

MREDI Quarterly Report: SYNERGISTIC IMPROVEMENT IN THE DIAGNOSIS & TREATMENT OF MENTAL ILLNESS, DEMENTIA, & CHRONIC PAIN
September, 2016

This progress report is organized “by project” for each of the Center’s four funded projects.

Objective 1: Combine EEG and fNIRS for clinical diagnostic development for anxiety and depressive disorder.

Overview:

Objective 1 is approximately six months behind schedule as the result of setbacks associated with the renegotiation of prices of the equipment being purchased with our Montana-based business partner, delays in equipment setup and training, changes in vendor personnel, and current delays in the acquisition of the remainder of the hardware from the vendors. We are currently waiting for the head caps, which will allow for combined EEG/fNIRS data collection, to be delivered in order to begin data collection.

To circumvent additional delays in data collection, we have partnered with a local business, Veridical Research and Design, to facilitate timely integration of the EEG and fNIRS systems. Although our business partners in the original proposal were expected to provide support for this integration, hiring Veridical Research Design has allowed for a more timely setup. In fact, a full integration of systems and setup of the stimuli to be used for data collection in the current study are expected to be complete by the end of September 2016.

Grommets to hold fNIRS sensors have been installed on a sample cap for practice collecting fNIRS data. Research assistants have been trained to collect both EEG and fNIRS data. Sample data has been sent to TechEn, Inc. to verify its usability. The task to be used for data collection has been programmed and tested on an alternative system. Veridical Research and Design has tested our task on both systems to assure that data can be collected. Pilot data collection will begin as soon as caps arrive and hardware setup is complete.

A project coordinator has assembled all recruitment materials, identified and created digital copies of study measures for computerized administration, and has programmed an online signup option for study participants. An IRB protocol has been submitted and approval has been obtained. Undergraduate research staff has been recruited and trained.

Equipment purchased:

Equipment has been purchased from Neuralynx, Inc. and TechEn, Inc. as described in the research proposal. Software has been ordered, received, and set up to begin processing EEG data as soon as it is collected. Brain Vision Analyzer software has been purchased for EEG data cleaning.

Progress towards milestones (since previous update):

- Research assistants have collected sample EEG and fNIRS data.

- Integration of EEG and fNIRS systems is nearly complete
- Computer systems have been added to MSU network for data storage
- Configuration to allow system integration is complete
- Integration of Presentation software with systems is complete
- Training cap grommet installation

Total amount of expenditures by report date:

Salaries:

- Project coordinator salary: \$2957.50
- Project coordinator benefits: \$142.72

Contracted Services/Consultation:

- Veridical Research and Design: \$2,200.00
- Veridical Research and Design parts reimbursement: \$12.39

Equipment:

- Neuralynx, Inc.: \$65,000 for EEG setup and caps
- TechEn, Inc: \$134,000 for fNIRS setup

Software:

- Software for EEG data processing: \$7902.80
- Neurobehavioral Systems software programming for experimental task: \$750.00
- Presentation software license for stimulus presentation: \$511.65

Other Costs:

- Facilities services charge to move equipment shipped from vendors: \$58.50
- Shipping cost for EEG data processing software: \$30.00
- University charges for purchasing hardware: \$158.88

Objective 2: Conduct a breakthrough study on the use of Deep TMS for Alzheimer's Disease (AD) in order to improve the lives of Montana families affected by AD and make Western Montana Mental Health Center in Butte a treatment destination for patients from across Montana.

Overview:

As with Objective 1 that is also using EEG-fNIRS technology, Object 2 remains approximately six months behind schedule as the result of setbacks associated with the renegotiation of prices of the equipment being purchased with our Montana-based business partner, delays in equipment setup and training, changes in vendor personnel, and current delays in the acquisition of the remainder of the hardware from the vendors. We are also currently waiting for the head caps, which will allow for combined EEG/fNIRS data collection, to be delivered in order to begin data collection.

A modification to alter the study protocol to reduce the burden of treatment and assessments on study participants was approved by the IRB on August 4, 2016.

Certification and training on the TMS machine was conducted in Butte on July 8-9, 2016 and four of our study team personnel participated. Additional practice of all technologies is ongoing. Due to the delay in receipt of the head caps, we now expect enrollment of the first study subject to be in late September 2016.

Hirings (since previous update):

No new hirings have occurred since our last update.

Equipment purchased:

No new equipment has been purchased since our last update.

Progress towards milestones (since previous update):

- TMS training occurred on July 8-9 at Western Montana Mental Health Center. The study coordinator, back-up nurse, study physician, and TMS consultant all participated in the training and our now each certified to deliver TMS.
- fNIRS set-up and training occurred in late July.
- Additional practice on the TMS machine, fNIRS system, and EEG system has been ongoing throughout July and August.
- Recruitment for the study is also ongoing. The research coordinator has conducted several information sessions for the Alzheimer's community in Butte and continues to have interested study participants.

Total amount of expenditures by report date:

- Neuralynx, Inc. : \$58,484.70 for EEG setup
- TechEn, Inc.: \$133,650 for fNIRS setup
- Brainsway, Inc: \$88,000
- Payroll of Research Managing Director, Business Manager, and Faculty Consulting: \$24,508.02
- Travel expenditures: \$14.69
- Western Montana Mental Health Center: \$25,327.65
- Consultants: \$1,856.94

Objective 3: Establish efficacy and safety in a non-human primate model to facilitate clinical candidate selection of non-opioid therapeutic agents for acute and chronic pain, common correlates of anxiety, depression and neurodegeneration.

Overview:

We have successfully tested 2 SiteOne clinical candidates in the primate model, demonstrating strong analgesia with no notable off-target toxicology signals. ST-2257 and ST-2262 have both demonstrated a dose-dependent analgesic response with a complete block of pain at the higher doses. These findings potentially validate these compounds as clinical candidates – additional in-vitro and in-vivo toxicology and pharmacology testing are ongoing to further validate these compounds as clinical candidates. Our medicinal chemistry team continues to synthesize additional compounds that will be tested in the primate model over the coming months.

Hirings:

Potential hires specifically supporting these activities are being evaluated for this calendar year.

Equipment purchased:

Cardiac/respiratory monitor at \$3,000.

Progress towards milestones:

- Screening of ST-2262, a novel, non-opioid drug candidate, has been successfully completed in this primate efficacy and safety model. Additional in-vitro and in-vivo characterization of this potential clinical candidate are ongoing.

Total amount of expenditures by report date:

- Total expenditures to date are ~\$120,000
- Site One Therapeutics: \$83,904.03
- Payroll of MSU Faculty Consultant: \$4,958.33

Objective 4: Investigate the ability of the Youth Aware of Mental Health Program (YAM) to prevent suicidal behaviors and improve mental health in freshmen high school students in Montana.

Overview:

Objective 4 continues to be on track for timelines. Over the summer months, we completed the cultural adaptation of YAM, an extensive and iterative process of examining project materials and acquiring detailed feedback from focus groups of youth to develop a culturally appropriate version of YAM. We are still on target with beginning the delivery of YAM in 8-10 schools starting in September 2016.

Hirings (since previous update):

We are currently in the process of hiring approximately 24 YAM Facilitator Assistants. We expect to have the majority of them complete the hiring process by the end of September.

Equipment purchased:

None.

Progress towards milestones (since previous update):

- We continue to have the support of the Office of Public Instruction and DPHHS for the proposed study.
- We have obtained official commitment to conduct the study in Terry High School, bringing our total to 9 committed schools.
- We expect to receive confirmation from additional schools in the coming months, as interested schools are still in the process of finalizing their curriculum and class schedules for the Fall 2016-Spring 2017 school year.
- We have continued next-step administrative/logistic activities with all of our committed schools.

- We are currently interviewing applicants for YAM Facilitator Assistants, and plan to conduct two half-day trainings for them in September.

Total amount of expenditures by report date:

- Contracted Services (YAM Training): \$18,976.66
- Travel & School Recruitment Costs: \$18,856.70.58
- Supplies: \$2,042.06
- Payroll of YAM Facilitators: \$16,007.01
- Payroll of Research Managing Director, Research Study Coordinator, & Business Manager: \$37,745.02