



The Next Wave of
Depression Treatment



Sooma tDCS™

A small and lightweight device, designed for routine clinical treatment of depression

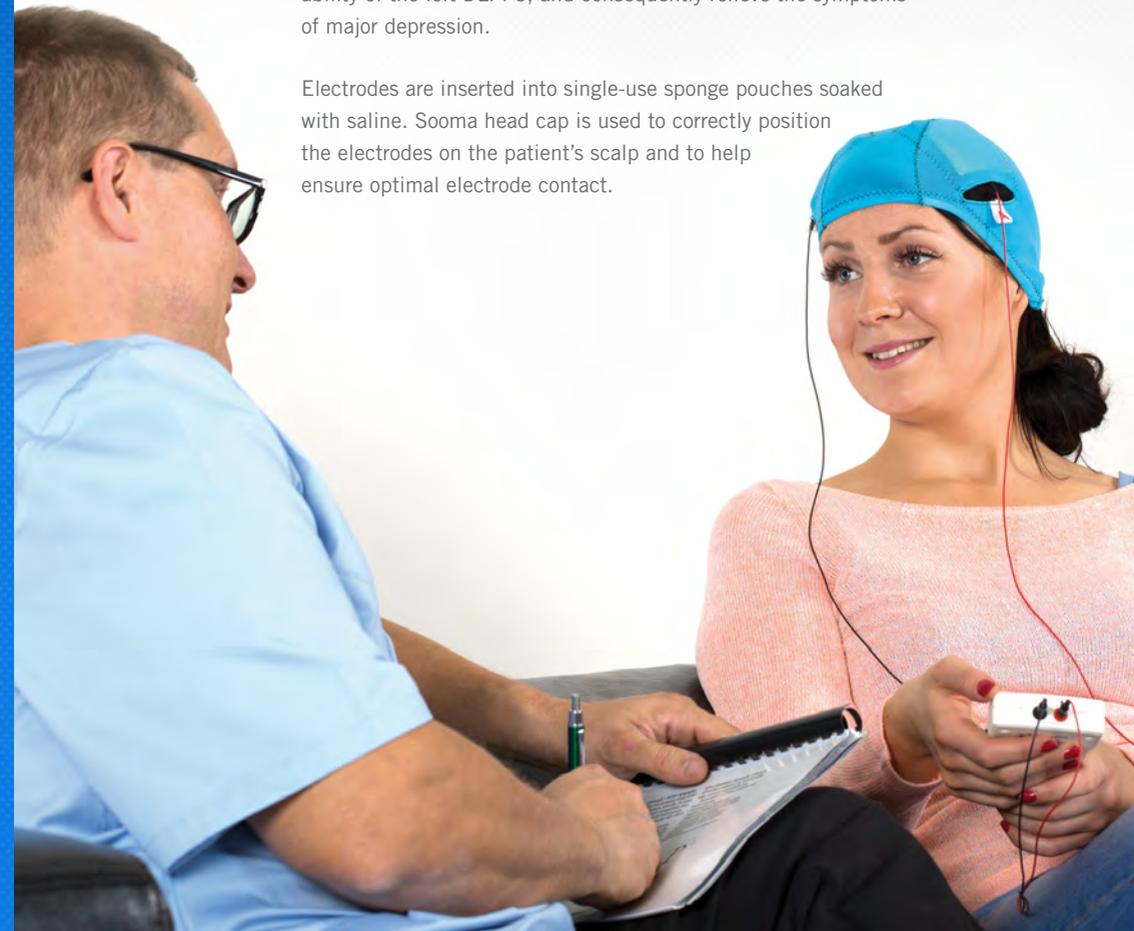
- Effective: additive effects to medication and psychotherapy. A viable monotherapy option even for those who do not benefit from medication⁽¹⁾
- Free from serious side effects: an alternative for patients who cannot tolerate antidepressants
- Easy to use: an automated procedure with only one button to press
- Affordable

The Method

Sooma Depression Treatment utilizes transcranial direct current stimulation (tDCS) to modulate brain activity on dorsolateral prefrontal cortex (DLPFC). A weak electric current is applied to the cortex through two electrodes placed over the scalp. In patients with major depression, the DLPFC is the cortical area where brain function is known to be changed⁽²⁾.

The goal of Sooma Depression Treatment is to increase the excitability of the left DLPFC, and consequently relieve the symptoms of major depression.

Electrodes are inserted into single-use sponge pouches soaked with saline. Sooma head cap is used to correctly position the electrodes on the patient's scalp and to help ensure optimal electrode contact.



Sooma Depression Treatment

Standard protocol

The standard treatment protocol for acute major depression consists of ten daily sessions, excluding weekends. Once all the daily sessions have been completed, there is a maintenance phase of one session every other week, delivered twice. During each session Sooma tDCS™ delivers a constant current of 2 mA for 30 minutes.

Modifications to the standard protocol

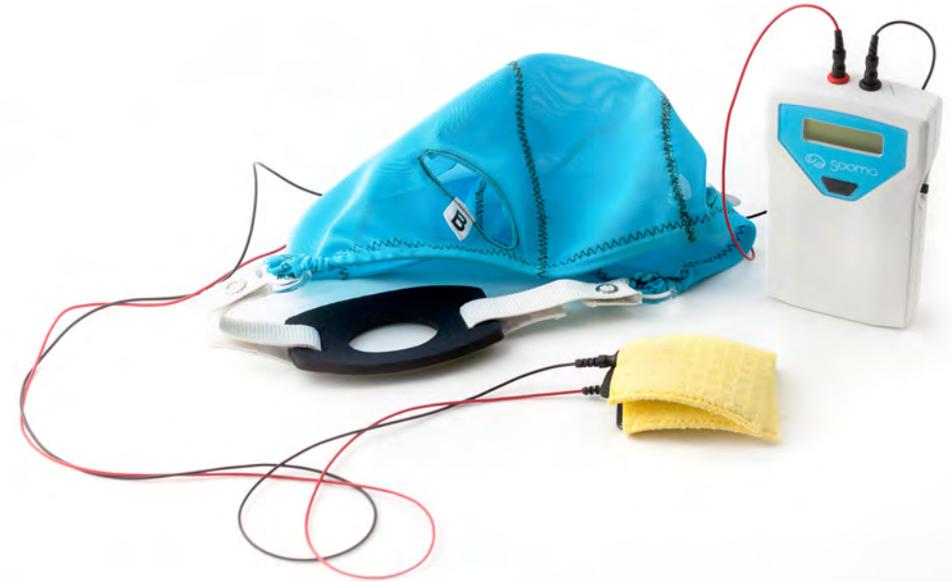
Under the supervision of the attending psychiatrist, the standard protocol may be adjusted for an individual patient's special needs. Such adjustment may include adding one or two extra weeks of daily stimulation to the initial phase or extending the duration of the maintenance phase.

Note that other treatment parameter modifications – either to the placement of electrodes, the duration of the sessions or the stimulation current employed – may require research permission from your institution's ethics committee. For research cooperation, please contact Sooma Oy.

Initial phase



Maintenance regime (after initial phase)



Suitable for most patients

Sooma Depression Treatment is a potential option for most adult patients with major depression. Stimulation can be used as a monotherapy and has been found to have additive effects to both medication^(3,4) and psychotherapy⁽⁵⁾.

Contraindications for the use of Sooma Depression Treatment: implanted active or non-active devices in the head area (excluding dental implants), cardiac pacemaker implantation or acute eczema in the skin under the electrode pouches.

Easy to use anywhere

Starting a treatment session is straightforward. The Sooma tDCS™ device has a single control button. There is no possibility to modify the function of the device by accident. The device has embedded features to ensure that it delivers a constant 2mA current.

Unless the session is combined with simultaneous psychotherapy, presence of a medical professional is not required during the 30 minute stimulation period.

Clinical Impact

Efficacy

In a study by Brunoni et al.⁽⁹⁾, the use of tDCS alone led to a remission rate of 40%, whereas the remission rate for tDCS and sertraline combined was 47%. Shiozawa's⁽⁷⁾ meta-analysis of tDCS studies concluded that the results of active tDCS treatment in depression are clinically relevant.

Duration of effects

In a study by Martin et al.⁽⁸⁾, with weekly maintenance 84% of patients avoided relapse for three months after the acute treatment stage. In Boggio et al's⁽⁹⁾ study, patients were found to be free from relapse without active maintenance for one month after completion of a treatment period.

Safety and Tolerability

tDCS is well tolerated and is not associated with serious side-effects or withdrawal effects^(10,11). Itching or tingling of the skin under the electrodes and a mild headache are relatively common but harmless symptoms of tDCS treatment.



References

1. Rush AJ, Trivedi MH, Wisniewski SR, Nierenberg AA, Stewart JW, Warden D, Niederehe G, Thase ME, Lavori PW, Lebowitz BD, McGrath PJ, Rosenbaum JF, Sackeim HA, Kupfer DJ, Luther J, Fava M: Acute and long-term outcomes in depressed outpatients requiring one or several treatment steps: a STAR*D report. *Am J Psychiatry* 2006 Nov; 163(11): 1905-17
2. Mayberg HS, Brannan SK, Tekell JL, Silva JA, Mahurin RK, McGinnis S, Jerabek PA: Regional metabolic effects of fluoxetine in major depression: serial changes and relationships to clinical response. *Biol. Psychiatry*. 2000 Oct 15;48(8):830-43
3. Brunoni AR, Valiengo L, Baccaro A, Zanão TA, de Oliveira JF, Goulart A, Boggio PS, Lotufo PA, Benseñor IM, Fregni F. The sertraline vs. electrical current therapy for treating depression clinical study: results from a factorial, randomized, controlled trial. *JAMA Psychiatry*. 2013 Apr; 70(4):383-91.
4. Meron, D., Hedger, N., Garner, M., Baldwin, D.S., Transcranial direct current stimulation (tDCS) in the treatment of depression: systematic review and meta-analysis of efficacy and tolerability, *Neuroscience and Biobehavioral Reviews* (2015)
5. Segrave RA, Arnold S, Hoy K, Fitzgerald PB. Concurrent cognitive control training augments the antidepressant efficacy of tDCS: a pilot study. *Brain Stimul*. 2014 Mar-Apr; 7(2):325-31.
6. Brunoni AR, Ferrucci R, Bortolomasi M, Vergari M, Tadini L, Boggio PS, Giacopuzzi M, Barbieri S, Priori A. Transcranial direct current stimulation (tDCS) in unipolar vs. bipolar depressive disorder. *Prog Neuropsychopharmacol Biol Psychiatry*. 2011 Jan 15;35(1):96-101
7. Shiozawa P, Fregni F, Benseñor IM, Lotufo PA, Berlim MT, Daskalakis JZ, Cordeiro Q, Brunoni AR. Transcranial direct current stimulation for major depression: an updated systematic review and meta-analysis. *Int J Neuropsychopharmacol*. 2014 Sep;17(9):1443-52.
8. Martin DM, Alonzo A, Ho KA, Player M, Mitchell PB, Sachdev P, Loo CK. Continuation transcranial direct current stimulation for the prevention of relapse in major depression. *J Affect Disord*. 2013 Jan 25; 144(3):274-8.
9. Boggio PS, Rigonatti SP, Ribeiro RB, Myczkowski ML, Nitsche MA, Pascual-Leone A, Fregni F. A randomized, double-blind clinical trial on the efficacy of cortical direct current stimulation for the treatment of major depression. *Int J Neuropsychopharmacol*. 2008 Mar;11(2):249-54.
10. National Institute for Health and Care Excellence (NICE) guidance 2015: Transcranial direct current stimulation (tDCS) for depression. Available from www.nice.org.uk/IPG530
11. Brunoni AR, Amadera J, Berbel B, Volz MS, Rizzerio BG, Fregni F. A systematic review on reporting and assessment of adverse effects associated with transcranial direct current stimulation. *Int J Neuropsychopharmacol*. 2011 Sep; 14(8): 1133-45

About Sooma

Finland-based Sooma Oy is a medical device manufacturer developing innovative neuromodulation solutions. Sooma tDCS™ is a CE-marked device that is affordable, easy to use, and easily adaptable to various clinical routines. Sooma's products are designed and manufactured according to internationally recognized standards of performance. Sooma is an ISO 13485 and ISO 9001 certified company, and has international patents granted.

Contact

Sooma Oy

Kuortaneenkatu 2

00510 Helsinki

Finland

www.soomamedical.com

+358 10 328 9811

e-mail: info@soomamedical.com