**Investigating cognitive and therapeutic effects of transcranial electric stimulation
(TES): a short guide for reproducible and transparent research**

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ABSTRACT

Non-invasive brain stimulation (NIBS) is a useful tool for assisting causal inferences in cortical structure–function relationships and for developing treatment alternatives in neuropsychiatric disorders. Transcranial electrical stimulation (TES) techniques, namely transcranial direct stimulation (tDCS), transcranial alternating current stimulation (tACS), and transcranial random noise stimulation (tRNS), have grown in popularity in recent years because they are well tolerated, safe, and less costly compared to other forms of NIBS such as transcranial magnetic stimulation (TMS). The rigour and reproducibility of TES studies and their findings is therefore of key importance. However, in recent years, uncertainty has grown regarding the effectiveness of TES and the quality of its evidence base. Current recommended steps to improve the rigour and reproducibility of TES research have mainly focused on reducing variation and ambiguity in reported findings. To effectively deal with reported issues, Open Science practices provide a possible answer. The goal of this article is to give an overview of Open Science practices relevant to TES research (i.e., open materials/data, preregistration, registered reports, collaboration) and guidance in how to overcome challenges one may face in their implementation (e.g., data anonymity, costs of sharing materials/data, inappropriate incentives). The ultimate goal of this article is to instigate more engagement from TES researchers in how Open Science practices can be incorporated into standard research practice.

INTRODUCTION

Non-invasive brain stimulation (NIBS) is a useful tool for assisting causal inferences in cortical structure–function relationships and for developing treatment alternatives in neuropsychiatric disorders (Parkin et al., 2015). Transcranial electrical stimulation (TES) techniques, namely transcranial direct stimulation (tDCS), transcranial alternating current stimulation (tACS), and transcranial random noise stimulation (tRNS), have grown in popularity in recent years because they are well tolerated, safe, and less costly compared to other forms of NIBS such as transcranial magnetic stimulation (TMS) (Bikson et al., 2016). The rigour and reproducibility of TES studies and their findings is therefore of key importance (Bikson et al., 2018; Buch et al., 2017; Filmer et al., 2020).

However, in recent years, uncertainty has grown regarding the effectiveness of TES and the quality of its evidence base. Meta-analyses report small and/or inconsistent effects in cognitive studies in healthy controls and clinical effects in neuropsychiatric samples (Horvath et al., 2015; Mancuso et al., 2016; Westwood et al., 2019; Westwood & Romani, 2017; Westwood, in preparation). Low statistical power is commonplace (Medina & Cason, 2017; Minarik et al., 2016; Mitra et al., 2019), double-blinding is not routine (Buch et al., 2017; Fonteneau et al., 2019; Horvath et al., 2014), and there are concerns surround selective reporting (Buch et al., 2017; Medina & Cason, 2017; Westwood et al., 2019; Westwood, in preparation). One survey of 154 TES researchers showed that 40% were aware of researchers adjusting statistical analyses to optimise results, and selectively reporting study outcomes and experimental conditions (Héroux et al., 2017; see also, Riggall et al., 2015). Robust calls for caution when interpreting these findings have been made (Bikson et al., 2018; Filmer et al., 2020). Inconsistent outcomes

are to be expected given that TES effects are a complex interaction between applied stimulation parameters, the neurophysiological response and state-dependent activity (de Graaf & Sack, 2011), all of which is compounded by the wide variation in study methodologies. These issues naturally hamper meaningful interpretation of findings and thwart approaches to evidence synthesis (Nitsche et al., 2015). Moreover, when larger, higher quality studies are conducted that address these issues then informative and reproducible data has been generated (Boayue et al., 2019; Filmer et al., 2020). This provides a clearer indication of what conditions TES may or may not be effective, and the quality of studies improves over time (e.g., Filmer et al., 2020; Loo et al., 2018; Minarik et al., 2016; Russo et al., 2017).

Current recommended steps to improve the rigour and reproducibility of TES research have mainly focused on reducing variation and ambiguity in reported findings. These include identifying best practice in TES administration, combining TES with neuroimaging techniques (e.g., EEG, fMRI, fNIRS), avoiding oversimplified explanations of cognitive and clinical effects of TES, and complete reporting of stimulation parameters (Bestmann et al., 2015; Bestmann & Walsh, 2017; Bikson et al., 2018; Buch et al., 2017; Fonteneau et al., 2019; Parkin et al., 2015; Woods et al., 2016). Although these steps are necessary, they are not sufficient. To effectively deal with reported issues, Open Science practices provide a possible answer.

Open Science

The Open Science movement was initiated because of a series of large-scale projects that reported difficulty in reproducing studies and/or their main findings, most notably in the life and health sciences (R. A. Klein et al., 2014; Nosek et al., 2012; Nosek

& Bar-Anan, 2012; Silberzahn et al., 2018, 2018; Uhlmann et al., 2019). The objective of the movement was to identify the causes of irreproducibility and to provide solutions. The main identified causes included a research culture that places a premium on publication and grant-funding track records (i.e., 'publish or perish culture') and values novelty, innovation and statistically significant results, which can undermine verification, confirmation and replication (Nosek et al., 2012). The problem is exacerbated by widespread questionable research practices, such as low power, reporting bias, flexibility in statistical analysis and hypothesis testing (Cumming, 2014; Martinson et al., 2005). The solutions that have been proposed revolve around making every component of research as transparent as possible, thus permitting greater scrutiny and assisting replication.

Given that TES research is subject to the same misalignment between incentives and best practices as other research fields, and given the aforementioned evidence of questionable research practices, we have every reason to suspect that Open Science practices can afford the same gains in TES research as seen in other fields that have adopted them (Allen & Mehler, n.d.; Munafò et al., 2017; Popkin, 2019; Weston et al., 2019). However, there are many and varied resources available to researchers, and navigating the literature is difficult and overwhelming (Crüwell et al., 2019; McKiernan et al., 2016). Furthermore, Open Science practices were formulated mainly by lab-based experimenters in social and psychology, and are therefore often not easily transferable to TES researchers without some customisation. The goal of this article is to give an overview of Open Science practices relevant to TES research and guidance in how to overcome challenges one may face in their implementation. The ultimate goal of this

article is to instigate more engagement from TES researchers in how Open Science practices can be incorporated into standard research practice. In what follows, I list easy to adopt Open Science practices followed by several key barriers that will stymie their uptake.

Sharing materials and/or data. Central to reproducible and transparent research is making materials and/or data publicly available on an online repository (Munafò et al., 2017). Often overlooked, open materials — in particular metadata — include items that are necessary to reproduce a study procedure and/or analyses without direct instruction from the authors (see Table 2 for Glossary, O. Klein et al., 2018). This would allow thorough scrutiny of a study as well as facilitating standardization, evidence synthesis and replication of TES studies. For example, the open access, community-driven transcranial Direct Current Stimulation Studies Open Database (tDCS-OD) (<http://tdcsdatabase.com>) allows researchers to store and share study parameters (e.g., stimulation intensities, duration, electrode sizes, montages), subject information, and results (if applicable), with the aim of reducing ambiguity in reported parameters and to help identify optimal stimulation protocols (Grossman et al., 2018). In addition to enhancing reproducibility, open materials can facilitate accurate stimulation site localisation and parameters or provide efficient workflows (e.g., pipelines for data analysis or processing), thus cutting down on the wasteful expense of time and money. Apart from website silos, no central repository for NIBS open materials of this nature exists, thereby hampering discoverability and sharing. I have therefore created the Open Materials in Non-Invasive Brain Stimulation (OMNIBS), a crowd-source database that aims to serve

as a central repository for identifying and sharing open materials that are routinely used or considered most useful by researchers using NIBS.

Table 1: Glossary of Open Materials (adapted from O. Klein et al., 2018).

Glossary Open Materials

Study Protocol

This includes a clear and unambiguously worded report specifying hypotheses, and methods and analysis protocol.

Materials

Broadly, these include content in materials and methods sections of an article, such as questionnaire items, presented stimuli stimulation or neuronavigation parameters, analysis pipeline/code.

Data

The term *data* referred to in this article is “raw data”. Although important, summary statistics (e.g., means and standard deviations) cannot be used to verify if your statistical analysis is error free. Raw data also facilitates effect size calculation in evidence synthesis (e.g., meta-analyses).

Metadata

Metadata refers to the descriptive text that allows readers to navigate and understand a dataset (e.g., how and when data were collected, number of variables, excluded datums, value labels)

Analysis Procedure

Highly descriptive document detailing the data analysis undertaken

Sharing data improves verification, reproducibility and reliability of reported data, especially when data are archived on an online public repository (Munafò et al., 2017; Nosek & Bar-Anan, 2012). This manner of data sharing is not normative in TES research. The Research Data statement of the leading journal *Brain Stimulation* states *to facilitate*

reproducibility and data reuse, this journal also encourages you to share your software, code, models, algorithms, protocols, methods and other useful materials related to the project. In a pilot audit, 100 papers published in *Brain Stimulation* between 2016 to 2019 were randomly selected, and of these 33 measured cognitive and clinical effects of TES. None of the papers had archived data and materials on a public repository, while five papers declared that data were available on request. An audit of the willingness of these authors to share data when requested is ongoing. The wider literature suggests that making data available upon request is notoriously unreliable (Teunis et al., 2015; Wicherts et al., 2011), and an estimated 2% of corresponding author email addresses become invalid each year (Rodriguez-Esteban et al., 2019). Routinely making TES research data available via an online public repository is therefore an urgent culture shift in TES research that needs to happen (for similar calls, see Belardinelli et al., 2019)

Preregistration & Registered Reports. Preregistration involves posting a time-stamped, publicly available record of the planned study procedure prior to data collection and/or analysis (Nosek et al., 2018; Wagenmakers et al., 2012). Common practice is to register a basic outline of the study design and protocol, with relatively less attention to pre-specifying data analysis. However, best practice should include preregistering the study with a commitment to making results public along with a detailed pre-specification of the study procedures, outcomes and statistical analysis plan, whenever possible (Munafò et al., 2017; Nosek et al., 2018; Wagenmakers et al., 2012). Such strict preregistration increases discoverability, openness to evaluation, and can unambiguously distinguish confirmatory from exploratory hypothesis testing. The latter is of crucial importance given the many analytical degrees of freedom one has to find statistically

significant results or to retrofit hypotheses to the data (i.e., hypothesizing after the results are known or HARKing, Kerr, 1998). Such data exploration is frequently underreported, and when it is reported it can be presented as confirmatory hypothesis testing, thereby potentially contributing to the number of false-positive in published findings (Wagenmakers et al., 2012).

The above pilot audit showed that of the 33 studies measuring cognitive and clinical effects, only 4 were preregistered. This might be because preregistration is not always seen as appropriate in TES research given that research is still in its exploratory phase, and hypothesis development is hampered by unpredictable recruitment of participants especially in clinical samples. There is also a lack of preregistration agreement and guidance, especially for hypothesis-driven TES studies where it is important to specify the hypothesis, experimental design, power analysis and data processing pipeline (Buch et al., 2017; Nosek et al., 2018; Vazire, 2018). Another reason might be simple lack of awareness of available resources to store and share preregistrations. General preregistration templates are available on the Open Science Framework ([OSF](#)), and I have created a TES specific [one](#). The OSF also allows researchers to preregister hypotheses, data collection and analysis protocols, which are given a persistent digital object identifier (DOI) and can be made publicly available or given permission-based access.

Vague preregistrations, low incentives to adhere to preregistration, and journal bias in publishing positive results, mean that preregistration does not end of biased reporting. Registered Reports (RR) obviate these problems by guaranteeing publication based on the scientific merit of a preregistered protocol. Specifically, before results are

known, an in principle acceptance is given to a prospective study and/or analysis following successful peer-review. Providing that the authors closely follow the protocol, the final submitted manuscript is published regardless of the results. Thus, journals/reviewers cannot be biased by results, data mining is constrained, and researchers can carry out research in the safe knowledge that null findings can be published (Chambers, 2019). Since RRs were implemented in 2013 at *Cortex*, the number of participating journals has increased to 225, including *Brain and Behavior*, *Nature Human Behaviour*, *Behavioral Neuroscience*, *Journal of European Neuroscience*, and there are several RRs in TES research (Boayue et al., 2019; Chambers et al., 2019; Horne et al., 2017)

Multisite collaborations. Low statistical power — whether due to small samples and/or effect sizes — lowers the chances of finding a true effect if one exists, but it can also inflate true effect sizes (Button et al., 2013). Thus, for robust findings and effect size estimates, adequately powered sample sizes are required (Minarik et al., 2016; Russo et al., 2017). The often prohibitive cost of TES equipment means a lack of resources for large studies, a problem exacerbated by the fact that samples often come from populations that are hard-to-reach or rare, are physically disabled, suffer from debilitating mental disorders, non-compliant, or have safeguarding or ethical concerns (paediatric populations, for instance), all of which give rise to small sample sizes. Multisite collaborations permits pooling of resources between labs and boosts statistical power, and there is a growing number of examples to demonstrate that they are feasible (e.g., Psychological Science Accelerator, Moshontz et al., 2018; Human Connectome Project, Van Essen et al., 2013). Equally, large-scale replications are relatively rare and limited to single labs, but recently multisite replication initiatives have been set up to replicate

effects in tACS (i.e., [tACS Challenge](#)), [TMS](#), and I am conducting a tDCS multi-site replication.

Barriers to Open Science practices

Concerns over sharing data/materials. Sharing data incurs ethical issues and legal requirements to protect the privacy of participants. Identification of participants in TES research is a particular issue given that sensitive information is routinely collected for screening purposes or for inclusion in sub-analyses -- e.g., to control for the moderating effects of menstrual cycle, age, education, gender (Antal et al., 2017). Sharing anonymised data in tabular format (ideally in a readable format, such as comma-separated values, or CSV) should be possible without compromising participant privacy, and -- if fully anonymised -- should not apply to the European Union's General Data Protection Regulation (GDPR). However, in cases where identification is possible, GDPR promotes the use of pseudonymisation as standard practice (i.e. where personal data can no longer be associated with a participant without additional information, such as an assigned ID code), but given only three pieces of demographic information are required to identify individuals (e.g., postal code, profession, age; Sweeney, 2000), pseudonymisation procedures must be a three-way consultation with ethics board, participants and your funder. An extra layer of protection is to upload data to a third-party repository that offers restricted access, such as the OSF. The easiest preventative solution is to inform participants upfront before data collection, thereby giving them the opportunity to consent to all potential uses of their data before data are collected (O. Klein et al., 2018; see <https://osf.io/g4jfv/> for consent forms templates). Finally, data sharing guides (Keerie et al., 2018; O. Klein et al., 2018) and consensus-based transparency

checklists (Aczel et al., 2020; Antal et al., 2017; Bikson et al., 2018; Buch et al., 2017) can inform TES researchers what materials and data to share. This checklist information should be included in the final submitted manuscript and/or in a separate document stored in a public repository, wherever and whenever possible. If information is not included (e.g., task stimuli could not be shared due to copyright infringement), researchers should state clearly the reasons why this information is not included.

Costs of sharing data/materials. Sharing data/materials introduces costs that are borne by individual researchers, including loss of control over its use -- whether in terms of its misuse, scooping, or losing a competitive advantage -- and loss of time required to archive data. Researchers can exert control over sharing with embargoes (i.e., where materials, code, data and/or research products are released after a prespecified period), thereby giving time for researchers to publish from their dataset before others can. One can easily archive and share data sets with new data journals (e.g., *Harvard Dataverse* <https://dataverse.harvard.edu/>; *Nature's Scientific Data* <http://nature.com/sdata>; *DataCite* <http://datacite.org>; *figshare* <http://figshare.com>, *Dataverse Project* <http://dataverse.org>; *Dryad* <http://datadryad.org>; <https://www.nwb.org>). Data and code can be archived and assigned a license and a persistent DOI in a free third-party repository that also offers the option of restricted access, such as GitHub, OSF and Zenodo. Together, these mean that data and code can be citeable, discoverable, and reuseable with permission based access, thus increasing transparency while enabling researchers to including them in their hiring and promotion applications (Cousijn et al., 2019; Munafò et al., 2017; Popkin, 2019).

One potentially unintended outcome in TES research is the disincentivization of primary data collection. TES often requires undertaking time-consuming and resource-intensive primary data collection. In a highly competitive field that relies on publication and grant-funding track records to decide career progression, there is a risk that researchers will migrate to secondary data analysis given that it is target rich with potentially publishable articles. This migration is most likely going to be a good thing since it means greater verification of past work, plus it is fertile ground for further research projects. However, in anticipation of TES researchers exhausting secondary datasets (i.e., tragedy of the commons), they should follow sound recommendations (Weston et al., 2019) and avoid multiple statistical testing of the same dataset to minimize the likelihood of false positives in the literature (Thompson et al., 2019). In line with other fields, secondary data is becoming more and more common in TES research. Only by broadening the conversation across the TES research community can we begin to strike the right balance between primary and secondary data collection (Cialdini, 2009; Vazire, 2018; Weston et al., 2019).

Appropriate incentives. The recommended Open Science practices listed above will make little effect without structural incentives. A growing number of large funders require applications to include data management plans to share data, which include National Science Foundation (www.nsf.gov/bfa/dias/policy/dmp.jsp, 2014), [National Institutes of Health](#), and the [Netherlands Organisation for Scientific Research \(2017\)](#), while UK Research and Innovation (UKRI) plan to scrap impact sections from grant applications (Inge, 2020), and some funders are directly funding open research (e.g., Wellcome Trust [Open Research Fund](#)). Alongside funders, journals have an important

part to play. A growing number of neuroscience journals – including *Brain and Behavior*, *Cortex*, *European Journal of Neuroscience*, *Nature Human Behaviour* -- have adopted Transparency and Openness Promotion Guidelines (TOP; <https://cos.io/top/>), which provide a set of standards to instigate the uptake of Open Science practices mentioned above (e.g., preregistration, replication, data/ code/ analysis transparency). Alternatively or additionally, journals adopting voluntary “opt-in” incentives, namely the Centre for Open Science's Badges, which are badges afforded to articles with open data, open materials and a preregistered protocol. The invariable outcome in journals that have adopted these badges has to increase in the prevalence of three, with data sharing in particular rising from 3 to 40% (Kidwell et al., 2016; Lindsay, 2019).

CONCLUDING REMARKS

Given the available evidence from the broader literature, we have every reason to assume that where there is a misalignment between incentives and best practice, issues with reproducibility will most likely propagate (Nosek et al., 2012). Thus, though researchers are motivated by the desire to conduct research in accordance with best practice, many are prevented from doing so because of the lack of structural incentives and norms, and/or lack of resources and training. It is therefore important to stress that TES researchers generally do not depart from standards expected in top journals in brain stimulation and the wider research community. Optimal reproducibility and transparency in TES research is simply not a central requirement for publication. Removing these barriers will help a wider and further engagement of TES researchers in Open Science practices. Although there are green shoots of change, the unique challenges of TES

mean that how effective these changes will be is an open question. Furthermore, given that Open Science practices can place a burden on researchers, more training and development in the necessary skills is required to make these practices commonplace. It is therefore imperative that TES researchers develop materials, incentives, and standard practices to help researchers overcome obstacles to the implementation of open research practices and to optimize their applicability. The purpose of this article is to instigate this change.

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