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RANZCP clinical memoranda provide targeted information about emerging evidence relating to aspects of psychiatric practice.

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. There is emerging evidence for the use of tDCS in the treatment of depression, but insufficient evidence to conclude that tDCS has efficacy in treating symptoms of schizophrenia or other psychiatric disorders. There is also no evidence that it is useful for cognitive enhancement in healthy people. The RANZCP recommends ongoing research into the use of tDCS in the treatment of psychiatric disorders to develop a more substantial body of evidence to identify and support its efficacy.

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 a psychiatrist and under the supervision of a psychiatrist.
- There is emerging evidence for the use of tDCS in the treatment of depression, but insufficient evidence to conclude that tDCS has efficacy in treating symptoms of schizophrenia or other psychiatric disorders.

Background

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

In Australia the Therapeutic Goods Administration (TGA) has approved devices for tDCS for use in depression and other psychiatric and neurological disorders (TGA, 2016; TGA, 2017). It is not currently being studied for clinical use in New Zealand.

tDCS is also being used in a 'do-it-yourself' setting by members of the public, believing it to be useful for cognitive enhancement or as a treatment for disorders, with the potential for unintended consequences from brain stimulation. tDCS kits are available to purchase directly from commercial suppliers.

What is tDCS?

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. The aim is to modify cortical excitability and activity in key brain areas, and it is thought to work by the depolarisation and hyperpolarisation of cortical neurons (NICE, 2015).

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 duration and waveform), and there are uncertainties about the specific mode of administration, the number of treatments needed and the duration of effect for optimal therapeutic effects. tDCS is typically applied for 20-30 minutes each session, with several 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 equipment which are 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.

Evidence of efficacy

Depression

In addition to earlier evidence from old studies of 'brain polarisation' (Arul-Anandam and Loo, 2009) an evidence base of recent randomised controlled trials of tDCS involving a placebo-control (sham stimulation) suggests that tDCS has meaningful efficacy in treating depression, particularly depression that is not highly treatment resistant (Loo et al., 2010; Loo et al., 2012; Brunoni et al., 2016; Lefaucheur et al., 2017; Al-Kaysi et al., 2017; NICE, 2015; Loo et al., 2018; Brunoni et al., 2017; Brunoni et al., 2013).

Trials of tDCS for depression have typically involved anodal stimulation to the left dorsolateral prefrontal cortex, given at a low intensity (1–2 milliamperes) for 20-30 minutes, each weekday for 2-4 weeks.

Schizophrenia

Several trials have investigated the use of tDCS to treat auditory verbal hallucinations, negative symptoms and cognitive impairment in schizophrenia. While some promising results have been reported (Brunelin et al., 2012; Padinjareveetil et al., 2015; RANZCP, 2016) findings from other studies have been mixed (Fitzgerald et al., 2014). To date, all studies have been conducted in relatively small samples ($N \leq 30$) and there is insufficient evidence to conclude that tDCS has efficacy in treating symptoms of schizophrenia.

Other

There is some evidence that tDCS can provide pain relief in chronic pain syndromes, such as neuropathic pain, fibromyalgia etc. These syndromes are prevalently associated with a number of neuropsychiatric disorders such as depression, anxiety, somatoform disorders and personality disorders (Lefaucheur et al., 2017).

There is no good evidence that it is useful for cognitive enhancement in healthy people (Mancuso et al., 2016; Hill et al., 2017). There is research into, and some emerging evidence on, its use for cognitive enhancement in conditions with cognitive impairment, though whether it can lead to clinically meaningful effects is yet to be established.

Clinical indications

There is some evidence that tDCS has antidepressant efficacy. It is recommended that tDCS be given within research trials under formal research ethics governance, or if given in clinical settings, this should be done with appropriate organisational governance and oversight, and with detailed collection of efficacy and safety data for further analysis.

Patients receiving tDCS should be informed that the evidence base for its use in depression is currently limited.

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.

tDCS use with other treatments

Treatment with tDCS can occur in conjunction with psychological therapies or medications. This depends on the care needs and symptom profile of the particular patient.

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 only be undertaken within a formal research study with ethical review and approval.
- There is little 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.

Adverse effects

- Trials to date have reported tDCS to be well tolerated and safe, with no major adverse side effects (Aparício et al., 2016; Bikson et al., 2016; Nikolín et al., 2017) when patients are carefully screened for relevant exclusions, and stimulation is given within recommended parameters, with careful technique.
- 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.

tDCS administration and the role of the psychiatrist

- Each organisation that conducts clinical tDCS treatment should have in place formal policies and procedures which govern the prescription and use of tDCS, qualifications, training and credentialing of clinicians involved, treatment protocols, 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 the 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, such 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.

- When tDCS is conducted within hospitals, these organisations are required to comply with hospital governance and accreditation procedures. tDCS is also conducted by other organisations such as private outpatient clinics. In this instance each clinic should be accredited by an accepted accreditation agency such as International Standards Organisation (ISO) or Australian Council of Healthcare Standards (ACHS), and ensure appropriate credentialing processes are in place.
- 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 unexpected complications from tDCS, including skin damage.
- 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. The provision of treatment outside of the boundaries of what has been formally tested in trials, with demonstration of efficacy, should only be done within ethics committee approved clinical trials.
- Patients should be monitored during a course of tDCS, and this should include their progress and any side effects.
- 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 as relevant. For example, in Australia two different devices have been approved, one for 'unipolar depression in the adult population under the supervision of a qualified health practitioner' (TGA, 2016) and one 'to treat different neurological and psychiatric disorders' (TGA, 2017).

Recommendations

RANZCP recommends that:

- tDCS for the treatment of psychiatric disorders should only be administered after careful evaluation by a psychiatrist and under the supervision of a psychiatrist.
- For depression tDCS should be given within research trials or if used clinically using approaches that are consistent with available evidence and with clinical governance in place, including arrangements for full audit and review of clinical outcomes of all patients. Patients should be informed that the evidence base for its use in depression is currently limited. These requirements should also be applied for the use of tDCS in chronic pain management.
- All research and clinical use of tDCS in depression should record outcomes to contribute to the further assessment of efficacy and safety to build on the emerging evidence to suggest that tDCS can modify mood in depressed patients.
- For psychiatric disorders other than depression, tDCS is given within research trials and clinical outcomes recorded.
- 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.
- As there is no good evidence that tDCS is useful for cognitive enhancement in healthy people that it should not be used for this purpose outside of ethically approved research trials.

- Further research be undertaken into the long term effects of repeated tDCS, which are currently unknown.

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Disclaimer

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