

AWARD NUMBER: W81XWH-16-1-0521

TITLE: Treatment of Memory Disorders in Gulf War Illness with High-Definition Transcranial Direct Cortical Stimulation

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CONTRACTING ORGANIZATION: The University of Texas, Richardson, TX

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14. ABSTRACT The present study consists of the application of 1 ma anodal HD tDCS over the preSMA for 20 minutes a session for 10 sessions over a two week period. The treatment is hypothesized to lead to improvement in verbal retrieval, detectable in both performance measures of verbal retrieval tasks and in ERP markers of verbal retrieval processing. Our objective is to determine if 10 sessions of 1 ma anodal HD tDCS to the preSMA for 20 minutes a session are an effective treatment for verbal retrieval deficits in GWI. We have established the research team, laboratory setting, maintained approval of all regulatory documents for the study, and established recruiting procedures. We have recruited 74 subjects for the study and enrolled 27 out of 80 subjects. Nineteen subjects have completed treatment.					
15. SUBJECT TERMS Gulf War Illness; High Definition Transcranial Direct Current Stimulation; word finding; semantic memory					
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1. INTRODUCTION:

The present study consists of the application of 1 ma anodal HD tDCS over the preSMA for 20 minutes a session for 10 sessions over a two-week period will lead to improvement in verbal retrieval that will be detectable in both performance measures of verbal retrieval tasks and in ERP markers of verbal retrieval processing. Our objective is to determine if 10 sessions of 1 ma anodal HD tDCS to the preSMA for 20 minutes a session are an effective treatment for verbal retrieval deficits in GWI.

2. KEYWORDS:

Gulf War Illness; High Definition Transcranial Direct Current Stimulation; word finding; semantic memory

3. ACCOMPLISHMENTS:

What were the major goals of the project?

1. Approval of Regulatory Documents for use of HD tDCS in Therapeutic Setting
 - a. UTD IRB approval – 100% complete
 - b. HRPO approval – 100% complete
 - c. Obtain lab space, purchase and set-up HD tDCS and EEG, test units – 100% complete
 - d. Train staff in EEG and HD tDCS – 100% complete
 - e. Establish recruiting procedures – 100% complete, but we continue to expand all recruiting efforts
2. Recruiting and Screening Patients for Study
 - a. Recruitment of patients – 62% complete (74 patients recruited and screened out of 120 goal)
 - b. Screening of patients – 62% complete (74 patients recruited and screened out of 120 goal)
3. Performing Pre-Treatment Assessments
 - a. Perform pre-treatment neuropsychological assessments - 34% completed (have completed 27 out of 80 goal)
 - b. Perform pre-treatment EEGs - 34% completed (have completed 27 out of 80 goal)
4. Performing HD tDCS vs. Sham HD tDCS Treatment
 - a. Randomize patients to 10 sessions of active or sham 1 ma anodal preSMA HD tDCS - 25% completed (have completed 20 out of 80 goal)
 - b. Perform 20 minutes of active or sham 1 ma anodal HD tDCS over the preSMA region for 10 daily sessions - 24% completed (have completed 19 out of 80 goal)

5. Perform Follow-up Neuropsychological and EEG Studies of Treatment Effect
 - c. Perform post-treatment neuropsychological assessments – 24% completed (have completed 19 out of 80 goal)
 - d. Perform post-treatment EEG tests of word retrieval - 24% completed (have completed 19 out of 80 goal)
6. Data Analysis
 - a. Perform longitudinal analyses of neuropsychological and EEG measures for treatment efficacy- 0% complete
7. Dissemination of Findings – Manuscript and Report Preparation – 0% complete

What was accomplished under these goals?

We have established the research team and laboratory settings, maintained continued approval of all regulatory documents for the study, and refined recruiting procedures. We continue to grow our recruiting network and social media presence.

We have recruited 74 subjects for the study and enrolled 27 out of 80 subjects. Nineteen subjects have completed treatment. To increase enrollment and completed treatment numbers, we received a no cost extension for the project until 29 September 2022.

The COVID-19 pandemic has had a tremendous impact on recruitment, but we are trying to minimize its effects. During this last quarter, we were able to resume in-person recruitment efforts and contacted over 55 organizations. In-person events attended include a resource fair at the University of Texas at Dallas, a Veteran hockey League tournament, a trip to the Patriot Paws Organization headquarters and Equest Therapeutic Horsemanship, and a visit to the DFW airport to give an informational speech to the airport police force. Our recruitment team has future recruitment events on the calendar, and we continue to correspond with previous organizations and reach out to new ones.

Participants Screened, Consented, Enrolled, and Tested during this reporting period

Screened: 2

Consented, enrolled, and tested: 2

Completed: 2

Stated Goals Not Met

Recruitment continues to be an issue. We resumed human subject research in September 2020, but the pandemic continues to have an impact on enrollment. We are working with other Veteran Research labs and organizations to share ideas. We recently resumed attending live recruiting events. Participants continue to show reluctance in enrolling in a study requiring 10 daily sessions of HD tDCS. Last month, we received a no cost extension to continue the study until September 2022.

What opportunities for training and professional development has the project provided?

Nothing to Report

How were the results disseminated to communities of interest?

Nothing to Report.

What do you plan to do during the next reporting period to accomplish the goals?

We will increase recruiting efforts and will continue to actively pursue partnerships for other avenues of recruitment while mitigating risks of Covid-19 by conducting on-line procedures where possible, practicing social distancing, and increasing safety protocols.

4. IMPACT:

What was the impact on the development of the principal discipline(s) of the project?

Nothing to Report.

What was the impact on other disciplines?

Nothing to Report.

What was the impact on technology transfer?

Nothing to Report.

What was the impact on society beyond science and technology?

We have made presentations to various agencies about our project and Gulf War Illness to create awareness of both.

5. CHANGES/PROBLEMS:

Changes in approach and reasons for change

Nothing to Report.

Actual or anticipated problems or delays and actions or plans to resolve them

Covid-19 pandemic has impacted recruitment, and we are realistic about the lasting effects of the pandemic. We are monitoring the number of Covid-19 cases in our area, following local and CDC guidelines, and conducting screening and testing protocols on-line where possible. Other safety measures include reconfiguring space for social distancing, wearing masks, gloves and goggles, providing access to hand washing or hand sanitizing stations, reducing touch points, and adding additional cleaning procedures.

While we are now able to recruit, there are other issues related to Covid-19 that reduce ease of enrollment including lack of scheduled meetings/events to recruit from and continued reticence from subjects to participate in “in-person” studies. We are constantly working to improve recruitment and reach our overall recruitment goals, and we are putting extra effort into recruitment efforts to adjust for delays. We are hoping recruitment efforts for a new study will increase potential participants for this one as well.

Changes that had a significant impact on expenditures

Nothing to Report.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Significant changes in use or care of human subjects

Nothing to Report.

Significant changes in use or care of vertebrate animals

Nothing to Report.

Significant changes in use of biohazards and/or select agents

Nothing to Report.

6. PRODUCTS:

- **Publications, conference papers, and presentations**

Journal publications.

Nothing to Report.

Books or other non-periodical, one-time publications.

Nothing to Report.

- **Other publications, conference papers and presentations.**

Nothing to Report.

- **Website(s) or other Internet site(s)**

Nothing to Report.

- **Technologies or techniques**

Nothing to Report.

- **Inventions, patent applications, and/or licenses**

Nothing to Report.

- **Other Products**

Nothing to Report.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Name: John Hart, Jr., MD, Principal Investigator – no change

Name: Michael Motes, PhD, Co-Investigator, PhD – no change

Name: Jeffrey Spence, PhD, Co-Investigator – no change

Name: Elizabeth Ellen Morris, PhD, Project Coordinator – no change

Name: Justin Jacquain, BS, Research Technician – no change

Name: Kelsey Watson, Research Assistant – no change

Name: Tyler Rawlinson, Veteran Outreach Coordinator – no change

Name: Jill Ritter, Coordinator – no change

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

Nothing to Report.

What other organizations were involved as partners?

Nothing to Report.

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS:

QUAD CHARTS:

9. APPENDICES: