

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

REPORT DATE: July 2020

TYPE OF REPORT: Annual Report

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

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REPORT DOCUMENTATION PAGE

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1. REPORT DATE JUL 2020		2. REPORT TYPE Annual		DATES COVERED 1 JUL 2019 - 30 JUN 2020	
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	
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7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) New York University School of Medicine, 240 East 38 th 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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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. <u>Specific Aim 1</u> is to determine the extent to which tDCS paired with manual dexterity training improves fine motor execution on a grasp and lift task. <i>We expect that the impairment in grasp execution will be significantly reduced with active tDCS versus sham tDCS from pre- to post-treatment.</i> <u>Specific Aim 2</u> 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. Interim data analysis compiled for American Academy of Neurology 2020 abstract.					
15. SUBJECT TERMS tDCS, telemedicine, motor, MS					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
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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

Achieved Major Task 1 (100% Completed): 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

In progress 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 3

In progress Major task 2: Study Enrollment Months 9-30

Subtask 1 (71% Completed): Screening and study entry Month 9-27

Subject task 2 (61% Completed): Pilot study (20 sessions of 20 minutes each remotely supervised; 40 active vs 40 sham) Months 9 -40: Ongoing

- Begin subject recruitment and extends over 18 months, average enrollment 15pts/month
Months 9-38: Ongoing
 - o Participants enrolled during this period = 26, including 3 withdrawals.
 - o Participants completed during this period = 24
 - o Total study enrollment = 57
- Last participant (n=80) complete 4 week randomly-assigned condition (active or sham)
Month 40
- Follow-up assessment period Months 10 - 40

Milestone to Achieve (**61% Complete**): Last participant to complete follow-up assessment Month 40

A No-cost extension request was submitted to DoD for review and it was approved on 4.30.2020.

Study End Data Analyses and Reporting (Preliminary analysis ongoing)

- Perform all analyzes according to specifications, share output, and finding with all investigators Months 41 - 48
- Work with data core and dissemination of findings (abstracts, presentation, publications, DoD) Months 45 - 48

Milestone to Achieve: Report results from data analyses Month 48

What was accomplished under these goals?

For this annual reporting period only 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.

Annual Year 3

- 1) Major activities
 - a. Enrollment continued reaching 57 out of 80 participants
 - b. Received a No Cost Extension, project now ending 6.30.2021
- 2) Specific objectives: Continued collecting data per protocol to address specific aim 1 "To determine the extent to which tDCS paired with manual dexterity training improves fine motor execution on a grasp and lift task" and specific aim 2 "To assess the adaptation or learning of fingertip forces to object weight when tDCS is paired with manual dexterity training."
- 3) Significant results/key outcomes: Ongoing preliminary analysis shows a program of daily manual dexterity training delivered at home via telerehabilitation is feasible for individuals with progressive MS despite advanced disability, cognitive impairment and older age. 98.1% participant adherence to the protocol. Dr. Raghavan is preprocessing grip device data in prep for analysis.
- 4) Other achievements: Even during the global pandemic, through IRB-approved e-consenting and remote visits, we were able to continue enrollment of new participants. Initially, enrollment was paused beginning in March (submitted to HRPO and confirmed receipt on 3.26.2020). We received IRB approval to consent participants remotely using electronic consent and resumed recruitment at the end of April. Research visits are administered virtually in accordance with institutional guideline (submitted to HRPO and confirmed on 4.15.2020).

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:

Protocol (of total):

Protocol [HRPO Assigned Number]:

Title:

Target required for clinical significance:

Target approved for clinical significance:

Submitted to and Approved by:

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

Status:

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.

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

PROTOCOL (1 of 1 total):

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: 68
Number of subjects screened during this annual report period: 52
Number of patients enrolled during this annual report period: 26
Number of patients completed during this annual report period: 24

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

Submitted continuing review to HRPO 11.38.2019.

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 performing 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).

MOD 21 (approved by IRB on 7/16/2019): Personnel modification to add Chelsea Prudent as a research volunteer and remove Claire Choi.

MOD 22: Discarded

MOD 23 (approved by IRB on 9/13/2019): Personnel modification to add Tehila Eilam-Stock to the study team and remove Michael Shaw, Vincent Huang and Gregory Belizaire.

MOD 24 (approved by IRB on 9/27/2019): Personnel modification to add David Halim-Banoub and John Shymansky to the study team

MOD 25 (approved by IRB on 10/15/2019): Personnel modification to remove Preeti Raghavan and Maria Palmeri from study team, and add Ibraheem Mirza (student research intern).(Since Dr.

Raghavan switched intuitions she does not need to be on the NYU IRB, new subaward with John Hopkins University and Dr. Raghavan was approved by DoD November 2019)

Continuing Review (approved by IRB on 10/29/2019): IRB approved for renewal period 10/29/2019-10/28/2020

MOD 26 (approved by IRB on 1/9/2020): Personnel modification to add Giuseppina Pilloni as non-traditional volunteer

MOD 27 (approved by IRB on 1/14/2020): Personnel modification to add Hannah Zimmermann as non-traditional volunteer

MOD 28 (approved by IRB on 3/25/2020): Personnel modification to update Giuseppina Pilloni's status to Post-Doc Fellow

MOD 29 (approved by IRB on 4/10/2020): Protocol and ICF modification to obtain remote electronic informed consent (e-ICF).

MOD 30 (approved by IRB on 4/16/2020): Approval of REDCap e-ICF link.

MOD 31 (approved by IRB on 5/15/2020): Updated phone script and the screening checklist to allow for study team signature.

(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.

(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.*

Abstract: Malik, M., Lustberg, M., Raj Kumar, A., Krupp, L., Sherman, K., Kapila, V., Raghavan, P., Charvet, L. *Upper Extremity Telerehabilitation for Progressive Multiple Sclerosis*, accepted presentation at the 2020 American Academy of Neurology Annual Conference

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: Dr. Raghavan continues to receive updates from Dr. Charvet on the progress of the project. Fully executed subcontract effective 2.25.2020 and data analysis resumes on data to-date.

Name: Vikram Kapila
Project Role: Engineer
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 0.82 calendar month
Contribution to Project: No change

Name: Ying Lu
Project Role: Statistician
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 0.428 summer month
Contribution to Project: No change.

Name: Marom Bikson
Project Role: Co-I
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 0.3 summer months
Contribution to Project No change.

Name: Martin Malik
Project Role: MS Division Data Associate
Nearest person month worked: 8.40 calendar months.
Contribution to Project: Runs sessions for participants and assists with data entry. Recruits, screens and consents participants. Performs baseline and follow-up assessments.

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: Ashwin Raj Kumar
Role: Engineering post-doc
Nearest person month worked: 6.0 calendar 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: 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. Completed her position in August 2019.

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. Completed his position in August 2019.

Name: Giuseppina Pilloni
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: Tehila Eliam-Stock
Project Role: MS Division Post-doctoral fellow
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 0.1 calendar months (no salary support from this award)
Contribution to Project: Runs sessions for participants.

Name: Allan George
Project Role: MS Division Research Coordinator
Nearest person month worked: 0.2 calendar months (no salary support from this award).
Contribution to Project: Helps run sessions with participants

Name: Lillian Walton Masters
Project Role: MS Division Research Coordinator
Researcher Identifier (e.g. ORCID ID):
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: Pamela Best
Project Role: MS Division Research Coordinator
Researcher Identifier (e.g. ORCID ID):
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: Amy Ro
Project Role: MS Division Student Research Intern
Nearest person month worked: 0.5 (no salary support on this award)
Contribution to Project: Runs sessions for participants and assists with data entry (no salary support from this award).

Name: Jon Links
Project Role: MS Division Student Research Intern
Researcher Identifier (e.g. ORCID ID):
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: 0.1 calendar months (no salary support on this award)
Contribution to Project: Runs sessions for participants and assists with data entry. Completed position in August 2019.

Name: Gregory Belizaire
Project Role: Student Research Intern
Nearest person month worked: 0.1 calendar months (no salary support on this award).
Contribution to Project: Runs sessions for participants and assists with data entry. Completed position in August 2019.

Name: Kelly Lee
Project Role: MS Division Student Research Intern
Researcher Identifier (e.g. ORCID ID):
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: David Halim-banoub
Project Role: MS Division Student Research Intern
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 0.1 calendar months (no salary support from this award)
Contribution to Project: Runs sessions for participants and assists with data entry.

Name: John Shymansky
Project Role: MS Division Student Research Intern
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 0.1 calendar months (no salary support from this award)
Contribution to Project: Runs sessions for participants and assists with data entry

Name: Ibraheem Mirza
Project Role: MS Division Student Research Intern
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 0.1 calendar months (no salary support from this award)
Contribution to Project: Runs sessions for participants and assists with data entry.

Name: Hannah Zimmermann
Project Role: MS Division Volunteer
Research Identifier (e.g. ORCID ID):
Nearest person month worked: 0.1
Contribution to Project: Runs sessions for participants and assists with data entry

Name: Chelsea Prudent
Project Role: MS Division Volunteer
Research Identifier (e.g. ORCID ID):
Nearest person month worked: 0.1
Contribution to Project: Runs sessions for participants and assists with data entry. Completed her position in Fall 2019.

- 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.

The COVID-19 pandemic impacted recruitment in Quarter 4. Enrollment of new participants was paused beginning in March (submitted to HRPO and confirmed receipt on 3.26.2020). We received IRB approval to consent participants remotely using electronic consent and resumed recruitment at the end of April. Research visits are administered virtually in accordance with institutional guideline (submitted to HRPO and confirmed on 4.15.2020).

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.

While we were able to resume research visits virtually, safety precautions to curb the spread of COVID-19 may affect recruitment.

5. Special Reporting Requirements:

Quad Charts: If applicable, the Quad Chart (available on <https://www.usamraa.army.mil>) should be updated and submitted with attachments.