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

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

CONTRACTING ORGANIZATION:

Boston VA Research Institute, Inc.

Boston, MA 02130

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13. SUPPLEMENTARY NOTES

14. ABSTRACT

There are no significant research findings to report during this period as 24 couples have been enrolled and only 3 have been through the 3-month follow up.

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

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRMC
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Annual Report for Period: Oct 01, 2017 to Sept 30, 2018

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

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

2. **KEYWORDS:** intimate partner violence, domestic violence, partner violence, prevention, veterans, military, couples treatment, marital relationship, trauma, PTSD, relationships, implementation

3. **ACCOMPLISHMENTS:**

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

- Hire and Train Study Staff (months 1-6; 100% complete)
    - The major activities have been to hire and train a research technician at the Boston home site (accomplished Dec 2016) and to hire and train a MA-level project coordinator at the site of the implementation, Madigan Army Medical Center.
    - The study Stakeholder Advisory Board has been assembled and an in person meeting with the Board occurred on September 20, 2017. Topics of discussion included participant recruitment, barriers and facilitators to implementation, and leadership support on base.
    - A total of 12 clinicians were trained in SAH-C on September 20-21, 2017.
    - Stemming from initial discussions with the Advisory Board and IRB staff on the installation, it was determined that it was advisable for us to hire a project coordinator at the study site. This hire of the project coordinator, Brittany Groh, was completed in September 2017.
- Recruitment and intervention for Phase I (100% complete)
    - Recruitment was delayed significantly due to a delay in receiving HRPO approval. HRPO approval was received on 11/21/17.
    - Eight couples were enrolled in pilot phase (three in the active treatment group and five in the supportive group).
    - A total of 11 clinicians have been identified as the clinician research participants. They will be consented if they elect to participate in the implementation research questionnaires. Currently 4 clinicians are clinician participants.
    - Following from consultation with the site PI and the Advisory Board, Ms. Groh has had several meetings with possible referring clinics, Chaplains, Yellow Ribbon, Strong Bonds events, Family Readiness Groups and Family Readiness Liaisons, and other referral sources on the installation.
- Recruitment and Intervention for Phase II (11.4% complete)

- 16 couples have enrolled in the clinical trial phase (10 in the active treatment group and six in the supportive group).

Clinical Trial Status

Recruitment has begun for the trial. 32 individuals (16 couples) have been enrolled in the trial. Please see Consort diagram.

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 are 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

No adverse events

- **What opportunities for training and professional development has the project provided?**
  - Nothing to Report
- **How were the results disseminated to communities of interest?**
  - Nothing to Report
- **What do you plan to do during the next reporting period to accomplish the goals?**
  - Continue to recruit participants, conduct groups, and collect data.

4. **IMPACT:**

- **What was the impact on the development of the principal discipline(s) of the project?**
    - Study staff have reported positive training effects from the *SAH-C* training they attended. The clinicians currently facilitating groups have reported positive results and growth within the couples involved in the study. Further, each clinician believes the curriculum set forth bolsters the working alliance within the couples and group members as a whole.
- **What was the impact on other disciplines?**
    - *Nothing to Report*
- **What was the impact on technology transfer?**
    - *Nothing to Report*
- **What was the impact on society beyond science and technology?**
    - *Nothing to Report*

5. **CHANGES/PROBLEMS:** *The Project Director/Principal Investigator (PD/PI) is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, "Nothing to Report," if applicable:*

- **Changes in approach and reasons for change**
- **Actual or anticipated problems or delays and actions or plans to resolve them**
    - As noted, waiting on HRPO and IRB approvals significantly delayed recruitment, but recruitment has since increased. We have worked closely with all IRBs and have responded promptly when any changes or edits were suggested for the study protocol. Barriers present in the implementation of the program include chain of command, childcare vouchers, chaplains, and the family readiness group. Assistants and secretaries to the Garrison Commander and other high-ranking officers have continually blocked or reduced access to these individuals who have the ability to provide additional support and help with the success of the program. Coordinator has open communication with Garrison Commander's assistant and is going through the appropriate channels to gain the support of the Commander, but it has been a slow process. Staff was promised childcare vouchers, but we have not received any recently due to missing vouchers on the

providers' side and not being able to purchase additional ones until the new budget has been approved. Currently waiting on approved budget and currently working with the Daycare Director to determine who the missing vouchers were given to. There have been a few chaplains who have not been receptive to the program due to the program not meeting the Strong Bonds requirements. We have worked with the LTC for the Madigan Chaplains and have 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 have been difficult to penetrate due to the names and contact information being kept private. Coordinator has made a contact who has educated the coordinator on who to contact about getting into the events and has 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.

- **Changes that had a significant impact on expenditures**
    - *Subawards to Dr. Creech and Dr. Wiltsey-Stirman were executed during Q3 and Q4. We are requesting funds be carried over into Year 4.*
- **Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents**
    - N/A
- **Significant changes in use or care of human subjects: N/A**
- **Significant changes in use or care of vertebrate animals: N/A**
- **Significant changes in use of biohazards and/or select agents: N/A**

6. **PRODUCTS:**

Nothing to Report

7. **PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS:**

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

Name:	Dr. Casey Taft
Project Role:	Principal Investigator

Researcher Identifier (e.g. ORCID ID):	0000-0002-9323-3190
Nearest person month worked:	4
Contribution to Project:	Dr. Taft is in charge of training and supervising project staff via weekly telephone meetings with on-site study personnel and separate weekly meetings with those involved with data management and analysis, and will participate in all aspects of the implementation of the treatment program.
Funding Support:	Boston VA Research Institute

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

Name:	Brittany Groh
Project Role:	Project Coordinator
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	12
Contribution to Project:	Oversees administration of the project from the VA Boston Healthcare System, including coordination with the project sites doing the implementation, preparation of IRB submissions, management of data received from the sites, and supervision of research technicians.

Funding Support:	Boston VA Research Institute

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

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

  - N/A

What other organizations were involved as partners

a.) Organization name: Palo Alto Veterans Institute for Research (PAVIR)
Location: Palo Alto Veterans Institute for Research
3801 Miranda Ave
P. O. Box V-38
Palo Alto, CA 94304-0038

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

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

Location: Central Texas Veterans Research Foundation
1901 South 1st Street
Temple, TX 76504

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

c.) Organization name: Ms. Kristine Blake from Madigan Army Medical Center Family Advocacy Program

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

9490 Jackson Avenue

Tacoma, WA 98431

8. **SPECIAL REPORTING REQUIREMENTS:**

- **QUAD CHARTS:** See Appendix

9. **APPENDIX:**

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

Strength at Home Couples Program to Prevent Military Partner Violence

PT140092, Psychological Health/Traumatic Brain Injury Research Program

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

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

Study/Product Aim(s)

- To test the effectiveness of *SAH-C* for military couples on an installation.
- To explore differences in compliance and process factors across conditions
- To facilitate future implementation of *SAH-C*
  - (a) Examine the barriers to and facilitators for program implementation
  - (b) to test the effectiveness

Approach

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

Timeline and Cost

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

Updated: (10/26/18)

Goals/Milestones

CY15 Goal – Pre-Conditions

☒ Refine and review treatment 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 treatment program

☒ Hire new personnel to be onsite

CY18 Goal – Randomized controlled trial

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

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

CY19 Goal – Randomized control trial

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

❑ Data analysis and preparation for conference presentations will occur

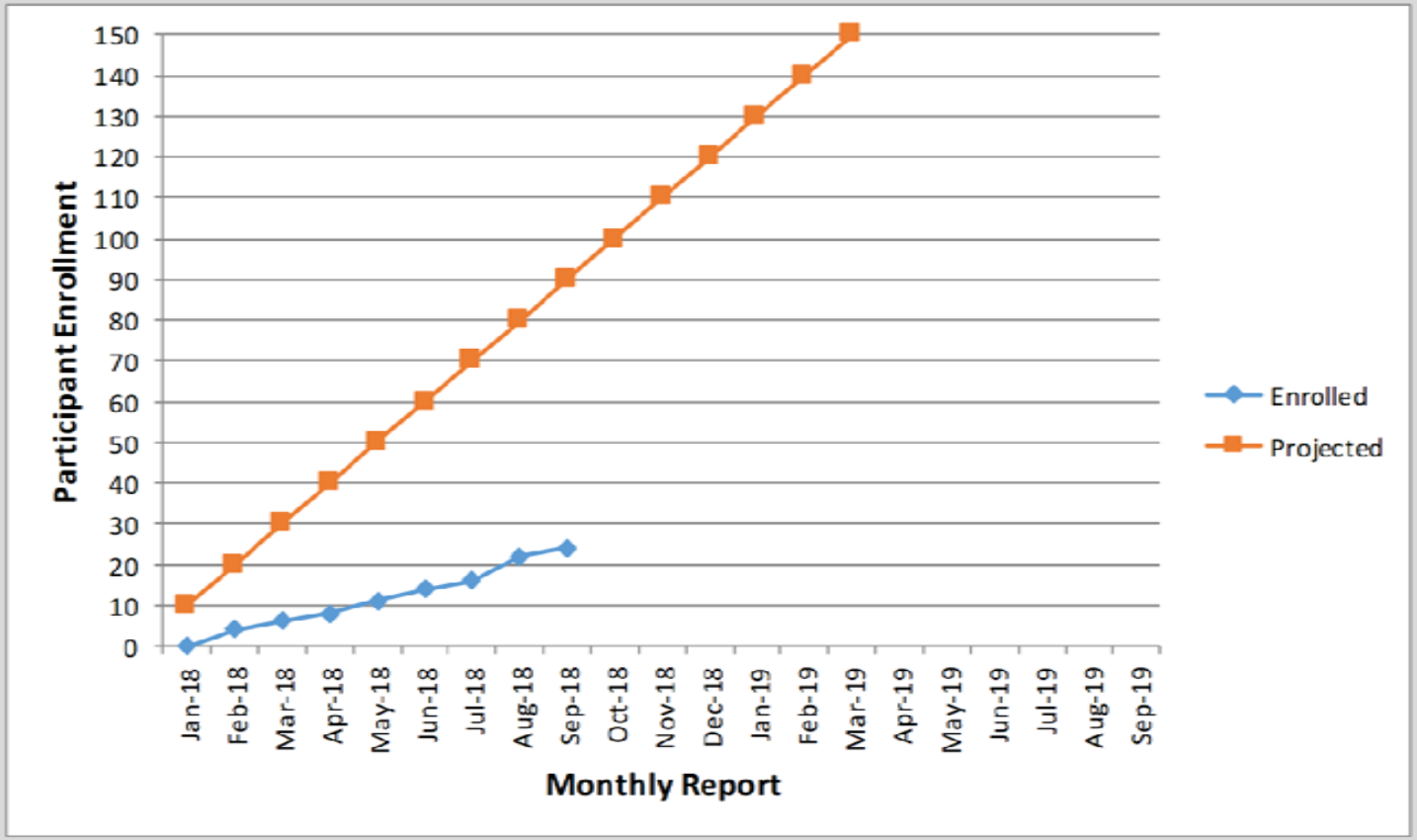
Comments/Challenges/Issues/Concerns: Lower recruitment numbers than expected.

Budget Expenditure to Date

Projected Expenditure: $663,308 *Expected to need a no cost extension*

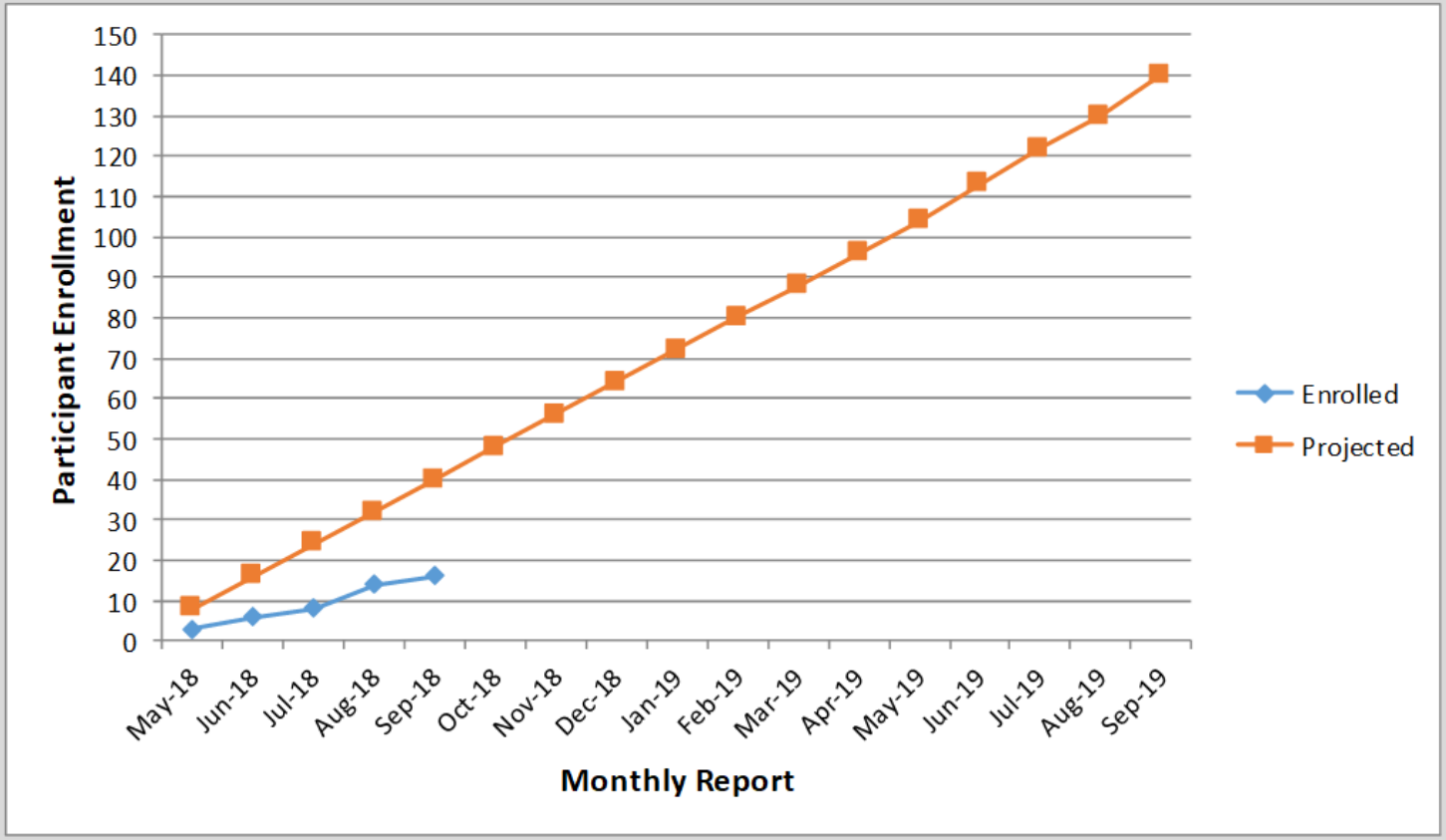
Actual Expenditure: $451,720

Initial Recruitment and Retention Timeline



Note: Projected timeline based on monthly recruitment currently needed to meet project goals given delayed start date.

Updated Recruitment and Retention Timeline



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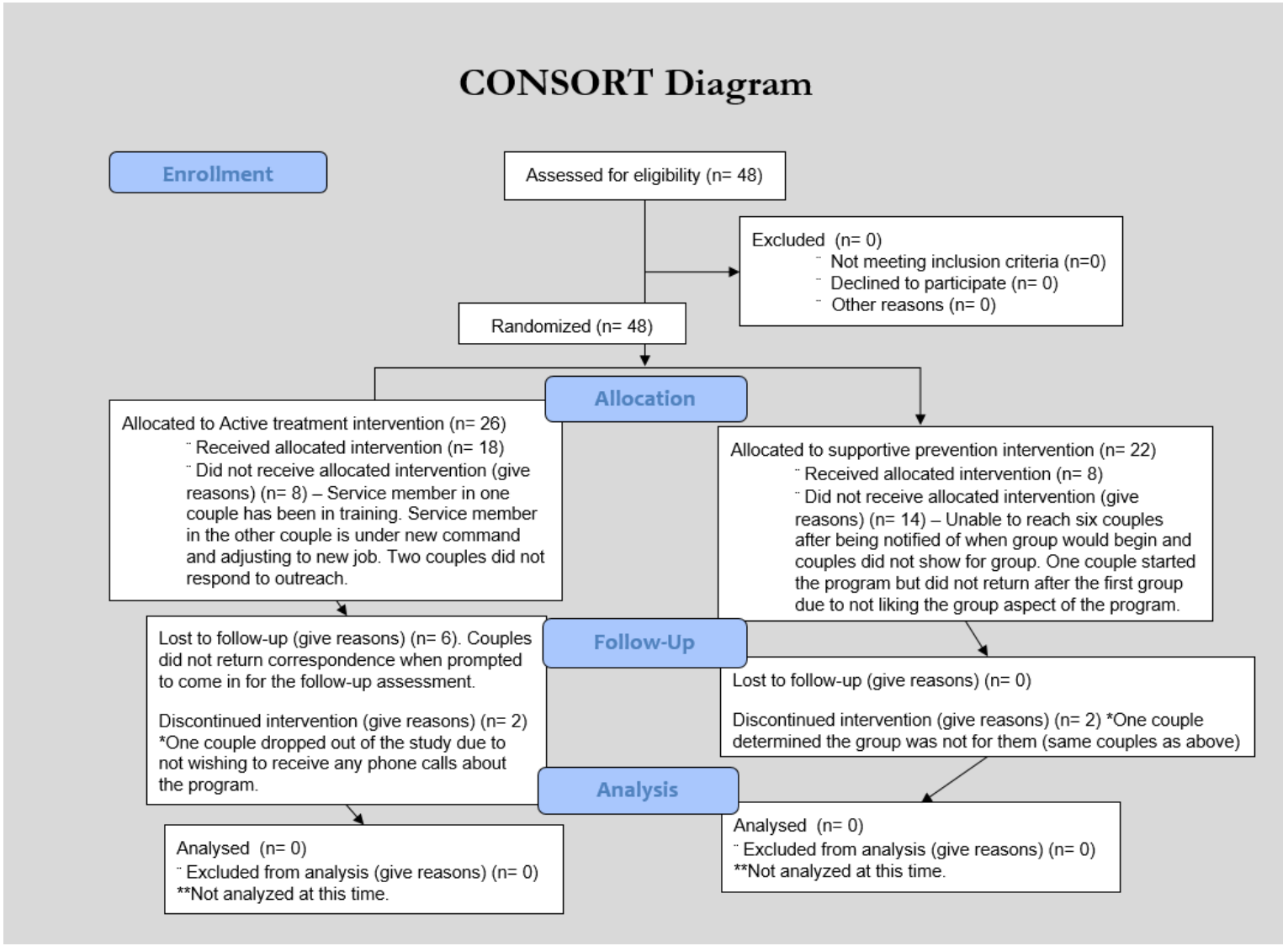
CONSORT Diagram
Enrollment
Assessed for eligibility (n= 48)
Excluded (n= 0)
¨ Not meeting inclusion criteria (n=0)
¨ Declined to participate (n= 0)
¨ Other reasons (n= 0)
Randomized (n= 48)
Allocation
Allocated to Active treatment intervention (n= 26)
¨ Received allocated intervention (n= 18)
¨ Did not receive allocated intervention (give reasons) (n= 8) – Service member in one couple has been in training. Service member in the other couple is under new command and adjusting to new job. Two couples did not respond to outreach.
Allocated to supportive prevention intervention (n= 22)
¨ Received allocated intervention (n= 8)
¨ Did not receive allocated intervention (give reasons) (n= 14) – Unable to reach six couples after being notified of when group would begin and couples did not show for group. One couple started the program but did not return after the first group due to not liking the group aspect of the program.
Follow-Up
Lost to follow-up (give reasons) (n= 6). Couples did not return correspondence when prompted to come in for the follow-up assessment.
Discontinued intervention (give reasons) (n= 2) *One couple dropped out of the study due to not wishing to receive any phone calls about the program.
Lost to follow-up (give reasons) (n= 0)
Discontinued intervention (give reasons) (n= 2) *One couple determined the group was not for them (same couples as above)
Analysis
Analysed (n= 0)
¨ Excluded from analysis (give reasons) (n= 0)
**Not analyzed at this time.
Analysed (n= 0)
¨ Excluded from analysis (give reasons) (n= 0)
**Not analyzed at this time.