PROTOCOL TITLE:

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

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REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?
4	9/12/2017	IRB application (V4) transferred to protocol template for Ethos migration; incorporates all CIP that were submitted and approved after this original application and up until Ethos migration.	NA
5	3/28/2018	Updated process for Smartphone/Android application (App)	NA
6	5/4/2018	Addition of three measures (Life Events Checklist (LEC-5), Child Lifetime Events and DRRI-Section K 1 and 2) to be collected at time point 4 (T4). See updated attached measures list.	NA

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ABBREVIATIONS/DEFINITIONS

Include any abbreviations or definitions for key or technical terms you use in your protocol.

STUDY SUMMARY

Study Title	Comparing Web, Group, and Telehealth Formats of a Military Parenting Program
Study Design	Randomized Control Trial
Primary Objective	Advance the research on family-based prevention of negative outcomes for reintegrating Operation Enduring Freedom/Operation Iraqi Freedom personnel by evaluating different formats of a parenting program, After Deployment, Adaptive parenting Tools (ADAPT).
Secondary Objective(s)	
Primary Study Intervention or Interaction	Delivery of three different formats (in-person, tele-health and online) of ADAPT.
Study Population	National Guard and Reserve (former and present) personnel in MN and MI, and their families
Sample Size (number of participants)	360
Study Duration for Individual Participants	2 years

1.0 Objectives

1.1 Purpose:

The overarching goal of this study is to advance research on family-based prevention of negative child outcomes for reintegrating Operation Enduring Freedom/Operation Iraqi Freedom personnel by evaluating different formats of a parenting program, After Deployment, Adaptive Parenting Tools/ADAPT. The ADAPT program is based upon the Parent Management Training-Oregon Model/PMTO, but adapted for military deployed families. We will examine which of three delivery formats of ADAPT is most effective at reducing youth risk behaviors associated with negative childhood outcomes by improving parenting, child, and parent adjustment. There is a clear intent to benefit all subjects in this study (except surveyed teachers), including children.

We will conduct a three-group, two-site randomized trial to test the comparative effectiveness of ADAPT delivery approaches. The study will randomly allocate 360 NGR families to one of three conditions: (i) group-based web-enhanced ADAPT; (ii) individualized web-facilitated ADAPT; or (iii) self-directed web ADAPT.

Thus, specific aims are as follows:

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

    a. Families will complete a pre-intervention baseline assessment and post-intervention follow-up assessments at 6, 12- and 24 months.

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

    a. Test the value-added impact of group-based delivery relative to facilitated and self-directed web approaches

    b. Comparative effectiveness will be tested by specifying a non-equivalence hypothesis for group based and individualized facilitated relative to self-directed web only

We hypothesize that (1) individualized web-facilitated parenting intervention will be equally effective as the group-based web-enhanced intervention, and (2) both individualized and group-based ADAPT will be more effective than a self-directed web-condition. Effective internet delivery methods will facilitate development of new approaches to engage military families separated by deployment, isolated by geographical location, and in need of strategies to deal with deployment and reintegration stressors, directly addressing limitations and barriers to access to evidence based prevention programs.

Analysis of Aim 1: ADAPT comparative effectiveness hypotheses will be tested using standard normal theory Analysis of Variance and multiple regression techniques in structural equation modeling (SEM) with a focus on growth curve analyses for follow up data. We will specify analyses to test Hypothesis 1: NGR families in both the ADAPT group-based condition and the ADAPT web-facilitated condition will show greater pre-post improvements in observed parenting, and parent, child, and couple functioning relative to the self-directed web condition; and Hypothesis 2: ADAPT group-based condition will be equally effective as the individualized ADAPT web-facilitated condition.

Analyses for Hypothesis 1 of Aim 1. We will employ standard normal theory pre-post Analysis of Variance and structural equation modeling (SEM) growth curve analyses for the long-term follow up. For the immediate pre-post analyses we will conduct a 3 group by 2 repeated measures Analysis of Variance for parenting, child, and couple functioning constructs focusing on the comparison of change across the Group Based, Individualized Facilitated, and Self-directed ADAPT conditions. The study randomly allocates 360 NGR families across the three conditions (n = 120 per group). For the 6-month assessment, we estimate a projected 5% attrition rate and over the 24-month follow up we expect roughly 15% attrition. In two prior PMTO randomized trials with intensive multiple-method family assessments, family retention was 88% and 86%, respectively, at 30-month follow-ups [2, 12]. In both of those studies, there were no differential rates of attrition between intervention and controls, there was less than 5% attrition by the immediate 6 month post-test assessment, and less than 15% attrition by the 24 month assessment. Using an alpha level of .05 and considering 5% attrition over the first 6 months, a pre-post design with 3 groups of 114, within subject SD = 1, and between groups SD = .71; the study is powered .81 to minimally detect a small group by time interaction effect (ES = .12), small time effect (ES = .15), and small group effect (ES = .21) for given parenting, child, couple or parent constructs.

Follow Up Analyses. For the intent to treat (ITT) analyses of long term follow up, we will specify latent growth models (LGM) recommended for long term effectiveness designs involving maximum likelihood SEM. LGMs have become more standard because they more reliably assess change. Growth models combine individual and group levels of analysis, taking into account mean growth and individual variation. Fixed effects (e.g., random assignment to ADAPT, parent and child gender) and time-varying random effects may be estimated using chronometric time weights. A model specifying an initial status latent variable (assessing variance in BL differences) and a linear slope latent variable (estimating individual differences in change over time), would be specified using factor weights of 1, 1, 1, 1, for the respective repeated measures, and factor weights of 0, 1, 2, and 4 for growth. The first step in LGM is to

identify the model that best characterizes patterns of growth. We can also specify an additional nonlinear quadratic factor, a higher order polynomial function to capture any nonlinearity. Accelerated or decelerated change would be specified with loadings fixed at 0, 1, 4, and 16. A sequential set of models tests the latent variances and model fit across a random intercept, linear growth, and quadratic model to determine the optimal growth pattern. The comparative effectiveness hypothesis for observed parenting is shown in Figure 2 as linear growth. Group Based and Web Facilitated will be contrasted to the Self-Directed omitted group. Analyses will test that the Group Based effect ($\beta1 > 0$) and the Web Facilitated ($\beta2 > 0$) will show greater 2-year improvements relative to Self-Directed. For the LGM in Figure 2 we estimated power using Mplus Monte Carlo simulations with 1000 replications. An advantage of this approach is the ability to incorporate specific patterns of expected attrition over time. For the figure in Figure 3, contrasts for Group Based and Web Facilitated were fixed at a mean of .33 and variance of .22 representing the random allocation across groups. The latent initial status intercept and latent growth factors were specified reflecting a commonly observed ratio of 5:1 for the variance components (Initial Status ψ 2 = .5 and SD = .70; and Linear Growth $\psi2$ = .1, SD = .31). The effect size (ES) is then the ratio of group contrast mean differences in the latent growth factor divided by the SD for growth. A sample size of 306 (cumulative attrition of 15% over 2 years, specified as .05, .10 and .15 over time) obtained power of .98 respectively to detect small effects (ES=.10) for $\beta1$ and $\beta2$ relative to Self-Directed and likewise for child, couple, parent adjustment.

Analyses for Hypothesis 2 of Aim 1. To test whether the ADAPT Group Based and Web Facilitated have similar effects we will employ two related approaches to test whether ($\beta1 = \beta2$) for the paths shown in Figure 2. First, using the same model specification shown in Figure 2, we will further specify equality constraints in the LGM model to directly compare the relative magnitude of $\beta1$ and $\beta2$. Second, we will conduct a one-sided non-inferiority test (i.e., a test of equivalence) for the intent to treat growth slope factor means and variances for the respective parenting, child, couple, and parent adjustment constructs; hypothesizing no differences between the Group Based and Web Facilitated conditions. We used the non-inferiority module in the Power Analysis and Sample Size program for the equivalence test of means using two one-sided tests for two groups of 102 (Group Based and Web Facilitated). The study is powered .82 using a .05 one-sided alpha when the reference mean = 1 and the comparison mean = 1, and the range of difference still results in the conclusion of equal means when the comparison group is plus or minus a quarter of a standard deviation of the reference mean (± .25 SDs). Finally, we will also examine dosage, participation, and variation in fidelity as potential moderators of group intervention effects.

2.0 Background

2.1 Significance of Research Question/Purpose:

Combat deployment and related challenges are family stressors, associated with more negative parent-child interactions, ineffective and coercive parenting practices and lower levels of parenting satisfaction (e.g. Glenn et al.,2002; Jordan et al., 1992; Samper, Taft, King, & King, 2004). Disrupted parenting practices are well-known predictors of risk for child adjustment difficulties that are precursors to youth substance use, including behavior problems, school failure, deviant peer association, and depression (Patterson & Fisher, 2002; Sanders, Cann, & Markie-Dadds, 2003). These child adjustment problems can contribute to continuing parental stress, increasing parental distress, and further disrupting parenting (DeGarmo & Forgatch, 2004).

2.2 Preliminary Data:

With funding from NIH, the first adaptation of PMTO for military families was initiated by this research team, and is currently being evaluated in a randomized controlled trial/RCT of 400 reintegrating primarily National Guard and Reserve/NGR families with preliminary effectiveness. Known as After Deployment, Adaptive Parenting Tools/ADAPT, the program is a 14-week group-based parenting intervention with an online supplement. ADAPT addresses issues specific to deployment and combat stressors, enhances ecological validity by incorporating examples and materials relevant to NGR families, and addresses psychological and environmental barriers to accessing services. In addition to PMTO skills, ADAPT adds a mindfulness and emotion coaching component based on the hypothesis that the immediate reactivity and suppression of emotions learned on the battlefield may spill over at home following reintegration, leading to dys-regulated emotional interactions that increase family coercion. Preliminary data show improved parenting practices, mindfulness, parenting efficacy, and couple adjustment for ADAPT compared with controls (Gewirtz, 2013). The After Deployment, Adaptive Parenting Tools/ADAPT study is the only military parenting study of school-aged children to date with preliminary evidence from an RCT. We propose to address existing gaps in access to services by NGR families by testing the comparative effectiveness of different formats of this program including in-person, online, and telehealth.

2.3 Existing Literature:

PMTO is a well-established empirically supported intervention targeting highly stressed parents that applies Social Interaction Learning theory (SIL, Patterson, Chamberlain & Reid, 1982). Similar to family stress and stress amplification models (e.g., Elder Jr, Van Nguyen, & Caspi, 1985), SIL posits that parenting mediates the effects of family stressors on child adjustment. That is, deployment and related stressors would be expected to impair social interactional patterns, leading to increases in coercion, decrements in positive parenting, and increased risk for child maladjustment. PMTO interventions have demonstrated efficacy

and effectiveness, showing benefits for children including reductions in behavior problems that are precursors to substance use, actual substance use, and internalizing problems, as well as increases in social competence and school adjustment (for a comprehensive overview see Forgatch & Patterson, in press). Moreover, recent findings indicate that strengthening parenting practices contributes to improved outcomes for parents themselves (Patterson, Forgatch, & DeGarmo, 2010).

3.0 Study Endpoints/Events/Outcomes

3.1 Primary Endpoint/Event/Outcome:

This study is a three-group, two-site, randomized controlled effectiveness trial with baseline and three follow-up assessment points.

ADAPT Intervention Delivery Conditions. Prior grant funding has enabled the development of two modes of ADAPT delivery: group-based (with web enhancement) and web-only (self-directed). Group-based ADAPT includes 14 face-to-face parent group sessions with two facilitators plus access to the ADAPT web enhancement (7 mini-modules that consolidate skills learned in group). Web-only ADAPT provides additional web materials for a total of 10 modules covering all the topics taught in group. The web products run on a dedicated site hosted through IRIS' online service, using standard web platforms that can be accessed via computers, tablets, or smartphones. Each module contains the following: (a) Video-driven lessons, (b) Interactive assessments, (c) Interactive mastery exercises, (d) and Printable Resources. Activities in each module take 20-30 minutes to complete, for total interactivity of up to 40 minutes. The goal is to provide an engaging learning experience that imparts knowledge, motivation, and skill acquisition using compelling storylines, modeling situations, right way/wrong way lessons, and interactive learning exercises (e.g., quizzes). In the facilitator-enhanced condition we propose to augment the web-only ADAPT by providing individual telehealth facilitation of the web program (i.e. Google Hangout, enabling an ADAPT facilitator to guide families through the program in weekly video call meetings).

3.2 Secondary Endpoint(s)/Event(s)/Outcome(s): *NA*

4.0 Study Intervention(s)/Interaction(s)

4.1 Description:

Group-based ADAPT. Groups will meet weekly (excluding holidays; we conservatively estimate 3 sessions/month) for 120 minutes, at a time convenient to participants (usually early evening). Dinner and childcare are provided, and each family is receives $10 per session to cover transportation costs. (c) Group content. Groups cover core ADAPT/PMTO topics: 1.Program introduction; identifying strengths in military families; reintegration-related stressors. 2. Promoting cooperation through use of effective parental directions. 3. Parents as effective teachers: teaching strategies using contingent positive encouragement. 4-5. Observing emotions and regulating emotions: recognizing and regulating

emotions, specific emotions, differentiating between parents' and children's emotions; regulating emotions; strategies to cope with deployment- and combat-related stressors (e.g., PTSD, injury, separation stressors, renegotiation of family roles). 6. Setting limits and 7. Following through: establishing family rules and strategies for use of negative sanctions that are consistent, contingent, mild, and non-corporal. 8. Communicating with children: active listening skills; family meetings, and responding to children's anxiety; emotion coaching. 9. Family Problem Solving: strategies to anticipate and address stressors, problem family situations, and plan positive family activities. 10. Managing conflict: builds upon sessions 4, 5, 8, and 9 to manage family and other relationship conflicts; 11. Monitoring children's activities: keeping children safe and engaged in well supervised prosocial activities; tracking children's whereabouts, peers, transportation. 12. Promoting school success; incorporates material from sessions 2, 3, 8, 9, and 11 with focus on positive involvement in academic development at home and at school; 13. Building skills: reinforces and integrates skills from earlier sessions with emphasis on emotional regulation, emotion coaching, decreasing coercive interactions and emphasizing positive parenting practices.14. Balancing work and play focuses on couple and family relationships and supports participants in developing future goals. Sessions begin with a 5-10 minute mindfulness practice; attention to deployment issues are addressed in each session. Home practice assignments reinforce skills learned in the group. Participants have access to the ADAPT website to reinforce and consolidate skills learned in group. Facilitators will offer referrals for other services as needed (e.g., PTSD) to VA and other mental health providers.

ADAPT Self Directed Web. In the self-directed web-only ADAPT condition, participants have access to the full ADAPT website (10 modules, online discussion forum) but do not have access to a 'live' in-person facilitator. 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 thank you gift card with directions to 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.

ADAPT individualized web-facilitated. This condition comprises access to the full ADAPT web program as described above, with augmentation of individual facilitator web support (i.e. the facilitator connects via Google Hangout). Facilitators meet with families at a mutually convenient time weekly (10-14 weeks, approximately 3 sessions per month). Sessions cover the same topics as in the group condition, but the material is tailored for families and sessions are shorter (1 hr vs 2 hrs) to reflect the pace of teaching skills to individual families

vs. groups. The web program is used as a springboard for each individual session and as a reference for home practice assignments. For example, in session 2, 'Giving Effective Directions', the facilitator introduces the family to effective and ineffective directions via role play (as in ADAPT groups), refers the family to the online skill video, and provides live (Hangout) role play practice with parents. The facilitator explains and shows parents the online home practice assignment. Facilitators will offer referrals for other services (e.g. individual therapy for PTSD) to VA and other community mental health providers, as needed.

5.0 Procedures Involved

5.1 Study Design:

This study is a three-group, randomized control effectiveness trial with baseline and three follow-up assessment points.

5.2 Study Procedures:

1. Eligible participants will complete a brief contact information form, followed by an online informed consent providing information about study risks, benefits and the possibility of being randomly assigned to one of three intervention conditions: group-based ADAPT (G), web-only/self-directed ADAPT (W), or individualized web-facilitated ADAPT (F). In reintegrating families with two at-home participating parents/caregivers, each will complete a separate informed consent.

2. Consenting participants will be provided a contact number to speak to the PI or study coordinator with questions. Families requesting a telephone screening will be asked for verbal consent for the team to maintain contact through reminder emails and phone calls as needed to complete informed consent and BL online assessments. Informed consent may also be completed at the in-home assessment.

3. Participants who submit informed consents will automatically be directed to log in to the BL assessment by providing their email and creating a password. Participants who lose their password can automatically retrieve it from the system. Upon logging in, participants will be given the online portion of the BL assessment. The BL online assessment includes self-report measures to be completed by each participating parent or caregiver. The assessment package takes approximately 45 minutes to complete; upon completion each participant is compensated $25 (per assessment completed; up to two per family). A 15-minute study orientation call and in-home assessment with project staff are scheduled. Families who do not complete the online assessment can complete the assessment by phone or during the home visit. In order to increase the T1 completion rate, families may be offered a $50 bonus for scheduling and keeping their appointment date and time. This would only be offered after multiple contacts and methods have been used to schedule the baseline assessment.

4. In-home assessments will be conducted by pairs of well-trained graduate research assistants with experience conducting home assessments using similar measures [3]. Assessors will schedule home visits to complete child assent and

assessments with the target 5-12 year old child, and complete parent-child observational tasks, and adult measures (approximately 100 minutes total). Families who prefer assessment outside the home may go to the local UMN or UM project office.

Note: Child care is offered to families for the siblings that are not participating in the research. In the event that child care staff are not available we will offer families a $30 gift card stipend to provide their own child care during the in-home assessment.

5. Teachers will be contacted (at each time point) 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 questionnaires. Teachers not responding will receive materials by mail, with follow-up calls. Teachers who do not want their compensation may choose to give the gift card back to ADAPT or to MCEC.

6. Following BL assessment, participants are electronically given random assignment to the G, W, or F study conditions, with 120 families assigned to each condition. The group condition will be run in three cohorts, with 2 groups of up to 10 families in each cohort of 20 families (up to 60 families in each of the two sites – i.e. 120 total, considerably more than we estimate will participate). In both online conditions, families may participate as they enter the study. However, given the necessity of running groups in cohorts and the need for equivalence in analysis, we will also assign individuals in the web conditions to a cohort.

7. Participants in the Group (G) condition will be assigned to a 14-week ADAPT facilitator-led group. Groups will be organized as follows: (a) Orientation. The group facilitator will provide a telephone orientation to the program to: 1) provide program information, 2) address any potential barriers to participation, and/or concerns about group attendance, 3) provide information about features and limits to confidentiality within intervention groups, and 4) direct attention to the ADAPT website and the consent for intervention form. The facilitator will explain information will be confidential except when harm to self or others is expressed, or child maltreatment reporting is mandated. Facilitators will describe the 14 week ADAPT group and the web-enhancement component, will encourage group participation of both parents/ caregivers in the home in 2-caregiver families, and will troubleshoot barriers to group participation. (b) Logistics and locations. Sessions will begin as soon as the group is full. Five to ten families (up to 20 individuals) will participate in each group. Two groups will be offered in each cohort. Groups will be facilitated by trained ADAPT facilitators, all of whom have previously delivered successful ADAPT or PMTO groups for mothers and fathers with high retention and satisfaction. We are currently training a cohort of VA therapists, and Michigan community mental health professionals in ADAPT, and these individuals will join our current ADAPT facilitator team of 14 individuals based in MN. The 14 week ADAPT group interventions will take

place at community locations in the Detroit, Ann Arbor, Twin Cities, and Duluth areas, convenient to participants. We have selected community locations (e.g., schools, libraries) rather than VA or Armories to reduce concerns about the stigma of services, to normalize the ADAPT groups as health promotion, and to ensure proximity to homes.

8. Participants assigned to the web-only (W)/self-directed condition will be instructed to log in to the ADAPT website. The website will offer a short (10 minute) introduction to the program, as well as an informed consent form to participate. Then, participants will be given access to the ADAPT dashboard (program content list) and instructions on going through the components.

9. Participants in the facilitator-enhanced (F) condition, will be have an ADAPT facilitator who will provide a telephone orientation to the program. Orientation calls will 1) provide program information, 2) address any potential barriers to participation, 3) provide information about features and limits to confidentiality, and 4) direct attention to the ADAPT website and the consent for intervention form. During this call, the facilitator will show parents how to log in to the ADAPT website. The website will offer a short (10 minute) introduction to the program, and an informed consent form to participate in the program that parents complete and submit online. The facilitator will inform participants that information is confidential except when harm to self or others is expressed, or child maltreatment reporting is mandated. Facilitators will describe the 14 week ADAPT program and the website, encourage participation of both parents/caregivers in the home in 2-caregiver families. Throughout the 14-week program, participants use the ADAPT website to complete and submit home practice assignments, and view materials online. As PMTO topics are introduced in the individual telehealth session, facilitators will show participants clips of the relevant online module to maintain and support learning. Participants whose spouses, or other caregivers are not present, are encouraged to go online between sessions, and can share material with other family members.

10. The modules will be accessible to all participants in all conditions for a six-month period from the start of the program. Parents may log on as often as they wish.

11. Six months post BL (after all conditions are completed), all participants will be contacted by email and given an online link to the T2 assessments on the study website. The assessment package takes each adult approximately 45 minutes to complete; upon completion participants are each compensated $25 (per assessment package completed; up to two per family). If a participant has not accessed the assessment within three days of the reminder email, a research assistant will follow up by phone at regular intervals. The same procedures are repeated for T3 (12 months post BL) and T4 (24 months post BL). If at any point during the study the participant family loses access to internet service, study staff will provide internet access at the in-home assessments so the online surveys can

be completed during the baseline or follow-up, or study staff will provide funds for the family to travel to a local library, University, etc. to gain computer access.

Sources of Materials

• Research material obtained from human subjects will consist of data collected specifically for this study.

The data will include:

1. Web-based questionnaires filled out by families
2. Observational coding data based on videotaped parent-child interaction tasks completed by families
3. Short questionnaire packets filled out by families and teachers
4. Short surveys and web conference calls completed by expert panel members.
5. Audio and video tape of parent's response to KidVid (video of parenting tasks)

Measures and Assessments:

There are 4 assessments: Time 1- baseline (BL, prior to start of the intervention), Time 2 - six months post BL (post-intervention, given 4-5 month intervention at 3 sessions/month, allowing for holidays, etc), Time 3- 12 months following BL, and Time 4, 24 months after BL. Assessments are weighted to be gathered in the first year, (BL, 6, and 12 months) to gauge intervention effects immediately at posttest (i.e., T2) and at T3, which is when parenting and teacher report outcomes indicated change in prior studies. All measures (i.e., child, parent, and teacher report, and direct observations) will be gathered annually (T1, T3, T4), ensuring that teachers are different at each assessment. At T2, only parent report data will be gathered, online, (no in-home assessment) to minimize participant burden in Year 1, and because in prior studies observed parenting and teacher report outcomes indicated change at 12 months, while parent report indicated some change immediately posttest. Child self-report measures will be gathered (and were standardized with) children over age 8. Measures are summarized below:

Parenting practices: (i) Observations. Parent(s) and child participate in a Family Interaction Task (FIT) comprising five separate tasks lasting a total of 30-45 minutes. We have successfully used the FIT in our current ADAPT and prior PMTO studies with less than 5% refusals. Coder ratings yield reliable and valid measures of parenting practices with short- and long-term predictive validity for child and parent outcomes. Tasks include planning a family activity, two, 5-minute problem-solving tasks to resolve current conflict issues; three game/teaching tasks, discussion of an emotional deployment cycle issue from Deployment Issues Checklist; and a monitoring task. Families are debriefed to address any concerns or questions.

Parent-child interactions are scored using validated Coder Impressions. The ratings yield three primary constructs: positive parenting (family problem-solving,

skill encouragement, positive involvement, monitoring), coercive parenting (inept discipline/non-contingent parenting) and emotion socialization. Scale scores yield reliable Cronbach alphas (ranging from .74-.92) and interrater reliabilities in the 70% range [12-13]. (ii) Self-report. Alabama Parenting Questionnaire. The APQ is a widely measure of parenting practices, with three subscales: Positive Parenting, Inconsistent Discipline and Poor Supervision. The 9-item scale has been validated in military and community samples, and has validity in distinguishing parents of children with and without behavior disorders.

Child adjustment and substance use. Child adjustment will be assessed with the Behavioral Assessment Scale for Children (BASC-2; teacher, parent, and child self-report, a system assessing broad domains of externalizing problems, internalizing problems, and adaptive skills. Items are rated on a 4-point scale. Gender-specific normative scores are provided in the form of T-scores. Parents use the parent version of the BASC2 (BASC2-PRS; (alphas = .80-.87); teachers use the Teacher Report Form (BASC2-TRS; alphas = .85-.89). Child intentions and use of substances will be assessed using self-report for children in 5th grade and up, given sensitivity of questions, and given data suggesting that some children begin experimenting with substances at this age: in a study of 2300 students, 16.1% of 5th graders, and 29.4% of 6th graders reported ever having used alcohol. Tobacco use will be assessed with 6 items reflecting tobacco use behavior (ever taken a puff, smoked a whole cigarette, current smoking, α=.84) and intentions to smoke; α=.78 [17]. Alcohol Use Intentions and Behavior Scale. This 9-item scale measures alcohol use in the past year, month, week, heavy drinking (5+ drinks in past 2 weeks), ever having been drunk, and intentions to drink if offered by a friend, in the next month, in high school and as an adult (scale range 9-49; α=.82). The combined scale and two subscales (Alcohol Use Behavior and Alcohol Use Intentions) have adequate internal consistency and test-retest reliability. Child distress will be measured using the Children's Depression Inventory [19], a 27-item symptom-oriented summative index (e.g., "I am sad," "nobody loves me") that has been repeatedly shown to correlate highly with similar measures of depression and to distinguish between clinical and non-clinical samples. Since the CDI is designed to be sensitive to change over time, test-retest reliability varies between .38 and .87 depending on the sample and the time interval being used. PTSD Reaction Index is a 20-item child interview assessing posttraumatic 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. Child peer adjustment will be measured using a 16-item scale assessing loneliness and dissatisfaction with peer relations. Items include "I have nobody to talk to," "I don't have any friends," and "It's hard to get other kids to like me." The Describing Friends is a measure of deviant peer association – a summative index of five items scored true of false. Items are child reports of friends' deviant behavior (e.g., my friends get into fights, clown around, get into trouble, do not like schoolwork, find schoolwork too hard). Childhood exposure to stressful and traumatic events will be collected using the Children Lifetime Events questionnaire previously and successfully used in the original ADAPT study. These questions will be collected at T4 only.

Parent/caregiver adjustment: Post-Traumatic Stress Checklist; (17 items; alphas = .94) is a clinically validated, self-report screening tool assessing presence and severity of PTSD symptoms as defined by the Diagnostic and Statistical Manual of Mental Disorders Fourth Edition (DSM-IV). Respondents rate each PTSD symptom in the past month using a 5-point scale. Center for Epidemiologic Studies Depression Scale assesses depressive mood, motor and somatic difficulties and has been validated in national health surveys. Items are on a 4-point scale indicating symptom frequency over the past week. Higher scores indicate greater impairment; total scores of 16 or more indicate a "depressive case" (Eaton et al., 2004). Additional stressful and traumatic lifetime events will be collected using the LEC-5. The LEC-5 assesses exposure to 16 events known to potentially result in PTSD or distress and includes one additional item assessing any other extraordinarily stressful event not captured in the first 16 items. Alcohol Use Disorders Identification Test/AUDIT is a self-report measure developed by the World Health Organization as a reliable screen for excessive drinking, validated in over two decades with multinational samples and deemed effective for early identification in military populations. Cut-off scores of 8 show adequate sensitivity; scores between 9-10 are suggested for heavy drinking populations (e.g., veterans). Parent mindfulness is assessed using the Five Facet Mindfulness Questionnaire/FFMQ, a 39-item questionnaire with five subscales (observing, acting with awareness, non-judging, and non-reactivity). Questions are on a 5-point Likert scale; α = .72-.92. Difficulties in Emotion Regulation/DERS is a 36-item questionnaire assessing six domains of adult emotion dys-regulation: non-acceptance, avoidance, difficulties in impulse control, lack of emotional clarity, and awareness. Items are on a 5-point Likert scale (α = .94). Working memory: Operational Span (OSPAN) requires individuals to remember an unrelated sequence of 3-7 letters while solving arithmetic problems; total OSPAN working memory is the sum letters recalled in correct sequence. Data with military personnel show change following intervention.

Parenting stress and support: Parenting Stress Index-Short Form (36 items, alphas>.90), assesses extent to which parents feel burdened by caretaking, and satisfaction with their relationship with their child. Receipt of Help (5 items), developed for the National Survey of Families and Households, assesses the numbers of persons available for practical help (e.g., babysitting, transportation); one or less indicates very low support.

Participant satisfaction with intervention uses two 10-item measures: (i) Group satisfaction questionnaire completed at the end of each session. A principal components factor analysis of the 10 parent ratings of satisfaction (e.g., info provided was helpful, leader seemed to understand me, enjoyed group) obtained a single factor solution for intervention group (eigenvalue = 5.60 explaining 56% of the variance) (α = .91). (ii) An online user satisfaction measure will be completed at the end of each online module to assess 1) stimulation, 2) comprehension, 3) acceptability, 4) ownership, 5) persuasiveness, and 6) support.

Context Measures: Demographic information include: gender, age, racial and ethnic identity for parents/children; employment, income, date(s) and numbers of deployment. Deployments will be assessed from three questions to obtain information about the extent of respondents' deployment history. Combat exposure will be measured with the Deployment Risk and Resilience Inventory (DRRI), an ecologically valid instrument for assessing risk and resilience factors among military personnel participating in recent and current deployments. Extent and nature of combat injury (5 items) will be assessed using an adapted assessment from the National Veterans Readjustment Study designed for OEF/OIF/OND veterans. In addition, section K 1 and 2 from the DRRI-2 will be administered to collect information about general and sexual harassment. This information will be collected at T4 only.

An ADAPT4U Smart Phone App has been created for study participants who have an Android phone and are participating in the ADAPT4U study. This App is free by downloading from the App store and will be used voluntarily by study participants. Study participants are given a username and password to access the App. This information is de-indentified to the engineer managing the App. Only research staff will have access to identifying information and data collected through the App. When study participants log in they are asked to give consent to their data being collected by research staff and if they agree, to allow access to their App usage data for uploading to the University of Minnesota's server. If study participants do not agree to this, then the data will be uploaded to the University of Minnesota's server when their phone becomes connected to WiFi. The App has observing exercises, already presented in the ADAPT4U curriculum that can be used individually for home practice. They are: Mindful Eating, Ten Deep Breaths, Sitting Observing, Body Scan, Notice 5 Things, Drop Anchor, Leaves on A Stream, Bell Ringing, Hexaflexercise, Wisdom, Loving Kindness, Self-Compassion, and Stretching.
To begin, study participants select the observing activity they want to practice. The App collects data on three questions before study participants begin the observing activity. They are: (1) How do you feel right now, (2) I argued or had conflict with my children or spouse in the past 6 hours, and (3) How much awake time have you spent with your children today so far. Study participants practice the observing activity by listening to the guided audio and/or viewing still pictures. After completing the activity they answer a final question (How do you feel right now?). Data is tracked regarding selected activities, frequency of practice, and responses to the pre and post questions. Study participants that use the App will be put into a monthly drawing for a $50 gift card. The greater the usage, the more chances they have to win the gift card.

Some Smart Phone Application users may be asked to participate in a short interview (via phone or email) about their use of the App to help improve it for other users and for the development of other versions of the App (i.e. for I-phones). The purpose of the interview is for program improvement only. This would be a one-time phone call lasting no more than 10-15 minutes with study participants who have used the App during the course of the study. Participants

will be emailed first to ask if they would be willing to answer some questions and when is a good time to call. Participants who are interested, but do not have time for a call, may be emailed the questions and asked to respond in that manner. Study participants will be given a $5 gift card for their one time participation in this interview. The goal would be to obtain feedback from at least 10 study participants. Note: See list of interview questions.

5.3 Follow-Up:

There are 4 assessments: Time 1- baseline (BL, prior to start of the intervention), Time 2 - six months post BL (post-intervention, given 4-5 month intervention at 3 sessions/month, allowing for holidays, etc), Time 3- 12 months following BL, and Time 4, 24 months after BL. Assessments are weighted to be gathered in the first year, (BL, 6, and 12 months) to gauge intervention effects immediately at posttest (i.e., T2) and at T3, which is when parenting and teacher report outcomes indicated change in prior studies. All measures (i.e., child, parent, and teacher report, and direct observations) will be gathered annually (T1, T3, T4), ensuring that teachers are different at each assessment. At T2, only parent report data will be gathered, online, (no in-home assessment) to minimize participant burden in Year 1, and because in prior studies observed parenting and teacher report outcomes indicated change at 12 months, while parent report indicated some change immediately posttest. Child self-report measures will be gathered (and were standardized with) 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.
- December 31, 2017
- May 31, 2019

9.0 Study Population

9.1 Inclusion Criteria:

Inclusion criteria are: (a) one parent has returned from deployment to OIF or OEF or stateside deployment in support of the Global War On Terrorism, (b) at least one child ages 5-12 in their custody and living with parent(s) in the home, and (c) high speed internet access at home (a MN study indicates that 97% deployed families have internet, with 70% using internet daily; Sayer et al., 2009). 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 analyses. Participants must live within an hour's

travel time of Grand Rapids, Kalamazoo, Battle Creek or Selfridge, MI, the Twin Cities Metro area, St. Cloud or Duluth, MN, agree to randomization, and indicate willingness to interact with study materials and complete assessment batteries.

9.2 Exclusion Criteria:

Exclusion criteria include: (a) active psychosis, (b) an open child protection case for abuse or neglect in the family, (c) a serious child mental health diagnosis, (d) families who piloted material or participated in or are currently participating in the original ADAPT RCT. MN ARNG data indicate that fewer than 10% families would be excluded based on a-c, above (personal correspondence, Polusny). There is no reason to exclude women of childbearing potential. There will be no exclusion of racial or ethnic groups.

9.3 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:

Child Participants: 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. 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). 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. 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.

Families will be provided with a copy of all consent forms they have signed.

The following consent forms will be obtained from participants:

a. Adult consent for participation in the clinical study (all family adults screened for participation in the clinical study)

b. Parental consent for child's participation in baseline and follow-up assessments (all parents of children in the study)

c. Child Assent Form for participation in baseline and follow-up assessments (all children in study)

d. Adult Consent to release observational assessment video data (all families)

e. Teacher consent to participate in study (teachers of targeted child only)

11.0 Number of Participants

11.1 Number of Participants to be Consented: 630

12.0 Recruitment Methods

12.1 Recruitment Process:

Recruitment flyers promoting the study will be distributed to our partners (NG, VA, M-SPAN). In addition, the PI has been invited by the MN ARNG to present at reintegration workshops which are mandatory for all soldiers returning from OEF/OIF deployment, and flyers will be handed out there. Flyers provide the phone and email contact information for the researchers, and the study site URL. The website guides parents to a brief explanation of the project, and a description of project confidentiality and its limits. Refer a friend post cards will be distributed to previous ADAPT study participants and current participants (as recruitment occurs). A recruitment/outreach booth will be set-up at the MN State Fair on Military Appreciation Day.

Interested participants will be directed to an anonymous online screening instrument. This screen determines eligibility based on the above stated inclusion and exclusion criteria. Eligible 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 either an intervention (E) group or SAU comparison group. In reintegrating families with two at-home participating parents/caregivers, each will complete a separate informed consent.

Eligible participants will next complete a brief contact information form, followed by an online informed consent providing information about study risks, benefits and the possibility of being randomly assigned to one of three intervention conditions: group-based ADAPT (G), web-only/self-directed ADAPT (W), or individualized web-facilitated ADAPT (F). In reintegrating families with two at-home participating parents/caregivers, each will complete a separate informed consent.

Consenting participants will be provided a contact number to speak to the PI or study coordinator with questions. Families requesting a telephone screening will be asked for verbal consent for the team to maintain contact through reminder emails and phone calls as needed to complete informed consent and BL online assessments. Informed consent may also be completed at the in-home assessment.

Participants who submit informed consents will automatically be directed to log in to the BL assessment by providing their email and creating a password.

Attrition and Enhancing retention: We expect attrition to be 5-20%, based on current study data, and have calculated power accordingly.

Assessors in all conditions will use retention tools successful in this and other stressed populations: 1) Families give contact information for themselves and 3 friends/family members. 2) Parents receive pre-stamped cards with study address and receive $20 for providing their new address. 3) We provide study updates in newsletters, and bi-yearly mailings. We will use evidence-based strategies for enhancing retention. To encourage assessment completion we will compensate participants. To enhance participation in group (G) activities, we will hold two drawings at each session: group start for timeliness, group end for home practice completers, for small prizes (e.g. chocolate; journals; stress balls). In W and F conditions, participants will receive small online gift cards for participation and online completion ($10 per module completed). We will hold groups at convenient times for families (e.g, early evening hours), include meals for participants, and onsite childcare. Transportation stipends and free parking will be provided. If increasing recruitment numbers become a challenge, we will offer a refer a friend bonus of a $5 gift card and/or put the referrer and referee into a drawing for a $100 gift card.

12.2 Source of Participants:

Military (current or former) and their families who self-identify and live in within an hour's travel time of Grand Rapids, Kalamazoo, Battle Creek or Selfridge, MI, the Twin Cities Metro area, St. Cloud or Duluth, MN.

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.

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.

12.5 Payment:

Subjects will be compensated utilizing Target (or similar) gift cards for assessment activities as follows:

Effectiveness trial participants (N=360 families) will be paid $50 for in-home assessments at baseline and 12 months, and $100 at 24 months post-baseline; children will be provided a small gift valued at $5. Each adult completing an online assessment (at baseline, 6, 12, 24 months), up to 2 adults per family, will be compensated $25 per assessment. 2 parent families who complete all surveys and in-home assessments can make up to $400 and 1 parent families can make up to $300.

Families randomly assigned to the face-to-face group intervention (N= 120 families) will be compensated $10 for each group session attended to offset travel costs, as well as an additional $5 when they complete at least two online assignments per module (14 maximum). Small prizes will be distributed at each group session for attendance and homework completion. Full participation would entail 14 sessions and result in a $210 incentive per family.

Families randomly assigned to the online-facilitated intervention (N= 120 families) will be compensated $5 per one-hour session with a facilitator, as well as an additional $5 when they complete at least two online assignments per module (140 maximum). Full participation would entail 140 sessions and result in a $1400 incentive per family.

Families randomly assigned to the online-only intervention (N= 120 families) will be compensated $5 for each parent who completes at least two online assignments per module (140 maximum). Full participation would entail 140 sessions for each parent and result in a $1400 incentive per family.

2 parent families have the potential to be compensated up to $610, and single parent families have the potential to be compensated up to $510.

Teachers will be compensated $15 for completing yearly assessments (at baseline, 12, and 24 months)

Compensation will be provided along the way as subjects complete each in-home assessment and online surveys, and each week as they complete either the in-person groups or the online modules.

Subjects will be compensated for all of the assessments, surveys, and group sessions they attend.

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

14.1 Foreseeable Risks:

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 below. 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 NG, 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.

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.

Effectiveness Trial Family Participants:

• We will create and distribute recruitment flyers to our partners (MN NG, MI NG), providing a study website URL and phone number. We will recruit families in close collaboration with the MN, MI, ND, and WI NG, by: (a) postings on the NG websites, (b) flyers and pamphlets at armories and announcements via email, (c) attending NG family support groups, family readiness academies, and Yellow Ribbon family reintegration training.

• To manage study participation and administer online measures, we use a secure web site (Qualtrics, 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.

• Interested participants will be directed to an anonymous online screening instrument. This screen determines eligibility based on the inclusion criteria mentioned above. To be eligible for the study, families must agree to random assignment to experimental or control conditions, be willing and able to complete assessment and intervention, and live within the catchment area. See Inclusion/Exclusion Criteria for eligibility guidelines.

• 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 three conditions. Families will be assured that no services or relationship

with the NG or the University of Minnesota or University of Michigan will change or be adversely affected regardless of whether or not they choose to participate in the study.

• 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.

• 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.

• Child Participants: 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. 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). 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. 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.

Families will be provided with a copy of all consent forms they have signed. The following consent forms will be obtained from participants:

a. Adult consent for participation in the clinical study (all family adults screened for participation in the clinical study)
b. Parental consent for child's participation in baseline and follow-up assessments (all parents of children in the study)
c. Child Assent Form for participation in baseline and follow-up assessments (all children in study)
d. Adult Consent to release observational assessment video data (all families)
e. Teacher consent to participate in study (teachers of targeted child only)

Planned procedures for protecting against or minimizing potential risks, including risks to privacy of individuals or confidentiality of data, and assess their likely effectiveness.

• Potential risk #1 (discomfort with assessment procedures) and #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.

• 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.

• Potential risk #4 (violation of confidentiality): Safeguards. Extensive procedures are in place to prevent confidentiality violation and errors resulting from data processing. We will complete and submit an application for a Certificate of Confidentiality to provide further protection of our study participants and our data. 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.

• 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 or, for children an assent 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.

The anticipated potential adversity inherent in assessment is limited to those situations described above and is addressed by the timely intervention of a licensed clinical psychologist skilled in risk assessment and mandatory reporting requirements.

We have never had a staff safety issue while in a subject's home and have done more than 500 in-home assessments to date. In our assessment tech training, our techs are given a manual with instructions for dealing with different situations, and we do discuss this issue so all of our techs know what to do in case of an emergency.

As a part of the ongoing statistical analyses conducted to evaluate the effectiveness of the prevention trial, the experimental and control groups will be routinely compared on several dimensions, including the occurrence of the type of adverse events described above. With any significant group difference, the relevant covariates will be thoroughly examined in order to understand more completely the relationship between the variables of interest and potential effects of the intervention. The results of our analyses, including the occurrence of adverse events, will be reported both to our IRB and to NIDA through annual progress reports. We will also report adverse events to others, as directed by our IRB or NIDA Program Official.

Reporting Procedure for Serious Unanticipated Adverse Events
In the event of an unanticipated serious adverse event, the project PI will ensure that these events are reported to the NIDA Program Official within 24 hours by phone, fax, and/or email and will submit a written report to the Program Official no more than two days later. The project staff will also utilize the following reporting procedures:
1. When the grant staff and/or PI become aware of a serious adverse event, reporting requirements must be implemented in a timely manner.

2. PI completes a University of Minnesota "Adverse Event Reporting Form" and submits the form to the Human Subjects Officer at the U of Minnesota.
3. The Human Subjects officer immediately distributes the form to the following individuals or groups as required: Center Administrator, Center Management Committee, and Center IRB Officials.
4. The Human Subjects Officer will convene an expedited meeting of the IRB either on site or via telephone. The IRB, with the input of the PI will review the study protocol and determine what further action to take based on the best interests of the participants and of the research.

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. Families will be compensated for their participation in assessments. 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:

Descriptive analyses will be computed to determine the usability and acceptability of the delivery formats. We will examine family demographics, included age and gender of parent(s) and child(ren), as well as family structure. We will also compute descriptive analyses on the recruitment data, including the number and percentage of families expressing interest in the study, time to recruit families, the percentage of families screened who meet inclusion criteria. We will also examine retention data including weekly attendance, participants completing home practice assignments, as well as their reasons for absences or drop out.

Complex long-term follow up analyses will also be computed. We will employ standard normal theory pre-post Analysis of Variance and

structural equation modeling (SEM) growth curve analyses. For the immediate prepost analyses we will conduct a 3 group by 2 repeated measures Analysis of Variance for parenting, child, and couple functioning constructs focusing on the comparison of change across the Group Based, Individualized Facilitated, and Self-directed ADAPT conditions.

For the intent to treat (ITT) analyses of long term follow up, we will specify latent growth models (LGM) recommended for long term effectiveness designs [110] involving maximum likelihood SEM. Fixed effects (e.g., random assignment to ADAPT, parent and child gender) and time varying random effects may be estimated using chronometric time weights. A model specifying an initial status latent variable (assessing variance in BL differences) and a linear slope latent variable (estimating individual differences in change over time), would be specified using factor weights of 1, 1, 1, 1, for the respective repeated measures, and factor weights of 0, 1, 2, and 4 for growth. The first step in LGM is to identify the model that best characterizes patterns of growth. We can also specify an additional nonlinear quadratic factor, a higher order polynomial function to capture any nonlinearity. Accelerated or decelerated change would be specified with loadings fixed at 0, 1, 4, and 16. A sequential set of models tests the latent variances and model fit across a random intercept, linear growth, and quadratic model to determine the optimal growth pattern [113].

17.2 Power Analysis:

sing an alpha level of .05 and considering 5% attrition over the first 6 months, a pre-post design with 3 groups of 114, within subject SD = 1, and between groups SD = .71; the study is powered .81 to minimally detect a small group by time interaction effect (ES = .12), small time effect (ES = .15), and small group effect (ES = .21) for given parenting, child, couple or parent constructs.

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 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 (Secure Sockets Layer) and 40, 56, or 128-bit Public Key Encryption. All data collection is performed using the Secure Sockets Layer (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 U of O 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, U OF O, ISII and IRIS Media 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. IRIS Media has developed a self-directed training program for its employees that includes the videotape entitled "Protecting Human Subjects," and utilizes the web-based training program from the Office of Human Research Protections. 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. Finally, the PI will apply for a Certificate of Confidentiality 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.

All data will be stored in digital form on secure University of Minnesota servers. Access to files is password protected. Most data will be stored electronically, but some situations may require the use of paper forms

Certificate of Confidentiality has been obtained to provide further protection of our study participants and our data.

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.

Breaking of confidentiality: There is the risk that we may learn that a child has been abused, neglected, or endangered and need to report it to child protective services. Thus, we will fully inform parents of the limits of confidentiality, both verbally and in writing. Given that the intervention we will be offering teaches non-abusive parenting strategies, we believe that the potential benefits in this area outweigh the risks. Project staff will be properly trained to identify signs of potential child abuse, neglect, or child endangerment, and will report any suspicions immediately to the Principal Investigator. Suspicions of child abuse, neglect, or endangerment will be reported to child protective services in accordance with Minnesota law, and the parents will be told of the report. In addition, those who present an imminent threat of harm to themselves or others will be reported to the proper authorities. Project staff will also be properly trained in responding to parents who are experiencing significant life difficulties and require additional professional assistance. The statement of informed consent will include the following statement: "It is possible that you may experience serious life difficulties that are beyond the ability of the ADAPT program to help you with. This program is not a substitute for professional help for serious difficulties you might be having. If you feel you are having an emergency situation, please seek outside professional help. If you are experiencing serious difficulties, please let us know [project staff email and phone provided] and we will work with you to find resources in your community that can help you." Staff will be equipped with specific guidelines and a referral list for referring parents to specialized treatment for PTSD, substance abuse, depression, domestic violence, other mental illness, and similar problems beyond the scope of ADAPT. Procedures to prevent the violation of confidentiality in accordance with reporting requirements are limited by the mandatory nature of these requirements. Subjects are informed in the consent document that staff must report to authorities 1) physical injury to any child caused by other than accidental means, as required by Minnesota Statutes; and 2) information from a study participant which leads staff to believe a person is in imminent danger of physical harm. Staff will inform parents or guardians if, in the judgment of the professional staff, their child (under 18) is in imminent danger of trying to kill him/herself.

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 convenient to participants (i.e. libraries, community centers). As participants are recruited we will determine optimum group locations. For example, given the prevalence of ARNG families in Stillwater, we anticipate that one location will be a library or community center in Stillwater. In each location we will rent a private room with no capacity for those outside to overhear or see what is being said. The University of Minnesota project office in the Department of Family Social Science will be used as a default location for assessments in the event that any family requests not to have a home visit assessment

20.2 Access to Participants: NA

21.0 Compensation for Research-Related Injury

21.1 Compensation for Research-Related Injury: NA

21.2 Contract Language: NA

22.0 Consent Process

22.1 Consent Process (when consent will be obtained):

Initial consent is obtained online. The consent form will be divided to be easily read on separate screens without the needs to scroll. Participants will need to check a box indicating that they have read that part of the consent form before they can proceed to the next screen of the consent form. On the last screen, participants will need to check a box saying that they have read the form, asked questions, and understand what they are being asked to participate in before they click the "agree to participate" button. During the online consent, participants will all be offered the opportunity (i) for a phone call to complete the consent process, or (ii) to complete the consent process at the start of the in-home (i.e. in person) baseline assessment. In addition, contact information for researchers (phone and email) is provided on the website and the consent document. Additionally, assent from minor participants will be obtained at the first in-home visit. Subjects who are randomized to the experimental (intervention) condition will complete an additional consent to participate in the program and for videotaping of the intervention. This additional consent will be gathered during the first group session for those randomized to in-person groups, or online for those randomized to individualized, web-facilitated ADAPT.

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): *NA*

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 be conducted at the following locations: participants' homes, neutral community location, University of Minnesota (ADAPT offices), and at the Michigan ADAPT office.
- Recruitment will take place in the following ways: Recruitment flyers promoting the study will be distributed to our partners (NG, VA, M-SPAN). In addition, the PI has been invited by the MN ARNG to present at reintegration workshops which are mandatory for all soldiers returning from OEF/OIF deployment, and flyers will be handed out there. Flyers provide the phone and email contact information for the researchers, and the study site URL. The website guides parents to a brief explanation of the project, and a description of project confidentiality and its limits. Refer a friend post cards will be distributed to previous ADAPT study participants and current participants (as recruitment occurs). A recruitment/outreach booth will be set-up at the MN State Fair on Military Appreciation Day.

  Interested participants will be directed to an anonymous online screening instrument. This screen determines eligibility based on the above stated inclusion and exclusion criteria. Eligible 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 either an intervention (E) group or SAU comparison group. In reintegrating families with two at-

home participating parents/caregivers, each will complete a separate informed consent.

24.0 Multi-Site Research

24.1 Study-Wide Number of Participants: 360

24.2 Study-Wide Recruitment Methods: Recruitment methods for both MN and MI are described earlier in protocol.

24.3 Study-Wide Recruitment Materials: Recruitment materials are described earlier in the protocol.

24.4 Communication Among Sites:

• The Project Manager 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 Project Manager at the U of MN has weekly one on one meetings with participating site.
• Participating site has a Project Coordinator that have access to the U of MN secure server where all applicable study documents are maintained and available.
• Second site has the most current version of the protocol, consent document(s), and, when applicable, HIPAA authorization.
• Engaged participating site 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:

- The Project Manager at the U of MN has weekly one on one meetings with participating site.
- Site Coordinator is part of weekly team call.

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 advisement on data management issues.

26.0 References

ADAPT4U MEASURES

KEY:
OL = Collected online prior to the interview
IH = Collected during the in-home interview

	Items	T1		T2		T3		T4	
Measures - Parents		OL	IH	OL	IH	OL	IH	OL	IH
Demographics (vary slightly by time point)		x		x	N/A	x		x	
Dyadic Adjustment Scale (DAS-7)	7	x		x	N/A	x		x	
Five Facet Mindfulness Questionnaire (FFMQ)	39	x		x	N/A	x		x	
The Alcohol Use Disorders Identification Test (AUDIT)	10	x		x	N/A	x		x	
Difficulties in Emotion Regulation Scale (DERS)	36	x		x	N/A	x		x	
Center for Epidemiologic Studies Depression Scale (CES-D)	20	x		x	N/A	x		x	
ODS Interpersonal Support Evaluation List (ISEL)	16	x		x	N/A	x		x	
Life Events Checklist (LEC-5)	17	x			N/A			x	
The List of Threatening Experiences (LTE)	12	x			N/A	x		x	
Military Organization (Sheila's Questions)	6	x		x	N/A	x		x	
Child Lifetime Events	19							x	
Deployment Risk and Resilience Inventory – 2 (DRRI-2) Section K (number of questions dependent on exposure to military context and deployment)	16-64							x	
PTSD Checklist - Military (PCL-M) (parents who were deployed/mobilized in support of GWOT)	18		x	x	N/A		x		x
PTSD Checklist – Civilian (PCL-C) – (parents who were not deployed/mobilized in support of GWOT)	17		x	x	N/A		x		x
Deployment Risk and Resilience Inventory (DRRI) – Sections I & J (Deployed Parent Only)	30		x		N/A		x		x
Deployment Risk and Resilience Inventory – 2 (DRRI-2) – Items 1, 2, 5, 6 from Section I (parents who were deployed/mobilized in support of GWOT)	4		x		N/A		x		x
Behavioral Assessment System for Children – 2 (BASC) PRS-P (parents of children age 5)	134		x	x	N/A		x		x
Behavioral Assessment System for Children – 2 (BASC) PRS-C (parents of children ages 6-11)	160		x	x	N/A		x		x
Behavioral Assessment System for Children – 2 (BASC) PRS-A (parents of children 12 and older)	150		x	x	N/A		x		x
Alabama Parenting Questionnaire – short (APQ)	9		x	x			x		x
Coping with Children's Negative Emotions Scale (CCNES)	72		x	x	N/A		x		x
Parent Locus of Control – short (PLOC)	24		x	x	N/A		x		x
Wechsler Abbreviated Scale of Intelligence – 2 (WASI-2) – vocabulary and matrix reasoning only	61		x		N/A				
Operation Span Task (OSPAN) – working memory	N/A		x		N/A		x		x
Family Interaction Tasks	N/A		x		N/A		x		x

	Items	T1		T2		T3		T4	
Measures - Child		OL	IH	OL	IH	OL	IH	OL	IH
DADS Loneliness & Social Dissatisfaction Scale (LONE) administered to children between 4-7	24		x		N/A		x		x
DADS Loneliness & Social Dissatisfaction Scale-Y (LONE-Y) administered to children 8 and older	24		x		N/A		x		x
Child Depression Inventory – short version (CDI) administered to children 7 and older	10		x		N/A		x		x
DADS Describing Friends (DESS) - administered to children between 4-7	25		x		N/A		x		x
DADS Describing Friends (DESS) – administered to children 8 and older	44		x		N/A		x		x
Behavioral Assessment System for Children – 2 (BASC) – SRP-I (administered to children 5-7)	65		x		N/A		x		x
Behavioral Assessment System for Children – 2 (BASC) – SRP-C (administered to children 8-11)	139		x		N/A		x		x
Behavioral Assessment System for Children – 2 (BASC) – SRP-A (administered to children 12 and older)	176		x		N/A		x		x
The American Drug and Alcohol Survey (ADAS) & 8 supplemental questions (administered to children 10+)	88		x		N/A		x		x
Wechsler Abbreviated Scale of Intelligence – 2 (WASI-2) – vocabulary and matrix reasoning only	61		x		N/A				
Family Interaction Tasks	N/A		x		N/A		x		x

	Items	T1		T2		T3		T4	
Measures - Teacher		OL	IH	OL	IH	OL	IH	OL	IH
Behavioral Assessment System for Children – 2 (BASC) PRS-P (administered to teachers of kids age 5)	100	x			N/A	x		x	
Behavioral Assessment System for Children – 2 (BASC) – TRS-C (administered to teachers of kids age 6-11)	139	x			N/A	x		x	
Behavioral Assessment System for Children – 2 (BASC) – TRS-A (administered to teachers of kids age 12+)	139	x			N/A	x		x	