Clinical Memorandum

Transcranial direct current stimulation (tDCS)

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The Royal Australian & New Zealand College of Psychiatrists

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Purpose

The Royal Australian and New Zealand College of Psychiatrists (RANZCP) has developed this memorandum to inform psychiatrists who are interested in using transcranial direct current stimulation (tDCS) as a treatment for psychiatric disorders.

Key messages

- tDCS is a brain stimulation technique that uses constant, low intensity, unidirectional current delivered through electrodes placed on the scalp to subtly modify brain activity.
- tDCS for the treatment of psychiatric disorders should only be administered after careful evaluation by, and under the supervision of, a psychiatrist with training and expertise in tDCS.
- There is evidence for the use of tDCS in the treatment of depression, emerging evidence of efficacy in treating symptoms of schizophrenia and insufficient evidence for treatment of other psychiatric disorders. There is also no definitive evidence that it is useful for cognitive enhancement.
- Further ongoing research into the use of tDCS in the treatment of neuropsychiatric disorders to develop a more substantial body of evidence to identify and support its clinical efficacy is encouraged.

Background

tDCS is an emerging neuromodulation technique that is already offered in some private clinics in Australia and internationally as a treatment for depression. tDCS is also being studied in clinical trials for other indications.

In Australia the Therapeutic Goods Administration (TGA) has approved two tDCS devices, one for use in unipolar depression, and one for major depressive disorder as well as chronic pain. [1, 2] It is not currently approved for clinical use in New Zealand, although may be used for research purposes.

tDCS kits are available to purchase directly from commercial suppliers, and tDCS is also being used in a 'do-it-yourself' setting by members of the public in the belief that it is useful for cognitive enhancement or as a treatment for disorders. ‘Do-it-yourself’ treatments are not subject to quality and safety assurance which has potential for unintended consequences from brain stimulation, and should be avoided. [3]

What is tDCS?

tDCS is a non-invasive brain stimulation technique that uses constant, low intensity, unidirectional current delivered through electrodes placed on the scalp to subtly modify brain activity. The aim is to modify cortical excitability and activity in key brain areas, and it is thought to work in the acute phase of stimulation by the partial depolarisation and hyperpolarisation of the membrane of cortical neurons. [4] This potentially induces activity-dependent modulation of connected brain circuits and networks. [5] The long-term effects of multiple sessions of tDCS are hypothesized to involve neuroplastic mechanisms similar to long-term potentiation (LTP) and long-term depression (LTD). [6]

There is a wide range of variables which can be modified in the delivery of tDCS (e.g., stimulation site, frequency and spacing of treatment sessions, size and number of electrodes, stimulation intensity and session duration). There are also uncertainties about the specific mode of administration, the number of treatments required and frequency of sessions for optimal therapeutic effects. tDCS is typically applied for 20-30 minutes each session, with daily sessions scheduled each week for 2-6 weeks, in therapeutic applications. The patient is completely alert and conscious throughout the procedure.

Modern tDCS uses commercially available, small, battery-operated devices. In earlier decades, tDCS was known by other terms such as 'brain polarisation', which often involved custom made devices, resulting in less standardised stimulation.

tDCS is the most widespread form of transcranial electrical stimulation (tES), which encompasses forms of low-intensity electrical stimulation delivered through electrodes placed on the scalp, with a variety of stimulus waveforms, including also transcranial alternating current stimulation (tACS) and transcranial random noise stimulation (tRNS). At present, there is insufficient evidence for the clinical use of forms of tES other than tDCS.

Evidence and current research

Depression

Since the reintroduction of tDCS in its modern form at the turn of the 21st century, evidence based on sham-controlled randomized clinical trials of tDCS in depression indicates that this intervention is moderately effective in reducing depressive symptomatology. [7-10] Although findings from some clinical trials have been mixed [11-13] there is evidence supporting the efficacy of tDCS for depression from recent aggregated data meta-analyses [14, 15], individual patient data meta-analysis [16] and network meta-analysis of brain stimulation treatments. [17] Albeit significantly superior to sham for depression improvement, the overall efficacy of tDCS was moderate, showing small to medium effect sizes with interindividual variability in response.

Trials of tDCS for depression have typically involved anodal stimulation to the left dorsolateral prefrontal cortex (DLPFC), given at a low intensity (1–2.5 milliampere) for 20-30 minutes, each weekday for 2- 4 weeks. The optimal placement of the cathode, whether over the right DLPFC, right supraorbital or frontotemporal regions, is still less clear and may depend on the level of depression severity and treatment-resistance of the population. [18, 19]

Schizophrenia

Several trials have investigated the use of tDCS to treat auditory verbal hallucinations (AVH), negative and positive symptoms and cognitive impairment in schizophrenia with mixed results. [20-23] More recently, clinical trials with larger sample sizes showed that active tDCS was superior to sham in ameliorating persistent AVH [24] and negative symptoms. [25] The most recent systematic review and meta-analysis found that tDCS significantly improved positive symptoms, negative symptoms and auditory hallucination in schizophrenia [26], having potential as a safe and well-tolerated adjunctive intervention for this disorder. The anode is typically placed over the left prefrontal cortex, with the cathode over the left temporoparietal junction. [18, 19]

Obsessive-compulsive disorder (OCD)

The preliminary studies examining tDCS in OCD were case reports and a small pilot, sham-controlled RCT [27] that presented mixed findings and used a heterogeneous array of stimulation montages and treatment parameters [28]. More recent RCTs with larger sample sizes indicated that OCD patients who received active tDCS achieved a significantly greater reduction of OCD symptoms than those receiving sham stimulation. [29, 30] Although the studies conducted so far have shown promising results, there are important aspects of the montage (e.g. the polarity of the electrode placed over the pre-supplementary motor area) and other treatment parameters still to be clarified.

Other psychiatric conditions

There have been limited randomized sham-controlled trials to date into the use of tDCS for Post Traumatic Stress Disorder (PTSD) [31] and Generalised Anxiety Disorder (GAD) [32] with mixed findings, although interest in the potential utility of tDCS for these disorders is ongoing. [33, 34]

There are also a small number of sham-controlled studies that suggest that tDCS DLPFC stimulation is possibly effective in reducing craving in a variety of different substance use disorders (including alcohol and nicotine), but there is currently no recommendation for the use of tDCS on crack-cocaine and methamphetamine. [18, 19]

Neurological conditions

tDCS is also the subject of research into neurological conditions. There is some meta-analytical evidence that tDCS can provide pain relief in chronic pain syndromes, such as neuropathic pain, fibromyalgia and migraine. [35, 36] These syndromes are prevalently associated with a number of neuropsychiatric disorders such as depression, anxiety, somatoform disorders and personality disorders. [18]

Although multiple studies suggested benefical effects from tDCS on motor recovery post stroke, most recent metanalyses and systematic reviews did not demonstrate significant beneficial effects. [37-40]

Cognitive enhancement

There is still limited evidence that tDCS is useful for cognitive enhancement in healthy people. [41, 42] Nonetheless, recent meta-analyses suggest that tDCS coupled with cognitive training has a small but significant effect in specific cognitive domains of healthy older adults. [43, 44] Further studies are still needed to assess whether these effects are reliable and extend beyond test settings. There is research into, and some emerging evidence on, its use for cognitive enhancement in conditions associated with cognitive impairment, though clinically meaningful efficacy is yet to be established.

Clinical indications

- For depression, it is recommended that tDCS be given within research trials under formal research ethics governance, or in clinical settings with appropriate organisational governance and oversight. Data on efficacy and safety outcomes should be collected for further evaluation. Patients receiving tDCS should be informed that there is evidence for its use in depression though research is ongoing into the optimisation of treatment.
- Until further data are available, tDCS should only be used in the treatment of other psychiatric disorders within a research protocol which has had formal ethical review and approval.

- For other uses other than the above, it should only be used within specialist centres with appropriate experience in the use of tDCS, after thorough assessment and discussion of treatment options with the patient, with detailed provision of information about the level of evidence base available, and under institutional governance approval.
- As there is limited evidence that tDCS is useful for cognitive enhancement in healthy people, it should not be used for this purpose outside of ethically approved research trials.

Adverse effects

- Trials to date have reported tDCS to be well tolerated and safe, with no major adverse side effects when patients are carefully screened for relevant exclusions, and stimulation is given within recommended parameters, with careful technique. [45-47]
- Potential adverse effects of tDCS include skin irritation and burns. Correct treatment technique is essential in preventing skin damage.
- The long-term effects of repeated tDCS use are unknown, with limited information available from case reports. [48]

tDCS use with other treatments

Treatment with tDCS can occur in conjunction with psychological therapies and/or medications, as clinically indicated.

Patient selection and consent

- Careful screening and selection of candidates is essential and should be conducted by a psychiatrist with appropriate training and expertise in tDCS.
- There is little safety data on the use of tDCS in pregnant women. Use of tDCS in pregnant women should be undertaken within a formal research study with ethical review and approval.
- There is limited safety and efficacy data on the use of tDCS in children and adolescents. tDCS should only be given to those under 18 within an approved research protocol.
- Valid consent is essential for all patients considering tDCS. Enough information and time should be provided for patients to make an informed decision along with families and caregivers. The consent process must be undertaken by a psychiatrist with knowledge and expertise in tDCS therapy, and should detail alternative treatment considerations, the possible benefits of tDCS, and possible adverse effects.

tDCS administration and the role of the psychiatrist

- All practitioners who administer tDCS should be properly trained in the theory, technique and safe operation of tDCS, and in the identification, assessment and early management of complications from tDCS, including induction of elevated mood states and skin damage. There should be continuing professional education to ensure the tDCS practitioner is kept updated on treatment advances.
- Psychiatrists overseeing and prescribing tDCS should be thoroughly familiar with treatment protocols that have been subject to evaluation in substantive clinical trials, with evidence of efficacy and safety. The provision of treatment outside of the boundaries of what has been formally tested in trials, with demonstration of efficacy and safety, should only be done within ethics committee approved clinical trials.

- The prescribing psychiatrist should be familiar with the evidence base for efficacy and safety and discuss this information with the patient during the consent process.
- Patients should be monitored during a course of tDCS, and this should include their progress and any side effects.
- Each organisation conducting clinical tDCS treatment should have in place formal policies and procedures which govern the prescription and use of tDCS. This should include qualifications, training and credentialing of clinicians involved, treatment protocols, a process for monitoring outcomes (efficacy and adverse events) and clinical indicators, as well as the appropriate maintenance of tDCS machines and ancillary equipment.
- tDCS should be prescribed by a psychiatrist knowledgeable in tDCS, and administered by a psychiatrist, or suitably qualified and trained health professional under the supervision of a psychiatrist. The psychiatrist / health professional administering tDCS (tDCS practitioner) should have appropriate expertise and be credentialed by their organisation for tDCS treatment. There should be continuing professional education to ensure the tDCS practitioner is kept updated on treatment advances.
- Each organisation that conducts clinical tDCS treatment should have a process for ensuring the adequate training of tDCS practitioners and a process of credentialing, to ensure that practitioners have appropriate levels of both theoretical knowledge and practical experience. Each organisation should have a formal time period for re-credentialing of practitioners involved with tDCS.
- Hospitals are required to comply with their own governance and accreditation procedures when tDCS is conducted within hospitals.
- There is some evidence from an open label trial (N = 34) for the use of home-administered tDCS. [49] This study showed that an acute four-week treatment period with daily home-administered tDCS was associated with significant improvement in mood, with a favourable tolerability profile. While this suggests the feasibility and potential utility of home-administered tDCS, the use of home-administered tDCS should be limited at this stage to those centres with adequate experience in the training of patients of this treatment modality, with appropriate remote monitoring protocols. [49]
- tDCS practitioners should ensure that they use devices appropriately approved by the Australian Therapeutic Goods Administration and the New Zealand Medicines and Medical Devices Safety Authority as relevant.

Summary

There is evidence for the use of tDCS in the treatment of depression, emerging evidence of efficacy in treating symptoms of schizophrenia and insufficient evidence for treatment of other psychiatric disorders. There is also no definitive evidence that it is useful for cognitive enhancement.

tDCS for the treatment of psychiatric disorders should only be administered after careful evaluation by a psychiatrist and under the supervision of a suitably qualified psychiatrist. For depression, tDCS should be given within research trials, or in clinical settings using approaches that are consistent with available evidence and with appropriate organisational governance and oversight. When given within clinical settings, this includes arrangements for a full audit and review of clinical outcomes of all patients. For psychiatric disorders other than depression, tDCS should be given within research trials, or in specialist centres with appropriate experience in the use of tDCS and clinical outcomes recorded.

All research and clinical use of tDCS should record outcomes to contribute to the further assessment of efficacy and safety to build on the evidence base for use of tDCS. There should be further research into the use of tDCS for cognitive enhancement in conditions with cognitive

impairment to build on the emerging, but not yet clinically meaningful, evidence in this area. Further research is required to be undertaken into the long-term effects of repeated tDCS, which are currently unknown.

As the evidence for the use of tDCS continues to evolve, this memorandum will be reviewed and revised.

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