Implementation of Strength at Home for Military Couples

(1) **Rationale**

(a) Statement of the Problem.

Approximately 4.7 million women are physically assaulted by an intimate partner in the United States annually.[1] The most likely assailant of a victim of violence is his or her relationship partner,[2] and IPA victimization is associated with poorer physical and psychological health.[3-8] Physical health problems range from injuries or conditions directly caused by physical assault, to other chronic nervous system, musculoskeletal, cardiovascular, gastrointestinal, and urogenital symptoms and conditions.[9,10] Psychological and emotional problems often include posttraumatic stress disorder (PTSD), depression, anxiety, insomnia, substance abuse, and social difficulties.[7,9,11] The children who witness IPA also suffer from a variety of emotional and social problems.[12,13] As a result of IPA, society incurs substantial costs related to health care, criminal justice interventions, education, child and social services, housing, and lost worker productivity.[14]

IPA prevalence rates in military samples vary widely, with rates ranging from 13.5% to 58%.[15] IPA results in far reaching consequences not only for family members, but also for the service members themselves. IPA alienates service members and negatively impacts social support networks. This is particularly important in the context of traumatic exposure, as social support is a critical factor with regard to mitigating the negative impacts of trauma on health.[16,17] Poor family functioning of military populations has been strongly associated with mental and physical health problems, increased use of medical and psychiatric services, and lost workdays.[18-22] Among active military, family problems are more powerful predictors of military morale, motivation, readiness, and retention than resource variables, unit-related factors, and work conditions.[20,23-25] Service members experiencing intimate relationship problems are also more likely to exhibit concentration problems and deficits in cognitive acuity that may compromise mission safety and job performance.[26]

(b) Hypotheses or Key Question.

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. The study site for this proposed effort is Joint Base Lewis McChord, Washington.

The primary hypotheses are that those receiving *SAH-C* will evidence greater reductions in physical and psychological IPV, and greater increases in relationship satisfaction, relative to those receiving *Supportive Prevention* across the follow up time points.

(c) Specific Objectives.

AIM 1: To test the effectiveness of *SAH-C* for military couples on an installation, we will conduct a randomized trial comparing 10 sessions of *SAH-C* to 10 sessions of Supportive Prevention (*SP*) under representative conditions, with 140 couples who are at risk for the development of IPA (risk is established if at least one member of the couple reports at or below a score of 100 on the Dyadic Adjustment Scale (DAS), a cutoff score used to distinguish relationship distress, or they report the presence of psychological aggression in the past three months). This aim will be fulfilled by accomplishing the following subaims:

Subaim 1.1: To compare the frequency of physical IPA perpetration of both members of the couple across conditions as reported by service members and their collateral relationship partners at post-intervention and two 3-month follow ups.

Subaim 1.2: To compare the frequency of psychological IPA perpetration of both members of the couple across conditions as reported by service members and their collateral relationship partners at post-intervention and two 3-month follow ups.

Subaim 1.3: To compare relationship satisfaction across conditions as reported by service members and their collateral relationship partners at post-intervention and two 3-month follow ups.

AIM 2: To explore differences in compliance factors across conditions, we will compare session attendance.

AIM 3: To facilitate future implementation of *SAH-C*, we will employ a mixed-methods approach, guided by complementary implementation frameworks, to examine potential barriers, facilitators, and potential for intervention refinement. This aim will be fulfilled by accomplishing the following subaims:

Subaim 3.1: To identify system, facilitator, and dyadic-level barriers and facilitators to implementation.

Subaim 3.2: To assess the acceptability of *SAH-C* among stakeholders in a military setting.

(2) **Background and Significance**

(a) Background.

Only one experimentally controlled evaluation of IPA intervention effectiveness has been conducted in a military setting. Among a large sample of married Navy couples in which the husband used IPA, Dunford[27] found that none of the randomly assigned year-long intervention modalities were effective in reducing IPA at six and 12 months post-intervention. Dunford's[27] findings highlighted a need for program modification efforts to meet the needs of military families and also mirrored findings of a lack of program efficacy in civilian settings.[28] These data highlight a need for prevention programs focusing on improving intimate relationships and reducing the risk of onset of IPA,[29] particularly given that relationship conflict typically serves as a precursor to IPA,[30] and more subtle forms of IPA early in relationships are predictive of later violence.[31]

The *SAH-C* intervention is based on a social information processing model of IPA holding that trauma may negatively impact on one's ability to interpret and respond to social situations effectively, and highlights the importance of cognitive behavioral strategies to monitor one's thoughts and responses to difficult interpersonal situations. [32] The model derives from prior theory[33,34] and research indicating that those who use IPA are more likely to exhibit irrational beliefs, problematic thinking, and hostile interpretations of others' intentions.[35-38] Through the improvement of social information processing, conflict and IPA risk should decrease. Core themes that underlie social information processing and relationship problems, including those related to power and control conflicts, low self-esteem, and trust difficulties are also addressed throughout the program.

(b) Significance.

There is currently no empirically supported IPA prevention intervention used on military installations. The proposed research to utilize the *SAH-C* intervention, that has been shown to be efficacious in VA and community settings, is innovative in its application to target this problem in this unique context. Moreover, *SAH-C* in itself is novel in its integration of interventions focused on trauma, IPA, and couples-based

intervention approaches, as well as its focus on prevention of IPA rather than attempting to manage the repercussions of IPA once it is already ongoing. Clearly, since IPA is difficult to stop and manage once the cycle of violence begins, a focus on prevention is timely and much needed.

Our proposed design is innovative as well. There is a well-documented gap between the identification of effective interventions and their implementation into service systems.[48,49] This delay between research discovery and uptake is partially slowed by delimited research methodology, in which efficacy is first established, followed by effectiveness research, with little systematic effort to study or understand the potential for implementation of effective interventions. An innovative and efficient solution is to collect implementation information in the context of effectiveness research.[48,49] Factors such as motivated participants, adequately trained provider, and a receptive context for implementation are crucial for effective implementation, and it is imperative to study whether and how these components interact systemically to facilitate translation from science to practice.[50]

One strategy to bridge the implementation gap is to capitalize on both researchers' and stakeholders' knowledge to ensure fit between the intervention training, provider needs, and organizational context. Recently described by Curran and colleagues,[48] a hybrid Type I implementation-effectiveness research design allows for the conduct of a rigorous effectiveness trial while simultaneously investigating potential barriers and facilitators to implementation. This information can guide future refinements to the intervention to improve the fit between the intervention and the service setting and inform the selection or development of an appropriate implementation strategy. Hybrid research methodologies, by increasing the efficiency of the research necessary to facilitate implementation, can reduce the time between the identification of effective interventions and their introduction into service systems and settings. The proposed design will position the research team and its operational partners to rapidly act on findings to enhance the effectiveness or fit of *SAH-C* in military settings if needed, and to roll the intervention out more broadly if our findings warrant doing so.

(c) Outline of *SAH-C*

SAH-C derives from a unique fusion of interventions for trauma and IPA, integrating elements of cognitive processing therapy for PTSD,[39] couples therapy for PTSD,[40] and a cognitive behavioral intervention for IPA.[41] *SAH-C* consists of 10 two-hour weekly sessions, led by a provider. This was the minimum length deemed necessary to incorporate components addressing the proposed IPA mechanisms and is consistent with the briefest IPA interventions.[42] During each session, couples are provided assignments to practice skills together and to assist with the consolidation of material. A group couples format is used because group cohesion among clients appears to be associated with IPA prevention.[43] Group interventions also use less time and resources than individual-based interventions. In this psychoeducation intervention, the couples participating in the program are the learners. What follows is a brief outline of each of the 10 *SAH-C* sessions.

Session 1: Introduction and Welcoming

This session introduces couples to the structure, expectations, and philosophy of the group. The main tasks are to begin establishing an alliance with each couple, to validate and address concerns, and to encourage healthy group interactions. Group leaders teach participants the skill of paraphrasing, the foundation of active listening. Leaders will refer to this skill and encourage participants to use it throughout the program.

Session 2: Trauma and Relationships I

Group members explore their beliefs about healthy and unhealthy relationships and review assignments designed to enhance intimacy and solidify mutual intervention goals. The session then shifts to discussing psychoeducational material that focuses on understanding forms of IPA and the impact of trauma on couples'

functioning. The main tasks of the session are to enhance motivation, educate group members about abuse and trauma, and help members gain insight into the effects of trauma on their own relationship.

Session 3: Trauma and Relationships II

This session begins with a discussion of the practice assignment focusing on understanding how trauma has affected the couples' relationship. The discussion shifts to themes related to trauma that can affect relationships, including trust, power and control, self-esteem, and intimacy. Group material facilitates further contemplation of behavior change and intervention goals, building upon psychoeducational material from Session 2.

Session 4: Conflict Management I: Assertiveness

This session focuses on conflict management and expressing anger assertively, with some material focused on how conflict management styles were learned in the military and elsewhere. The goals of this session are to further facilitate an understanding of the impact of trauma on relationships, and to help couples identify positive (i.e., assertive) versus harmful (i.e., aggressive, passive) communication styles during conflict.

Session 5: Conflict Management II: Time Outs

Group members review the self-monitoring assignment designed to assess group members' assertive, passive, and aggressive responses to conflict situations. Discussion then focuses on developing strategies to deescalate conflict situations. Couples are asked to generate and put into practice a detailed "Time Out Plan" to use during conflict situations. Development of these plans is an important crisis management tool to ensure safety for the couple, and provides a skill that helps to lay the groundwork for future work on communication.

Session 6: Communication Skills I: Active Listening

After discussing Time Outs and self-monitoring practice assignments, good and bad communication is discussed. Listening skills are emphasized since they are the foundation of good communication, de-escalating conflict, and enhancing intimacy. Listening is particularly important when trauma symptoms are present because information processing abilities are often compromised by emotional arousal.

Session 7: Communication Skills II: Assertive Messages

After reviewing group members' communication self-monitoring forms, group discussion focuses on how to give an assertive message. Group members are introduced to a role play depicting assertive messages and active listening and practice these skills in session. The continued focus on enhanced communication skills is intended to reduce the negative impact that deployments and trauma may have on communication, and to further enhance intimacy, improve relationship problem solving, and facilitate the sharing of trauma-related material.

Session 8: Communication Skills III: Expressing Feelings

Group members review their communication self-monitoring forms and the assertive messages and active listening practice assignment and then discuss how trauma-related avoidance can lead to difficulties in expressing emotions. Strategies for expressing feelings are provided and couples practice these skills during the session. Emotional expression skills are important for enhancing intimacy and understanding among couples.

Session 9: Communication Skills IV: Common Communication Traps

Group material focuses on five communication traps that undermine assertive communication. These traps are particularly important for those experiencing deployments and trauma. Strategies to avoid these common communication traps and to cope productively when they arise are introduced and discussed.

Session 10: Reviewing Gains and Planning for Future

Group members explore gains made in the group. They identify goals and strategies for future change along with barriers to change and strategies to overcome these barriers. Much of the session is spent discussing thoughts and feelings about the group ending, exploring plans for future change, and saying goodbye.

(d) Relevance to Veterans Health.

There is currently no empirically supported IPA prevention intervention used on military installations. The proposed research to utilize the *SAH-C* intervention, that has been shown to be efficacious in VA and community settings, is innovative in its application to target this problem in this unique context. Moreover, *SAH-C* in itself is novel in its integration of interventions focused on trauma, IPA, and couples-based intervention approaches, as well as its focus on prevention of IPA rather than attempting to manage the repercussions of IPA once it is already ongoing. Clearly, since IPA is difficult to stop and manage once the cycle of violence begins, a focus on prevention is timely and much needed.

(3) Work Accomplished

(a) Preliminary Studies

SAH-C Pilot Study

For Phase 1 of a CDC funded trial, we examined *SAH-C* relative to *SP* in 9 couples and assessed IPA using the Revised Conflict Tactics Scales (CTS2).[44] Results, published in the journal *Partner Abuse: New Directions in Research, Intervention, and Policy* suggest the effectiveness of *SAH-C* in reducing IPA.[32] All *SAH-C* male Veterans who engaged in physical IPA during the pre-intervention period evidenced complete IPA cessation at 3-month follow-up according to self and partner reports, with large effect sizes. Female partners participating in *SAH-C* also evidenced reductions in mild physical IPA perpetration with a moderate effect size, while female partners participating in the *SP* groups evidenced large increases in their physical IPA. Of note, while we were not able to truly determine prevention of physical IPA in this small sample, none of the participants increased their IPA or went from nonviolent to violent after participating in *SAH-C*, while one of three *SP* female partner participants went from nonviolent to violent. Mild psychological IPA, perpetrated by both the Veteran and the female partner, decreased more in *SAH-C* than *SP* and these effect sizes were large. Reductions in severe psychological IPA perpetrated by the Veteran and partner were moderate and large, respectively.

SAH-C Randomized Clinical Trial

We have recently examined the data from 78 returning male Veterans and their partners via Phase 2 of the CDC trial, with impressive results obtained. The mean incidents of Veteran and partner perpetrated psychological IPA, based on CTS2 and Multidimensional Measure of Emotional Abuse[45] reports, are presented in Table 1. Analyses of Covariance (ANCOVA) at 6 months post-intervention (controlling for baseline scores) revealed a significant effect of group whereby psychological IPA was significantly lower among *SAH-C* couples than *SP* couples, $F(1,46) = 6.37$, $p = .015$ (Figure 1). For partner perpetrated psychological IPA, an ANCOVA demonstrated a significant effect of group with *SAH-C* couples reporting a significant decrease in partner-perpetrated psychological IPA at 6 month follow-up compared to *SP* couples, $F(1,46)= 7.64$, $p = .008$ (Figure 2). MMEA results for Veteran and partner-perpetrated psychological IPA can be found in Figures 3 and 4, respectively. While based on the MMEA there was no difference in male Veteran-perpetrated psychological

IPA at 6-month follow-up for either the *SAH-C* or *SP* conditions, there was a trend-level reduction in partner-perpetrated IPA at the 6-month follow-up for *SAH-C* couples, $F(1,46)=3.822$, $p= .057$.

Table 1.

Reported IPA perpetration over time

	SAH Condition		ST Condition		
Type of IPA	T1 (n=41) M(SD)	T3 (n=31) M(SD)	T1 (n=37) M(SD)	T3 (n=18) M(SD)	Results of ANCOVA
Veteran-Perpetrated					
Psychological (CTS)	30.76 (25.9)	15.26 (17.0)	37.94 (26.7)	35.78 (25.9)	F(1,46)=6.37, p=.015
Psychological (MMEA)	66.98 (57.0)	41.48 (52.9)	95.46 (73.9)	76.28 (77.1)	F(1,46)=1.46, p= .233
Physical	.44 (2.5)	.74 (2.1)	.14 (.48)	.94 (2.1)	F(1,46)=.378, p=.541
Partner-Perpetrated					
Psychological (CTS)	30.29 (24.3)	11.94 (13.5)	32.84 (21.5)	32.40 (25.8)	F(1,46)=7.64, p=.008
Psychological (MMEA)	52.76 (38.9)	31.13 (34.1)	61.96 (67.3)	59.61 (67.8)	F(1,46)=3.82, p= .057
Physical	1.24 (3.4)	.51 (1.7)	.73 (1.7)	1.00 (2.1)	F(1,46)=.971, p=.330

The mean incidents of Veteran and partner perpetrated physical IPA are reported in Table 1. There was no significant effect of group type on physical IPA perpetration by either the Veteran or partner (p-values >.05; see Figures 5 and 6, respectively). As physical IPA was an exclusion criterion for the Veterans this study, we did not expect a significant decrease in this measure as a function of group. For both the *SAH-C* and *SP* groups, physical IPA did not significantly increase at 6-month follow-up. However, there appears to be a trend toward an interaction whereby those in the *SAH-C* group reported a decrease in partner perpetrated physical IPA, while those in the *SP* group reported an increase. Furthermore we see a greater (albeit non-significant) increase in Veteran-perpetrated physical IPA (Figure 6).

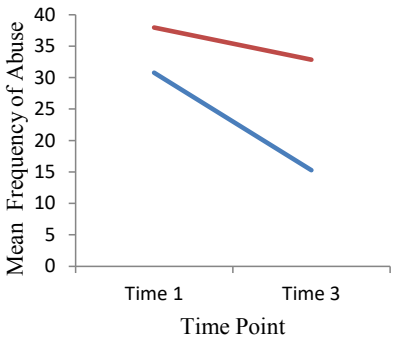


Figure 1. Veteran Psychological IPA Perpetration (CTS)

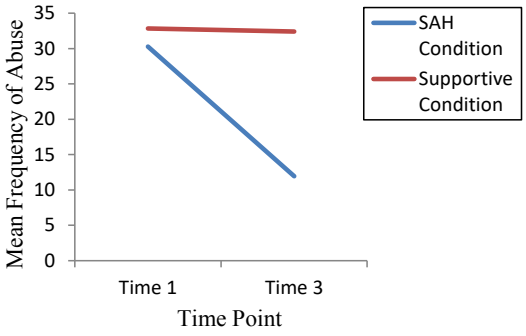


Figure 2. Partner Psychological IPA Perpetration (CTS)

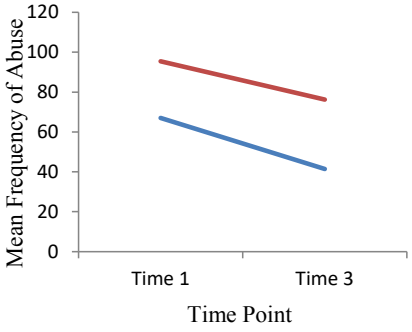


Figure 3. Veteran Psychological IPA Perpetration (MMEA)

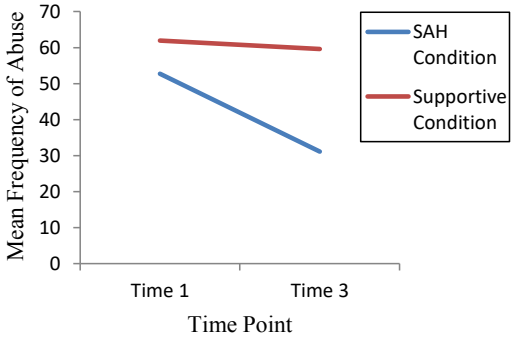


Figure 4. Partner Psychological IPA Perpetration (MMEA)

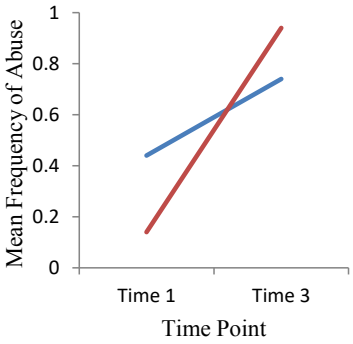


Figure 5. Veteran Physical IPA Perpetration

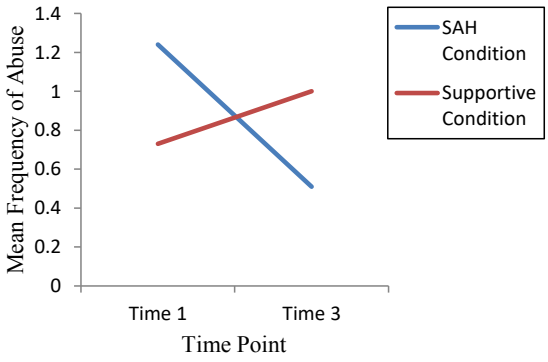


Figure 6. Partner Physical IPA Perpetration

SAH-C Community Implementation Study

We examined the impact of the *SAH-C* intervention delivered in a community setting serving Veterans through a grant funded by the Blue Shield Foundation of California, with the results recently published in the *Journal of Clinical Psychiatry*.[46] In a sample of 85 dyads, we first examined the impact of the intervention on psychological and physical aggression perpetrated by both Veterans and their loved ones. Descriptive statistics and effect sizes representing intraindividual changes for these outcomes are presented in Table 2. Results indicated significant decreases in psychological aggression from pre-intervention to program completion for

both Veterans and their loved ones, and these effects were maintained when examining changes from pre-intervention to follow-up. Again, as expected, there were no significant increases in levels of physical aggression perpetrated by Veterans or loved ones.

Table 2. Means, Standard Deviations, and Intraindividual Effect Sizes (ESsg with 95% CI) for Aggression Perpetration and Secondary Outcomes

	T1		T2		T3		T1- T2		T1- T3		T2- T3	
Outcome	*M*	*SD*	*M*	*SD*	*M*	*SD*	*ESsg*	95% CI	*ESsg*	95% CI	*ESsg*	95% CI
Veteran Psychological Aggression	4.01	2.09	3.21	2.25	2.95	2.65	-0.36	-.64 : -.08	-0.45	-.75 : -.15	-0.11	-.41 : .19
Veteran Physical Aggression	.94	1.66	.87	1.89	.71	3.16	-0.05	-.23 : .13	-0.09	-.40 : .22	0.00	-.32 : .32
Partner Psychological Aggression	3.54	2.13	2.92	2.06	2.84	2.49	-0.30	-.56 : -.03	-0.30	-.59 : -.02	-0.04	-.35 : .27
Partner Physical Aggression	.79	1.95	.88	2.06	.87	3.47	0.05	-.14 : .23	0.03	-.37 : .43	-0.04	-.40 : .31
Veteran DAS	99.88	28.76	94.17	20.62	90.19	44.64	-0.22	-.48 : .04	-0.26	-.63 : .11	-0.14	-.50 : .22
Veteran QRI	66.27	34.56	61.82	17.86	64.54	24.21	-0.02	-.26 : .21	0.11	-.10 : .32	-0.11	-.30 : .09
Veteran PHQ	12.06	7.62	9.62	8.13	18.12	6.84	-0.30	-.51 : -.10	0.85	.60 : 1.11	1.18	.89 : 1.47
Veteran PCL	52.76	18.48	50.59	21.94	42.22	22.27	-0.12	-.31 : .07	-0.52	-.74 : -.30	-0.40	-.59 : -.21
Partner DAS	91.51	17.29	96.64	17.84	89.69	32.50	0.33	.09 : .57	-0.07	-.48 : .33	-0.32	-.72 : .07
Partner QRI	63.42	17.93	64.40	15.08	62.96	17.24	0.13	-.22 : .47	-0.02	-.36 : .31	-0.11	-.37 : .15
Partner PHQ	9.30	7.22	5.79	5.35	13.96	5.60	-0.55	-.77 : -.33	0.72	.45 : .99	1.51	1.17 : 1.85
Partner PCL	43.33	17.00	32.33	15.75	32.52	16.78	-0.54	-.76 : -.31	-0.52	-.72 : -.32	-0.02	-.23 : .19

We also examined Veterans' and their loved ones' perceived relationship quality and mental health (depressive and PTSD symptoms) as secondary outcomes of the *SAH-C* intervention. Descriptive statistics and effect sizes representing intraindividual changes for these outcomes are also presented in Table 2. Loved ones reported a significant improvement from pre-intervention to program completion in relationship adjustment, as measured by the Dyadic Adjustment Scale.[47] Veterans and their loved ones also reported significant decreases in depressive and PTSD symptoms from pre-intervention to program completion, and the PTSD symptom improvements were maintained at follow-up.

(b) Personnel

The Principal Investigator (PI) for the proposed work is Dr. Casey Taft. Dr. Taft is a staff psychologist at the National Center for Posttraumatic Stress Disorder (PTSD) in the VA Boston Healthcare System, and Professor of Psychiatry at Boston University School of Medicine. Dr. Taft has served as PI on funded grants focused on understanding and preventing intimate partner aggression (IPA) through the Department of Defense, National Institutes of Mental Health, Department of Veterans Affairs, and the Centers for Disease Control. He is the primary developer and director of the *SAH* programs, the focus of the current proposal. Through his experience coordinating and directing randomized clinical trials for IPA in military populations, Dr. Taft is uniquely qualified to understand and address the needs of violent Veterans and lead this work.

Dr. Shannon Wiltsey-Stirman will serve as a Co-Investigator on the proposed project. Dr. Wiltsey-Stirman is a clinical psychologist and researcher in the Women's Health Sciences Division of the National Center for PTSD. She has background and training in conducting qualitative studies, implementation research, and treatment effectiveness research. She has experience in the implementation of evidence-based interventions for trauma and related problems and has familiarity with the implementation frameworks used to guide data collection. Dr. Wiltsey-Stirman will oversee implementation-related data collection, analysis, and interpretation.

Dr. Suzannah Creech will serve as a consultant on the proposed project. Dr. Creech is a research psychologist and a licensed clinical psychologist at the Providence VAMC, and an Assistant Professor (research) at Brown University. She is also an affiliate of the VA National Center for PTSD. Dr. Creech conducts research in the area of improving family functioning in vulnerable Veteran populations (e.g. women

Veterans, homeless Veterans, returning Veteran parents). Dr. Creech has expertise developed through 3 years of experience as the project coordinator and then as the site PI for two *Strength at Home* clinical trials. Dr. Creech will contribute to all aspects of the proposed project.

Ms. Brittany Groh will serve as a research coordinator on the proposed project. Ms. Groh is a recent graduate from Western Kentucky University M.S. Psychological Sciences program. She will oversee administration of the project on-site at Joint Base Lewis-McChord. This includes coordination with the project sites doing the implementation, recruitment of participants, administration of eligibility assessments and follow-ups, facilitating groups, preparation of IRB submissions, and management of data received.

Ms. Alecia Grady will serve as a consultant on the proposed project. Ms. Grady is the Director of Personnel and Family Readiness. She will assist in getting the letter of support from the Garrison Commander, recruitment, securing office space for the research coordinator and a conference room for the group.

Ms. Karen Fox will serve as a consultant on the proposed project. Ms. Fox is the Intervention Branch Manager for the Family Advocacy Program, Prevention. She will assist in recruitment, securing office space for the research coordinator, and securing a conference room for the group.

Ms. Kate Comtois will serve on the stakeholder advisory board. She is an implementation specialist with the University of Washington Medicine.

Ms. Wendy Long will serve on the stakeholder advisory board. She is a licensed independent clinical social worker (LICSW) with the Department of Behavioral Health at Madigan Army Medical Center.

Ms. Lynn Robinson will serve on the stakeholder advisory board. She is the family engagement program manager for children's administration in Vancouver, WA.

(4) **Work Proposed**

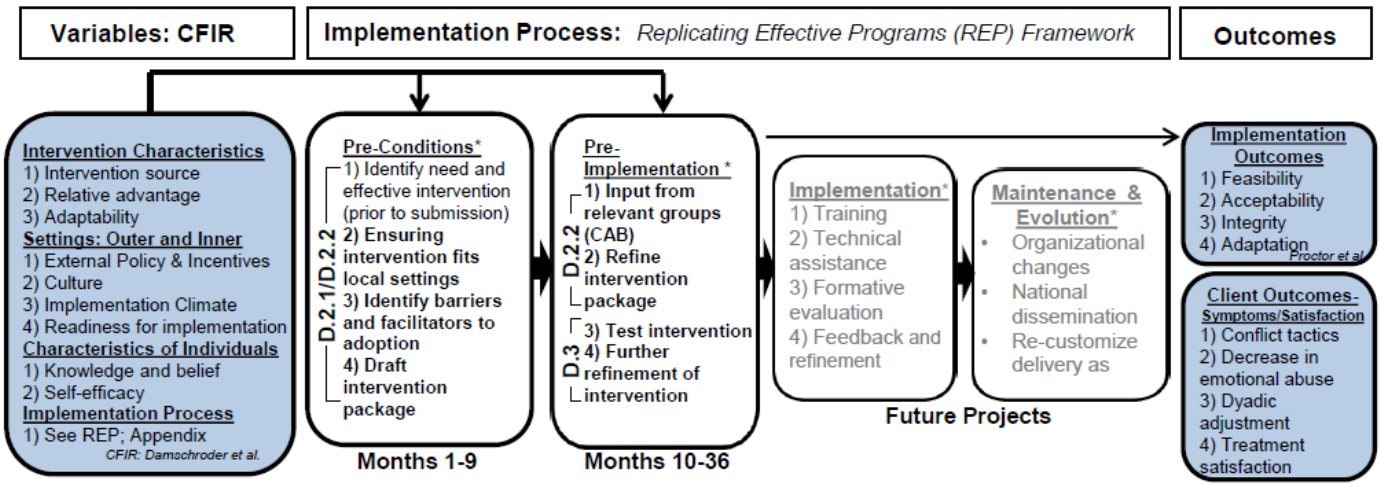
(a) Timeline of Proposed Research

Figure 7 presents the framework for the study, blending 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;[51-54] 2) Consolidated Framework for Implementation Research (CFIR);[55] and 3) the Proctor et al. taxonomy for implementation outcome variables.[56]

As illustrated in Figure 7, the *implementation process* of the current study will use the REP framework.[51,52] Based on social learning theory[57] and Diffusion of Innovations,[58] REP focuses on identifying and addressing barriers to implementation among stakeholders, facilitators, and group participants in order to prepare interventions for implementation. REP attends to factors including packaging, training, and ongoing technical assistance. The stages of REP are conceptually separate, though sometimes chronologically overlapping,[52,59] allowing for formative, iterative research. This study will include activities recommended for the Pre-Conditions and Pre-Implementation phases. The *potential influences on implementation* that will be examined in each of the REP stages are theoretically driven by the CFIR[55,60] and are described in Figure 7. The CFIR[55] is a "meta-theoretical" implementation framework generated specifically for research in health care that draws upon 19 different implementation models to create a typology of constructs to guide different phases of implementation studies. As such, specific CFIR variables will be studied at each of the REP stages, and findings will be used to guide future implementation efforts. Finally, the *implementation outcome variables* are based on Proctor et al.'s identification of implementation outcomes.[56] We have narrowed our choice of implementation

outcomes based on the scope of the current study and ensured that they would best match study aims. However, future studies would examine additional implementation outcomes such as cost, efficiency, and penetration.

Figure 7. Proposed Implementation Framework for Current Study



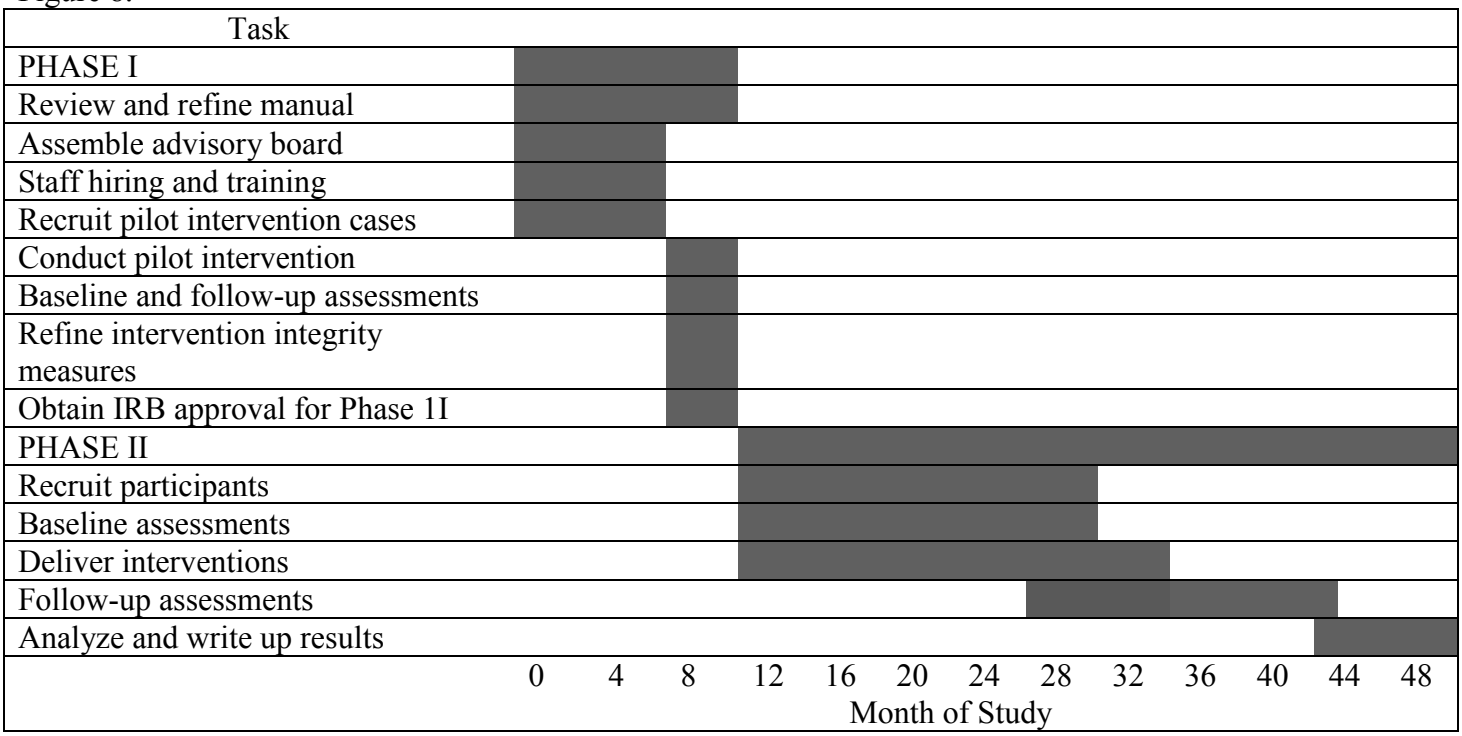
This project will be carried out in two phases (Figure 8). Phase 1 (Pre-Conditions) will be conducted during the first ten months. Throughout this phase, the intervention manual, already developed via our prior studies with Veterans, will be reviewed and refined for use on a military base. During the first 6 months of Phase 1, the advisory board will be assembled, staff will be hired and trained, and pilot study intervention cases will be recruited to examine and refine the fit between *SAH-C* and the local setting. The pilot interventions will include two groups of 5 couples (one from each condition), and will be conducted from month 6 through month 10. Baseline assessments will be conducted prior to the beginning and end of the groups to assess the effectiveness of *SAH-C* and *SP* strategies. These data and information provided by study facilitator and other stakeholders will be used to inform refinements to the manuals throughout this time period, as well as the refinement of *SAH-C* integrity measures (months 6 through 10). This work will be accomplished with input from our stakeholder advisory board. IRB approval for Phase 2 of the study, including the refinements to the manuals, will be sought from months 6 to 10.

During the second phase, a randomized controlled trial will be conducted among 140 couples to compare the *SAH-C* intervention to a *SP* condition, and the intervention manual and adherence measures refined in Phase 1 will be field tested. Participants will be recruited and baseline assessments with the service member participants and their partners will be conducted during months 10 through 30. The interventions will be delivered from months 10 through 34, and follow-up assessments will be conducted with the service members and their partners from months 26 through 44. Data analysis and the preparation of conference presentations

and manuscripts for publication will begin in month 42 and continue through the end of the project. Additionally, these findings will be presented to our stakeholder advisory board, which will make recommendations for further refinement to *SAH-C* and assist with the selection of appropriate training and strategies for future implementation.

Study activities involving human subjects will occur at Joint Base Lewis McChord, Washington. The PI will facilitate coordination across the two project locations (Boston and Washington). Local project staff will administer in session measures and primary study assessments will be conducted via REDCap, which is a secure online data collection system.

Figure 8.



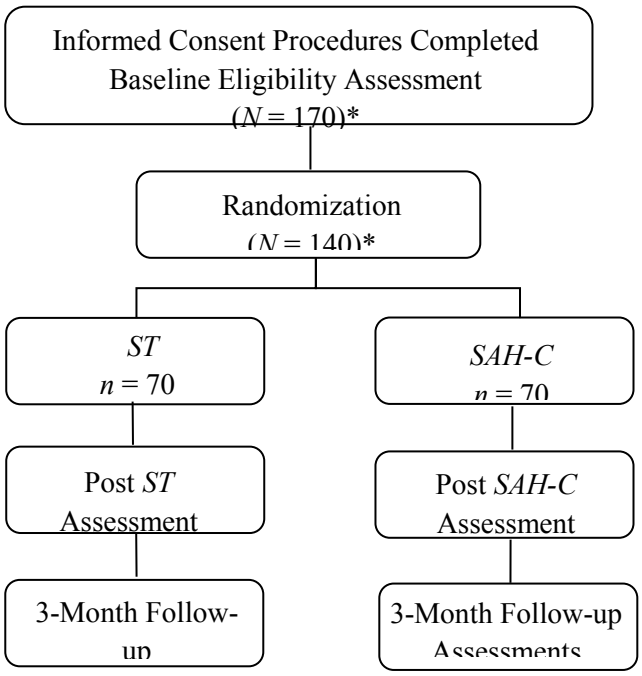
(b) Independent variables and Dependent (outcome) variables

Questionnaires

An electronic data collection tool, REDCap, will be utilized to collect self-report data. REDCap is a secure and widely used web application for collecting, managing online data. REDCap is designed to support data capture for research studies. This system provides and intuitive interface for users to enter data, and all information transmission is encrypted, and the data are stored on a protected network. All access to data is restricted on a role-specific basis. The REDCap system was specifically developed around HIPAA Security guidelines, and meets DoD information security standards. The REDCap system provides a number of advantages over traditional data collection methods. Participants are offered a higher level of privacy and convenience, which minimizes the likelihood that they will be observed or overheard and allows for confidential IPA assessments to be conducted in the military context. Participants are asked to enter responses using an electronic tablet and no verbalizations are required. The elimination of written data insures that information cannot be discovered or surreptitiously read by others.

Using the REDCap system, questions are presented in a standardized form that does not vary from participant to participant, thereby reducing one source of experimental error common in the structured interview format. Further, the hardware records data directly into a data base, eliminating data entry labor and errors.

Figure 9.



**The N here is for the entire sample; we expect that 20% will not be eligible for payment due to active military status.*

The REDCap survey will consist of a demographic questionnaire, a Partner Contact form, the *PTSD Checklist* (PCL)[81], the *Alcohol Use Disorders Identification Test* (AUDIT)[82], the Childhood Trauma Questionnaire (CTQ)[83], a suicidality measure, the *Revised Conflict Tactics Scale-2* (CTS-2),[44] the *Multidimensional Measure of Emotional Abuse* (MMEA)[80], the *Dyadic Adjustment Scale* (DAS)[69], an ongoing intervention questionnaire, and a Post-intervention Satisfaction assessment.

During baseline assessment, the demographics questionnaire, partner contact form, CTS-2 (time one), DAS, MMEA, PCL, AUDIT, ongoing intervention assessment, the suicidality measure, and CTQ will be given to the participants. At the post-intervention assessment, the partner contact form, CTS-2 post-intervention, DAS, MMEA, PCL, AUDIT, ongoing intervention assessment, the suicidality measure, and post-intervention satisfaction measures will be given. At the 3-month follow up, partner contact, the CTS-2 post-intervention, DAS, MMEA, AUDIT, ongoing intervention assessment, the suicidality measure, and PCL will be assessed.

The PCL is widely used as an assessment for screening individuals for PTSD and monitoring change across time. This questionnaire includes a list of potential responses an individual may have following an extremely stressful experience[81].

The AUDIT is a widely used screening tool to assess alcohol consumption and alcohol-related behaviors developed by the World Health Organization (WHO)[82].

The CTQ is a self-report measure reflecting on childhood abuse and neglect. The five subscales include emotional, physical, and sexual abuse as well as emotional and physical neglect (Emotional, Physical, and Sexual) and two assessing neglect (Emotional and Physical)[83].

The ongoing intervention questionnaire has been adapted from the United States Army Medical Command (MEDCOM) behavioral health intake form. The two questions asked request participants to explain the types of services they currently receive (i.e., alcohol and drug, community behavioral health, chaplains, etc.) and the type of therapy they are attending (i.e., individual, couples, family, or group).

The suicidality measure is comprised of items from other scales. Items 1-4 are from the Depression Symptom Index-Suicidality Subscale by Metalsky & Joiner[84], 1997; 5-6 created by Joiner and Gutierrez, 7-8 from the Beck Scale for Suicide Ideation by Beck & Steer, 1991[85], 9-11 from the Beck Hopelessness Scale by Beck, Weissman, Lester, & Trexler, 1972[86], and 12-16 from the Interpersonal Needs Questionnaire by Van Orden et al., 2012[87]. This assessment examines thoughts about killing oneself, the number of suicide attempts since the last suicide risk assessment, wish to live/die, and feelings of belongingness within relationships. This suicide assessment was recommended by Centers for Disease Control suicide researchers, is currently being used within DoD, and derives from 5 different validated assessments.

The CTS-2 is the most widely used measure of IPA, with excellent internal consistency reliability, content validity, and construct validity.[44,66] The measure assesses physical, psychological, and sexual aggression in intimate relationships. Respondents report on the frequency of each item for themselves and their partners. Combined partner reports are used to reduce IPA underreporting.

Because the CTS-2 assesses a fairly limited number of psychologically abusive behaviors, the Multidimensional Measure of Emotional Abuse (MMEA) will also be administered to assess psychological IPA.[96]

The DAS is appropriate for use with both married and cohabitating couples. In addition to a global satisfaction score, this 32-item measure consists of four subscales: Dyadic Consensus, Affectional Expression, Dyadic Satisfaction, and Dyadic Cohesion. Several studies provide evidence for this measure's strong psychometric properties.[67-69]

The post-intervention satisfaction questionnaire asks questions to determine barriers and facilitators of the program. This information will be used to make adjustments to the program if necessary.

The partner contact form consists of a single item assessing the frequency of contact with the participant's partner.

In addition to the self-report questionnaires, a collateral contact form will be completed by each individual to ensure research staff will be able to contact the individual if they move away prior to the final time point. The form includes contact information for themselves as well as up to three others that research staff can contact if there is difficulty getting in contact with the participants.

Intervention and Integrity Measure Refinement

To facilitate the rapid integration of the information into the refinement of the intervention and materials, meeting summaries will be content analyzed using a rapid coding technique based on methods of Sobo et al.[70,71]

Based on Stakeholder Advisory Board recommendations and an examination of the pilot data, refinements will be made to the *SAH-C* manual. As a final working version becomes available, intervention integrity measures will be refined based on changes to the manual and psychoeducational intervention integrity ratings

(5) Phase 2: Randomized Trial/Pre-Implementation Phase

(a) Study Design

The refined intervention manual and integrity measures from Phase 1 will be tested in Phase 2 in a randomized trial. Figure 9 illustrates the study design, procedures, and schedule of assessments planned for Phase 2. This choice in study design is analogous to that used in our prior CDC trial within a VA setting and is consistent with recommendations about the appropriate progression of control conditions when determining the efficacy of any intervention.[73]

Participants for Phase 2 will be 140 service members and their partners. The same recruitment procedures employed for Phase 1 will be used for Phase 2. Informed consent procedures will be almost identical to those described for Phase 1 in Section D.2.3.**,** with the exceptions that they will be notified that they will participate in one of two possible interventions.

As in Phase 1, all assessments will remain confidential and will be stored separately from one another. Each assessment will also entail the provision of information regarding safety planning and IPA resources.

(b) Assignment to Groups

Random assignment will be completed after study enrollment using computer-generated random numbers. Assignment to conditions will be conducted using urn randomization methods to balance conditions on case severity. Urn randomization alters the probability of assignment to study conditions based on imbalances that resulted from prior random assignments.[74] This methodology allows for random assignment of each case, and maintains the possibility that each individual will be assigned to either condition, while at the same time reducing the chance of imbalances in prognostic factors that can threaten the validity of small-sample clinical trials.

(c) Interventions

In total, 28 intervention groups will be conducted (14 for each condition), with five couples per group. Please see Section 2.c. for an initial outline of the *SAH-C* intervention. The *SP* intervention, used in our prior trial, is based on the work of Jennings[76] and on Yalom's[77] primary therapeutic factors for group intervention. This intervention involves minimal facilitator-directed intervention beyond encouragement of a mutually supportive environment and focus on relationship issues. In *ST*, the provider will allow group members to set the session agenda and address themes and topics that spontaneously emerge in the group interaction. The provider will emphasize a collaborative group norm and refrain from using active skills-training interventions. The provider will be instructed to address the group as a whole rather than individuals, and use brief verbalizations and nonverbal gestures to stimulate vigorous and helpful group interactions. This intervention was chosen to examine the relative benefits of the cognitive and behavioral interventions used in *SAH-C*.

(d) Intervention Integrity

Intervention integrity for *SAH-C* will be monitored using the intervention integrity measures used during Phase 1, as outlined in Section D.2.5. The same procedure will be used to measure intervention integrity for the *SP* condition, utilizing the modified *SP* codes developed in our previous trial. A framework of adaptations and modifications to evidence-based interventions[78] will be used to complement the integrity measure and identify any adaptations that the trained psychoeducational facilitator makes within session to address potential challenges or participant needs. Intervention integrity and adaptation data will be examined as implementation outcomes and will also be integrated with qualitative data to understand challenges to delivering the intervention with an adequate level of integrity and perceptions of the effectiveness of any adaptations that are made.

(e) Additional Intervention and Early Termination

Participants may receive additional types of intervention during this trial. Any additional intervention will be monitored for descriptive purposes. Study participants may be terminated from the group if they become actively suicidal or homicidal or fail to attend three consecutive scheduled meetings without a reason deemed appropriate by their providers. All participants who are terminated early will continue to be followed for all subsequent assessments.

(f) Feasibility

In order to enhance recruitment and achieve our target recruitment goals, we will seek approval from the Medical Treatment Facility Commander and the Garrison Commander. We will then attend all hands meetings in order to brief the troops on this research. All necessary permissions from Medical and Line Commanders will be obtained in order to accomplish this research. Preliminary conversations have already commenced with these officers, who have expressed their willingness to meet with us to find the best way to implement the study once the grant has been awarded.

There are currently 383 referrals annually to the Family Advocacy Program at Madigan Army Medical Center that do not meet the criteria for domestic abuse, but still require help in working through the various challenges associated with solving differences about money, children, sex, and friends. In addition, there are 4 M&FTs who work full time providing services to couples who have not yet come to the attention of the Family Advocacy Program. These providers average around 210 couples per year each. Thus, there is a pool of more than 1,600 couples who could be referred for *SAH-C* during the recruitment period, which would help us easily meet our recruitment goal.

(g) Attrition

We expect relatively low attrition since we are only including participants if they indicate that they plan to remain on base for the next six months and given previous rates of attrition obtained by members of the study team. To limit attrition, the research coordinator will contact participants to schedule their in-person assessments. We have planned for a 12% attrition rate. Reasons for attrition will be assessed as potential barriers to implementation.

Participants (service members and partners) will separately receive remuneration of a $50 Visa Gift Card or a $50 check sent to their address for completion of each assessment. Due to military compensation restrictions, and to ensure no conflict, if the service member is active duty, they may only be compensated if they fill out their surveys while on off-duty or on leave status.

(h) Intervention after Completion of Trial

Following the completion of the final assessment, all participants assigned to the *SP* condition will be offered the opportunity to participate in a *SAH-C* group. This participation would be entirely voluntary and would involve no further assessment or remuneration.

(6) Measures

(a) Outcome Measures

Outcome assessments are identical to those from Phase 1, though the assessment window for Phase 2 assessments refers to the prior three months. Data collected will include demographics questionnaire, partner contact form, PCL, AUDIT, Post-Intervention satisfaction, suicidality measure, MMEA[80], CTS2[44], ongoing intervention questionnaire, and DAS[69].

(b) Intervention Compliance Measure

Session Attendance will be measured as the total number of group sessions attended by each client.

(7) Stakeholder Meetings

Stakeholder meetings will be held to discuss study performance and needs of the study, such as discussions related to study recruitment, barriers to participation, and dissemination of research findings.

(c) Intent-to-Treat (ITT) versus "Adequate Dose" Analyses

An ITT philosophy will be strictly adopted. Experts in clinical trials have noted that no consensus exists about how missing data should be handled in ITT analyses, and different imputation approaches result in various potential biases. Thus, there is no single definition of ITT, and the phrase carries different meanings for different researchers.[87,88] Therefore, every effort will be made to collect complete outcome data for all randomized participants, regardless of their intervention completion. As discussed in section D.3.7., measurement losses are expected to be relatively small due primarily to the use of tracking procedures, as well as the relatively short follow-up assessment periods.

Analyses will first be conducted on the ITT sample, and then on the subset of participants who are considered to have received an "adequate dose" of the group intervention over the course of the study. We intend to focus on a comparison of those who had an adequate dose versus completed the intervention, because the group sessions will continue in spite of a couple's non-attendance. This approach is consistent with prior group interventions.[89] It is recognized that the ITT and adequate dose analyses address different questions, and only the ITT analyses permit strong inferences. However, there is important information to be gained in looking at the data both ways.

(d) Primary Data Analyses

Formal data analyses will be conducted only on those subjects recruited during Phase 2 of the project, as this is the only phase that includes random assignment. Differences between the *SAH-C* groups and *SP* groups on the frequency of physical and psychological IPA and relationship satisfaction (Aim 1) will be examined with random-effects regression models, using Hierarchical Linear Modeling (HLM5).[90] Random-effects regression models provide more flexibility in modeling missing data than general linear models. They do not require data to be missing completely at random, but only missing at random (that is, the probability of missingness is

assumed to be a function of observed covariates and previously measured outcomes, but not unobserved outcomes). Based on such considerations, this type of an approach has been recommended for analyzing outcomes in prevention trials as it is generally more powerful than traditional repeated measures analyses of variance.[91] In the current project it is of interest to model person-specific effects (i.e., time course for each participant), as well as the variation of responses between individuals. In addition, because of the suspected intraclass correlation between individuals nested within intervention groups, couples, and perhaps intervention site, these variables will be treated as fixed effects in the analyses. Time will be modeled as a random effect, and condition (*SAH-C* and *ST*) will be a fixed effect. Change in intervention outcomes over time and differences between the conditions over time (intervention by time interactions) will be examined. The primary effect size for the study will be derived from the random regression analyses, and specifically the intervention by time interaction, which will compare the two groups across intervention and follow ups. There are covariates that are *a priori* hypothesized to be associated with intervention outcomes, including socioeconomic status and education, and these will be included in follow-up analyses to significantly reduce error variance.

(e) Exploratory Analyses

Differences between the two group conditions in participant intervention compliance (Aim 2) will be explored by examining condition differences in session attendance using ANOVAs.

(f) Qualitative Analytic Strategy and Data Integration

Both intervention integrity and adaptation will be assessed. Descriptive statistics will be examined. Findings will be linked with interview data to facilitate understanding of reasons for, and perceived benefits of, any adaptations that are made to *SAH-C* within session, as well as to understand any barriers to, or facilitators of, intervention integrity. To examine Subaims 3.1 and 3.2, we are embedding qualitative methods within the study and connecting them to quantitative data (e.g., intervention credibility and satisfaction measures, study outcomes, reasons for attrition, homework compliance and therapeutic alliance) for the purpose of expansion and development. Established procedures to enhance validity will be used, including development of an audit trail documenting analytical decisions. All data will be checked for accuracy and entered into NVivo qualitative data management software. All coding decisions will be noted for further review. Rater agreement will be assessed through a second rater coding a subset of the data, and agreement will be reported. We will also use a check-coding model where the primary coder will code and recode the same material to ensure there is over a 90% consistency.

We will use a theory-driven approach to explore the relationship between the findings and the CFIR framework. The goals, objectives and key research questions will guide all aspects of the qualitative analyses. Using content analysis, we will identify analytical categories to describe and explain observations. Our work will occur in five stages, outlined in the Mays et al.[92] approach to qualitative analysis: 1) Familiarization, 2) Identifying a Thematic Framework, 3) Indexing, 4) Charting, and 5) Mapping and Interpretation. In stage 2, codes will be derived deductively by identifying categories at the beginning of the research (e.g., elements of the CFIR framework) and inductively by identifying those that emerge gradually from the data. We will work from a list of research questions (e.g., What provider, participant, and setting-level factors might explain outcomes if outcomes are inconsistent with prior research? What are potential barriers and facilitators to future deployment? What adaptations might be needed to *SAH-C* for successful future deployment in routine care military settings?). We will develop a codebook with operational definitions of each code. Using constant comparison, we will update the coding model to reflect further refinement. In the charting and mapping phases, we will integrate the qualitative and quantitative data for expansion, development, and convergence, identify themes, and look for the commonalities and variations in themes and findings related to training, feasibility, acceptability, and intervention integrity-related issues. Data integration will assist a fine-grained understanding of processes and characteristics that may influence effectiveness and implementation outcomes.

Consistent with the REP process, findings will be presented to the Stakeholder Advisory Board at the end of the study, and will guide decisions regarding next steps for intervention refinement if needed, or for broader implementation. If, for example, findings indicate effectiveness of *SAH-C*, we will use findings regarding modifiable barriers and facilitator that can be leveraged to facilitate broader implementation and to guide the selection of appropriate implementation strategies and models for use in future research. In this case, a future study might be a Type-III Hybrid study, which would allow the testing of an implementation model for military settings. If, on the other hand, findings suggest that effectiveness is lower than in previous research, we will use qualitative findings to determine whether intervention-related contextual variables may have contributed to these findings, and determine appropriate next steps for research accordingly.

(g) Power Analysis

Power analyses were based on the main hypotheses that *SAH-C* would reduce the level of IPA to a greater degree than the *SP* condition by the 3-month follow-up assessments. Estimates affecting power (e.g., effect size, intra-class correlations, attrition) were derived from our prior CDC funded study.

Our first consideration in estimating the necessary sample size for detecting differential change over time in *SAH-C* versus *SP* in terms of IPA incidence was the expected incidence rate of IPA during the follow-up period. Our sample is at high risk for such incidence as defined by the presence of high levels of marital distress. While there is no prospective military data available that directly speaks to such incidence rates, available estimates suggest a 33% one-year prevalence of IPA among trauma exposed service members.[93] Conservatively, it would be expected that during the current project, approximately 16% of cases of IPA would emerge (half of the one year prevalence). However, inclusion of only couples with high levels of marital distress will increase this estimated incidence rate. Accordingly, we expect an increase of 10% in the incidence rate. Together, we based power analyses on an estimated 26% one-year incidence rate. Our second consideration involved expected sample attrition. Based on our prior trial and the specific plan for data capture outlined for the project, we estimate that about 15% of participants will provide no follow-up assessment data. However, power analyses were conducted based on the conservative estimate of 20% assessment dropout. Consistent with an ITT approach, regardless of intervention dropout, we will assess participants randomized into the trial. Thus, dropout from measurement versus intervention is of greatest concern. Our third consideration involved expected within-subjects correlations. The within-subjects correlation was estimated as the average correlation observed in our previous trial for pre-intervention, post-intervention, and follow-up data on reports of physical and psychological IPA on the Revised Conflict Tactics Scale (CTS-2).[44] These correlations ranged from .53 to .90. We also considered the expected intra-class (group) correlation, which was approximately .05. Finally, consistent with recommendations,[94] we considered the intra-class (dyadic) correlation among couples. We did not incorporate an estimate of such correlations into power analyses because of our proposed use of a composite measure of IPA, which results in a single index of IPA, thereby eliminating intra-dyad correlations. Together, we assumed an intra-class correlation of .38 for power analyses. Our fifth consideration involved the expected effect size of the *SAH-C* relative to *ST*. Our prior work suggested an ITT effect size of $d = 1.01$. A conservative estimate of a mean effect size of $d = .5$ for the *SAH-C* in terms of reduction of IPA incidence was utilized for the power analysis.

Each of these considerations was used to calculate the needed sample size for testing the main hypotheses in the proposed project. Power analyses were conducted for the main hypothesis tests involving IPA perpetration and were conducted using the GEESIZE Macro in SAS Proc Mixed according to recommendations for estimating sample sizes needed in repeated measures experiments.[95] Together, assuming (1) 26% incidence of IPA in the control condition, (2) 20% overall attrition, (3) .70 within-subjects correlation, (6) $d = .5$, (5) two-tailed, and (6) $p < .05$, the proposed total N of 280 (140 couples) will provide ample power (> .9) to detect differences in IPA frequency across experimental conditions.

(8) Human Studies Section

(a) Risk to Subjects

Human Subjects Involvement and Characteristics

The study population consists of service members attached to an installation who may be at risk for intimate partner aggression (IPA) and their intimate partners. The participants will be 150 service members (10 in Phase 1; 140 in Phase 2) and their partners who will provide data on IPA. The research team has conducted several intervention studies with military samples. There are currently 383 referrals annually to the Family Advocacy Program at Madigan Army Medical Center that do not meet the criteria for domestic abuse, but still require help in working through the various challenges associated with solving differences about money, children, sex, and friends. In addition, there are 4 M&FTs who work full time providing services to couples who have not yet come to the attention of the Family Advocacy Program, Madigan Army Medical Center. These providers average around 210 couples per year each. Thus, there is a pool of more than 1,600 couples who could be referred for *SAH-C* during the recruitment period, which would help us easily meet our recruitment goal.

Inclusion/Exclusion Criteria

Inclusion criteria are as follows: (a) couples (heterosexual and same-sex dyads) must be in an intimate relationship; (b) participants and their partners must be over the age of 18, due to our emphasis on adult IPA, and so that all participants will be legally able to provide consent without parental involvement; (c) both members of the couple report no occurrence of physical IPA in the past 3 months; (d) at least one member of the couple reports at or below a score of 100 on the Dyadic Adjustment Scale (DAS), a cutoff score used to distinguish relationship distress, or they report the presence of psychological aggression in the past three months; and (e) both members of the couple provide research consent. Pregnant women are eligible to participate in this study. Research indicates that pregnant women may be at increased risk for intimate partner victimization. Thus, violence prevention interventions may be particularly applicable and important for this group. Potential participants will be excluded on the basis of reading difficulties that preclude valid completion of the assessment instruments.

Gender Inclusion

The couples-based interventions studied make it likely that equal numbers of men and women will participate. However, we will make no exclusions related to gender/gender identity, and same-sex couples are also eligible for participation.

Minority Inclusion

Across the study sites, 70% of potential participants are Caucasian, 20% are African American, and 10% are of another ethnicity.

(b) Sources of Materials

Data will be obtained from subjects from self-report measures completed through the online data collection tool, REDCap. Data will not be collected from routine medical care. All data gathered and analyzed will be obtained for this specific study. Study participation will not be documented in participants' electronic medical records.

(c) Potential Risks

Given that all participants will be in a program designed to improve relationships and prevent IPA, the added risks are those associated with the research assessments. All participants will be encouraged to discuss any painful issues that arise during the initial assessment. Those who do not receive intervention will be provided with referrals for counseling during the assessments as well as information on safety and resources for victims of abuse, such as 24-hour hotline numbers and shelter/legal services information. All participants who complete the *Supportive Prevention* group intervention will also have the option to participate in the *Strength at Home-Couples'* intervention.

AEs/SAEs will be reported according to VABHS IRB SOP by our on-site study coordinator. Reporting will be directed to Dr. Taft, who will ensure this is reported to the VABHS IRB.

A second risk involves the possibility that material discussed during research assessments will become the topic of a violent conflict. To minimize this risk, all assessments will be conducted separately with partners.

Additionally, the loss of confidentiality by another group member is a risk. To minimize this risk we discuss that group members will use only their first names and they agree to not discuss what is said in the group with others outside of the group.

(9) **Adequacy of Protection from Risks**

(a) Recruitment and Informed Consent

Recruitment will occur through referrals made by providers at Madigan Army Medical Center who they feel may be eligible for and may benefit from participating in this research study. Referrals will come from the Family Advocacy Program (FAP), Embedded Behavioral Health, Chaplain services, Military and Family Life Counselor Program (MFLC), couples retreats, other program and prevention facilities, and through the posting of fliers and brochures in public areas and media advertising to promote the program and to be more inclusive. We will not disclose willingness to participate to anyone else in the service members' unit or in the U.S. Armed forces other than research regulatory bodies. We will also omit the witness signature to protect confidentiality. Finally, only the investigators or the Boston without compensation (WOC) project coordinator may obtain consent from potential participants. Study staff will be available at all times to oversee this process and respond to questions. Two copies of each consent form will be completed. Study volunteers will be given a copy of the consent form for their records. The investigators will keep the other. The original paper copies of the ICFs will be stored on site in a locked filing cabinet in a secure data storage room during the project and will then be securely shipped to the Boston VA via a trackable shipping method (e.g., FedEx). To ensure confidentiality, ICFs will ultimately be stored in a locked filing cabinet in a secure data storage room at the Boston VA.

Informed consent

The consent process will be conducted by program staff at the study site. Informed consent will be conducted with each member of the dyad in separate rooms. No study procedures will occur prior to participants giving informed consent.

For the consent procedure, each individual will meet one-on-one briefly with the study staff member to indicate his/her willingness to participate in the study. The study staff member will review the study procedures and have the individual sign the form if he/she would like to participate.

Screening procedures.

All appropriate service members aged 18 or older, with partners over the age of 18, reporting no occurrence of physical IPA over the prior 3 months in their relationship will be invited with their partners to participate in a screening to determine appropriateness for group intervention and assess study eligibility. Members of the couple will arrive together but be screened separately to ensure confidentiality and safety. Both members of the couple will be administered the DAS to assess relationship distress, partner contact frequency, the MMEA for emotional abuse, the PCL to screen for PTSD, the AUDIT to screen for alcohol use, the CTQ for child abuse and neglect history, the CTS-2 to assess lifetime history of IPA in their current relationship, the suicidality measure, and the demographics questionnaire. If either participant fails to meet study eligibility requirements, the couple's participation will end. If IPA is reported by either partner, the trained psychoeducational facilitator will separately inform them that they are not eligible for this study, and will assess the victim or victims' perceptions of safety, discuss safety planning with the victim(s) (e.g., packing a small bag with a change of clothes and important papers in the event that s/he needs to escape), and will provide them with local contact information for Victim Advocacy services. Victims will be educated by the Victim Advocate about reporting options which include restricted reporting.

In the event a participant endorses suicidal ideation, the facilitator will conduct safety planning and offer a referral to FAP for additional assistance. If there is imminent threat, the facilitator will inform FAP to conduct a formal suicide assessment or accompany the participant to the emergency room. Additionally, if they have a counselor we will direct them to contact their counselor immediately.

(b) Protection Against Risk

Given that all participants will be in a program designed to improve relationships and prevent IPA, the added risks are those associated with the research assessments. All participants will be encouraged to discuss any painful issues that arise during the initial assessment. Those who do not receive intervention will be provided with referrals for counseling during the assessments as well as information on safety and resources for victims of abuse, such as 24-hour hotline numbers and shelter/legal services information. All participants who complete the *Supportive Prevention* group intervention will also have the option to participate in the *Strength at Home-Couples'* intervention.

A second risk involves the possibility that material discussed during assessments will become the topic of a violent conflict. To minimize this risk, all assessments will be conducted separately with partners.

All identifying information (e.g., signed consent forms) will be stored separately from the research questionnaires. Separate locked, secure files will be used to store study materials for each participant, and couple's files will be kept in separate storage areas to ensure confidentiality and safety. Identity masking subject numbers assigned to each participant will be the only means by which collected information is labeled. Each participant will have his or her own assigned number. Subject numbers will reflect the link between participating members of the couple. The only list that will link the names of the participants with their subject numbers will be kept in a secure, password-protected computer account accessible only to the on-site study staff. Study results will be presented and/or published in a fashion to ensure that participants cannot be identified.

Data collected through the REDCap system will be encrypted and unidentifiable to REDCap staff. It will be accessed only by the study staff at Joint Base Lewis-McChord and Boston VA Healthcare System.

(10) **Potential Benefit of the Proposed Research to the Subject and Others**

The risks associated with the project are deemed to be justified on several grounds. First, there may be benefits associated with the research assessment, particularly for those reporting relationship problems and potential IPA, who will have an opportunity to discuss their situation with a trained psychoeducational facilitator. The facilitator will be prepared to complete a safety plan with the victim, provide support, and give information about local hotlines and shelter/legal services. Second, all participants will be scheduled to receive a program designed to prevent aggressive behavior. Finally, the findings are likely to benefit others through the possible enhancement of relationships and prevention of IPA in the future.

(11) **Importance of the Knowledge to be Gained**

There is no currently available evidence-based intervention for military couples to prevent negative trajectories that may include IPV from developing after deployment or upon exposure to trauma. The *Strength at Home-Couples' (SAH-C)* program was designed to fill this gap in services and assist in preventing IPA in those couples who may be at risk for relationship problems. Through a recently completed randomized controlled trial funded by the Centers for Disease Control, we have shown *SAH-C* to be effective in preventing both physical and psychological IPV relative to those receiving a *Supportive Prevention* intervention among veterans and service members within the Department of Veterans Affairs. Before we disseminate *SAH-C* on a large scale on military installations, it would be important to examine its efficacy in this particular setting and to identify any potential barriers and facilitators for implementation. Potential short-term impacts from the current study would be to demonstrate best clinical practices in reducing IPV risk and preventing IPV in military dyads. Long term, study results could assist in changing the way we manage and prevent IPV, not only in military settings, but also beyond the military context since trauma is linked with violence in civilians in addition to military members.

(12) **Resources**

(a) Research Space

The Principal Investigator is a staff psychologist in the National Center for PTSD at the Boston VA Medical Center. He has an office and research lab space at the Jamaica Plain Campus of the Boston VA.

Study staff will be provided an office space and a conference room on Joint Base Lewis-McChord to recruit, assess participants, and hold groups.

(b) Other Research Resources

Joint Base Lewis-McChord maintains its own computer support staff for hardware and software computer assistance.

The software to be used in this study is already in place for all lab studies, and no additional licenses will be required.

(13) **Publications from previous funding period N/A**

(14) **References cited**

See below.

References

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