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TITLE: Secondary Analysis of Data from a Randomized Controlled Trial of  
Stellate Ganglion Block for Treating Symptoms of Posttraumatic Stress Disorder

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# REPORT DOCUMENTATION PAGE

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<b>14. ABSTRACT</b> This study seeks to conduct a secondary analysis of quantitative and qualitative data gathered during a recently completed randomized controlled trial of stellate ganglion block (SGB) for treating symptoms of posttraumatic stress disorder (PTSD). We will conduct analyses to evaluate the durability of SGB treatment over time; to explore topics including post-SGB Horner's syndrome, PTSD diagnostic categories, duration of PTSD symptoms, and concurrent medication use and to validate the PCL-5 against the gold-standard CAPS-5.						
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**Table of Contents**

	<u>Page</u>
<b>1. Introduction.....</b>	<b>4</b>
<b>2. Keywords .....</b>	<b>4</b>
<b>3. Accomplishments .....</b>	<b>4</b>
<b>4. Impact .....</b>	<b>5</b>
<b>5. Changes/Problems.....</b>	<b>6</b>
<b>6. Products .....</b>	<b>6</b>
<b>7. Participants and Other Collaborating Organizations .....</b>	<b>6</b>
<b>8. Special Reporting Requirements .....</b>	<b>6</b>
 <b>Appendix</b>	
<b>A: Study Quad Chart.....</b>	<b>7</b>

## 1. Introduction

This study seeks to conduct a secondary analysis of data gathered during a recently conducted randomized controlled trial (RCT) of stellate ganglion block (SGB) for treating symptoms of post-traumatic stress disorder (PTSD). The proposed study will investigate the following secondary hypotheses and their respective areas:

1. SGB for PTSD (Effectiveness)
  - H1. SGB will show durable treatment effects between baseline and Week 2, and Week 2 and Week 4. Durability will decline between Weeks 4 and 8.
  - H2. Symptoms from PTSD criterion E (marked alterations in arousal and reactivity) from the DSM-5 will be more improved following the SGB procedure than symptoms from other criteria.
  - H3. Post-SGB Horner's syndrome density will not moderate the relationship between treatment group and improvements in PTSD symptoms.
  - H4. The effectiveness of SGB for PTSD symptoms will not be related to the duration of PTSD symptoms experienced by the patient.
  - H5. Concurrent medication use will not be related to SGB effectiveness.
2. SGB for PTSD Acceptability
  - H6. SGB will be considered an acceptable treatment by RCT participants, with few drawbacks.
3. PTSD Assessment
  - H7. The PCL-5 will have a reasonable test-retest reliability using the screening and baseline scores from the clinical trial. Based on prior studies, the expected correlation between the two measures should be in the range of 0.8 to 0.9.
  - H8. The PCL-5 will have good DSM-5 diagnostic capability as defined by the operating characteristics (sensitivity, specificity, predictive value, receiver operating characteristic [ROC] curve) and will therefore represent a good assessment measure in lieu of CAPS-5.
  - H9. The PCL-5 will be sensitive to change when comparing the change in the total score and each of the subscales between those who are classified as moving from symptomatic to asymptomatic from baseline to 8 weeks.
  - H10. The PCL-5 will show convergent and discriminant validity separately at baseline and 8 weeks.

## 2. Keywords

Stellate ganglion block, Post-Traumatic Stress Disorder, secondary analysis, randomized controlled trial

## 3. Accomplishments

The major goals of this project for year 1 focused on the U.S. Army Medical Research and Materiel Command's regulatory (i.e., clinical protocol and Institutional Review Board [IRB]/ Human

Research Protection Office [HRPO]) activities, drafting version 1 of a statistical analysis plan, preparing a dataset, initiating the conduction of quantitative and qualitative analyses, and preparing manuscripts.

During year 1, the study team drafted the IRB package and submitted it to the RTI IRB for review with few challenges. The package was deemed not human subjects research. It was understood that no work involving human subjects data may take place until the approval from HRPO. We were able to clarify the correct IRB process in quarter 4 of the performance period.

Also, during year 1, the team coordinated with co-investigators and drafted version 1 of the statistical analysis plan which was submitted with the IRB package. In addition, we communicated regularly with co-investigators to apprise them of the study’s status.

<b>Task 1: Regulatory</b>		
<b>Subtask 1: IRB and HRPO packages submitted</b>		
<b>Milestone</b>	<b>Complete?</b>	<b>Comments</b>
All IRB and HRPO determinations received and documented	No	
Receive All IRB and HRPO Approvals	No	Awaiting approval from internal IRB to submit package to HRPO.
<b>Task 2: Statistical Analysis Plan</b>		
<b>Subtask 1: Draft Statistical Analysis Plan</b>		
<b>Milestone</b>	<b>Complete?</b>	<b>Comments</b>
Finalized quantitative statistical analysis plan	Yes	Version 1 completed (note that this is a “living document”
<b>Task 3: Prepare Dataset</b>		
<b>Subtask 1: Clean dataset</b>		<b>Complete?</b>
	No	Will need to await HRPO approval before beginning
<b>Subtask 2: Create new analytic variables, labels, and codebooks</b>		
<b>Milestone</b>	<b>Complete?</b>	<b>Comments</b>
Dataset cleaned and prepared for analysis	No	Will need to await HRPO approval before beginning
Final codebook produced	No	Will need to await HRPO approval before beginning

For the upcoming project year (i.e., year 2), we anticipate receiving IRB and HRPO approval. We will then initiate the following tasks: preparing the dataset (cleaning the dataset and creating new analytic variables, labels, and codebooks); conducting quantitative and qualitative analyses; and manuscript writing.

**4. Impact**

Nothing to report.

**5. Changes/Problems**

Changes: Nothing to report.

Problems: During year 1, we had difficulty identifying the proper procedures for submitting the study IRB package, which have changed significantly since we submitted the package for the original SGB study. After deciphering the proper procedures in quarter 4 of year 1, we were able to submit the IRB package to our internal IRB. Upon approval, we will submit the package to Naval Medical Center Portsmouth and then HRPO.

**6. Products**

Nothing to report.

**7. Participants and Other Collaborating Organizations**

No one from the study team has worked on the project for a minimum of 160 hours during project year 1. There has been no change in support of the Principal Investigator, co-investigators, or key personnel, and no other organization was involved as a partner.

<b>Name</b>	<b>Project Role</b>	<b>Person Months Worked</b>	<b>Contribution to the Project</b>

**8. Special Reporting Requirements**

Not applicable.

## Appendix A: Study Quad Chart

### Secondary Analysis of Data from a Randomized Controlled Trial of Stellate Ganglion Block for Treating Symptoms of Posttraumatic Stress Disorder W81XWH2010847

PI: Kristine Rae Olmsted

Org: RTI International

Award Amount: \$499,000

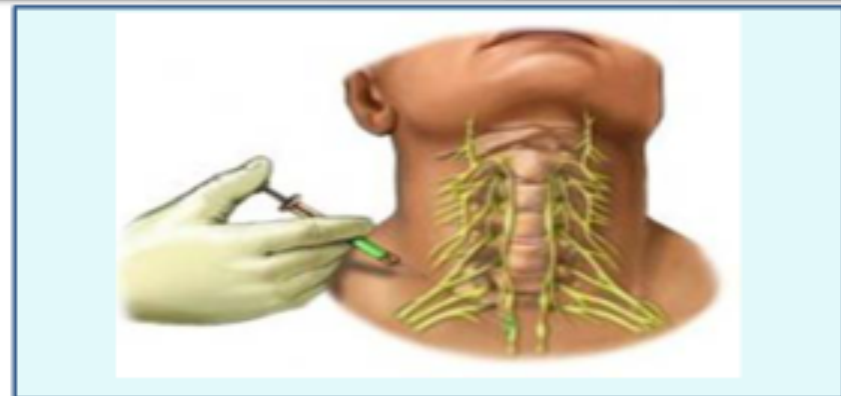


#### Study/Product Aim(s)

**Specific Aims:** Conduct secondary analysis of quantitative and qualitative data gathered during our recently completed randomized controlled trial of stellate ganglion block (SGB) for treating symptoms of posttraumatic stress disorder (PTSD). Conduct analyses to evaluate the durability of SGB treatment over time; to explore topics including post-SGB Horner's syndrome, PTSD diagnostic categories, duration of PTSD symptoms, and concurrent medication use and to validate the PCL-5 against the gold-standard CAPS-5.

#### Approach

Data from the previous trial lends itself to a number of secondary hypotheses: SGB for PTSD (Effectiveness): 5 hypotheses, SGB for PTSD (Acceptability): 1 hypothesis, and PTSD Assessment (4 hypotheses). We will 1) characterize previously unknown aspects of SGB as indicated for PTSD treatment; 2) characterize the degree to which participants believe SGB to be acceptable as treatment option, and 3) characterize PLC-5 validity and effectiveness in measuring PTSD symptomatology.



#### Timeline and Cost

Activities	CY 20	CY 21	CY 22
Task 1: Regulatory			
Task 2: Stat Analysis Plan			
Task 3: Prepare Dataset			
Task 4: Conduct Quantitative Analyses			
Task 5: Conduct Qualitative Analyses			
Task 6: Write and submit manuscripts			
Estimated Budget (\$k)	\$62k	\$250k	\$187k

Updated: October 2021

**Accomplishments:** Regulatory package and statistical analysis plan are near completion. Received clarification on IRB process.

#### Goals/Milestones

**CY20 Goals** –work on preparing IRB and HRPO packages (months 1-8); work on statistical analysis plan (months 1-3); prepare dataset (months 3-9)

**CY21 Goals** – work on preparing IRB and HRPO packages (months 1-8); prepare dataset (months 3-9); conduct quant analysis (months 13-21); conduct qual analysis (months 13-16)

**CY22 Goals** –write and submit manuscripts (months 25-36)

#### Comments/Challenges/Issues/Concerns

- IRB/HRPO delays in review/approval have result in delays to timeline
- Covid-19 has potential to delay activities on the timeline

#### Budget Expenditure to Date

Projected Expenditure: \$249,500  
Actual Expenditure: \$88,000