Outcomes of Sooma Depression Treatment

Summary

- Treatment outcomes from 119 patients administered with Sooma Depression Treatment either as add-on treatment or monotherapy.
- The treatment was well tolerated. No serious adverse events occurred during almost 1500 treatment sessions.
- Patients visited an outpatient clinic to receive the treatment, or self-administered it at home. 66% of patients achieved treatment response and 20% complete remission.
- The mean improvement was 54% after two or three weeks of treatment.

Sooma Depression Treatment

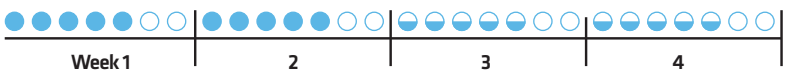
The Sooma tDCS™ medical device consists of a small, battery-powered stimulator, electrodes with saline-soaked sponges and a headcap with pockets for correct electrode positioning. Each session delivers a constant current of 2 mA for 30 minutes, which is repeated each weekday for 2 to 3 weeks. After the acute treatment phase, the sessions can be continued once a week up to 6 months.

Sooma tDCS™ session:

2mA direct current for 30 minutes

● standard protocol ◒ as required

Acute phase: 1 session per day, 5 days a week for 2 to 4 weeks



Maintenance phase: 1 session fortnightly for 4 weeks.
Patients with high risk of relapse: 1 session per week for up to 6 months or as required.

Introduction

Sooma Depression Treatment uses transcranial direct current stimulation (tDCS) to modulate brain activity of the areas affected by depression. It is an effective and well-tolerated treatment option for patients with depression. Sooma Depression Treatment can be prescribed as a monotherapy, or it can be added to pharmaceutical or psychosocial treatment options.

Ten clinics have provided treatment outcomes from patients administered with Sooma Depression Treatment. The outcome data reflect how the treatment is applied in clinical practice today. Moreover, it shows what can be realistically expected as a treatment outcome. The data includes both unipolar and bipolar patients.

Methods

Outcome data from a total of 125 patients (64 females) was provided by ten clinics worldwide. Six patients were excluded from the analysis: Two patients did not have an ongoing depressive episode and four patient forms had incomplete data. Sixty-one of the 119 included patients were females and the patients were aged from 18 to 80.

Majority of patients received the treatment as an add-on while undergoing simultaneous pharmaceutical and / or psychosocial intervention. Of the 98 patients with simultaneous treatments, 80 had at least one antidepressant medication. Twenty-one patients had no other ongoing therapies and 39 had no antidepressant medication.

Five of the reporting clinics represent university hospitals, three are municipality level primary mental healthcare establishments and two offered the treatment as private service providers. The clinics used their preferred depression scale when reporting baseline and end-point data. Treatment response was defined as a 50% decrease in the depression score. Remission was defined by the grading guideline of each depression scale.

All patients were treated using the standard Sooma Depression Treatment protocol shown in front page. Each patient received stimulation sessions with Sooma tDCS™: 2mA current amplitude, 30-minute session duration, electrode size 35cm^2, and bifrontal electrode positioning (anode and cathode on F3 and F4, respectively). Clinicians were allowed to adjust the number of treatment sessions according to patient need. There was no control group.

Results

The treatment course was completed by 103 patients (49 females). Sixteen patients (14%) dropped out before the end of treatment. Six patients dropped out for lack of perceived effect, two patients were referred to ECT and two patients missed too many sessions. Two patients wanted to discontinue after feeling more anxiety and one patient after an undefined side effect. There was no dropout reason given for three patients.

Forty-two patients received an acute treatment of two weeks (10 sessions) while 61 patients were administered with three-week treatment (15 sessions). Three patients had their planned two-week treatment extended to three weeks to improve response. After the acute treatment, 0-10 maintenance sessions were administered in weekly or bi-weekly basis. On average, patients received 14.3 treatment sessions in total. Overview of the patient demographics is shown in Table 1.

Table 1. Overview of the patient demographics. Appreviations: SD = standard deviation, AD = antidepressant.

Subjects	119
Completed treatment	103
Age mean years (SD)	37 (± 14)
Gender	
- Female	49
- Male	54
Simultaneous treatments	
- Monotherapy	20
- Add on therapy	83
- No AD	34
- One AD	46
- Two or more ADs	23
- Antipsychotic	26
- Benzodiazepine	17
Pre-treatment severity	
- Mild	7
- Moderate	38
- Severe	58
Treatment duration	
- 2 weeks	42
- 3 weeks	61
Treatment sessions in total (SD)	14.3 (± 4)

The majority of patients experienced a marked improvement as a result of Sooma Depression Treatment. Sixty-eight patients (65% of all patients) responded to the treatment. There was a statistically significant and clinically meaningful difference in pre-treatment (Mean 27.3 ± Standard deviation = 7.2) and post-treatment scores (13.6 ± 8.0); $p < 0.001$. In total, 22 patients achieved complete remission.

The mean improvement in depression score was 54%. Ten patients improved by more than 75% whereas the score increased for five patients. For the majority of patients, depression score improvement was between 50% and 75% as shown in Figure 1.

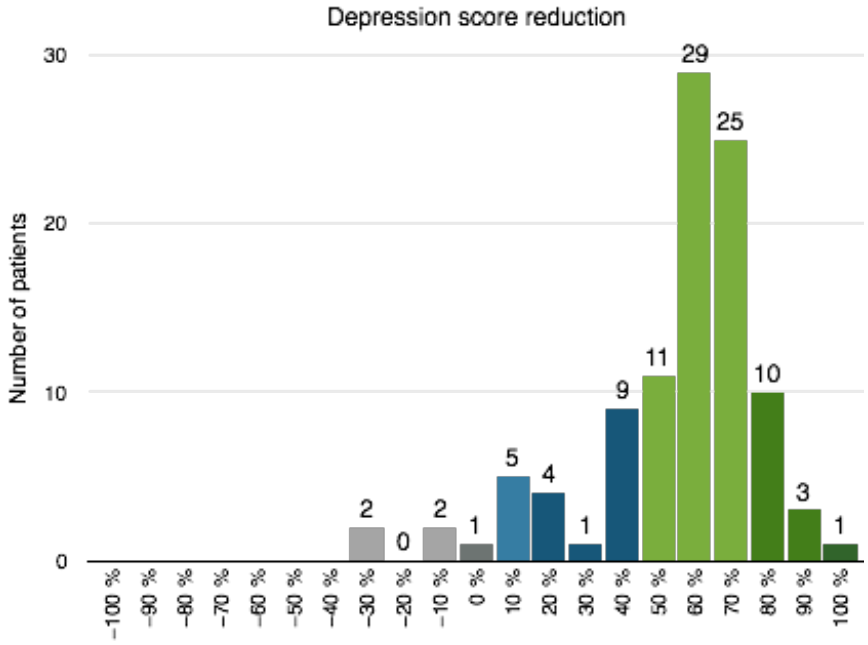


Figure 1. Depression score change after Sooma Depression Treatment.

The depression was severe for most patients before treatment. Thirty-eight of the patients had moderate depression (37%) and seven patients were suffering from mild depression (7%). After two or three-week treatment 84% of the patients had either a mild depression or were in remission. Ten patients (10%) had moderate depression post-treatment, five of who started with severe depression and five with moderate. One patient started with moderate depression but ended with severe depression. Six patients had severe depression in both baseline and post-treatment assessment. Figure 2 shows the depression severity of the patients before and after treatment.

Eighty of the patients (67%) had simultaneous antidepressant medication. Thirty-four were treated with SSRI-class medication, while 31 had SNRI-class antidepressant. On average, these patients had 1,3 ongoing antidepressant pharmaceuticals. Interestingly, patients without simultaneous antidepressant medication improved more (Mean improvement 57% ± Standard deviation = 6,5%) than patients with medication (46% ± 5,5%); $p<0,02$. There was no difference between patients on SNRI and SSRI medications. The dropout rate was similar between patients with and without antidepressant medication.

Twenty-six patients (22%) had antipsychotic pharmaceuticals during Sooma Depression Treatment. Notably, use of antipsychotic medication increased the dropout rate from 9% to 31%. Moreover, patients with antipsychotic medication had lower symptom improvement (Mean improvement 32% ± Standard deviation = 11%) than patients not taking such medication (53% ± 4%); $p<0,001$.

Use of benzodiazepines also increased the likelihood of discontinuing the treatment. The dropout rate was 29% for patients with benzodiazepines and 11% for patients without. A similar increase was also seen for patients taking Zopiclone. Seventeen patients had ongoing benzodiazepine medication and 7 were treated with Zopiclone. Use of benzodiazepines did not affect response rate.

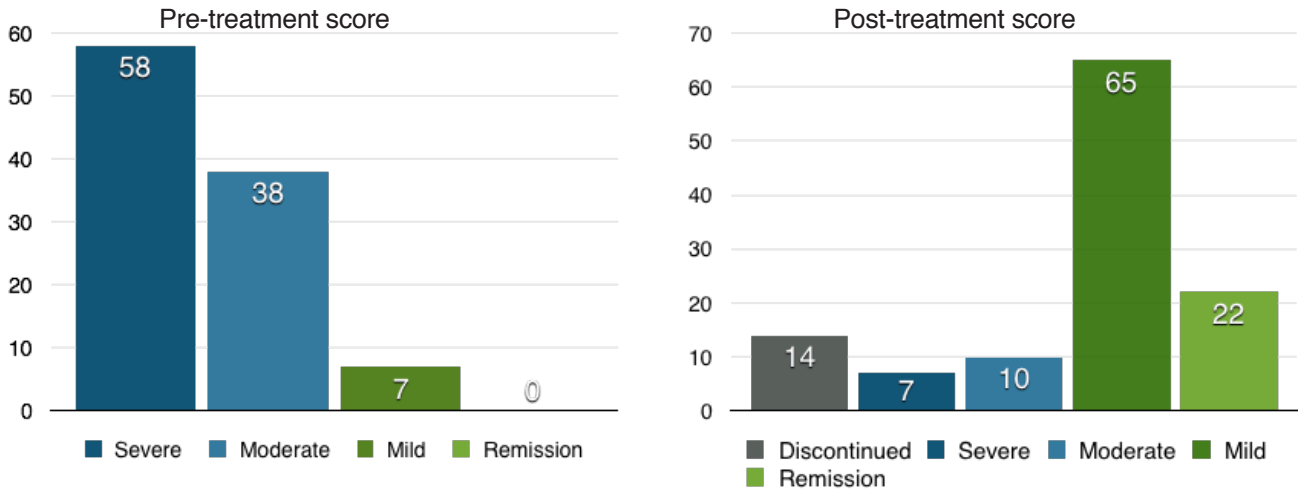


Figure 2. Depression severity before and after treatment. On average, patients had severe depression when starting the treatment and ended up with mild depression after completion of treatment.

"Mornings feel easier, thinking feels clearer"

-Patient with severe depression pre-treatment, who achieved a partial treatment response.

"The patients' mood was significantly better already during the second treatment week. Treatment also positively affected sensations of pain and anxiety"

-Psychotherapist describing the treatment effect for a patient who started with moderate depression and achieved a treatment response.

Patient perspective

Beyond the change in depression score, patients and nurses were encouraged to describe the experienced effects. Decreased anxiety was the most commonly described effect aside from mood improvement. Several patients reported increased activity and better functionality in daily life. Normalized appetite and sleep patterns were also among the effects reported. Notably, positive self-experienced symptom improvements did not always correlate with significant improvement in depression score.

Safety and adverse effects

Sooma Depression Treatment was safe and well tolerated by patients. The 103 patients who completed the treatment received 1477 treatment sessions and over 700 hours of stimulation in total. Most common side effects were itching sensations under the electrode during treatment session (61% of patients reported at least one itching occurrence during treatment phase) and transient headache (25%). The dropout rate was 14%. One patient discontinued the treatment after expressing a side effect. Two cases of mania or hypomania were reported, but they did not result in discontinuation of treatment.

Conclusions

Based on 119 patients reported by ten different clinics, Sooma Depression Treatment is safe and effective treatment for patients suffering from major depressive disorder. Further, the treatment is well tolerated and can be effectively administered either as monotherapy or as add-on treatment. Moreover, there were no technical issues in administering Sooma Depression Treatment in clinical routine use.

Supplementary material including patient demographics and simultaneous medications can be found at www.soomamedical.com/blog/treatment-outcomes

How to get started

Sooma Depression Treatment system is portable and does not require fixed installation or specialized facilities. The treatment session can be administered by a trained nurse in a clinic, or by the patient in a home environment. The treatment is easy to combine with psychotherapy or group therapy. Preparations take only a few minutes and the patient is free to engage in normal activities during the session. Sooma will train you and your staff in the use of the system and in how to deliver further training to your patients. Get in touch to learn more at:

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About Sooma

Sooma Oy is a Finnish medical device manufacturer, which provides innovative neuromodulation technologies. Sooma Depression Treatment utilizes Sooma tDCS, a CE-marked, TGA- and Health Canada approved medical device, that is affordable, easy to use and easily adaptable to clinical routines. Sooma Oy holds ISO13485 and ISO9001 certificates.

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