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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 at Dallas

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14. ABSTRACT

The 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 an established research team, laboratory setting, and procedures, and have maintained regulatory approval. We have screened 89 subjects for the study and enrolled (consented) 33 subjects. Twenty-two subjects have completed treatment.

15. SUBJECT TERMS
Gulf War Illness; High Definition Transcranial Direct Current Stimulation; word finding; semantic memory

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9. Appendices	**N/A**

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 – 74% complete (89 patients recruited and screened out of 120 goal)
    b. Screening of patients – 74% complete (89 patients recruited and screened out of 120 goal)
3. Performing Pre-Treatment Assessments
    a. Perform pre-treatment neuropsychological assessments - 41% completed (have completed 33 out of 80 goal)
    b. Perform pre-treatment EEGs - 39% completed (have completed 31 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 - 30% completed (have completed 24 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 - 29% completed (have completed 23 out of 80 goal)

5. Perform Follow-up Neuropsychological and EEG Studies of Treatment Effect
    c. Perform post-treatment neuropsychological assessments – 28% completed (have completed 22 out of 80 goal)
    d. Perform post-treatment EEG tests of word retrieval - 28% completed (have completed 22 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 maintained approval of regulatory requirements and continue to revise recruiting procedures to increase numbers. The study is live on ClinicalTrials.gov.

This past year, we have seen an increase of 25% in recruitment and 33% in randomization. We have recruited 89 subjects for the study and enrolled 33 out of 80 subjects. Twenty-two subjects have completed treatment. We received a no cost extension for the project until 29 September 2024.

<u>Participants Screened, Consented, Enrolled, and Tested during this reporting period</u>
9/30/2022 – 9/29/2023

Screened: 18
Consented, enrolled, and tested: 10 consented; 6 randomized
Completed: 4

<u>Stated Goals Not Met</u>

Recruitment continues to be an issue. We are working with other Veteran Research labs and organizations to share ideas, and we are seeking new avenues to recruit. We continue to use our social media platforms to recruit.

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 focus on recruiting efforts by actively pursuing partnerships with VSOs and seeking other avenues of recruitment. We are utilizing a targeted recruitment strategy via Facebook and Instagram for other Veteran studies in our lab and have leveraged it for this study as well.

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

We will continue to improve recruitment procedures, explore new options, and share ideas.

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.

- **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: Jared Brooks, Veteran Outreach Coordinator – no change
Name: Jill Ritter, Coordinator – no change
Name: Mika Esquillo, Research Coordinator and Technician – no change
Name: Ashna Adhikari, Research Technician – 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: *N/A*
   QUAD CHARTS: *N/A*

9. **APPENDICES:** *N/A*