EXAMPLE #2 – R01

Title: A Randomized Controlled Trial of tDCS-Augmented CBT for Veterans with Pain and Opioid Misuse

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[1]Hook
[2]Current knowledge
[3]Gap in knowledge
[4]Critical need
[5]Narrowing context
[6]Path to hypothesis
[7]Hypothesis
[8]Outcome
[9]Specific objectives
[10]Outcome (re-stated)
[11]Innovation
[12]Qualifications (potential for success)
[13]Public health-related impact

First Phase

[1]As a result of sustained operations in Afghanistan and Iraq, an increasing number of U.S. military personnel and Veterans are in need of effective pain management treatment. [2]Chronic low back pain (CLBP) is the most common pain condition among returning Veterans and is associated with high levels of opioid analgesic prescribing in VA clinics. [3]Although opioids are effective for acute pain, they are not very effective as a long-term treatment strategy. Furthermore, opioids are associated with significantly increased risk of misuse, addiction, diversion, overdose and death. [4]Consequently, there is a critical need for the development of alternative, effective treatments for CLBP that can be implemented in VA-based healthcare settings.

Second Phase

[5]Although cognitive behavioral therapy (CBT) is the most widely used, evidence-based, non-pharmacologic treatment for pain, its effects on pain are modest when used in isolation. Enhancing the effectiveness and durability of CBT is critical to providing a viable non-pharmacologic treatment option to the millions of Veterans suffering from chronic pain and reducing their reliance on problematic chronic opioid therapies. [6]Transcranial Direct Current Stimulation (tDCS) is a novel, minimally-invasive brain stimulation technique that demonstrates analgesic effects when applied over the dorsolateral prefrontal cortex (DLPFC). Accumulating data from our group and others suggest that tDCS may augment the treatment effects of CBT for chronic pain. However, no studies to date have directly investigated potential synergistic effects of combining these therapies. [7]The proposed study directly addresses this gap in the literature by testing the feasibility and preliminary efficacy of tDCS in combination with CBT to reduce pain (Aim 1) and severity of prescription opioid use disorders (Aim 2) among U.S. military Veterans (including National Guard and Reservists) who have served in Operation Enduring Freedom, Operation Iraqi Freedom or Operation New Dawn (OEF/OIF/OND) with CLBP and co-morbid prescription opioid use disorders. [8]tDCS may prime and modulate prefrontal circuitry resulting in enhanced capacity to tolerate and down-regulate the emotional component of pain experience, while CBT can teach the skills necessary to maintain these gains, thus resulting in a synergistic effect.

[9]The primary objective of the proposed Stage II study is to evaluate the effects of CBT in combination with tDCS in (1) improving pain and functionality, (2) reducing severity of opioid use disorders, and (3) reducing impairment in associated mental health areas (e.g., depression, anxiety, PTSD, sleep). We will also determine the effects of treatment on neural activity in cognitive and limbic brain regions involved in pain regulation using functional magnetic resonance imaging (fMRI), and examine its relationship to opioid use severity. Secondary objectives are to evaluate acute lab-based pain markers and neural correlates of improvement in chronic pain using quantitative sensory testing. In order to accomplish this we are: using a manualized, evidence-based CBT intervention that is already widely-disseminated within the VA system; employing a randomized, between- groups, double-blind experimental design; and examining standardized, repeated, dependent measures of change in: (a) clinical outcomes such as pain, opioid and other substance use disorders (e.g., alcohol, illicit drugs, other prescription drugs), depression, anxiety, sleep and PTSD symptomatology; and (b) process variables such as participant satisfaction, quality of life and treatment retention.

Third Phase

Specific Aim 1: To compare the efficacy of CBT + real tDCS vs. CBT + sham tDCS, in reducing pain.

Specific Aim 2: To compare the efficacy of CBT + real tDCS vs. CBT + sham tDCS, in reducing severity of prescription opioid use disorders, as well as impairment in associated areas (i.e., other substance use disorders, depression, anxiety, PTSD, sleep).

Specific Aim 3: To use fMRI to determine the effects of CBT (with and without tDCS) on the neural response to pain and its relationship with opioid use severity.

[10]The proposed study will answer critical questions regarding the ability of tDCS to augment the effects of CBT for pain, and elucidate possible mechanisms underlying improved outcomes. [11]tDCS is inexpensive and highly portable, making it a very scalable tool to add to current CBT interventions within the VA healthcare system. [12]This study has the particular advantages of building directly on positive preliminary findings among civilians and is being led by a multi-disciplinary team of experts who have successfully collaborated in the past and are uniquely qualified to implement this type of investigation. [13]The results of this study will provide important information regarding two non-pharmacologic, evidence-based interventions (CBT and tDCS), and will help inform policies and programs to better serve the needs of U.S. military personnel, Veterans, and their families. The findings from this study may help reduce public health costs and morbidity/mortality associated with chronic pain and co-morbid prescription opioid use disorders among our nation's Veterans.