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 ORGANZATION: Shepherd Center

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6. AUTHOR(S)

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5e. TASK NUMBER

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13. SUPPLEMENTARY NOTES

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 completed data reduction, but continue ot work actively with the biostatistician analyze the data is a way that extracts the greatest value for understanding the results and informing clinical practice. 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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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: 90%

Major Task 5: Randomized Controlled Trial
Milestone 9: Report findings from overall studies
target date:6/15/2020- 08/15/2020; percent completion: 20%

What was accomplished under these goals?

ACCOMPLISHMENTS IN YEAR 1
In Y1 we refined the eligibility criteria, exclusion criteria, and screening protocol. Developed the database. We finalized the human subjects protocol and informed consent form, and were successful in obtaining approval from both our institutional IRB and HRPO to begin studies. We trained all study staff and completed competency check-offs. We began recruitment and enrollment activities, and initiated participant training. We completed required reporting activities

ACCOMPLISHMENTS IN YEAR 2
In Y2 we continued to monitor data collection procedures, and trained new study staff and performed fidelity checks for staffs to ensure continued competency. We continued recruitment and enrollment activities, and continued participant training, reaching our target of 50% of total participants enrolled and completed training. Due to recruitment being ahead of schedule, we requested to expand the target sample size from 70 to 83 (including attrition). We completed required reporting activities.

ACCOMPLISHMENTS IN YEAR 3
In Y3 we continued recruitment and enrollment activities, and continued participant training. A total of 83 participants were expected to enroll in the study, 58 participants with acute spinal cord injuries (>6 months post injury), 15 participants with chronic injuries (>1 year post injury), and 10 additional slots allocated to expected attrition. This past reporting period, we completed enrollment with 80 total participants, 7 lost to attrition,

therefore meeting enrollment goals. Data reduction and processing became the primary focus of the study team, to prepare for data analysis and dissemination of results.

ACCOMPLISHMENTS IN YEAR 4 (INCLUDING NCE PERIOD AND ONGOING)
In Y4 , we continued the reduction of the electrophysiologic data. New MATLAB codes were developed to analyze the electrophysiologic data from evoked cortical potentials and muscle electromyography. We continue working with the biostatistics team to analyze the large volume of clinical and electrophysiologic data acquired as part of this study. The analyses related to the research questions is progressing.

The first abstract using data from the study was presented at **Fourth International Brain Stimulation Conference, Dec 6-9, 2021 in Charleston SC,**

Title: Comparative effectiveness of multisession transcranial direct current stimulation and peripheral nerve somatosensory stimulation for enhancing corticospinal excitability and improving hand function in individuals with chronic cervical spinal cord injury
Authors: Anastasia Zarkou, PT, PhD; Jennifer Iddings, PhD; Edelle Field-Fote, PT, PhD

More details of the poster can be found under Subsection 6: Publications.

When complete, we will be able to address the following questions:

1. Between intervention group (PNSS, tDCS, sham) assessment of change between post and pre-test for all outcomes (clinical, self-report and neurophysiologic) with separate comparisons for the subacute active and subacute passive stratifications (i.e. active PNSS vs active tDCS vs active sham; passive PNSS vs passive tDCS vs passive sham)
2. Within intervention group assessment of change between post and pre-test and effect size data for all outcomes (clinical, self-report and neurophysiologic) that are both stratified and separated by group (i.e. subacute active PNSS, subacute active tDCS, subacute active sham; subacute passive PNSS, subacute passive tDCS, subacute passive sham)
3. Relationship between post-pre change in clinical outcome measures (total prehension score, total prehension time, key pinch, and total SWM) and post-pre change in neurophysiologic outcome measures (TMS MEP amp, EMG avg RMS, EMG peak RMS, EMG time to peak RMS, spasticity RTA)
4. Retention of changes (follow-up - post changes)
5. Comparisons of two subacute hand function stratifications with collapsed intervention groups (i.e. all subacute active participants vs all subacute passive participants) for all outcomes (clinical, self-report and neurophysiologic) as described in 2nd bullet point above.
6. Establish the minimal clinically important difference in the GRASSP test of upper extremity function using the statistical distribution method.

These questions will address clinically meaningful issues regarding not only the value of the interventions, but also will provide evidence about predictive factors that can help to guide optimal clinical care.

Below is a sampling of the analysis thus far, comparing data from baseline to study conclusion of six of the outcomes.

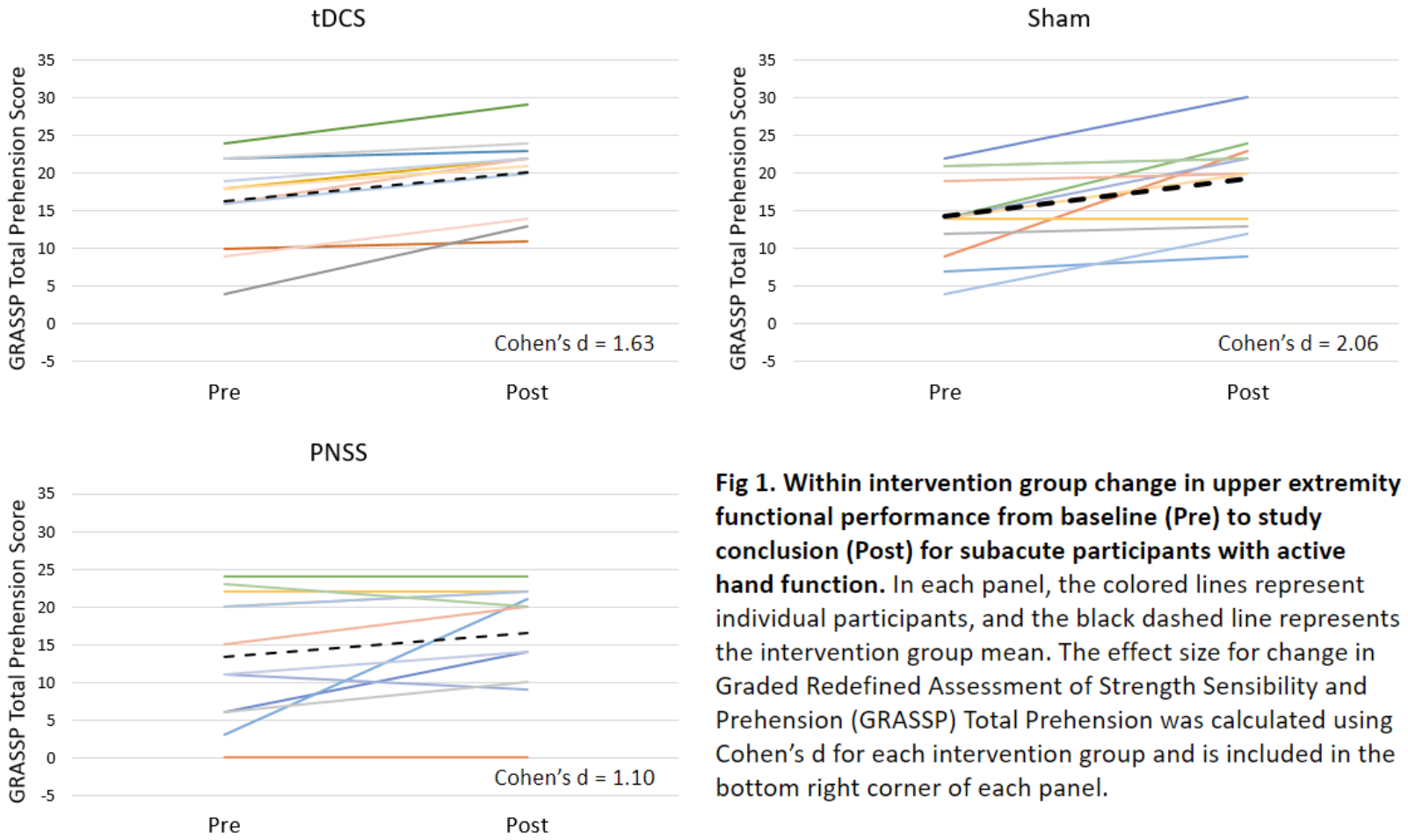


Fig 1. Within intervention group change in upper extremity functional performance from baseline (Pre) to study conclusion (Post) for subacute participants with active hand function. In each panel, the colored lines represent individual participants, and the black dashed line represents the intervention group mean. The effect size for change in Graded Redefined Assessment of Strength Sensibility and Prehension (GRASSP) Total Prehension was calculated using Cohen's d for each intervention group and is included in the bottom right corner of each panel.

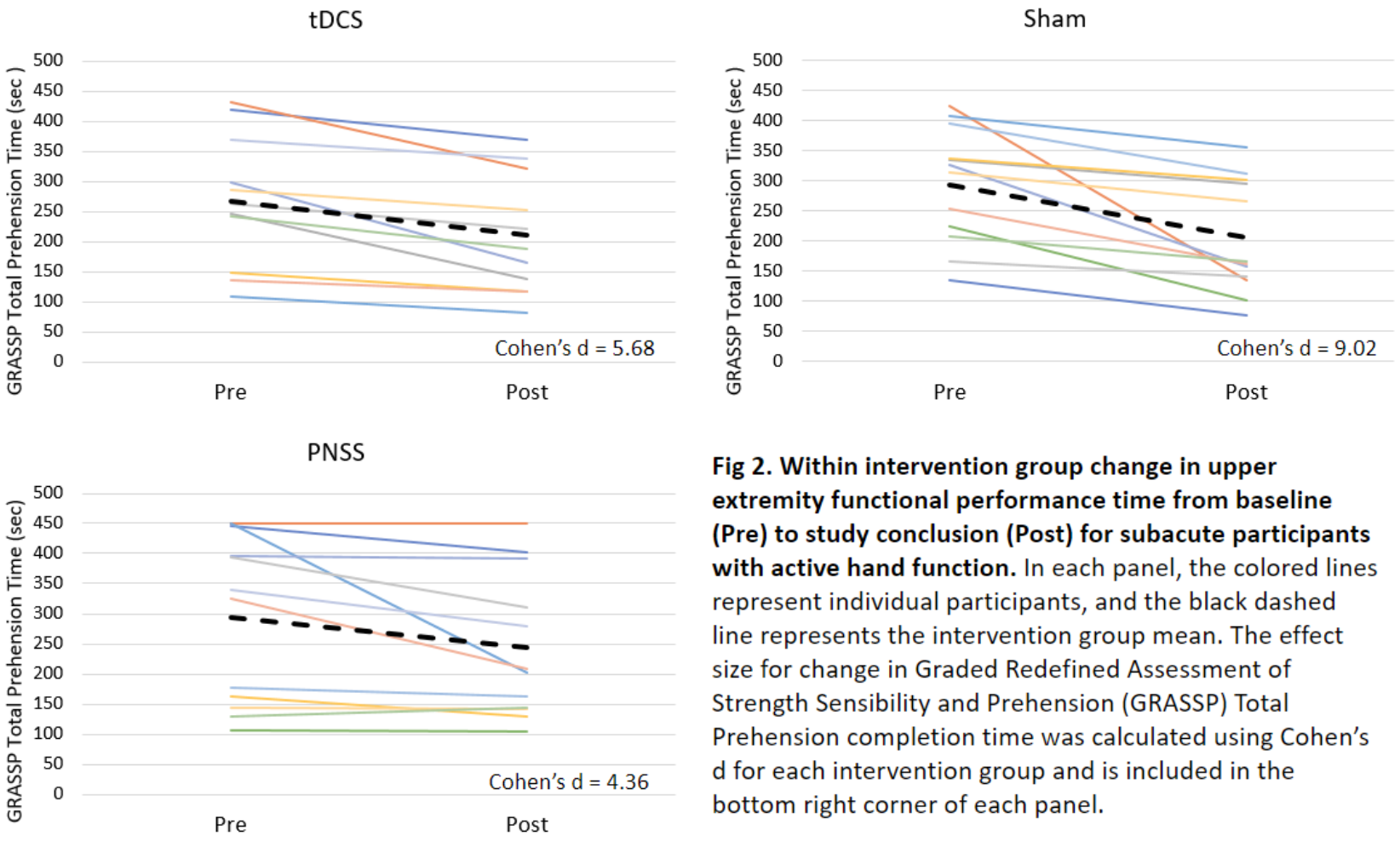


Fig 2. Within intervention group change in upper extremity functional performance time from baseline (Pre) to study conclusion (Post) for subacute participants with active hand function. In each panel, the colored lines represent individual participants, and the black dashed line represents the intervention group mean. The effect size for change in Graded Redefined Assessment of Strength Sensibility and Prehension (GRASSP) Total Prehension completion time was calculated using Cohen's d for each intervention group and is included in the bottom right corner of each panel.

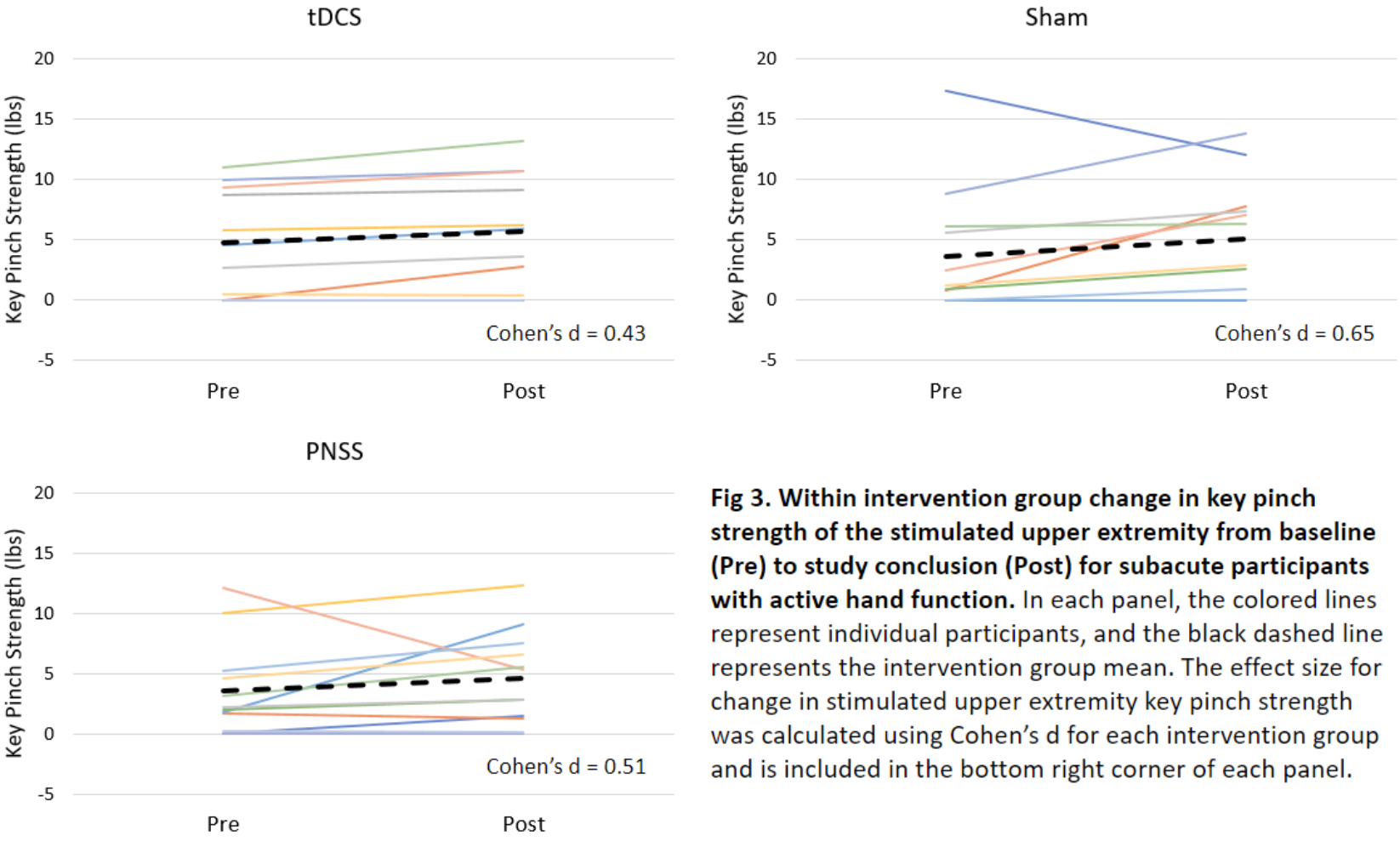


Fig 3. Within intervention group change in key pinch strength of the stimulated upper extremity from baseline (Pre) to study conclusion (Post) for subacute participants with active hand function. In each panel, the colored lines represent individual participants, and the black dashed line represents the intervention group mean. The effect size for change in stimulated upper extremity key pinch strength was calculated using Cohen's d for each intervention group and is included in the bottom right corner of each panel.

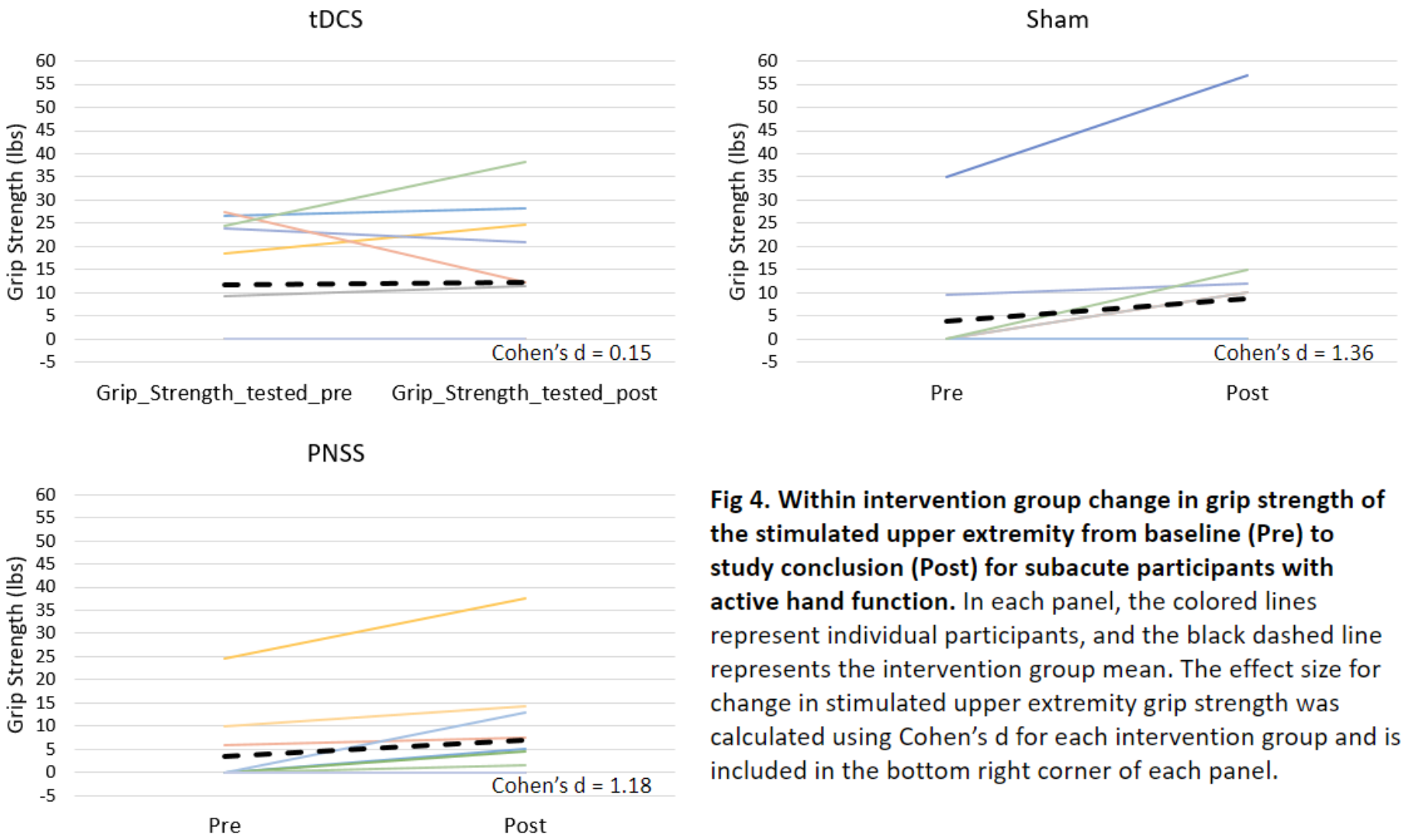
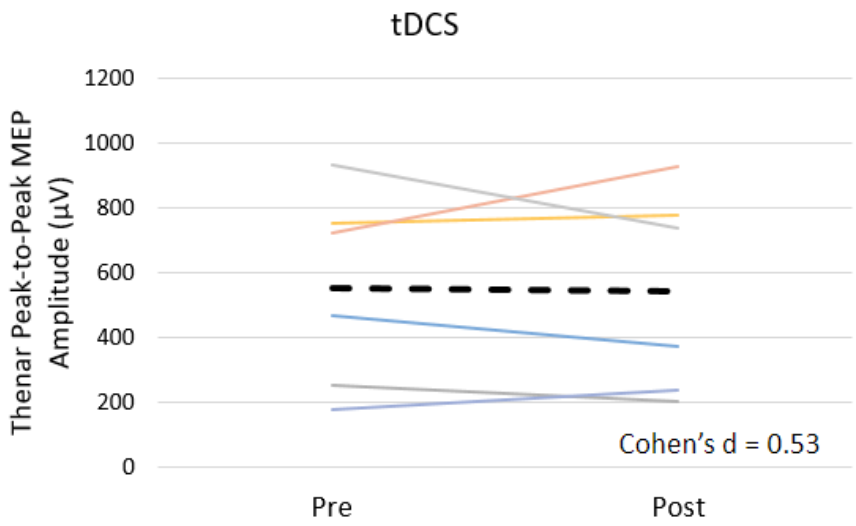
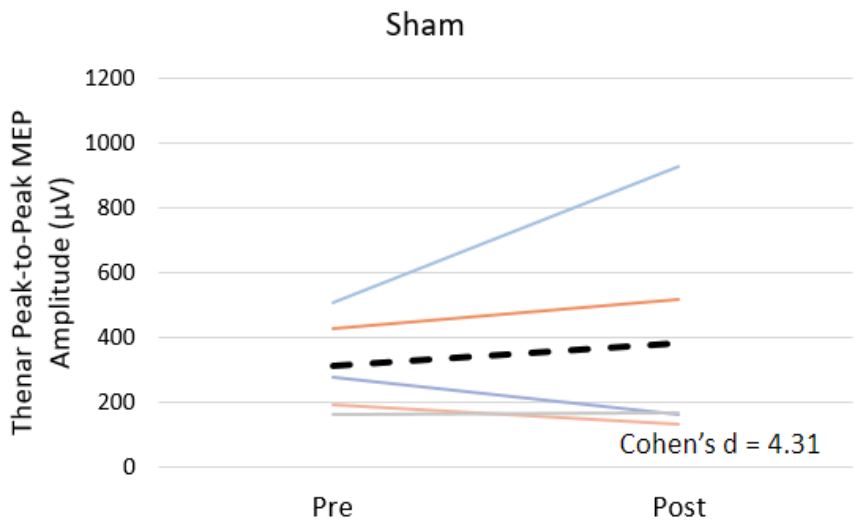


Fig 4. Within intervention group change in grip strength of the stimulated upper extremity from baseline (Pre) to study conclusion (Post) for subacute participants with active hand function. In each panel, the colored lines represent individual participants, and the black dashed line represents the intervention group mean. The effect size for change in stimulated upper extremity grip strength was calculated using Cohen's d for each intervention group and is included in the bottom right corner of each panel.





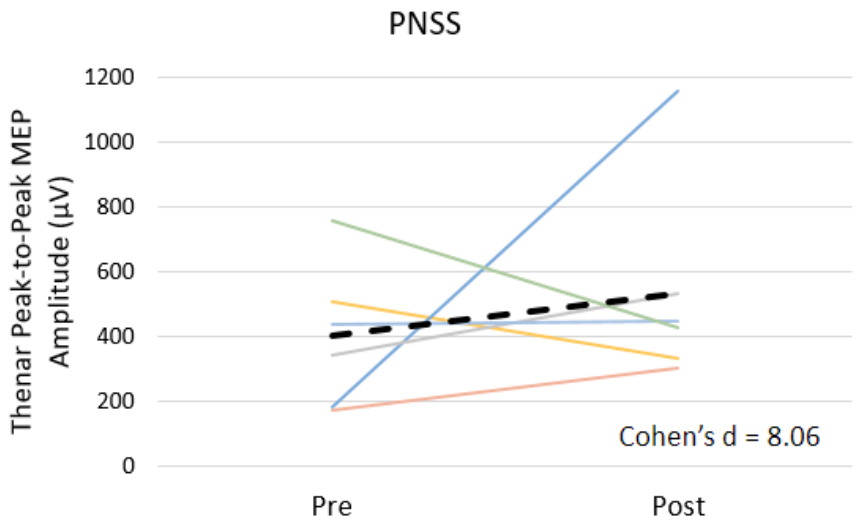


Fig 5. Within intervention group change in corticospinal excitability of the stimulated upper extremity from baseline (Pre) to study conclusion (Post) for subacute participants with active hand function. In each panel, the colored lines represent individual participants, and the black dashed line represents the intervention group mean. Thenar transcranial magnetic stimulation motor evoked potential (TMS MEP) amplitude was obtained at 100% maximum stimulator output. The effect size for change in MEP amplitude was calculated using Cohen's d for each intervention group and is included in the bottom right corner of each panel.

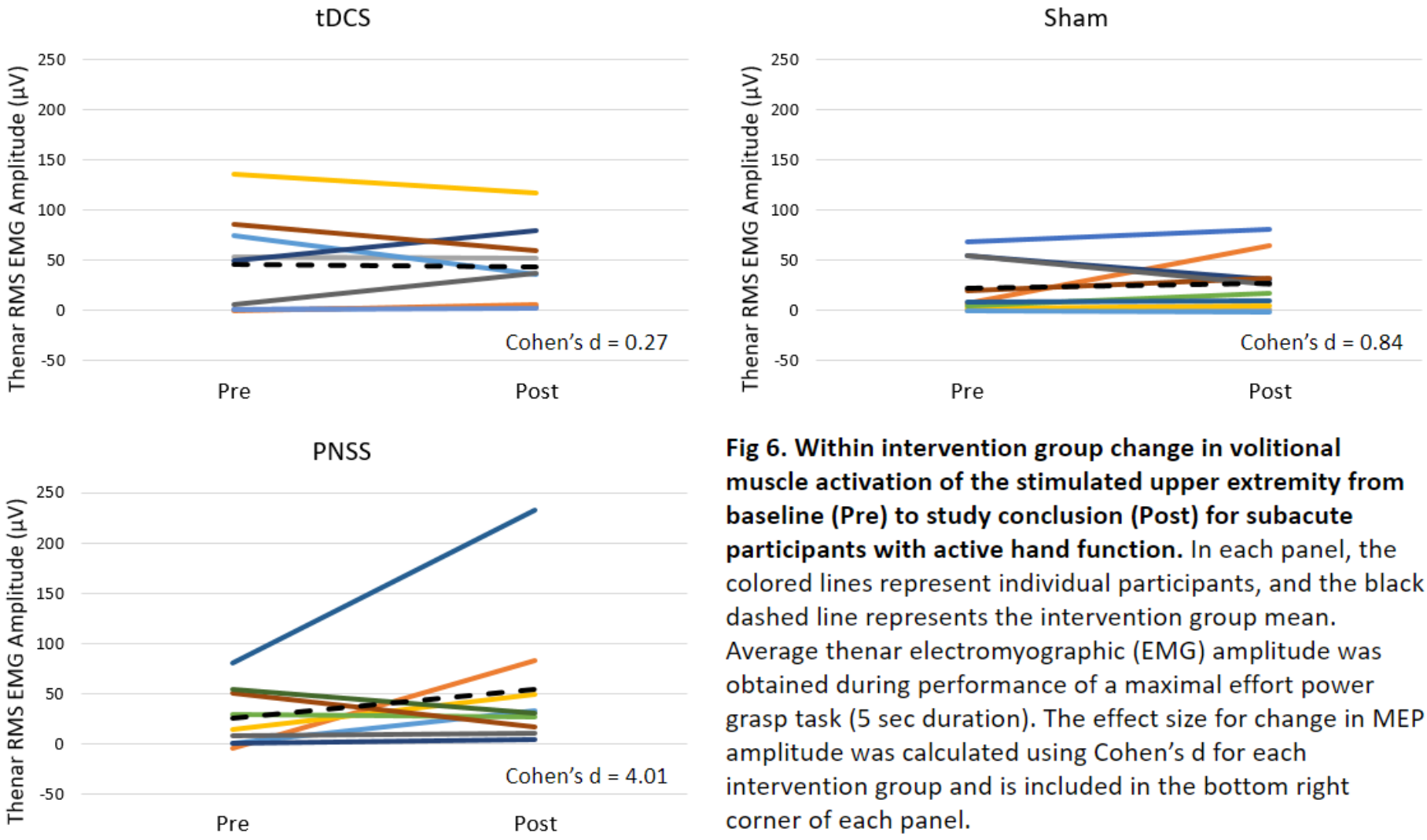


Fig 6. Within intervention group change in volitional muscle activation of the stimulated upper extremity from baseline (Pre) to study conclusion (Post) for subacute participants with active hand function. In each panel, the colored lines represent individual participants, and the black dashed line represents the intervention group mean. Average thenar electromyographic (EMG) amplitude was obtained during performance of a maximal effort power grasp task (5 sec duration). The effect size for change in MEP amplitude was calculated using Cohen's d for each intervention group and is included in the bottom right corner of each panel.

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?

Thus far preliminary results have been disseminated as a conference presentation at the 4th International Brain Stimulation Conference, Dec 6-9, 2021 in Charleston SC, Title: Comparative effectiveness of multisession transcranial direct current stimulation and peripheral nerve somatosensory stimulation for enhancing corticospinal excitability and improving hand function in individuals with chronic cervical spinal cord injury. Authors: Anastasia Zarkou, PT, PhD; Jennifer Iddings, PhD; Edelle Field-Fote, PT, PhD

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

Following complete and careful analysis of the large amount of valuable data that has been collected as part of this study, we will develop the following manuscripts:

1) Cortical versus somatosensory stimulation for neuromodulation as an adjunct to hand training in persons with tetraplegia (target journal: Physical Therapy and Rehabilitation)

2) Predicting outcomes of task-specific hand training in persons with subacute tetraplegia (target journal: Neurorehabilitation and Neural Repair)

3) Influence of neuromodulation approach on outcomes of functional task practice training in persons with chronic tetraplegia (target journal: Journal of NeuroEngineering and Rehabilitation)

4) Minimal clinically important difference in the GRASSP test of upper extremity function for persons with tetraplegia due to spinal cord injury.

Our **lead candidate product** is a knowledge project. This project will aid all persons with spinal cord injury whether they are a warfighter, veteran, or member of the general population. The knowledge product will be articles in peer-reviewed journals that educate clinicians about how they can improve outcomes in persons with tetraplegia. Specifically this products are expected to improve clinical practice by identifying the most effective approach to train for improved hand function in persons with subacute cervical spinal cord injury, identify characteristics that predict outcomes to allow focus on useful interventions during the acute rehabilitation stay, and establish the minimal clinically important difference in the GRASSP test of upper extremity function.

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:

Nothing to report.

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.

Fourth International Brain Stimulation Conference, Dec 6-9 Charleston SC
Title: Comparative effectiveness of multisession transcranial direct current stimulation and peripheral nerve somatosensory stimulation for enhancing corticospinal excitability and improving hand function in individuals with chronic cervical spinal cord injury

Authors: Anastasia Zarkou, PT, PhD; Jennifer Iddings, PhD; Edelle Field-Fote, PT, PhD

An image of the poster to be presented is on the following page. This is a working draft that will be completed prior to the International Brain Stimulation Conference.
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Comparative effectiveness of multisession transcranial direct current stimulation and peripheral nerve somatosensory stimulation for enhancing corticospinal excitability and improving hand function in individuals with chronic cervical spinal cord injury

Anastasia Zarkou[1], Jennifer A. Iddings[1], Edelle C. Field-Fote[1,2]
[1]Shepherd Center Crawford Research Institute, Atlanta GA; [2]Emory University, Atlanta GA

Background & Purpose

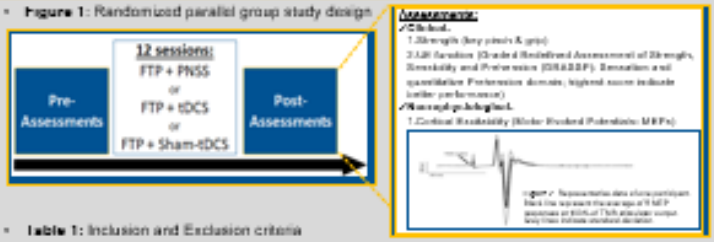
background

•Restoration of upper extremity (UE) function is a primary rehabilitation goal for individuals with cervical spinal cord injury (cSCI). Transcranial direct current stimulation (tDCS) and peripheral nerve somatosensory stimulation (PNSS) have been shown to improve UE function in persons with cSCI via direct and indirect effects on corticospinal excitability, respectively. However, the effectiveness of multisession application of these two stimulation modalities has yet to be compared.

Objective:
The goal of this pragmatic study was to investigate the effectiveness of PNSS, tDCS and sham-tDCS in individuals with cSCI when utilized as an adjunct to functional task practice (FTP) in a clinical neurorehabilitation setting.

Methods

- **Figure 1:** Randomized parallel group study design



- **Table 1:** Inclusion and Exclusion criteria

Inclusion criteria:	Exclusion criteria:
18- 74 years of age	Implanted metallic device in the head
Chronic cervical SCI (> 1-year post-injury)	Severe hypersensitivity, pain, contractures
Functional limitations in at least one hand (GRASSP quantitative prehension: <26 out of 30)	Prior tendon or nerve transfer surgery in the training UE
Active hand function (Brain Hand Upper Extremity Function (BH-UEF): level 4 or 5)	Shoulder weakness or injury limiting participation in FTP
Ability to pick up objects with one hand without assistive devices (GRASSP quantitative prehension: >4 out of 30)	History of seizures
Ability to maintain sitting position for one hour of therapy	History of frequent and or severe headaches
	Pregnancy

- **Table 2:** Stimulation characteristics

Results: Between-group comparisons

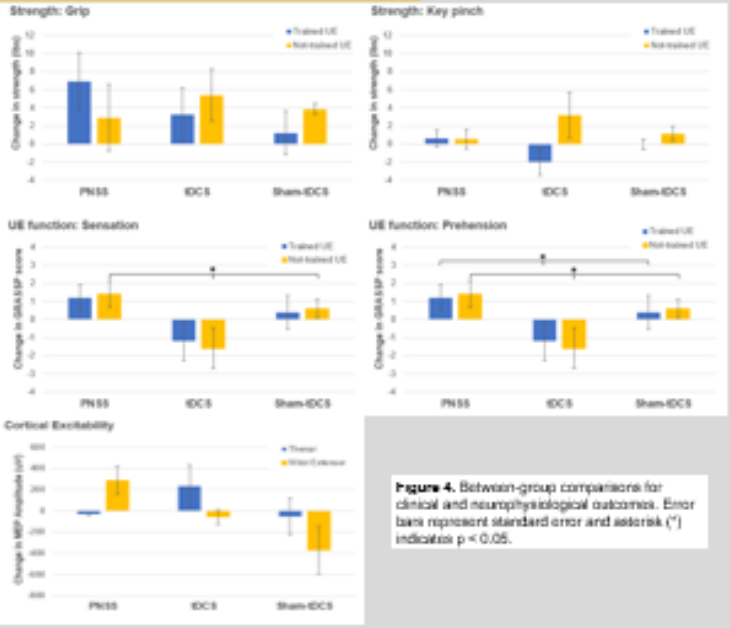


Figure 4. Between-group comparisons for clinical and neurophysiological outcomes. Error bars represent standard error and asterisk (*) indicates $p < 0.05$.

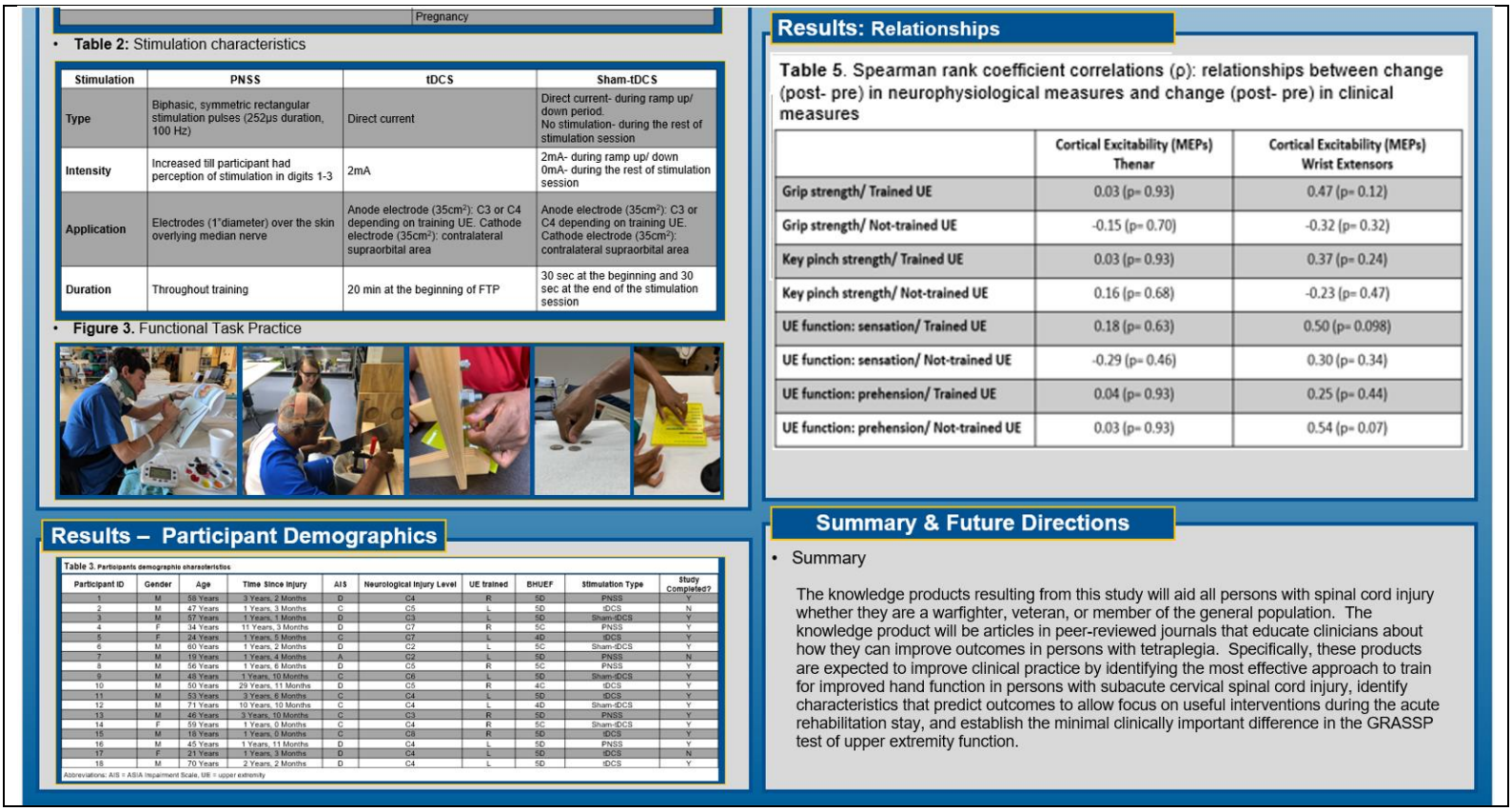
Results: Within-group comparisons

Table 4. Clinical and neurophysiological outcomes during pre and post assessments.

	PNSS				tDCS				Sham-tDCS			
	Pre	Post	P-value	Effect size	Pre	Post	P-value	Effect size	Pre	Post	P-value	Effect size
Clinical Assessments												
Strength (lbs)												
Grip: Trained UE	22.47(9.71)	25.37(9.10)	0.08	0.62	16.33(20.19)	19.60(24.97)	0.47	0.14	24.33(7.62)	25.53(10.69)	1.00	0.13
Grip: Not trained UE	25.03(27.07)	32.43(20.19)	0.05	0.12	11.20(19.93)	15.60(24.45)	0.11	0.24	36.75(25.61)	42.60(29.11)	0.10	0.14
Key Pinch: Trained UE	10.75(5.36)	11.37(4.69)	0.50	0.12	6.05(6.50)	4.10(4.16)	0.26	-0.35	9.37(3.64)	9.53(4.03)	0.72	-0.01
Key Pinch: Not trained UE	11.45(7.77)	12.05(8.14)	0.50	0.07	5.85(7.46)	10.80(10.09)	0.11	0.36	11.60(5.64)	12.93(7.19)	0.27	0.18
UE function: GRASSP												
Sensation: Trained UE	19.20(3.77)	20.40(3.05)	0.14	0.41	19.60(3.15)	19.60(5.03)	0.27	-0.28	19.40(5.73)	19.80(4.21)	0.59	0.08
Sensation: Not trained UE	19.60(5.05)	21.00(3.41)	0.10	1.01	21.40(2.30)	19.80(3.49)	0.10	-0.54	19.50(3.32)	20.25(2.63)	0.26	0.25
Prehension: Trained UE	20.80(3.81)	22.80(2.27)	0.04	0.75	18.20(4.09)	19.60(5.37)	0.07	0.30	20.00(1.41)	19.80(2.68)	0.71	-0.09
Prehension: Not trained UE	21.20(2.68)	22.40(2.30)	0.11	0.48	15.40(6.31)	17.40(6.80)	0.07	0.30	20.50(2.38)	21.75(2.22)	0.10	0.76
Neurophysiological Assessments												
Cortical Excitability: Post-to-post MEP Amplitude (uV)												
Tremor	305.04(186.58)	352.46(199.39)	0.11	-0.17	228.06(72.26)	462.43(264.02)	0.47	0.91	518.66(330.96)	466.13(142.14)	0.67	-0.20
Wrist Extension	1070.48(1096.72)	1807.92(1610.70)	0.11	0.18	1099.30(1324.70)	1041.30(1067.38)	0.23	-0.04	951.04(810.85)	870.67(884.30)	0.67	-0.09

Results: Relationships

Table 5. Spearman rank coefficient correlations (ρ): relationships between change



- **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: Samantha Engel - no longer working on the project

Name: Cazmon Suri – no change

Name: Anastasia Zarkou – no change

Name: Dr. Raeda Anderson
Project Role: Biostatistician
Researcher Identifier (e.g. ORCID ID): 0000-0003-0023-6649
Nearest person month worked: 1.2cm
Contribution to Project: Providing statistical analysis and support

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: *below*

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).

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: 29Oct2021

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

Projected Expenditure (budgeted): $1,906,189
Actual Expenditure: $1,906,189 (all additional costs were issued from lab funds)

9. APPENDICES: none attached