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

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14. ABSTRACT By December of 2012 approximately 2.2 million US military personnel will have served one or more times in Iraq or Afghanistan in support of Operations Enduring Freedom, Iraqi Freedom (OEF/OIF), and New Dawn (Institute of Medicine/IOM 2013). Stress associated with family separation, combat, and reintegration is extremely disruptive for parents and children. Returning service members and their families are particularly vulnerable during the reintegration period post-deployment. Risks include increases in stress, anxiety and depression, PTSD, and substance use and abuse. These outcomes lead to disruptions in interactions between parents, children, and spouses, increasing risk for children's emotional, behavior problems, and substance use. The overarching goal of our study is to address existing gaps and identified National Guard Reserve (NGR) needs that will inform the portability and access of NGR families to evidence-based programs by conducting a three-group, two-site randomized trial to test the comparative effectiveness of three ADAPT delivery approaches for 360 reintegrating NGR families randomly assigned to: (i) ADAPT group-based; (ii) ADAPT individualized web-facilitated; or (iii) ADAPT self-directed online. Families will complete pre-intervention baseline (BL) assessment (pre-test) and three post-test assessments at 6, 12- and 24 months. We hypothesize that NGR families in both the ADAPT group-based condition and the ADAPT individualized web-facilitated condition will show greater pre-post improvements in observed parenting, and parent, child, and couple functioning relative to the self-directed online condition and the ADAPT group-based condition will be equally effective as the individualized ADAPT web-facilitated condition.					
15. SUBJECT TERMS Parenting, military, comparative effectiveness, children, randomized trial, prevention					
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1. INTRODUCTION:

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

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

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

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

- **Aim 3 Hypothesis 1.** NGR families in both the ADAPT group-based condition and the ADAPT individualized web-facilitated condition will show greater pre-post improvements in observed parenting, and parent, child, and couple functioning relative to the self-directed online condition.
- **Aim 3 Hypothesis 2.** In testing intent to treat comparative effectiveness, the ADAPT group-based condition will be equally effective as the individualized ADAPT web-facilitated condition

2. KEYWORDS:

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

3. ACCOMPLISHMENTS:

What were the major goals of the project?

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

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

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

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

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

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

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

- 5a. Convene expert panel (Y1 Mos. 4-5)

- 5b. Refine existing ADAPT materials (online/Google Hangout and manual) (Y1 Mos 1-10)

- 5c. Conduct pilot group to test usability (Y1 Mos. 6-9)

- 5d. Analyze pilot group data to inform materials and RCT (Y1 Mos. 9-10)

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

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

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

- 7a. Obtain informed consent and complete baseline and subsequent assessments of adult adjustment, observational measures of parenting, measures of child, and couple adjustment. (Y1 Mos 11 – Y5 Mo 50)

- 7b. Randomly assign families to online ADAPT, web-facilitated ADAPT or group ADAPT; families invited to program (Cohort 1: Y1 Mos. 11-13; Cohort 2: Y2 Mos. 18-20; Cohort 3: Y2 Mos. 24 - Y3. Mo. 26)

- 7c. Assess parent satisfaction ratings via questionnaires at end of each session (Y1 Mo. 12 – Y3 Mo. 30)

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

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

- ***Quarterly Enrollment Targets (# of families): Yr 1: Q1=0 ; Q2 =0 ; Q3 =5 ; Q4 =68 ; Yr 2: Q1=78 ; Q2 =78 ; Q3 =78 ; Q4 =78 ; Yr 3: Q1= 0; Q2 =0 ; Q3 =0 ; Q4 =0 ; Yr 4: Q1=0 ; Q2 =0 ; Q3 =0 ; Q4 =0 ;***

What was accomplished under these goals?

- **Task 1, 3 and 4:** We obtained University of Minnesota IRB and Department of Defense HRPO approval.
- **Task 2:** We staffed study key positions. The project manager was hired December 1, 2014, while Michigan Project Coordinator was hired May 31, 2015. Data manager was hired in May 2015 but will resume work June 2015
- **Task 5:** We modified ADAPT web-facilitated delivery format in consultation with Advisory Group
 - 5a. We convened our expert panel and had our first meeting in the month of February 2015
 - 5b. Existing ADAPT material and manual was refined. The modified version was piloted with a family online via WEBEX for a period of 14 weeks. Result from the pilot is being used to make minor revisions to the manual
- **Task 6:** We conducted first training workshop for facilitator staff in Minnesota to deliver ADAPT group with fidelity

Other accomplishments:

- We created and piloted our online Qualtrics survey collection tool
- We created our study website and other promotional marketing and recruitment materials
- We advertised the study via press and radio, attending military outreach events

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

We conducted a 4-day training workshop for study facilitators that will deliver group intervention.

How were the results disseminated to communities of interest?

Nothing to report

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

Our main goal for the second year is active recruiting utilizing multiple platforms.

- We plan to use the media (radio and television) to advertise our study.
- We plan to actively engage Minneapolis, St Cloud and Battle Creek VA to enhance recruitment numbers.
- In addition we plan to use social media (Facebook for advertising) so also Amazon
- Collaborate with Military primary care clinics and providers to boost recruitment efforts.

4. IMPACT:

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

Nothing to report

What was the impact on other disciplines?

Nothing to report

What was the impact on technology transfer?

Nothing to report

What was the impact on society beyond science and technology?

Nothing to report

5. CHANGES/PROBLEMS:

Changes in approach and reasons for change

Nothing to report

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

We delayed the timeline, in discussion with our program officer, because of the timing of the award: beginning recruitment at Month 11 would have meant starting our interventions in the summer, which is a difficult time to deliver programming for families because of summer disruptions to family routines and schedules. So recruitment began instead in early July 2015, with study program delivery to begin this fall.

Changes that had a significant impact on expenditures

Changes that impacted our expenditure are:

- Moving a portion of the University of Michigan sub award back to the University of Minnesota because we changed the primary recruitment center from Ann Arbor MI to Grand Rapids and Battle Creek MI where there is higher concentration of underserved military families
- We had a delay in hiring the project manager for Minnesota and project coordinator for Michigan, because we wanted to identify the right candidate for the position.
- We increased the project coordinator position for Michigan site from 50% to 100% calendar year effort.
- We decreased Dr. David DeGarmo's effort on the project from 27.5% to 15% calendar year effort. We used the funds from the reduction to supplement the position of Data Manager to 100% calendar year effort.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Significant changes in use or care of human subjects

Nothing to report

Significant changes in use or care of vertebrate animals.

Nothing to report

Significant changes in use of biohazards and/or select agents

Nothing to report

6. PRODUCTS:

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

Journal publications.

Nothing to report

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

Nothing to report

Other publications, conference papers, and presentations.

Nothing to report

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

Our study website which is used for recruiting and will be used to disseminate study result is ADAPT4U.umn.edu

- **Technologies or techniques**

Nothing to report

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

Nothing to report

- **Other Products**

Our study curriculum will be utilized for intervention.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Name:	Gewirtz, Abigail
Project Role:	PI
Person months worked:	1.0 month
Contribution to Project:	Overall study oversight and strategic decision making on research methodology. Ensuring study outcomes are achieved
Funding support:	This award
 Name:	 Harcourt, Nonyelum
Project Role:	Project Manager
Person months worked:	6.0 months
Contribution to Project:	Overall management of study task and assigning task to study personnel. Tracking study milestones and designing study data collection tools
Funding support:	This award
 Name:	 Baker, Sarah
Project Role:	Recruitment outreach
Person months worked:	1.0 months
Contribution to Project:	Creating and enhancing recruitment relationships with military outreaches and community members. Attend recruitment events and present ADAPT study at the events
Funding support:	This award
 Name:	 Tiede, Shauna
Project Role:	Assessment Coordinator
Person months worked:	2.0 months
Contribution to Project:	Overall management of the in-home assessment of the participants. Responsible for creating study manuals and training study technicians.
Funding support:	This award

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

Gewirtz, Abigail: Current Support

Title: Evaluation of TF-CBT Learning Collaborative (PI)

ID#: 56797

Period: 2/7/2013 – 12/31/2016

Effort: 1%

Funding: Minnesota Department of Human Services

Supporting agency & contact:

Patricia Nygaard, pat.nygaard@state.mn.us

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

Change: N/A

Title: Preventing Military Post-Deployment Adjustment Problems: Key Family Processes (Sub PI)

ID#: R21 DA034166

Period: 5/1/2013 – 4/30/2016

Effort: 10%

Funding: (currently in no cost extension)

Supporting agency & contact:

Wichita State University (prime funding source: NIH)

Fran Cook, WSU Research Administrator,

researchcontracts@wichita.edu

Goals/Specific Aims: Dr. Gewirtz's portion of this project is to develop a micro-social family interaction coding system and macro-level family interaction rating systems, applying her experience and knowledge in the family interaction of individuals who have experienced trauma and in the family interaction of military service members during post-deployment periods.

Change: No cost extension

Title: ADAPT: After Deployment Adaptive Parenting Tools (Sub PI)

ID#: R44 HD066896

Period: 10/1/2013 – 10/31/2015

Effort: 5%

Funding: (currently in no cost extension)

Supporting agency & contact:

IRIS Media (prime funding source: NIH)

Joanne Dwinell, Business Manager, jdwinell@irised.com

Goals/Specific Aims: The goal of this Phase II project, ADAPT Online (After Deployment: Adaptive Parenting Tools), is to strengthen family functioning and improve child outcomes in reintegrating military families. By developing an empirically supported, standalone, web-based parenting intervention for military families with school-aged children, we expect to strengthen parenting practices in families and prevent behavioral and emotional maladjustment in children.

Change: No cost extension

Title: Midwest Continuum of Care for Child Trauma (PI)

ID#: U79 SM056177

Period: 12/30/2005 – 9/29/2016

Effort: 50%

Funding:

Supporting agency & contact:

DHHS SAMHSA

Cicely Burrows-McElwain, Program Official

cicely.burrows-mcelwain@samhsa.hhs.gov

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

Title: Effectiveness of a Web-enhanced Parenting Program for Military Families (PI)

ID#: R01 DA030114

Period: 7/15/2010 – 6/30/2016

Effort: %

Funding: (currently in no cost extension)

Supporting agency & contact:

National Institutes of Health

Belinda Sims, Program Official, bsims@nida.nih.gov

Goals/Specific Aims: The overarching goal of this study is to advance research on family-based substance use prevention for reintegrating OEF/OIF personnel by examining whether an Oregon Parent Management Training (PMTO) prevention intervention, enhanced with e-technology and adapted for combat-deployed families' needs, will reduce risk behaviors associated with youth substance use by improving parenting, child, and parent adjustment. Specific aims are 1) examine the usability and feasibility of an adapted PMTO prevention program: After Deployment Adaptive Parenting Tools (ADAPT); 2) assess effectiveness and satisfaction with ADAPT program compared with a services-as-usual comparison group among 400 reintegrating MN Army National Guard families with 6-12 year old children; and 3) within the ADAPT intervention group, detail and describe responsiveness to intervention.

Change: No cost extension

Title: DCISR for Adaptive Intervention Models in Children's Mental Health (Co-I)

ID#: P20 MH085987

Period: 8/24/2010 – 6/30/2016

Effort: 5%

Supporting agency & contact:

National Institutes of Health

Change: No cost extension, effort reduction

What other organizations were involved as partners?

Organization Name: University of Michigan

Location of Organization: Ann Arbor, MI

Partner's contribution to the project: Collaboration

Organization Name: University of Oregon

Location of Organization: Eugene, OR

Partner's contribution to the project: Collaboration

Organization Name: IRIS Media, Inc.

Location of Organization: Eugene, OR

Partner's contribution to the project: Collaboration

Organization Name: Implementation Sciences International, Inc.

Location of Organization: Eugene, OR

Partner's contribution to the project: Collaboration

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: Not applicable

9. APPENDICES:

The following materials are available upon request:

- Online questionnaire for baseline data collection (9 pages)
- Online parent survey for time point 1 (69 pages)
- ADAPT4U facilitator curriculum manual (300 pages)
- Access to ADAPT4U online program