

AWARD NUMBER: W81XWH-17-1-0002

TITLE: Improving Voluntary Engagement for PTSD Treatment among Soldiers

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REPORT DATE: December 2017

TYPE OF REPORT: Annual

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

DISTRIBUTION STATEMENT: Approved for Public Release; Distribution Unlimited

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REPORT DOCUMENTATION PAGE*Form Approved*
OMB No. 0704-0188

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1. REPORT DATE December 2017		2. REPORT TYPE Annual		3. DATES COVERED 15 Nov 2016 - 14 Nov 2017	
4. TITLE AND SUBTITLE Improving Voluntary Engagement for PTSD Treatment among Soldiers				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER W81XWH-17-1-0002	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Denise Walker, PhD and Debra Kaysen, PhD E-Mail: ddwalker@uw.edu ; dkaysen@u.washington.edu				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) University of Washington 4333 Brooklyn Ave NE Seattle, WA 98195				8. PERFORMING ORGANIZATION REPORT	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012				10. SPONSOR/MONITOR'S ACRONYM(S)	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited					
13. SUPPLEMENTARY NOTES					
14. ABSTRACT Year 1 focused on pre-trial activities, including the development of the clinical and control PTSD interventions, corresponding counselor manuals, research protocols, recruitment advertisements and recruitment plan. IRB approvals from the University of Washington and HRPO for Phase 1 (pre-trial) research activities were obtained. IRB approval from the University of Washington for Phase 2 (randomized controlled trial) was obtained; IRB approval from HRPO is pending upon review of Phase 2.					
15. SUBJECT TERMS Posttraumatic stress disorder, early intervention, motivational enhancement therapy, service members, Army, Air Force					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRMC
Unclassified	Unclassified	Unclassified	Unclassified	10	19b. TELEPHONE NUMBER (include area code)

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INTRODUCTION:

This study will develop and test a brief telephone-delivered motivational enhancement intervention (MET) for active duty Army and Air Force personnel who are experiencing symptoms of posttraumatic stress disorder (PTSD), but who are not currently engaged in PTSD treatment. The intervention is designed to prompt: (1) a willingness to participate voluntarily in a self-appraisal of PTSD symptoms, (2) increased perceptions of PTSD treatment effectiveness, (3) reduced perceptions of stigma associated with mental healthcare, (4) engagement in PTSD treatment or other self-help programs, and (5) reductions in PTSD symptoms. Following focus groups of 23 participants, this study will recruit 200 Army and/or Air Force service members who have a current PTSD diagnosis via local publicity. The recruitment period will extend over a period of 24 months. Following screening and a baseline assessment, enrolled participants will be randomly assigned to one of two study conditions: (1) the experimental MET condition or (2) treatment as usual (TAU) condition. The MET intervention will consist of three 45-90 minute telephone delivered sessions that will be staggered to occur 1 week, 1 month, and 2 months after the baseline assessment. The first MET session intervention will involve a counselor using motivational interviewing (MI) strategies to establish an empathic therapeutic relationship and focus learning about the PTSD symptoms the participant is experiencing and exploring ambivalence about seeking treatment services. MET sessions 2 and 3 will focus on identifying and responding to risk factors for dropping out of treatment (increases in ambivalence, avoidance behavior, concerns about stigma, life chaos), identifying and responding to barriers to participant's active engagement in treatment, and facilitating enrollment in alternate therapeutic resources if necessary. The TAU condition was selected to mirror the existing process in the Army and Air Force for identifying and encouraging treatment for personnel who screen positive for PTSD. TAU will include a written referral list comprised of PTSD resources including information on in-person treatments, self-help, web-based and bibliotherapy options. At the completion of the study, participants in the TAU condition will be offered the MET intervention.

KEYWORDS:

Posttraumatic stress disorder, early intervention, motivational enhancement therapy, service members, Army, Air Force

ACCOMPLISHMENTS:

What were the major goals of the project?

The purpose of this study is to (1) develop a marketing campaign to reach and elicit voluntary enrollment in a PTSD Check-Up of untreated Army and Air Force personnel with PTSD, to (2) develop a 3-session motivational enhancement therapy (MET) feedback protocol that promotes treatment engagement and/or self-directed PTSD recovery, and to (3) evaluate the efficacy of this novel intervention in a randomized clinical trial (RCT; $N = 200$), using a treatment as usual (TAU) comparison condition.

The major goals for this project are as follows:

1. Coordinate study staff and collaborator relationships
 - 1.1. Hire and train study staff (*October 2017*)

- 1.2. Develop and maintain collaborator relationships
 - 1.2.1. Obtain letters of support from key stakeholders at JBLM (*April 2017*)
 - 1.2.2. Provide regular updates to, and maintain relationships with stakeholders (ongoing)
2. Develop marketing campaign and PTSD Check-Up Intervention
 - 2.1. Conduct 3 focus groups with key constituencies to inform materials development (*May 2017*)
 - 2.2. Develop marketing/recruitment campaign (*October 2017*)
 - 2.3. Develop 3-session MET intervention (*November 2017*)
3. Conduct RCT comparing novel MET intervention to TAU
 - 3.1. Obtain necessary regulatory documents (*August 2017*)
 - 3.2. Begin RCT (*November 2017*)
 - 3.3. Complete RCT (*May 2020*)
4. Data analysis and dissemination (*October 2020*)

What was accomplished under these goals?

The major activities for the past year of the project were focused on continuation of building collaborative relationships with stakeholders at Joint Base Lewis-McChord (JBLM), completed Phase 1 of the study (i.e., coordinated and conducted focus groups), using feedback from the focus groups to further develop our novel intervention and marketing campaign, obtaining human subject approvals, and hiring and training study personnel.

With regard to the goals enumerated above, we are meeting our targets for timely completion of the study. We successfully completed the series of three focus groups (goal 2.1). We hired study staff (goal 1.1) and are on-track to complete the training of study staff by mid-November 2017. We have completed all activities from Phase 1 of the study. We obtained letters of support for Phase 2 of the study from key stakeholders at JBLM (goal 1.2.1) from Garrison Commander COL Nicole M. Lucas, Ms. Alecia Grady (Chief, Armed Forces Community Service), and Mr. Mark Brown (Director of Human Resources).

We conducted three focus groups, with a total of 23 participants who provided feedback on our recruitment and intervention materials (goal 2.1). We analyzed the data collected during those groups and incorporated the feedback into subsequent iterations of those materials, having completed our clinical manual, which will continue to be shaped as we train our counselors (goal 3.2). We also received and incorporated the feedback from Dr. Charles Engel into subsequent iterations of the intervention materials. We received methodology and assessment selection feedback from Dr. Isaac Rhew. We have developed the first wave of our recruitment campaign (goal 2.2) as well. Because the recruitment period is quite long, we will refresh marketing efforts periodically with new advertisements. Barring any major delays from relevant bodies of oversight, we should be able to begin recruitment (goal 3.2) by December 2017.

In regard to obtaining necessary regulatory documents (goal 3.1) for Phase 1 of the study, we submitted Phase 1 protocol to the University of Washington's (UW) IRB in September 2016, it was approved by UW IRB in October 2016, and we received confirmation of closure of review for Phase 1 in August 2017 from UW IRB. In regard to obtaining necessary regulatory documents (goal 3.1) for Phase 2 of the study, UW's IRB approved Phase 2 (randomized

controlled trial) in September 2017. We obtained the Certificate of Confidentiality in September 2017. Department of Defense's Human Research Protection Office (HRPO) approved Phase 2 of the study on 11/16/2017. We have also spent a significant amount of effort working with the Madigan IRB for a determination that Madigan IRB will not have oversight of the current project. Madigan IRB will review Phase 2 once HRPO has approved it.

The study team continues to meet weekly to collaborate on development of protocols, manuals, recruitment materials, and strategic relationships with collaborators at JBLM. The postdoctoral fellow has served as the full-time Project Director since August 2017. The part-time Project Director transitioned to the new role as Data Manager/Research Consultant in August 2017. We hired a study Assessor and Counselor in October 2017.

To date, we have met all informal goals, as well as those outlined in the approved statement of work.

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

Dr. Walker is providing training to the Project Director and Counselor on Motivational Interviewing techniques. Dr. Walker will provide ongoing supervision and guidance to study personnel.

Dr. Kaysen is providing training to the Project Director, Assessor, and Data Manager on conducting the Clinician-Administered PTSD Scale for DSM-5 (CAPS-5), measure used in the current study to determine PTSD diagnosis. Dr. Kaysen will provide ongoing supervision and guidance to study personnel. Dr. Kaysen is also providing research training and professional mentoring to the Project Director, relevant to her postdoctoral training goals.

Dr. Walker attended the Motivational Interviewing Network of Trainers (MINT) Annual Forum In October 2017. Dr. Walker's experience included networking and receiving advanced training in effective techniques for training others in Motivational Enhancement Therapy, the model used in this trial. The MINT forum, training and Cognitive Behavioral Therapy workshop would be directly related to this project's Counselor training and supervision.

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?

IRB: We completed and submitted Phase 2 protocols to Madigan IRB for approval. We hope to have a determination from Madigan IRB that they are "not involved" in the current research and thus, will be exempt from acting as an additional oversight authority by the end of the next reporting period.

Initiation of Main Trial: We will finalize an initial round of recruitment advertisements and program out data collection systems. We hope to begin recruitment by the end of the next reporting period.

IMPACT:

What was the impact on the development of the principle 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.

CHANGES/PROBLEMS

Changes in approach and reason for change?

Nothing to Report.

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

Nothing to Report.

Changes that had a significant impact on expenditures?

Nothing to Report.

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

Nothing to Report.

PRODUCTS:

Publications, conference papers, and presentations

Nothing to Report.

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)

A website, <https://www.uwstresscheck.com/>, was created for the study. It was initially used to for Phase 1 recruitment purposes for the Focus Groups. It will be updated for Phase 2

recruitment purposes.

Technologies or techniques

Nothing to Report.

Inventions, patent applications, and/or licenses

Nothing to Report.

Other products

Motivational Enhancement Therapy Clinical Manual (clinical intervention)

Personal Feedback Report (PFR; clinical intervention)

Understanding Your PFR (educational materials for participants)

Resource Booklets – PTSD treatment options, alcohol and substance use treatment options, tobacco cessation resources (educational materials for participants)

PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS:

What individuals have worked on the project?

Denise Walker, PhD: no change

Debra Kaysen, PhD: no change

<i>Name:</i>	Hannah Bergman, PhD
<i>Project Role:</i>	Project Director
<i>Researcher Identifier:</i>	orcid.org/0000-0002-6997-4052
<i>Nearest person months worked:</i>	4
<i>Contribution to Project:</i>	Dr. Bergman has contributed to the study by: <ul style="list-style-type: none">• Day-to-day oversight of all study activities• Primary supervision of study staff• Clinical consultation• Coordinating collaborative activities with JBLM stakeholders• Contributing to the development of the novel intervention and other study materials, such as the PFR• Development of Resource Booklets• Assist with IRB compliance• Implementation of all study activities and protocols• Quality assurance of data collection and intervention fidelity

<i>Name:</i>	Thomas Walton, MSW
<i>Project Role:</i>	Data Manager & Research Consultant
<i>Researcher Identifier:</i>	orcid.org/0000-0001-9011-8333
<i>Nearest person months worked:</i>	7

<i>Contribution to Project:</i>	<p>Mr. Walton has contributed to the study by:</p> <ul style="list-style-type: none"> • Development and management of data collection systems • Design and creation of recruitment materials • Assist with IRB compliance • Provide consultation and guidance on conducting clinical trials in a military context • Transitioned from Project Director to Data Manager/Research Consultant in August 2017
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<i>Name:</i>	Devon Bushnell
<i>Project Role:</i>	Program Operations Specialist
<i>Researcher Identifier:</i>	n/a
<i>Nearest person months worked:</i>	3
<i>Contribution to Project:</i>	<p>Ms. Bushnell has contributed to the study by providing:</p> <ul style="list-style-type: none"> • Budget oversight • Human resources management • Office administration

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

Nothing to Report.

What other organizations were involved as partners?

Nothing to Report.

SPECIAL REPORTING REQUIREMENTS:

The Quad Chart was updated and submitted with attachments.

APPENDICES: N/A

Improving Voluntary Engagement for PTSD Treatment among Service Members

W81XWH1710002



Co-PIs: Denise Walker & Debra Kaysen **Org:** University of Washington **Award Amount:** \$2,648,171

Study/Product Aim(s)

- Develop and manualize study/intervention recruitment mechanisms.
- Develop a 3-session motivational enhancement intervention for military personnel with PTSD who are not engaged in treatment
- Evaluate the efficacy of the intervention in promoting treatment seeking and engagement.
- Assess the intervention’s effect on stigma and perceptions of treatment efficacy.

Approach

A randomized controlled trial with two study conditions

- 1) The experimental Motivational Enhancement Therapy (MET)
- 2) Written information about treatment options (treatment as usual)

Participants in both conditions will be reassessed at three and six months post-baseline.

A key element of this study is to develop a recruitment campaign that will elicit participation from service members with posttraumatic stress who are not treatment-seeking.

Trauma memories keeping you up at night?
 Call us to check in and explore your options.
 Command NOT notified
 Private & confidential
 Free & all by phone
 Non-judgmental
 After duty hours
Earn up to \$175
(866) 866-0137
www.uwstresscheck.com
 STRESS CHECK | W A University of Washington Study

The figure above is a recruitment ad strongly favored by focus group participants, which incorporates feedback provided by those groups.

Timeline and Cost

Activities	Study Year			
	1	2	3	4
Coordinate staff & collaborator relationships	█			
Develop intervention & recruitment materials	█			
Conduct RCT		█	█	█
Data analysis & dissemination				█
Estimated Budget (\$K)	\$574	\$744	\$767	\$764

Updated: 1 December 2017

CY	Goals / Milestones
17	<input checked="" type="checkbox"/> Secure IRB approval for focus group activities <input checked="" type="checkbox"/> Obtain feedback on materials from 3 focus groups <input checked="" type="checkbox"/> Establish collaborative relationships at JBLM <input checked="" type="checkbox"/> Finalize manual for experimental intervention
18	<input checked="" type="checkbox"/> Obtain IRB approval for RCT <input type="checkbox"/> Begin recruitment for RCT
19	<input type="checkbox"/> Recruit participants at rate of 2 per week
20	<input type="checkbox"/> Complete recruitment & data collection (n=200) <input type="checkbox"/> Analyze results & Disseminate findings
Comments/Challenges: None at this time	
Budget Expenditure to Date	
Projected Expenditure: \$301,505	
Actual Expenditure: \$272,262	