

AWARD NUMBER: W81XWH-18-1-0464

TITLE: Multi-site Confirmatory Efficacy Treatment Trial of Combat-Related PTSD

PRINCIPAL INVESTIGATOR: Dr. John Hart, M.D.

CONTRACTING ORGANIZATION: The University of Texas at Dallas

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TYPE OF REPORT: Annual

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|  |                    |                                 |                                   |   |  |
|--|--------------------|---------------------------------|-----------------------------------|---|--|
| <b>1. REPORT DATE</b><br>August 2023   |                    | <b>2. REPORT TYPE</b><br>Annual |                                   | <b>3. DATES COVERED</b><br>1AUG2022 - 31JUL2023 |  |
| <b>4. TITLE AND SUBTITLE</b><br><br>Multi-site Confirmatory Efficacy Treatment Trial of Combat-Related PTSD  |                    |                                 |                                   | <b>5a. CONTRACT NUMBER</b><br>W81XWH-18-1-0464  |  |
|  |                    |                                 |                                   | <b>5b. GRANT NUMBER</b>                         |  |
|  |                    |                                 |                                   | <b>5c. PROGRAM ELEMENT NUMBER</b>               |  |
| <b>6. AUTHOR(S)</b><br><br>Dr. John Hart, M.D.<br><br>E-Mail: jhart@utdallas.edu   |                    |                                 |                                   | <b>5d. PROJECT NUMBER</b>                       |  |
|  |                    |                                 |                                   | <b>5e. TASK NUMBER</b>                          |  |
|  |                    |                                 |                                   | <b>5f. WORK UNIT NUMBER</b>                     |  |
| <b>7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)</b><br>The University of Texas at Dallas<br>800 West Campbell Road,<br>Richardson, TX 75080  |                    |                                 |                                   | <b>8. PERFORMING ORGANIZATION REPORT NUMBER</b> |  |
| <b>9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)</b><br><br>U.S. Army Medical Research and Development Command<br>Fort Detrick, Maryland 21702-5012  |                    |                                 |                                   | <b>10. SPONSOR/MONITOR'S ACRONYM(S)</b>         |  |
|  |                    |                                 |                                   | <b>11. SPONSOR/MONITOR'S REPORT NUMBER(S)</b>   |  |
| <b>12. DISTRIBUTION / AVAILABILITY STATEMENT</b><br><br>Approved for Public Release; Distribution Unlimited  |                    |                                 |                                   |   |  |
| <b>13. SUPPLEMENTARY NOTES</b>   |                    |                                 |                                   |   |  |
| <b>14. ABSTRACT</b><br>The present study is a multisite trial with randomization of 330 OEF/OIF/OND veterans with combat related post-traumatic stress disorder (PTSD) to one of three treatment arms - 1 Hz repetitive transcranial magnetic stimulation (rTMS) to the right dorsal lateral prefrontal cortex (rDLPFC) alone, 1 Hz rDLPFC rTMS + Cognitive Processing Therapy (CPT), or sham rTMS + CPT to determine which of these treatments is most effective for reducing PTSD symptoms, as measured by the CAPS-5, and PCL-5.<br><br>We have established the research team, laboratory setting, maintained approval of all regulatory documents for all performance locations for the study, and established recruiting procedures. We have recruited 399 subjects for the study and enrolled (randomized) 92 out of 330 subjects. |                    |                                 |                                   |   |  |
| <b>15. SUBJECT TERMS</b><br>Post-traumatic Stress Disorder (PTSD), Cognitive Processing Therapy (CPT), repetitive magnetic transcranial stimulation (rTMS)   |                    |                                 |                                   |   |  |
| <b>16. SECURITY CLASSIFICATION OF:</b>   |                    |                                 | <b>17. LIMITATION OF ABSTRACT</b> | <b>18. NUMBER OF PAGES</b>                      | <b>19a. NAME OF RESPONSIBLE PERSON</b>           |
| <b>a. REPORT</b>   | <b>b. ABSTRACT</b> | <b>c. THIS PAGE</b>             |                                   |   | <b>19b. TELEPHONE NUMBER</b> (include area code) |
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## 1. INTRODUCTION:

The present study is a multisite trial with randomization of 330 OEF/OIF/OND veterans with combat related post-traumatic stress disorder (PTSD) to one of three treatment arms – 1 Hz repetitive transcranial magnetic stimulation (rTMS) to the right dorsal lateral prefrontal cortex (rDLPFC) alone, 1 Hz rDLPFC rTMS + Cognitive Processing Therapy (CPT), or sham rTMS + CPT to determine which of these treatments is most effective for reducing PTSD symptoms, as measured by the CAPS-5 and PCL-5.

## 2. KEYWORDS:

Post-traumatic Stress Disorder (PTSD), Cognitive Processing Therapy (CPT), repetitive magnetic transcranial stimulation (rTMS)

## 3. ACCOMPLISHMENTS:

**What were the major goals of the project?**

|  | Timeline<br>Months | Status            | %<br>Complete |
|--|--------------------|-------------------|---------------|
| PreStudy Tasks   |                    | Complete          | 100           |
| Aim 1: Conduct multisite trial with randomization of 330 Veterans with combat related PTSD to one of three treatment arms  |                    |                   |               |
| Task 1: Contact, recruit and screen patients for study enrollment. Screen 505 participants                                 | 4-48               | In process        | 57%           |
| Task 2: Perform pre-treatment neuropsychiatric assessments for 330   | 4-48               | In process        | 28%           |
| Task 3: Perform active rTMS/CPT, sham rTMS/CPT, or rTMS alone for 330  | 4-48               | In process        | 26%           |
| Task 4: Perform post-treatment neuropsychiatric assessment at 1 mo, 6 mo, and 12 mo after last treatment for 231           | 8-54               | In process        | 23%           |
| Task 5: Perform longitudinal analysis on neuropsychiatric measures of treatment efficacy                                   | 37-60              | Not yet initiated | -             |
| Task 6: Prepare and submit manuscript on treatment efficacy  | 49-60              | Not yet initiated | -             |
|  |                    |                   |               |
| Aim 2: Use functional MRI and Event Related Potential to better understand brain changes that occur upon treatment of PTSD |                    |                   |               |
| Task 1: Perform pre-treatment ERPs for threatening stimuli for 330   | 4-48               | In process        | 28%           |
| Task 2: Perform pre-treatment fMRIs for threatening stimuli for 255  | 4-48               | In process        | 19%           |
| Task 3: Perform post-treatment ERP for threatening stimuli at 6 and 12 mo for 231  | 8-54               | In process        | 11%; 7%       |
| Task 4: Perform post-treatment fMRI for threatening stimuli at 6 and 12 mo for 179   | 8-54               | In process        | 11%; 6%       |
| Task 5: Perform longitudinal analysis of ERP measures of treatment efficacy  | 37-60              | Not yet initiated | -             |
| Task 6: Prepare longitudinal analysis of fMRI measures of treatment efficacy   | 37-60              | Not yet initiated | -             |
| Task 7: Prepare and submit manuscripts on ERP measures   | 49-60              | Not yet initiated | -             |
| Task 8: Prepare and submit manuscripts on fMRI measures  | 49-60              | Not yet initiated | -             |

## **What was accomplished under these goals?**

We have maintained approval of regulatory requirements for all performance sites and continue to revise recruiting procedures to increase numbers. The study is live on ClinicalTrials.gov with a Certificate of Confidentiality from NIH.

We continue to grow our recruiting network and social media presence across sites. This year, the UTD site launched 6 ad campaigns on Facebook/Instagram. They are handling this process in-house. The FSU site has also launched ad campaigns through a contract with Local IQ to implement ad services on Facebook and sponsored search ads.

The Steven A. Cohen Military Family Clinic at Metrocare site is continuing to have the research assistant prescreen all incoming clients and coordinating with clinicians to screen interested candidates. Metrocare is tracking why potential candidates may not be interested in the study, through their clinicians, in hopes they may identify and reduce barriers to participation.

This past year, we have seen an increase of 86.4% in recruitment and 56% in randomization. Across sites, we have recruited 399 and randomized 92 subjects cumulatively. Of the 92 randomized, 54 completed treatment phase and 34 completed 6 month follow up phase with 26 withdrawn during treatment and 1 lost during follow up.

### **PROTOCOL (1 of 1 total):**

Protocol [HRPO Assigned Number]: E00131.1

Title: Multi-site confirmatory efficacy treatment trial of combat-related PTSD

Target required and approved for clinical significance: Enroll 330 with expectation of 231 (estimate of 30% possible attrition) for the final outcome measures

### **SUBMITTED TO AND APPROVED BY:**

- 18 April 2019 – DoD HRPO approval of protocol
- 5 July 2023 – UT Southwestern acceptance of continuing review for all sites
- 28 July 2023 – DoD OHRO acceptance of continuing review for all sites

Number of subjects recruited/original planned target: 399/505

Number of subjects screened/original planned target: 287/505

Number of patients enrolled/original planned target: 92/330

Number of patients completed/original planned target: 34/231

No unanticipated problems involving risks to subjects or others to report. One adverse event unrelated to study occurred.

## **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?**

During this no cost extension period, enrollment efforts will remain a priority. All three treatment sites continue to focus on finding new recruitment sources, streamlining procedures to remove any barriers, and leveraging resources where possible. The sites are in regular contact with each other.

All sites will continue to actively recruit participants. Funds were redistributed to sites where recruitment is projected to be the highest. UTD staff will assist FSU with CPT therapy as needed. Since UTD and Metrocare are in the same geographical area, Metrocare has agreed to assist UTD with treatment procedures and therapy as needed. This could make it more convenient for some subjects and will allow for more participants to be enrolled by shortening the timeframe between screening and enrollment.

UTD plans to continue to run ads on Facebook and fine tune the strategy to effectively reach potential participants. It launched its eighth Facebook campaign at the end of July with a 9<sup>th</sup> campaign scheduled in September. FSU will continue to work with Local IQ to handle its social media recruitment campaigns.

In the upcoming quarter Metrocare plans to continue to do more paid social media ads and use its monthly newsletter. Metrocare has also added another CPT therapist that can take on more clients for the study for the expected increase in volume.

**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 post-traumatic stress disorder 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 across sites. Current and proposed recruitment efforts are described in Section 3 above.

### **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**

Nothing to Report.

### **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.**

Tillman, G. D., Morris, E. E., Bass, C., Turner, M., Watson, K., Brooks, J. T., Rawlinson, T., Kozel, F. A., Kraut, M. A., Motes, M. A., & **Hart, J., Jr** (2023). P3a amplitude to trauma-related stimuli reduced after successful trauma-focused PTSD treatment. *Biological Psychology*, 182, 108648. Advance online publication. <https://doi.org/10.1016/j.biopsycho.2023.108648>

Tillman, G. D., Morris, E. E., Rawlinson, T., Bass, C., Turner, M., Watson, K., Didehbani, N., Kozel, F. A., Kraut, M. A., Motes, M. A., & **Hart, J., Jr.** (in press). Intelligence quotient, combat experiences, psychosocial functioning, and depressive symptoms' roles in PTSD symptom severity and treatment completion. *Journal of Behavioral and Cognitive Therapy*.

**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?**

John Hart, Jr., MD, Principal Investigator – No change

F. Andrew Kozel, MD, Co-Investigator, Site PI, Florida State University – No change

Michael Motes, PhD, Co-Investigator, UT Dallas – No change

Michael Kraut, MD, PhD, Co-Investigator, Johns Hopkins University – No change

John Burruss, MD, Co-Investigator, Site PI, Metrocare Services of Dallas – No change

Anushka Pai, MD, Co-Investigator, Site PI, UT Southwestern – No change  
Elizabeth “Ellen” Morris, PhD, Project Coordinator/CPT Therapist, UT Dallas – No change  
Jill Ritter, Research Manager, UT Dallas – No change  
Kelsey Watson, Research Assistant, UT Dallas – No change  
Jared Brooks, Research Assistant, UT Dallas – No change  
Elliot Ingram, Research Assistant, UT Dallas – No change  
Vadym Zhyrov, Research Assistant, UT Dallas – No change  
Christina “Tina” Bass, M.S., LPC, CPT Therapist, UT Dallas – No change  
Mary Turner, PhD, Independent Evaluator, UT Southwestern – No change  
Kevin Johnson, PhD, RN, Co-I and TMS Administrator, Florida State University – No change  
Isabelle Taylor, Research Program Manager, FSU Neuromodulation, Florida State University – No change  
Jessica Greil-Burkhart, LCSW, CPT Therapist, Florida State University – No change  
Megan Senda, Research Assistant, Florida State University – No change  
Christina Riccardi, PhD, CPT Therapist, Florida State University – No change  
Joseph Frascella, PhD, Backup unblinded study staff, Florida State University – No change  
Sharon Liebrich, MSN, RN, Additional backup unblinded study staff, Florida State University – No change  
Mariah Jensen, CMA, Research Assistant, Florida State University – No change  
Chelsea Fiduccia, PhD, Co-Investigator, Metrocare Services of Dallas – No change  
Jordan Petry, Research Assistant, Metrocare Services of Dallas and UT Dallas – No change  
Tanya Mac, Outreach Director, Metrocare Services of Dallas – No change  
Keah Odom, LCSW-S, CPT Therapist, Metrocare Services of Dallas – No change  
Ashton Steele, PhD, CPT Therapist, Metrocare Services of Dallas – No change  
John Bennett, MD, On-site Medical Director, Metrocare Services of Dallas – No change  
Toni Adams, MA, LPC-A, Intake Coordinator, Metrocare Services of Dallas – No change  
Jameson Miller, Intake Coordinator, Metrocare Services of Dallas – 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:** Attached

**9. APPENDICES:** Consort diagrams attached. One for each site.

# Multi-site confirmatory efficacy treatment trial of combat-related PTSD



Log # BA160594; Award # W81XWH-18-1-0464

PI: John Hart, Jr., MD

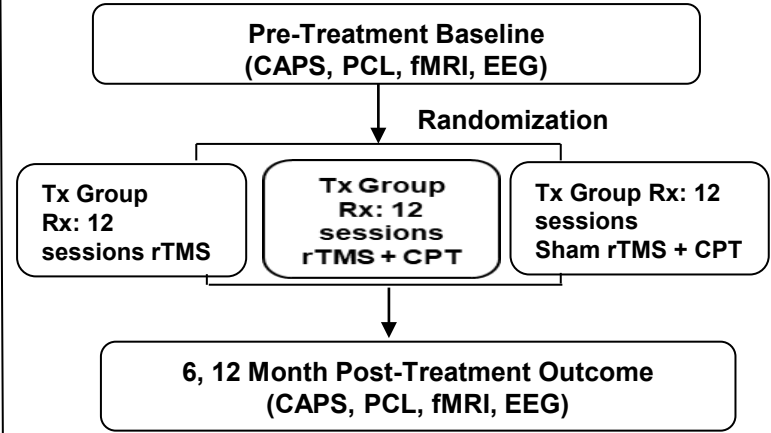
Org: The University of Texas at Dallas

Award Amount: \$7,359,925

## Study/Product Aim(s)

- Aim 1: Conduct multisite trial with randomization of 330 OEF/OIF/OND veterans with combat-related PTSD to one of three treatment arms – 1 Hz rDLPFC rTMS alone, 1 Hz rDLPFC rTMS+CPT, or sham rTMS+CPT, and evaluations at 1 (neuropsychiatric behavioral measures and EEG only), 6 and 12 months post-treatment (neuropsychiatric, EEG, and fMRI measures).
- Aim 2: Use fMRI and ERP to better understand brain changes that occur upon treatment of PTSD symptoms.

**Approach:** Veterans with PTSD will be screened with neuropsychiatric questionnaires to establish eligibility. Then the CAPS-5, SCID, BDI-II, PCL-5, and neuropsychiatric self-report measures will be administered. Participants will then undergo ERP and MRI exams, including the fMRI visual threat task. They will then be randomly assigned (n=110 per group) to one of three treatment arms: 1) 12 sessions of 1 Hz rDLPFC for 30 min each immediately followed by a CPT session, 2) 12 sessions of 1 Hz rDLPFC for 30 mins without CPT, and 3) 12 sessions of sham rDLPFC rTMS each immediately followed by a CPT session. This study will be conducted at 3 sites: 1) Callier Center at UTD, 2) Metrocare of Dallas, and 3) Florida State University in Tallahassee, FL. One month following completion of the treatment sessions, participants will undergo a repeat of the above noted behavioral and EEG measures. At 6 and 12 months post-treatment, participants will again undergo these behavioral, ERP, and MRI including fMRI visual threat task.



## Timeline and Cost

| Activities Yr   | 2019       | 2020       | 2021   | 2022       | 2023   | 2024 |
|---|------------|------------|--------|------------|--------|------|
| 1. Screening 505 veterans for PTSD diagnoses.         | [Blue bar] |            |        |            |        |      |
| 2. Acquiring pre-treatment neuropsychiatric baselines | [Blue bar] |            |        |            |        |      |
| 3. Acquiring pre-treatment fMRI and EEG               | [Blue bar] |            |        |            |        |      |
| 4. Treatment of 330 veterans                          |            | [Blue bar] |        |            |        |      |
| 5. Acquiring post-treatment                           |            |            |        | [Blue bar] |        |      |
| 6. Analyzing data and disseminating findings          |            |            |        | [Blue bar] |        |      |
| Estimated Budget (\$K)                                | \$1.5M     | \$1.5M     | \$1.5M | \$1.5M     | \$1.3M |      |

## Goals/Milestones

### CY18 Goals

- Approval of regulatory documents
- Recruiting 30 subjects in treatment across sites

### CY18-23 Goal

- Enrolling 330 subjects in the study

### CY24 Goal

- Enrolling and Analyzing data

## Comments/Challenges/Issues/Concerns

- Recruitment impacted by Covid-19 pandemic

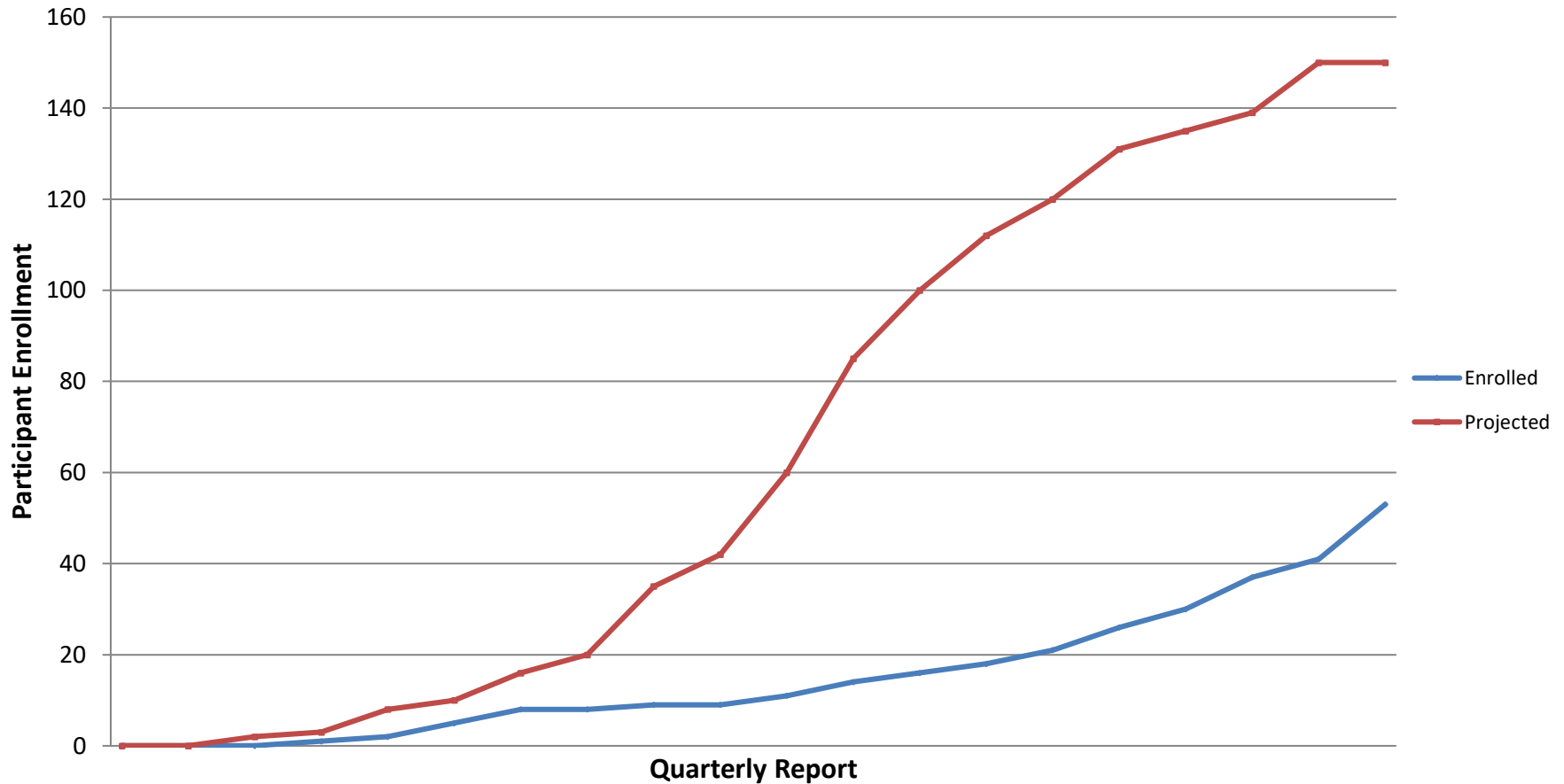
## Budget Expenditure to Date

Projected Expenditure: \$7,359,925

Actual Expenditure: \$6,116,571

Updated: 15 Aug 2023

# Recruitment and Retention – UT Dallas, Dallas, TX



**Percent of participants that have completed the study**

**13%**

# CONSORT Diagram – UT Dallas, Dallas, TX

Enrollment

Assessed for eligibility (n=297)

In Process (n=9)  
Excluded (n=235)

Enrolled (n=53)

Active  
rTMS/CPT

Sham rTMS/CPT

rTMS only

Allocated to intervention (n=20)  
· Completed allocated intervention (n=11)  
· Did not receive allocated intervention (give reasons) (n=0)

Allocated to intervention (n=18)  
· Completed allocated intervention (n=8)  
· Did not receive allocated intervention (give reasons) (n=0)

Allocated to intervention (n=15)  
· Completed allocated intervention (n=13)  
· Did not receive allocated intervention (give reasons) (n=0)

Lost to follow-up (give reasons) (n=0)  
Discontinued intervention (give reasons) (n=4)  
- Scheduling conflict with new job  
- Decided not to participate x2  
- Multiple no shows

Lost to follow-up (give reasons) (n=0)  
- Participant not responding  
Discontinued intervention (give reasons) (n=6)  
- Decided not to participate x4  
- Multiple no show; un-responsive x2

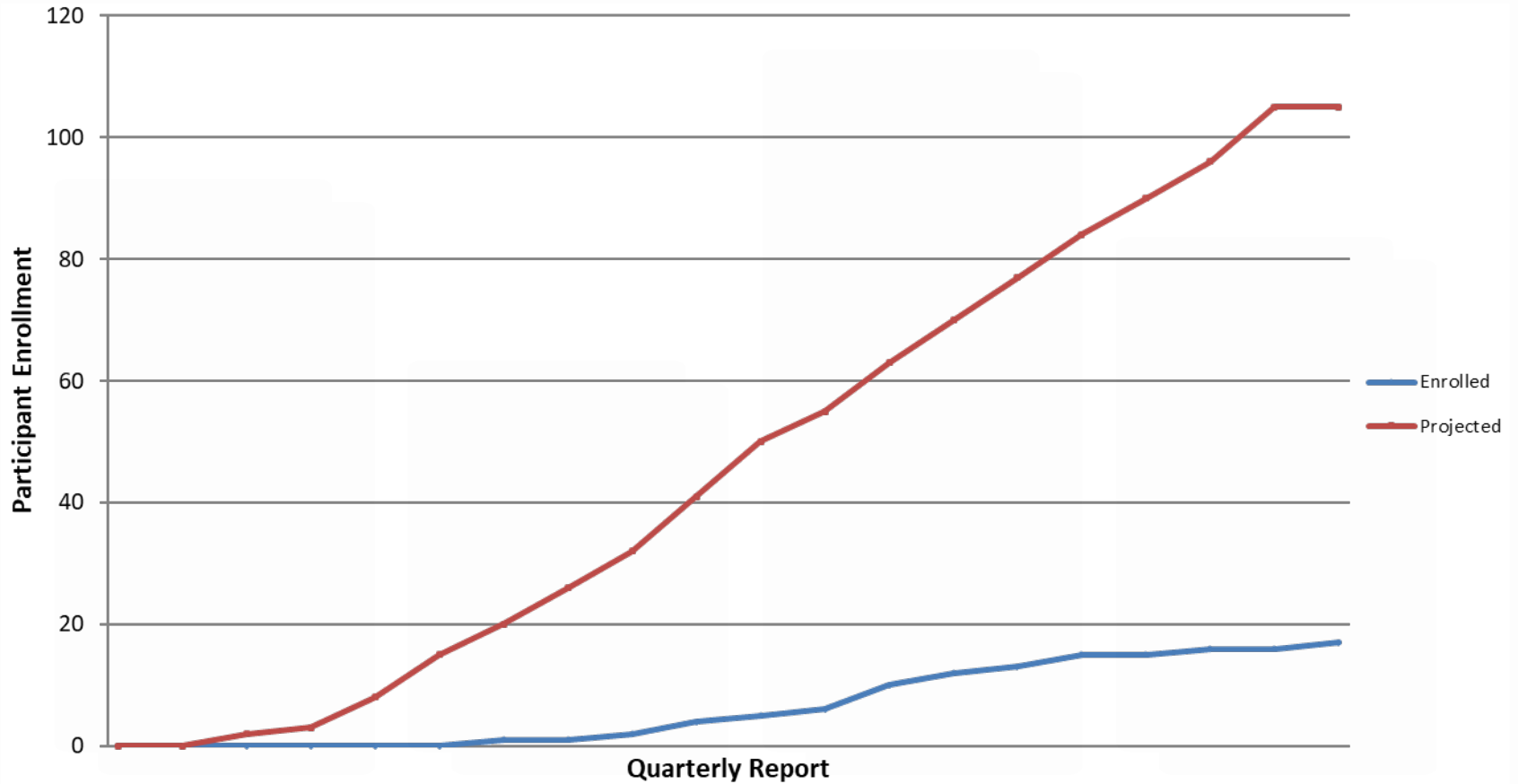
Lost to follow-up (give reasons) (n=0)  
Discontinued intervention (give reasons) (n=1)  
- Decided not to participate

Analysed (n=0)  
· Excluded from analysis (give reasons) (n=0)

Analysed (n=0)  
· Excluded from analysis (give reasons) (n=0)

Analysed (n=0)  
· Excluded from analysis (give reasons) (n=0)

# Recruitment and Retention – Metrocare Services, Dallas, TX



|  |           |
|--|-----------|
| <b>Percent of participants that have completed the study</b> | <b>8%</b> |
|--|-----------|

# CONSORT Diagram – Metrocare Services, Dallas, TX

Enrollment

Assessed for eligibility (n=36)

In Process (n=0)  
Excluded (n=19)

Enrolled (n=17)

Active  
rTMS/CPT

Sham rTMS/CPT

rTMS only

Allocated to intervention (n=5)  
.. Completed allocated intervention (n=3)  
.. Did not receive allocated intervention (give reasons) (n=0)

Lost to follow-up (give reasons) (n=0)  
Discontinued intervention (give reasons) (n=2)  
-Multiple no shows

Analysed (n=0)  
.. Excluded from analysis (give reasons) (n=0)

Allocated to intervention (n=7)  
.. Completed allocated intervention (n=6)  
.. Did not receive allocated intervention (give reasons) (n=0)

Lost to follow-up (give reasons) (n=0)  
Discontinued intervention (give reasons) (n=1)  
-Decided not to participate

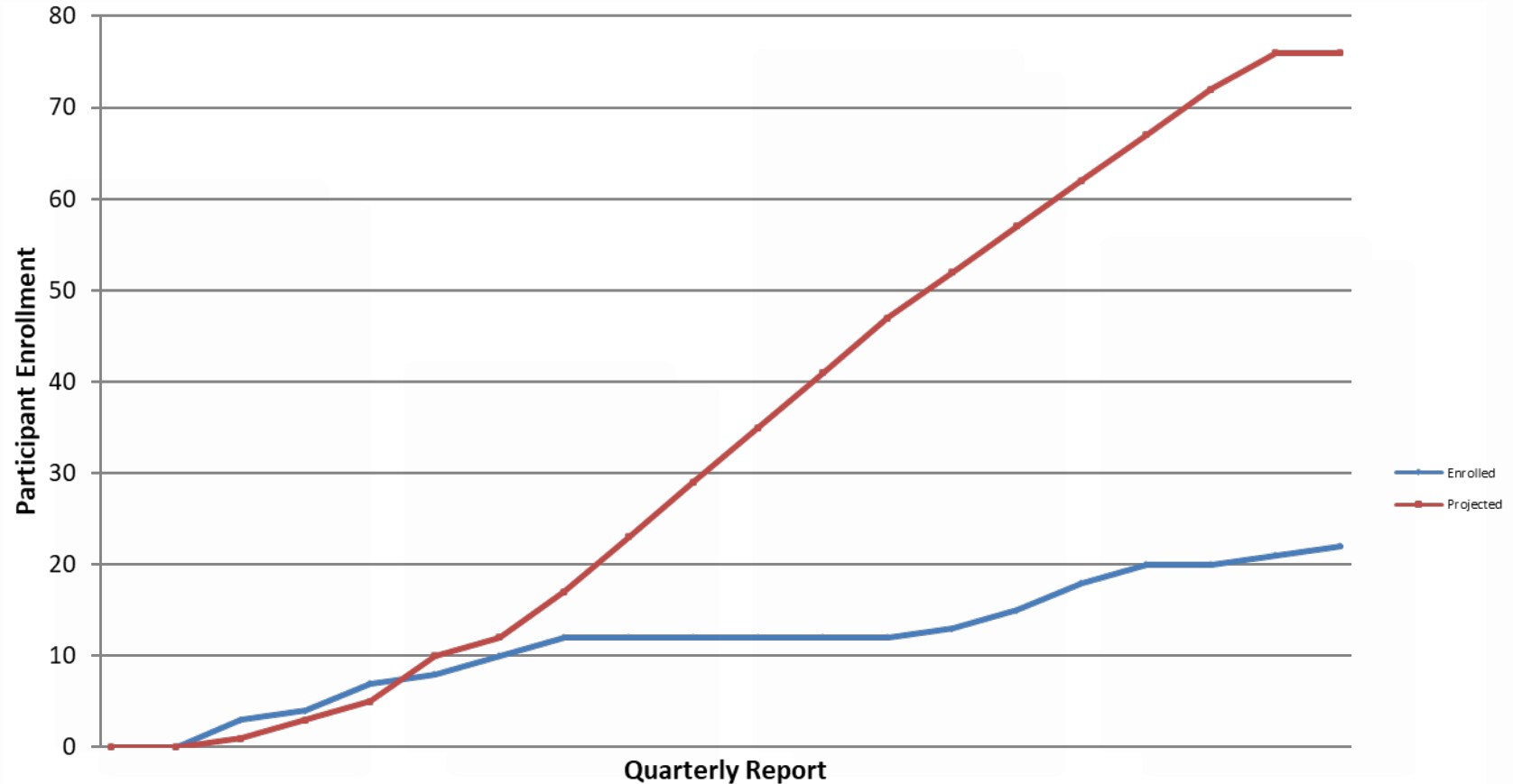
Analysed (n=0)  
.. Excluded from analysis (give reasons) (n=0)

Allocated to intervention (n=5)  
.. Completed allocated intervention (n=4)  
.. Did not receive allocated intervention (give reasons) (n=0)

Lost to follow-up (give reasons) (n=0)  
Discontinued intervention (give reasons) (n=1)  
- Participant not responding

Analysed (n=0)  
.. Excluded from analysis (give reasons) (n=0)

# Recruitment and Retention – James A. Haley VA Hospital, Tampa, FL & Florida State University, Tallahassee, FL



**Percent of participants that have completed the study**

*Haley VA site was closed to recruiting in October 2020 and 5 participants reconsented at UTDallas to complete follow up. FSU enrolled participants starting in Y4Q2.*

**8%**

# CONSORT Diagram – Haley VA Hospital & Florida State University, FL

**Enrollment**

Assessed for eligibility (n=66)

In Process (n=3)  
Excluded (n=41)

Enrolled in Treatment (n=22)

**Active  
rTMS/CPT**

**Sham rTMS/CPT**

**rTMS only**

Allocated to intervention (n=8)  
 .. Completed allocated intervention (n=4)  
 .. Did not receive allocated intervention (give reasons) (n=1) – withdrew before starting treatment

Allocated to intervention (n=7)  
 .. Completed allocated intervention (n=0)  
 .. Did not receive allocated intervention (give reasons) (n=1) withdrew before starting treatment

Allocated to intervention (n=7)  
 .. Completed allocated intervention (n=2)  
 .. Did not receive allocated intervention (give reasons) (n=1) withdrew before starting treatment

Lost to follow-up (give reasons) (n=1)  
 -Participant not responding  
 Discontinued intervention (give reasons) (n=2)  
 -Participants withdrew unrelated to study  
 -Participant moved before starting treatment

Lost to follow-up (give reasons) (n=0)  
 Discontinued intervention (give reasons) (n=7)  
 -withdrawn after missing several appointments  
 -withdrew to start treatment outside  
 -Treatment interrupted by Covid; site closure  
 -Withdrew unrelated to study  
 -Withdrew as CPT bringing up too many emotions  
 -Participant not responding  
 -Participant moved before starting treatment

Lost to follow-up (give reasons) (n=0)  
 Discontinued intervention (give reasons) (n=2)  
 -Participant moved before starting treatment  
 -Participant not responding

Analysed (n=0)  
 .. Excluded from analysis (give reasons) (n=0)

Analysed (n=0)  
 .. Excluded from analysis (give reasons) (n=0)

Analysed (n=0)  
 .. Excluded from analysis (give reasons) (n=0)