## Plan Overview

*A Data Management Plan created using DMPTool*

**DMP ID:** https://doi.org/10.48321/D17S7Q

**Title:** Pre-frontal tDCS as a novel intervention to reduce effects of post-stroke fatigue while improving language and attention in aphasia

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## Pre-frontal tDCS as a novel intervention to reduce effects of post-stroke fatigue while improving language and attention in aphasia

Data generated for this project will include participant demographic data (e.g., age, race, gender), medical information related to the participant's stroke (e.g., date of stroke onset, lesion location), standardized test scores from language and cognitive tests (e.g., Western Aphasia Battery, NIH Toolbox), and behavioral testing data collected during pre-/post- testing sessions. Behavioral pre-/post- data will specifically include accuracy and reaction time data from attention tasks (e.g., Continuous Performance Task, Attention Network Test), accuracy data from sentence comprehension tasks, and scores on the Fatigue Severity Scale. We will also collect MRI images from participants' medical records. All data will be de-identified. We expect to generate data of all of these types for approximately 40 participants with aphasia. All shared data files will be in plain text (ASCII) format.

All demographic, stroke history, standardized testing, and behavioral task data will be preserved and shared. MRI images from participants' medical records will not be preserved or shared because participants in this study will not receive MRI scans as part of our research protocol; these images will be used only to determine eligibility for the study and to generate e-field models to ensure adequate stimulation in target brain areas. We will share de-identified individual-participant level data. Participants will be assigned an alphanumeric code to identify their data, which will be used in shared data; informed consent forms will reflect those plans.

To facilitate interpretation of the data, a data dictionary, protocols for treatment, and data collection instruments will be created, shared, and associated with the relevant datasets. In addition to the individual participant dataset being shared by restricted access, the researcher will share information regarding the interpretation of standardized test scores (e.g., lower scores = greater severity). Documentation and support materials will be compatible with the clinicaltrials.gov Protocol Registration Data Elements.

Experimental data will be made available in csv format and will not require the use of specialized tools to be accessed or manipulated. Data dictionaries and instructions for linking files will be included.

Whenever possible, we will use NIH Common Data Elements to structure and organize our data. Some of the measures we will use have specific recommended formats (e.g., Fatigue Severity Scale), however, formal standards for our experimental measures have not yet been widely adopted.

All datasets that can be shared will be deposited in Open Science Framework.

Open Science Framework provides searchable study-level metadata for dataset discovery. Open Science Framework assigns DOIs as persistent identifiers, and has a robust preservation plan to ensure long-term access. Data will be discoverable online through standard web search of the study-level metadata as well as the persistent pointer from the DOI to the dataset.

Shared data generated from this project will be made available as soon as possible, and no later than the time of publication or the end of the funding period, whichever comes first. The duration of preservation and sharing of the data will be a minimum of 6 years after the end of the funding period.

There are no anticipated factors or limitations that will affect the access, distribution or reuse of the scientific data generated by the proposal. Data will be de-identified before sharing.

Controlled access will not be used. The data that is shared will be shared by unrestricted download.

In order to ensure participant consent for data sharing, IRB paperwork and informed consent documents will include language describing plans for data management and sharing of data, describing the motivation for sharing, and explaining that personal identifying information will be removed.

To protect participant privacy and confidentiality, shared data will be de-identified using alphanumeric code assignment and handled according to HIPAA policy.

Lead PI Ellyn Riley, will be responsible for the day-to-day oversight of lab/team data management activities and data sharing. Broader issues of DMS Plan compliance oversight and reporting will be handled by the PI and Co-I team as part of general Syracuse University stewardship, reporting, and compliance processes.

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