

AWARD NUMBER: W81XWH-15-2-0015

TITLE: Effectiveness and Patient Acceptability of Stellate Ganglion Block (SGB) for Treatment of Posttraumatic Stress Disorder (PTSD) Symptoms among Active Duty Military Members

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14. ABSTRACT This study seeks to evaluate the effectiveness and acceptability of stellate ganglion block (SGB) for treatment of Posttraumatic Stress Disorder (PTSD) symptoms. We will conduct two parallel studies: a randomized, controlled trial (RCT) to evaluate the effectiveness of SGB for treating PTSD, and a qualitative study to determine the degree to which the procedure is deemed acceptable by active duty service members with PTSD, their spouses, and their providers. Up to 240 individuals will be enrolled for the RCT portion of the study; qualitative study participants will be convenience sampled from among the RCT participants. For the RCT study, participants will be randomized 2:1 active (SGB) to sham across three study sites. Participants will receive the intervention (active or sham) at weeks 0 (baseline) and 2, and assessments will be conducted at weeks 0, 2, 4, 6, and 8. For the qualitative study, individuals enrolled in the RCT will be asked to participate either in a focus group or an interview with their spouse. In addition, we will conduct focus groups and key informant interviews with providers: those who refer individuals to the study, and those who provide SGB to service members.						
15. SUBJECT TERMS Stellate ganglion block, Posttraumatic Stress Disorder, randomized controlled trial, qualitative research						
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1. Introduction

This study seeks to evaluate the effectiveness and acceptability of stellate ganglion block (SGB) for treatment of Posttraumatic Stress Disorder (PTSD) symptoms. We are conducting two parallel studies: a randomized, controlled trial (RCT) to evaluate the effectiveness of SGB for treating PTSD, and a qualitative study to determine the degree to which the procedure is deemed acceptable by active duty service members (SMs) with PTSD, their spouses, and their providers. A total of up to 240 individuals will be enrolled for the RCT portion of the study; qualitative study participants will be convenience sampled from among the RCT participants and service members who received the SGB outside of the RCT. For the RCT study, participants are randomized 2:1 active (SGB) to sham across three study sites: Womack Army Medical Center (WAMC; Fort Bragg, NC), Tripler Army Medical Center (TAMC; Honolulu, HI), and Landstuhl Regional Medical Center (LRMC; Landstuhl, Germany). Participants receive the study intervention (active or sham) at weeks 0 (baseline) and 2, and assessments are conducted at weeks 0, 2, 4, 6, and 8. For the qualitative study, individuals who have received at least one SGB within the past 3 months are asked to participate either in a focus group, individual interview, or an interview with their spouse. In addition, we are conducting focus groups and key informant interviews with providers: those who refer individuals to the study, and those who provide SGB to service members.

2. Keywords

Stellate ganglion block, Posttraumatic Stress Disorder, randomized controlled trial, qualitative research

3. Accomplishments

The major goals of this project for year three focused on regulatory, recruitment, enrollment, and data collection activities for both the RCT and qualitative study. In sum, 6 IRB amendments/actions were submitted, and HRPO (the U.S. Army Medical Research and Materiel Command's Human Research Protection Office) approval was obtained. The amendments focused on implementation of new means of recruitment (study poster revisions, Facebook page and advertising campaign, informational video and materials for potential participants, and increased PAO involvement), new study coordinators, and the addition of non-clinical trial participants in the qualitative acceptability study.

During year three, RCT data collection continued at all three study sites. As of February 28, 2018, 248 SMs have been prescreened (69 at WAMC, 60 at LRMC, 119 at TAMC), 180 SMs were consented (47 at WAMC, 46 at LRMC, 87 at TAMC), 115 SMs were screen-eligible (20 at WAMC, 36 at LRMC, 59 at TAMC), and 88 SMs have completed the trial (15 at WAMC, 23 at LRMC, 50 at TAMC).

Qualitative data collection for the acceptability study also began at each site. In-person qualitative data collection visits were conducted at LRMC (November 13-15, 2018) and TAMC (January 22-24, 2018), with additional data collection by phone. As of February 28, 2018, qualitative data collection had been completed with 29 SMs (1 at WAMC, 15 at LRMC, 13 at TAMC), 5 SM and spouse dyads (0 at WAMC, 1 at LRMC, 4 at TAMC), and 14 providers (2 at WAMC, 2 at LRMC, 10 at TAMC).

RCT- Task 1: Conduct Randomized Controlled Trial (Months 1-36)		
Subtask 1: Prepare Regulatory Documents and Research Protocols		
Milestone	Complete?	Comments
Finalize Clinical Protocol	Yes	
Receive Common Access Cards	No	Determined to be unnecessary
Receive all IRB and HRPO approvals	Yes	All IRB and HRPO approvals received
Subtask 2: Develop Study Infrastructure		
Milestone	Complete?	Comments
Finalized Data Platforms	Yes	
Research Coordinators in place and trained	Yes	
Subtask 3: Collect, Analyze, and Disseminate Data		
Milestone	Complete?	Comments
RCT dataset complete	No	In process
Cleaned and edited analytic dataset	No	In process
Analyses and manuscript(s)/briefings for publication/presentation complete	No	In process
Qualitative Study- Task 1: Conduct Qualitative Study		
Subtask 1: Prepare Regulatory Documents and Research Protocols		
Milestone	Complete?	Comments
Finalized qualitative study instrumentation	Yes	
Receive all IRB and HRPO approvals	Yes	All IRB and HRPO approvals received
Subtask 2: Collect, Analyze, and Disseminate Data		
Milestone	Complete?	Comments
Subject data complete	No	In process

During year three, study staff gave oral and poster presentations the 2017 Military Health System Research Symposium (MHSRS) conference entitled “Stellate Ganglion Block for Treatment of Posttraumatic Stress Disorder Symptoms: A Multi-Mode Study.” In addition, we submitted an abstract to present at the 2018 MHSRS conference.

Also during year three, the study team worked with the Public Affairs Offices at WAMC to develop and disseminate a short video about SGB. Study staff were interviewed for articles in the Independent Journal Review (IJR) and the Wall Street Journal (WSJ), which was further disseminated by other outlets including Fox News. Study staff also collaborated on a spot on the Buck Sexton radio show. These pieces and others can be found in the “Latest News” section of our study website, <https://sgbstudy.rti.org>.

During year three, we conducted regulatory site visits to LRMC (March 2017) and to TAMC (May 2017) to ensure that all study protocols, documentation, and procedures were being implemented correctly. In addition, two visits were made to LRMC to train replacement Research Coordinators.

Multiple site visits were conducted at WAMC due to its proximity to RTI. These visits focused on meeting with IRB staff, consulting with research coordinators from other studies to brainstorm enrollment activities, and meeting with clinicians, their staff and individual units to try to increase referrals to the study.

During year three, we continued examining data collected to date to ensure that all data management and analytic processes are functioning appropriately. These regular reports have been, and will continue to be, run monthly. These reports do not include unblinded information, even in aggregate. We are also in the process of finalizing the statistical analysis plan and programming.

During the upcoming project year, we anticipate finishing data collection for both the RCT and the qualitative study. We will submit an IRB amendment to revise our primary outcome criterion of a change of 15 points in the CAPS-5 to a change of 10 points (as a result of psychometric data regarding CAPS-5 that have been released since we wrote the protocol). We also anticipate conducting closeout site visits to LRMC, WAMC and TAMC, closing out each site, and submitting the appropriate accompanying materials to the IRB. We anticipate cleaning and finalizing analytic data sets for both studies and conducting the appropriate analyses. Study staff will begin preparing manuscript(s)/briefings for publication and will present preliminary findings at the 2018 MHSRS conference.

4. Impact

Nothing to report.

5. Changes/Problems

Changes

A revision to the inclusion criteria for our qualitative study allows patients who have received a SGB at the study sites outside of the RCT to participate. In addition, new recruitment efforts were implemented.

Problems

Over year three, study enrollment continued to be significantly slower than anticipated, despite significant efforts to increase recruitment, including the following:

- Continued briefings with providers who are potential referral sources
- Engagement with interested community groups
- Creating a study Facebook page and Facebook advertising campaign
- Dissemination of an informational video developed with WAMC PAO about the SGB procedure
- Renewed efforts to place study materials in high-traffic locations
- Revised study poster to include pull-off tabs at the bottom and a QR code linking to the study website
- Tabling by study staff at events and populated areas

6. Products

During the course of year three, study staff gave oral and poster presentations at Military Health System Research Symposium.

Additional products include the news media items described above in Section 3, “Accomplishments,” paragraph 4.

7. Participants and Other Collaborating Organizations

The following individuals have worked at least 160 hours on the project in total during project year three. There has been no change in support of the PIs or key personnel, and no other organizations were involved as partners.

Name	Project Role	Person months worked	Contribution to the project
Rae Olmsted, Kristine L	Co-Principal Investigator	5.7	Daily study operations; management and substantive oversight (IRB/HRPO submissions, budget, substantive materials)
Peeler, James R	Logistics Task Manager	4.3	Coordination and oversight of all study logistics (hiring and training Research Coordinators, co-designing the control system, coordination with study sites)
Croxford, Julie A	Regulatory Specialist	1.7	Regulatory/monitoring support (training, liaison with research monitor, AE/PD reporting, site visits, oversight of regulatory binder)
Zemonek, Richard D	Computer Programming Task Leader	1.3	Oversight of all computer programming activities (web and assessment programming, co-designing the control system, quality control for all systems)
Charm, Samantha	IRB and Qualitative Study Assistant	1.1	Coordination of IRB/HRPO submissions and assistance with qualitative study (coordination and data collection)

8. Special Reporting Requirements

Not applicable.

Appendix A: Study Press

Could a Shot of Local Anesthetic Block PTSD’s Harmful Effects? The Army Is Trying to Find out (6/20/17)

<http://ijr.com/the-declaration/2017/06/901975-shot-local-anesthetic-block-ptsds-harmful-effects-army-trying-find/>

Can a Single Injection Conquer PTSD? The Army Wants to Find Out (6/12/17)

<https://www.wsj.com/articles/can-a-single-injection-conquer-ptsd-the-army-wants-to-find-out-1497279572?mod=e2fb>

Buck Sexton show (radio; piece starts at 1:18. 6/14/17)

<https://art19.com/shows/buck-sexton-with-america-now/episodes/dc507234-f8b2-4f12-a05e-503339da620b>

Appendix A. Quad Chart

Effectiveness and Acceptability of Stellate Ganglion Block (SGB) for Treatment of PTSD Symptoms

Log # 13046044 - FY 13 Applied Research and Advanced Technology Development Psychological Health Award
W81XWH-15-2-0015



PI: Bradford Walters, MD, PhD

Org: RTI International

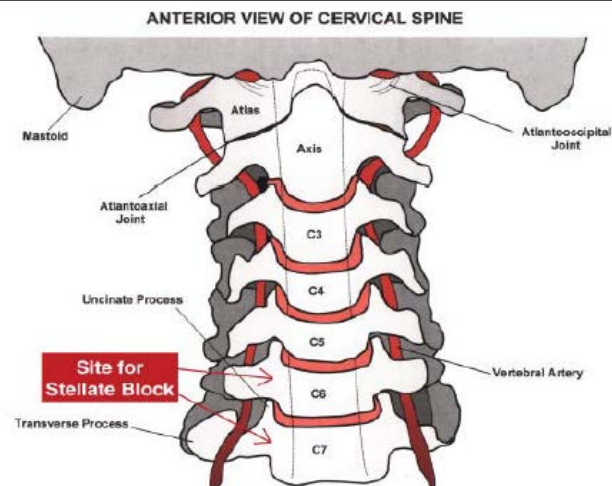
Award Amount: \$2,198,738.00

Study Aims

- Determine effectiveness of SGB vs placebo in treating PTSD symptoms
- Describe the degree to which study participants are accepting of SGB

Approach

- Conduct a double-blind, sham-procedure-controlled, randomized clinical trial of 240 active duty participants with PTSD at 3 sites; primary outcome measure is CAPS-5 pre and 8-weeks-post intervention
- Conduct focus groups and structured interviews with RCT participants (as well as spouses and clinical providers) to characterize the acceptability of the procedure



Accomplishment: Began qualitative/acceptability study data collection

Timeline and Cost

Activities	CY	15	16	17	18
Conduct Randomized Controlled Trial		[Green bar spanning CY 15-18]			
Conduct Qualitative Study			[Green bar spanning CY 16-18]		
Analyze Data				[Green bar spanning CY 17-18]	
Prepare and Submit Reports, Manuscripts and Briefings				[Green bar spanning CY 17-18]	
Estimated Budget (\$K)		\$561	\$855	\$677	\$106

Updated: 3/22/2018

CY 15 (funded 3/2015)

Prepare Regulatory Documents & Research Protocols

- Approved by WAMC IRB
- Submitted to HRPO

Develop Study Infrastructure

- Instrumentation programming complete
- RC identified for each site and training materials in development

CY 16

Prepare Regulatory Documents & Research Protocols

- Approved by HRPO

Develop Study Infrastructure

- In place & operational

Collect, Analyze, and Disseminate Data

- Subjects enrolling, collecting data

CY 17

Collect, Analyze, and Disseminate Data

- Enrollment complete
- Analyses Complete and data dissemination underway

Comments/Challenges/Issues/Concerns

- Enrollment is significantly lagging projections.

Budget Expenditure to Date: Projected: \$2,093,000 Actual: \$1,913,206