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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

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E-Mail:

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13. SUPPLEMENTARY NOTES

14. ABSTRACT

There are no significant research findings to report during this period as we are not viewing the data until completion of the study to maintain blinding.

15. SUBJECT TERMS
Trauma, Treatment, Intimate Partner Violence, Veterans Health

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRMC
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Annual Report for Period: Oct 01, 2018 to Sept 30, 2019

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 MA-level 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.
- Recruitment and intervention for Phase I (100% complete)
  - Recruitment was delayed significantly due to a delay in receiving HRPO approval. HRPO approval was received on 11/21/17.
  - Eight couples were enrolled in pilot phase (three in the active treatment group and five in the supportive group).
  - 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 questionnaires. Currently 4 clinicians are clinician participants.
  - Following from consultation with the site PI and the Advisory Board, Ms. Groh has had several meetings with possible referring clinics, Chaplains, Yellow Ribbon, Strong Bonds events, Family Readiness Groups and Family Readiness Liaisons, and other referral sources on the installation.
- Recruitment and Intervention for Phase II (47.14% complete)

- 66 couples have enrolled in the clinical trial phase (32 couples in the active treatment group and 33 couples in the supportive group; 1 couple waiting for randomization).

Clinical Trial Status

Recruitment has begun for the trial. 66 couples (132 individuals) have been enrolled in the trial. Please see Consort diagram.

Amendments:

- 01/28/19 Boston IRB
  - Protocol – clarified that those providing the intervention would either be our own staff or staff on post who are psychoeducation facilitators, clarified that the intervention be psychoeducational in nature, removed the former site PI, and added two site consultants to the program, and added media advertising to our recruitment procedures.
- 02/25/19 Boston IRB
  - Protocol – removed subaim 3.1 and all associated language as this is no longer an aspect of the study, Described Brittany Groh's role in greater detail, and clarified the role of the stakeholder advisory board.
- 02/21/19 Regional Health Command Pacific IRB
  - Protocol – Requested to complete post-treatment follow-up visits for couples who were in the program prior to the temporary halt imposed by the Family Advocacy Program.
- 03/11/19 Regional Health Command Pacific IRB
  - Closure of protocol associated with Madigan Army Medical Center. Oversight transferred to Garrison side of Joint Base Lewis McChord
- 03/25/19 Boston IRB
  - Flyers and Brochures – updated phone number, location of classes, and compensation amount for eligible participants from $20 to $50, up to $300 per couple

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?**
  - Continue to recruit participants, conduct groups, and finish collecting data.

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. The clinicians previously facilitating groups have reported positive results and growth within the couples involved in the study. Further, each clinician believed the curriculum set forth bolsters the working alliance within the couples and group members as a whole. The current facilitator agrees with previous observations and has received positive feedback in regard to how the program has enhanced their relationship.

- **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**
- **Actual or anticipated problems or delays and actions or plans to resolve them**
  - As noted, IRB approval delays significantly delayed recruitment, but recruitment has since increased. We have worked closely with all IRBs and have responded promptly when any changes or edits were suggested for the study protocol. Barriers present in the implementation of the program include change of location, temporary halt in research, and childcare issues for participants. Madigan Army Medical Center (MAMC) submitted a memorandum for record to suspend the program at the Family Advocacy Program (FAP) effective 27 December 2018. Reasons cited included the inability of FAP to provide clinicians due to staffing issues at MAMC and their concerns with a lack of clinical documentation. The Regional Health Command – Pacific requires no documentation due to this being a study and FAP ultimately decided to withdraw their support based on these

issues. The memorandum allowed us to continue completing follow-ups until all data was collected for current participants. On 11 March 2019 Regional Health Command Pacific closed our protocol and transferred our program to the Garrison side of Joint Base Lewis McChord. During the transition time from January to March the project coordinator moved locations and set up an office near the Family Advocacy Program – Prevention. Our team spoke with the new overseers of the program and discussed how they could assist us in promoting the program and making up for the two months where recruitment did not happen. This included placing our information in the commander packets they create, inviting Ms. Groh to speak at their unit trainings, and posting the information on their Facebook page. Childcare has continued to be a barrier for many families. We have access to a few vouchers to help pay for childcare during our classes but if the classes begin before 0830 and end after 1630, the childcare facility does not provide care. In addition, there are frequently wait lists for hourly care and it is not guaranteed that parents will be able to get their children into care during the class time. Additionally, there have been a few chaplains who have not been receptive to the program due to the program not meeting the Strong Bonds requirements. Finally, the FRGs have been difficult to penetrate due to the names and contact information being kept private.

- **Changes that had a significant impact on expenditures**
    - *Subawards to Dr. Creech and Dr. Wiltsey-Stirman were executed during Q3 and Q4. Subawards have not been renewed for the no-cost extension year.*
    - DoD has agreed to provide supplemental funding for an additional year for the project coordinator at the study site, Brittany Groh, which was necessary for study success.
- **Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents**
    - 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:	4
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. ORCID ID):	N/A
Nearest person month worked:	12
Contribution to Project:	Oversees administration of the project from the VA Boston Healthcare System, including coordination with the project sites doing the implementation, facilitation of groups, 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

- **Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?**
    - N/A

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 Contribution 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 Contribution to the Project: Collaboration, Other- clinical trainer and consultor (see above table for more information)

c.) Organization name: Ms. Kristine Blake from Madigan Army Medical Center Family Advocacy Program. This partnership was terminated 11 March 2019.

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:**

- Enrollment and Consort Chart (See attached document)
- Quad Chart:

Strength at Home Couples Program to Prevent Military Partner Violence

PT140092, Psychological Health/Traumatic Brain Injury Research Program

W81XWH-14-PHTBI-PHRA Award #: W81VWH-15-1-0374

PI: Casey Taft, Ph.D. **Org: Boston VA Research Institute, Inc.** **Award Amount: $700,454**

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*
- (a) Examine the barriers to and facilitators for program implementation
- (b) to test the effectiveness

Approach

A Hybrid Type-I Implementation-effectiveness research design will allow the research team, comprising investigators with expertise in intervention 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	16	17	18
Pre-Conditions, hire staff, obtain IRB approval				
Begin Phase 1 Pilot Study				
Begin Phase II Enrollment and Intervention Implementation				
Complete Follow-up Assessments, Analyze Data				
Estimated Budget ($711k)	**$57k**	**$219k**	**$223k**	**$212k**

Updated: (10/28/19)

Goals/Milestones

CY15 Goal – Pre-Conditions

- ☑ Refine and review intervention manual; staff hired and trained

CY16 Goals – Preconditions

- ☑ IRB approval obtained from VA, pending from other sites and DoD (completed 2018 with final FARS approval from MAMC)

CY17 Goal – Preconditions

- ☑ Training of all clinicians to be providers of intervention program
- ☑ Hire new personnel to be onsite

CY18 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
- ☑ Continue recruitment, assessment, interventions, and follow-up for Phase II

CY19 Goal – Randomized control trial

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

Comments/Challenges/Issues/Concerns: Began working with advertising firm to increase our referrals. Awarded a no-cost extension for one year on 07/09/19.

Budget Expenditure to Date

Projected Expenditure: $700,454 *Granted a no-cost extension*

Actual Expenditure: $659,003.01