

AWARD NUMBER: W81XWH-16-1-0407

TITLE: SMART Optimization of a Parenting Program for Active Duty Families

PRINCIPAL INVESTIGATOR: Abigail Gewirtz, Ph.D.

RECIPIENT: Regents of the University of Minnesota
Minneapolis, MN

REPORT DATE: October 2021

TYPE OF REPORT: Annual report

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

DISTRIBUTION STATEMENT: Approved for Public Release; Distribution Unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. **PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.**

1. REPORT DATE October 2021			2. REPORT TYPE Annual			3. DATES COVERED 30Sep2020 - 29Sep2021			
4. TITLE AND SUBTITLE SMART Optimization of a Parenting Program for Active Duty Families						5a. CONTRACT NUMBER W81XWH-16-1-0407			
						5b. GRANT NUMBER			
						5c. PROGRAM ELEMENT NUMBER			
6. AUTHOR(S) Abigail Gewirtz, PhD. E-Mail: agewirtz@umn.edu						5d. PROJECT NUMBER			
						5e. TASK NUMBER			
						5f. WORK UNIT NUMBER			
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Regents of the University of Minnesota Office of Sponsored Projects 200 Oak Street SE 450 McNamara Alumni Center Minneapolis, MN 55455-2070						8. PERFORMING ORGANIZATION REPORT NUMBER			
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012						10. SPONSOR/MONITOR'S ACRONYM(S)			
						11. SPONSOR/MONITOR'S REPORT NUMBER(S)			
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited									
13. SUPPLEMENTARY NOTES									
14. ABSTRACT The objective of this study is to provide ways to meet the needs of military families experiencing deployments by testing a program to strengthen parenting and family resilience (i.e. children's wellbeing, parents' adjustment, and marital relationships). After Deployment, Adaptive Parenting Tools (ADAPT) is a family resilience program which helps parents to be their children's best teachers by providing them with effective positive parenting tools. Prior rigorous research on ADAPT has shown that it benefits service members, their partners, and their children. The program appears to improve parents' sense of control, or feelings of confidence in their parenting, and these improvements lead to better observed parenting, children's better adjustment, and less distress among and between parents. Families' needs differ – some parents need or want less intensive or online programs, whereas others may need more intensive or in-person programs; some parents may do better in a group program whereas others may need individual support. This study examines multiple formats, 'doses,' and sequences of the ADAPT program in a sequential, multiple assignment, randomized trial (SMART) study design. This is a 2-stage study, whereby families are first randomized to one of two 'small dose' ADAPT interventions (i.e. workshop or online programs), and if they need further support (i.e. are not helped by the program, as indicated by their responses on a measure of parenting sense of control) they are subsequently randomized again, either to have access to a booster group program or a booster individual family ADAPT format. The various formats and sequences are evaluated against each other to determine what works best for whom. This is an innovative study that will advance the field of personalization or tailoring; it is the first military family personalization SMART that we know of. Based on earlier research, we expect the program to benefit families (improving adult, child, and couple adjustment, as well as parenting) but we also expect it to benefit military family providers, giving options for alternative sequences, doses, and components. Another contribution of this study is that it is one of the few studies that will examine how high operational tempo conditions affect family resilience, and how a parenting program might buffer those conditions, strengthening resilience.									
15. SUBJECT TERMS Parenting, children, family resilience, military, SMART design, prevention									
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						
Unclassified	Unclassified	Unclassified	Unclassified		25	19b. TELEPHONE NUMBER (include area code)			

TABLE OF CONTENTS

	<u>Page No.</u>
1. Introduction	3
2. Keywords	3
3. Accomplishments	4
4. Impact	6
5. Changes/Problems	7
6. Products	8
7. Participants & Other Collaborating Organizations	9
8. Special Reporting Requirements	17
9. Appendices	17

1. INTRODUCTION:

The objective of this study is to provide ways to meet the needs of military families experiencing deployments by testing a program to strengthen parenting and family resilience (i.e. children's wellbeing, parents' adjustment, and marital relationships). After Deployment, Adaptive Parenting Tools (ADAPT) is a family resilience program which helps parents to be their children's best teachers by providing them with effective positive parenting tools. Prior rigorous research on ADAPT has shown that it benefits service members, their partners, and their children. The program appears to improve parents' sense of control, or feelings of confidence in their parenting, and these improvements lead to better observed parenting, children's better adjustment, and less distress among and between parents. Families' needs differ – some parents need or want less intensive or online programs, whereas others may need more intensive or in-person programs; some parents may do better in a group program whereas others may need individual support. This study examines multiple formats, 'doses,' and sequences of the ADAPT program in a sequential, multiple assignment, randomized trial (SMART) study design. This is a 2-stage study, whereby families are first randomized to one of two 'small dose' ADAPT interventions (i.e. workshop or online programs), and if they need further support (i.e. are not helped by the program, as indicated by their responses on a measure of parenting sense of control) they are subsequently randomized again, either to have access to a booster group program or a booster individual family ADAPT format. The various formats and sequences are evaluated against each other to determine what works best for whom. This is an innovative study that will advance the field of personalization or tailoring; it is the first military family personalization SMART that we know of. Based on earlier research, we expect the program to benefit families (improving adult, child, and couple adjustment, as well as parenting) but we also expect it to benefit military family providers, giving options for alternative sequences, doses, and components. Another contribution of this study is that it is one of the few studies that will examine how high operational tempo conditions affect family resilience, and how a parenting program might buffer those conditions, strengthening resilience.

2. KEYWORDS:

Parenting, children, family resilience, military, SMART design, prevention

3. ACCOMPLISHMENTS:

What were the major goals of the project?

NOTE: A revised SOW was submitted and approved. Major changes: addition of Forts Belvoir/Myer as a third study site, inclusion of all active duty branches for Forts Belvoir/Myer, new N of 525 since no SOF recruitment at Forts Belvoir/Myer.

Specific aims are as follows:

1. Compress existing ADAPT group and individual programs for active-duty SO and RA deployed military families.
2. Conduct a SMART with 525 active-duty families to examine the impact of ADAPT on *multiple outcomes* (i.e., (i) coercive family interactions, positive parenting, couple adjustment and co-parenting, (ii) adult PTSD symptoms, depression symptoms, substance use, and (iii) child behavior and emotional problems, and positive adjustment. Specific *optimization* questions are as follows:
Research Question 2a: Is starting with condensed group modality more effective in improving multiple outcomes than starting with online self-directed?
Research Question 2b: Among non-responders to ADAPT condensed group or ADAPT online is subsequent individual or group based programming more effective for improving multiple outcomes?
Research Question 2c: Which of the four embedded sequences of adaptive interventions has the greatest impact (i.e., effect size/ES) on multiple outcomes?
3. Address the following *exploratory optimization* research questions to examine the ability of putative secondary tailoring variables (OPTEMPO, gender) to predict differential response to the 4 embedded AIS sequences
 - a) Will high OPTEMPO (SO) families benefit most from AIS beginning with condensed groups when compared with AIS beginning with a flexible online self-directed format?
 - b) Will fathers benefit most from AIS that include group-based, second-stage interventions when compared to AIS with individually-based, second-stage interventions?
4. Describe and document key process variables: parents' participation and satisfaction with the programs, and fidelity of implementation by providers delivering the in-person programs.

Major Task 1: Pre-award tasks

Subtask 1: Prepare regulatory documents and research protocol

Subtask 2: Coordinator study staff for SMART

Major Task 2: Adapt existing ADAPT curricula for active-duty contexts

Note: Curriculum adjustments will be initially made based on installation staff feedback during two weeks of facilitator training, as well as feedback obtained from non-study participants (military parents) during mock-workshops and groups led by newly trained facilitators. A focus group will be convened after the first workshop is delivered. Findings will be shared as noted below and further modifications of the curriculum will be made, if deemed appropriate.

Subtask 1: Compress ADAPT group and individual curriculum for retreat-style and 5-session formats

Subtask 2: Collect informal feedback from participants attending mock-workshops and groups at FC and FB

Subtask 3: Convene 1 focus group of RA and SO military families at FB after completion of first workshop

Subtask 4: Share focus group findings and discuss further curriculum modifications with Expert Panel for feedback

Major Task 3: Conduct 2-stage SMART to assess effectiveness and satisfaction of ADAPT in 315 RA and 210 SO active duty military families

Subtask 1: Recruit 315 RA and 210 SO active duty military families

Subtask 2: Randomly assign families to intervention condition

Subtask 3: Detail responsiveness to ADAPT

Subtask 4: Based on responsiveness, re-randomize non-responders to second intervention condition (booster group or booster individual ADAPT)

Subtask 5: Assess effectiveness of ADAPT interventions

Major Task 4: Data analysis

Subtask 1: Coordinate with sites and data team for monitoring data collection rates and data quality

What was accomplished under these goals?

Major Task 3 update – Despite COVID limitations to executing in-person recruitment activities, 422 families consented to be part of this study. This represents 80% of the original N. Families who had not completed their initial baseline assessment (T1) prior to COVID took part in a newly developed virtual data collection process using Zoom and phone call interviews. In total, 290 families completed a T1 representing close to 70% of the consented families. We consider this an amazing accomplishment given the multiple challenges this study has faced (i.e. loss of an installation, wavering partner support/temporary pause, on-going PCS of families, withdraw of USASOC participation and mostly recently a pandemic).

In addition, final families have completed Phase 1 of intervention with Phase 2 (booster sessions) occurring in Oct/Nov 2021.

Major Task 4: Data analysis – Currently T1 data is being cleaned and analyzed.

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

All examples are on-going.

- Site coordinators receive weekly mentoring from the project manager at the University of Minnesota.
- As supervisors, site coordinators also have access to all of the University of Minnesota's online supervisory development resources/courses and are encouraged to participate.
- Volunteer coders are provided initial and ongoing training for coding our observational data.
- Graduate students are provided training on data cleaning and analysis.
- Assessment technicians are provided initial and ongoing training on data collection with families.
- Facilitators who deliver our intervention are provided initial training and on-going coaching on the ADAPT curriculum and program fidelity.

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?

Primary objectives for the next reporting period are, (1) deliver booster sessions to families randomized to Phase 2, (2) complete cleaning and analysis of T1 data, move onto T2, (3) continue with virtual data collection for final time points, and (4) continue to implement a comprehensive retention plan across all study sites through remaining time points.

4. IMPACT:

What was the impact on the development of the principal discipline(s) of the project?

Nothing to report

What was the impact on other disciplines?

Nothing to report

Nothing to report

What was the impact on society beyond science and technology?

Nothing to report

5. CHANGES/PROBLEMS:

Changes in approach and reasons for change

Nothing to report

Changes that had a significant impact on expenditures

Nothing to report

Significant changes in use or care of human subjects

Nothing to report

6. PRODUCTS:

- **Publications, conference papers, and presentations**
Report only the major publication(s) resulting from the work under this award.

Journal publications.

Nothing to report

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

Book Chapter regarding SMART Trial:
DeGarmo, D.S., & Gewirtz, A. H. (2018). Fixed allocation and dynamic adaptive intervention designs for family psychology. In, *APA Handbook of Contemporary Family Psychology*
<https://www.apa.org/pubs/books/4311537.aspx?tab=2>

Other publications, conference papers, and presentations.

Nothing to report

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

www.adapt.umn.edu hosts our series of ADAPT studies, including articles with outcomes from our first ADAPT study.
<https://adapt4u.talentslms.com/> hosts our online curriculum.

- **Technologies or techniques**

Nothing to report

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

Nothing to report

- **Other Products**

Compressed ADAPT curriculum (workshop, group and individual formats) have been created for this study.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

NOTE: Funding Support for all personnel listed is this award and is for the past quarter rounded to the nearest month.

Other staff have been involved in the study as assessment technicians and facilitators delivering the intervention, but none of those staff have individually contributed 1.0 month or more.

Name: Gewirtz, Abigail
Role: PI
Person months: 1.0 month
Contribution: Responsible for preparing, conducting, and administering the project in compliance with applicable regulations and institutional policies. Responsible for staff management, curriculum writing, facilitator training and coaching, fidelity and implementation of intervention.

Name: Majerle, Amy
Role: Staff: Project Manager
Person months: 1.0 month
Contribution: Study oversight and compliance tasks, assist with study implementation

Name: Tiede, Shauna
Role: Staff: Assistant Project Manager/Assessment Coordinator (half-time)
Person months: 2.0 months
Contribution: Assessment oversight: develop and ensure adherence of assessment protocols, train assessment technicians, assist in the development of data flow management

Name: Willer, Molly
Role: Staff: Intervention Coordinator (half-time)
Person months: 1.0 month
Contribution: Curriculum writing, facilitator training and coaching, fidelity and implementation of intervention

Name: Martin, Amberlee
Role: Staff: Site Coordinator, Fort Campbell
Person months: 3.0 months
Contribution: Day-to-day oversight and implementation at the Fort Campbell site

Name: Dangel (Heinecke), Cheryle
Role: Staff: Site Coordinator, Fort Bragg
Person months: 3.0 months
Contribution: Day-to-day oversight and implementation at the Fort Bragg site

Name: McKissick, Meagan
Role: Staff: Site Coordinator, Forts Belvoir/Myer
Person months: 3.0 months
Contribution: Day-to-day oversight and implementation at the Forts Belvoir/Myer site

Name: Phelps, Marin
Role: Staff: Community Program Assistant
Person months: 2.0 months
Contribution: Data quality control, data cleaning, family timelines

Name: Lee, Susanne
Role: Staff: Data Manager
Person months: 1.0 month
Contribution: Oversees data cleaning team, ensures data quality control

Name: Clark, Misty
Role: Staff: Site Coordinator Assistant, Fort Bragg (75% time)
Person months: 1.0 month
Contribution: Assist site coordinator with implementation at the Fort Bragg site

Name: Anderson-Ion, Arianne
Role: Staff: Site Coordinator Assistant, Forts Belvoir/Myer
Person months: 1.0 month
Contribution: Assist site coordinator with implementation at the Forts Belvoir/Myer site

Name: Forgatch, Marion
Role: Co-Investigator
Person months: 2.0 months
Contribution: Curriculum writing, training and coaching

Name: DeGarmo, David
Role: Co-Investigator
Person months: 2.0 months
Contribution: Analyze data and monitor data management

Name: Bloomstrom, Glen
Role: Co-Investigator
Person months: 1.0 month
Contribution: Advise key personnel on recruiting regular Army and Special Operations personnel, establish connections with key military and community personnel to market the program

Name: Piehler, Tim
Role: Co-Investigator
Person months: 1.0 month
Contribution: Advise on SMART research design and data analysis

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

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

(PI: A Gewirtz)

ID#: W81XWH-14-1-0143 *Period:* 6/1/2014 – 8/31/2020

Effort: 13.5% *Funding:* /year

Role: PI

Supporting agency & contact: US Department of Defense

Ray Santullo, Program Official, orazio.f.santullo.civ@mail.mil

Goals/Specific Aims: This study will 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, through the following specific aims:

Aim 1: Evaluate the usability and acceptability of the individualized web-facilitated ADAPT condition.

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

Aim 3: Evaluate generalizability of ADAPT effectiveness across three intervention delivery approaches using intent to treat (ITT) analyses, specifying a non-equivalence hypothesis for group-based and web-facilitated relative to self-directed only.

If results are positive, ADAPT could be widely deployed so that many more military, and especially NG/R families can benefit from improvements to parenting, child, couple, and parental adjustment.

Overlap: This project examines the same parenting program (ADAPT) but with different delivery formats, randomization, and participant pools.

Change: Grant ended 8/31/2020

Title: The Center for Resilient Families (PI: A Gewirtz)

ID#: U79 SM080009 *Period:* 9/30/2016 – 9/29/2021

Effort: 20% *Funding:* year

Role: PI

Supporting agency & contact: DHHS SAMHSA

Cicely Burrows-McElwain, Program Official,

cicely.burrows-mcelwain@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.

Overlap: None

Change: None

GEWIRTZ, Abigail

Title: SMART Optimization of a Parenting Program for Active Duty Families

(PI: A Gewirtz)

ID#: W81XWH-16-1-0407

Period: 09/30/16 – 09/29/20

Effort: 2.7 calendar months

Role: PI

Supporting agency & contact:

US Department of Defense

Ray Santullo, Program Official, orazio.f.santullo.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).

Overlap: This project examines the same parenting program (ADAPT) but with different delivery formats, randomization, and participant pools.

Change: 2-year grant extension to 9/29/2022

Title: Large scale implementation of the ADAPT program in a primary care system at FT Bragg, NC

(PI A. Gewirtz)

ID#

Period: 05/01/19 – 05/31/23

Effort: 1.20 calendar months

Funding:

Role: PI

Supporting agency & contact:

Bristol-Myers Squibb Foundation

Katherine Masuch, Program Manager,

Katherine.Masuch@bms.com

Goals/Specific Aims: The goal of this project is the large-scale implementation of the ADAPT parenting suite of services via screening through primary care and pediatric clinics at Womack Army Medical Center, which serves the population of approximately 250,000 service members and their dependents associated with FT Bragg.

Overlap: This project includes the same parenting program (ADAPT) but is an implementation effort.

Change: None

Title: Examining the Utility and Feasibility of Mobile Technology in Prevention Interventions to Promote Child and Family Mental Health: A Demonstration and Feasibility Project

(PI A. Gewirtz)

ID#

Period: 07/16/19 – 06/30/22

Effort: 0.60 calendar months

Funding:

Role: PI

Supporting agency & contact:

Lynne & Andrew Redleaf Foundation

Goals/Specific Aims: The goal of this study is to examine the potential for stress wearables (Fitbit watches) to monitor parental stress in order to offer “just in time” stress management and parenting strategies.

Overlap: None

Change: None

FORGATCH, Marion

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

(PI: A Gewirtz)

ID#: W81XWH-14-1-0143

Period: 6/1/2014 – 5/31/2019

Effort: 5%

Funding: Role: Co-I /year (subaward)

Supporting agency & contact:

Subaward from University of Minnesota

Amy Rollinger, Grants Administrator, amyg@umn.edu

Prime source of funding: US Department of Defense

Ray Santullo, Program Official, orazio.f.santullo.civ@mail.mil

Goals/Specific Aims: This study will 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, through the following specific aims:

Aim 1: Evaluate the usability and acceptability of the individualized web-facilitated ADAPT condition.

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

Aim 3: Evaluate generalizability of ADAPT effectiveness across three intervention delivery approaches using intent to treat (ITT) analyses, specifying a non-equivalence hypothesis for group-based and web-facilitated relative to self-directed only.

If results are positive, ADAPT could be widely deployed so that many more military, and especially NG/R families can benefit from improvements to parenting, child, couple, and parental adjustment.

Overlap: This project examines the same parenting program (ADAPT) but with different delivery formats, randomization, and participant pools.

Change: None

Title: The Center for Resilient Families (PI: A Gewirtz)

ID#: U79 SM080009

Period: 9/30/2016 – 9/29/2021 /

Effort: 5%

Funding: year (subaward)

Role: Co-I

Supporting agency & contact:

Subaward from University of Minnesota

Amy Rollinger, Grants Administrator, amyg@umn.edu

Prime source of funding: DHHS SAMHSA

Cicely Burrows-McElwain, Program Official,

cicely.burrows-mcelwain@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.

Overlap: None

Change: None

DeGARMO, David

Title: Comparing Web, Group and Telehealth Formats of a Military Parenting Program (PI: A Gewirtz)

ID#: W81XWH-14-1-0143 *Period:* 6/1/2014 – 5/31/2019

Effort: 15% *Funding: Role:* Co-I (subaward)

Supporting agency & contact: Subaward from University of Minnesota

Kevin McKoskey, SPA Associate Director, kevin@umn.edu

Prime source of funding: US Department of Defense

Ray Santullo Program Official, orazio.f.santullo.civ@mail.mil

Goals/Specific Aims: This study will 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, through the following specific aims:

Aim 1: Evaluate the usability and acceptability of the individualized web-facilitated ADAPT condition.

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

Aim 3: Evaluate generalizability of ADAPT effectiveness across three intervention delivery approaches using intent to treat (ITT) analyses, specifying a non-equivalence hypothesis for group-based and web-facilitated relative to self-directed only.

Overlap: This current project is examining the same parenting program (ADAPT) but with different delivery formats, randomization, and participant pools that the proposed project.

Change: Grant ended 8/31/2020

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

ID#: W81XWH-16-1-0407 *Period:* 09/30/16–09/29/21

Annual Effort: 3.6 calendar months *Funding:* (sub only)

Role: Co-Investigator

Supporting agency & contact: DOD/US Army Medical Research

Jennifer Hayden, jennifer.e.hayden.civ@mail.mil

Goals/Specific Aims: The objective of this study is to provide ways to meet the needs of military families experiencing deployments by testing various programs to strengthen parenting and family resilience (i.e., children's well-being, parents' adjustment, and marital relationships). The Sequential Multiple Assignment Randomized Trial will involve an adaptive research design strategy for over 500 families and will monitor their responsiveness and compliance. Using double randomization, we will better understand the roles of tailoring interventions and optimal sequencing of condensed group delivery versus regular ADAPT with and without boosters.

Overlap: None

Change: None

DeGARMO, David

Title: Prevention Research Center: Parenting Among Women Who Are Opioid Users (PIs: Leve and Fisher)

ID#: P50 DA048756-02 *Period:* 08/15/19 - 06/30/24

Annual Effort: 1.2 calendar months *Funding:* (annual direct costs)

Role: PI Data Science Core

Supporting agency & contact: NIH/ NIDA, Dr. Belinda Sims, Program Officer, bsims@nida.nih.gov

Goals/Specific Aims: The overall aim of the Prevention Research Center is to improve the well-being of individuals, families, and communities affected by the opioid crisis through a focus on behavioral and neurocognitive systems that underlie mechanisms common to both addiction issues and parenting challenges. A funded supplement (01S1) will adapt and test a telehealth intervention in rural areas of Oregon (Stormshak, Leve).

Overlap: None

Change: None

Title: The Early Growth and Development Study Pediatric Cohort (PI: Leve)

ID#: UH3 OD023389 *Period:* 09/01/16–08/31/23

Annual Effort: 1.2 calendar months *Funding:* (annual direct costs)

Role: Co-Investigator

Supporting agency & contact: NIH/ Office of the Director, Dr. Sonia S. Arteaga, Program Officer, arteagass@mail.nih.gov

Goals/Specific Aims: The major goals for this project are to leverage and build upon a unique existing “dual-family” adoption design to isolate early environmental exposures from heritable influences on familial clustering of health problems to contribute to ECHO’s overall goal of investigating the role of early life exposures and underlying biological mechanisms in childhood health and disease. We will use our well- established prospective adoption sample to (a) help clarify causal inferences about environmental influences on neurodevelopment and obesity, and (b) explore the unfolding interplay between inherited child characteristics and environmental influences from birth to adolescence.

Overlap: None

Change: None

Title: Family-centered intervention in schools to reduce social and behavior problems from early elementary school to adolescence (PI: Stormshak)

ID#: R324A180037 *Period:* 07/01/18-06/30/23

Annual Effort: 1.8 calendar months *Funding:*

Role: Co-Investigator

Supporting agency & contact: US Dept of ED/ IES Jacquelyn Buckley, jacquelyn.buckley@ed.gov

Goals/Specific Aims: The purpose of this grant is to follow a sample of children who were recruited in kindergarten as part of a randomized trial into the middle school years. The goal is to reduce behavior problems and enhance academic achievement, and to test the effects of early vs. late intervention on risk behavior.

Overlap: None

Change: None

DeGARMO, David

Title: Testing the Efficacy of Mindfulness-Based Stress Reduction Combined with Behavioral Parent Training in Families with Preschoolers with Developmental Delay (PI: McIntyre)

ID#: R01HD093667

Period: 09/10/18 – 05/31/23

Annual Effort: 0.6 calendar months Funding: (annual direct costs)

Role: Co-Investigator

Supporting agency & contact: NIH/NICHD Alice S. Kau, kaua@mail.nih.gov

Goals/Specific Aims: The proposed study will test the benefit of addressing parental stress prior to delivering behavioral parent training (BPT) in order to more effectively reduce child behavior problems once the intervention is delivered, as well as investigate the mechanisms through which intervention outcomes occur.

Overlap: None

Change: None

What other organizations were involved as partners?

Organization: University of Oregon

Location: Eugene, OR

Contribution: Collaboration (subaward)

Organization: Implementation Sciences International, Inc.

Location: Eugene, OR

Contribution: Collaboration (subaward)

Organization: Fort Campbell, Army Community Services

Location: Tennessee/Kentucky

Contribution: Collaboration and networking, facilities, marketing consultation and product

Organization: Fort Bragg, Family Advocacy Program and USASOC Family Programs

Location: North Carolina

Contribution: Collaboration and networking, facilities, marketing consultation and product

Organization: Fort Belvoir, Army Community Services, MWR and Family Advocacy Program

Location: Virginia

Contribution: Collaboration and networking, facilities, marketing consultation and product

Organization: Joint Base Myer-Henderson Hall, Family Advocacy Program

Location: Virginia

Contribution: Collaboration and networking, facilities, marketing consultation and product

8. SPECIAL REPORTING REQUIREMENTS

QUAD CHART: Attached

9. APPENDICES:

Consort Diagrams

SMART optimization of a parenting program for active duty families

eBRAP Log Number: PT150093

Award Number: 16-1-0407



PI: Gewirtz, Abigail

Org: University of Minnesota, Twin Cities

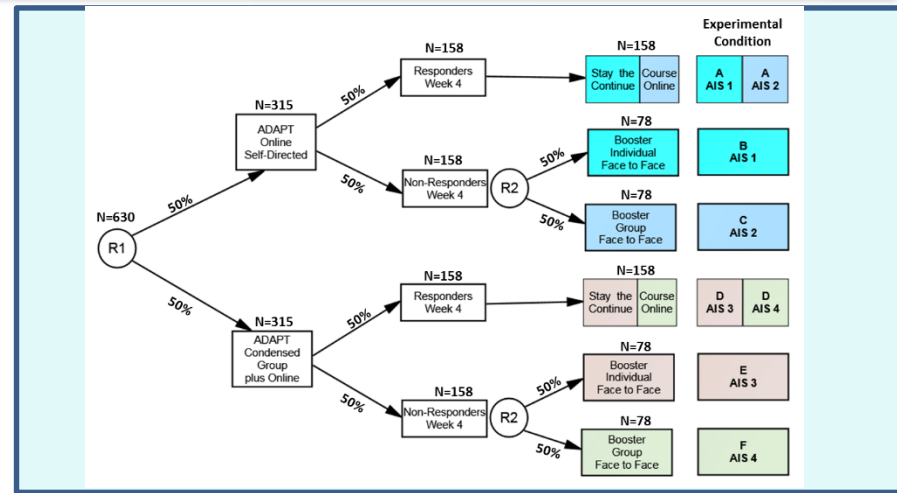
Award Amount: \$4,304,180 total (\$3,000,000 direct)

Objective

The **objective** of this study is to yield the optimal dosage, components, and sequence of a parenting program for active duty military families in diverse OPTEMPO contexts (i.e., regular Army (RA) families and Special Operations (SO) families). We will examine the effects of first and second stage interventions (condensed group, online, booster group, booster individual) on family resilience (i.e. observed parenting, parent and couple adjustment, and child adjustment), among program responders and non-responders, and explore whether certain program sequences or formats are more effective for high OPTEMPO (i.e. SO vs. RA) and male gender.

Approach

Phase III clinical trial with 525 Special Operations/SO and Regular Army/RA families in 3 installations; randomization occurs within each base and by SO/RA. Families are randomly assigned to either ADAPT online or condensed group ADAPT. At 4 weeks post baseline, responder status is assessed. Responders (i.e., parents scoring above the cut threshold on parenting locus of control) stay the course. Non-responders are again randomized to 5-session booster individual ADAPT or 5-session booster group ADAPT. Multi-method, multi-informant assessments are conducted at baseline, 6 (parents only) 12, and 24 months with parents, children, and teachers.



Accomplishment: ADAPT is an evidence-based parent training intervention demonstrating effectiveness in improving parent and child outcomes. The proposed study will optimize ADAPT to enhance efficiency, scalability, and sustainability.

Timeline and Cost

Activities	FY	17	18	19	20
Aim 1: Compress ADAPT program		█			
Aim 2: Examine optimization effects in a SMART trial			█	█	█
Aim 3: Examine exploratory optimization questions					█
Aim 4: Describe participation, satisfaction, & fidelity			█	█	█
Estimated Budget (total)		\$709,466	\$1,795,438	\$929,513	\$869,763

Goals/Milestones

FY17 Goal – Condense group ADAPT program and begin recruitment

- Listening sessions and focus groups (**see explanation under goals accomplished**)
- Begin recruitment of Cohort 1

FY18 Goals – Program delivery/assessments begin

- Continue recruitment of Cohorts 2 and 3
- Complete program delivery for Cohort 1
- Begin assessment of Cohort 1

FY19 Goal – Completion of program delivery

- Program delivery for Cohorts 2 and 3
- Begin assessments for Cohorts 2 and 3

FY20 Goal – Completion of assessments and data analysis

- Complete assessments for Cohorts 2 & 3
- Analyze Data

Comments/Challenges/Issues/Concerns

All baseline assessments have been completed. Phase 2 of the final intervention is being delivered in October/November. Data collection for remaining time points are underway at all sites.

Budget Expenditure to Date

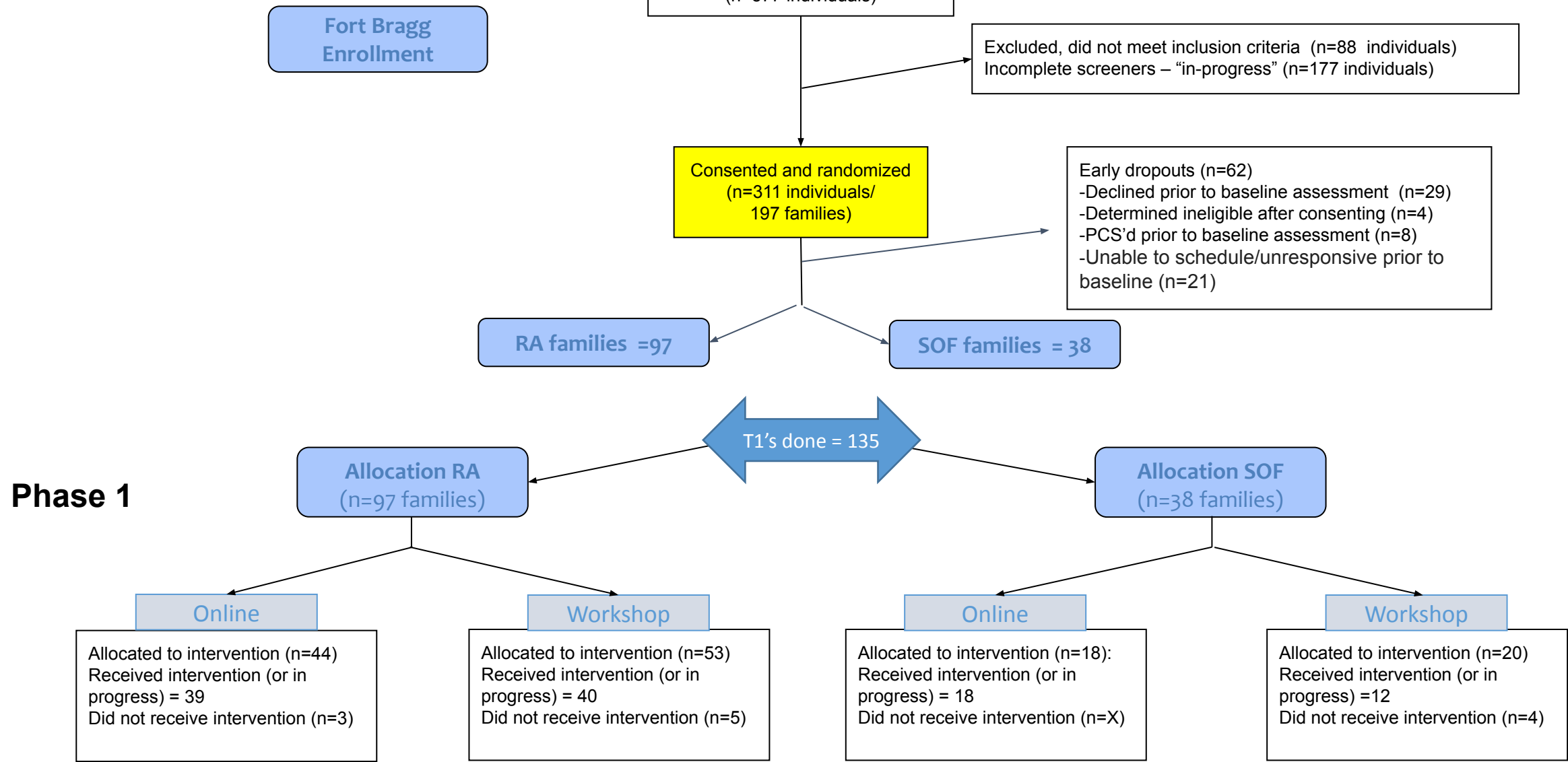
Y5 Q4 (7/01/2021 – 9/29/2021): \$154,191.21

To date (09/30/16 – 9/29/2021): \$4,182,278.56

Updated: October 26, 2021

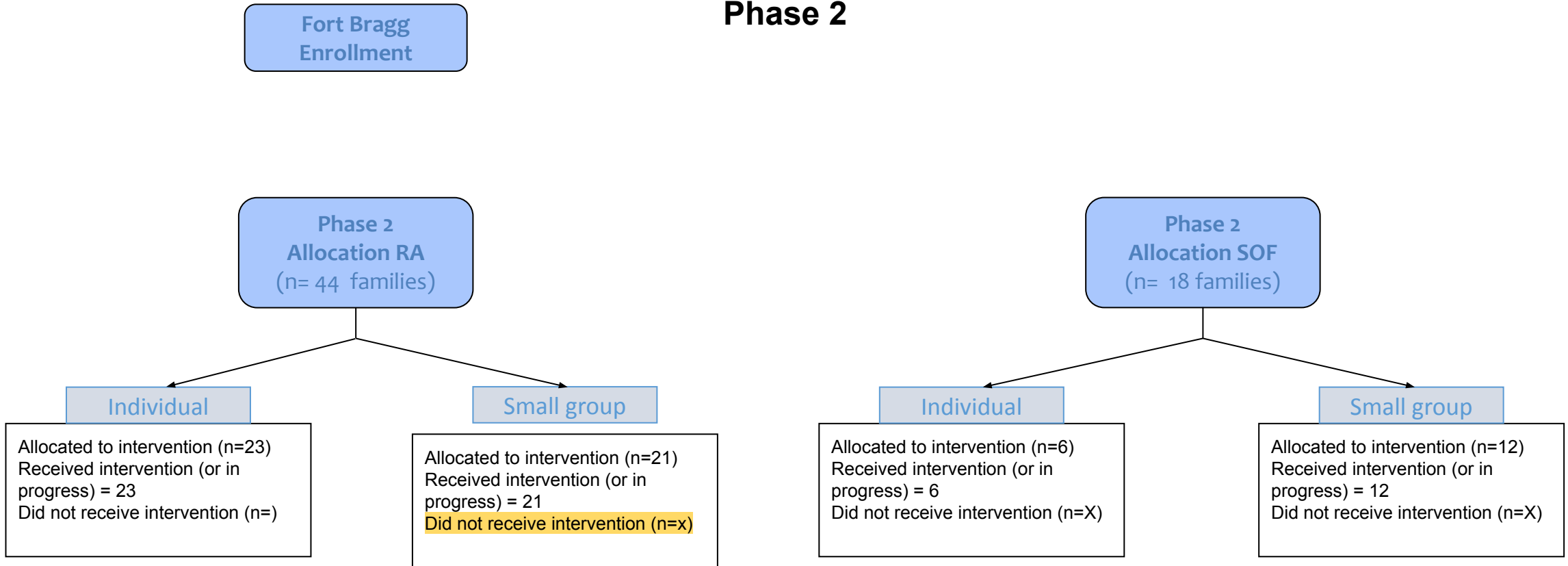
Updated as 09/28/2021

CONSORT Diagram



CONSORT Diagram

Phase 2



CONSORT Diagram

Forts Belvoir and Myer Enrollment

Screened for eligibility
(n=275 individuals)

Excluded, did not meet inclusion criteria (n=55 individuals)
Incomplete screeners – “in-progress” (n=56 individuals)

Consented and randomized
(n=151 individuals/
110 families)

Early dropouts (n=27)
-Declined prior to baseline assessment (n=16)
-Determined ineligible after consenting (n=0)
-PCS'd prior to baseline assessment (n=2)
-Non-responders (n=9)

Active Families = 83

Phase 1

T1's done = 83

Online

Allocated to Intervention (n=33)
Received intervention (or in progress) = 32
Did not receive intervention (n=0)

Workshop

Allocated to intervention (n=50)
Received intervention (or in progress) = 44
Did not receive intervention (n=3)

CONSORT Diagram

Forts Belvoir and Myer
Enrollment

Phase 2

Phase 2
Allocation
(n=39 families)

Individual

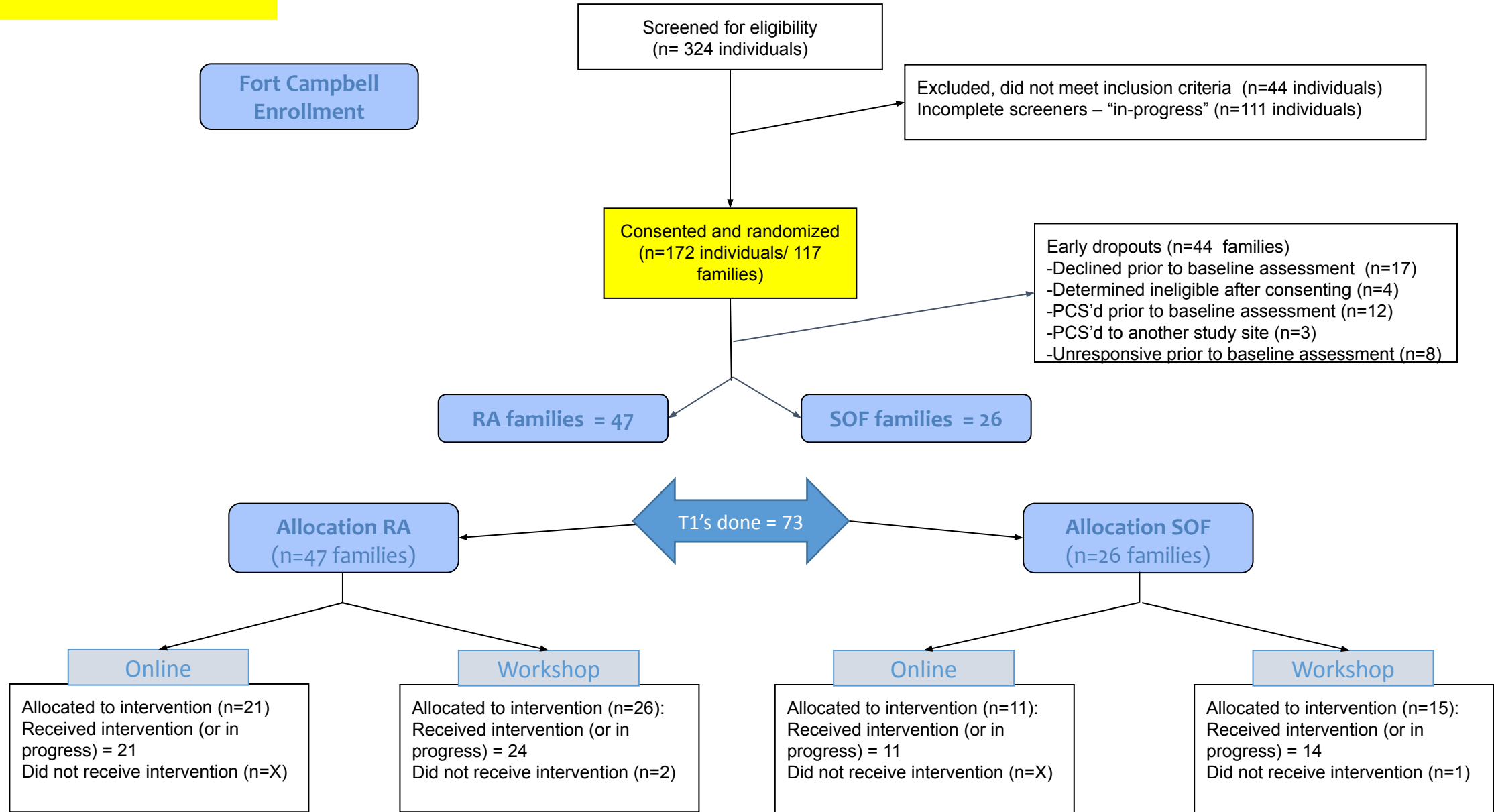
Allocated to intervention (n=20)
Received intervention (or in
progress) = 16
Did not receive intervention (n=2)

Small group

Allocated to intervention (n=19)
Received intervention (or in
progress) = 15
Did not receive intervention (n=2)

Updated as of 10/01/2021

CONSORT Diagram



Fort Campbell Enrollment

Screened for eligibility
(n= 324 individuals)

Excluded, did not meet inclusion criteria (n=44 individuals)
Incomplete screeners – “in-progress” (n=111 individuals)

Consented and randomized
(n=172 individuals/ 117 families)

Early dropouts (n=44 families)
-Declined prior to baseline assessment (n=17)
-Determined ineligible after consenting (n=4)
-PCS'd prior to baseline assessment (n=12)
-PCS'd to another study site (n=3)
-Unresponsive prior to baseline assessment (n=8)

RA families = 47

SOF families = 26

Allocation RA
(n=47 families)

T1's done = 73

Allocation SOF
(n=26 families)

Online

Allocated to intervention (n=21)
Received intervention (or in progress) = 21
Did not receive intervention (n=X)

Workshop

Allocated to intervention (n=26):
Received intervention (or in progress) = 24
Did not receive intervention (n=2)

Online

Allocated to intervention (n=11):
Received intervention (or in progress) = 11
Did not receive intervention (n=X)

Workshop

Allocated to intervention (n=15):
Received intervention (or in progress) = 14
Did not receive intervention (n=1)

CONSORT Diagram

Phase 2

