

AWARD NUMBER: W81XWH-16-1-0395

TITLE: Reactivating Neural Circuits with Clinically Accessible Stimulation to Restore Hand Function in Persons with Tetraplegia

PRINCIPAL INVESTIGATOR: Dr. Edelle Field-Fote

CONTRACTING ORGANIZATION: Shepherd Center

REPORT DATE: September 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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14. ABSTRACT

This study is designed to examine arm and hand function after receiving fine motor training combined with stimulation to increase brain excitability in individuals with cervical spinal cord injuries. The project is studying two types of stimulation- transcranial direct current stimulation (tDCS), a type of non-invasive brain stimulation, and peripheral nerve somatosensory stimulation, which is stimulation to the median nerve. A total of 80 participants enrolled in the study, 63 participants with acute spinal cord injuries (>6 months post injury) and 18 participants with chronic injuries (>1-year post injury). 7 participants out of the 80 enrolled did not complete the study. The project was performed in a real-world clinical setting, making the results immediately relevant for application to clinical practice. Our hypothesis is that the brain's ability to push information through the remaining spinal pathways will result in more effective therapy and larger improvements in hand function. We are currently in the data reduction and analysis phase of the study. We collected outcome measures that looked both at the clinical presentation of the participants, using standardized rehabilitation therapy assessments, and the neurophysiological presentation of the participants, using electromyography (EMG) and transcranial magnetic stimulation (TMS). With 10 outcome measures total, we have been actively continuing with data reduction and analysis. Further information about our current progress is below under accomplishments.

15. SUBJECT TERMS

Spinal cord injury; tetraplegia; rehabilitation; tDCS; somatosensory stimulation; spinal cord injury; cervical spinal cord; non-invasive brain stimulation

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TABLE OF CONTENTS

Page

1. INTRODUCTION:.....	5
2. KEYWORDS:.....	5
3. ACCOMPLISHMENTS:	5
4. IMPACT:	16
5. CHANGES/PROBLEMS:.....	17
6. PRODUCTS:.....	18
7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS ..	19
8. SPECIAL REPORTING REQUIREMENTS	20
9. APPENDICES.....	22

1. INTRODUCTION:

This study was designed to examine arm and hand function after receiving fine motor training combined with stimulation to increase brain excitability in individuals with cervical spinal cord injuries. The project studied two types of stimulation- transcranial direct current stimulation, a type of non-invasive brain stimulation, and peripheral nerve somatosensory stimulation, which is stimulation to the median nerve. The study supplemented daily therapy, so that the results will be immediately relevant for application to clinical practice. We believe that increasing the ability of the brain to push information through the remaining spinal pathways will demonstrate larger improvements in hand function and more effective therapy.

2. KEYWORDS:

spinal cord injury; tetraplegia; rehabilitation; tDCS; somatosensory stimulation; spinal cord injury; cervical spinal cord; non-invasive brain stimulation

3. ACCOMPLISHMENTS:

What were the major goals of the project?

Major Task 1: Adapt Study Protocol to Facilitate Larger Trial Supported by DoD Grant

Milestone 1: IRB approval obtained

target date: 11/15/2016; completion date: 07/26/2016

Milestone 2: HRPO approval obtained

target date: 03/15/2017; completion date: 09/28/2016

Major Task 2: Coordinate Study Staff for Subacute and Chronic Groups

Milestone 3: Research and clinical staff trained

target date: 11/15/2016- 03/15/2017; completion date: 1/25/2017

Milestone 4: Maintain trained and available Independent Evaluators throughout duration of clinical trial

target date: 04/15/2017-02/15/2020; completion date: 1/13/2017

Major Task 3: Participant Recruitment, Therapy, Participant Evaluation

Milestone 5: 1st participant consented, screened and enrolled
target date:04/15/2017; completion date: 02/09/17

Milestone 6: Data collection initiated
target date:04/15/2017; completion date: 02/16/17

Milestone 7: 50% of subjects recruited and completed intervention
target date:04/15/2018; completion date: 02/08/18

Major Task 4: Data Analysis

Milestone 8: Data analyzed
target date:3/15/2020; percent completion: 50%

Major Task 5: Randomized Controlled Trial

Milestone 9: Report findings from overall studies
target date:6/15/2020- 08/15/2020; percent completion: 0%

What was accomplished under these goals?

Major Task 4: Data Analysis

Milestone 8: Data analyzed

Our study team is continuing to analyze data from the primary outcome measures and reduce data from the secondary outcome measures. See below for initial methods & results from the clinical outcome measures. We expect this data will be analyzed further prior to publication, with descriptive data and effect size for chronic and acute groups analyzed separately, and variability for both of the groups analyzed.

Neurophysiologic data will be analyzed once all reduction is complete. The data from 2 of 3 neurophysiologic outcome measures have been reduced using custom MATLAB codes and validated by study staff. In that past quarter, data reduction and coding of the TMS data at 100% MSO and area under the recruitment curve, as well as reflex threshold angle and Modified Ashworth Scale outcomes of the spasticity data were completed. Our biostatistician team, led by Dr. Matt Hayat, has merged these outcome measures with the other data and brought the data into SAS in anticipation of analysis once all parts of the reduction are complete.

Our bioengineer, Cazmon Suri, is building a custom MATLAB code to reduce our final neurologic outcome measure, subclinical EMG outcomes. We anticipate that the MATLAB code will be completed in the upcoming quarter. Once the code is completed and validated, the remaining neurologic data will be prepared for analysis.

Methods for analysis of clinical outcome measures:

Descriptive statistics were applied to all study measures, with measures of central tendency and dispersion used for continuous variables and frequency distributions for categorical variables.

The original study plan was to use the general linear mixed model (GLMM) for the statistical analysis of all study outcomes. The GLMM assumes a normally distributed outcome. We assessed the distribution for each study outcome. Histograms showed that each was positively skewed to the right. Transformations were not adequate. We discussed categorizing each outcome with meaningful clinical cut points.

However, such carving of the data results in a loss of information and statistical power. For this reason, we decided to calculate pre- to post-change scores, since this distribution of change scores may normalize even in the presence of skewed outcomes across time.

The distribution for the change scores were improved from the highly positively skewed raw outcomes at each time point. However, the change scores were still not reasonably close to normality. For this reason, we decided to apply quantile regression to each study outcome. This statistical modeling method does not require a normally distributed outcome. The median is modeled as a function of covariates, thus relaxing the normality requirement.

Results

Table 1 displays baseline results for study participant characteristics across treatment groups.

Table 2 displays summary statistics describing the distribution for each change score.

Table 3 displays multivariable modeling results for quantile regression models for each study outcome.

Figures 1 thru 9 show each outcome variable over time and stratified by active versus passive hand function.

Table 1. Baseline study characteristics (n=80, overrecruited with permission from HRPO).

	Active						Passive						Total	
	PNSS		tDCS		sham/placebo		PNSS		tDCS		sham/placebo			
	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Sex														
Female	2	11.1	4	20.0	3	17.7	3	33.3	3	33.3	2	28.6	17	21.3
Male	16	88.9	16	80.0	14	82.4	6	66.7	6	66.7	5	71.4	63	78.8
Trained Hand BHUEF Level (hand score):														
2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	14.3	1	1.3
3	0	0.0	0	0.0	0	0.0	8	88.9	9	100.0	6	85.7	23	28.8
4	3	16.7	7	35.0	7	41.2	1	11.1	0	0.0	0	0.0	18	22.5
5	15	83.3	13	65.0	10	58.8	0	0.0	0	0.0	0	0.0	38	47.5
Trained Hand BHUEF Level (shoulder score):														
1	0	0.0	1	5.0	0	0.0	1	11.1	0	0.0	0	0.0	2	2.5
3	7	38.9	4	20.0	6	35.3	2	22.2	8	88.9	4	57.1	31	38.8
4	11	61.1	15	75.0	11	64.7	6	66.7	1	11.1	3	42.9	47	58.8
ASIA classification (most recent, if known)														0.0
A	3	16.7	3	15.0	2	11.8	5	55.6	4	44.4	4	57.1	21	26.3
B	1	5.6	1	5.0	2	11.8	3	33.3	4	44.4	3	42.9	14	17.5
C	6	33.3	10	50.0	8	47.1	1	11.1	1	11.1	0	0.0	26	32.5
D	8	44.4	6	30.0	5	29.4	0	0.0	0	0.0	0	0.0	19	23.8
Level of injury (cervical)														
1	2	11.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	2.5
2	2	11.1	3	15.0	3	17.7	1	11.1	0	0.0	0	0.0	9	11.3
3	2	11.1	2	10.0	3	17.7	0	0.0	1	11.1	0	0.0	8	10.0
4	8	44.4	4	20.0	5	29.4	2	22.2	4	44.4	5	71.4	28	35.0
5	1	5.6	5	25.0	2	11.8	2	22.2	4	44.4	2	28.6	16	20.0
6	1	5.6	2	10.0	3	17.7	3	33.3	0	0.0	0	0.0	9	11.3
7	2	11.1	3	15.0	1	5.9	1	11.1	0	0.0	0	0.0	7	8.8
8	0	0.0	1	5.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.3
	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Age	1	41.1	2		1			37.6						
	8	(15.1)	0	37.1 (15.8)	7	51.5 (16.7)	9	(15.4)	9	24.6 (6.3)	7	39.6 (14.4)	80	39.9 (16.3)
Weeks from injury	1	74.7	2	112.3	1	54.3								
	8	(141.1)	0	(344.7)	7	(134.5)	9	7.0 (3.1)	9	12.7 (5.9)	7	8.7 (2.2)	80	59.4 (195.1)

* SD= Standard Deviation

Table 2. Summary statistics for pre- to post- change by treatment group.

	PNSS Change (post - pre)				tDCS Change (post - pre)				Sham/Placebo Change (post - pre)			
	n	Median	Interquartile Range		n	Median	Interquartile Range		n	Median	Interquartile Range	
			25th	75th			25th	75th			25th	75th
Total_Prehension	25	3.0	1.0	4.0	27	3.0	2.0	6.0	24	1.5	1.0	6.5
Total_SWM (sensation)	25	2.0	0.0	3.0	27	1.0	0.0	3.0	24	1.0	-0.5	3.0
Grip_Strength	24	0.0	0.0	4.7	26	0.0	0.0	1.7	21	0.0	0.0	0.0
Key_Pinch_Strength	25	0.7	0.0	2.0	27	0.0	0.0	0.9	24	0.0	0.0	1.7
Tip_Tip_Pinch	25	0.3	0.0	1.7	27	0.0	0.0	0.8	24	0.0	0.0	1.2
Palmer_Pinch	25	0.5	0.0	1.1	27	0.0	0.0	1.3	24	0.0	0.0	1.5
Composite Pinch	25	0.9	0.0	4.6	27	0.0	0.0	3.3	24	0.0	0.0	4.5
sciqol_1	25	1.0	0.0	2.0	27	1.0	0.0	2.0	24	1.0	-0.5	1.5
sciqol_2	25	1.0	0.0	2.0	27	1.0	0.0	2.0	24	1.0	0.0	2.0
sciqol_3	25	0.0	0.0	1.0	27	0.0	0.0	2.0	24	0.0	0.0	1.0

Table 3. Results of multivariable quantile regression models for each SCI outcome.*,**

	Model Estimates					
	tDCS vs Sham			PNSS vs Sham		
	Parameter Estimate	95% Confidence Interval		Parameter Estimate	95% Confidence Interval	
	Lower	Upper		Lower	Upper	
Total_Prehension	0.096	-1.578	1.753	-0.752	-2.064	0.985
Total_SWM (sensation)	3.205	-2.498	4.976	-1.221	-2.632	2.382
Grip_Strength	-0.016	-0.029	0.001	-0.042	-1.678	-0.022
Key_Pinch_Strength	-0.323	-1.037	-0.012	-0.452	-1.238	-0.002
Tip_Tip_Pinch	-0.007	-0.009	0.001	-0.011	-0.500	-0.001
Palmer_Pinch	-0.011	-0.263	-0.005	-0.017	-0.368	-0.002
Composite Pinch	-0.093	-0.946	-0.011	-0.153	-1.886	0.012
sciqol_1	0.041	-1.100	0.814	-0.302	-1.027	0.020
sciqol_2	-0.246	-1.872	1.293	-0.249	-0.970	0.674
sciqol_3	0.000	0.000	0.000	0.590	-0.122	1.511

*Each model was adjusted for Sex, Active VS Passive, Acute VS Chronic, Age, ASIA, Weeks since injury, BHUEF hand, BHUEF shoulder

****Bold indicates a statistically significant result.**

Figure 1. Composite pinch strength outcome over time stratified by active/passive hand function.

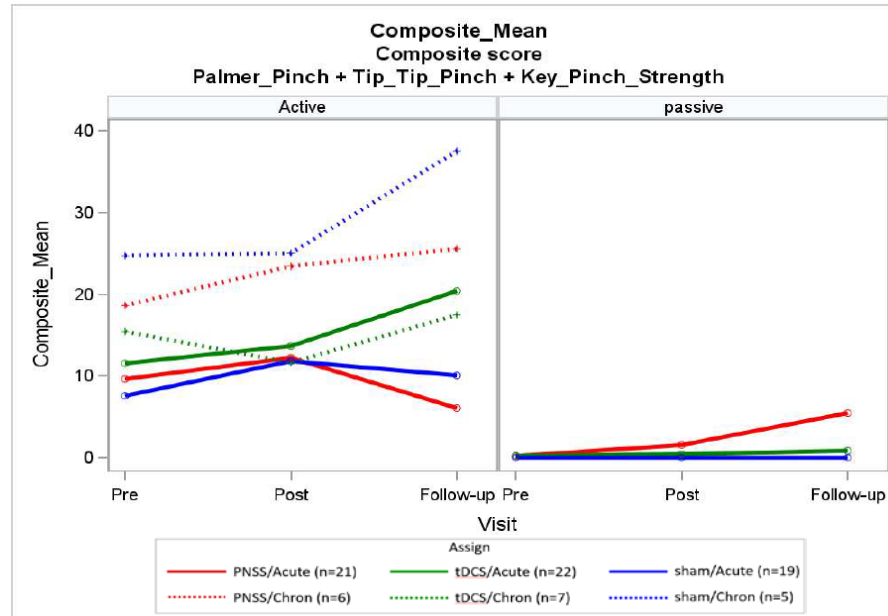


Figure 2. Grip strength outcome over time stratified by active/passive hand function

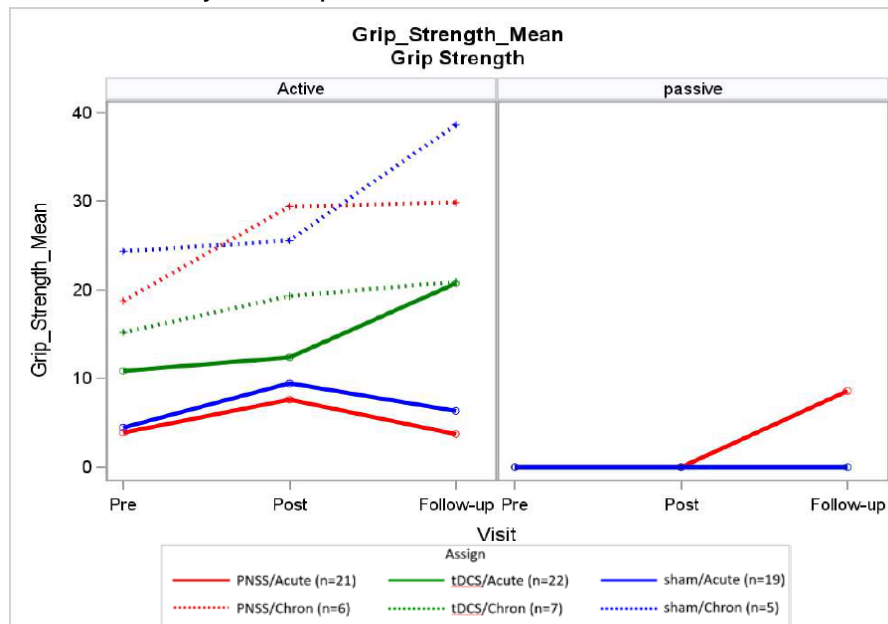


Figure 3. Total of 6 functional prehension tasks from the GRASSP outcome over time stratified by active/passive hand function.

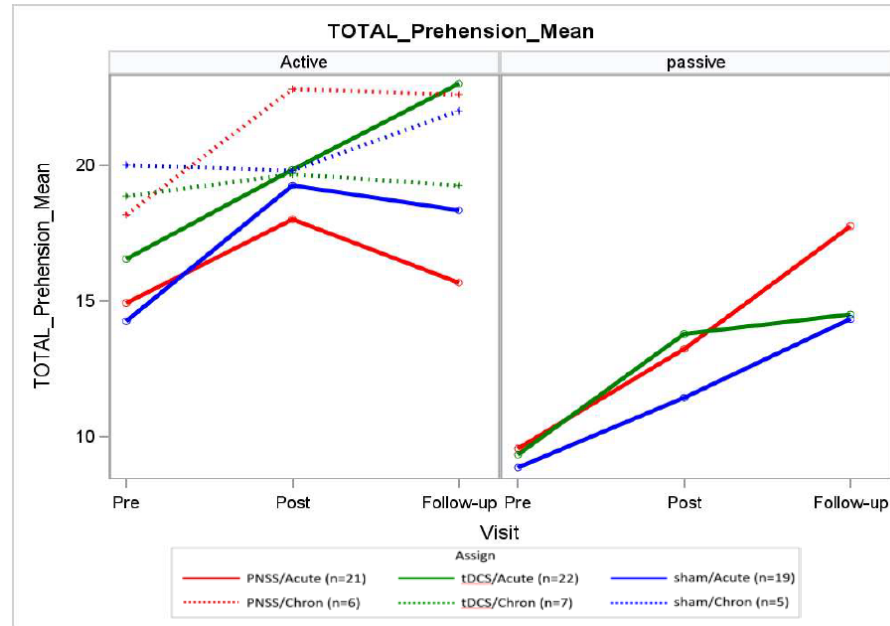


Figure 4. Semmes-Weinstein monofilament (SWM) sensory outcome over time stratified by active/passive hand function.

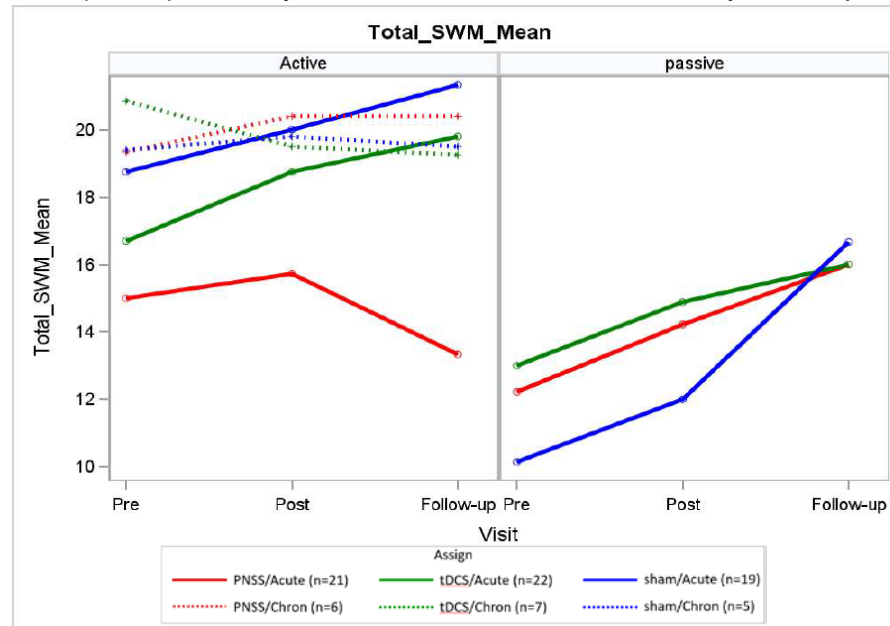


Figure 5. Quality of life question #1 outcome over time stratified by active/passive hand function.

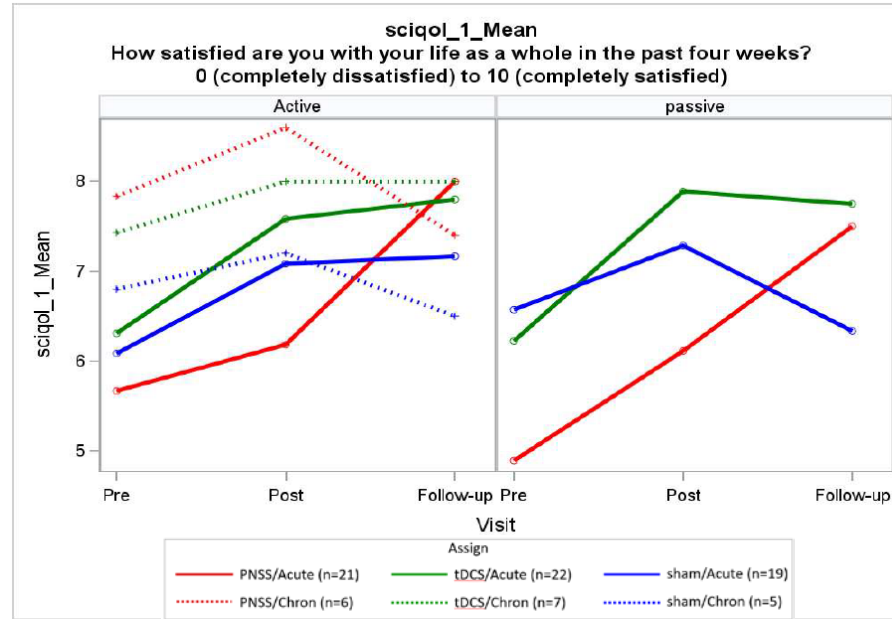


Figure 6. Quality of life question #2 outcome measure over time stratified by active/passive hand function.

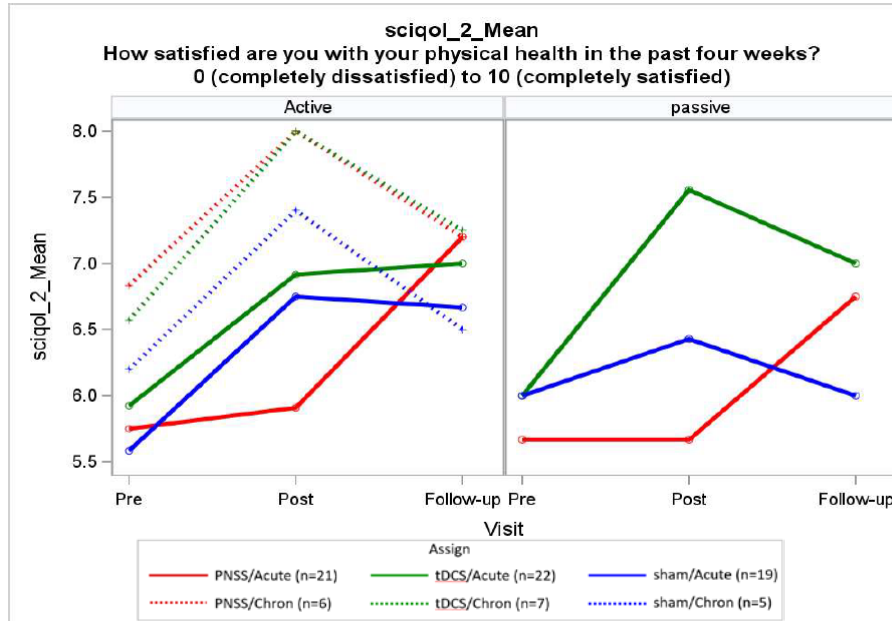


Figure 7. Quality of life question #3 outcome measure over time stratified by active/passive hand function.

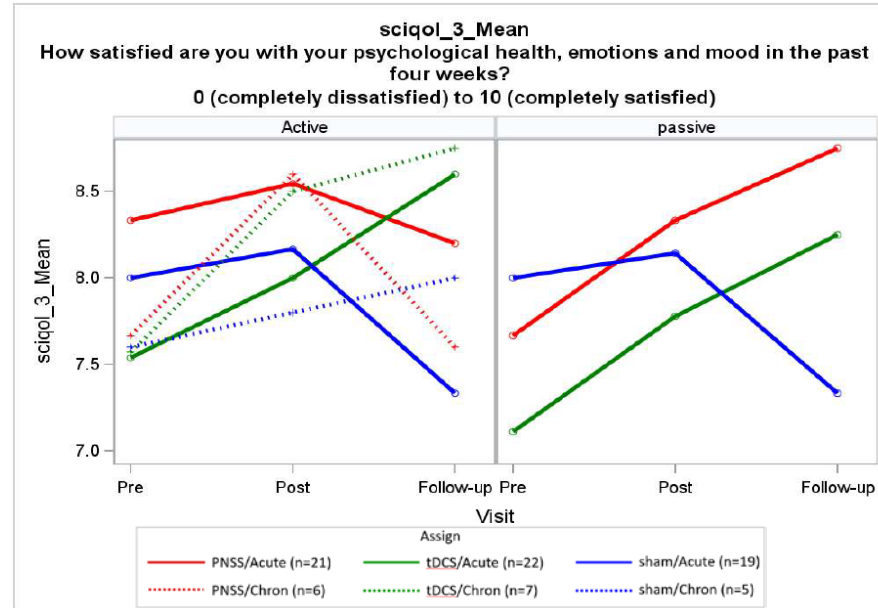


Figure 8. Total self-reported performance score from the Canadian Occupational Performance Measure (COPM) over time stratified by active/passive hand function.

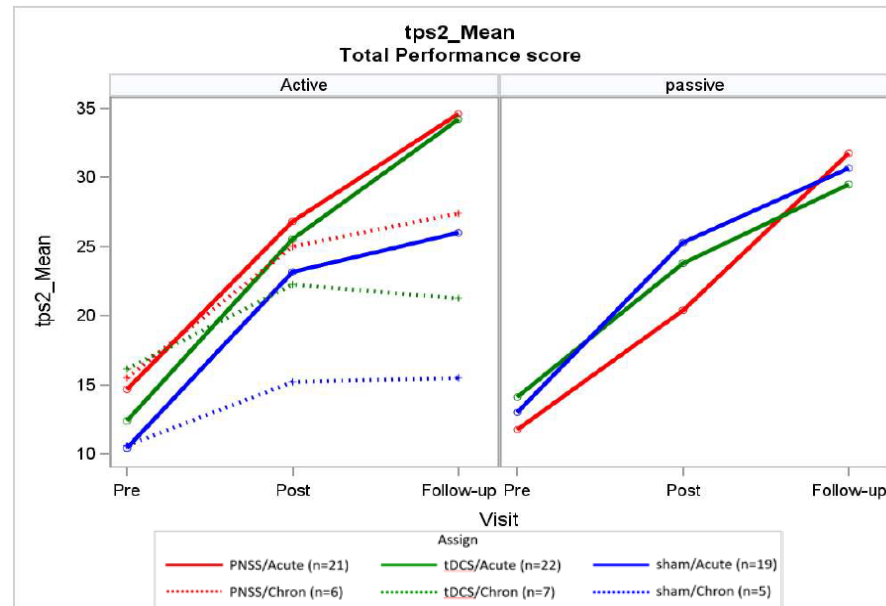
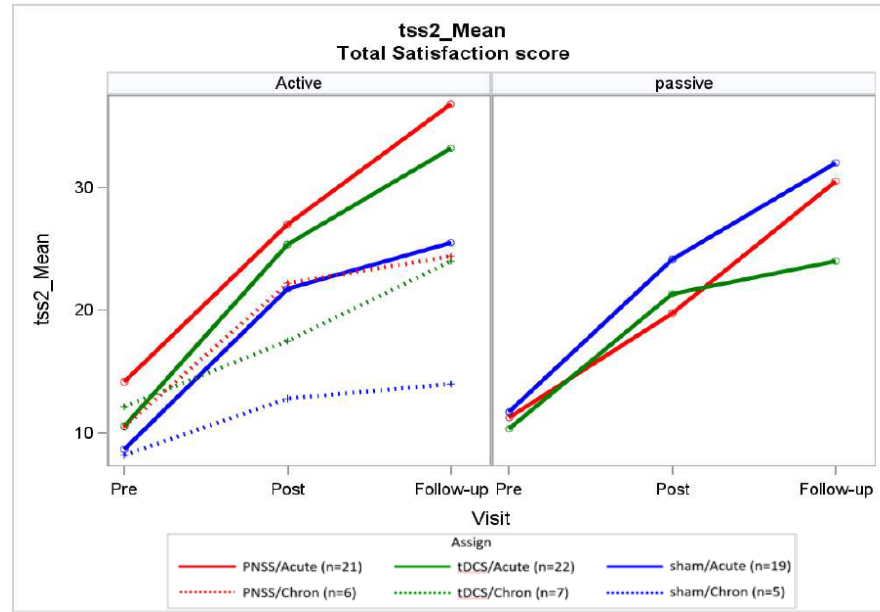


Figure 9. Total self-reported satisfaction score from the COPM over time stratified by active/passive hand function.



What opportunities for training and professional development has the project provided?

One-on-one and group mentoring has been ongoing by senior researchers to educate research staff on reduction and analysis methodology and interpretation of results. Weekly meetings, journal clubs, and directed reading discussions continue to be held under the direction of the principal investigator to further enhance the knowledge and skills of the research lab team as related to physiology of the spinal cord, pathophysiology of spinal cord injury, mechanisms of neuroplasticity and principles underlying interventions.

How were the results disseminated to communities of interest?

Nothing to Report, no results have been disseminated at this time.

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

During the next quarter, we plan to complete data reduction of neurophysiologic data in preparation for analysis. Analysis of both the neurophysiologic data and clinical data will continue in the next quarter as well as preliminary writing for planned manuscripts and dissemination of the results.

4. IMPACT: Describe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:

What was the impact on the development of the principal discipline(s) of the project?

The processes implemented during this study, allowing for acute and inpatient participants to take part in the research study, has influenced and impacted the Shepherd Center's approach for further studies. We now have a clear process to implement research into patients' therapy schedules, as well as buy-in from Shepherd Center therapists and staff to complete research concurrently with patients' regularly scheduled therapy.

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?

Nothing to report.

- 5. CHANGES/PROBLEMS: The PD/PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official 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:**

As we noted in our previous Quarterly Report, we encountered challenges in the past 6 months that have led to a delay in completing data analysis. This has been caused by several factors, including research staff shifting work efforts to assist Shepherd Center with essential duties as a result of COVID-19, but most significantly this has been due to challenges in data reduction and analysis processes. Extensive additional work has been necessary to identify parameters for categorizing and identifying meaningful outcomes from both the clinical and the neurophysiological data. We will be using our one-year extension without funds to complete the data analysis and manuscript writing portion of the project.

Changes in approach and reasons for change

Nothing to report.

Actual or anticipated problems or delays and actions or plans to resolve them

Nothing to report.

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

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**
Report only the major publication(s) resulting from the work under this award.

Journal publications.

Nothing to report.

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?

Name: Dr. Edelle Field-Fote – no change

Name: Dr. Jennifer Iddings – no change

Name: Allison McIntyre – no change

Name: Brandon Poe – completed work with Shepherd Center in May 2020

Name: Samantha Engel

Project Role: Data Manager

Researcher Identifier (e.g. ORCID ID): none

Nearest person month worked: 1

Contribution to Project: Assumed the role of Data Manager in May 2020. Providing ongoing data management support for data exportation.

Name: Sarah Callahan – completed work with Shepherd Center in August 2019

Name: Barry McKay – completed work with Shepherd Center in December 2019

Name: Cazmon Suri – no change

Name: Anastasia Zarkou – 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: none

QUAD CHART:

Conditioning Neural Circuits to Improve Upper Extremity Function

Supporting Proposal: Reactivating Neural Circuits With Clinically Accessible Stimulation to Restore Hand Function in Persons With Tetraplegia
SC150103

W81XWH-16-1-0395



PI: Edelle Field-Fote, PT, PhD

Org: SHEPHERD CENTER

Award Amount: \$1,906,189

Study/Product Aim(s)

- Aim 1.** Compare the effects on hand motor function of a multi-session course of stimulation-augmented functional task practice (FTP)
- Aim 2.** Compare changes in hand-related sensory function, self-reported function and participation, and quality of life associated with a multi-session course of stimulation-augmented FTP
- Aim 3.** Compare the effects on cortical and spinal excitability (spasticity) of a 3-week course of stimulation-augmented FTP
- Aim 4.** Compare differences in rates of conversion from passive hand function to active hand function in persons with subacute SCI among the 3 intervention groups
- Aim 5.** (exploratory) In subjects with tetraplegia, compare differences in responsiveness between persons with subacute (1-6 months post) versus chronic (≥ 1-year post) SCI

Approach

Using commercially available forms of transcranial direct current stimulation (tDCS) and peripheral nerve somatosensory stimulation (PNSS), assessors will compare the relative value of cortical versus peripheral stimulation as adjuncts to a 4-week course of FTP. Changes will be compared as described in Aims 1, 2, and 3, and as an exploratory aim, outcomes will be compared in subacute vs chronic SCI to gather evidence regarding relative value of these approaches for early intervention (Aim 5).

	Pinch Strength Model Estimates (lbs.)					
	tDCS vs Sham			PNSS vs Sham		
	Parameter Estimate	95% Confidence Interval		Parameter Estimate	95% Confidence Interval	
		Lower	Upper		Lower	Upper
Key Pinch Strength	-0.323	-1.037	-0.012	-0.452	-1.238	-0.002
Tip-to-Tip Pinch	-0.007	-0.009	0.001	-0.011	-0.500	-0.001
Palmer Pinch	-0.011	-0.263	-0.005	-0.017	-0.368	-0.002
Composite Pinch	-0.093	-0.946	-0.011	-0.153	-1.886	0.012

Results of quantile regression modeling for pinch strength outcome measures. Bold indicates a statistically significant result. Based on the modeling, we saw the greatest change in key pinch strength while comparing tDCS vs sham stimulation and PNSS and sham stimulation, with parameter estimate pinch strength improvement of 0.323 pounds and 0.452 pounds respectively from pre-assessments to post-assessments.

Timeline and Cost

Activities	CY 16	17	18	19	20
Adapt Study Protocol to Facilitate Larger Trial Supported by DoD Grant	█				
Coordinate Study Staff for Subacute and Chronic Groups		█	█	█	█
Participant Recruitment, Therapy, Participant Evaluation		█	█	█	█
Data Analysis					█
Randomized Control Trial					█
Estimated Budget (\$K)	\$183	\$473	\$468	\$480	\$302

Updated: 09/11/2020

Goals/Milestones

CY16 Goal – Adapt Study Protocol to Facilitate Larger Trial Supported by DoD Grant

- IRB approval obtained
- HRPO approval obtained
- Research and clinical staff trained

CY17 Goal – Coordinate Study Staff for Subacute and Chronic Groups

- Research and clinical staff trained
- Maintain trained and available Independent Evaluators for duration of clinical trial

CY17 – CY 19 Goal – Participant Recruitment, Therapy, Participant Evaluation

- 1st participant consented, screened and enrolled
- Data collection initiated
- 50% of subjects recruited and completed intervention

CY20 Goal – Data Analysis

- Data analyzed

CY20 Goal – Randomized Controlled Trial

- Report findings from overall studies

Budget Expenditure to Date (through July 31, 2020)

Projected Expenditure (budgeted): \$1,885,878.19

Actual Expenditure: \$1,719,150.80

9. APPENDICES: none attached