AWARD NUMBER: W81XWH-15-1-0374

TITLE: Strength at Home Couples Program to Prevent Military Partner Violence

PRINCIPAL INVESTIGATOR: Casey T. Taft, Ph.D.

CONTRACTING ORGANIZATION:

Boston VA Research Institute, Inc. Boston, MA 02130

REPORT DATE: October 2017

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command

Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release; Distribution Unlimited

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15. SUBJECT TERMS

Trauma, Treatment, Intimate Partner Violence, Veterans Health

16. SECURITY C	LASSIFICATION OF:		17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON USAMRMC
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Annual Report for Period: Sep 30, 2016 to Sept 29, 2017

Strength at Home Couples Program to Prevent Military Partner Violence Dr. Casey Taft, PI

- 1. INTRODUCTION: Intimate partner aggression (IPA) is a national public health problem. The Strength at Home Couples (SAH-C) program was developed to prevent IPA in at risk couples before it begins among military personnel and their partners. Results from multiple studies attest to the effectiveness of the intervention in VA settings and community contexts. Before widespread adoption of SAH-C on military installations can occur, it is important to examine its effectiveness in the military context and to identify any potential barriers to implementation. The goal of this study is to test the effectiveness of SAH-C for military couples on an installation and to examine potential barriers and facilitators for the successful implementation of the program within this setting. A Hybrid Type-I Implementation-effectiveness research design will allow the research team, comprising investigators with expertise in treatment development, efficacy and effectiveness research, and implementation science, to simultaneously investigate the effectiveness of SAH-C in a military sample while identifying potential implementation barriers. Considering the scope of the IPA problem, and since there is currently no IPA prevention intervention used on military installations, the proposed research is timely and much needed. This study has the potential not only to alleviate and prevent the suffering of military families, but also to advance the clinical science in this field of study and better understand how we might prevent violence among our service members and their partners.
- 2. **KEYWORDS:** intimate partner violence, domestic violence, partner violence, prevention, veterans, military, couples treatment, marital relationship, trauma, PTSD, relationships, implementation

3. ACCOMPLISHMENTS:

- What were the major goals of the project?
 - Prepare Regulatory Documents and Research Protocol for Phase I (100% complete)
 - Major activities include preparing IRB submissions for all sites. IRB approval has been obtained from Boston (Dec 2015) and Palo Alto (July 2015) and Regional Health Command Pacific (August 2017), and is pending final DoD HRPO Review (originally submitted March 2016).

- Hire and Train Study Staff (months 1-6; 100% complete)
 - The major activities have been to hire and train a research technician at the Boston home site (accomplished Dec 2016) and to hire and train a MAlevel project coordinator at the site of the implementation, Madigan Army Medical Center.
 - The study Stakeholder Advisory Board has been assembled and an in person meeting with the Board occurred on September 20, 2017. Topics of discussion included participant recruitment, barriers and facilitators to implementation, and leadership support on base.
 - A total of 12 clinicians were trained in SAH-C on September 20-21, 2017.
 - Stemming from initial discussions with the Advisory Board and IRB staff on the installation, it was determined that it was advisable for us to hire a project coordinator at the study site. This hire of the project coordinator, Brittany Groh, was completed in September 2017.
- o Recruitment and intervention for Phase I (50% complete)
 - Recruitment has been delayed due to delays in obtaining IRB approval from Madigan Army Medical Center and DoD HRPO Review.
 - A total of 11 clinicians have been identified as the clinician research participants. They will be consented if they elect to participate in the implementation research interviews upon final DoD HRPO Review.
 - Following from consultation with the site PI and the Advisory Board, Ms.
 Groh has had several meetings with possible referring clinics and other referral sources on the installation.
 - We have also revised the data collection plan following withdrawal of Dr. Milner from the project, moving to a completely electronic method of assessment administration, and revised the implementation assessment through discussions with our implementation scientist Dr. Wiltsey-Stirman. We have programmed all tablets with the questionnaires for the

study and have ensured that all equipment is operational and ready for data entry upon receiving final HRPO approval.

Clinical Trial Status

Recruitment has not begun

No amendments this period

No adverse events

- What opportunities for training and professional development has the project provided?
 - Nothing to Report
- How were the results disseminated to communities of interest?
 - Nothing to Report
- What do you plan to do during the next reporting period to accomplish the goals?
 - Upon receiving final approvals, we will begin to implement SAH-C and conduct data gathering.

4. **IMPACT**:

- What was the impact on the development of the principal discipline(s) of the project?
 - Study staff have reported positive training effects from the SAH-C training they attended. Further, as we await final HRPO approval, through our interactions with the study site at Madigan, we have agreed to conduct additional trainings beyond the proposed study to train hospital clinicians in a separate but related SAH program to intervene with those who are using IPV.
- . 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 Project Director/Principal Investigator (PD/PI) is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer 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:
 - Changes in approach and reasons for change
 - As noted, we have identified an increased need for administrative help at the study site and have eliminated consultant roles and other support staffing that was deemed less crucial to the study. The money saved allows us to have a project coordinator on site.
 - Actual or anticipated problems or delays and actions or plans to resolve them
 - As noted, significant delays in IRB approvals have prevented us from beginning subject recruitment. We have worked closely with all IRBS and have responded promptly when any changes or edits were suggested for the study protocol. We hired a project coordinator on site to facilitate our work with the IRB at the study site.
 - Changes that had a significant impact on expenditures
 - Subawards to Dr. Creech and Dr. Wiltsey-Stirman were executed during Q3 and Q4. We
 are requesting funds be carried over into Year 3.
 - Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents
 - o N/A
 - Significant changes in use or care of human subjects: N/A
 - Significant changes in use or care of vertebrate animals: N/A
 - Significant changes in use of biohazards and/or select agents: N/A
- 6. **PRODUCTS:**

Nothing to Report

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS:

What individuals have worked on the project?

Name:	Dr. Casey Taft
Project Role:	Principal Investigator
Researcher Identifier (e.g. ORCID ID):	0000-0002-9323-3190
Nearest person month worked:	1.8
Contribution to Project:	Dr. Taft is in charge of training and supervising project staff via weekly telephone meetings with on-site study personnel and separate weekly meetings with those involved with data management and analysis, and will participate in all aspects of the implementation of the treatment program.
Funding Support:	Boston VA Research Institute

Name:	Dr. Shannon Wiltsey-Stirman
Project Role:	Consortium-PI
Researcher Identifier (e.g. ORCID ID):	0000-0001-9917-5078
Nearest person month worked:	1
Contribution to Project:	Dr. Wiltsey-Stirman will contribute to the implementation-related data collection and analyses. She will oversee and assist with the implementation-related data collection, analysis, and interpretation. Furthermore, she will have completed all IRB related duties for her site at Palo Alto.
Funding Support:	Alto Veterans Institute for Research (PAVIR)

Name:	Brittany Groh
Project Role:	Project Coordinator
Researcher	
Identifier (e.g.	N/A
ORCID ID):	
Nearest person	6

month worked:	
Contribution to Project:	Oversees administration of the project from the VA Boston Healthcare System, including coordination with the project sites doing the implementation, preparation of IRB submissions, management of data received from the sites, and supervision of research technicians.
Funding Support:	Boston VA Research Institute

Name:	Dr. Suzannah Creech
Project Role:	Consortium-PI
Researcher Identifier (e.g. ORCID ID):	0000-0002-6582-1673
Nearest person month worked:	1
Contribution to Project:	Dr. Creech is in charge of co-managing training of staff at the study site. She also participates in weekly/biweekly meetings to provide consultation on project progress and help address any problems that may arise.
Funding Support:	Central Texas Veterans Research Foundation

Name:	Christopher Chiu
Project Role:	Research Technician
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	2
Contribution to Project:	Provides administrative and data management support for all aspects of the project at the VA Boston Healthcare System. Christopher Chiu, a new research technician, has been added to the project starting 08/08/16 and will responsible for administrative and data management support for all aspects of the project at the VA Boston Healthcare System. Mr. Chiu left the project

	on July 31, 2017.
Funding Support:	Boston VA Research Institute

- Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?
 - Since the last report, the PI has had a separate implementation study for the Department of Veterans Affairs funded by the Bob Woodruff Foundation, and a Boston University/ NIH CTSI study funded to pilot Strength at Home in a civilian population. Funding for these two projects will not impact the current DoD project.

What other organizations were involved as partners

a.) Organization name: Palo Alto Veterans Institute for Research (PAVIR)

Location: Palo Alto Veterans Institute for Research

3801 Miranda Ave P. O. Box V-38 Palo Alto, CA 94304-0038

Partner's Contibution to the Project: Collaboration, Other- help with implementation of program (see above table for more information)

b.) Organization name: Dr. Suzannah Creech from VISN 17 Center of Excellence for Research on Returning War Veterans

Location: Central Texas Veterans Research Foundation 1901 South 1st Street

Temple, TX 76504**Partner's Contibution to the Project:** Collaboration, Other- clinical trainer and consultor (see above table for more information)

c.) Organization name: Ms. C. Robyn Kelley from Madigan Army Medical Center Family Advocacy Program

Location: Madigan Army Medical Center, Joint Base Lewis-McChord

9490 Jackson Avenue

Tacoma, WA 98431

8. SPECIAL REPORTING REQUIREMENTS:

QUAD CHARTS: See Appendix

9. APPENDIX:

Quad Chart:

PT140092, Psychological Health/Traumatic Brain Injury Research Program Strength at Home Couples Program to Prevent Military Partner Violence

W81XWH-14-PHTBI-PHRA

Org: Boston VA Research Institute, Inc.

PI: Casey Taft, Ph.D.



Study/Product Aim(s)

- To test the effectiveness of SAH-C for military couples on an installation.
- To explore differences in compliance and process factors across conditions
- To facilitate future implementation of SAH-C

Approach

A Hybrid Type-I Implementation-effectiveness research design will allow the research team, comprising investigators with expertise in treatment development, efficacy and effectiveness research, and implementation science, to simultaneously investigate the effectiveness of SAH-C in a military population while identifying any barriers to implementation that would need to be addressed before SAH-C could be successfully implemented on a larger scale



Timeline and Cost

Activities CY 15	15	16	17	18
Pre-Conditions, hire staff, obtain IRB approval				
Begin Phase 1 Pilot Study				
Begin Phase II Enrollment and Treatment Implementation				
Complete Follow-up Assessments, Analyze Data				
Estimated Budget (\$711k)	\$57k	\$57k \$219k \$223k \$212k	\$223k	\$212k

Updated: (10/18/2017)

Goals/Milestones

CY15 Goal - Pre-Conditions

□Refine and review treatment manual; staff hired and trained

CY16 Goals - Preconditions and Pilot Study

□IRB approval obtained from VA, pending from other sites and DoD

CY17 Goal - Randomized controlled trial

☐ Pilot study intervention cases will be conducted. Data from pilot study will be used to inform refinements to manual and integrity measures

□Recruitment, assessment, interventions, and follow-up for Phase II

CY18 Goal - Randomized controlled trial

☐ Continue recruitment, assessment, interventions, and follow-up for Phase II ☐ Data analysis and preparation for conference presentations will occur

Comments/Challenges/Issues/Concerns

 If off by more than one quarter in spending. Budget expenditures will increase with hire of new project coordinator.

Budget Expenditure to Date

Projected Expenditure: \$166.5K

Actual Expenditure: \$52,902.82