tDCS (and taVNS) for COVID and Long-COVID

: with a focus on how technology supports targeted trials

Marom Bikson
The City College of New York

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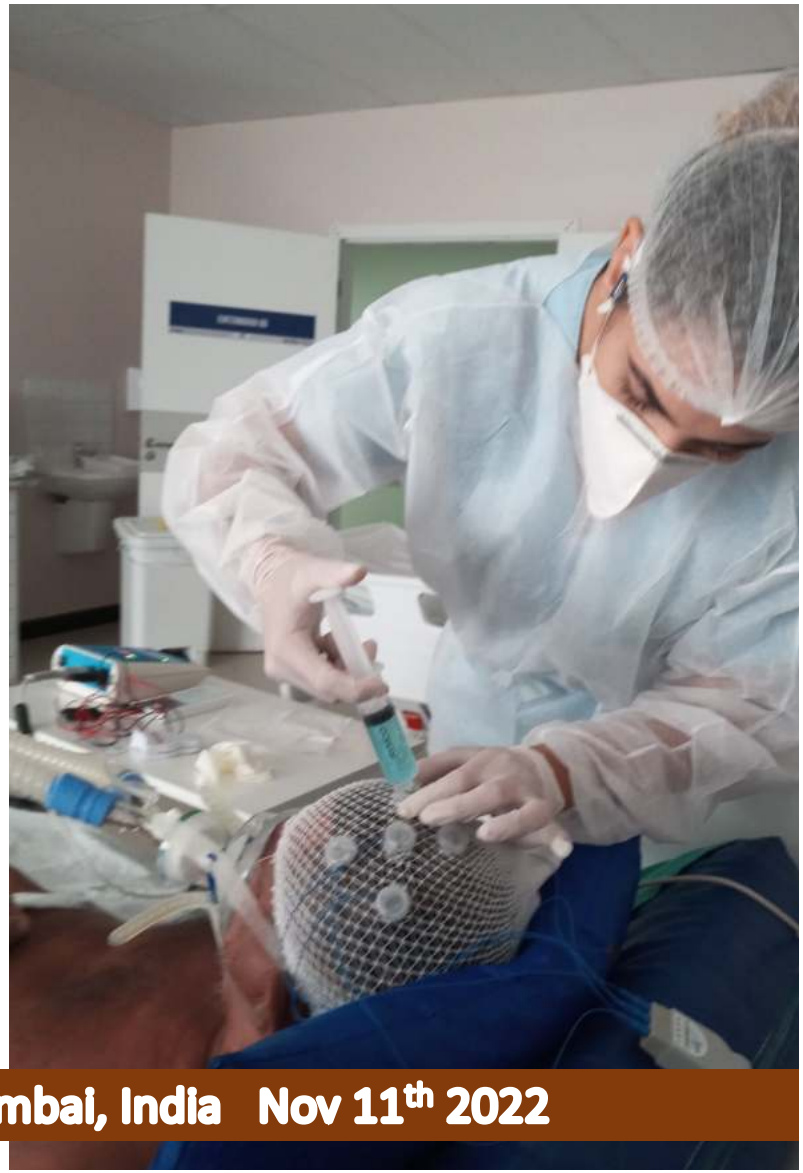


International Neuromodulation Society (INS) Mumbai, India Nov 11th 2022

Disclosure

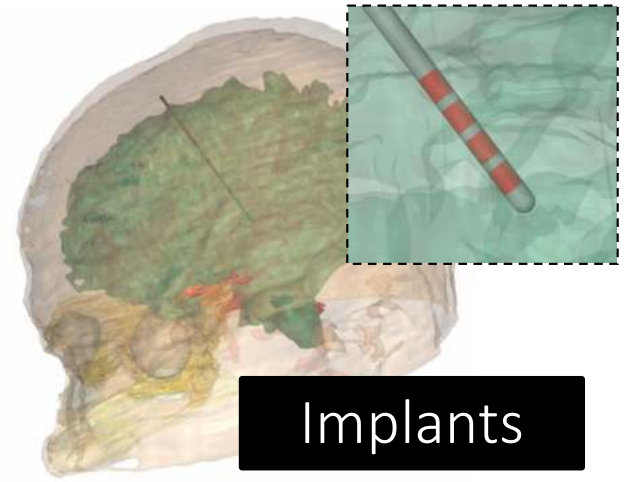
The City University of New York: Patents on brain stimulation.
Soterix Medical: Produces tDCS and High-Definition tDCS.
Grants, assigned inventions, and/or serves SAB for SafeToddles, Boston Scientific, GlaxoSmithKline, Biovisics, Mecta, Lumenis, Halo Neuroscience, Google-X, i-Lumen, Humm, Allergan (Abbvie), Apple

Support

Governo do Estado da Paraíba (Brazil). NYS DOH, NIH (NIMH, NINDS) – *BRAIN Initiative*, NSF, Grove Foundation, Harold Shames, CCNY Fund, 21st Century Fund

Slides and References @MaromBikson

Neuromodulation technologies platforms vary in how energy is delivered to what target.

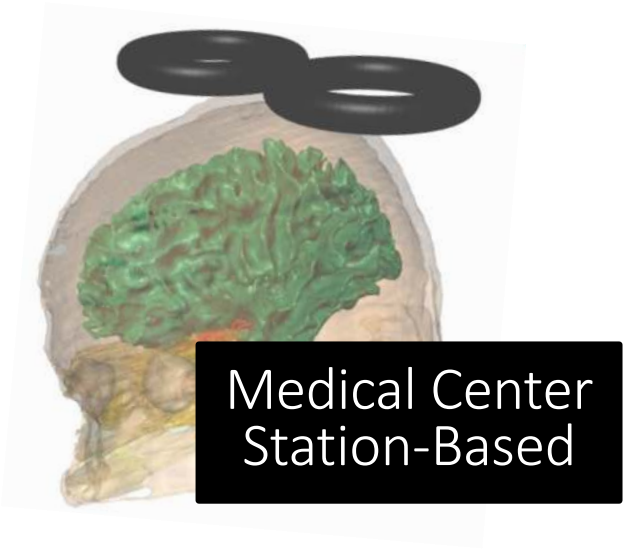


Implants

Deep Brain Stimulation (DBS)

Spinal Cord Stimulation (SCS)

Peripheral Nerve Stimulation (PNS)

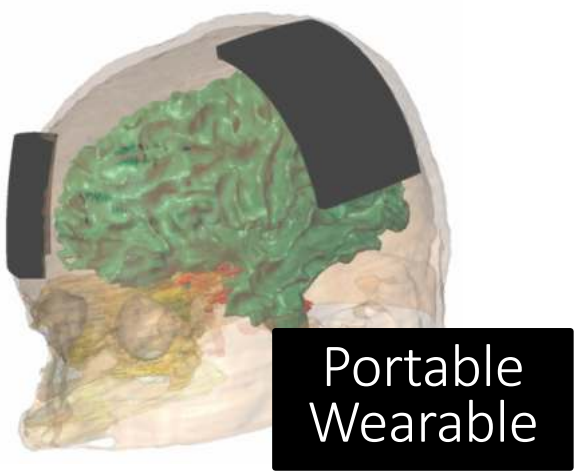


Medical Center Station-Based

Transcranial Magnetic Stimulation (TMS)

Electroconvulsive Therapy

High-Definition tES (HD-tES)



Portable Wearable

Transcranial Electrical Stimulation (tES) / tDCS

Non-invasive vagus nerve simulation / taVNS

Neuromodulation technologies platforms vary in how energy is delivered to what target.

Implants

Deep Brain Stimulation (DBS)

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Peripheral Nerve Stimulation (PNS)

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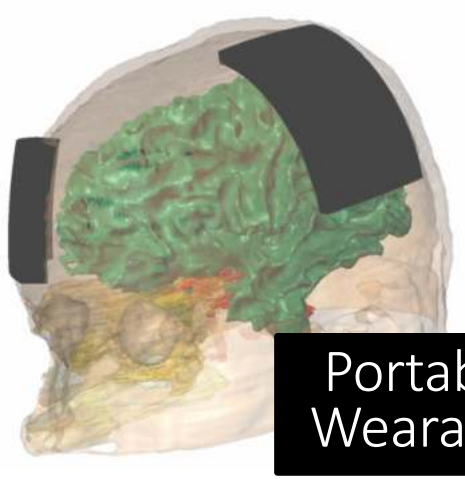
High-Definition tES (HD-tES)



Portable Wearable

Transcranial Electrical Stimulation (tES) / tDCS

Non-invasive vagus nerve simulation / taVNS

Focus on non-invasive, low-risk, rapidly-deployable, low-cost technology.

frontiers in Neurology

doi: 10.3389/fneur.2020.573718

Applications of Non-invasive Neuromodulation for the Management of Disorders Related to COVID-19

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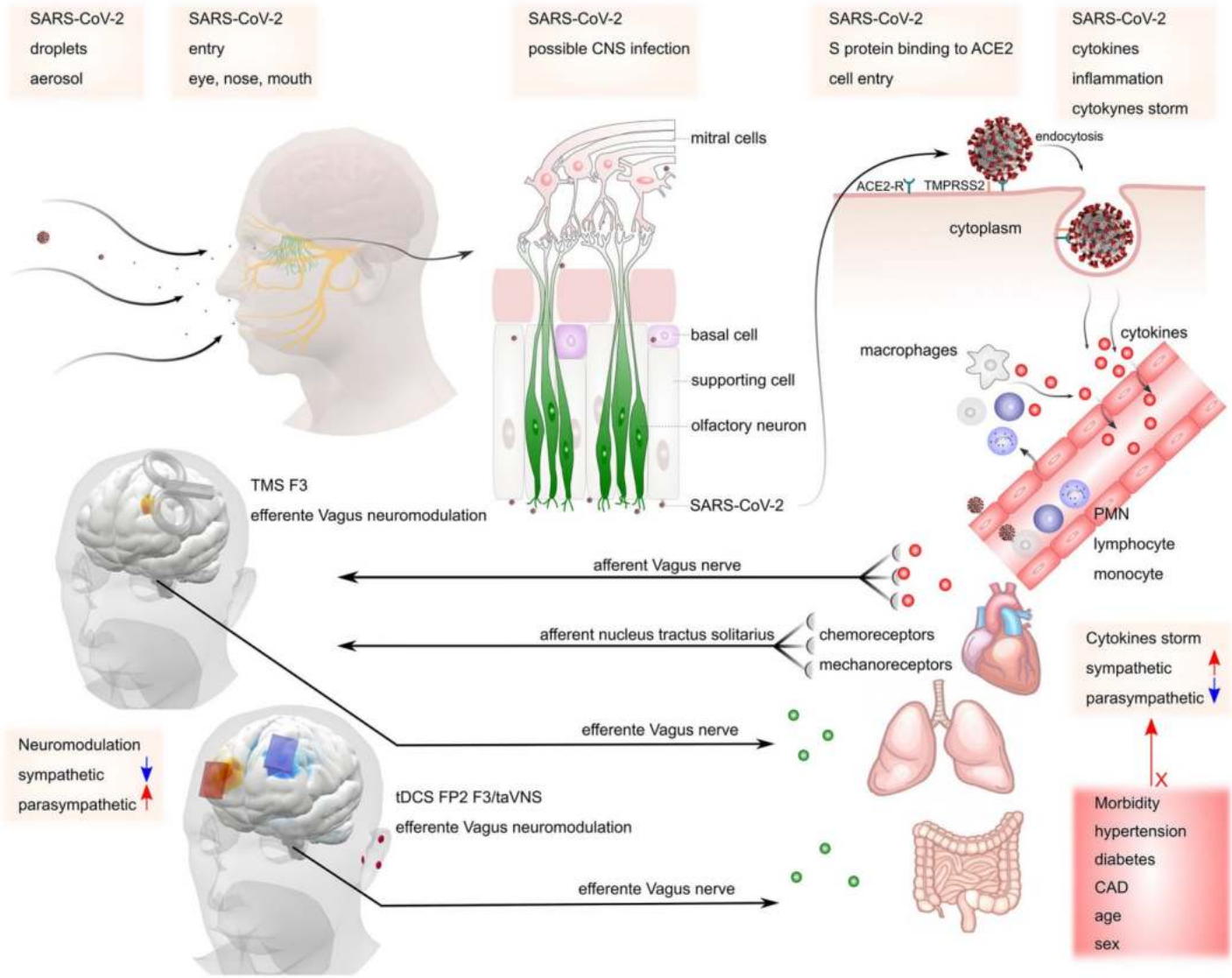
frontiers in Neurology

doi: 10.3389/fneur.2020.573718

1) Neuromodulation targets etiology of COVID-19.



frontiers in Neurology

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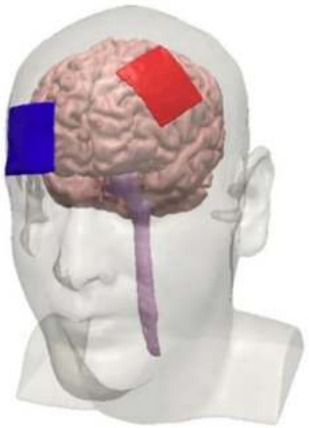
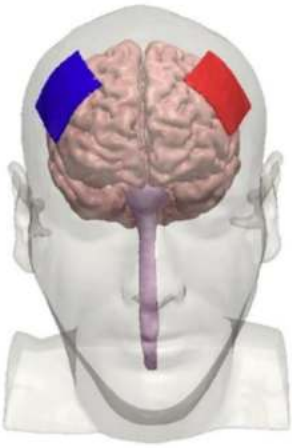
1) Neuromodulation targets etiology of COVID-19.

Pick the right neuromodulation technique based on mechanism of action (hypothesis).

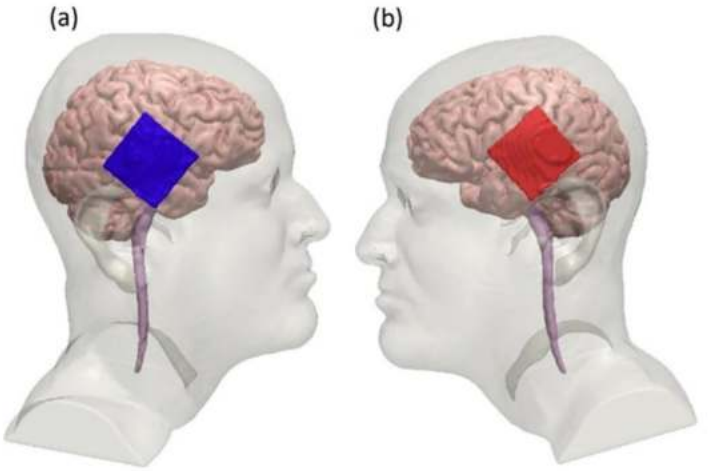
M1-tDCS



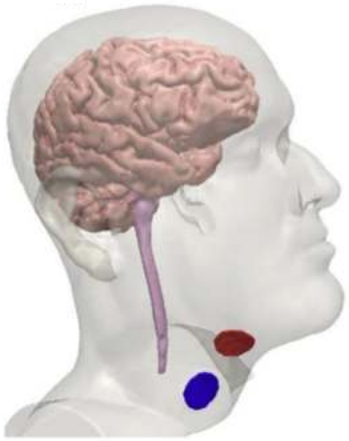
DLPFC-tDCS ("OLE")



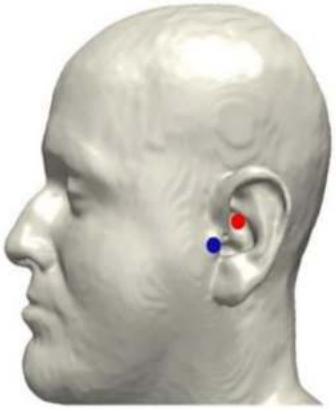
Temporal Cortex



Vagus nerve - cervical



Vagus nerve - auricular



Transcranial Magnetic Stimulation – DLPFC

frontiers in Neurology

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1) Neuromodulation targets etiology of COVID-19.

2) Neuromodulation treats symptoms of COVID-19.

Decades of trials in non-COVID-19 populations.

Ongoing trials.

Acute

A) Direct infection mitigation through the stimulation of regions involved in the regulation of systemic anti-inflammatory responses and/or autonomic responses.

B) Amelioration of COVID-19 symptoms of musculoskeletal pain and systemic fatigue.

Post-Acute

C) Outbreak-related mental distress including neurological and psychiatric disorders exacerbated by psychosocial stressors related to COVID-19.

D) Augmenting cognitive and physical rehabilitation following critical illness.

X) Long-COVID, Neuro-COVID, Post-Acute Sequelae of SARS-CoV-2 infection (PASC)

Brain Stimulation 13 (2020) 1124–1149

Guidelines for TMS/tES clinical services and research through the COVID-19 pandemic

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- Neuromodulation trials / treatment can and *should* continue through COVID-19.
- Home-based trials continued / expanded with modification (eg. 100% contactless)

1) Neuromodulation targets etiology of COVID-19.

2) Neuromodulation treats symptoms of COVID-19.

Acute

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Home transcranial Direct Current Stimulation (tDCS) for Depression +

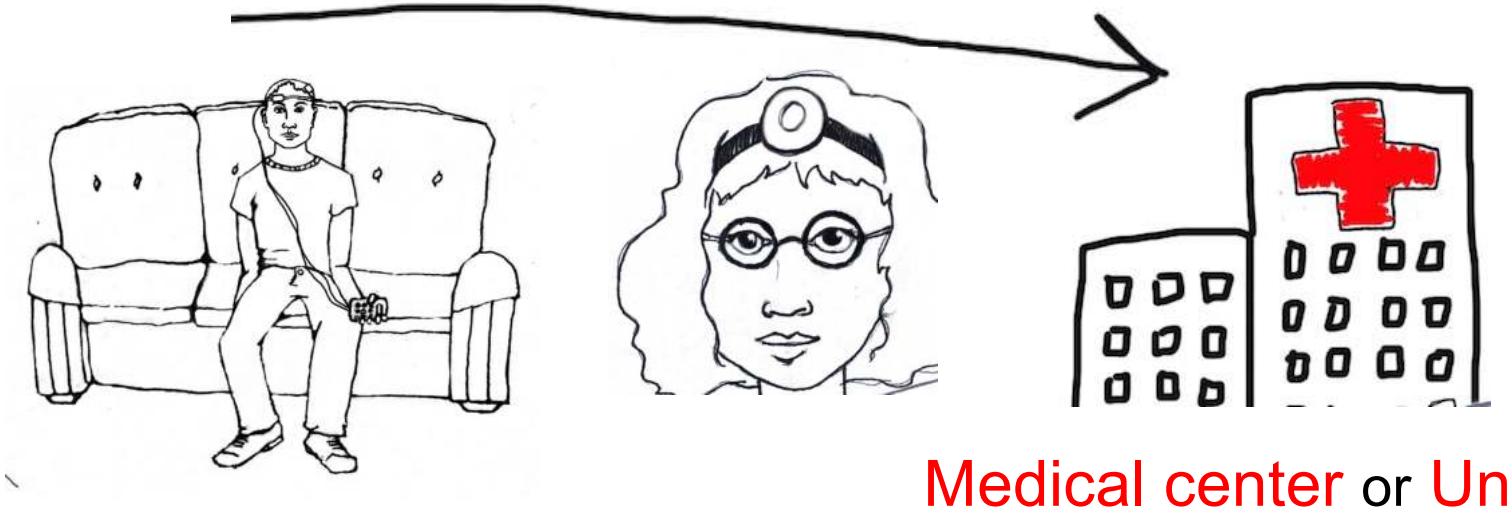
- Accelerated by limited in-clinical treatments (rTMS, ECT) during COVID-19 lockdown
- Intent-to-treat / RCTs
- Device: Remote control of dosing and compliance monitoring (Remote-Supervised)

Charvet et al. Remotely-supervised transcranial direct current stimulation (tDCS) for clinical trials: guidelines for technology and protocols. 2015

Expertise of operator

Home-use
Self application
or Supervised

Clinic
Trained operator



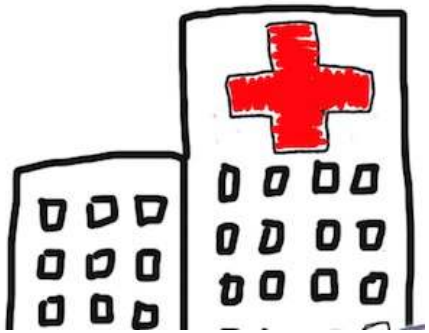
Medical center or University

Charvet et al. Remotely-supervised transcranial direct current stimulation (tDCS) for clinical trials: guidelines for technology and protocols. Frontiers. 2015

Increased automation

Home: Fully automatic, No flexibility

Clinic: Semi-automatic Some flexibility



Medical Center: Customization, flexibility, integration with other equipment

Charvet et al. Remotely-supervised transcranial direct current stimulation (tDCS) for clinical trials: guidelines for technology and protocols. Frontiers. 2015

Remote-supervised tDCS is a guidance to ensure compliance and tolerability. tDCS is not self-directed. The guidance is flexible to use-cases.

Charvet et al. Remotely-supervised transcranial direct current stimulation (tDCS) for clinical trials: guidelines for technology and protocols. Frontiers. 2015

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Charvet et al. Remotely-supervised transcranial direct current stimulation (tDCS) for clinical trials: guidelines for technology and protocols. 2015

- 100% Remote: Contactless. New York University (NYU) hospital
- Mix of automated symptom monitoring and telemedicine.
- Part of high throughout remote-supervised tDCS program at NYU Langone hospital (Department of Neurology)

Charvet et al. Tolerability and feasibility of at-home remotely supervised transcranial direct current stimulation (RS-tDCS): Single-center evidence from 6,779 sessions. *Brain Stim*. 2022

Trials ongoing

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Brain Stimulation 14 (2021) 1520–1522

Contents lists available at ScienceDirect

Brain Stimulation

journal homepage: http://www.journals.elsevier.com/brain-stimulation

Telehealth transcranial direct current stimulation for recovery from Post-Acute Sequelae of SARS-CoV-2 (PASC)

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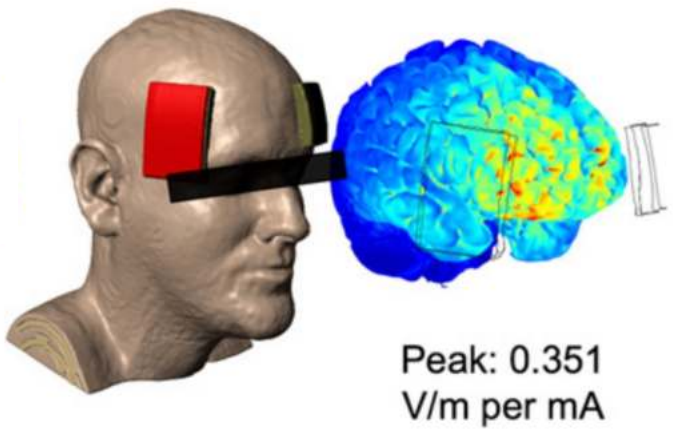


tDCS current flow modeling from Seibt *et al* Brain Stim 2015

To develop effective and personalized PASC treatments: Neuromodulation should be objective biomarker guided (target engagement)

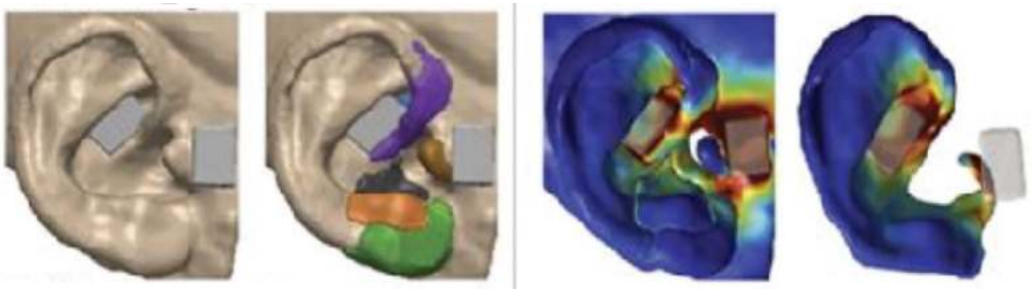
Patient 1: A 42-year-old, right-handed, Black woman presented for tDCS clinical treatment of PASC in 01/2021, approximately nine months following COVID-19 illness. She continued to experience fatigue, cognitive impairment, anxiety and depression, dyspnea, sleep disturbances, and numbness sensation in the right side of her face.

Patient started her tDCS treatment in January 2021. A comparison between initial (08/2020) and repeat (02/2021) neuropsychological evaluations following 4 weeks of treatment (15 sessions) demonstrated significant improvements (≥1 SD) in visual attention and processing speed, timed verbal fluency, and cognitive flexibility. Speeded fine motor dexterity was also improved in her left hand (and remained intact in her right hand). She also reported clinically significant improvements in cognitive functioning, ncreased, indicating her approaching re- within normal limits. mprovements across ourse of treatment, ncreasing her work

te woman presented for tDCS clinical treatment of PASC in November 2020, approximately seven months following COVID-19 illness. She experienced a constellation of persisting symptoms, including marked fatigue and "brain fog," emotional dysregulation, intermittent numbness in her extremities, and pain.

Transcutaneous auricular Vagus Nerve Stimulation (taVNS) for PASC

- Post-COVID subjects who experience any new and lasting neurological or psychiatric symptom. Very broad inclusion.
- tAVNS dual action: parasympathetic (anti-inflammatory) + direct brain (restorative)
- Device: Remote control of dosing and compliance monitoring. Contactless
- Integrated remote real-time physiology monitoring (HR, pressure, oximeter)
- Mix automated (digital healthcare) symptom monitoring and telemedicine
- Mild/moderate efficacy. Critical to distinguish symptoms.



taVNS current flow modeling from Kreisberg *et al* Brain Stim 2021

Badran et al. A pilot randomized controlled trial of supervised, at-home, self-administered transcutaneous auricular vagus nerve stimulation (taVNS) to manage long COVID symptoms. Bioelecton Med. 2022

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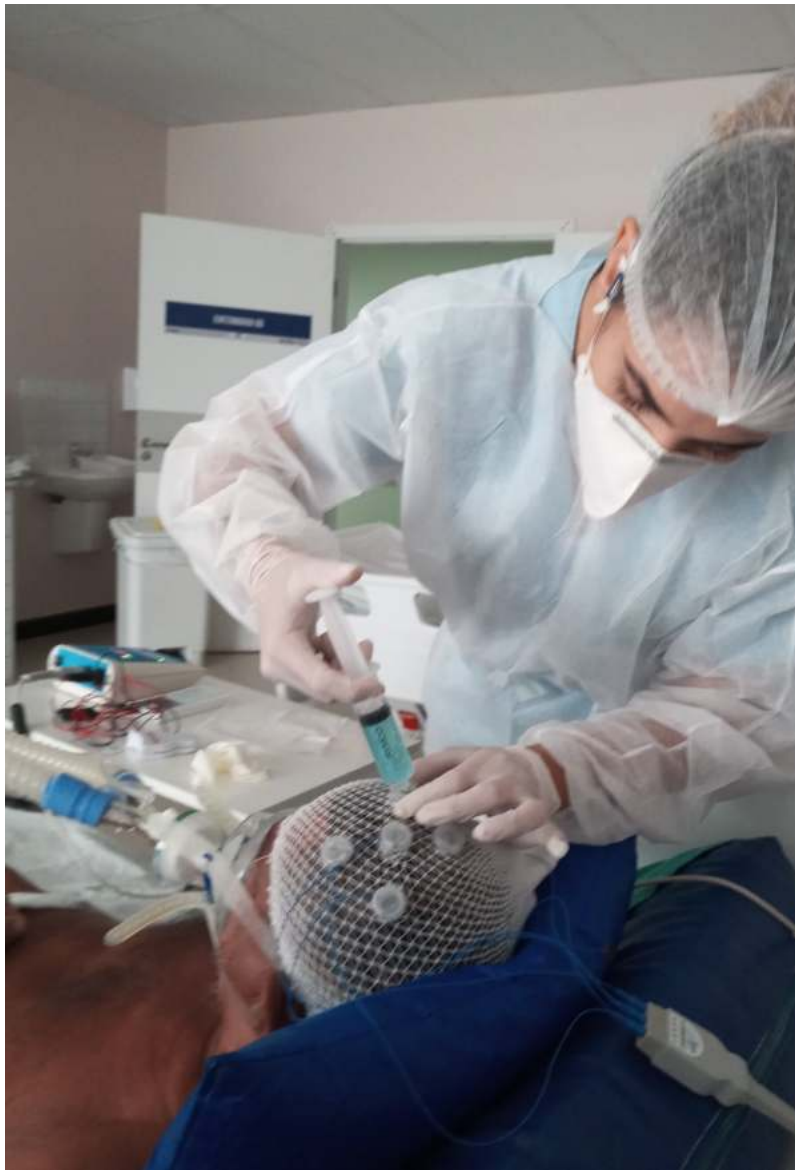
HD-tDCS to reduce duration of mechanical ventilation in COVID-19 ICU

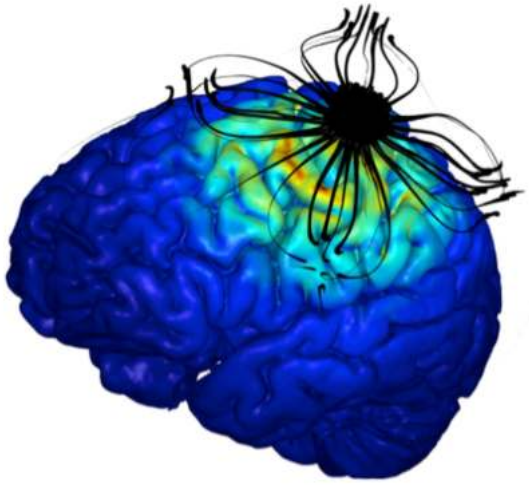
- COVID-19 patients admitted to the ICU (Paraíba, Brazil). RCT (n=56).
- 3 mA High-Definition tDCS (HD-tDCS) to allow targeting of cortical region (rapid deployment disposable, head-gear version)
- Left (diaphragmatic) primary motor cortex, 10 sessions (twice daily), paired with pulmonary rehabilitation.
- Ventilatory weaning in patients by improving respiratory performance (decreases in mechanical ventilation days during 28 days).

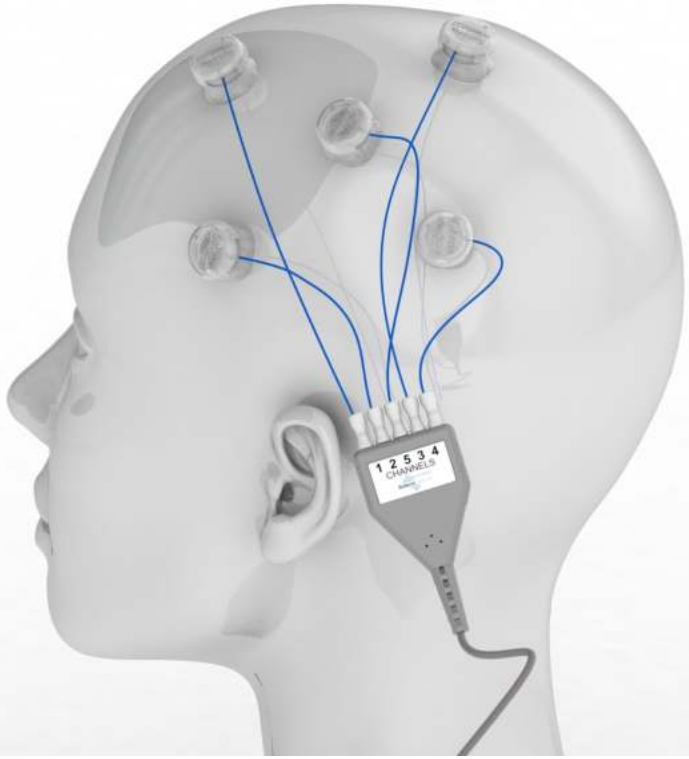


Suellen Andrade et al. Efficacy and safety of HD-tDCS and respiratory rehabilitation for critically ill patients with COVID-19 The HD-RECOVERY randomized clinical trial. Brain Stimulation 2022

High-Definition tDCS (HD-tDCS) uniquely combines features:

1) Non-invasive
2) Directional modulation of excitability (anode=increased function)
3) Targeted to any cortical region (e.g., motor)
4) Portable and deployable (battery powered)
5) Safe and tolerated, across diverse patients





Datta et al. Gyri-precise head model of transcranial direct current stimulation: improved spatial focality using a ring electrode versus conventional rectangular pad. Brain Stimulation 2009

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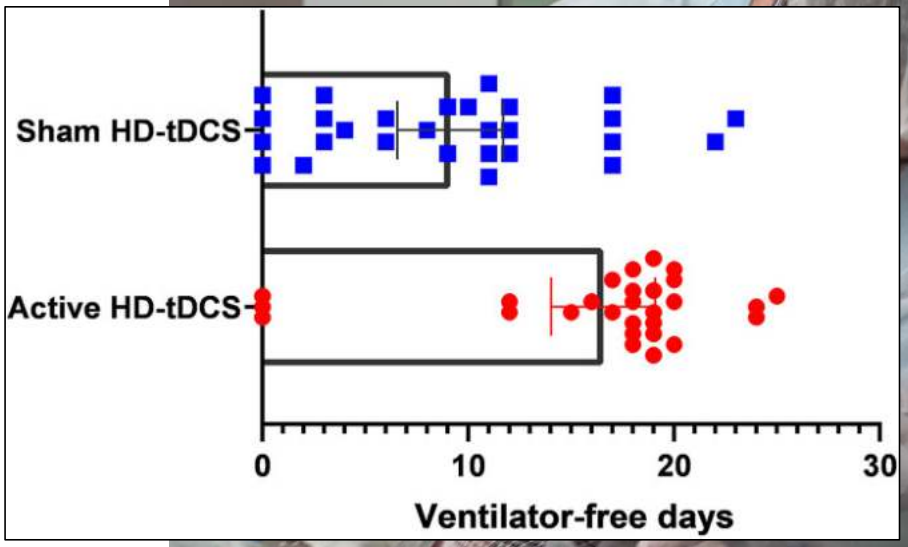
- Left (diaphragmatic) primary motor cortex, 10 sessions (twice daily), paired with pulmonary rehabilitation.
- Ventilatory weaning in patients by improving respiratory performance (decreases in mechanical ventilation days during 28 days).
- Significantly reduced days on ventilation also improves delirium, organ failure, hospital length of stay



Suellen Andrade et al. Efficacy and safety of HD-tDCS and respiratory rehabilitation for critically ill patients with COVID-19 The HD-RECOVERY randomized clinical trial. Brain Stimulation 2022

1) Neuromodulation targets etiology of COVID-19.

2) Neuromodulation treats symptoms of COVID-19.

Acute

A) Direct infection mitigation through the stimulation of regions involved in the regulation of systemic anti-inflammatory responses and/or autonomic responses.

B) Amelioration of COVID-19 symptoms of musculoskeletal pain and systemic fatigue.

Post-Acute

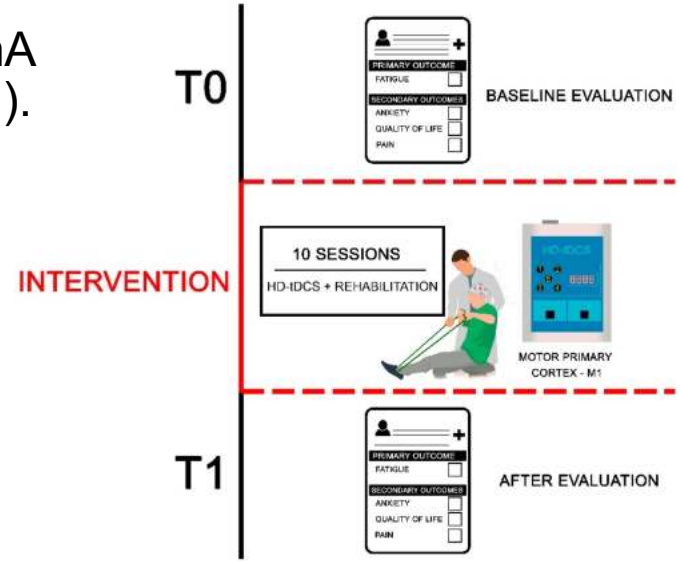
C) Outbreak-related mental distress including neurological and psychiatric disorders exacerbated by psychosocial stressors related to COVID-19.

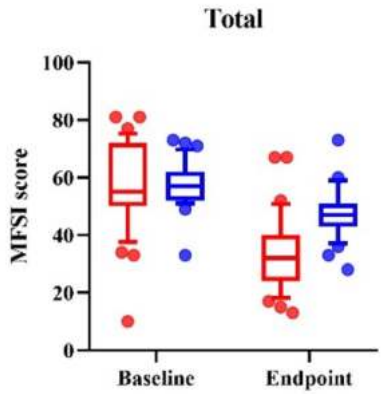
D) Augmenting cognitive and physical rehabilitation following critical illness.

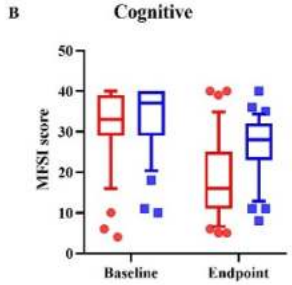
X) Long-COVID, Neuro-COVID, Post-Acute Sequelae of SARS-CoV-2 infection (PASC)

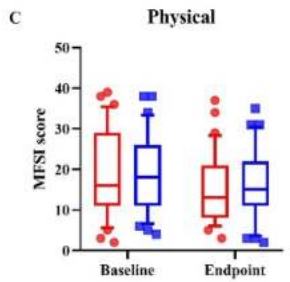
High Definition-tDCS (HD-tDCS) to reduce chronic fatigue in PASC

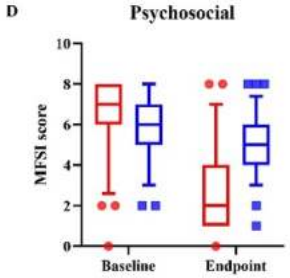
- 70 patients with PASC-related fatigue, randomized to 3 mA or sham HD-tDCS targeting the primary motor cortex (M1).
- 10 sessions of HD-tDCS paired with rehabilitation. Both brain stimulation and rehabilitation targeted to inclusion/symptoms.
- Fatigue as primary outcome
- Significant reduction in fatigue. Mean improvement for active HD-tDCS: 22.11 Modified Fatigue Impact Scale (MFIS).











Active HD-tDCS + Rehabilitation

Sham HD-tDCS + Rehabilitation

Suellen Andrade et al. Non-invasive Brain Stimulation for fatigue in Post-Acute Sequelae of SARS-CoV-2 (PASC) . In review

tDCS (and taVNS) for COVID and Long-COVID

: with a focus on how technology supports targeted trials

Marom Bikson
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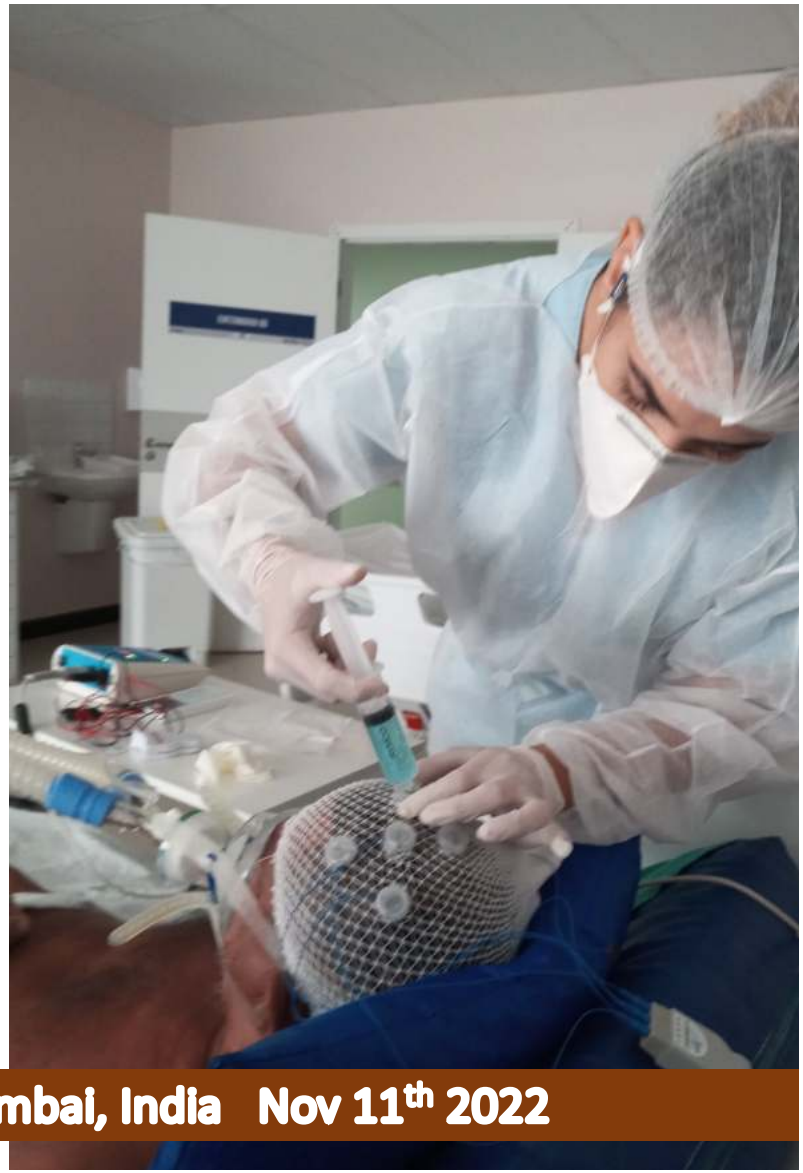

International Neuromodulation Society (INS) Mumbai, India Nov 11th 2022