INVESTIGATING THE ACCEPTABILITY AND TOLERABILITY OF TDCS IN PATIENTS WITH OCD
A FEASIBILITY STUDY

Smith, M. V. A[1] , Cinosi, E[2] , Busby, A[1], Hall, N[1] , Baldwin, D[3], Wellsted, D[1], Wyatt, S[1], and Fineberg, N. A.[1,2]

[1]School of Life and Medical Sciences, University of Hertfordshire, Hatfield, UK ,[2] Hertfordshire Partnership University NHS Foundation Trust, Welwyn Garden City, UK, [3] University of Southampton- Faculty of Medicine, Clinical and Experimental Sciences (CNS and Psychiatry)

Introduction

Obsessive Compulsive Disorder (OCD) is a neuropsychiatric disorder which often proves refractory to current treatment approaches, New treatment options are needed to improve health outcomes[1]. Brain imaging demonstrates abnormal cortico-striatal neurocircuitry as underlying OCD pathology and a target for neurostimulation[2].

Transcranial Direct Current Stimulation (tDCS), a non-invasive form of neurostimulation, with potential for development as a self-administered intervention, has shown potential as a safe and efficacious treatment for OCD in a small number of RCTs and uncontrolled studies[3]. The two most promising stimulation sites are located above the orbitofrontal cortex (OFC) and the supplementary motor area (SMA).

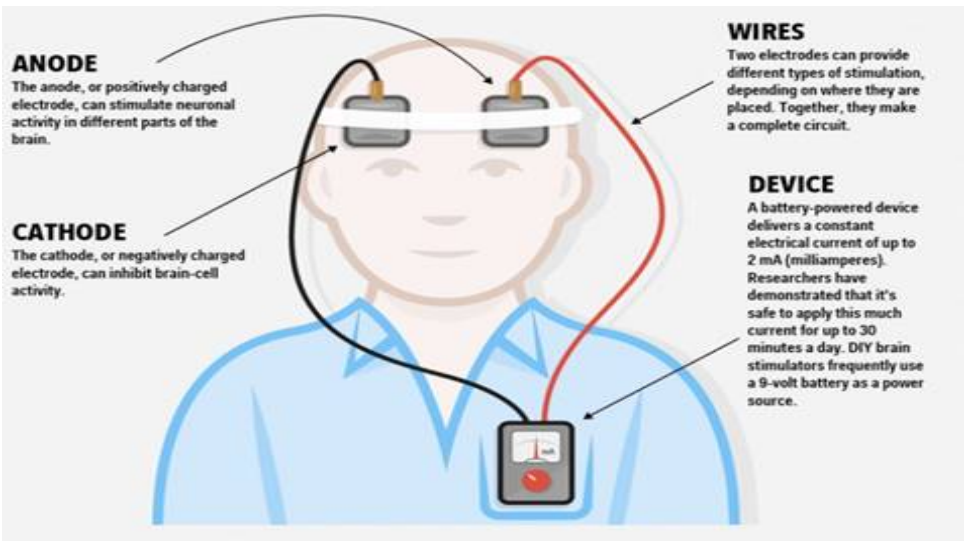
From our feasibility study of tDCS in OCD[3], results on acceptability, safety of the intervention, feasibility of recruitment, adherence and tolerability are presented in this poster.

Due to COVID-19 this study was paused in March 2020 and restarted in July 2020, consequently facing the challenges of recruiting and continuing face-to-face research during the pandemic.

FIGURE 1: PARTICIPANTS COMMENTS

Methods

- A double-blind, sham-controlled, cross-over randomised multicentre feasibility study in adults with non treatment-resistant OCD
- Potential participants were identified from OCD clinics, primary health care services (e.g. IAPTs), charity/support networks, advertisements and trust databases across two sites (Hertfordshire and Southampton)
- Individuals were screened, eligible participants received three courses of tDCS (SMA, OFC and sham/placebo), randomly allocated and given in counterbalanced order
- Each course comprised four sessions of 20-minute stimulations, 2 mA, cathodal, delivered over two consecutive days, separated by at least a four-week washout period
- Participants were evaluated using validated scales, by raters blinded to treatment allocation, at baseline, 1, 2 and 4 hours after stimulation
- Follow-up assessments were conducted via telephone at 24 hours, 7 and 14 days following the last stimulation of each round with a final assessment 28 days after the third round
- Intervention-related adverse events (AEs) were recorded at each time point, using a questionnaire specific to tDCS[4]



Results

A total of 135 individuals were identified as potentially eligible (through clinics or self-referral), of which 36 consented to eligibility screening. Four withdrew consent/were lost to follow up, so screening was completed for 32. Subsequently, 12 were excluded through ineligibility (n=9), withdrawal (n=2) or loss to follow up (n=1), with the remaining 20 randomised. Two participants withdrew prior to intervention both due to COVID-19 anxiety. All other participants (n=18, 90% of those randomised) completed all intervention rounds.

Across all tDCS sessions, the most commonly reported AEs were sleepiness (18.7% of sessions), trouble concentrating (13.0%) and headache (12.2%), with other AE types present at <7% of sessions (Table 1). For some AEs there is a relative higher reported number in the OFC treatment sessions compared to SMA and Sham, although severity was low.

Participant comments represented strong positivity and acceptability of the feasibility study (Figure 1).

TABLE 1: ADVERSE EVENTS

Type of Adverse Event (n %)	n	Treatment Condition		
		OFC	SMA	Sham
Sleepiness	166 (18.7%)	53 (18%)	53 (17.6%)	60 (20.3%)
Trouble Concentrating	116 (13.0%)	46 (15.6%)	29 (9.6%)	41 (13.9%)
Headache	109 (12.2%)	33 (11.2%)	41 (13.6%)	35 (11.9%)
Acute Mood Change	58 (6.5%)	27 (9.2%)	12 (4%)	19 (6.4%)
Skin Redness	50 (5.6%)	34 (11.6%)	14 (4.7%)	2 (0.7%)
Other	48 (5.4%)	28 (9.5%)	10 (3.3%)	10 (3.4%)
Tingling	37 (4.2%)	15 (5.1%)	16 (5.3%)	6 (2%)
Neck Pain	24 (2.7%)	12 (4.1%)	8 (2.7%)	4 (1.4%)
Burning Sensation	21 (2.4%)	12 (4.1%)	8 (2.7%)	1 (0.3%)
Scalp Pain	9 (1.0%)	4 (1.4%)	5 (1.7%)	0 (0%)
Itching	7 (0.8%)	1 (0.3%)	1 (0.3%)	5 (1.7%)
Total	645	265	197	183

Discussion

Despite the impact of COVID-19, this study successfully restarted after suspension with few adjustments, meeting the revised target sample with minimal participant drop-out. Reasons for drop-out were unrelated to the intervention itself, with some participants delayed or experiencing pandemic-related anxiety. Our study confirms tDCS a safe intervention which was accepted, adhered to and tolerated well by OCD patients, even amid a pandemic.

References

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Contact Information: Megan Smith (m.smith25@herts.ac.uk)