AWARD NUMBER: W81XWH-17-1-0320

TITLE: A Pilot Trial of Remotely Supervised Transcranial Direct Current Stimulation (RS-tDCS) to Enhance Motor Learning in Progressive Multiple Sclerosis (MS)

PRINCIPAL INVESTIGATOR: Leigh Charvet, PhD

CONTRACTING ORGANIZATION: New York University School of Medicine
New York, NY 10016-5802

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PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

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4. TITLE AND SUBTITLE
A Pilot Trial of Remotely Supervised Transcranial Direct Current Stimulation (RS-tDCS) to Enhance Motor Learning in Progressive Multiple Sclerosis (MS)

5a. CONTRACT NUMBER
W81XWH-17-1-0320

5b. GRANT NUMBER

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
Leigh Charvet, PhD

E-Mail: leigh.charvet@nyulangone.org

5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
New York University School of Medicine, 240 East 38th Street, Floor 10, 10016

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)

U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

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12. DISTRIBUTION / AVAILABILITY STATEMENT

Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT
The purpose of this randomized, double-blind pilot clinical trial is to test the novel treatment approach of anodal transcranial direct current stimulation (tDCS) to augment manual dexterity training targeted to rehabilitate fine motor functioning in individuals living with progressive multiple sclerosis (MS). Treatment will be delivered to individuals at home using a state-of-the-art remotely-supervised tele-medicine protocol, a major advantage for patients with respect to ease of access, feasibility, and minimal burden of in-clinic study visit participation. Specific Aim 1 is to determine the extent to which tDCS paired with manual dexterity training improves fine motor execution on a grasp and lift task. *We expect that the impairment in grasp execution will be significantly reduced with active tDCS versus sham tDCS from pre- to post-treatment.* Specific Aim 2 is to assess the adaptation or learning of fingertip forces to object weight when tDCS is paired with manual dexterity training. We predict that active vs. sham tDCS paired with training will optimize the difference in the peak load force rates between the light and heavy objects pre- to post-intervention. Training, material and database creation, and randomization/matching procedures complete. First participant enrolled and completed. Participant enrollment ongoing. No preliminary data analysis to date

15. SUBJECT TERMS
tDCS, telemedicine, motor, MS

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRMC
U	U	U	UU	16	19b. TELEPHONE NUMBER *(include area code)*

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1. **Accomplishments:** The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer whenever there are significant changes in the project or its direction.

   What were the major goals of the project?
   List the major goals of the project as stated in the approved SOW. If the application listed milestones/target dates for important activities or phases of the project identify these dates and show actual completion dates or the percentage of completion.

Approved Statement of Work (SOW) 5.27.17

<u>Achieved</u> Major Task 1: Prepare for Study Enrollment, Months 1 – 9

Subtask 1: Finalize Supporting Documents Months 1-3

- Finalize methods for administering eligibility criteria, exclusion criteria, screening protocol: Months 1-3
- Finalize consent form & human subjects protocol: Months 1-3
- Submit amendments, adverse events, and protocol deviations as needed

Milestone achieved: Local IRB approval at NYULMC Month 6
Milestone achieved: HRPO approval of all protocols and local IRB approval through NYULMC Month 9

Subtask 2: Measures, equipment purchasing, and staff training

- Finalize training of study staff: Months 6-9
- Acquire all necessary devices, equipment, and study computer setup: Months 6-9

Milestone Achieved: Study kits created and research staff trained Month 9

Subtask 3: Database creation, randomization, and matching procedures in place Months 6-9

Milestone Achieved: Database created, randomization and group matching procedure in place Month 9

Subtask 4: Initial advertising for recruitment: Month 8

Milestone Achieved: Initial screening waitlist finalized Month 9

<u>In progress</u> Major task 2: Study Enrollment Months 9-30

Subtask 1: Screening and study entry Month 9-27

Milestone Achieved: 1st participant consented, screened, and enrolled Month 9

Subject task 2: Pilot study (20 sessions of 20 minutes each remotely supervised; 40 active vs 40 sham) Months 9 -31

Milestone Achieved: Study 1 begins Month 9

- Begin subject recruitment and extends over 18 months, average enrollment 15pts/quarter Months 9-27
- Last participant (n=80) complete 4 week randomly-assigned condition (active or sham) Month 28
- Follow-up assessment period Months 10-31

Milestone to Achieve: Last participant to complete follow-up assessment Month 31

Study End Data Analyses and Reporting

- Perform all analyzes according to specifications, share output, and finding with all investigators Months 31-36
- Work with data core and dissemination of findings (abstracts, presentation, publications, DoD) Months 33-36

Milestone to Achieve: Report results from data analyses Month 36

Major activities accomplished:
Annual Year 2

<u>In progress</u> Major task 2: Study Enrollment Months 9-30

Subtask 1: Screening and study entry Month 9-27: Ongoing

Subject task 2: Pilot study (20 sessions of 20 minutes each remotely supervised; 40 active vs 40 sham) Months 9 -31: Ongoing

- Begin subject recruitment and extends over 18 months, average enrollment 15pts/month Months 9-27: Ongoing
    - 27 participants enrolled during this period, 1 screen fail, and 2 withdrawals.
    - Total study enrollment n = 32.
- Last participant (n=80) complete 4 week randomly-assigned condition (active or sham) Month 28
- Follow-up assessment period Months 10 -31

Milestone to Achieve: Last participant to complete follow-up assessment Month 31

What was accomplished under these goals?

For <u>this annual reporting period only</u> describe: 1) major activities; 2) specific objectives; 3) significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative); and/or 4) other achievements. Include a discussion of stated goals not met. Description shall include pertinent data and graphs in sufficient detail to explain any significant results achieved. A succinct description of the methodology used shall be provided.

Describe the Regulatory Protocol and Activity Status (if applicable).

Describe the Protocol and Activity Status for sections a-c, as applicable, using the format described for each section. If there is nothing significant to report during this reporting period, state "Nothing to Report."

(a) ***Human Use Regulatory Protocols***

TOTAL PROTOCOLS: *State the total number of human use protocols required to complete this project (e.g., 5 human subject research protocols will be required to complete the Statement of Work."). If not applicable, write "No human subjects research will be performed to complete the Statement of Work."*

PROTOCOL(S): *List the identifier and title for all human use protocols needed to complete the project. Include information about the approved target number for clinical significance, type of submission, type of approval with associated dates, and performance status.*

The following format shall be used:

<u>Protocol (of total):</u>

Protocol [HRPO Assigned Number]:

Title:

Target required for clinical significance:

Target approved for clinical significance:

<u>Submitted to and Approved by:</u>

Provide bullet point list of protocol development, submission, amendments, and approvals (include IRB in addition to HRPO).

<u>Status:</u>

Report (i) progress on subject recruitment, screening, enrollment, completion, and numbers of each compared to original planned target(s), e.g., number of subjects enrolled versus total number proposed; (ii) amendments submitted to the IRB and USAMRMC HRPO for review; and (iii) any adverse event/unanticipated problems involving risks to subjects or others and actions or plans for mitigation.

<u>TOTAL PROTOCOLS</u>: 1 human subjects protocol will be required to complete the Statement of Work.

<u>PROTOCOL (1 of 1 total):</u>

Protocol A-20444.1a:

Title: A Pilot Trial of Remotely Supervised Transcranial Direct Current Stimulation (RS-tDCS) to Enhance Motor Learning in Progressive Multiple Sclerosis (MS)

Target required for clinical significance: 80

Target approved for clinical significance: 80

SUBMITTED TO AND APPROVED BY:

- New York University School of Medicine IRB on 10/09/17:Approval on 11/27/17

STATUS:

(i) Number of subjects recruited during this annual report period: 91
Number of subjects screened during this annual report period: 64
Number of patients enrolled during this annual report period: 27
Number of patients completed during this annual report period: 22

(ii) Report amendments submitted to the IRB and USAMRMC HRPO for review:

MOD6: This phone script was approved in a modification (MOD6 approved by IRB on 7/19/18). Biweekly meetings were completed to review enrolled participant related documentation and study procedures and activities.

MOD 7: Personnel modification to remove Bryan Dobbs from study team (approved by IRB on 7/31/2018).

MOD 8: Amendments to protocol were created to remove non-applicable physical therapy assessments. This modification was approved by NYU's IRB (MOD8 approved by IRB on 8/14/18) and subsequently approved by HRPO (8/20/18). Along with the protocol modification, we modified subject consent forms, including both the Informed Consent Form and the Audio-Visual Consent, to reflect the changes made to the protocol. In the same modification, we made changes to our eligibility criteria to open our study to participants with more severe manual dexterity as we felt that our criteria was too narrow and left out participants capable of preforming the study procedures but were otherwise screened out of the study. With respect to this change, we modified our pre-screen telephone script and technician protocol.

MOD 9: Added personnel including Jen Stone, Nabil Khan and Claire Choi. Removal of Rhea Patel, Natalie Pawlak, Danielle Ladensack and Zena Moore. We also created a recruitment flyer to be placed in NYU facilities as a way to increase study recruitment (approved by IRB on 10/3/2018)

MOD 10: Added new staff members to the current protocol including Amy Ro, Vincent Huang, and Gregory Belizaire. Additionally, clarified study procedures as they related to Safety Data Monitoring Meeting after the first 10 active enrollees in the study (approved by IRB 12/10/2018).

MOD 11: Added new staff members to the current protocol including Matthew Lustberg and Allan George (approved by IRB on 12/18/2018).

MOD 12 (approved by IRB on 01/26/2019):
1. Per sponsor, protocol modification needed to add the following language:
"The Research Monitor is responsible to oversee the safety of the research subjects and report observations/findings to the IRB or a designated institutional official. The Research Monitor will review all unanticipated problems involving risks to subjects or others associated with the protocol and provide an independent report of the event to the IRB. The Research Monitor may discuss the research protocol with the investigators; shall have authority to stop a research protocol in progress, remove individual human subjects from a research protocol, and take whatever steps are necessary to protect the safety and well-being of human subjects until the IRB can assess the monitor's report; and shall have the responsibility to promptly report their observations and findings to the IRB or other designated official and the HRPO.
2. Add Karine Khoder to protocol.
3. Remove Charles Feinberg.
4. Update tDCS Patient Manual, modified contact information

MOD 13: Modification to update Vincent Huang's employment status from Volunteer to Student Research Intern (approved by IRB on 03/12/2019).

MOD 14: Modification to remove inadvertent text and clarify study language in the protocol and consent form (approved by IRB on 4/5/2019).

MOD 15: Personnel modification to add Jon Links to study team (approved by IRB on 4/4/2019).

MOD 16: N/A. Discarded.

MOD 17: Personnel modification to add Martin Malik to study team and remove Nabil Khan, Jen Stone and Karine Khoder from the study team (approved by IRB on 5/13/2019).

MOD 18: Personnel modification to add Kelly Lee to study team (approved by IRB on 6/4/2019).

MOD 19: Modification to protocol and ICF to (i) provide research compensation via gift card, and (ii) permit the use of a HIPAA compliant web program to assist with study management (e.g scheduling, assigning tasks to study team, etc.). Approved by IRB on 7/2/2019.

MOD 20: Personnel modification to add Pamela Best and Lillian Walton Masters to study team (approved by IRB on 7/2/2019).

(iii) Adverse event/unanticipated problems involving risks to subjects or others and actions or plans for mitigation:

There were no adverse events/unanticipated problems that involved the risk to subjects or others and actions or plans for mitigation.

(b) Use of Human Cadavers for Research Development Test & Evaluation (RDT&E), Education or Training

"Cadaver" is defined as a deceased person or portion thereof, and is synonymous with the terms "human cadaver" and "post-mortem human subject" or "PMHS." The term includes organs, tissues, eyes, bones, arteries or other specimens obtained from an individual upon or after death. The term "cadaver" does not include portions of an individual person, such as organs, tissue or blood, that were removed while the individual was alive (for example, if a living person donated tissue for use in future research protocols, that tissue is not considered a "cadaver" under this policy, regardless of whether the donor is living or deceased at the time of tissue use).

***TOTAL ACTIVITIES**: State the total number of RDT&E, education or training activities that will involve cadavers. If not applicable, write "No RDT&E, education or training activities involving human cadavers will be performed to complete the Statement of Work (SOW)."*

***ACTIVITIES:** Provide the following information in a bulleted list for all RDT&E, education or training activities involving human cadavers conducted or supported during the quarter:*

- *Title of the RDT&E, education or training activity*
- *SOW task/aim associated with the activity*
- *Date the activity was conducted*
- *Identification of the organization's responsible individual (e.g., PI or individual primarily responsible for the activity's conduct)*
- *Brief description of the use(s) of cadavers in the activity and the total number of cadavers used during the reporting period*
- *Brief description of the Department of Army organization's involvement in the activity*
- *Status of document submission and approvals*

- *Problems encountered in the procurement, inventory, use, storage, transfer, transportation and disposition of cadavers used for RDT&E, education or training. Examples of problems include but are not limited to: loss of confidentiality of cadaveric donors, breach of security, significant deviation from the approved protocol, failure to comply with state laws and/or institutional policies and public relations issues.*

TOTAL ACTIVITIES: *No RDT&E, education or training activities involving human cadavers will be performed to complete the Statement of Work (SOW).*

ACTIVITES:

(c) Animal Use Regulatory Protocols

TOTAL PROTOCOL(S):

State the total number of animal use protocols required to complete this project (e.g., 2 animal use research protocols will be required to complete the Statement of Work.). If not applicable, write "No animal use research will be performed to complete the Statement of Work."

PROTOCOL(S):

List the identifier and title for all animal use protocols needed to complete the project. Include information about the approved target number for statistical significance, type of submission, type of approval with associated dates, and performance status.

The following format shall be used:

Protocol (_ of _ total):

Protocol [ACURO Assigned Number]:

Title:

Target required for statistical significance:

Target approved for statistical significance:

Submitted to and Approved by:

Provide bullet point list of protocol development, submission, amendments, and approvals (include IACUC in addition to ACURO).

Status:

Provide bullet point list of performance and/or progress status relating to the above protocol and discuss any administrative, technical, or logistical issues that may impact performance or progress of the study (e.g. animal use protocol needs revision to minimize animal suffering, animal protocol modification to include additional staff) for the above ACURO approved protocol.

TOTAL PROTOCOL(S): *No animal use research will be performed to complete the Statement of Work.*

PROTOCOL (_ of _ total):
Protocol [ACURO Assigned Number]:
Title:
Target required for statistical significance:
Target approved for statistical significance:

SUBMITTED TO AND APPROVED BY:

STATUS:

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

Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.

- Consent, screen and enroll participants. Aiming for 15 participants per quarter.
- Continue to develop list of potential participants and contact them to inquire about ability to participate.
- Perform preliminary data analyses as we reach a larger sample size. Analyzing study compliance, feasibility, and early manual dexterity improvements in our cohort.
- Analyze grip device data to a more complete level
- Continue biweekly study meetings to check-in about enrollees, manage protocol as a team and ensure fluid data analysis.
- Regulatory and patient binder maintenance

2. Products: List any products resulting from the project during the reporting period. If there are no products to report for the current quarter, state "Nothing to report."

Examples of products include:

- *publications, conference papers, and presentations;*
- *website(s) or other Internet site(s);*
- *technologies or techniques;*
- *inventions, patent applications, and/or licenses; and*
- *other products, such as data or databases, biospecimen collections, germplasm, audio or video products, software, models, educational aids or curricula, instruments or equipment, data and research material, clinical or educational interventions, or new business creation.*

Nothing to report.

3. Participants & Other Collaborating Organizations

What individuals have worked on the project?

Provide the following information for: (1) Project Directors (PDs)/ PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours of effort).

Provide the name and identify the role the person played in the project. Indicate the nearest whole person month (Calendar, Academic, Summer) that the individual worked on the project. Show the most senior role in which the person worked on the project for any significant length of time. For example, if an undergraduate student graduated, entered graduate school, and continued to work on the project, show that person as a graduate student, preferably explaining the change in involvement.
Describe how this person contributed to the project. If information is unchanged from a previous submission, provide the name only and indicate "no change."

Example:
Name: *Mary Smith*
Project Role: *Graduate Student*
Researcher Identifier (e.g. ORCID ID): 1234567
Nearest person month worked: *5*
Contribution to Project: *Ms. Smith has performed work in the area of combined error-control and constrained coding.*

Name: Leigh Charvet
Project Role: PI
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 1.2calendar months
Contribution to Project: Oversight of all aspects of the study. Oversees patient recruitment and enrollment. Confirm eligibility of potential participants. Attended biweekly study meetings to provide guidance for study improvements. Provided suggestions about additional study kit generation and fund allocation. Oversees patient recruitment and enrollment.

Name: Lauren Krupp
Project Role: Co-I
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 0.6 calendar months (no salary support on this award)
Contribution to Project: Dr. Krupp reviews and completes medical clearance for enrolled participants.

Name: Preeti Raghavan
Project Role:Co-I
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 1.08 calendar months
Contribution to Project: Attended biweekly study meetings to provide suggestions about study improvements.

Name: Vikram Kapila
Project Role: Engineer
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 0.08 calendar months
Contribution to Project: Attended biweekly study meetings to provide suggestions about study improvements—in particular with respect to the grip device.

Name: Ying Lu
Project Role: Statistician
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 0.428 summer month
Contribution to Project: Provided randomization and matching procedures. Reviewed database fields in preparation for data analysis.

Name: Marom Bikson
Project Role: Co-I
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 0.3 summer months
Contribution to Project: He has served as a liaison for all tDCS equipment, including the optimization of headgear that will ensure consistent and accurate placement to the targeted regions based on his group's modeling of current flow and was available for guidance regarding training, setup of training materials and procedures, and meets regularly with Dr. Charvet to ensure quality control.

Name: Matthew Lustberg
Project Role: MS Division Coordinator
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 3.5 calendar months (no salary support on this award)
Contribution to Project: Coordinates study needs, runs sessions, and collects baseline and follow-up data for participants. Manages regulatory compliance and serves as primary regulatory contact with IRB. Prepares weekly meeting agenda and coordinates additional meetings as needed.

Name: Charles Feinberg
Project Role: MS Division Coordinator
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 2.1 calendar months
Contribution to Project: Coordinated biweekly meetings and weekly meetings between the Raghavan lab and grip device engineer to make progress making the study design more efficient. Generated three additional study kits. Made amendments to the protocol, communicating these amendments to NYU's IRB and the HRPO. Created files for oncoming participants. Runs sessions and collects baseline and follow-up data for participants

Name: Jennifer Stone
Role: Raghavan Lab Data Associate/post-doc
Nearest person month worked: 2.5 calendar months
Contribution to Project: Attended meetings with Mr. Lustberg and Mr. Feinberg to collect preliminary data and increase efficiency of data analysis. Performed data entry.

Name: Ashwin Raj Kumar
Role: Engineering post-doc
Nearest person month worked: 6.0calendar months
Contribution to Project: Attended both biweekly meeting and additional meetings with Mr. Lustberg. Oversees effectiveness of the grip device program and compatibility of all software and hardware programming used in the study.

Name: Seda Bilaloglu
Project Role: Raghavan Lab Data Associate
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 2.5 calendar months
Contribution to Project: Attended both biweekly meeting and additional meetings with Mr. Feinberg to collect preliminary data and increase efficiency of data analysis in anticipation of participant entry and analytical demands of the study design.

Name: Guadalupe Zuniga Estrada
Project Role: MS Division Coordinator
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 1 calendar month (no salary support from this award)
Contribution to Project: Attended biweekly meetings to inform study group about ongoing items with HRPO and IRB submission statuses. Managed study protocol and IRB compliance

Name: Bryan Dobbs
Project Role: MS Division Coordinator
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 0.125 calendar months (no salary support from this award)
Contribution to Project: Runs sessions for participants.

Name: Kathleen Sherman
Project Role: Program Manager
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 0.25 calendar months (no salary support from this award)
Contribution to Project: Assist with award management, progress reports, regulatory and IRB requirements.

Name: Maria Palmeri
Project Role: Ms Division Student Research Intern
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 0.5 calendar months (no salary support from this award)
Contribution to Project: Runs sessions for participants. Helps generate new study kits

Name: Rhea Patel
Project Role: Ms Division Student Research Intern
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 0.5 calendar months (no salary support from this award)
Contribution to Project: Assists with recruitment and data entry

Name: Danielle Ladensack
Project Role: MS Division Volunteer
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 0.125 calendar months (no salary support from this award)
Contribution to Project: Helped to contact potential participants, gage interest. Set up patient documentation files to efficiently file baseline, follow-up and mid-study questionnaire, consents, and all other documentation

Name: Michael Shaw
Project Role: MS Division Coordinator
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 0.5 calendar months (no salary support from this award)
Contribution to Project: Helps in coordinating study needs and runs sessions with participants.

Name: Nabil Khan
Project Role: MS Division Data Associate
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 0.5 calendar months (no salary support from this award)
Contribution to Project: Ran sessions for participants. Performed baseline and follow-up visits.

Name: Claire Choi
Project Role: MS Division Data Associate
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 0.5 calendar months (no salary support from this award)
Contribution to Project: Runs sessions for participants and assists. Performs baseline and follow-up visits.

Name: Martin Malik
Project Role: MS Division Data Associate
Nearest person month worked: 0.5 (no salary support on this award).
Contribution to Project: Runs sessions for participants and assists with data entry. Recruits, screens and consents participants. Performs baseline and follow-up assessments.

Name: Allan George
Project Role: MS Division Data Associate
Nearest person month worked: 1.0 calendar month
Contribution to Project: Helps run sessions with participants

Name: Amy Ro
Project Role: Student Research Intern
Nearest person month worked: 0.5 calendar months (no salary support on this award)
Contribution to Project: Runs sessions for participants and assists with data entry.

Name: Vincent Huang
Project Role: Student Research Intern
Nearest person month worked: 0.5 calendar months (no salary support on this award)
Contribution to Project: Runs sessions for participants and assists with data entry.

Name: Gregory Belizaire
Project Role: Student Research Intern
Nearest person month worked: 0.5 calendar months (no salary support on this award).
Contribution to Project: Runs sessions for participants and assists with data entry.

Name: Jon Links
Project Role: Student Research Intern
Nearest person month worked: 0.5 calendar months (no salary support on this award).
Contribution to Project: Runs sessions for participants and assists with data entry

4. Changes/Problems: The PD/PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, "Nothing to Report," if applicable:

a. Actual Problems or delays and actions to resolve them

Provide a description of current problems or issues that may impede performance or progress of this project along with proposed corrective action. Also describe changes during the reporting period that may have had a significant impact on expenditures, for example, delays in hiring staff or favorable developments that enable meeting objectives at less cost than anticipated.

For an award that includes the recruitment of human subjects for clinical research or a clinical trial, discuss any problems or barriers encountered, if applicable, and what has been done to mitigate those issues. Discussion may highlight enrollment problems, retention problems, and actions taken to increase enrollment and/or improve retention.

Nothing to report.

b. Anticipated Problems/Issues

Provide a description of anticipated problems or issues that have a potential to impede performance or progress. Also provide course of actions planned to mitigate problems or to take should the problem materialize.

Nothing to report.

5. Special Reporting Requirements:

Quad Charts: N/A