Sooma Pain Therapy

HOME-BASED BRAIN STIMULATION FOR PAIN RELIEF

An effective, drug-free chronic pain treatment indicated for:

- **Neuropathic pain**
  (MS, SCI, and phantom limb pain)
- **Fibromyalgia**
- **Knee osteoarthritis**

Discover a non-invasive solution for pain management with Sooma Pain Therapy

Personalized Therapies | Avoid Drug Interactions | Track Adherance Remotely | Cost Effective | Home or In-Clinic Treatments

OVERVIEW

Sooma Pain Therapy uses transcranial direct current stimulation (tDCS) to treat chronic pain. A portable device delivers a low 2 mA direct current to brain areas involved in pain processing. The treatment involves daily 20-minute sessions over several weeks, modulating brain activity to relieve pain symptoms. Sooma Pain Therapy is well tolerated, with no serious adverse effects reported. Patients who have not received a satisfactory response from medication or wish to avoid opioid use may find relief with Sooma Pain Therapy.

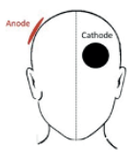
- Sooma Pain Therapy is an effective, drug-free treatment indicated for chronic pain due to neuropathic pain (MS, SCI and phantom limb pain), fibromyalgia and knee osteoarthritis (see chart on reverse page). It uses transcranial direct current stimulation (tDCS) to modulate brain activity. The therapy is suitable as a stand-alone treatment or when used in combination with other treatment methods.

Recurring pain can cause maladaptive neuroplasticity, leading to a persistent sensation of pain. tDCS enables modulation of the maladaptive neuroplasticity and a subsequent relief of pain symptoms.[1]

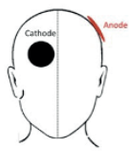
TREATMENT PROTOCOL

The treatment protocol consists of daily 20-minute treatment sessions over several weeks. With Sooma's easy-to-use portable device, a low 2 mA direct current is targeted to the brain areas involved in sensory and emotional pain processing and descending pain inhibitory controls.

An anodal electrode is positioned over the sensorimotor area, either contralaterally to local pain or over the dominant hemisphere, creating an excitatory effect. A cathodal electrode is positioned over the supraorbital region above the eye to ensure that the stimulation reaches the frontal areas of the brain. In fibromyalgia, also the more frontal bilateral electrode montage has been found effective: anodal stimulation of the left DLPFC, cathodal over the right DLPFC.



Left-sided pain or left-handed



Right-sided pain or right-handed

EFFICACY

The efficacy of tDCS for pain relief has been shown in several randomised, double-blinded studies (concluding a level B recommendation[2]) .

SAFETY

Sooma Pain Therapy is well tolerated, and no serious adverse effects have been reported. The therapy is suitable for patients who have not received a satisfactory response from medication or wish to avoid excessive use of opioids.

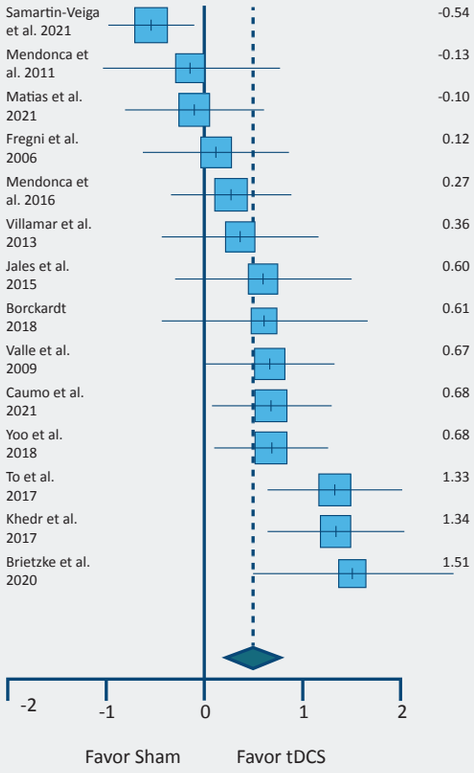
A safety review based on over 40,000 stimulation sessions concluded tDCS to be a safe treatment method. The common side-effects are transient redness and skin sensations under the stimulation electrodes (itching, tingling or burning), headache and tiredness.[3] Contraindications for use are devices or metal objects on or inside the skull, and acute eczema or broken skin in the stimulation area.

Recent meta-analyses of tDCS treatment in different chronic pain conditions

Authors	Year	Indication	n studies/ patients	Effect Size (95% CI)	Conclusions
Moshfeghinia et al.	2023	Fibromyalgia	11/ 414	SMD = -1.55 (-2.10 to -0.99); P=0.001	Both M1 and DLPFC stimulation were efficacious in mitigating pain in fibromyalgia patients.
Dissanayakaet al.	2023	Knee osteoarthritis	14/ 740	SMD = -0.52 (-0.78 to -0.25); P=0.001	tDCS is effective as a stand-alone and as an adjunct treatment in improving knee osteoarthritis pain (short-, medium- and long-term effects).
Gao et al.	2022	Neuropathic pain	4/ 138	SMD = -0.38 (-0.71 to -0.04); P = 0.030	Positive effects on pain reduction, but long-term analgesic effect of tDCS was not confirmed. NP patients with various origins (stroke, peripheral nerve lesion, SCI) were in the current study.
Li et al.	2022	Neuropathic pain after SCI	7/ 130	SMD = -0.70 (-1.31 to -0.10); P = 0.020	Non invasive neuromodulation can relieve neuropathic pain after SCI. Although both were found effective, rTMS effect was found superior to that of tDCS.
Hadoush et al.	2022	Multiple Sclerosis	N.I.	SMD –0.67 (–1.18 to –0.16); P = 0.01	Significant attenuative effect of tDCS on pain intensity in patients with MS.
Garcia-Pallero et al.	2022	Phantom limb pain	4/ 55	N.I.	tDCS may be beneficial to reduce pain sensation in phantom limb pain.
Hsu et al.	2021	Multiple Sclerosis	17/ 383	SMD –0.59 (–1.10 to –0.08); P = 0.02)	Results provide evidence that tDCS has a favorable effect on cognitive processing speed, mood disturbance, pain, and fatigue in MS.
Zhang et al.	2020	Neuropathic pain	6/ 146	N.I.	Studies suggest that tDCS might attaenuate neuropathic pain, with most effective parameters being anodal M1.
Zucchella et al.	2020	Multiple Sclerosis	5/ 62	N.I.	Anodal tDCS over M1 or left DLPFC appear to be effective protocol for pain in MS. More studies are needed to conclude and to learn about the duration of the effect.
Shen et al.	2021	Neuropathic pain after SCI	4/ N.I.	N.I.	Anodal tDCS over M1 or left DLPFC appear to be effective protocol for pain in MS. More studies are needed to conclude and to learn about the duration of the effect.
Fregni et al.	2020	Chronic pain	11/ 249 and 7/ 274	Pooled effect sizes Neuropathic pain: −0.29 (−0.60, 0.02) Fibromyalgia: −0.62 (−1.23, −0.01)	Evidence-based guidelines for the use of tDCS for neuropathic pain and fibromyalgia with level B recommendations (probably effective). No severe adverse events have been reported, however, long-term effects have not been established.
Pacheco-Barrios et al.	2020	Phantom limb pain	3/ 24	Effect size: -1.50 (-2.05 to 0.95)	Anodal M1 tDCS provided a significant decline in visual analog scale (VAS) scores for pain at the short term and midterm end points.
Yu et al.	2020	Neuropathic pain after SCI	6/ 116	SMD = −0.37 (−0.84 to 0.10)	Study found no significant effects of M1 tDCS over sham stimulation.
Lloyd et al.	2020	Fibromyalgia	9/ 265	SDM = -0.50 (-0.87 to -0.14)	Anodal M1 tDCS (at 2 mA, 20 mins/day, for 10 daily sessions) provided clinically important reduction in pain intensity score.

Clinical evidence on the efficacy of tDCS treatment of fibromyalgia

(From the meta-analysis by Cheng et al, 2023, Clinical Neurophysiology[4])



14 controlled studies including 369 patients
Effect size: Hedges' g = 0.50 (95% CI 0.18; 0.82) P = 0.0025

References

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3. Bikson, M. et al. Safety of Transcranial Direct Current Stimulation: Evidence Based Update 2016. Brain Stimul. 2016 Sep- Oct;9(5):641-61.
4. Cheng YC, et al. Treating fibromyalgia with electrical neuromodulation: A systematic review and meta-analysis. Clin Neurophysiol. 2023 Apr;148:17-28. doi: 10.1016/j.clinph.2023.01.011. Epub 2023 Feb 1. PMID: 36774784.

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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.

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