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Neuropsychological Perspectives on FDA-Approved At-Home Brain Stimulation for Depression: Integrating Music-Based Auditory Stimulation

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Abstract
Major Depressive Disorder (MDD) is being increasingly viewed as a network-level pathology of the brain involving dysfunctional neural connections, neuroplasticity impairments, as well as a lack of executive control of emotional processes. In December 2024, the U.S. FDA approved the at-home transcranial direct current stimulation device (tDCS) 'Flow Neuroscience's FL-100' for the treatment of moderate to severe depressive disorders in adults. The advent of this non-pharmacological approach represents a paradigmatic shift in circuit-level therapies for depression. In this paper, we investigate the neuropsychological basis of the FDA's approval of the FL-100 device within a modern conceptualization of depression involving disruptions in the regulatory circuitry of the prefrontal and limbic systems of the brain. In addition, this study advances a theoretically well-grounded multi-modal approach to integrate transcranial stimulation using music-driven auditory stimulation as a primary state-dependent amplifier of the electromagnetic impacts of FL-100 stimulation of underlying emotional, reward, as well as executive neural networks of the brain, as supported by empirical evidence in cognitive neuroscience, affective neuropsychology, as well as research in non-invasive brain stimulation techniques.

Keywords: depression, neuropsychology, transcranial direct current stimulation, FDA approval, music, neuromodulation

Introduction

Depressive disorders contribute significantly to the burden of public health, and the prevalence of these disorders has escalated considerably during the current decade. With respect to the United States alone, more than 20 million adults suffer from depressions annually, and the prevalence of depressions has been seen to escalate by 60% (Centers for Disease Control and Prevention, 2023). Conventional medications, despite their efficacy in this regard, tend to cause delay in onset of action along with systemic manifestations of various degrees, and remain ineffectual in a large group of patients (Rush, 2006). Such drawbacks have significantly fueled interest in novel, non-invasive brain stimulation modalities based on neuropsychological models of depression.

In December 2024, the FDA approved Flow Neuroscience's FL-100 as the first at-home tDCS system cleared for use within the US for treating patients with moderate to severe major depressive disorder (MDD). In contrast to pharmacological-driven methods, the system directly addresses a dysfunctional neural circuit known to underlie mood control as a potential causative factor of depressive symptoms. In this article, the neuropsychological context of this approval will be examined and a new hypothesis will be introduced on combining music-driven auditory stimulation with tDCS treatments.

Depression as a Network-Level Neuropsychological Disorder

The traditional view of depression was a problem of serotonin imbalance as well as other neurotransmitters. Recently, however, there has been a paradigm shift on how scientists perceive depression as a problem of specific regions or certain molecules; instead, scientists perceive it as a problem that involves brain networks; further research indicates that it affects the following brain networks:

Pre-Frontal Cortex (PFC): Specifically left dorsolateral pre-frontal cortex, characterised by hypoactivity and poor executive function with cognitive control over emotions. (Mayberg, 2003).

Limbic System: Involving hyperactivity of the amygdala in the arousal of heightened negative affect and emotionality.

Reward Circuitry: Dysregulation of dopamine circuits involving the nucleus accumbens, to mediate anhedonia.

Default Mode Network (DMN): Excessive self-related processing.

These changes lead to central neuropsychological deficits such as decreased flexibility, emotion dysregulation, negative bias, and deficits in motivation. To effectively treat these deficits, it is necessary that interventions work towards dysfunction at the level of the networks and facilitate neuroplastic reorganization.

Neuropsychological Rationale for Brain Stimulation Devices

Targeting Left DLPFC

FDA-approved methods of brain stimulation such as rTMS and tDCS have mainly focused on the left DLPFC, given the structures' involvement in regulating aspects of cognition such as executive functioning and cognitive reappraisal (Davidson, 2004). Underactivity of the region impairs top-down control over the limbic structures, which drives the symptoms of depression.

Mechanism of tDCS

In tDCS, a low intensity and constant electric current (2 mA) is passed through the scalp using electrodes. In anodal stimulation, there is an increased cortical excitability, and in cathodal stimulation, there is a decrease in cortical excitability (Nitsche, 2000). Notably, in tDCS, action potentials are not directly elicited; rather, resting membrane potentials are altered.

From the neuropsychological point of view, this modulation increases the susceptibility of the target regions to cognitive-emotional stimulation in the process of network reorganization. Repeated treatment sessions achieve long-term potentiation effects as well as the release of brain-derived neurotrophic factor (BDNF) (Brunoni, 2017).

Evidence Supporting FDA Approval of the Flow Device

The FDA approved the use of the FL-100 device based on clinical trials showing benefits in both efficacy and safety. In a mid stage clinical trial, 58% of patients had remission from their condition in 10 weeks, and this also applied to patients who were already under medical or psychotherapy treatment. In worldwide post market data, symptom relief had improved in 77% of patients in three weeks. Side effects were mostly mild and temporary and included skin irritation and headaches. (Administration, 2024).

On the neuropsychological level, these results support the hypothesis that frontoparietal excitability modulation is sufficient to optimize executive regulation over affective processing. Compared to the widespread neurochemical effects of pharmacotherapy, tDCS treatment has circuit level specificity and is non-systemic.

Limitations of tDCS as a Standalone Intervention

While community-based tDCS has been shown to hold great promise in therapeutic applications, it suffers from many limiting factors. The primary problem associated with tDCS is the individual variability in its response. This variability is created based on the neuroanatomical differences in each individual's brain and variations in their initial cortical excitability levels. Further, tDCS also depends on the functional state of the brain at the time of stimulation. When given in its passive form, tDCS also tends to discourage active participant engagement in the treatment. This reduces its capability to produce reliable neurological plasticity changes in the patient's treatment response.

Music and the Brain: A Neuropsychological Basis

Music processing engages a broad distributed brain network that not only encompasses the primary auditory cortex but further involves the prefrontal sectors associated with executive functions, limbic systems that play a pivotal role within emotional information processing, as well as dopaminergic reward circuits that underlie motivation and pleasure. From a neurochemical perspective, music perception is distinguished by increased dopamine activity, serotonin transport alterations, as well as a reduction in cortisol concentration; these brain systems remain frequently deregulated in depressed patients (Blood, 2001). In this manner, music has a regulatory as well as a stimulatory effect on brain activity associated with affective states.

In regard to the psychological and neuropsychological considerations, music has already been found to be associated with improved mood and intrinsic motivation and has been linked to decreased maladaptive rumination and hyperactivity in the DMN. Music use has also been related to emotional expression and improvement in emotion regulation based on its effects on limbic-pre-frontal connectivity in the brain, and reward circuit activation in the brain has been linked to the diminishment of anhedia experienced in depressive disorders. The current proposed project does not conform to any conventional music therapy trial; instead, it views music as an adjunct form of targeted auditory stimulation meant to integrate with neuromodulation techniques.

A Multimodal Neuromodulation Framework: tDCS + Music

State-dependent neuromodulation is an attractive theoretical basis for improving the effectiveness of tDCS, since it is known that stimulation outcome is enhanced when the stimulated neural networks are activated (Silvanto, 2008). Music can then play a role as a priming stimulus for prefrontal–limbic networks, making the brain more susceptible to stimulation by synchronizing the brain activity with the localization and the character of neuromodulation. On the other hand, music-induced activation of emotions may enhance the mechanisms of learning, especially when combined with increased excitability of the cortex due to tDCS, making it an effective adjunct for an enhanced likelihood of meaningful changes. Finally, linking music with tDCS may be helpful in terms of engagement, especially when community or home therapy is concerned, due to its ability to prevent blunting effects on emotions.

Conceptually, the model of choice posits that the use of anodal tDCS to stimulate the left dorsolateral prefrontal cortex leads to increased cortical excitability, which is then added to music-induced activation of limbic and reward pathways. Significantly, it should be noted here that this model has been reiterated as a hypothesis to be mutually validated by empirical research in the future because music and tDCS are currently considered to be a low-risk and non-invasive technique with inherent importance in psychology and other scientific disciplines.

A key consideration here is the observation that although music and tDCS have been assessed to be a low-risk and non-invasive technique in psychology and related disciplines because they are not injurious psychologically and physically to the subject being studied or intervened with, certain other factors are important in music and psychology and should be taken into account in future studies in psychology and related disciplines because they have inherent significance in psychology and related disciplines.

Ethical and Individual Difference Considerations

Though the combined use of music and tDCS is risk-free and does not pose the risk of injury to the subject, certain aspects related to the use of music with tDCS become important for its effective use. Variations in preferences related to music become especially important since what is interesting or comforting for one person may not work for another. In view of this aspect, the use of auditory stimulation related to preferences is important for maximum neural activation. (Bikson, 2018)

In addition, music has the capacity for emotional expression, thus introducing the risk of emotional triggering, particularly in more vulnerable clinical groups. Cultural factors must also be considered with caution, since musical meaning, emotional valence, and acceptability can vary considerably with specific cultural backgrounds. Lastly, risks of overstimulation, either emotional or neural in nature, should not be underestimated, particularly with sensitive emotional stimulation and neuromodulation procedures. To ensure that these risks are properly managed, a number of adjustments can be made in further research and implementation of music procedures.

Future Directions and Research Gaps

This model takes into consideration some of the important shortcomings that exist in current neuromodulation studies that focus on non-invasive methods. First, there is very limited study on multimodal neuromodulation in the home environment despite the current focus on scalable or community-based intervention. Current approaches to tDCS are largely unimodal and passive in that there is an ignorence of the possible advantages of combining multiple sensory modalities, some of which could potentially have an augmenting effect in state-dependent stimulation.

Second, sensory stimulation, especially auditory engagement, has not yet been tapped into properly in tDCS research, despite being known for its fundamental neuropsychological impact upon emotional processes, cognition, and the reward system. In fact, current devices do not leverage basic neuropsychological knowledge at all; namely, the design primarily targets stimulation characteristics and not the degree of usage or engagement or functional brain states. Thus, there would be value in conducting a randomized control trial focusing upon the efficacy of tDCS as well as music-based auditory stimulation as a means of stimulating further comprehensive and principled neuromodulation interventions.

Conclusion

Neuropsychologically, FDA-approved “at-home” brain stimulation technologies targeting depression signal an important paradigm shift from a 'chemical fix' model of treatment to 'rewiring' or 'circuit restoration.' By targeting prefrontal cortical excitability, especially in areas important to 'cognitive control, emotion regulation, and reward processing,' these devices could reverse dysfunctional 'top-down' control of the 'limbic system' that contributes to fundamental depressive symptoms of 'mind rumination, anhedonia, and affective dysregulation.' On a network level, this treatment strategy is well in line with the current paradigm of neuropsychological models of 'depression' that conceptualize 'depression' not as a 'chemical' but as a 'circuits' disorder.

Within this paradigm, incorporating music-driven auditory stimulation directly into device design offers a theoretically well-supported and novel adjunct. Music can actively engage prefrontal-limbic and reward circuitry, in this way driving the functional brain state during stimulation. By incorporating music as an in-built, variable option—in contrast to being integrated as an afterthought or supplementary modality--it is possible that auditory stimulation sessions can be coordinated with individualized music input, enhancing engagement and emotional saliency in at-home treatment regimens. While empirical support is necessary at this point, this multi-modal treatment paradigm has great promise for future-oriented customized depression treatment delivery.

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