



## Background & Introduction

- Post-traumatic headache (PTH)** is defined as a secondary headache disorder that develops within at least 7 days following head trauma such as mTBI (or after regaining consciousness following head trauma). The prevalence of mTBI and PTH is increasing among Operation Enduring Freedom (OEF) and Operation Iraqi Freedom (OIF). Headache is one of the most prominent symptoms following TBI. One study found a prevalence of PTH as high as 37% in US Army Troops who had a TBI during deployment.
- Transcranial direct current stimulation (tDCS)** applies a low direct electrical current through electrodes placed on the scalp, altering neuronal resting membrane potential and brain activity. There has been recent success utilizing tDCS to treat [depression](#), [chronic migraine](#), [cognitive impairment](#) involving attention, working memory and executive function, [loss of inhibitory control](#), [sleep disturbance](#) and [aphasia](#). A recent meta-analysis suggests that tDCS could be a promising non-pharmacological alternative treatment for [migraine pain](#). The exact mechanisms of this treatment on pain modulation are not yet well known. However, mounting evidence in pre-clinical and clinical studies suggests that tDCS can modify the neuronal excitability and is capable of improving connectivity of large-scale brain networks via improved synchronization.
- The effects of tDCS on persistent PTH have yet to be evaluated in [remotely administered](#), at-home setting. VA Telehealth real-time video monitoring for at home administered tDCS treatment offers unique advantages for care. Our goal is to be able to [supervise participants in real-time during tDCS sessions](#) in the comfort of their own home.

## Objectives

- 1: To assess the feasibility and efficacy of at-home transcranial direct current stimulation (tDCS) treatment, monitored via the VA Telehealth platform, in veterans with persistent post-traumatic headache.
- 2: To assess changes in total number of headache days per month, impact of headaches on quality of life, and pain medication use from baseline period to end of treatment.
- 3: To evaluate the changes in modulatory capacity of patients' cardio-autonomic function as a measure of heart rate variability (HRV) from baseline period to end of treatment.

## Materials & Methods

- A total of 20 participants will each undergo 20 tDCS sessions using the tDCS mini Clinical Trial device, with 10 participants in the treatment group receiving active tDCS and 10 participants in the sham group.
  - Active tDCS group will receive anodal stimulation to the dlPFC (Figure 1)
  - Sham tDCS group will receive sham stimulation to the dlPFC
- Both groups will receive the same mindfulness meditation via VA health system approved Mindfulness Coach application to ensure similar baseline in brain activity. First and last tDCS sessions will be done in the clinic. Subsequent visits will be completed via the VA Telehealth with supervision by study team. Before the first and after the last tDCS session, participant's heart rate will be monitored via electrocardiogram (ECG) while completing a physical and cognitive stress test. This will enable us to determine changes in heart rate variability (HRV) at the start of treatment to the end of treatment phases.
- A daily headache diary will be used to record changes in headache symptoms throughout the study. Study personnel will follow up by phone or during VA Telehealth monitored treatment sessions to answer headache assessment and quality of life questionnaires (HIT-6, PHQ-9, Rivermead PCS, PCL-5 Beck Anxiety Inventory, and Insomnia Severity Index).
- A 12-week follow-up phase will proceed after the last treatment session in which study personnel will call patients weekly to discuss headache severity and other impacts on quality of life.

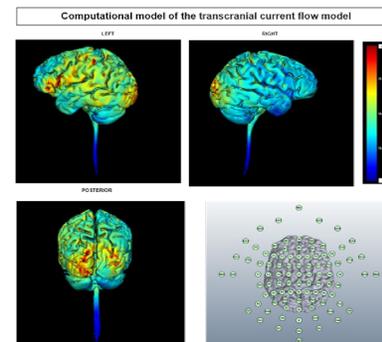


Figure 1: Computational modeling demonstrates flow of current from left PFC region to the occipital pole, with no current flow over right PFC or inferior frontal cortex.

## Preliminary Results

tDCS																
Medication Exposure Headache Days	Days w/ no headache	Days w/ mild headache	Days w/ light headache	Days w/ moderate pain	Days w/ functional disability	Days w/ moderate pain	Days w/ severe pain	Days w/ severe pain	Days w/ severe pain	PHQ-9 Score	HIT-6 Score	PCS Score	SAI Score	Rivermead PCS Score	Insomnia Severity	
Subject SH	29	11	27	27	26	3	16	11	-	-	22	66	66	25	42	-
Subject SH	6	0	0	0	6	0	0	-	6	-	3	60	28	7	23	3
TREATMENT PHASE																
Medication Exposure Headache Days	Days w/ no headache	Days w/ mild headache	Days w/ light headache	Days w/ moderate pain	Days w/ functional disability	Days w/ moderate pain	Days w/ severe pain	Days w/ severe pain	Days w/ severe pain	PHQ-9 Score	HIT-6 Score	PCS Score	SAI Score	Rivermead PCS Score	Insomnia Severity	
Subject SH	28	13	0	28	18	0	14	28	-	-	-	-	-	-	-	-
Subject SH	0	0	0	0	6	0	0	-	6	-	-	-	-	-	-	-
12-Week follow-up phase																
Medication Exposure Headache Days	Days w/ no headache	Days w/ mild headache	Days w/ light headache	Days w/ moderate pain	Days w/ functional disability	Days w/ moderate pain	Days w/ severe pain	Days w/ severe pain	Days w/ severe pain	PHQ-9 Score	HIT-6 Score	PCS Score	SAI Score	Rivermead PCS Score	Insomnia Severity	
Subject SH	-	-	-	-	-	-	-	-	-	18	64	29	01	26	-	
Subject SH	-	-	-	-	-	-	-	-	-	2	52	34	9	22	3	

## Conclusion & Future Directions

- There is a lack of evidence-based treatment strategies for persistent PTH.
- Veterans may benefit by decreased headache severity and an improved quality of life after tDCS treatment.
- With the use of [at-home supervised tDCS treatment sessions](#), veterans will benefit from improved access to care.
- Results of this research will make a significant contribution to the scientific knowledge regarding the use of remotely administered tDCS for persistent PTH and its impact on recovery in these patients.
- The proposed clinical study may lead towards identification of novel tDCS treatment target sites in the brain.
- Based on the results from this pilot study, we plan to submit a larger scale, randomized clinical trial to investigate the efficacy of remotely administered tDCS with real-time monitoring for PTH in veterans.

## Acknowledgements

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