

AWARD NUMBER: W81XWH-14-1-0143

TITLE: Comparing Web, Group and Telehealth Formats of a  
Military Parenting Program

PRINCIPAL INVESTIGATOR: Abigail Gewirtz, Ph.D.

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REPORT DATE: JUNE 2020

TYPE OF REPORT: Annual technical report

PREPARED FOR: U.S. Army Medical Research and Materiel Command  
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;  
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# REPORT DOCUMENTATION PAGE

*Form Approved*  
**OMB No. 0704-0188**

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<b>1. REPORT DATE</b> JUNE 2020			<b>2. REPORT TYPE</b> Annual		<b>3. DATES COVERED</b> 1 June 2019 - 31 May 2020	
<b>4. TITLE AND SUBTITLE</b> Comparing Web, Group and Telehealth Formats of a Military Parenting Program					<b>5a. CONTRACT NUMBER</b> W81XWH-14-1-0143	
					<b>5b. GRANT NUMBER</b>	
					<b>5c. PROGRAM ELEMENT NUMBER</b>	
<b>6. AUTHOR(S)</b> Abigail Gewirtz, PhD.  E-Mail: <a href="mailto:agewirtz@umn.edu">agewirtz@umn.edu</a>					<b>5d. PROJECT NUMBER</b>	
					<b>5e. TASK NUMBER</b>	
					<b>5f. WORK UNIT NUMBER</b>	
<b>7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)</b> Regents of the University of Minnesota Office of Sponsored Projects 200 Oak Street SE 450 McNamara Alumni Center Minneapolis, MN 55455-2070					<b>8. PERFORMING ORGANIZATION REPORT NUMBER</b>	
<b>9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)</b>  U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012					<b>10. SPONSOR/MONITOR'S ACRONYM(S)</b>	
					<b>11. SPONSOR/MONITOR'S REPORT NUMBER(S)</b>	
<b>12. DISTRIBUTION / AVAILABILITY STATEMENT</b>  Approved for Public Release; Distribution Unlimited						
<b>13. SUPPLEMENTARY NOTES</b>						
<b>14. ABSTRACT</b> By December of 2012 approximately 2.2 million US military personnel will have served one or more times in Iraq or Afghanistan in support of Operations Enduring Freedom, Iraqi Freedom (OEF/OIF), and New Dawn (Institute of Medicine/IOM 2013). Stress associated with family separation, combat, and reintegration is extremely disruptive for parents and children. Returning service members and their families are particularly vulnerable during the reintegration period post-deployment. Risks include increases in stress, anxiety and depression, PTSD, and substance use and abuse. These outcomes lead to disruptions in interactions between parents, children, and spouses, increasing risk for children's emotional, behavior problems, and substance use. The overarching goal of our study is to address existing gaps and identified National Guard Reserve (NGR) needs that will inform the portability and access of NGR families to evidence-based programs by conducting a three-group, two-site randomized trial to test the comparative effectiveness of three ADAPT delivery approaches for 360 reintegrating NGR families randomly assigned to: (i) ADAPT group-based; (ii) ADAPT individualized web-facilitated; or (iii) ADAPT self-directed online. Families will complete pre-intervention baseline (BL) assessment (pre-test) and three post-test assessments at 6, 12- and 24 months. We hypothesize that NGR families in both the ADAPT group-based condition and the ADAPT individualized web-facilitated condition will show greater pre-post improvements in observed parenting, and parent, child, and couple functioning relative to the self-directed online condition and the ADAPT group-based condition will be equally effective as the individualized ADAPT web-facilitated condition.						
<b>15. SUBJECT TERMS</b> Parenting, military, comparative effectiveness, children, randomized trial, prevention						
<b>16. SECURITY CLASSIFICATION OF:</b>			<b>17. LIMITATION OF ABSTRACT</b>  Unclassified	<b>18. NUMBER OF PAGES</b>  15	<b>19a. NAME OF RESPONSIBLE PERSON</b> USAMRMC	
<b>a. REPORT</b>  Unclassified	<b>b. ABSTRACT</b>  Unclassified	<b>c. THIS PAGE</b>  Unclassified			<b>19b. TELEPHONE NUMBER (include area code)</b>	

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## 1. INTRODUCTION

By December of 2012 approximately 2.2 million US military personnel will have served one or more times in Iraq or Afghanistan in support of Operations Enduring Freedom, Iraqi Freedom (OEF/OIF), and New Dawn (Institute of Medicine/IOM 2013). Stress associated with family separation, combat, and reintegration is extremely disruptive for parents and children. Returning service members and their families are particularly vulnerable during the reintegration period post-deployment. Risks include increases in stress, anxiety and depression, PTSD, and substance use and abuse. These outcomes lead to disruptions in interactions between parents, children, and spouses, increasing risk for children's emotional, behavior problems, and substance use. While the need to support military families has been identified as an important national priority by numerous government-supported task forces, major gaps in effectively serving military families remain. First, most intervention and outreach efforts are guided by models lacking empirical support or programs lacking a strong theoretical background. A large majority of evaluations do not include rigorous methodology, randomization, implementation in real world settings, or long-term follow up. Second, many barriers remain for military families not living near a military competent treatment center or Veterans Administration Medical Center. The After Deployment Adaptive Parenting Tool (ADAPT) study is the only study to date with preliminary evidence from an RCT. We propose to address existing gaps and identified NGR needs that will inform the portability and access of NGR families to evidence-based programs.

**Specific Aim 1:** Evaluate the usability and acceptability of the individualized web-facilitated ADAPT condition with 5 military families, and an expert stakeholder panel. Compare recruitment, retention, and satisfaction with the web-facilitated condition with existing data on the ADAPT group-based and self-directed conditions.

**Specific Aim 2:** Conduct a three-group, two-site randomized trial to test the comparative effectiveness of three ADAPT delivery approaches for 360 reintegrating NGR families randomly assigned to: (i) ADAPT group-based; (ii) ADAPT individualized web-facilitated; or (iii) ADAPT self-directed online. Families will complete pre-intervention baseline (BL) assessment (pre-test) and three post-test assessments at 6, 12- and 24 months.

**Specific Aim 3:** Evaluate generalizability of ADAPT effectiveness across three intervention delivery approaches using intent to treat (ITT) analyses. We will specifically test the value-added impact of group-based delivery relative to web-facilitated and web self-directed approaches. Comparative effectiveness will be tested by specifying a non-equivalence hypothesis for group-based and web-facilitated relative to self-directed only.

- ***Aim 3 Hypothesis 1.*** NGR families in both the ADAPT group-based condition and the ADAPT individualized web-facilitated condition will show greater pre-post improvements in observed parenting, and parent, child, and couple functioning relative to the self-directed online condition.

***Aim 3 Hypothesis 2.*** In testing intent to treat comparative effectiveness, the ADAPT group-based condition will be equally effective as the individualized ADAPT web-facilitated condition

## 2. KEY WORDS

Parenting, military, comparative effectiveness, children, randomized trial, prevention

## 3. ACCOMPLISHMENTS

### **What were the major goals of the project?**

Task 1: Prepare University of Minnesota IRB and DOD regulatory documents for review and approval.

- 1a. Finalize human subjects protocol and consent documents for pilot group (N=5 families), and randomized controlled trial (N=360 families).

Task 2: Recruit for open positions (coordinator in MI and MN) and process paperwork to hire all project staff.

Task 3: Obtain U of MN IRB approval (Y1 Mos. 1-3)

Task 4: Obtain DoD HRPO approval (Y1 Mos. 1-6)

### ***Aim 1: Examine the usability and acceptability of the delivery format for the individualized web-facilitated ADAPT:***

Task 5: Systematically modify ADAPT web-facilitated delivery format in consultation with Advisory Group

- 5a. Convene expert panel (Y1 Mos. 4-5)
- 5b. Refine existing ADAPT materials (online/Google Hangout and manual) (Y1 Mos 1-10)
- 5c. Conduct pilot group to test usability (Y1 Mos. 6-9)
- 5d. Analyze pilot group data to inform materials and RCT (Y1 Mos. 9-10)

Task 6: Train facilitator staff in MI and MN to deliver ADAPT group with fidelity (Y1 Mos 7-12)

### **Aim 2. Conduct a three-group, two-site randomized trial to test the comparative effectiveness of ADAPT delivery approaches.**

Task 7: Recruit three cohorts of 60 families per cohort in Minnesota (20 online, 20 group, 20 web-facilitated) and 60 families per cohort in Michigan (20 online, 20 group, 20 web-facilitated) for a total of 360 families (120 per cohort). (Y1 Mos. 11-12; Y2 Mos. 13-24; Y3 Mos. 25-26)

- 7a. Obtain informed consent and complete baseline and subsequent assessments of adult adjustment, observational measures of parenting, measures of child, and couple adjustment. (Y1 Mos 11 – Y5 Mo 50)
- 7b. Randomly assign families to online ADAPT, web-facilitated ADAPT or group ADAPT; families invited to program (Cohort 1: Y1 Mos. 11-13; Cohort 2: Y2 Mos. 18-20; Cohort 3: Y2 Mos. 24 - Y3. Mo. 26)
- 7c. Assess parent satisfaction ratings via questionnaires at end of each session (Y1 Mo. 12 – Y3 Mo. 30)

### **Aim 3. Test the generalizability of ADAPT effectiveness across three delivery approaches using intent to treat (ITT) analyses**

Task 8. Clean and analyze outcome data to examine differential effectiveness (Y2 Mo 24 – Yr 5 Mo 60)

## **What was accomplished under these goals?**

### Task 7

7a. Completing subsequent assessments of adult adjustment, observational measures of parenting, measures of child, and couple adjustment.

-47 T4 (2-year, final time points remaining) 30 MN, 17 MI

Task 8. Clean and analyze outcome data to examine differential effectiveness

-preliminary analysis presented below

### **Other accomplishments:**

-Retention has remained strong. Of the 244 families who have completed their T1, we have lost 20 due to attrition.

### **ADAPT4U Attendance**

A total of 244 families consented to participate in the study. Of those families, 78 families were randomized to online, 71 to telehealth, and 95 to group condition. Proportions of families who attended at least one session were 74.6% (n=53) for telehealth, 70.5% (n=55) for online and 53.7% (n=51) for group condition [ $\chi^2$  (2, N=244)=9.31,  $p = .010$ ]. Significant chi-square result indicated that telehealth and online had higher proportion of participants who attended one or more sessions compared to group. Mean attendance rates were online 83.3% (SD=28.0), telehealth 88.8% (SD=25.3), and group 65.6% (SD=29.5) [ $F(2, 156)=10.01, p<.001$ ]. Post-hoc Bonferroni tests showed that online ( $p=.004$ ) and telehealth ( $p<.001$ ) had significantly higher mean attendance rates compared to the group condition. Proportions of families who attended 50% or more sessions among those who attended at least one session were 88.7% (n=47) for telehealth, 85.5% (n=47) online, and 70.6% (n=36) group. Chi-square test showed that telehealth and online had significantly higher rates of 50%+ attendance compared to the group condition [ $\chi^2$  (2, N=159)=6.47,  $p = .039$ ].

### **Preliminary Outcome Analyses**

Intervention effects on outcomes assessed at post-intervention (T2) were analyzed using ANCOVAs with intervention condition (online, telehealth, group) as an independent variable, and site (MN and MI) and baseline outcome (T1) as covariates. Outcomes included parent variables (APQ, PLOC, CESD, PCL) and child externalizing and internalizing problems (BASC2). Results showed that there were no significant differences among the three conditions at T2. Next, telehealth and group conditions were combined and compared to the online condition. Post-intervention outcomes were analyzed using ANCOVAs with site and baseline outcome variable as covariates. At T2, the combined conditions showed significantly higher father-reported parenting efficacy (PLOC) compared to the online condition ( $p=.040$ ). Analyses of relationship satisfaction (DAS) at T2 revealed that mothers assigned to the online condition reported higher satisfaction compared to the telehealth and group combined ( $p = .029$ ). Analyses of child externalizing and internalizing problems showed that fathers assigned to telehealth and group (combined) reported significantly lower child externalizing and internalizing problems at T2 compared to fathers in the online condition ( $p=.023$  and  $p=.042$ , respectively).

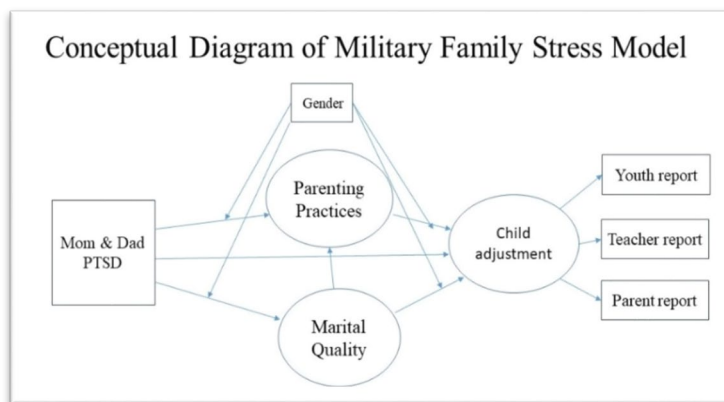
## Preliminary Outcome Analyses (UPDATED June 2020)

Latent growth curve modeling was used to examine the differential effects of the three interventions (online, telehealth, group) on outcomes assessed at baseline, post-intervention (6 months post-baseline), and 6-month follow-up (12 months post-baseline). Analyses included growth parameters (intercept and slope), intervention conditions as independent variables, and site (MN and MI) as covariates. Intervention effects were compared on parents' self-reports of parenting (APQ, PLOC), marital satisfaction (DAS), and mindfulness (FFMQ). Results showed that there were no significant differences in rates of change over time among the three conditions. Next, online and telehealth conditions were combined and compared to the group condition. Latent growth curve analyses showed that fathers in the group condition had significant improvement in marital satisfaction over time compared to those in the combined condition ( $p=.013$ ). Also, both fathers and mothers in the group condition showed significant improvement in mindfulness-nonjudging over time compared to those in the combined condition ( $p=.021$ ,  $p=.034$ , respectively). We will examine moderator effects (e.g., dosage, length of deployment, parent mental health) on the relationship between intervention conditions and parent/child outcomes.

### Military Family Stress Model Analysis

Examination and validation of a military family stress model is underway using the current study sample. Multi-method (self-report, observational), multi-informant (parent, teacher, child) data collected at baseline were used in the analyses. Hypothesized relationships between parents' posttraumatic stress, marital quality, parenting practices, and child adjustment are depicted in the figure. Each path is well supported by developmental and family process research.

Moderating effects of parent gender on the processes/pathways were also examined. Preliminary results showed that (1) mothers' and fathers' PTSD symptoms were negatively associated with marital quality; (2) marital quality was positively associated with parenting practices, which were in turn positively related to child adjustment; (3) there was a significant indirect effect of marital quality on child adjustment through parenting practices; (4) there was a marginally significant indirect association between PTSD symptoms and parenting practices through marital quality; and (5) no significant gender differences were found in the processes described in the military family stress model.



**What opportunities for training and professional development has the project provided?**

On-going assessment technician training is provided both in Minnesota and Michigan. Our data manager routinely trains students (5-6) to manage data and conduct analysis. Similarly, our coding manager has trained numerous cohorts of student volunteers (6-8) to code observational data.

As a side note: A non-research grant funded by Bristol Myers Squibb Foundation to implement ADAPT in the primary care system of Womack Army Medical Center on Fort Bragg, NC will also afford us the opportunity to train multiple cohorts of providers to deliver the ADAPT program to installation families.

**How were the results disseminated to communities of interest?**

As outcome data are generated we will be submitting conference abstracts to the Society for Prevention Research and other conferences, as well as stakeholders on the installations.

**What do you plan to do during the next reporting period to accomplish the goals?**

Our main goals for the next 3 months are to (1) actively engage with families in order to retain all 224 active families, (2) complete remaining data collection time points for 47 families and (3) continue data cleaning and analysis of outcome data.

**4. IMPACT****What was the impact on the development of the principal discipline(s) of the project?**

Nothing to report yet. Impact will be reported in our final report.

**What was the impact on other disciplines?**

Nothing to report yet. Impact will be reported in our final report.

**What was the impact on technology transfer?**

Nothing to report yet. Impact will be reported in our final report.

**What was the impact on society beyond science and technology?**

Nothing to report yet. Impact will be reported in our final report.

**5. CHANGES/PROBLEMS****Changes in approach and reasons for change**

We have an additional 3 month extension, beyond our year 6 no cost extension, to finish remaining data collection for 47 families and analyzing of outcome data.

**Actual or anticipated problems or delays and actions or plans to resolve them**

Beginning in March until present, in-person data collection was paused due to COVID-19. Recently we have been asked to be a Tier 4 study “pilot” to complete final time point data collection with 30 Minnesota families using a newly developed COVID-19 protocol. This protocol is currently being reviewed by the University’s IRB but has been approved by the Office of the Vice President for Research. The remaining study families – 17 in Michigan – will complete their final study time point by survey only.



**Changes that had a specific impact on expenditures**

Payments to study participants for data collection at corresponding time points will continue to be disbursed.

Current budget projections show that we are over. If needed, non-sponsored funds will be used to balance the final budget.

**Significant changes in use or care of human subjects**

Nothing to report

**6. PRODUCTS****Publications, conference papers, and presentations****Journal publications**

Nothing to report at this time

**Books or other non-periodical, one-time publications**

Nothing to report at this time

**Other publications, conference papers, and presentations**

Nothing to report at this time

**Website(s) or other Internet site(s)**

Our study website which is used for recruiting and will be used to disseminate study results is ADAPT.umn.edu

Online ADAPT curriculum can be accessed at <https://adapt4u.talentlms.com> with an assigned username and password.

**Technologies or techniques**

Nothing to report

**Inventions, patent applications, and/or licenses**

Nothing to report

**Other products**

Nothing to report

## 7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

While several additional individuals have contributed time and effort to the various goals and objectives reported during this period, none of them has individually contributed more than 160 hours (one person-month).

### What individuals have worked on the project?

Name: Gewirtz, Abigail

Role: PI

Person months: 2.0 months

Contribution: Overall study oversight and strategic decision making; ensure study outcomes are achieved

Funding support: This award

Name: Majerle, Amy

Role: Project Manager

Person months: 5.0 months

Contribution: Overall management of study tasks and personnel; track study milestones; design study data collection tools

Funding support: This award

Name: Tiede, Shauna

Role: Assistant Project Manager

Person months: 5.0 months

Contribution: Overall management of in-home assessments of participants; create study manuals; train study technicians

Funding support: This award

Name: Kadie Ausherbauer

Role: Coding Manager

Person months: 3.0 months

Contribution: Manage team performing coding of assessments, manage coded data

Funding support: This award

Name: Susanne Lee

Role: Data Manager

Person months: 5.0 months

Contribution: Management and analysis of study data

Funding support: This award

Name: Rachel Weiss

Role: Community Program Assistant

Person months: 5.5 months

Contribution: Teacher data collection, pre- and post-in-home assessment tasks

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

**GEWIRTZ, Abigail**

Current Support

*Title:* Comparing Web, Group, and Telehealth Formats of a Military Parenting Program (PI)  
[this award]

*ID#:* W81XWH-14-1-0143

*Period:* 6/1/2014 – 5/31/2019

*Effort:* 15%

*Funding:* \$555,334 for Year 5

*Supporting agency & contact:*

Department of Defense

Michelle Lane, [michelle.d.lane9.civ@mail.mil](mailto:michelle.d.lane9.civ@mail.mil)

*Goals/Specific Aims:* The goal of this project is to compare the effectiveness of three different delivery formats (online, group, and telehealth) of the After Deployment Adaptive Parenting Tools (ADAPT) preventive intervention, an empirically supported parenting program for military families.

*Title:* SMART Optimization of a Parenting Program for Active Duty Families (PI)

*ID#:* W81XWH-16-1-0407

*Period:* 9/30/2016 – 9/29/2020

*Effort:* 23%

*Funding:* \$900,840 for Year 3

*Supporting agency & contact:*

Department of Defense

Michelle Lane, [michelle.d.lane9.civ@mail.mil](mailto:michelle.d.lane9.civ@mail.mil)

*Goals/Specific Aims:* The objective of this study is to yield the optimal dosage, components, and sequence of a parenting program for active duty military families (ADAPT) in diverse operational tempo contexts (i.e. regular Army families and Special Operations families).

*Change:* This is a new active grant.

*Title:* The Center for Resilient Families (PI)

*ID#:* U79 SM080009-01

*Period:* 9/30/2016 – 9/29/2021

*Effort:* 20%

*Funding:* \$599,997 for Year 3

*Supporting agency & contact:*

DHHS SAMHSA

Maryann Robinson, [maryann.robinson@samhsa.hhs.gov](mailto:maryann.robinson@samhsa.hhs.gov)

*Goals/Specific Aims:* The Center for Resilient Families aims to raise awareness of and increase access to family interventions to promote resilience in traumatized children. The Center will reduce disparities in service access, use, and training by targeting trauma-informed family interventions to isolated families in transition: those with a parent deployed to war, Native American families on reservations, immigrant and refugee families, families involved in the juvenile justice and child welfare systems, and families in which a parent has been killed.

*Change:* This is a new active grant.

*Title:* Implementation of ADAPT across the FT Bragg, NC, military health system (PI)

*ID#:*

*Period:* 5/1/2019 – 1/31/2023

*Effort:* 10%

*Funding:* \$1,148,684

*Supporting agency & contact:*

Bristol-Myers Squibb Foundation

Katherine Masuch, [Katherine.Masuch@bms.com](mailto:Katherine.Masuch@bms.com)

*Goals/Specific Aims:* The goal of this project is to improve military family adjustment via the large-scale implementation of the ADAPT program within the medical system of care at Womack Army Medical Center on FT Bragg, NC.

#### Recently Completed Support

*Title:* Midwest Continuum of Care for Child Trauma (PI)  
*ID#:* U79 SM056177 *Period:* 12/30/2005 – 9/29/2016  
*Effort:* 50% *Funding:* \$399,997/year  
*Supporting agency & contact:* DHHS SAMHSA  
 Cicely Burrows-McElwain, Program Official  
[cicely.burrows-mcelwain@samhsa.hhs.gov](mailto:cicely.burrows-mcelwain@samhsa.hhs.gov)

*Goals/Specific Aims:* The goals of this project are to 1) improve access to trauma-informed practices and treatment for traumatized children and families; 2) implement and sustain evidence-based trauma treatment models in the Upper Midwest; and 3) build and maintain consensus for child trauma.

*Title:* Evaluation of a TF-CBT Learning Collaborative (PI)  
*ID#:* 56797 *Period:* 2/7/2013 – 12/31/2016  
*Effort:* 1% *Funding:* \$42,213/year  
*Supporting agency & contact:* Minnesota Department of Human Services  
 Patricia Nygaard, [pat.nygaard@state.mn.edu](mailto:pat.nygaard@state.mn.edu)

*Goals/Specific Aims:* The purpose of this contract was to provide evaluation of training and consultation efforts to expand within the mental health provider community the clinical capacity to provide Trauma-Focused Cognitive Behavioral Therapy.

*Title:* Evaluation of the Sesame Street for Military Families: Transitions Program (PI)  
*ID#:* NA *Period:* 1/22/2016 – 12/31/2016  
*Effort:* 5% *Funding:* \$170,000  
*Supporting agency & contact:* Sesame Workshop  
 David Cohen, [david.cohen@sesame.org](mailto:david.cohen@sesame.org)

*Goals/Specific Aims:* The goal of this project is to assess parental and child response to the Sesame Workshop's Military Families: Transitions program.

#### What other organizations were involved as partners?

Organization name: University of Michigan  
 Location of organization: Ann Arbor, MI  
 Partner's contribution: Collaboration

Organization name: University of Oregon  
 Location of organization: Eugene, OR  
 Partner's contribution: Collaboration

Organization name: Implementation Sciences International, Inc.  
 Location of organization: Eugene, OR  
 Partner's contribution: Collaboration

Organization name: Marquez Production  
Location of organization: Eugene, OR  
Partner's contribution: Collaboration

## **8. SPECIAL REPORTING REQUIREMENTS**

**Collaborative awards:** Not applicable

**Quad Chart:** See attached

## **9. APPENDICES**

# Comparing Web, Group, and Tele-health Formats of a Military Parenting Program

Log Number: NH13001 - EDMS 5832

W81XWH-14-1-0143



PI: Dr. Abigail Gewirtz

Org: University of Minnesota

Award Amount: \$3,051,363

## Study/Product Aim(s)

Specific Aim 1: Conduct a three-group, two-site randomized trial to test the comparative effectiveness of ADAPT delivery approaches.

Specific Aim 2: Test the generalizability of ADAPT effectiveness across three delivery approaches using intent to treat (ITT) analyses.

## Approach

The study will randomly allocate 360 NGR families to one of three conditions: (i) group-based web-enhanced ADAPT; (ii) individualized web-facilitated ADAPT; or (iii) self-directed web ADAPT. Families, with a child aged 5-12, will be enrolled if one parent has deployed to OEF or OIF. Families will complete a pre-intervention baseline (BL) assessment. Families will complete post-intervention follow-up assessments at 6, 12, and 24 months.

We will test the value-added impact of group-based delivery relative to facilitated and self-directed web approaches. Comparative effectiveness will be tested by specifying a non-equivalence hypothesis for group based and individualized facilitated relative to self-directed web only.



# ADAPT 4 U

Preliminary results suggest that ADAPT is feasible, acceptable, and associated with improvements in parenting, couple adjustment, and emotional awareness. Thus, we have experience engaging both military parents.

## Timeline and Cost

Activities	CY	14-15	15-16	16-17	17-18	18-19
Prepare IRB/DOD regulatory documents Recruit and staff open positions Modify ADAPT delivery format						
Recruit and randomize participants						
Complete baseline and subsequent participant assessments						
Conduct outcome data cleaning and analysis						
Examine differential effectiveness						
<b>Estimated Budget (\$K)</b>		\$255,831	\$536,315	\$749,455	\$821,636	\$688,125

## Goals/Milestones

### CY14 Goal –Project Preparation

- Obtained IRB/DOD approval
- Hire project staff- Staffed Key study personnel
- Modified ADAPT curriculum and delivery format
- Test ADAPT curriculum for usability- Piloted ADAPT curriculum for usability

### CY15 Goal – Recruit and Randomize Participants

- Participants recruitment commenced June 18, 2015
- Commenced baseline assessment on enrolled families

### CY16 Goal –Conduct Randomized Control Trial

- Deliver ADAPT group with fidelity

### CY 17 Goal – Conduct Randomized Control Trial and conduct participant assessments

- Deliver ADAPT group with fidelity
- Assess adult adjustment, observational parenting, child and couple measures

### CY 18 Goal - Data Cleaning and Analysis

- Create data management structure to organize, clean and analyze data

### CY19 Goal – Examine differential effectiveness

- Begin outcome data cleaning and analysis

### Comments/Challenges/Issues/Concerns

We are waiting on approval for our newly developed protocol that would allow us to complete our 30 remaining T4 (final time points) face to face during current COVID-19 restrictions. Office of the Vice President for Research requested that ADAPT serve as a pilot for Tier 4 studies.

### Budget Expenditure to Date

Amount spent in Y6 Q4 (03/01/2020 – 5/31/2020): **\$76,018.06 total costs**

Amount spent to date (06/01/14 – 05/31/2020): **\$3,103,267.31 total costs**

Updated: June 30th, 2020