Transcranial Direct Current Stimulation (tDCS) for mental illness

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Transcranial Electrical Stimulation (tES)

- Non-invasive brain stimulation

- Various methods, i.e., transcranial Direct Current Stimulation (tDCS), transcranial alternating current (tACS-oscillating currents), transcranial random noise (tRNS- alternating current oscillating at random frequencies)

- Modulates cortical ‘excitability’: with low direct current via scalp electrodes

Image adapted from Sekhar. Slideshare.net
https://www.slideshare.net/VInSekhar/brain-stimulation-methods-in-ocd
Electrodes both on scalp (bipolar or bicephalic montage), or reference electrode extracephalic (unipolar or monocephalic montage)

- **Current intensity** (ramp up/down, usually 0.5 - 2 mA)
- **Duration** of stimulation 5 - 40 min
- **Electrode size** 3 - 100 cm$^2$
- **Current density** (in A/m$^2$); total charge applied (in Coulombs)
- **Duration of effect** unknown? (peak within 30-120 min, continues after stimulation); increases with multiple stimulations

Transcranial Direct Current Stimulation (tDCS)

• **Growing interest**, over 6000 tDCS publications
• More than 200 clinical trials for **multiple psychiatric disorders**, **neurological disorders** (AD, PD, chronic pain, post stroke, tinnitus, fibromyalgia, epilepsy)
• **Neurocognitive and mechanistic studies**

“...First, the fluid took over a large part of my brain, which felt a strong shock, a sort of jolt against the inner surface of my skull. The effect increased further as I moved the electric arcs from one ear to the other. I felt a strong head stroke and I became insomniac for several days...”

Melanchonic patient Luigi Lanzarini: describing stimulation effects, 1801
tDCS: Some possible cons

- Current delivered is influenced by several uncontrollable factors (e.g. impedance of cephalic structures)
- Low precision of stimulation focality (electrode sizes, placement via international 10-20 EEG System)
- Debated sham (placebo) integrity

tDCS: Some pros

- Low cost
- Portability
- Simple to administer
- Safety and tolerability profile
- May be delivered as an adjunct to standard therapy
- Potential for home-based use (Remotely Supervised, Remotely Controlled)?

tDCS: Preparation and administration
tDCS: Safety

**Minimal risk** using standard parameters:
(1) Current ≤ 2.5 mA
(2) Equipment to minimize skin burns
(3) Duration ≤ 20–60 min per session
(4) Sessions max twice per day

**No SAEs reported in more than 10,000 subjects** including:
- Vulnerable clinical populations (independently from diagnostic group)
- Repeated sessions (no evidence of increased risk)
- Wide range of stimulation parameters

tDCS: Acceptability and tolerability

- Mild, short-lived AEs
- 209 RCTs (56%) mentioned AEs; (63%) reported at least one AE
- **Active VS sham, no statistical significance**: itching, tingling, headache, discomfort, burning sensations

tDCS acceptability and tolerability

• In studies reason for **drop outs** and **systematic report** of AEs not always adequately represented

• **Very rare reports** of mood elation, permanent skin lesions, temporary blurred vision, panic, nausea

• NICE specialist advisers **anecdotal/theoretical** AEs: phosphenes, precipitation of seizures, exacerbation of depression, interference with implanted electrical devices, twitching of facial muscles

tDCS: a ‘neuro-modulatory’ rather than a neuro-stimulatory approach

- Does not trigger action potentials in neurons, instead changes overall cortical excitability
- **Anode (positive electrode)** depolarize (increase excitability)
- **Cathode (negative electrode)** hyper-polarize (reduce excitability)
- Effects on sodium and calcium concentrations
tDCS mechanism of action

- not yet fully understood
- documented **modulation in neuroimaging and electrophysiology studies** (online and offline): fMRI (increased functional connectivity), PET (rCBF $H_2^{15}O$), MRS (GABA & Glx), NIRS (HbO$_2$ at the stimulation site), EEG (alpha power), MEG (alpha, beta, gamma power changes, synchronisation)
- not only transient membrane polarization changes, also **longer-lasting synaptic changes: long-term effects via glutamatergic NMDA receptor?**
- **other systems** hypothesised mediating and influencing its action (GABAergic, opioid, dopaminergic, serotonergic, noradrenergic, cholinergic)

GLUTAMATE?

- Active glutamate synapses ≈NMDA receptors trigger long-term potentiation (LTP)
- LTP leads to structural and functional changes of the synapse “strengthening” of synapses (via dysbindin, DISC1, neuregulin)

tDCS in Depression

- anode placed over **L- DLPFC**, cathode on cephalic location (e.g. R-DLPFC, R supraorbital, R frontotemporal) or extracephalic
- rationale: hypoactivity L-DLPFC, hyperactivity on the right-sided structures

Grimm et al. Biol Psychiatry. 2008
Moffa et al. Psychiatric Clinics of North America. 2018
tDCS in Major Depressive Disorder: early meta-analysis...

- Systematic review and meta-analysis of 7 RCTs (n = 259)
- Active VS sham significantly superior for all outcomes (g = 0.37; 95% CI 0.04-0.7)
- ORs for response and remission: 1.63; 95% CI = 1.26-2.12 and 2.50; 95% CI = 1.26-2.49
- low risk of publication bias
- Mixed findings and heterogeneity of studies
- No predictors of response identified

NICE guidance (Aug 2015)

Transcranial direct current stimulation (tDCS) for depression

- No major safety concerns
- Some evidence of efficacy but uncertainties about specific mode of administration, number of treatments needed and duration of effect
- Only to be used with special arrangements for clinical governance, consent and audit or research
- Ensure patients understand the uncertainty about efficacy and provide them with clear written information
- Encourage further research into tDCS: document selection criteria, other treatments, methods, outcome measures including the duration of effect

https://www.nice.org.uk/guidance/ipg530/chapter/2-Indications-and-current-treatments
Meta-analysis 6 RCTs (n=289) active tDCS VS sham

active tDCS statistically superior for all outcomes: depression improvement ($B = 0.35$, 95% CI 0.12-0.57); response (34% v. 19% respectively, OR = 2.44, 95% CI 1.38-4.32, NNT= 7), remission (23.1% v. 12.7% respectively, OR = 2.38, 95% CI 1.22-4.64, NNT = 9)

Small-moderate effect size, comparable with rTMS and ADs treatment in primary care

Sub-group analysis lower responses in treatment-resistant dep, higher “dose” of tDCS positively associated with efficacy
Statement on Transcranial Direct Current Stimulation (tDCS) in Depression

Position statement CERT04/17; Approved by the Royal College of Psychiatrists, Committee on ECT and Related Treatments: **February 2017**

- **May represent an effective treatment option for MD**

- **Acceptable tolerability profile**: useful alternative to antidepressant in patients who do not wish/cannot tolerate ADs

- Current evidence **does not support tDCS in treatment-resistant depression, or as an add-on augmentation** (for patient taking an AD or undergoing cognitive control training)
• Double-blind, **RCT, non-inferiority, unipolar depression** (n=245), 10 weeks period, primary outcome (HDRS-17)
• tDCS+ oral placebo (n=91) VS sham tDCS + escitalopram (n=94) VS sham tDCS + oral placebo (n=60)
• **Phase I (3 weeks)** : tDCS: 30-min, 2-mA, DLPFC, daily VS escitalopram 10 mg/day; **Phase II (7 weeks)** tDCS weekly VS escitalopram 20 mg/day
• tDCS failed non-inferiority cut-off
• tDCS higher rates skin redness, tinnitus, nervousness, new-onset mania in 2 pt; ESC more frequent sedation and constipation
...tDCS in MDD.. continued..

- Consistent small-medium effect size, well tolerated, inconsistent evidence for significant cognitive effects

Efficacy and acceptability of **transcranial direct current stimulation (tDCS)** for major depressive disorder: An individual patient data meta-analysis.

**Transcranial direct current stimulation** for the treatment of major depressive disorder: A meta-analysis of randomized controlled trials.
Wang Y.

Clinical Usefulness of Therapeutic Neuromodulation for Major Depression: A Systematic Meta-Review of Recent Meta-Analyses.
McGirr A, Berlim MT.
• 23 RCTs (cumulative n=439)
• tDCS superior to sham regarding endpoint depression scores (k = 25, g = 0.46, 95% confidence interval [CI]: 0.22-0.70), rates of response (k = 18, 33.3% vs. 16.56%, OR = 2.28 [1.52-3.42], NNT = 6) and remission (k = 18, 19.12% vs. 9.78%, OR = 2.12 [1.42-3.16], NNT = 10.7)
• Active tDCS acceptable as sham
• No risk of publication bias identified
tDCS efficacious across outcomes in pairwise and network meta-analyses (summary OR 2.65, 95% CI 1.55 to 4.55)

- Among non-surgical brain stimulation with more robust evidence and precision in treatment effect estimates.
tDCS in Bipolar Depression

From: Sampaio-Junio ret al. JAMA Psychiatry. 2018

- RCT (n=52 BAD type 1 and 2 in MDE )
- tDCS 30-minute, 2-mA, anodal L-DLPFC; (cathode R-DLPFC) ;10 daily sessions + 1 session fortnightly until week 6 VS Sham

- Active tDCS significantly superior in improvement (βint = -1.68; NNT 5.8; 95% CI, 3.3-25.8; P = .01)
- Rates of cumulative response (67.6% vs 30.4%; NNT 2.69; 95% CI, 1.84-4.99; P = .01),
- Not in remission (37.4% vs 19.1%; NNT 5.46; 95% CI, 3.38-14.2; P = .18).
- AEs similar; skin redness higher in the active group (54% vs 19%; P = .01)
## tDCS in Schizophrenia and psychotic disorders

<table>
<thead>
<tr>
<th>Theoretical model</th>
<th>tDCS montage</th>
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<tbody>
<tr>
<td><strong>negative symptoms:</strong></td>
<td>anode over L- DLPFC; catode over right supraorbital area (or others e.g. extra-cephalic)</td>
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<td>decreased DLPFC activity</td>
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<tr>
<td><strong>positive symptoms:</strong></td>
<td>anode over L-DLPFC; cathode over temporo-parietal junction</td>
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<td>increased L-temporo-parietal junction activity in auditory verbal hallucinations</td>
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tDCS in Schizophrenia

• Meta-analyses 9 RCTs (n=362) of tDCS on AVH: only in 6/9 studies efficacy; active tDCS superior to sham in sub-groups of repeated sessions (twice-daily, ≥10 stimulation) (AVH reduction≈ 28% VS 10%) (Rashidi et al. Neural Regen Res. 2021; Kim et al. J Psych Res. 2019)

• Meta-analyses 9 RCTs (n=270) on cognitive effects: tDCS improved working memory but no other domains (Narita et al. Schizophr Res. 2020)

• Overall mixed findings in cognition and negative symptoms (Yu et al. Schizophr Res. 2020)
tDCS in Schizophrenia

• Insufficient evidence for definitive conclusions

• Is “more better”?- increase frequency and numbers of stimulation to improve outcomes for positive and negative symptoms

• Need of better understanding factors impacting treatment response (age, severity/stage of illness, other treatments) and standardize protocols in future RCTs
tDCS in PTSD and Anxiety Disorders (GAD, SAD, phobias)

- Rationale: modulate PFC to reduce anxiety sx, fear, fear-memory
- Lack of studies: encouraging results from 2 RCT in PTSD (tot n=52; 1-10 sessions), 1 RCT in phobias (N = 49; single session), other uncontrolled studies; 1 RCT in GAD negative results (n= 30; 5 sessions)
- No evidence to draw conclusion on clinical efficacy
- To investigate in combination with other treatments and strategies? (e.g. exposure, virtual reality, CBT, medication)

Marković et al. Front Hum Neurosci. 2021
Stein et al.. Neuropsychiatr Dis Treat. 2020
de Lima et al. J Affect Disord. 2019
tDCS in Addiction

• Neuromodulation aims: craving, consumption, physiopathological & neurophysiological measures (e.g. impulsivity, executive functions)

• Preliminary findings on craving in Substance Use Disorder: small RCTs for alcohol, nicotine, amphetamine, opioids

• Lack of studies in Behavioural Addictions: sub-groups included in SUD trials, case reports & uncontrolled studies - gambling, food craving, eating disorders, compulsive buying, internet, gambling, sex, sport, gaming

<table>
<thead>
<tr>
<th>Author</th>
<th>Stimulation parameters</th>
<th>Current intensity</th>
<th>Sessions</th>
<th>Duration</th>
<th>Crossover or parallel</th>
<th>Double or single</th>
<th>Addiction type</th>
<th>Subjects</th>
<th>Craving measure</th>
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<td>A-R/L DLPFC</td>
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tDSC active VS sham significantly reduce craving (Hedges' $g = 0.416$, 95% CI: 0.262–0.570); sub-group analyses favour multiple stimulations
tDCS in Addiction

- Small and under-powered trials, significant methodological limitations and heterogeneities: **no strong conclusions on efficacy can be drawn**

- A research avenue **warranting further exploration** with large, high quality RCTs, **including standardised clinical outcomes and extended follow up**
tDCS in Borderline Personality Disorder: the dawn...

- 2 RCTs (tot n= 62)
- tDCS 2 mA, 20 min, anodal L-, cathodal R- DLPFC VS sham
- 10-15 sessions
- Active tDCS superiority on **core dimensions**: executive dysfunctions, emotional dysregulation and processing, impulsivity, aggression

**Clinical RCTs needed**

Molavi et al. J Affect Disord. 2020
Lisoni J, et al. Psychiatry Res. 2020
tDCS in Obsessive Compulsive Disorder

• Modulate abnormal cortico-striatal neurocircuitry: neurosurgery, DBS, TMS
• 4 RCTs (tot n=148), open label and case reports: promising results (preliminary) targeting OFC and pre-SMA/SMA
• Significant heterogeneity and methodological differences: inclusion criteria, concomitant treatment, tDCS stimulation protocols:
  ➢ Number of stim (1-20)
  ➢ Frequency (daily, twice daily)
  ➢ Duration (20-30 mins)
  ➢ Current intensity (2-3 mA)
  ➢ Polarity cathodal ≥ anodal
  ➢ Size of electrode(s) (25-35 cm²)
  ➢ Cortical targets and montage
  ➢ Brain state during sessions

From: Brunelin et al. Brain Scie. 2018
Reviewed in: Cinosi et al. Pilot and Feasibility Studies. 2021 (under review)
FEasibility and Acceptability Of Transcranial Stimulation in Obsessive Compulsive Symptoms (FEATSOCS)

Fineberg NA ¹,²,⁴, Baldwin D ³, Cinosi E ¹,², Meron D ³, Garner M ³, Gale T, ¹,² Wyatt S ², Wellsted ², Adam D ², Robbins TW ⁵

¹ Hertfordshire Partnership NHS University Foundation Trust. Highly Specialised OCD and BDD Service. Rosanne House, Parkway, Welwyn Garden City, Hertfordshire, United Kingdom

² University of Hertfordshire

³ University of Southampton- Faculty of Medicine, Clinical and Experimental Sciences (CNS and Psychiatry)

⁴ Behavioural and Clinical Neuroscience Institute, Dept. of Psychology, University of Cambridge

Funded by the National Institute for Health Research, Research for Patient Benefit (RfPB) [Ref. no PB-PG-1216-20005], study extension by Orchard OCD

RECRUITED TO TARGET (12th May 2021)
ONGOING INTERVENTION and FOLLOW-UP
tDCS in psychiatric disorders

Summary

• good safety and tolerability profile
• evidence of efficacy (small-medium effect size) in non-treatment-resistant depression, multiple stimulations better results
• some encouraging preliminary but overall inconclusive efficacy results for other disorders
• significant methodological issues in appraising efficacy: warranted define optimized stimulation protocols, maintenance & follow up, combination with other treatments, response predictors, mechanisms of action
• further evidence from large, well designed RCTs needed to clarify role in the treatment armamentarium
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Questions?
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