PROTOCOL TITLE:
SMART optimization of a parenting program for active-duty families

PRINCIPAL INVESTIGATOR or FACULTY ADVISOR:

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STUDENT INVESTIGATOR: NA

VERSION NUMBER/DATE:

V10, June 2019.

REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?
1	February 2017	Initial IRB application	
2	April 2017	U of MI removed, ISII added, IIA for Glen Bloomstrom, waiver of consent and waiver of documentation of consent added, teacher consent updated, clearer language about how a copy of consent is provided	Y- main consent, video consent and teacher consent
	June 2017	Main consent was updated to reflect more accurate language regarding intervention descriptions, subject payments and additional language regarding mandated reporting (requirement to report to FAP).	Y – main consent (v3 of consent)
	June 2017	Final marketing materials submitted	
3	August 2017	Updated measures list, updated description of FITS, addition of child care for in-home assessments, clarification of randomization of child participant, clarification/inclusion of waiver of documentation of consent and waiver of consent that was approved in original application, other minor grammatical and clarifying edits.	N
4	October 2017	Additional language added to the Consent Process section.	N
5	December 2017	Certificate of Confidentiality obtained by NICHD; updated confidentiality section	Y, main consent V4, teacher consent V3
6	May 2018	Additional recruitment method added (refer a friend postcard)	N
7	October 2018	Addition of IIA's for study sites with supervisor letters of support; added identification of facilitators at each site and description of their role; updated letter of support from study sites;	Y – teacher consent (V4), main consent (V5)

Revision #	Version Date	Summary of Changes	Consent Change?
		removal of JBLM as previous study site; addition of $100 drawing for online only participants; TPRISK was added to the teacher consent form as an already approved measure; addition of telehealth delivery for the individual booster condition in Phase 2.	
8	November 2018	Addition of childcare stipend to participants during intervention delivery	N
9	May 2019	Addition of Forts Belvoir and Myer as combined study site (FBM), recruitment from all active duty military branches affiliated with these sites, not just Army exclusive, as potential study participants. Updated power analysis.	N
10	June 2019	Moving of Focus Group activity to occur after Cohort 1 of intervention and not before program delivery per change in our Statement of Work approved by DoD. Submission of Fort Belvoir letter of support and Fort Myer Memo of Agreement.	Y, addition of Focus Group consents form (V1)

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ABBREVIATIONS/DEFINITIONS: NA

STUDY SUMMARY

Study Title	SMART optimization of a parenting program for active-duty families
Study Design	Sequential multiple assignment randomization trial
Primary Objective	advance the "development, adaptation, efficiency or optimization, and testing of a prevention intervention by using a sequential, multiple assignment, randomized trial/SMART to test multiple components of an empirically-supported parent training prevention intervention – After Deployment Adaptive Parenting Tools (ADAPT)
Secondary Objective(s)	
Primary Study Intervention or Interaction	ADAPT, which is a Parent Management Training-Oregon (PMTO) program for military families with children ages 5-12 years old.
Study Population	Active duty families
Sample Size (number of participants)	525
Study Duration for Individual Participants	2 years

1.0 Objectives

1.1 Purpose:

The overarching goal of the "SMART Optimization of a Parenting Program for Active-Duty Families" study is to advance the "development, adaptation, efficiency or optimization, and testing of a prevention intervention by using a sequential, multiple assignment, randomized trial/SMART to test multiple components of an empirically-supported parent training prevention intervention – After Deployment Adaptive Parenting Tools (ADAPT) for active-duty families negotiating multiple deployments and high deployment OPTEMPO (an army program that provides critical responses).

2.0 Background

2.1 Significance of Research Question/Purpose:

Deployment (and particularly high deployment operational tempo/OPTEMPO can generate family and personal stressors that disrupt supportive social relationships and functioning at home, thereby weakening the strength of our military force in the field. Stressors include separation from, and reunification with families, concerns about mobilizations and combat stressors. These stressors, in turn, are associated with reduced parenting effectiveness, marital/partner difficulties, emotion dys-regulation, and increased coercion. Coercion predicts risk for child maladjustment, as well as marital disruptions. Without effective prevention interventions, such environments may contribute to high divorce rates, child maladjustment, and reductions in service member wellbeing.

Most prevention interventions use a one-size-fits-all approach (i.e. all participants receive the same dose, format, and type of program) but this approach is often inefficient. Some families benefit from this approach but many do not. Adaptive interventions maximize efficiency, scalability, and sustainability, by providing families with a tailored dose, timing, program format, and/or sequence to improve outcomes based on their preferences and needs.

2.2 Preliminary Data:

After Deployment: Adaptive Parenting Tools (ADAPT) is a Parent Management Training-Oregon (PMTO) program for military families with children ages 5-12 years old. PMTO is a theoretically-based family of interventions with extensive research supporting efficacy and effectiveness. ADAPT was developed and tested primary with National Guard/Reserve families. Program findings, based on 3 RCTs, indicate positive outcomes. No empirically supported parent training programs have been validated in RCTs for active duty military families with school-aged children in regular and high deployment OPTEMPO contexts.

2.3 Existing Literature:

We are proposing a Phase III Clinical trial. The SMART optimization of a parenting program for active-duty families uses an adaptive intervention strategy

to optimize an evidence-based universal prevention intervention, After Deployment Adaptive Parenting Tools/(ADAPT). SMART trials are rapidly gaining recognition within the medical and mental health fields as an innovative approach to developing adaptive treatment regimens (Almirall, Compton, Gunlicks-Stoessel, Duan & Murphy, 2012). SMARTs have been successfully implemented in diverse areas including interventions for cancer (Thall et al., 2007), autism spectrum disorders (Kasari et al., 2014), adolescent depression (Almirall et al., 2012), and alcoholism (Murphy, Lynch, Oslin, McKay, & Ten Have, 2007). SMARTs also show considerable promise in innovating intervention approaches within prevention contexts (August, Piehler, & Bloomquist, 2014).

3.0 Study Endpoints/Events/Outcomes

3.1 Primary Endpoint/Event/Outcome:

In this study, we will compress and test a variety of formats, sequences, and doses of ADAPT. We will provide two 'first line' ADAPT programs and two slightly more intensive booster ADAPT programs for families who do not 'respond' to the first line intervention. Adaptive intervention strategies involve decision rules that specify how the type or intensity of an intervention should change depending on participants' response on a predetermined indicator of initial progress within an intervention.56, 57, 58 Within a SMART, a measure of initial response is used following delivery of an intervention in order to evaluate each families' need for further intervention programming. In this way, programming is tailored to meet the needs of individual families by providing additional services only to those families who are likely to benefit. This measure of initial response is referred to as a primary tailoring variable. In the proposed study, the primary tailoring variable is parental locus of control, a key variable shown in our prior studies to predict change in observed parenting effectiveness, as well as change in other outcomes (PTSD symptoms, suicidality, and child adjustment).

4.0 Study Intervention(s)/Interaction(s)

4.1 Description:

The tested formats, sequences, and doses of ADAPT include:
(1) Begin with ADAPT Online. Parents exhibiting initial response receive continued access to online resources. Parents exhibiting non-response are stepped-up to booster individual face-to-face ADAPT.
(2) Begin with ADAPT Online. Parents exhibiting initial response receive continued access to online resources. Parents exhibiting non-response are stepped -up to booster group-based ADAPT.
(3) Begin with ADAPT condensed group (with online support). Parents exhibiting initial response receive continued access to online resources. Parents exhibiting non-response are stepped to booster group-based ADAPT.
(4) Begin with ADAPT condensed group (with online support). Parents exhibiting initial response continue access to online resources. Parents exhibiting non-response are stepped-up to booster group-based ADAPT.

This approach allows families who do not need intensive services to receive appropriately brief services. Those higher-need families receive more intensive services.

5.0 Procedures Involved

5.1 Study Design:

To address Aim 1, we will compress the ADAPT group and individual curriculum, through consultation with service members, spouse, and content experts. 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. Focus groups 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.

Focus Groups: We will conduct two focus groups with participating study families, one group with 12 Special Operations (SO) participants and one group with 12Regular Army (RA) participants, both at Fort Bragg, NC. To ensure gender sensitivity, we will recruit and ask similar questions of mothers and fathers.

Study participants (parents) who have already received the study intervention (N = 40 families) will be sent an email asking if they would be available for a Focus Group to collect feedback on (i) relevance of materials for active duty and high OPTEMPO populations, (ii) examples of key parenting challenges related to high OPTEMPO, and (iii) preferences for specific program formats (length/time of days/days of week). If participants are not able to attend an in person focus group, an opportunity to share this feedback by phone with study staff will be offered. With permission, anecdotes about deployment will be anonymized and incorporated into scripts as teaching vignettes and role plays. Focus groups and phone interviews will be scheduled when it is convenient for participants.

After reviewing the report of the focus group results, our Expert Panel will gather via videoconference (Month 4). Panel experts will weigh in on the results and be provided with two weeks to provide written recommendations. Expert panel and focus group feedback will inform (i) how to best compress key ADAPT skills, and (ii) address issues specific to high deployment OPTEMPO conditions. The focus group data and panel feedback will be used to adjust components for the SMART that do not fundamentally change the core components while increasing our program deliverers (facilitators) awareness of challenges facing active duty populations for future program delivery.

To address Aims 2,3,4: Among 210 SO and 315 RA families (i.e., total N=525 families) with 5-12 year-old children, we will examine effects of ADAPT modalities and sequences/timing on multiple behaviors and outcomes (i.e., (i) coercive family interactions, positive parenting, couple adjustment, and co-

parenting, (ii) parents PTSD symptoms, depression symptoms, substance use, (iii) child behavior and emotional problems, and positive adjustment, by conducting a 2-stage SMART, and (iv) document participation, satisfaction, and fidelity. To assess behaviors and outcomes, we will administer and collect a series of assessments (Table 1 appendix) at 4 timepoints.

For Aims 2, 3, and 4, we will use a 2-stage SMART design to examine the optimal sequence, dosage, and delivery formats of ADAPT for active duty military families living in a range of operational tempo contexts. We will recruit a total of 525 families living on three installations: Fort Bragg (North Carolina), Fort Campbell (Kentucky) and Forts Belvoir/Myer, with 210 families recruited from Fort Bragg and Fort Campbell and 105 from Forts Belvoir/Myer.

5.2 Study Procedures:

Subjects for this study include: (I) 525 active duty clinical trial participants recruited from 4 bases who will be randomized to first stage (brief interventions) and second stage (more intensive booster ADAPT programs for families who do not benefit from the first stage interventions; (II) Twelve current study families (N = 24) who will participate in focus groups; (III) 525 children participants between the ages of 5-12 of clinical trial participants who will be asked to participate in assessments only; (IV) Up to 1890 teachers who will be asked to complete the Behavior Assessment System for Children, Second Edition (BASC-3) each yr that the child is in the study (usually 3 grades)

Focus group Participants
We will hold two focus groups with study parents to inform program modifications. Each focus group will consist of 12 participants, one group Special Operations (SO) participants and one group Regular Army (RA) participants, both on Fort Bragg, NC.

Clinical Trial Participants
Active duty families will be living in a range of operational tempo (OPTEMPO) contexts (i.e., Regular Army/RA and Special Operations/SO) on one of four military installations. All participants will be in units with deployments occurring during the study period. 525 families will be recruited from target bases as follows: (a) Fort Bragg, NC – 210 families recruited, including 105 SO and 105 RA. (b) Forts Belvoir/Myer, VA – 105 Active Duty families recruited. (c) Fort Campbell, KY– 210 families recruited, including 105 SO and 105 RA.

Clinical Trial Participants will be asked to do the following:
(1) Complete assessments at four time points. Assessments are listed and described below and included on the final page of the protocol.
a. T1 (baseline (BL) and prior to the start of the intervention); both on-line and in-home data is collected from families; child self-report measures will be gathered and are standardized with children over 5.
b. Responder Checkpoint – Parent Locus of Control 22-item questionnaire completed by parents 4 weeks after they start the intervention

c. T2 (6 months following baseline); only online parent data will be gathered, (no in-home assessment)
d. T3 (12 months following BL, i.e. following the end of the reintegration session(s) and program completion); both on-line and in-home data is collected from families, child self-report measures will be gathered from children over age 5.
e. T4 (24 months after BL); both on-line and in-home data is collected from families, child self-report measures will be gathered from children over age 5.
2. Participate in videotaped (with audio) in-home parent-child interaction tasks lasting a total of 30 minutes at three time points (BL/T1, T3, and T4). These interaction tasks are administered and videotaped by trained assessment technicians in the participants' homes. If preferred, participants may complete assessments outside the home at project offices. Video and audio of study participants will be accessed only by the investigators and trained members of the coding team.

3. Fill out online questionnaires at the time of in-home assessments (BL/T1, T3, and T4).

Note: childcare provided by study staff is offered during in-home assessments for siblings. If study staff are not available to provide childcare, a $30 gift card stipend will be offered to the family so that they can arrange their own childcare.

All measures are listed in the table below and include: (1)The Parenting Locus of Control (PLOC); (2) The Family Interaction Task (FIT); (3) The Alabama Parenting Questionnaire (APQ-22); (4) Deviant Peer Association (PERS); (5) The Behavior Assessment System for Children, Third Edition (BASC-3); (6) Coping with Children's Negative Emotions (CCNES); (7) The UCLA PTSD-Reaction Index (PTSD-RI); (8) the Children's Depression Inventory (CDI); (9) Describing Friends; (10) PTSD Checklist (PCL); (9) Difficulties in Emotion Regulation Scale (DERS); (11) The Five Facet Mindfulness Questionnaire (FFMQ); (12) Receipt of Help (PSI); (13) Alcohol Use Disorders Identification Test (AUDIT); (14) Center for Epidemiologic Studies Depression Scale (CESD); (15) Deployment Risk and Resilience Inventory (DRRI); (16) Differential Ability Scales (DAS-7); (17) Moral Injury (MIES); (18) Parenting Mindfulness (IEM-P); Parenting Identity; (19) NIH Toolbox Flanker (EF – Inhibitory Control); (20) NIH Toolbox Peadbody Picture Vocabulary Test; (21) Deviant Peer Association (TPRISK) Process measures include: satisfaction questionnaires, attendance, practice, online use, and coder ratings to measure fidelity.

(i) The PLOC will be used as the primary tailoring variable measure by all participants at 4 weeks following the start of the intervention (when condensed group or online programming is completed). The PLOC is a 22-item questionnaire that takes about 5 minutes. A link sent to each parent's email address will provide access to the questionnaire. The results of this questionnaire will determine responder status for each individual. If a parent scores below the cut-score

threshold on the PLOC or does not complete the PLOC, that family will be re-randomized to the second stage ADAPT interventions.

(ii) Context measures:
(a) Demographic information such as gender, age, racial, and ethnic identity for parent and child;
(b) employment;
(c) income,
(d) date/s and number of deployments for parents. Number and length of deployments will be assessed from 3 open-ended questions to obtain information about the extent of respondents' deployment history. Combat exposure will be measured using subscales from the DRRI, an ecologically valid instrument for assessing risk and resilience factors among military personnel participating in recent and current deployments.
(iii) Parenting practice measures:
(a) Observations of parents and children using the Family Interaction Task (FIT) will last approximately 30 minutes. The child will complete a problem-solving task and discuss an emotional deployment challenge with each participating parent separately. The other tasks include: planning a fun family activity, a game/teaching task, and a monitoring task in which parents seek information about an activity in which the child was unsupervised. If two parents are participating in the study, they will also problem solve a parenting challenge in their household. Coder ratings of these tasks yield reliable and valid measures of parenting practices that have predictive validity for parent and child;
(b) Self report measures including the APQ short form, a widely used 9 item measure of parenting practices validated in military and community samples.

(iv) Child Adjustment measures:
(a) The BASC-3 teacher, parent, and child self-report. The BASC is a multi-dimensional system assessing broad domains of externalizing problems, internalizing problems, and school problems as well as adaptive skills. Items are rated on a 4-point scale. Gender-specific normative scores are provided. Parents rate child behaviors using the parent version of the BASC2 while teachers use the Teacher Report Form. The child self-report version has been validated and demonstrated responsive to intervention and will target children ages 5 and older;
(b) The CDI will be used to measure child distress. The CDI is a 27-item symptom-oriented index, validated with 7-17 year olds, has been shown to correlate highly with similar measures of depression, and is sensitive to change over time;
(c) The PTSD-RI is a 20-item child interview assessing post-traumatic stress reactions. The child is asked to endorse how frequently each reaction occurs on a four-point scale. Scores are strongly associated with diagnostic measures of PTSD;
(d) Describing Friends is a 5 item index to measure deviant peer association, used in previous ADAPT studies and is sensitive to change as a result of the intervention;

(v) Parent Adjustment measures:
(a) The PCL is a 17 item, clinically validated, self-report screening tool used to assess the presence and severity of PTSD symptoms as defined the DSM-IV;
(b) The CESD - 20 items - assesses depressive mood, motor, and somatic difficulties in the general population and has been widely used and validated in national health surveys;
(c) The AUDIT is a self-report measure developed by the World Health Organization as a fast, reliable way to screen for excessive drinking and validated in over 2 decades of research with multinational samples and deemed effective for early identification in military populations;
(d) The FFMQ is a 39-item questionnaire used to assess parent mindfulness with 5 subscales (observing, describing, acting with awareness, non-judging, and non-reactivity);
(e) The DERS is a 36-item questionnaire used to assess emotion regulation/dysregulation in adults in six domains;
(f) Receipt of Help (5 items) was developed for the National Survey of Families and Households and assesses the degree to which parents receive practical help using a scale from low to high.

(vi) Couple Adjustment measures:
(a) The DAS-7 Short version is a 7 item scale assessing couple adjustment. The DAS-7 has well-established criterion validity and discriminant validity.

4. Participate in one randomly assigned intervention:
a. ADAPT Online. Participants will have access to the full ADAPT website (12 modules, online discussion forum). Participants are directed to the first ADAPT session, and as each session is completed (all materials in a session opened by at least one parent) families receive a personalized congratulations email and continue to the next module. Participants may see the entire program on the ADAPT dashboard; they are encouraged to proceed in the specified order. Each online session consists of a skills video (demonstrating a specific skill), a practice video (modeling how parents practice skills with child(ren), downloadable summaries of key skills, fillable PDF forms with home practice assignments, a knowledge quiz, and downloadable mindfulness exercises that can be played directly from the ADAPT site as well as from smartphones, tablets, and computers. Participants are compensated at the end of their time period according to the portion of the modules completed. In addition, they are encouraged to respond to the 7 questions prompted by the online facilitator. To encourage this exchange, participants who respond will be entered into a drawing for a $100 gift card (up to 7 entries). At the end of the online group, one winner will be drawn at random. For example, if there are 10 participants in Cohort 1 and all 10 of them answer each of the 7 facilitator questions then there would be 70 entries for the drawing (10 participants x 7 entries each). This would give each participant a 7% chance that their name would be drawn to receive a $100 gift card;

b. Condensed group-based ADAPT. Participants will meet for 2 week/weekend days two weeks apart, for 6 hours each day (excluding holidays) at a time convenient to participants. Dinner and childcare are provided. If families are unable to or elect not to register for CYS childcare on the installation or the minimum number of children for CYS childcare is not met, participants will be offered a $50 stipend in the form of a gift card to arrange their own childcare in order to attend workshop;

Facilitators who deliver the ADAPT intervention are a combination of U of MN paid staff, U of MN volunteers and military affiliated professionals on those installations who have the required approval for program delivery. Facilitators complete comprehensive face-to-face training prior to starting groups. An extensive training and coaching infrastructure already exists (i.e., training manuals, videotapes, a HIPAA-compliant database for uploading and storage of training and group video material). In our current and past DOD and NIH funded ADAPT studies we have successfully trained over 50 individuals as facilitators. Training will be delivered either on the installation by Drs. Gewirtz and Willer or in Minnesota with prior DOD/MOMRP approval. ADAPT training, which consists of two workshops, and, following workshop training, bi-weekly coaching focused on facilitation of group sessions.

Facilitators are not involved in the randomization or assessment of participants, and it is up to them if they chose to share information about the study with military families in order to assist with recruitment. Facilitators will be told when there is sufficient number of families to begin a workshop and they are given the list of families who will be invited to the workshop. Facilitators plan the workshop logistics with the site study coordinator, including the best day and time to offer the workshops with facilitator schedules, needs of families and space availability in mind. The workshops take place on two full days (6 hours per day, excluding breaks and lunch), two weeks apart (e.g. week 1, week 3 of a month). Two to three facilitators run each workshop. Attendance and end of day evaluations are collected by facilitators and given to the study site coordinator for processing. Between workshops, facilitators contact families by phone once a week to check in and assist with home practice completion, and troubleshoot skills that have been taught. A brief record of this contact is recorded in a secure on-line portal by facilitators for the purposes of coaching.

Following the end of the workshop, participants complete a questionnaire about their parenting. This questionnaire is delivered online by the study team, and facilitators have no involvement in the survey and no knowledge of participant responder status. Based on participants' responder status, some participants are further randomized to an additional program (3 session group, or 3 sessions individually). Facilitators will again receive a name or list of names if they are delivering a group or individual ADAPT program. (Not all facilitators will conduct all groups, instead it is determined by logistics, schedules, etc.). They will work directly with the participants during the groups/individual sessions as with the workshops. The 3-session groups are delivered weekly, 3 times, on the

installation with approximately 6 families per group and two facilitators. The 3 individual sessions are delivered weekly by one facilitator with an individual couple/parent, likely on the installation, at times convenient for the facilitator and the family. Once the intervention is over, the facilitator has no further study involvement with the family.

All program components (i.e. workshops, group, and individual sessions) are videotaped for quality assurance purposes – i.e. to ensure that facilitators are delivering the program with fidelity. Facilitators receive bi-weekly coaching from the study team in Minnesota. During coaching, the coach and facilitators meet by WebEx (HIPAA-compliant) and view video of the sessions. Videos are later used to assess fidelity for the purposes of certifying facilitators in the ADAPT program. (Certification is not a research aim, but a practice commitment to the sites – i.e. that they would be able to sustain the program after the research ends).

Current ADAPT Trained Facilitators:
**Note: Per the request of the Human Research Protection Office at the US Army Medical Research and Materiel Command, University of Minnesota Individual Investigator Agreement (IIA) and Supervisor Letter of Support have been obtained for all installation staff involved in the delivery of the ADAPT intervention (noted with asterisks by name).

Location	Name	Position
Fort Bragg	Cheryle Dangle	U of MN Employee
Fort Bragg	Chris Balduf*	U of MN Employee
Fort Bragg	Krista Melton	U of MN Employee
Fort Bragg	Michelle Keller*	Child Advocate Instructor, Contract employees of Strategic Resources Inc.
Fort Bragg	Nicollette Love*	Child Advocate Instructor, Contract employees of Strategic Resources Inc.
Fort Bragg	Scott Chase*	ACS Child Advocate - civilian
Fort Bragg	Shadia Young*	Child Advocate Instructor, Contract employees of Strategic Resources Inc.
Fort Campbell	Cortney O'Neal	U of MN Employee
Fort Campbell	Dianna Roberts	U of MN Volunteer
Fort Campbell	Elizabeth Eversole	U of MN Employee
Fort Campbell	Elke Sampson	Military spouse
Fort Campbell	Jim Mitchem*	Active Duty Army Chaplain
Fort Campbell	Jonathan McPherson*	Active Duty Army Chaplain

5. Depending on participants' response to the Condition A and B interventions, they may be asked to participate in one of the following:
• Individual booster ADAPT. Participants will meet for 3 weekly face-to-face sessions for individual families with a trained facilitator. Each session lasts 1.5 hours. Individual sessions include discussion, role-play, and audio-visual material about different aspects of parenting such as encouragement, discipline, and problem solving. Depending on facilitator availability, individual sessions may take place by telehealth (i.e. HIPAA compliant Webex) using U of MN based staff in order to keep families on their timeline;
• Booster Group ADAPT. Participants attend weekly groups for 3 weeks with up to 10 other families. Each session lasts 2 hours and includes dinner and childcare. If families are unable to or elect not to register for CYS childcare on the installation or the minimum number of children for CYS childcare is not met, participants will be offered a $30 stipend in the form of a gift card to arrange their own childcare in order to attend group. Groups include discussion, role-play, and audio-visual material about different aspects of parenting such as encouragement, discipline, and problem-solving.

It should be noted that we are not allowed to ask substance use questions to Active Duty participants and will encode the online survey with "if-then" logic routing that will eliminate those questions from the battery of assessments for active duty participants. Lastly, active duty participants are not allowed to receive incentives.

Children Participants:
a. Families must have at least one child between the ages of 5-12;
b. If participating families have more than one child between the ages of 5 and 12, staff will randomly select the child to participate in the study. Children are included in the assessment phase only to examine the effectiveness of ADAPT in reducing risk for substance use, child maladjustment, and related behavior problems.

Teachers will be asked to do the following:
Up to 1890 teachers will be asked to complete the BASC-3, a 100-139 item instrument designed to evaluate various aspects of behavior and personality in children, youth, adults ages 2-25. The BASC-3 takes between 10-20 minutes to fill out. Teachers will be asked to fill out the questionnaire at T1, T3, and T4. In addition, teachers will be asked to complete the TPRISK - a measure on deviant peer association.

ADAPT is a resilience-building program designed to strengthen families through the transitions associated with deployment, targeting multiple outcomes in service members, spouses, children, and families. This study will yield knowledge about the optimal components, sequence, and dosage for improving family adjustment in diverse OPTEMPO contexts, yielding an efficient, scalable and sustainable universal prevention intervention to strengthen the family at home, and the soldier's functioning at home and in the field.

Potential Risks
Potential discomfort and risks participants may experience as a result of their involvement in this study include the following:
1. Discomfort with assessment procedures (e.g., videotaping)
2. Discomfort in disclosing sensitive information
3. Violation of confidentiality as a result of compliance with mandatory reporting requirements
4. A possible violation of confidentiality due to mishaps with identified data
5. Discomfort resulting from misunderstanding the planned use of data
Participation in this research involves minimal risk, defined in the Federal guidelines, as "the probability and magnitude of harm anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." (Federal Register, 1991, 45CFR 46.102(i). Procedures are in place to minimize risk of violation of confidentiality, as indicated: If the study child or participating caregiver discloses information regarding child abuse or threat to self or others, professionals are mandated to report the information to appropriate authorities. This information will be clearly stated verbally and on the consent forms. It is not likely that participants will experience physical, social or legal risks due to enrollment in the study because state mandated procedures exist to protect them. There are no financial risks to participants. Procedures are in place for providing suitable informed consent, clearly describing the assessment activities, emphasizing the voluntary nature of the study, and communicating the purpose and use of the data collected. These procedures are intended to minimize participant's misunderstanding of or dissatisfaction with the research.

For informed consent, all letters/online instructions will clearly state that participation in this study is voluntary, that the participant's relationship with their employer, the military, and the University of Minnesota will not be adversely affected regardless of whether or not they decide to participate. It will be clearly stated in written form and verbally expressed in person that participants may withdraw from the study at any point without any consequences to themselves or these relationships. The consent process will clearly indicate that all information gathered from participants will be kept confidential and de-identified for all analysis or reports that will be conducted or generated during and after the study period. Participants will be given an opportunity to ask questions of the PI and research staff during informed consent and throughout the research study and will be provided with the University of Minnesota, Office of Human Subjects Protection phone number if they have further questions or concerns about the study.
1. Teachers
At each assessment point, work designated contact information for teachers of each targeted child will be obtained from families enrolled in the study. Teachers will be contacted via secure, encrypted email, with an explanation of the study and a copy of the parent's release of information. They will be directed to the

study website to complete online informed consent and study questionnaires. Teachers not responding will receive materials by mail with follow-up calls.
2. Focus Group Participants
Each focus group will consist of 12 families for a total of 24 focus group participants. Focus group participants will be recruited by emailing the 40 families who have already received the study intervention to gather interest. If interested, study participants will be scheduled to attend a focus group that is convenient to them. If they are interested but cannot attend, an opportunity to give feedback by phone with study staff will be offered. If they chose not to participate, their decision will not affect their relationship with the military, their employer, or the University of Minnesota. If they chose to participate, they may discontinue at any time without consequences. Their identity will remain anonymous.

Per military regulations, all participants will be informed that to be compensated for their participation in the research study, they must participate on their own time and not while on duty (e.g., in training events). Informed consent will be explained verbally and through written consent forms.

3. Clinical Trial Family Participants:
a. We will create and distribute recruitment flyers to our partners providing a study website URL and phone number. We will recruit families in close collaboration with the military installations, by (i.) postings on the websites, (ii.) flyers and pamphlets at armories and announcements via email, (iii.) attending family support groups, family readiness academies, and family reintegration training.
b. To manage study participation and administer online measures, we will create a secure web site (separate from the training site) that maintains extremely stringent levels of encryption and data storage while also providing flexible design options, and sophisticated data management and collection features. The website guides parents to a brief explanation of the project, and a description of project confidentiality and its limits. This website will be accessible to project staff so that they can track participant progress and provide support when needed. Given the focus on technology use to enhance outreach and access, as well as minimize researcher intervention, participant screening and informed consent (adult only) will take place online, unless participants specifically request this process to be accomplished by phone.
c. Eligible adult family participants will next complete a brief contact information form, followed by an online informed consent that will provide information about study risks, benefits and about the possibility of being randomly assigned to one of the conditions. Families will be assured that no services or relationship with the military base or the University of Minnesota will change or be adversely affected regardless of whether or not they choose to participate in the study.
d. The voluntary nature of participation and the ability to withdraw from the project at any time without penalty will be emphasized. In reintegrating families

with two at-home participating parents/caregivers, each will complete a separate informed consent.
e. Consenting adult family participants will be provided a contact number in order to speak to the PI or study coordinator with any questions. Families who request a telephone screening (e.g., families whose internet is not accessible at the time of the call) will be asked for verbal consent for the research team to maintain contact through weekly reminder emails and phone calls as needed to complete informed consent and baseline (BL) online assessments. Where informed consent is not completed prior to the home visit, it may be completed at the beginning of the in-home assessment.
4. Child Participants
a. Parental consent to have child included in the study was completed electronically prior to the first in-home assessment.
b. The informed consent process (assent) for child participation will be conducted during the in-home assessment process. The study, procedures, and tasks of the study will be explained to the child using developmentally appropriate and child friendly language. The research staff will verbally check for the child's understanding of the information shared.
c. Research staff will ask the child if they have any questions or concerns about the study. It will be stated very directly to the child that no one will be angry or upset with them if they decide not to participate in the study and that they can change their mind or ask more questions at any time during the study.
d. Once the research staff has been able to ascertain that the child understands the procedures of the study and what the child will be asked to do, a written signature will be requested from the child on the Child Assent form.
I. Individuals who complete their consent electronically are given the option to print the consent form immediately or they can request to have one sent to them. If consent is not electronically obtained before first in-home visit, a hard copy is reviewed in the home and a signature is obtained.
The following consent forms will be obtained from participants:
1. Adult consent to participate in the focus groups (focus group adults only)
2. Adult consent for participation in the clinical study (all family adults screened for participation in the clinical study). A copy of the signed consent is provided at baseline and follow-up assessments to all adults.
3. Child Assent Form for participation in baseline and follow-up assessments (all children in study)
4. Adult Consent to release observational assessment video data (all families)
5. Teacher consent to participate in study (teachers of targeted child only)

II. Protections Against Risk
There are planned procedures in place for protecting against or minimizing potential risks, including risks to privacy of individuals or confidentiality of data.
1. Potential risk #1 (discomfort with assessment procedures), and
2. Potential risk #2 (discomfort in disclosing sensitive information
Safeguards: Participants may choose not to answer questions or not to participate in particular assessment components. Participants have the right to withdraw from

this program at any time. All research staff receives training in building rapport with participants and skillful interviewing in order to minimize discomfort and embarrassment. Each study participant receives a verbal and written description of the study. If a staff member determines that a participant's reading skills are limited, all materials will be presented verbally and questionnaires will be administered as an interview. Informed consent is received from the legal guardian(s) of all children participating in the study and children will be asked to assent through a Child Assent form. Participants are advised of their right to withdraw from the project at any time. Experienced research staff members are available at all points of the study process to answer questions and to make the data collection as easy as possible for families. Assessment results will be shared with participants upon completion of the assessments.

3. Potential risk #3 (violation of confidentiality in accordance with mandatory reporting requirements)
Safeguards: To prevent violation of confidentiality, reporting requirements are limited to the mandatory nature of these requirements. Participants are informed verbally and in the consent document that professional staff are required by law to report to the appropriate authorities any danger of serious physical harm to the child, physical injury to any child caused by anything other than accidental means, or any case where the professional suspects a child is being neglected. The consent document also states that staff will inform parents or guardians if, in the judgment of professional staff, their child (under age 18) is in imminent danger of attempting to kill him or herself. Licensed psychologists (e.g., the PI) are available at all hours to provide resources for parents whose child appears to be in imminent danger of suicide.

4. Potential risk #4 (violation of confidentiality)
Safeguards: Extensive procedures are in place to prevent confidentiality violation and errors resulting from data processing. Participants are assigned a coded identification number that is used on all data collection measures. Identifying information necessary for participant contact, such as names, addresses, and telephone numbers are kept in locked filing cabinets or in our secure participant database. Access to the online database is restricted to those with valid usernames and passwords and limited to those staff members whose jobs require use of this information for contacting participants. Individuals using this database receive unique and identifiable usernames and passwords. Relational database passwords must be changed on a regular basis. All staff members are required to close password-protected applications or lock their workstations when they are away from their desks. During data analysis all identifying information, with the exception of the participant identification number is removed from the data. No information about identities of the study participants will be published or presented at conferences.

5. Potential risk #5 (misunderstanding regarding the use of the research data)
Safeguards: Prior to participating in the study, all participants, including children, will read or have read to them a detailed consent form described in the Recruitment and Informed Consent section above. Participants will only be asked to sign the consent form after all of their questions and concerns have been

addressed to their satisfaction. In addition to explaining the assessment procedures, all potential uses of the collected data, and confidentiality procedures, the consent forms emphasize that participation is completely voluntary, and participants have the right to withdraw from the study at any time. To avoid feelings of coercion, it will be made clear that participation in the study is completely voluntary.

5.3 Follow-Up:

Complete assessments at four time points. Assessments are listed and described below and included in the Table 1 Appendix.
a. T1 (baseline (BL) and prior to the start of the intervention); both on-line and in-home data is collected from families; child self-report measures will be gathered and are standardized with children over 8.
b. Responder Checkpoint – Parent Locus of Control 22-item questionnaire completed by parents 4 weeks after they start the intervention
c. T2 (6 months following baseline); only online parent data will be gathered, (no in-home assessment)
d. T3 (12 months following BL, i.e. following the end of the reintegration session(s) and program completion); both on-line and in-home data is collected from families, child self-report measures will be gathered from children over age 8.
e. T4 (24 months after BL); both on-line and in-home data is collected from families, child self-report measures will be gathered from children over age 8.

6.0 Data Banking

NA

7.0 Sharing of Results with Participants

NA

8.0 Study Duration

8.1 Describe:

- Study participants can expect to be involved in the study for 2 years.
- 21 months (complete recruitment May 2018).
- 4 years (complete study September 30, 2020).

9.0 Study Population

9.1 Inclusion Criteria:

Recruitment is limited to families meeting the following inclusion criteria: (a) one parent has returned from deployment (b) at least one child age 5 to 12 in their custody and living with parent(s) in the home. (c) We will include both single-and two-parent families, as well as families where care is shared between non-partnered adults (e.g. grandparent and mother), and will control for relationship status in the analyses. (d) Participants must agree to randomization, and (e) indicate willingness to interact with study materials and complete assessment

batteries. Women and minorities are included in the study. Inclusion criteria (a), (b), (c), (d), and (e) are necessary to meet the specific aims of the study and to meet the requirements of PMTO/ADAPT.

9.2 Exclusion Criteria:

Exclusion criteria include: (a) families with children younger than 5 or older than 12 – see the above rationale for the age limitation of children; (b) parent has an active psychosis, (c) an open child protection case for abuse or neglect in the family, (d) a serious child mental health diagnosis, i.e., autism, child psychosis (e) youth do not meet age criteria, (f) youth have a documented pervasive developmental disability or mental retardation, (g) less than a 5th grade comprehension level in English. Children and families will not benefit from a prevention intervention if either the parent or the child has a serious mental illness, if the family has an active child protection case, or if the parents are not able to comprehend the materials.

Screening:

Potential participants will be asked to take an online eligibility survey that will screen for inclusion criteria.

10.0 Vulnerable Populations

10.1 Vulnerable Populations:

- ☒ Children
- ☐ Pregnant women/Fetuses/Neonates
- ☐ Prisoners
- ☐ Adults lacking capacity to consent and/or adults with diminished capacity to consent, including, but not limited to, those with acute medical conditions, psychiatric disorders, neurologic disorders, developmental disorders, and behavioral disorders
- ☐ Non-English speakers
- ☐ Those unable to read (illiterate)
- ☐ Employees of the researcher
- ☐ Students of the researcher
- ☐ None of the above

10.2 Adults lacking capacity to consent and/or adults with diminished capacity to consent:

NA

10.3 Additional Safeguards:

Potential Risks
Potential discomfort and risks participants may experience as a result of their involvement in this study include the following:
1. Discomfort with assessment procedures (e.g., videotaping)
2. Discomfort in disclosing sensitive information

3. Violation of confidentiality as a result of compliance with mandatory reporting requirements
4. A possible violation of confidentiality due to mishaps with identified data
5. Discomfort resulting from misunderstanding the planned use of data
Participation in this research involves minimal risk, defined in the Federal guidelines, as "the probability and magnitude of harm anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." (Federal Register, 1991, 45CFR 46.102(i). Procedures are in place to minimize risk of violation of confidentiality, as indicated: If the study child or participating caregiver discloses information regarding child abuse or threat to self or others, professionals are mandated to report the information to appropriate authorities. This information will be clearly stated verbally and on the consent forms. It is not likely that participants will experience physical, social or legal risks due to enrollment in the study because state mandated procedures exist to protect them. There are no financial risks to participants. Procedures are in place for providing suitable informed consent, clearly describing the assessment activities, emphasizing the voluntary nature of the study, and communicating the purpose and use of the data collected. These procedures are intended to minimize participant's misunderstanding of or dissatisfaction with the research.

Practices to minimize the risk with children.
a. The informed consent process for child participation will be conducted during the in-home assessment process. The study, procedures, and tasks of the study will be explained to both the parent and the child. Both child assent and parental consent forms will be presented to the family and explained.
b. The research staff conducting the informed consent process will ask each child to explain the study process in their own words to assure that they understand what is being asked of them and what they will be asked to do (e.g. answer questions, play a game with their parents, be willing to be video-taped while playing the game).
c. Research staff will ask both the parent and child, separately and directly, if they have any questions or concerns about the study. It will be stated very directly to the child that no one will be angry or upset with them if they decide not to participate in the study and that they can change their mind or ask more questions at any time during the study.
d. Once the research staff has been able to ascertain that both the child and the parent understand the procedures of the study and what the child will be asked to do, written signatures will be requested from the parent and child on both the Child Assent form and the Parental Consent form.

11.0 Number of Participants

11.1 Number of Participants to be Consented:

525

12.0 Recruitment Methods

12.1 Recruitment Process:

We will recruit subjects with the assistance of a broad base of collaborators including United States Special Operations Command (USSOCOM) Protection of the Force and Family (POTFF) staff, component and installation Chaplains, Military Family Life Consultants (MFLCs), Family Advocacy Program staff and Behavioral Health staff.

We will recruit using three methods found to be effective in prior studies: (i) convenience sampling and extensive outreach to military service providers (USSOCOM and USASOC directors and deputy directors, Command Chaplains, Family Readiness Group (FRG) leaders, Family Readiness Support Assistants (FRSAs), Military Family Life Consultants (MFLCs), social workers, psychologists, and medical providers); (ii) media and local installation publicity including print, television, and social media, and (iii) direct outreach to eligible families (via presence at family picnics, reintegration and other installation events, and letters, emails, and phone calls to those who indicate initial interest and provide contact information to our internet site or at outreach events. Recruitment flyers promoting the study will be distributed to our partners (chaplains, MFLCs, installation providers) and via installation and unit/group websites, picnics, and other outreach events. Flyers will provide the study site URL and phone number.

If recruitment becomes a challenge, a "refer a friend" postcard will be used to encourage current study participants to share the opportunity with eligible participants. Refer a friend postcards will be distributed to current participants at one of their in-home assessments. Current participants will be given five postcards to share with up to five friends. Since the referred friend must consent to be in the study their enrollment is considered voluntary. The referred friend will be asked to name, by typing in, the referring friend (current participant) during their initial screening for eligibility and consent process. Current participants can earn a $10 gift card per new participant recruited/enrolled as long as the new participant completes their initial in-home visit (T1). This requirement is stated on the postcard. The total amount they can be compensated for referring a friend is $50 in gift cards (5 postcards given x $10 gift card per referred friend that completes a T1).

12.2 Source of Participants:

Eligible families will reside on or near the following installations and have at least one parent belonging to SO or RA, as follows:
(i) SO (to include elements of the US Army Special Operations Command (USASOC) located at Fort Bragg, NC: 3rd Special Forces Group, JFK Special Warfare Center and School, 4th PsyOps Group; 95th Civil Affairs Brigade; 528th Sustainment Brigade for a total of roughly 9,000 SO population) or RA (to include XVIII Airborne Corps Headquarters, the 1st Theater Sustainment Command, 82nd Airborne Division, and associated sustainment units and separate Corps support units) assigned to Ft. Bragg.

(ii) SO elements of USASOC located at Fort Campbell, KY including 5th Special Forces group, 160th Special Operations Aviation Regimental headquarters, 1st and 2nd Battalions) or 101st Airborne Division and associated separate support units 21,500 (not including 5000 SO) service members, (not including SO units) of whom approximately 18,000 are married).
(iii) Active Duty families assigned to, living on or served by Fort Belvoir, VA. Fort Belvoir is home to several Army command headquarters, units and agencies of nine different Army major commands, 16 different agencies of the Department of the Army, eight elements of the U. S. Army Reserve and Army National Guard and nine DOD agencies. In addition to U.S. Army forces, the U. S. Navy construction battalion, a Marine Corps detachment, one U. S. Air Force unit, and an agency of the Department of Treasury are also located at Fort Belvoir.
(iv) Active Duty families assigned to, living on or served by Fort Myer, VA. Joint Base Myer–Henderson Hall (JBMHH) consists of military installations at Fort Myer, Virginia, Crystal City, The Pentagon, Fort McNair, the District of Columbia, and Henderson Hall – Headquarters Marine Corps, Virginia. It is commanded by the United States Army but has resident commands of Army, Navy, & Marines. Fort Myer is headquarters to service personnel working throughout the National Capital Region.

We will recruit using three methods found to be effective in prior studies: (i) convenience sampling and extensive outreach to military service providers (USSOCOM and USASOC directors and deputy directors, Command Chaplains, Family Readiness Group (FRG) leaders, Family Readiness Support Assistants (FRSAs), Military Family Life Consultants (MFLCs), social workers, psychologists, and medical providers); (ii) media and local installation publicity including print, television, and social media, and (iii) direct outreach to eligible families (via presence at family picnics, reintegration and other installation events, and letters, emails, and phone calls to those who indicate initial interest and provide contact information to our internet site or at outreach events. Recruitment flyers promoting the study will be distributed to our partners (chaplains, MFLCs, installation providers) and via installation and unit/group websites, picnics, and other outreach events. Flyers will provide the study site URL and phone number.
If recruitment becomes a challenge, a "refer a friend" postcard will be used to encourage current study participants to share the opportunity with eligible participants. Refer a friend postcards will be distributed to current participants at one of their in-home assessments. Current participants will be given five postcards to share with up to five friends. Since the referred friend must consent to be in the study their enrollment is considered voluntary. The referred friend will be asked to name, by typing in, the referring friend (current participant) during their initial screening for eligibility and consent process. Current participants can earn a $10 gift card per new participant recruited/enrolled as long as the new participant completes their initial in-home visit (T1). This requirement is stated on the postcard. The total amount they can be compensated for referring

a friend is $50 in gift cards (5 postcards given x $10 gift card per referred friend that completes a T1).

12.3 Identification of Potential Participants:

Participants will self-identify in response to media and local installation publicity, attendance at outreach/unit/family events, and through contact with service providers such as chaplains, military and family life consultants, and so on. Initial contact will be made by site coordinator on each installation only after participants express interest and provide their contact information.

If recruitment becomes a challenge, a "refer a friend" postcard will be used to encourage current study participants to share the opportunity with eligible participants. Refer a friend postcards will be distributed to current participants at one of their in-home assessments. Current participants will be given five postcards to share with up to five friends. Since the referred friend must consent to be in the study their enrollment is considered voluntary. The referred friend will be asked to name, by typing in, the referring friend (current participant) during their initial screening for eligibility and consent process. Current participants can earn a $10 gift card per new participant recruited/enrolled as long as the new participant completes their initial in-home visit (T1). This requirement is stated on the postcard. The total amount they can be compensated for referring a friend is $50 in gift cards (5 postcards given x $10 gift card per referred friend that completes a T1).

12.4 Recruitment Materials:

Primary recruitment materials will be flyers. Flyers will be available through service providers and military partners, at installation events and on social media. Flyers can also be send as email attachment or embedded as a picture into communications.

If recruitment becomes a challenge, a "refer a friend" postcard will be used to encourage current study participants to share the opportunity with eligible participants. Refer a friend postcards will be distributed to current participants at one of their in-home assessments. Current participants will be given five postcards to share with up to five friends. Since the referred friend must consent to be in the study their enrollment is considered voluntary. The referred friend will be asked to name, by typing in, the referring friend (current participant) during their initial screening for eligibility and consent process. Current participants can earn a $10 gift card per new participant recruited/enrolled as long as the new participant completes their initial in-home visit (T1). This requirement is stated on the postcard. The total amount they can be compensated for referring a friend is $50 in gift cards (5 postcards given x $10 gift card per referred friend that completes a T1).

12.5 Payment:

I. Incentives for Participation in Assessments:
Off-duty and civilian parents will be paid $25 for each online assessment (up to 2 parents/caregivers per family); $50.00 for each in-home assessment/family (50);

$100.00 for the final in-home / family; $10.00/parent for the PLOC; $25.00/parent at 6 month follow-up online only; $25.00/parent at 12 month and 24 month follow-ups; $25.00.
II. Incentives for Participation in the Interventions:
(a) Self-directed online only: $50.00/family
(b) Condensed ADAPT: $50.00/family
(c) Full group ADAPT: $50.00/family
(d) Individual ADAPT: $50.00/family
We will also provide small incentives for home practice assignment and group attendance via a drawing for snow scrapers, candles, etc.
Self-directed online only participants will have a chance to enter into a drawing based on the number of times (up to 7) that they respond to facilitator questions. One winner will be selected per cohort to receive a $100 gift card.
III. Incentives for Children Participants:
Children will be given a gift worth approximately $5.00 at Times 1, 3, and 4 for participating in the observation (FIT). Families are eligible to receive up to $520.00 in total incentives.
IV. Incentives for Teacher Participants:
Teachers will be paid $10.00 for completing assessments at Times 1, 3, and 4.
V. Incentives for Focus group Participants
(a) Focus group participants will be paid $25.00 per feedback session.
NOTE: Active duty participants are not allowed to receive incentives per DoD policy.

13.0 Withdrawal of Participants

13.1 Withdrawal Circumstances:

Participants will be involuntarily withdrawn from the study in the event of their death or the target child or in the case of a parent's loss of custody of the target child.

13.2 Withdrawal Procedures:

If a participant voluntarily withdraws from the study there is no further data collection and data collected prior to their withdraw date will not be analyzed.

13.3 Termination Procedures:

Data that is already collected from participants who are withdrawn without their consent (as described in 13.1), will still be used unless they explicitly request that we do not.

14.0 Risks to Participants

For each risk or set of risks below, include the procedures to be performed to lessen the probability, magnitude, duration, or reversibility of those risks.

14.1 Foreseeable Risks:

Potential Risks

Potential discomfort and risks participants may experience as a result of their involvement in this study include the following:
1. Discomfort with assessment procedures (e.g., videotaping)
2. Discomfort in disclosing sensitive information
3. Violation of confidentiality as a result of compliance with mandatory reporting requirements
4. A possible violation of confidentiality due to mishaps with identified data
5. Discomfort resulting from misunderstanding the planned use of data
Participation in this research involves minimal risk, defined in the Federal guidelines, as "the probability and magnitude of harm anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." (Federal Register, 1991, 45CFR 46.102(i). Procedures are in place to minimize risk of violation of confidentiality, as indicated: If the study child or participating caregiver discloses information regarding child abuse or threat to self or others, professionals are mandated to report the information to appropriate authorities. This information will be clearly stated verbally and on the consent forms. It is not likely that participants will experience physical, social or legal risks due to enrollment in the study because state mandated procedures exist to protect them. There are no financial risks to participants. Procedures are in place for providing suitable informed consent, clearly describing the assessment activities, emphasizing the voluntary nature of the study, and communicating the purpose and use of the data collected. These procedures are intended to minimize participant's misunderstanding of or dissatisfaction with the research.

II. Protections Against Risk
There are planned procedures in place for protecting against or minimizing potential risks, including risks to privacy of individuals or confidentiality of data.
1. Potential risk #1 (discomfort with assessment procedures), and
2. Potential risk #2 (discomfort in disclosing sensitive information
Safeguards: Participants may choose not to answer questions or not to participate in particular assessment components. Participants have the right to withdraw from this program at any time. All research staff receives training in building rapport with participants and skillful interviewing in order to minimize discomfort and embarrassment. Each study participant receives a verbal and written description of the study. If a staff member determines that a participant's reading skills are limited, all materials will be presented verbally and questionnaires will be administered as an interview. Informed consent is received from the legal guardian(s) of all children participating in the study and children will be asked to assent through a Child Assent form. Participants are advised of their right to withdraw from the project at any time. Experienced research staff members are available at all points of the study process to answer questions and to make the data collection as easy as possible for families. Assessment results will be shared with participants upon completion of the assessments.
3. Potential risk #3 (violation of confidentiality in accordance with mandatory reporting requirements)

Safeguards: To prevent violation of confidentiality, reporting requirements are limited to the mandatory nature of these requirements. Participants are informed verbally and in the consent document that professional staff are required by law to report to the appropriate authorities any danger of serious physical harm to the child, physical injury to any child caused by anything other than accidental means, or any case where the professional suspects a child is being neglected. The consent document also states that staff will inform parents or guardians if, in the judgment of professional staff, their child (under age 18) is in imminent danger of attempting to kill him or herself. Licensed psychologists (e.g., the PI) are available at all hours to provide resources for parents whose child appears to be in imminent danger of suicide.

4. Potential risk #4 (violation of confidentiality)
Safeguards: Extensive procedures are in place to prevent confidentiality violation and errors resulting from data processing. Participants are assigned a coded identification number that is used on all data collection measures. Identifying information necessary for participant contact, such as names, addresses, and telephone numbers are kept in locked filing cabinets or in our secure participant database. Access to the online database is restricted to those with valid usernames and passwords and limited to those staff members whose jobs require use of this information for contacting participants. Individuals using this database receive unique and identifiable usernames and passwords. Relational database passwords must be changed on a regular basis. All staff members are required to close password-protected applications or lock their workstations when they are away from their desks. During data analysis all identifying information, with the exception of the participant identification number is removed from the data. No information about identities of the study participants will be published or presented at conferences.

5. Potential risk #5 (misunderstanding regarding the use of the research data)
Safeguards: Prior to participating in the study, all participants, including children, will read or have read to them a detailed consent form described in the Recruitment and Informed Consent section above. Participants will only be asked to sign the consent form after all of their questions and concerns have been addressed to their satisfaction. In addition to explaining the assessment procedures, all potential uses of the collected data, and confidentiality procedures, the consent forms emphasize that participation is completely voluntary, and participants have the right to withdraw from the study at any time. To avoid feelings of coercion, it will be made clear that participation in the study is completely voluntary.

14.2 Reproduction Risks: *NA*

14.3 Risks to Others: *NA*

15.0 Incomplete Disclosure or Deception

15.1 Incomplete Disclosure or Deception: *NA*

16.0 Potential Benefits to Participants

16.1 Potential Benefits:

Families will benefit from receiving prevention services from well-trained and well-supported group facilitators. Families will have increased possibility of experiencing significant improvements in their child's adjustment as well as delay and prevention of substance use and abuse. The web-enhancement will give families access to an online training platform which allows already overburdened parents to balance the demands of work and family with their commitment to improving their parenting skills and fostering optimal development for their children. Additionally, participating in a parenting program designed specifically for the families of reintegrating military personnel will reduce the psychological barriers to help-seeking for this high-risk population. In light of the considerable personal and public costs associated with compromised parenting, the potential benefits of participating in this study greatly exceed the potential risks.

17.0 Data Management

17.1 Data Analysis Plan:

Analyses will be conducted in several steps, starting with preliminary and preparatory analyses including data reduction and evaluation of psychometric properties, followed by evaluation of missing data of criterion measures. For the primary efficacy evaluation aims of main effect components and the four adaptive intervention strategies we will employ standard normal theory Analysis of Covariance factorial and fractional factorial analyses to address study aims using pre-post assessment scores for parent and child adjustment constructs. To address the non-independence of subjects in the embedded adaptive intervention designs we will estimate Linear mixed models and weighted least squares regressions for estimation of the embedded adaptive intervention contrasts. Descriptive statistics (mean, range, SD) will be used in reporting participation, satisfaction (for fathers and mothers), and implementation fidelity (for each provider and the group of ADAPT providers).

17.2 Power Analysis:

First, we chose a power convention of .80 with a two-sided alpha level of .05 to reduce the probability of obtaining a false positive improvement or intervention effect rejecting the null when it is true (Type-I error at 5% chance). Second, we powered the study to detect small to medium effect sizes for the first and second stage randomizations. The first stage randomization is allocated with a 1:1 ratio to group conditions as depicted in Figure 6. Based on the ROC analyses we estimate a potential 50% non-response rate for both the online and weekend condensed groups. After the Week 4 assessment of response criteria, non-responders will also be randomized to second stage interventions with a 1:1 allocation.

More specifically, power needed to be estimated by addressing the restricted randomization scheme and appropriate weighting of the overrepresentation of responders and underrepresentation of nonresponders. We employed procedures outlined by Oetting and colleagues for estimating power in SMART trial designs. As recommended, we specified an alpha level of .10 and power of .80. The first main research question (2a) addresses main effects of initial stage randomization,

the second question (2b) addresses the main effects of the second stage randomization for non-responders. Finally, the third main question (2c) addresses the overall optimal adaptive intervention strategy for military. Following methods outlined by Oetting et al. (2011), the proposed SMART trial is adequately powered to detect small to medium effects for Research Questions 2a, 2b, and 2c. Based on our prior studies outlined above, power was estimated using an estimated 10% to 20% attrition over the study. See chart below.

ADAPT SMART Trial Mimimally Detectable Effect (MDE) with .80 Power and 10% and 20% Attrition

Total Sample	Research Question	Analysis Contrasts	Correct Strategy *p*	10% Attrit. MDE δ	20% Attrit. MDE δ
525-10% = 473	Q2a	[A+B+C] vs. [D+E+F]		.324	.343
262-10% = 236	Q2b	[B+E] vs [C+F]		.458	.485
Nmax = 473[1]	Q2c	[A+B]vs [A+C]vs [D+E]vs [D+F]	.95	.285	.301

17.3 Data Integrity:

Site coordinators and the project manager will oversee assessment technicians and conduct quality control checks regularly throughout the data collection process. If needed, additional training will be provided to assessment technicians. Video recordings of family interaction tasks will be monitored by the coding coordinator to ensure high quality and consistency across assessment technicians. Survey data will be cross-checked and cleaned shortly after in-home assessments are conducted to ensure data were collected accurately as well as resolve any discrepancies in key study variables (e.g., deployment status, marital status, gender, etc).

18.0 Confidentiality

18.1 Data Security:

Participants are assigned a coded identification number that is used on all data collection measures. This includes a family id (e.g. individual #1 in family #1 is 0001-1). Identifying information necessary for participant contact, such as names, addresses, and telephone numbers are kept in locked filing cabinets or in our secure participant database. Access to the online database is restricted to those with valid usernames and passwords and limited to those staff members whose

jobs require use of this information for contacting participants. Individuals using this database receive unique and identifiable usernames and passwords. Relational database passwords must be changed on a regular basis. All staff members are required to close password-protected applications or lock their workstations when they are away from their desks. During data analysis all identifying information, with the exception of the participant identification number is removed from the data. No information about identities of the study participants will be published or presented at conferences.

To ensure confidentiality, all information will be coded so that it cannot be associated with any individual. To minimize the risk of loss of confidentiality, the data collected online in this study will be protected by the use of separate databases. The first will include the subject consent forms, first names only and subject ID. Other databases will include the questionnaire data from the project, and participants' study ID will be the only unique piece of information linking the data files to the consent file. Video files of observational assessment tasks will be stored in a separate storage area online. Only study IDs will be used to link videos to questionnaire data. These files will all be password protected and accessible to only a limited number of project personnel. In order to protect participant data during internet based research, the project will use Qualtrics, a sophisticated online data management system that maintains extremely stringent levels of encryption and data storage.

Qualtrics is specifically designed to meet and exceed industry standards for Internet security as well as Institutional Review Board (IRB) and Data Safety and Monitoring Board (DSMB) standards for the protection of research participants. For participants, secure servers with registered site certificates provided by VeriSign Internet Trust Services provide for advanced encryption over the wire. To ensure an even greater level of security and confidentiality, Qualtrics also requires that participants are authenticated to gain access to the data entry forms. Participants will receive an email with the survey name specified as a query string parameter in the URL, which is encrypted by Secure Sockets Layer (SSL). As users move through the data entry forms, the responses are encrypted while in-transit between the browser and Qualtrics's server using SSL and 40, 56, or 128-bit Public Key Encryption. All data collection is performed using SSL with 128-bit secure key encryption whenever possible. Data will be stored on the Qualtrics server and will be downloaded to U of MN and de-identified data to ISII in Oregon for analysis. Qualtrics servers are stored in a locked, well-ventilated room in locked server cabinet/racks and are protected by alarm security.

Questionnaires will be designed so that individuals cannot be identified on the basis of their data alone, and as noted above, all identifying information will be stored in a separate database from the data files. All subject identification data will be destroyed at the end of the project. The collected materials will be used only for research purposes; participants' records with identifying information will not be released to anyone without participants' written permission.

All University of Minnesota and ISII employees who will work on this project, including administrative, research, and production staff, have attended at least one training session on protecting the rights and welfare of human research subjects.

The session(s) included an overview of the history of human subjects' protection, an overview of the Belmont Report, a review of IRB policies and procedures, and a discussion of the regulatory requirements regarding informed consent. The University of Minnesota has a mandatory IRB curriculum for all Principal Investigators, which Dr. Gewirtz and all other project investigators and staff have completed. In addition, all project staff received adequate training in the responsible conduct of research involving human subjects through participation and completion of the CITI Human Subjects Research Educational Model course (delivered by the NIH).

All data entered into the computerized database will be identifiable by subject code number only. All research staff sign confidentiality agreements. No one except the research staff will have access to records identifying subjects' names at any time. The information gathered will be used only for scientific, educational, or instructional purposes. A Certificate of Confidentiality was approved by the National Institute of Child Health and Human Development (expires 09/30/2020), to further protect privacy of each participant and avoid compelled "involuntary disclosure" (e.g., subpoenas) of identifying information about a research subject. It should be noted that we are not allowed to ask substance use questions to Active Duty participants and will encode the online survey with logic if-then routing that will eliminate those questions from the battery of assessment for active duty participants.

The link between identifiers and code will be maintained for 10 years following the end of data collection.

Data will be kept for ten years following the end of data collection in order to allow sufficient time for analysis of videotaped observations, which are coded using microsocial/second-by-second techniques, and are very time-consuming to code. Following this, videotaped data will be destroyed.

A Certificate of Confidentiality was approved by the National Institute of Child Health and Human Development (expires 09/30/2020), to provide further protection of our study participants and our data.

Most data will be stored electronically, but some situations may require the use of paper form.

Data will be stored on secure, password-protected servers.

Access to data will be restricted to the Project Offices at the University of Minnesota. All space accessible to the public is separated from research offices by locked doors. All staff entrances are secured with locked doors. All paper forms will be kept in locked file cabinets. The Department's computing system is protected from outside access. The planned complexity of this system helps increase the security of the local network. Servers maintain logs and generate reports of access attempts, which are reviewed by the Network Administrator.

During the analysis of the data, all identifying information with the exception of the subject identification number is removed from the data. No information about the identities of study participants will be published or presented at conferences.

19.0 Provisions to Monitor the Data to Ensure the Safety of Participants

NA

20.0 Provisions to Protect the Privacy Interests of Participants

20.1 Protecting Privacy:

Assessments are conducted either online or, if in person, in subjects' homes, to ensure convenience for participants. We have conducted in-home assessments in prior studies without problems. Military populations may be especially resistant to coming to a university or hospital setting for assessment or intervention, which is why program activities (for in-person groups) will be held in community locations or on base locations convenient to participants (i.e. libraries, community centers). As participants are recruited we will determine optimum group locations.

20.2 Access to Participants: NA

21.0 Compensation for Research-Related Injury

21.1 Compensation for Research-Related Injury: NA

22.0 Consent Process

22.1 Consent Process (when consent will be obtained):

(1) Interested participants will be directed to an anonymous online screening instrument, which determines eligibility based on inclusion criteria.

a. To manage study participation and administer online measures, we have a secure website that maintains stringent, HIPAA-compliant levels of encryption and data storage, and sophisticated data management and collection features.

b. The website guides parents to an explanation of the project, and a description of project confidentiality and its limits. Online procedures adhere to guidelines to guarantee the same level of human subjects' protection to online participants as participants in more traditional studies.

(2). Eligible participants will next complete a brief online contact information form, followed by an online informed consent that provides information about study risks, benefits and the possibility of being randomly assigned to an online or group-based ADAPT program, as well as the possibility of being further randomized to additional program components. In families with two participating parents, each will complete an informed consent. The consent form is attached.

(3). Consenting participants will be provided a contact number in order to speak to the PI or study coordinator with any questions. Families who request a telephone screening (e.g., families whose internet is not accessible at the time of the call) will be asked for verbal consent for the research team to maintain contact through weekly reminder emails and

phone calls to complete informed consent and baseline (BL) online assessments. Where informed consent is not completed prior, it may be completed at the beginning of the in-home assessment.

(4). Participants who submit their informed consent will automatically be directed to log in to the baseline (BL) assessment by providing their email and creating a password (the study website will use our existing assessment infrastructure to post and administer assessments). Participants who lose their password can retrieve it from the system.

(5). Upon logging in, participants will be given the online portion of the BL assessment.

The assessment package includes self-report measures (Table 1) to be completed by each participating parent or caregiver. The assessment package takes each adult approximately 35 minutes to complete, and upon completion participants are each compensated $25 (per assessment package completed; up to two per family). Parents also are asked to schedule a 15-minute study orientation call, and in-home assessment appointment with project staff. Families who do not complete the online assessment will be asked to complete the assessment during the assessment in-home visit.

(6). A copy of the parental consent form will be offered to and left with families at the first (BL) in-home visit and all subsequent visits (T3 and T4).

(7). Child assent will be completed at the first (BL) in-home assessment. The assent form is attached.

a. In-home assessments will be conducted by pairs of well-trained research assistants located on or near each base who will be employees of the University of Minnesota with extensive experience with military families (as veterans, spouses or relatives, and/or service providers) and with some research experience. They will be provided extensive training in data privacy, HIPAA, human subjects' protection, the consent process, and assessments.

Note: childcare provided by study staff is offered during in-home assessments for siblings. If study staff are not available to provide childcare, a $30 gift card stipend will be offered to the family so that they can arrange their own childcare.

b. Families who prefer assessment outside the home may go to the local project office. Following the BL assessment, participants are electronically (via computer program) given random assignment to clinical trial conditions, which have been explained during the consent process.

c. Teachers will be contacted via secure, encrypted email, with an explanation of the study, and a copy of the parent's release of information (see attached) . They will be directed to the study website to complete questionnaires. Teachers not

responding will receive materials by mail, with follow-up calls (this has been a very effective strategy in our prior studies).

22.2 Waiver or Alteration of Consent Process (when consent will not be obtained, required information will not be disclosed, or the research involves deception):

Waiver of consent is being requested because identifying information is collected via our online (using Qualtrics) screening process where we administer an eligibility survey before potential participants can give consent. After being determined eligible, potential participants continue to the on-line consent information and are asked to type their name in the box to show "signed" consent. A waiver of documentation of consent is also being requested since participant signature is collected on-line, by typing, and not in-person with live signature. It is essential that we screen for participation before obtaining consent and because this process is done on-line, we are asking for a waiver of consent for this process.

22.3 Non-English Speaking Participants: *NA*

22.4 Participants Who Are Not Yet Adults (infants, children, teenagers under 18 years of age):

One parent will give consent for their child, under the age of 18, but who is between 5 and 12 years old per our eligibility criteria, to take part in the study.

Assent will be obtained by the child assessment technician from the child participant during the first in-home assessment.

22.5 Cognitively Impaired Adults, or adults with fluctuating or diminished capacity to consent: NA

22.6 Adults Unable to Consent: NA

23.0 Setting

23.1 International Research: NA

23.2 Community Based Participatory Research: NA

23.3 Research Sites:

Research will occur on 3 military installations owned by a component of the Department of Defense.

24.0 Multi-Site Research

24.1 Study-Wide Number of Participants: *525*

24.2 Study-Wide Recruitment Methods:

Local recruitment methods are described earlier in the protocol.

24.3 Study-Wide Recruitment Materials:

Recruitment methods are described earlier in the protocol.

24.4 Communication Among Sites:

- A Site Coordinator at the U of MN has been assigned to ensure proper dissemination of all relevant study information and has the responsibility to ensure that participating sites are conducting the study according to provided documents.
- The Site Coordinator at the U of MN has weekly one on one meetings with participating sites and periodic meetings with all three sites.
- Participating sites are encouraged to hold their own meetings to collaborate and share best practices.
- Participating sites have Site Coordinators that have access to the U of MN secure server where all applicable study documents are maintained and available.
- All sites have the most current version of the protocol, consent document(s), and, when applicable, HIPAA authorization.
- All engaged participating sites will safeguard data, including secure transmission of data, as required by local information security policies.
- All local site investigators conduct the study in accordance with applicable federal regulations and local laws.
- All non-compliance with the study protocol or applicable requirements will be reported in accordance with university or local policy.
- All other reportable events in accordance with university or local policy.

24.5 Communication to Sites:

- A Site Coordinator at the U of MN has been assigned to ensure proper dissemination of all relevant study information and has the responsibility to ensure that participating sites are conducting the study according to provided documents.
- The Site Coordinator at the U of MN has weekly one on one meetings with participating sites.
- Participating sites have Site Coordinators that have access to the U of MN secure server where all applicable study documents are maintained and available.
- The Site Coordinator at the U of MN sends a monthly power point update to each site with relevant and occurring study information.

25.0 Resources Available

25.1 Resources Available:

We are collaborating with Co-Investigators Dave DeGarmo at University of Oregon to provide data analysis and Marion Forgatch at Implementation Sciences International, Inc. (ISII) to advise on program implementation and fidelity.

We will recruit subjects with the assistance of a broad base of collaborators including United States Special Operations Command (USSOCOM) Protection of the Force and Family (POTFF) staff, component and installation Chaplains, Military Family Life Consultants (MFLCs) and Family Advocacy Program staff. See attached support letters from our military consultants and collaborators.

26.0 References

Almirall, D., et al., Designing a pilot sequential multiple assignment randomized trial for developing an adaptive treatment strategy. Stat Med, 2012. 31(17): p. 1887-902.

Kasari, C., et al., Communication interventions for minimally verbal children with autism: a sequential multiple assignment randomized trial. J Am Acad Child Adolesc Psychiatry, 2014.53(6): p. 635-46.

Thall, P.F., et al., Adaptive therapy for androgen-independent prostate cancer: a randomized selection trial of four regimens. J Natl Cancer Inst, 2007. 99(21): p. 1613-22.

Murphy, S.A., et al., Developing adaptive treatment strategies in substance abuse research. Drug Alcohol Depend, 2007. 88 Suppl 2: p. S24-30.

August, G.J., T.F. Piehler, and M.L. Bloomquist, Being "SMART" About Adolescent Conduct Problems Prevention: Executing a SMART Pilot Study in a Juvenile Diversion Agency. J Clin Child Adolesc Psychol, 2014: p. 1-15.

	Domain	Measure	Location	Number of Items	Time to Complete
Parents	Parenting sense of control	PLOC	In home	24	5 minutes
	Parenting Practices	APQ-22	In home	22	5 minutes
	Deviant peer association	PEERS	In home	18	5 minutes
	Child internalizing and externalizing	BASC-3	In home	160	10 minutes
	Coping with children's neg emotions	CCNES	In home	72	10 minutes
	PTSD supplement question	Ever experienced trauma	Either	1	1 minute
	PTSD	PCL	In home	18	5 minutes
	Context measures	DRRI (Sections I&J Only)	In home	30	5 minutes
		Total Time for In-Home Parent Survey Measures:			**46 minutes**
	Demographic questionnaire	Assorted items	Online		5-10 minutes
	Couple adjustment	DAS-7	Online	7	2 minutes
	Mindfulness	FFMQ	Online	39	7 minutes
	Substance use	AUDIT	Online	10	1 minute
	Emotion regulation	DERS	Online	36	5 minutes
	Depression	CESD	Online	20	3 minutes
	Parenting support	PSI/receipt of help	Online	48	5 minutes
	Moral Injury	MIES	Online	9	2 minutes
	Parenting mindfulness	IEM-P	Either	10	2 minutes
	Parenting Identity	DeGarmo Scale	Either	8	2 minutes
		Total Time for Online Parent Survey Measures:			**40 minutes**
Parent	EF – Inhibitory Control	NIH Toolbox – Flanker	In home		5 minutes
	Verbal Ability	NIH Toolbox – Peabody Picture Vocabulary test	In home		5 minutes
		Total Time for IQ/EF tasks:			10-15 minutes
Child	Deviant peer association	Describing friends	In home	44	5-10 minutes
	Internalizing and externalizing	BASC-3	In home	176	10-25 min

	Internalizing	CDI	In home	10	5 minutes
	PTSD-RI	Combo of DSM-IV/V items	In home	52	5-10 minutes
		Total Time for Child In Home Measures (minus PTSD):			**45-50 minutes**
Teacher	Deviant peer association	TPRISK	Online	24 items	5 minutes
	Internalizing and externalizing	BASC-3	Online	139	10-20 min
		Total Time for Teacher Measures:			**15-25 minutes**