICE) and the Canadian Network for Mood and Anxiety Disorders (CANMAT) have published detailed treatment guidelines of the use of tDCS in MDD.^{7,8,16}

Real-world use of Sooma tDCS™

Patients and Methods

Sooma Depression Therapy is conducted using a portable device and proprietary Sooma accessories (Figure 1). This maximises patient comfort while enabling reproducible electrode placement to targeted locations on the scalp.

The real-life effectiveness and tolerability of Sooma tDCS™ Depression Therapy was evaluated in a cohort of 302 MDD patients collected from ten primary and secondary care clinics worldwide. All patients were treated according to the standard Sooma tDCS™ stimulation protocol: a 2-mA current for 30 minutes every weekday for a total of 2 to 4 weeks, followed by optional maintenance treatment. Clinicians were allowed to adjust the number of treatment sessions according to the patients' needs.

Baseline (pre-treatment) and end-point (post-treatment) depression was scored by the treating nurse or psychotherapist according to their preferred depression scale: HDRS-17, HDRS-21, HDRS-24, BDI-21, MADRS, MDI, or GDS. Study outcomes were clinical response (defined as >50% reduction from the baseline depression score), remission (defined by the grading guideline of each depression scale), and the change in depression score from baseline to the end of treatment.

At baseline, the majority of patients were severely (47%) or moderately (45%) depressed (Table 1). Sooma tDCS™ was used as a monotherapy with 60 patients and as an add-on to medication or psychotherapy for others. The simultaneous treatments were not modified during Sooma Depression Therapy. Altogether, 259 (86%) of the patients completed the treatment course.

Table 1. Patient demographics and treatment characteristics.

Subjects	n (%)
Total number of patients	302 (100)
Patients with depression score available	297 (98)
Completed treatment	259 (86)
Mean age in years ± SD (range)	39 ± 13 (17–82)
Gender	n (%)
Female	146 (57)
Male	111 (43)
Pre-treatment severity	n (%)
Severe	122 (47)
Moderate	116 (45)
Mild	21 (8)
Simultaneous treatment	n (%)
Monotherapy	60 (23)
Add-on therapy*	199 (77)
Psychotherapy	6 (2)
Antidepressant	184 (71)
Antipsychotic	52 (20)
Benzodiazepine	25 (10)
Sooma tDCS™ Depression Therapy	
Total number of treatment sessions	4,022
Mean number of treatment sessions / person	15 ± 4 (6–27)
Duration of follow-up in days ± SD (range)	21 ± 6 (11–37)

* Includes pharmacological treatment and psychotherapy
SD, standard deviation

Effectiveness

The majority of patients experienced a marked improvement as a result of Sooma tDCS™ Depression Therapy. Altogether, 158 patients (61%) achieved clinical response. Post-treatment, 51 patients (20%) were in remission, whereas 160 patients (62%) had mild, 32 (12%) had moderate, and 16 (6%) had severe depression.

Almost all study subjects (95%) experienced an overall decrease in the depression score, the mean improvement being 50%. Monotherapy patients had a higher response rate (77%) compared to patients receiving treatment as an add-on therapy (52%).

Safety

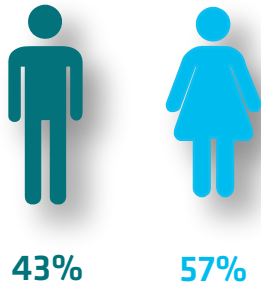
There were no serious adverse events in the cohort during the 4,022 treatment sessions. The majority of reported adverse events were mild and transient reactions to the treatment.

The most common adverse events were itching (54% of patients reported at least once during a treatment course), headache (27%) and skin redness at electrode sites (17%). Two patients (1%) experienced a single episode of hypomania that did not require pharmaceutical intervention.

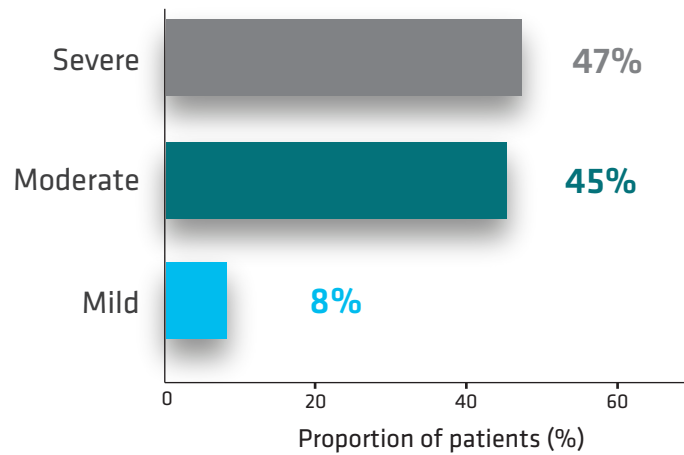
Real-world evidence of Sooma tDCS™ Depression Therapy

Patients

n=259



Baseline severity

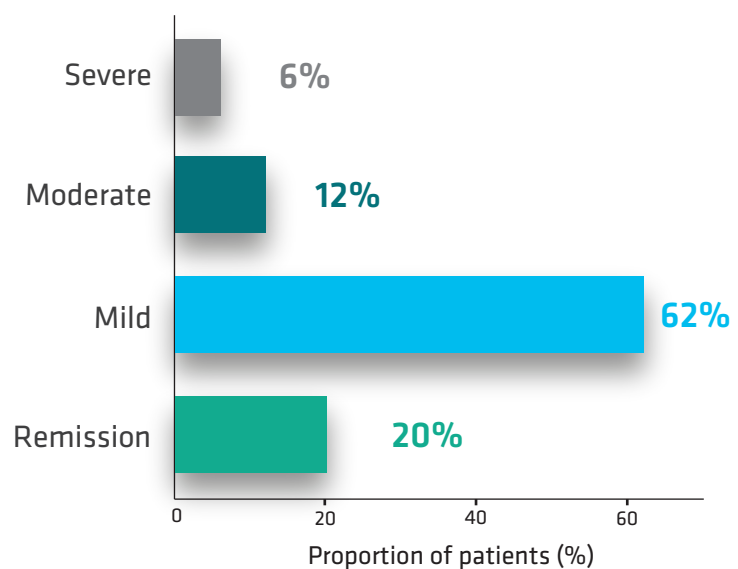


Treatment outcomes

61%
Response rate

50%
Average improvement

Post-treatment severity



Serious adverse events

0%

Most common adverse events

54%

Itching

27%

Headache

17%

Skin redness
at electrode sites

Conclusions

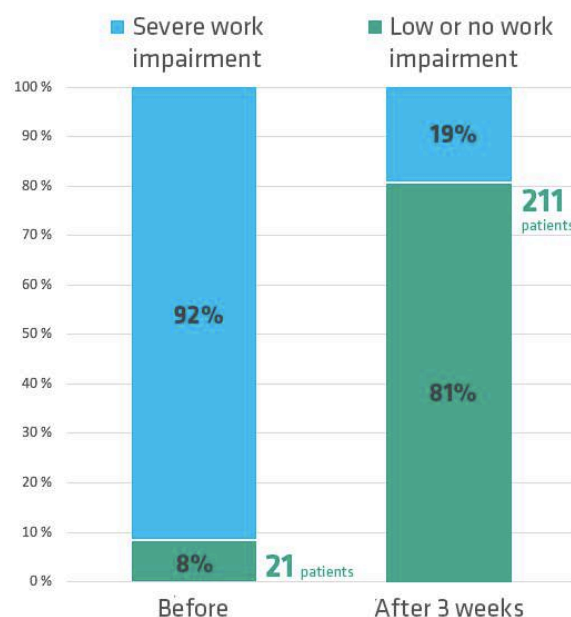
Based on evidence from clinical trials and meta-analyses, tDCS is an effective and well-tolerated treatment for MDD.^{4,6,9-11} The efficacy is now also confirmed with Sooma Depression Therapy.

In this real-world cohort of 302 patients, almost all patients treated with Sooma tDCS™ experienced an overall decrease in the depression score. Before treatment, depressive symptoms caused severe work impairment in 92% of the patients, which was reduced to 19% after treatment with Sooma tDCS™ Depression Therapy. Following the therapy, the majority of patients (81%) experienced low or no work impairment.

There were no serious adverse events and the majority of the reported adverse events were mild and transient. The treatment response was fast: the majority of patients achieved treatment response within the mean follow-up period of 21 days.

Sooma tDCS™ is an easy-to-use and cost-effective treatment option for patients with MDD. The stimulation can be administered by a trained nurse in a clinic, or by the patient at home. The treatment is safe to combine with pharmacological treatment, psychotherapy or group therapy.

Table 2. Improvements in work impairment severity in the majority of patients



Training on the use of Sooma tDCS™ is provided to health care professionals by Sooma Oy on request.

References

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About Sooma

Sooma is a Finnish manufacturer of innovative neuromodulation technologies. Sooma tDCS™ is a CE-marked, TGA and Health Canada approved medical device. Sooma Oy holds ISO13485 certificate.



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