MANUAL

TDCS FOR THE TREATMENT OF MAJOR DEPRESSIVE DISORDER: FREQUENTLY ASKED QUESTIONS

sooma

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MK40- 1.0 EN Sooma Oy 2022

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Keywords: *tDCS, MDD, depression, neuromodulation, treatment, therapy.*

ABOUT SOOMA

MISSION AND VISION

SOOMA OY IS A FINNISH MEDICAL DEVICE COMPANY ESTABLISHED IN 2013. SINCE THE START, WE HAVE BEEN WORKING CLOSELY WITH LEADING EXPERTS IN PSYCHIATRY AND CLINICAL NEUROPHYSIOLOGY TO DEVELOP EFFECTIVE TREATMENT SOLUTIONS FOR HEALTH CONDITIONS IN THESE AREAS.

TUOMAS NEUVONEN

CEO AND FOUNDER

Tuomas is a medical device entrepreneur with extensive expertise in n brain stimulation devices. He is the mind behind the idea about the company and the product, and has built them up from the ground to a international business in over 30 countries.

MIKA NIKANDER

COO

Mika is our experienced expert with a portfolio of projects from product development, quality and regulatory affairs, and clinical support activities. He joined Sooma already in 2013 after finishing his own medical device product development project.

PETER HILGERT

CCO

With more than 20 years of experience in different commercial roles in the pharmaceutical industry, Peter has a profound knowledge of marketing and sales in large organizations, as well as extensive experience in the start-up environment.

SOOMA TDCS

In 2014, we launched Sooma Depression Therapy, a brain stimulation treatment for Major Depressive Disorder, along with Sooma tDCS, the high-end stimulation device that is used to conduct the treatment. Sooma tDCS medical devices are manufactured in Finland in accordance with the international ISO 13485 quality management system for medical devices. The treatment device developed by Sooma has received the following approvals from the world's health authorities, among others:

2014: Class IIA CE marking (Depression) | 2015: Malaysian Medical Device Authority (MDA) | 2016 Australian TGA (Therapeutic Goods Administration) | 2016: Health Canada (Chronic pain class II) | 2017: Singapore HSA (Health Science Authority) | 2017: CE marking (Chronic pain) | 2017: Turkey (Depression) | 2018: Mexican COFEPRIS (Federal Commission for Protection against Health Risks) | 2019: Indonesia (Depression)

TDCS FOR THE TREATMENT OF MAJOR DEPRESSIVE DISORDER: FREQUENTLY ASKED QUESTIONS

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. 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. The flow of current from the positive to the negative electrode influences the activity in the prefrontal cortex, relieving symptoms in depressed patients.

tDCS therapies are an increasingly used, safe, and effective method to treat MDD. However, in our daily practice we find the same doubts and questions regarding tDCS being raised time and again. The goal of this manual is to provide science-based answers to the most frequently asked questions regarding the use of tDCS for the treatment of MDD.

01

The treatment

In this section, we cover the most common questions regarding the use of tDCS therapies for the treatment of MDD.

We review the main differences between tDCS and other neuromodulation treatment options, as well as the possible synergistic effects of those in combination with tDCS.

We cover the possible expected results of the treatment in terms of response to the treatment, duration of the response, and effect on common concomitant depressive symptoms such as anxiety and sleep disorders.

02

Patients selection criteria

In this section, we cover the most common questions regarding the criteria for determining which patients are the best suited to be treated with tDCS.

We describe the hypothetical most suitable patient to be treated with tDCS and take a look at special cases, such as patients suffering from bipolar depression or other neurological disorders.

We also present the feasibility of using tDCS in patients being treated with other non-neuromodulation treatments, and the possible synergistic effects of such combination.

03

Contraindications and side-effects

In this section, we take a look at the contraindications and possible safety considerations regarding the use of tDCS therapies, with a special mention to the most common side-effects.

USING TDCS IN THE TREATMENT OF MDD

INTRODUCTION

TDCS RELIEVES THE SYMPTOMS OF MDD BY MODULATING CORTICAL EXCITABILITY OF THE DORSOLATERAL PREFRONTAL CORTEX WITH A WEAK STIMULATION CURRENT.

The use of neuromodulation techniques for the treatment of mood disorders has been ongoing since the beginning of the 20th century.

Starting with Electro-convulsive Therapy (ECT) and moving towards a wider range of invasive and non-invasive therapies, the use of electricity or electromagnetic fields to regulate neuronal activity is a proven method to treat diverse psychiatric conditions.

Invasive neuromodulation involves surgically implanting several components into the body: a small stimulation device –often placed in the chest area; electrodes, placed in the stimulation targets; and leads connecting the two. The stimulation device sends stimulus, in the form of electric impulses, through the leads to the electrodes, stimulating the target area for the desired result. Examples of invasive neuromodulation are Deep Brain Stimulation (DBS), Spinal Cord Stimulation (SCS), and Vagus Nerve Stimulation (VNS), which are most commonly used to treat movement disorders, pain, and epilepsy, respectively.

In **non-invasive neuromodulation**, the stimulation electrodes or the electromagnetic coil are placed externally on top of the scalp, in such locations that the electric field will be formed to the target areas of the brain. To treat major depressive disorder (MDD), ECT and Transcranial magnetic stimulation (TMS) are currently the most commonly used methods. Transcranial direct current stimulation (tDCS) is a relatively newer stimulation method to treat depression and is the method used by Sooma Therapies.

tDCS relieves the symptoms of 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 (for review see Tortella et al. 2015). 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

tDCS is an effective and well-tolerated treatment for MDD with an A level of evidence

	Condition	Recommendation	Pooled effect sizes*
Pain	Neuropathic pain	Anodal M1 tDCS probably effective in reducing neuropathic pain (Level B)	−0.29 (−0.60, 0.02)
	Fibromyalgia	Anodal M1 tDCS probably effective in reducing fibromyalgia pain (Level B)	−0.42 (−1.23, −0.40)
	Migraine	Anodal M1 tDCS probably effective in reducing migraine pain (Level B)	−0.41 (−1.40, 0.59)*
	MPS	No recommendation	Not estimable
	Postoperative acute pain	Postoperative anodal M1 tDCS probably effective in reducing patient-controlled analgesia and pain (Level B)	−0.70 (−1.09, −0.30)
	Low back pain	No recommendation	Not estimable
PD	Motor Function	Anodal motor/premotor/SMA tDCS possibly effective for motor function in PD (Level C); anodal prefrontal tDCS probably not effective for motor function in PD (Level B)	−0.38 (−0.68, −0.09)
	Cognitive Function	Anodal DLPFC tDCS probably effective for cognitive function in PD (Level B)	−0.33 (−1.02, 0.35)
Chronic stroke	Motor Function	Anodal tDCS of ipsilesional M1 probably effective for motor rehab in chronic stroke (Level B); Anodal tDCS of ipsilesional M1 to enhance robotic therapy probably not effective for motor rehab in chronic stroke (Level B); Cathodal tDCS of contralesional M1 probably effective for motor rehab in chronic stroke (Level B); Bilateral tDCS of M1 probably effective for motor rehab in chronic stroke (Level B)	0.52 (−0.04, 1.09); 0.23 (−0.31, 0.77); 0.44 (−.18, 1.06); 0.44 (0.10, 0.79)
	Aphasia	Anodal tDCS of Broca's area, its homologue, or Wernicke's area is possibly effective in chronic post−stroke aphasia rehab (Level C); Cathodal right frontoorbital tDCS is possibly effective in chronic post−stroke aphasia rehab (Level C); Bilateral tDCS w/ anodal stimulation of Broca's area and cathodal stimulation of its homologue is possibly effective in chronic post−stroke aphasia rehab (Level C)	Broca's Area: 0.65 (0.25, 1.01); Not estimable; Not estimable
Subacute stroke	Motor Function	Anodal tDCS of ipsilesional M1 probably effective for motor rehab in subacute stroke (Level B); Anodal tDCS of ipsilesional M1 to enhance robotic therapy is definitely not effective for motor rehab in subacute stroke (Level A); Cathodal tDCS of contralesional M1 probably effective for motor rehab in subacute stroke (Level B); Cathodal tDCS of contralesional M1 to enhance robotic therapy probably not effective for motor rehab in subacute stroke (Level B); Bilateral tDCS of M1 is possibly effective for motor rehab in subacute stroke (Level C)	0.44 (−0.19, 0.91); 0.01 (−0.31, 0.34); 0.47 (0.10, 0.84); Not estimable; 0.39 (−0.07, 0.86)
Epilepsy	Seizure frequency	Cathodal tDCS probably safe (no increase in seizures) and effective (decrease in seizures) in epilepsy (Level B)	−0.70 (−1.38, −0.02)
MDD	Depression	Anodal left DLPFC tDCS is definitely effective for treatment of depression in MDD (Level A)	−0.96 (−0.46, −0.96)
OCD and TS	OCD	Anodal pre−SMA tDCS is possibly effective in improving OCD symptoms (Level C)	−0.61 (−3.87, 0.64)
	TS	No recommendation	Not estimable
Schizophrenia	Auditory hallucinations and positive/negative symptoms	Anodal left prefrontal w/ cathodal left temporoparietal tDCS probably effective for reducing auditory hallucinations in schizophrenia (Level B)	−0.47 (−0.72, −0.22)
Addiction	Alcohol: craving or relapses	Right DLPFC anodal w/ left DLPFC cathodal tDCS probably effective in decreasing relapses or craving in alcohol addiction (Level B)	0.23 (−0.08, 0.40)
	Crack−cocaine	No recommendation	Not estimable
	Methamphetamine	No recommendation	Not estimable

Summary of Recommendations on tDCS Efficacy According to Clinical Indications (Fregni et al. 2021)

in depressed patients (Fitzgerald et al. 2006, Grimm et al. 2008). The flow of current from the positive to the negative electrode influences the neuronal activity in the prefrontal cortex (Tortella et al. 2015), and leads to relieving symptoms in depressed patients (Brunoni et al. 2010).

tDCS can be administered as a monotherapy, or as an adjunct treatment to enhance the effect of pharmaceutical or psychological therapy (Brunoni et al. 2013, Segrave et al. 2014). The efficacy and safety of tDCS have been shown in randomized controlled clinical studies, either as a monotherapy or as an adjunct therapy to pharmaceutical or psychosocial treatments (Brunoni et al. 2013, National Institute for Health and Care Excellence 2015a, National Institute for Health and Care Excellence 2015b, Brunoni et al. 2011, Mutz et al. 2018, Brunoni et al. 2016).

Based on evidence from clinical trials and meta-analyses, tDCS is an effective and well-tolerated treatment for MDD with an A level of evidence (Fregni et al. 2021).

THE TREATMENT

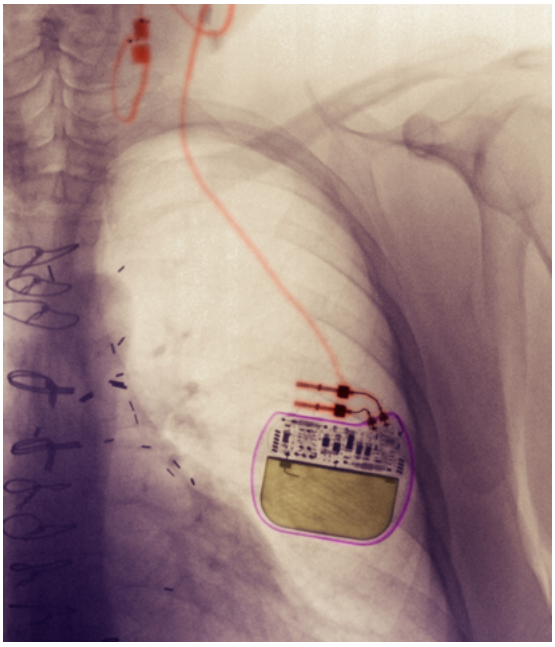
BASICS OF TDCS

WHAT ARE THE MAIN DIFFERENCES BETWEEN TDCS THERAPIES AND OTHER NEUROMODULATION TREATMENT OPTIONS FOR MDD?

tDCS therapies are a non-invasive neuromodulation method that uses a weak electric current (approx. 2mA) to stimulate targeted areas of the brain. The treatment protocol often involves a daily stimulation session for 3-6 weeks, which totals about 15-30 sessions. tDCS is regarded as a safe treatment method and does not cause any serious adverse effects (Brunoni et al. 2010, Segrave et al. 2014). Non-serious side effects include mild headache, and an itching sensation or redness in the stimulated area (Russo et al. 2017). In addition to using tDCS as monotherapy or augmentation therapy, tDCS can be used as a maintenance treatment to retain the effects after acute treatment with either Electro-convulsive Therapy (ECT) or Transcranial Magnetic Stimulation (TMS). More importantly, certain tDCS therapies–like Sooma Therapy, can be administered at home by the patient, alleviating the workload of clinics and hospitals.

In contrast, other non-invasive therapies like ECT or TMS, require the patient to visit the hospital or clinic daily for the administration of the treatment either because the patient needs to be under medical super-vision due to anesthesia (ECT), risk of seizures (TMS), and just simply because the equipment is not mobile and the treatment is not suitable for self-administra-tion. Also, associated risks and side-effects, even when uncommon, are more serious (Taylor, Galvez, and Loo 2018, Andrade, Arumugham & Thirthalli 2016).

Finally, invasive treatments like Deep brain stimulation (DBS), Spinal Cord Stimulation (SCS), and Vagus Nerve Stimulation (VNS) require a surgical procedure during which implants are inserted into the patient's body, and they carry the risks associated with demanding invasive surgery and post-surgery recovery as well as a wider range of associated side-effects. Furthermore, the first two treatments require subsequent surgeries for the replacement of the device batteries every 2-10 years, depending on the device and battery type.

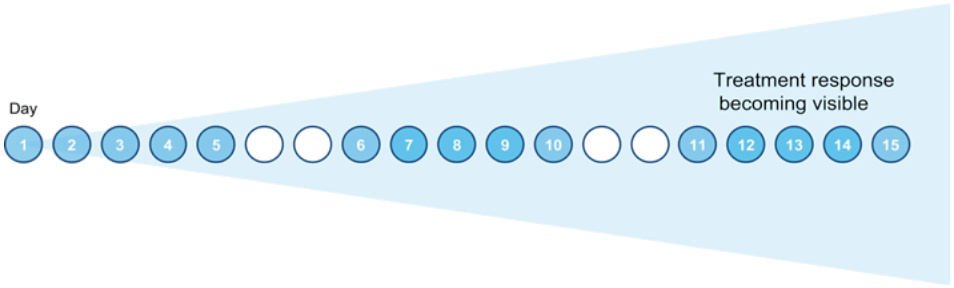


VNS implant on a patient's chest (Image: Shutterstock)

Neuromodulation technique	Treatment protocol	Location of session	Anesthesia required	Hospitalization required	Side-effects and associated risks	Follow ups
Invasive neuromodulation						
Deep Brain Stimulation (DBS)	Pre-surgery evaluations and test. Surgical implant installation with a few days hospitalization. Programming of the device a few weeks after surgery. Adjustment of the protocol over a few weeks to months.	Hospital (several visits before, durign and after implant surgery) and home (stimulation)	Yes	Yes	Risks associated with major surgery and general anesthesia, seizure, headache, confussion, difficulty concentrating, hardware complications.	Need to change the device batteries every 3-5 years (new surgery required)
Vagus Nerve Stimulation (VNS)	Pre-surgery evaluations and test. Surgical implant installation with a few days hospitalization. Programming of the device a few weeks after surgery. Adjustment of the protocol over a few weeks to months.	Hospital (several visits before, durign and after implant surgery) and home (stimulation)	Yes	Yes	Risks associated with major surgery and general anesthesia, difficulty swallowing, vocal cord paralysis, throat pain/hoarseness, tingling or prickling of the skin, shortness of breath.	Need to change the device batteries every 3-8 years (new surgery required)
Non-invasive neuromodulation						
Electro-Convulsive Therapy (ECT)	Pre-treatment evaluation. 1 hour treatment sessions 2/3 times a week during 3/4 weeks.	Hospital	Yes	Temporary (outpatient)	Risks associated with seizure induction and anesthesia,loss of memory, heacaches, nausea, muscle pain or soreness, disorientation and confusion.	Mantainance sessions either by ECT, TMS or tDCS therapies.
Transcranial Magnetic Stimulation (TMS)	Pre-treatment evaluation. 1 hour treatment, 5 times a week, during 4/6 weeks.	Hospital	No	Temporary (outpatient)	Risk of seizures, maniac switch, hearing loss. Headaches, skin discomfort during stimulation, muscle spasms, lightheadedness.	Mantainance sessions either by TMS or tDCS therapies.
Transcranial Direct Current Stimulation (tDCS)	30 minutes treatment, 5 times a week, for a minimum of 3 weeks.	Hospital or home	No	No	Redness of the stimulation area, itching or tingling sensation on the skin, transient headache.	Mantainance sessions by tDCS if needed.

HOW LONG DOES ONE COURSE OF TREATMENT TAKE?

One course of treatment usually lasts a minimum of 3 weeks, depending on the patient profile, after which maintenance treatment can be applied. Generally, a longer treatment period –that is a higher number of sessions, correlates with a better response.



According to our clinical data, the minimum recommended treatment course with Sooma Depression Therapy is 3 weeks of acute treatment, followed up by a maintenance period. However, the clinical practice of most of our customers seem to indicate that a longer period treatment will yield better results. During the acute treatment phase, a 30-minutes stimulation session is performed five times a week.

HOW LONG DOES IT TAKE FOR THE EFFECTS OF THE TDCS THERAPY TO BE NOTICED?

The successful response to the therapy will depend on the characteristics of the patient such as the severity of the depressive episode, the type of depressive episode (unipolar versus bipolar), or a concurring treatment with antidepressants or other drugs (Brunoni et al. 2016). Although some patients can receive significant improvement in their condition already starting after one week of tDCS therapy, in most cases the response will require several weeks of treatment (Goerigk et al., 2020). Furthermore, the level of response is correlated with tDCS dose (the number of sessions, their duration and current level used), and it is inversely associated with existing treatment-resistance (Brunoni et al. 2016).

Generally speaking, the treatment-resistant MDD patients are a challenging patient group also for tDCS therapy, and the three clinical studies using a one, two or three weeks tDCS treatment protocol, respectively, each failed to find significant improvement with tDCS therapy in the treatment-resistant MDD patients (Bennabi et al, 2014; Palm et al., 2011 and Blumberger et al., 2012). It was concluded after these studies that more intensive (more sessions, longer treatment period, etc) tDCS treatment could be required in this chronic and harder to treat depression group.

However, it must be considered that the response rate is very patient-specific and that the more adequate the patient selection process, the faster and more optimal the results of the therapy will be. More on the patient's selection criteria will be explored in upcoming sections.

HOW LONG DO THE TDCS TREATMENT EFFECTS LAST?

Regarding the duration of therapeutic effects on the long-term, there is scarce literature with follow ups after acute treatment sessions for MDD patients. Valiengo et al. (2013) analyzed the 24-weeks follow-up period after a-two-week-acute tDCS treatment (10 sessions) followed by maintenance treatment with one tDCS session every other week. They found that 23% of the nontreatment-resistant and 90% of the treatment-resistant MDD patients relapsed during the follow-up, the mean response duration being 11,7 weeks (Valiengo et al, 2013).

Later, Aparicio et al. (2019) did a 6-month's follow up study where the patients received three weeks of acute tDCS treatment (15 sessions), followed by maintenance treatment with two tDCS sessions every week for relapse prevention. Similarly to previous study, they found a lower relapse trend for the nontreatment-resistant vs. the treatment-resistant patients, the rates of relapse being 7.7% and 45.5%, respectively. The mean response duration in their study was 17,5 weeks.

Interestingly, these data suggest that longer acute tDCS schedules with more intense maintenance treatment improve prevention of relapse and underline the importance of scheduling long enough tDCS treatment periods especially to the more severe and treatment-resistant patients.

CAN TDCS THERAPY BE COMBINED WITH OTHER NEUROMODULATION THERAPIES?

Absolutely. There is evidence both in the literature and clinical practice that patients that respond positively to other non-invasive neuromodulation treatments will also respond well to tDCS as a maintenance treatment option (Cha et al. 2016). Furthermore, tDCS can be used as preconditioning treatment prior to the administration of an acute phase treatment with rTMS, as it has been demonstrated that tDCS preconditioning enhances cortical plasticity and can shape the direction of rTMS-induced after-effects. (Lang et al. 2004, Consentino et al. 2012, Alkhasli et al. 2022).

HOW ARE OTHER DEPRESSIVE SYMPTOMS SUCH AS ANXIETY OR SLEEP DISORDERS AFFECTED BY TDCS THERAPY?

In a recent publication, Goerigk et al (2021) analysed the therapeutic effect to four different depression symptoms clusters: core depressive symptoms, atypical, sleep/insomnia and guilt/anxiety. Among the symptoms' clusters, tDCS treatment results were superior to placebo in core depressive and sleep/insomnia scores. On the other hand, tDCS and pharmacotherapy seemed to differ to some extent in their efficacies against different symptoms of depression. tDCS was effectively reducing the core depressive and sleep/insomnia cluster symptoms whereas escitalopram was reducing the core depressive and guilt/anxiety cluster symptoms. Also the efficacy of tDCS on the guilt/anxiety cluster symptoms was better than with placebo, but due to high variability this difference did not reach statistical significance.

Sleep/ insomnia	Atypical	Core depressive	Guilt/ Anxiety
Sleep-onset insomnia	Suicide	Mood (sad)	Guilt and delusions
Early morning insomnia	Psychomotor agitation	Loss of interest	Energy/ Fatigability
Midnocturnal insomnia	Psychomotor slowing		Reduced libido
	Hypochondriasis		Psychological anxiety
			Somatic anxiety

MDD symptoms clusters as per HDRS-scale.

PATIENT SELECTION CRITERIA

USUAL AND SPECIAL CASES

ANY PATIENT SUFFERING FROM MDD WHO IS NOT OTHERWISE INCLUDED IN THE CONTRAINDICATIONS SECTION OF THIS DOCUMENT CAN BE TREATED WITH TDCS THERAPY

WHO IS A SUITABLE PATIENT FOR TDCS THERAPY?

As a general rule, any patient suffering from MDD who is not otherwise included in the contraindications section of this document can be treated with tDCS therapy. However, it is worth noting that the patient profile will have an effect on the final result of the treatment.

According to the literature, tDCS has lesser efficacy in treatment-resistant depressed patients (Bennabi & Haffen 2018, Brunoni et al. 2016). On the other hand, depression severity is positively related to clinical improvement (Bennabi & Haffen 2018).

Therefore, it could be stated that tDCS is suitable for patients with a mild-to-severe form of MDD who do not meet the criteria for resistant depression (Bennabi & Haffen 2018).

HOW DOES TDCS THERAPY WORK IN COMBINATION WITH OTHER NON-NEUROMODULATION DEPRESSION TREATMENTS?

The combination of treatment methods has been researched and showed that the final effects of tDCS are affected to a great extent by using concomitant pharmacotherapy and/or other interventions, such as cognitive control therapy (CCT).

Regarding the use of antidepressant medication, setraline has been shown to have a synergistic therapeutic effect when combined with tDCS (Brunoni et al. 2013a). On the other hand, the use of benzodiazepines has been correlated with a worse improvement through neuromodulation treatments such as tDCS and rTMS, which could be due to the fact that cortical excitability is decreased when using benzodiazepines (Goerigk et al. 2020).

Concerning the effects of combining tDCS with cognitive therapy, the results are mixed. While Segrave et al. (2014) found preliminary evidence that concurrent CCT enhances antidepressant outcomes from tDCS, Brunoni et al. (2014) could not find significant relevance on the superiority of combined active treatments versus sham.

CAN TDCS BE USED TO TREAT MDD IN EPILEPTIC PATIENTS?

The safety of tDCS has been extensively studied in regards to epilepsy across multitude of stimulation paradigms. There are no reports of epileptic seizures caused by tDCS in the literature (Bikson et al. 2016). tDCS has also been used for epileptic patients. In a meta-analysis of 6 articles including 65 stimulated subjects, San Juan et al. (2015) found evidence that tDCS are shown to be preliminary safe and effective for patients with epilepsy.

Furthermore, the evidence points towards cathodal tDCS leading to reduction in seizure frequency (Regner et al. 2018) and may lead to better seizure control in drug-resistant focal epilepsy (Sudbrack-Oliveira et al. 2021). Therefore, Sudbrack-Oliveira et al. (2021) concluded that cathodal tDCS is overall safe and not directly associated with seizures in adults and children with drug-resistant epilepsy.

CAN PATIENTS WITH BIPOLAR DEPRESSION BE TREATED WITH TDCS THERAPY?

Bipolar depression is challenging to maintain in balance and unfortunately the available antidepressant treatment options are unsatisfactory and carry the risk of switching from depression to hypomania/mania (Roger et al. 2019). Thus, there is an apparent need to develop new antidepressant treatments for patients with bipolar depression.

tDCS treatments have shown promise as an effective and safe treatment option for bipolar depression (Sampaio-Junior et al. 2018, Dondé et al. 2017, Dondé et al. 2018). However, as with other antidepressant treatments, a risk for hypomania/mania switch has been reported with tDCS treatment of bipolar depression, suggesting that concomitant use of mood stabilizers and closer monitoring of the patients is prudent (Dondé et al 2017, Dondé et al. 2018).

Regarding the effects of tDCS stimulation in HDRS-17 Score on bipolar patients, Sampaio-Junior et al. (2018) demonstrated that, over the course of 6 weeks, the active tDCS stimulation was superior to sham. Active stimulation provided a steady decrease from the baseline score, that in week 6 was more than 10 points lower than in the beginning of the research. On the other hand, while sham stimulation initially also caused a decrease of the score, this was smaller, and was not sustained over the duration of the experiment, increasing again after the fourth week. Furthermore, active tDCS was superior to sham for providing sustained response (reduction in depression score of more than 50%), showing that the effect of active tDCS was also clinically significant in this patient group.

Most importantly, some emerging data suggest that tDCS improves neurological soft signs and sleep quality in euthymia, and therefore can be useful for relapse prevention (Dondé et al. 2018).

CONTRAINDICATIONS

AND SIDE-EFFECTS

WHAT ARE THE CONTRAINDICATIONS FOR THE USE OF TDCS IN THE TREATMENT OF MDD?

Most patients are eligible for tDCS therapy, but the eligibility of those suffering from some very specific comorbidities and acute conditions must be consulted with a specialist.

The list of widely accepted contraindications includes patients who present:

- pacemakers

Although scientific studies have shown that a mild electrical current administered on the scalp will not affect a pacemaker (Roncero et al. 2020), it is a vital implant to the patient, and thus extra care is necessary.

- metal inside the skull

An object inside or at the skull is generally a contraindication for receiving electrical currents, since there is a risk that those will damage the brain tissue surrounding the metallic implant. If the metal is located in the neck or the jaw, for instance dental fillings, it is safe to use tDCS.

- Acute eczema on the stimulation area

Broken skin on the stimulation area is a contraindication for using the treatment, as the current, even if mild, can worsen the condition.

WHAT ARE THE SIDE-EFFECTS ASSOCIATED WITH THE USE OF TDCS THERAPY?

No serious side effects or long term effects have been associated with the use of tDCS treatments. However, minor side effects during the stimulation might include (Liu et al. 2017):

1. Burning or tingling sensation on the electrode placement area

2. Transient headache

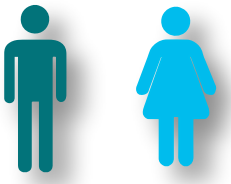
3. Redness of the scalp

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. **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.

Real-world evidence of Sooma tDCS™ Depression Therapy

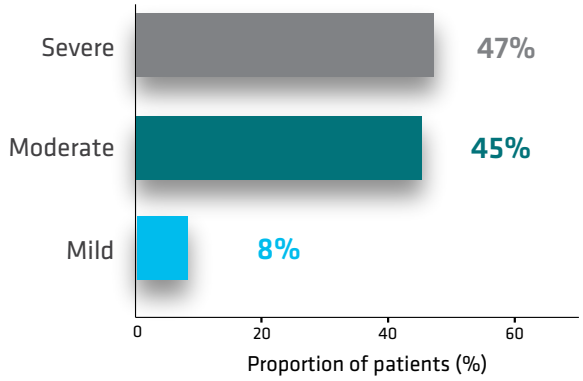
Patients

n=259



43% **57%**

Baseline severity

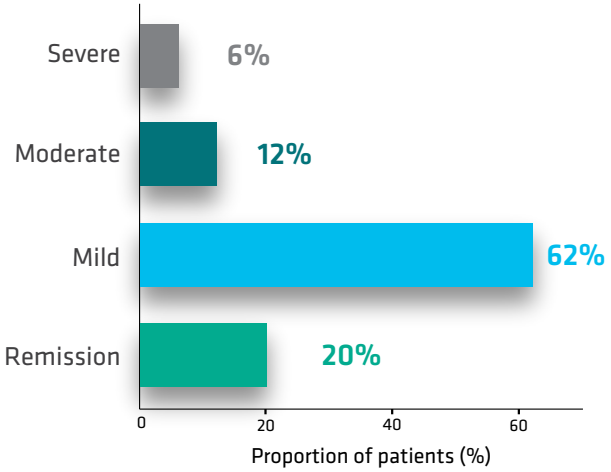


Treatment outcomes

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

USING SOOMA TDCS THERAPY FOR TREATING MDD

PRACTICALITIES

A TYPICAL TRAINING PROGRAM FOR NEW USERS OF SOOMA DEPRESION THERAPY CONSISTS OF TWO ONE-HOUR SESSIONS.

HOW LONG DOES IT TAKE TO TRAIN THE STAFF ON USING SOOMA DEPRESSION THERAPY?

A typical training program for people new to Sooma Depression Therapy consists of two one-hour sessions. The first session provides a general overview on what tDCS is, how it can help patients, along with a very brief overview of the scientific background Sooma treatment is based on. The second session consists of a workshop, where nurses and doctors get hands-on practice in administering the treatment. We arrange training sessions for medical staff on-demand. You can contact us to arrange a training session at your convenience.

HOW OFTEN DOES THE STAFF NEED TO BE UPDATED ON HOW TO USE SOOMA DEPRESSION THERAPY?

Generally, it is not necessary to update the staff about the device. However, if some new uses or changes occur, we will publish new training videos on our online learning platform for you to access them easily and at your convenience.

HOW LONG WILL IT TAKE TO TRAIN THE PATIENT ON HOW TO USE SOOMA DEPRESSION THERAPY AT HOME?

Typically, a one-hour-long session is enough for the patient to get a correct understanding on how the treatment is administered. However, up to 3 sessions can be

done onsite in the clinic for the patient to be confident enough with the device, after which the treatment can be continued at home.

If the patients have any doubts during the self-administration of the treatment, they can access our Patient Material Bank at any time to check how-to videos and printed materials.

IS IT SAFE FOR THE PATIENT TO PERFORM THE TREATMENT BY THEMSELVES AT HOME?

Absolutely. Given the absence of serious side-effects, tDCS therapies can be safely self-administered by anyone who has previously received adequate teaching by a medical professional. Always provided that the treatment has been prescribed by a doctor or specialist who will oversee the establishment of an ongoing communication, frequent feedback, and controlled device settings (Alonzo et al. 2019).

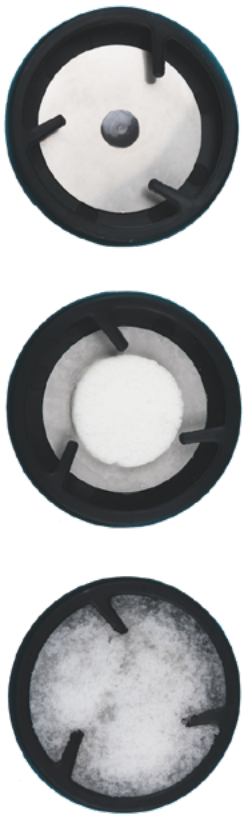
IS THERE A RECOMMENDATION WHETHER TO START THE TREATMENT AT THE CLINIC OR AT HOME?

Although the goal of Sooma Depression Therapy is to decongest the clinics by providing a treatment solution that can be easily used at home by the patients, it is recommended to have at least one first session under the supervision of a health professional. Doing the first session at the clinic can help to ensure that the patient (or a caregiver) knows how to use the device and is a good candidate for the treatment.

Typically, a one-hour-long session is enough for the patient to get a correct understanding on how the treatment is administered. However, it can be done for up to 3 sessions onsite in the clinic for the patient to be confident enough with the device, after which the treatment can be continued at home.

HOW CAN I ENSURE THAT MY PATIENTS ARE FOLLOWING THE PRESCRIBED TREATMENT CORRECTLY?

The ComfoPads that we provide are a reliable means of monitoring compliance. They are single use and you provide the patient with the exact amount of disposables that they would need for a course of treatment. In that way you can make sure that they will only perform the amount of sessions prescribed.



HOW CAN I MAKE SURE THAT MY PATIENTS RETURN THE DEVICE AFTER THE TREATMENT PERIOD IS OVER?

We have a loan agreement document in place that you can give for the patient to sign prior to starting the treatment. Furthermore, we recommend charging the patient a small deposit fee for the rental of the device which is adequate to the price level of your country, but still taxing to the patient. Such deposit will then be reimbursed upon the end of the treatment when the device is returned in a good condition.

TESTIMONIALS

THESE TESTIMONIALS HAVE BEEN GIVEN BY MEDICAL PROFESSIONALS ALL AROUND THE WORLD WHO USE SOOMA TDCS TO TREAT PATIENTS WITH MDD

Anu Kinnunen, MD and Chief Psychiatrist

North Karelia Hospital District (Siun Sote), Finland

"In our experience, tDCS has also enhanced the recovery of the hospitalized depressed patients - and if the patient has benefited from tDCS treatment, the treatment initiated in the hospital has been continued at home after discharge"

Margus Lõokene, MD and Senior Psychiatrist

North Estonia Medical Centre, Estonia

"The first thing we notice is the reduced anxiety […] later on patients get more emotional, active, and after treatment we often get feedback from patients that they are functioning better in every day life, including work and social activities"

Rechdi Ahdab MD, PhD, Associated Professor of Medicine

Lebanese American University, Lebanon

"I have had an excellent experience with Sooma tDCS therapy specifically. The device is user friendly, easy to operate and reliable. Given its excellent safety profile, I mention this therapeutic options to my patients"

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MK40- 1.0 EN Sooma Oy 2022