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

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**CONTRACTING ORGANIZATION:**

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**14. ABSTRACT: 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 was 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 allowed 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.**

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

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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 was 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 allowed 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 included preparing IRB submissions for all sites. IRB approval was obtained from Boston (Dec 2015) and Palo Alto (July 2015) and Regional Health Command – Pacific (August 2017), and was approved by the DoD HRPO (originally submitted March 2016).
        - Hire and Train Study Staff (months 1-6; 100% complete)
            - The major activities were 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 was 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 were identified as the clinician research participants.
  - Following from consultation with the site PI and the Advisory Board, Ms. Groh 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 (100% complete)
  - 148 couples were enrolled in the clinical trial phase (75 couples in the active treatment group and 73 couples in the supportive group).
- Clinical Trial Status
  - Recruitment was completed for the trial. 148 couples (296 individuals) were enrolled in the trial. Please see Consort diagram. No cost extension granted through September 2021.
  - Amendments:
    - 12/18/17
      - Protocol – removed measures; changes in personnel; removed interviews; updated language to include same-sex dyads
      - Consent Documents – Revised format to reflect RHC-P IRB format at Madigan Army Medical Center
      - Site-Specific Addendum – Added to Boston documents to be consistent with RHC-P IRB requiring this document

- 02/05/18
    - Protocol – Removed section about telephonic assessments as they were in-person assessments; included additional referral sources as recruitment site
    - Site-Specific Addendum – Use of recruitment materials; additional recruitment sites
    - Participant Consent Document – Added information on the Certificate of Confidentiality that would be applied for
    - Recruitment materials (fliers and brochures); SOP; added suicidality measure; added a collateral contact form
- 02/26/18
    - Protocol and Site-Specific Addendum – Updated inclusion criteria time frame for any physical aggression to 3 months to be more inclusive
- 05/21/18
    - Removed Christopher Chiu, Tracie Ebalu, Jeremiah Schumm, Blair Starnes, and Robin Weatherill
- 08/06/18
    - Updated clinician consent form to reflect site-PI change to Kristine Blake
- 08/07/18
    - Added Hannah Cole to the protocol
- 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
- 03/17/2020 Boston IRB
    - Protocol – Study activities to be completed via a HIPAA-compliant telehealth system if in-person study activities are discontinued due to the COVID-19 public health emergency
- 03/23/2020 Boston IRB
    - Protocol – Included examination of sexual aggression, suicidality, and belongingness. These data are already being collected, but were not previously part of the study's primary aims
- 08/09/2021 Boston IRB
    - Added Matthew Gallagher to protocol as a consultant
- 12/16/2021 Boston IRB
    - Protocol – Requested to use DocuSign to reconsent five couples before we could conduct final analyses using their data.

- **What was accomplished under these goals?**
    - We successfully prepared regulatory documents and the research protocol for Phase I. IRB approval was obtained from Boston, Palo Alto, and Regional Health Command – Pacific; we also received approval from DoD HRPO. Study staff was successfully hired and trained, including a research assistant, an on-site project coordinator, and twelve clinicians. Additionally, we assembled a Stakeholder Advisory Board. We successfully completed Phase I (pilot) and Phase II (enrollment and intervention) of the study. Eight couples were recruited for the pilot and 148 couples were enrolled in the clinical trial. The

study is now closed for enrollment. Group 27, the final group, was completed on October 11, 2020 and the final follow-up questionnaires were completed on February 22, 2021.

- Analyses were conducted using Mplus 8.0 (Muthén & Muthén, 1998–2016). Outcomes included service member and partner combined scores on measures calculated from the Revised Conflict Tactics Scales reflecting psychological aggression and both severe and overall physical aggression, and the Restrictive Engulfment subscale of the Multidimensional Measure of Emotional Abuse. Consistent with past SAH-C clinical trials, analyses consisted of calculating means within each condition using multiple imputation to account for missing data so that outcomes are calculated for all randomized participants. Within (standardized mean gain; ESsg) and between condition (Hedges g) effect sizes with 95% confidence intervals were then calculated to quantify the magnitude of changes within each condition from time 1 to time 2 and time 1 to time 3 and the magnitude of differences in outcomes between the two conditions at each time point. Effect size analyses were calculated for all IPV outcomes.
- We began by examining differences in IPA perpetration for both service members and partners across time by intervention condition. Imputed means, standard deviations, and between condition effect sizes (with 95% CI) are presented in Table 1. IPA scores for both service members and partners were generally higher in the SAH-C condition at baseline than in Supportive Prevention despite randomization. However, the magnitude of the between condition effect size differences in IPA outcomes generally decreased from time 1 to time 3, particularly in service members. We next examined within condition effect sizes (ESsg with 95% CI) to quantify treatment effects within each condition. Change scores from time 1 to time 2 and from time 1 to time 3 and ESsg effect sizes with 95% CI are presented in Table 2. These effect sizes include a correction for the correlation between assessments across time. SAH-C resulted in moderate to large decreases in service member perpetration of psychological aggression and coercive control and small effect size decreases in service member severe assault and total physical assault. The reductions in these service member violence outcomes were generally larger in SAH-C than the reductions in Supportive Prevention. The pattern of findings for partner perpetration outcomes was less consistent, but SAH-C was generally associated with a greater reduction in partner perpetration outcomes as well.

- Regarding qualitative analyses, our study framework blended three distinct yet complementary implementation frameworks to guide an implementation process, understand potential influences on implementation, and guide assessment of key implementation outcomes: 1) Replicating Effective Programs (REP) framework; 2) Consolidated Framework for Implementation Research (CFIR); and 3) the Proctor et al. taxonomy for implementation outcome variables. Using content analysis, we identified analytical categories to describe and explain observations. Codes were derived deductively by identifying categories at the beginning of the research and inductively by identifying those that emerged gradually from the data. We developed a codebook with operational definitions of each code. Using constant comparison, we updated the coding model to reflect further refinement.
- Following the completion of coding, six themes emerged: Engagement, Endorsement, and Execution; Knowledge and Belief about the Intervention; Networks and Communication; Cultural Alignment; Readiness for Implementation; and Scheduling Conflicts. Each theme includes a number of related codes that were categorized as either positive, negative, or neutral sentiment. We evaluated each theme and its influence on the implementation by examining the total sum of sentiments. We found that Engagement, Endorsement, and Execution was the biggest barrier to implementation. Specifically, local leadership engagement was a challenge. Although they were supportive of the program initially, leadership slowly pulled support and eventually cut the program altogether. This left the study team without local clinicians to run groups and resulted in a significant delay in the program's implementation. A quote from one of the local clinicians captures this challenge: "The lack of support from Behavioral Health Clinic Chiefs, Chaplains, and Commanders at the study location was poor at best". Clinicians reported that leadership support was retracted due to social work staffing limitations and because leadership was not happy about us using conference rooms to hold groups. Other barriers to implementation fell under Networks and Communication, Cultural Alignment, Readiness for Implementation, and Scheduling Conflicts, although these obstacles were less influential than lack of leadership support. Challenges under these themes include lack of referrals, stigma associated with attending treatment, lack of available local resources, and participant scheduling conflicts with available group times.

- Alternatively, we found that Knowledge and Beliefs about the Intervention included more positive sentiments. Although leadership support was a barrier, clinician knowledge and beliefs about the program were generally supportive. Clinicians expressed that they thought it was a great program and that it would be good to have as an additional resource, more specifically one found it "very valuable" and another stated "It worked well and was well received." They also appreciated having an evidence-based intervention available; one clinician stated that they gained "exposure to new material that has been studied and researched" by participating in SAH Couples.

**Table 1. Between condition means (SD) and effect sizes (hedges g with 95 % CI)**

| Domain | | | Supportive Prevention(n=67) | SAH-C (n=71) | | |
|---|---|---|---|---|---|---|
| Service Member Perpetration | Outcome | Time | M (SD) | M (SD) | Hedges g | (95% CI) g |
| | Psychological Aggression | T1 | 18.57 (19.54) | 29.06 (30.63) | 0.4 | 0.07:0.74 |
| | | T2 | 8.11 (10.24) | 12.43 (15.07) | 0.33 | 0.00:0.67 |
| | | T3 | 6.57 (10.03) | 9.58 (16.33) | 0.22 | -0.12:0.55 |
| | Severe Assault | T1 | 0.02 (0.12) | 0.17 (0.68) | 0.32 | -0.02:0.65 |
| | | T2 | 0.17 (0.91) | 0.16 (0.56) | -0.01 | -0.34:0.32 |
| | | T3 | 0.02 (0.14) | 0.09 (0.32) | 0.27 | -0.07:0.60 |
| | Total Physical Assault | T1 | 0.23 (0.65) | 0.59 (1.59) | 0.29 | -0.04:0.63 |
| | | T2 | 0.38 (1.59) | 0.43 (1.22) | 0.03 | -0.30:0.36 |
| | | T3 | 0.18 (0.46) | 0.31 (1.01) | 0.16 | -0.17:0.49 |
| | | T2 | 0.37 (0.91) | 0.33 (0.59) | -0.06 | -0.39:0.28 |
| | | T3 | 0.22 (0.64) | 0.31 (0.7) | 0.12 | -0.21:0.46 |
| | Restrictive Engulfment | T1 | 8.48 (13.17) | 16.51 (29.33) | 0.35 | 0.01:0.68 |
| | | T2 | 4.28 (9.38) | 6.37 (15.2) | 0.16 | -0.17:0.5 |
| | | T3 | 3.89 (7.99) | 3.23 (23.38) | -0.04 | -0.37:0.3 |
| Partner Perpetration | Psychological Aggression | T1 | 20.8 (20) | 29.31 (31) | 0.32 | -0.01:0.66 |
| | | T2 | 10.58 (12.28) | 13.71 (19.61) | 0.19 | -0.15:0.52 |
| | | T3 | 6.98 (11.08) | 11.39 (15.34) | 0.33 | -0.01:0.66 |
| | Severe Assault | T1 | 0.01 (0.12) | 0.16 (0.67) | 0.29 | -0.04:0.63 |
| | | T2 | 0.1 (0.92) | 0.14 (0.48) | 0.07 | -0.27:0.4 |
| | | T3 | 0.02 (0.13) | 0.07 (0.32) | 0.19 | -0.15:0.52 |
| | Total Physical Assault | T1 | 0.34 (0.93) | 0.81 (1.8) | 0.32 | -0.01:0.66 |
| | | T2 | 0.34 (1.61) | 0.46 (1.28) | 0.09 | -0.25:0.42 |
| | | T3 | 0.13 (0.51) | 0.3 (0.84) | 0.23 | -0.1:0.57 |
| | | T2 | 0.19 (0.87) | 0.1 (0.3) | -0.14 | -0.48:0.19 |
| | | T3 | 0.11 (0.36) | 0.19 (0.71) | 0.14 | -0.19:0.47 |
| | Restrictive Engulfment | T1 | 18.97 (23.47) | 30.61 (38.52) | 0.36 | 0.02:0.7 |
| | | T2 | 8.21 (13.5) | 10.97 (14.38) | 0.20 | -0.14:0.53 |
| | | T3 | 8.88 (15.7) | 10.94 (23.46) | 0.10 | -0.23:0.44 |

**Table 2. Within Condition Change Scores and Effect Sizes (ESsg with 95% CI)**

| **Domain** | | | Change Scores with 95% CI | | ESsg (95% CI) | |
|---|---|---|---|---|---|---|
| **Service Member Perpetration** | Outcome | Condition | T2-T1 | T3-T1 | T2-T1 | T3-T1 |
| | Psychological Aggression | SAH | -15.77 (-21.37:-10.16) | -18.03 (-24.56:-11.5) | -0.56 (-0.79:-0.34) | -0.7 (-0.98:-0.42) |
| | | SP | -10.2 (-14.52:-5.88) | -11.93 (-15.94:-7.93) | -0.63 (-0.92:-0.34) | -0.72 (-1.08:-0.36) |
| | Severe Assault | SAH | -0.04 (-0.17:0.09) | -0.12 (-0.3:0.05) | -0.06 (-0.26:0.14) | -0.23 (-0.57:0.11) |
| | | SP | 0.14 (-0.08:0.36) | 0.01 (-0.04:0.06) | 0.22 (-0.13:0.56) | 0.07 (-0.27:0.41) |
| | Total Physical Assault | SAH | -0.22 (-0.54:0.09) | -0.36 (-0.78:0.06) | -0.15 (-0.37:0.06) | -0.27 (-0.59:0.05) |
| | | SP | 0.13 (-0.28:0.54) | -0.05 (-0.23:0.12) | 0.11 (-0.23:0.45) | -0.09 (-0.43:0.25) |
| | | SP | 0.06 (-0.16:0.27) | -0.03 (-0.21:0.15) | 0.07 (-0.2:0.34) | -0.05 (-0.39:0.28) |
| | Restrictive Engulfment: | SAH | -10.74 (-16.82:-4.66) | -13.96 (-22:-5.92) | -0.43 (-0.68:-0.18) | -0.51 (-0.81:-0.2) |
| | | SP | -4.33 (-6.83:-1.82) | -4.48 (-7.27:-1.68) | -0.36 (-0.58:-0.14) | -0.39 (-0.73:-0.04) |
| | | | | | | |
| **Partner Perpetration** | Psychological Aggression | SAH | -15.14 (-20.85:-9.43) | -18.34 (-24.66:-12.02) | -0.54 (-0.77:-0.32) | -0.69 (-0.95:-0.42) |
| | | SP | -9.52 (-13.3:-5.75) | -14.03 (-17.63:-10.43) | -0.53 (-0.76:-0.3) | -0.77 (-1.13:-0.4) |
| | Severe Assault | SAH | -0.01 (-0.19:0.17) | -0.08 (-0.25:0.09) | -0.02 (-0.33:0.29) | -0.15 (-0.48:0.17) |
| | | SP | 0.14 (-0.08:0.36) | 0 (-0.04:0.05) | 0.21 (-0.13:0.56) | 0.03 (-0.31:0.37) |
| | Total Physical Assault | SAH | -0.29 (-0.71:0.13) | -0.46 (-0.89:-0.02) | -0.18 (-0.45:0.09) | -0.32 (-0.63:-0.01) |
| | | SP | 0.05 (-0.39:0.49) | -0.25 (-0.49:-0.01) | 0.04 (-0.3:0.37) | -0.33 (-0.67:0.01) |
| | | SP | 0 (-0.18:0.18) | -0.09 (-0.2:0.02) | 0 (-0.24:0.24) | -0.23 (-0.57:0.11) |
| | Restrictive Engulfment | SAH | -19.08 (-27.49:-10.68) | -19.55 (-28.72:-10.38) | -0.61 (-0.89:-0.32) | -0.6 (-0.9:-0.3) |
| | | SP | -10.67 (-15.45:-5.89) | -10.18 (-14.42:-5.94) | -0.53 (-0.78:-0.27) | -0.48 (-0.83:-0.14) |

- **What opportunities for training and professional development has the project provided?**
    - Nothing to Report.
- **How were the results disseminated to communities of interest?**
    - We have presented results from this study in two recent talks at an international conference. The PI has also presented findings from this study at the quarterly meeting of the DoD Family Advocacy Program Manager's Meeting held in Washington D.C.
- **What do you plan to do during the next reporting period to accomplish the goals?**
    - We plan on submitting at least two manuscripts reporting the results of this study and to continue to present at scientific conferences, to Family Advocacy Program leaders, and other interested parties in DoD and the larger community.

***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 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. Our own staff 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:**

- **Changes in approach and reasons for change**
    - 2016:
        - We requested the change of the implementation site for reasons described in the next section.
        - We identified an increased need for administrative help at the Boston site and eliminated 2 consultant roles that were deemed less crucial to the study;

therefore, the funds saved from the consultant fees was reallocated to research assistant salary in years 3 and 4.

- 2017:
  - As noted, we identified an increased need for administrative help at the study site and eliminated consultant roles and other support staffing that was deemed less crucial to the study. The funds saved allowed us to have a project coordinator on site.
- 2018:
  - See next section.
- 2019:
  - See next section.
- 2020:
  - Recruitment and facilitation of groups changed significantly due to the COVID-19 pandemic. Recruitment events were no longer occurring, and all groups were conducted online via a confidential video conferencing system.

- **Actual or anticipated problems or delays and actions or plans to resolve them**
  - 2016:
    - As we began planning the implantation at MAMC, it became clear that staff there did not have the promised time to participate in the study. With the help of Co-I Robichaux, we approached several departments to identify a site PI and begin IRB submissions.
  - 2017:
    - As noted, significant delays in IRB approvals prevented us from beginning subject recruitment. We worked closely with all IRBs and 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.
  - 2018:
    - As noted, waiting on HRPO and IRB approvals significantly delayed recruitment, but recruitment increased. We worked closely with all IRBs and responded promptly when any changes or edits were suggested for the study protocol. Barriers present in the implementation of the program include chain of command, childcare vouchers, chaplains, and the family readiness group. Assistants and secretaries to the Garrison Commander and other high-ranking officers continually blocked or reduced access to these individuals who had the ability to provide additional support and help with

the success of the program. Coordinator had open communication with Garrison Commander's assistant and was going through the appropriate channels to gain the support of the Commander, but it was a slow process. Staff was promised childcare vouchers, but these were not received at some point due to missing vouchers on the providers' side and not being able to purchase additional ones until the new budget was approved. There were a few chaplains who were not receptive to the program due to the program not meeting the Strong Bonds requirements. We worked with the LTC for the Madigan Chaplains and received approval from them to speak at certain events with the understanding we keep the presentation to activities that bolster the presentation given by the Chaplains. Finally, the FRGs were difficult to penetrate due to the names and contact information being kept private. Coordinator made a contact who has educated the coordinator on who to contact about getting into the events and worked closely with another individual who is an FRG leader. Additionally, our Site-PI C. Robyn Kelley left JBLM and the co-site PI took over as the main site-PI.

- 2019:
  - As noted, IRB approval delays significantly delayed recruitment, but recruitment since increased. We worked closely with all IRBs and 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 continued to be a barrier for many families. We had access to a few vouchers to help pay for childcare during our classes but if the classes began before 0830 and ended after 1630, the childcare facility does not provide care. In addition, there were frequently wait lists for hourly care and it was not guaranteed that parents would be able to get their children into care during the class time. Additionally, there were a few chaplains who have not been receptive to the program due to the program not meeting the Strong Bonds requirements. Finally, the FRGs were difficult to penetrate due to the names and contact information being kept private.

- 2020:
  - As noted, the COVID-19 pandemic changed group facilitation beginning 17 MAR 2020. Additional advertising occurred online and in social media groups notifying potential participants about the change to online groups. There was an initial increase in participants once classes went online and service members were no longer working regular hours. However this changed once service members returned to work as usual, citing class times as a reason for not participating. The project coordinator changed group times and began offering weekend group options to be more flexible with the schedules of the military couples.
- 2021:
  - As we prepared to conduct final data analysis, we were subject to a series of audits at VA Boston including a full audit of the entire study that caused significant delays. No serious deviations from protocol were found from these audits though we were required to reconsent five couples before we could conduct final analyses using their data.

- **Changes that had a significant impact on expenditures**
  - 2016:
    - *Subawards to Dr. Creech and Dr. Wiltsey-Stirman were executed during Q3 and Q4. We are requesting funds be carried over into Year 2.*

        - We eliminated the consultant roles for Dr. Monson and Dr. King, and requested those funds be reallocated to research technician salary in Years 3 and 4
    - 2017:
        - *Subawards to Dr. Creech and Dr. Wiltsey-Stirman were executed during Q3 and Q4. We requested funds be carried over into Year 3.*
    - 2018:
        - *Subawards to Dr. Creech and Dr. Wiltsey-Stirman were executed during Q3 and Q4. We requested funds be carried over into Year 4.*
    - 2019:
        - *Subawards to Dr. Creech and Dr. Wiltsey-Stirman were executed during Q3 and Q4. Subawards were not renewed for the no-cost extension year.*
        - DoD 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.
    - 2020:
        - *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.*
        - Effective 01 OCT 2020, Brittany Groh reduced effort to continue facilitating the final group and collecting data during the no-cost extension year.
    - 2021:
        - Nothing to Report.
- **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

- **PRODUCTS:**
    - Nothing to Report.

## 6. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

**What individuals have worked on the project?**

Dr. Casey Taft – No Change
Dr. Shannon Wiltsey-Stirman – No Change
Brittany Groh – No Change
Dr. Suzannah Creech – No Change
Dr. Matthew Gallagher – No Change

**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?**

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)

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

- Location: Central Texas Veterans Research Foundation
  901 South 1st Street
- Temple, TX 76504Partner's Contribution to the Project: Collaboration, Other - clinical trainer and consultor (see above table for more information)

Organization name: Dr. Matthew Gallagher from University of Houston

- Location: University of Houston
  4849 Calhoun Rd, Ste 373
  Houston, TX 77204
- Partner's Contribution to the Project: Collaboration, Other - Data Analyst (see above table for more information)

## 7. SPECIAL REPORTING REQUIREMENTS

- **QUAD CHARTS:** *See Appendices*

## 8. APPENDICES:

- Enrollment and Consort Chart (See attached document)

### 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:** (12/28/2021)

**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

**CY20 Goal** – Randomized control trial
- ☒ Continue recruitment, assessment, interventions, and follow-up for Phase II
- ☒ Data analysis and preparation for conference presentations will occur

**Budget Expenditure to Date**
Projected Expenditure: $791,726.43 *Granted a no-cost extension*
Actual Expenditure: $791,726.43

- Quad Chart