

AWARD NUMBER: W81XWH-17-1-0002

TITLE: Improving Voluntary Engagement for PTSD Treatment among Soldiers

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REPORT DATE: December 2018

TYPE OF REPORT: Annual

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

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

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1. REPORT DATE Decemebr 2018		2. REPORT TYPE Annual		3. DATES COVERED 15 Nov 2017 - 14 Nov 2018	
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 2 focused on completing pre-trial activities, including finalizing the clinical and control PTSD interventions, corresponding counselor manuals, research protocols, recruitment advertisements, and recruitment plan. Year 2 primarily focused on randomized controlled trial (RCT) activities (Phase 2), including recruitment, enrollment and data collection that began in January 2018. We obtained necessary approvals for Phase 2 from University of Washington IRB, Madigan IRB, and HRPO.					
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	13	19b. TELEPHONE NUMBER (include area code)

Standard Form 298 (Rev. 8-98)
Prescribed by ANSI Std. Z39.18

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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, hiring and training study personnel, and starting Phase 2 of the study (randomized controlled trial [RCT]) in early January 2018.

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 completed the training of study staff in mid-November 2017. We obtained necessary regulatory documents (goal 3.1) from University of Washington (UW) IRB, Madigan IRB, and HRPO.

We conducted three focus groups, with a total of 23 participants who provided feedback on our recruitment and intervention materials in Summer 2017 (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 was shaped as we train our study 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) and because the recruitment period is quite long, we continue to refresh marketing efforts every 4-6 months with new advertisements. We began recruitment, enrollment, and data collection in early January 2018. To date, we have enrolled 27 participants.

In regard to obtaining necessary regulatory documents (goal 3.1) for Phase 2 of the study, we obtained UW'S IRB approval for Phase 2 (RCT) in September 2017 and received the Continuing Review approval in August 2018. 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; we received that determination in December 2017.

The study team continues to meet weekly to collaborate on development of protocols, manuals, recruitment materials, and strategic relationships with collaborators at JBLM. The Project Director (Dr. Bergman) has served full-time 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. The study Assessor left the project in August 2018; the Data Manager/Research Consultant assumed study Assessor responsibilities in August 2018.

We have continued our recruitment efforts with recurrent trips down to JBLM every 1-3 weeks, including in-person briefings to potential participants (e.g., service members attending PRIME for Life classes, MP units, service members in Warrior Transition Battalion, 1st SGT), meetings with providers and key military stakeholders, and refreshing our posted study advertisements. We have also posted our study advertisements at off-post locations that are frequented by service members and their family members. Powerpoint slides advertising the study have been created and distributed to Madigan healthcare providers JBLM prevention personnel to include in their briefings with the Healthy Learning Academy and routine briefings with service members. We are continuing to do military-related outreach events to expand our recruitment efforts. We are continuing to develop recruitment materials and are pursuing additional strategies on and near JBLM.

We have also sought other methods of recruitment. In May 2018, we submitted a request for access to the DMDC Reporting System in order to obtain JBLM .mil email addresses for recruitment purposes. We obtained approvals from UW's IRB (March 2018) and from HRPO (June 2018) for this request. Once our request has been approved, we plan to send out an email to JBLM .mil email addresses to invite service members (Army and Air Force) to participate in the study. This invitation email will be sent from the study's email account (ucheckup@uw.edu). The length of and frequency for using JBLM .mil email addresses will be in accordance to agreement as determined by DoD. We are working with LTC James McKnight, DrPH, MS, CPH to obtain the .mil email addresses. LTC McKnight works at the US Army Medical Research & Materiel Command and serves as one of our DoD contacts for help with recruitment purposes. As of December 2018, we are still working on the Memorandum of Understanding (MOU) that must be completed and submitted in order to finalize the request for access to the DMDC Reporting System in order to obtain JBLM .mil email addresses for recruitment purposes. The Project Director is tracking down UW documents that are needed for the MOU. Because we expect a high volume of .mil email addresses (if our request is approved), we are exploring U.S. based third party service that can help us administer the process of sending out the email invitations. Additionally, we are working on the language of the email invitation.

Additionally, in response to our Science Officer's suggestion of increasing recruitment, we have explored and considered StudyKik and TrialFacts. We rejected StudyKik as we believe that their recruitment methodology does not meet our recruitment needs. For example, they would not be able to directly target the JBLM population, but rather would capture the population within 25 miles of the installation. They also would not be able to directly target those with PTS symptoms. Based on this, we had concerns about a high rate of false positives, which would then

strain our study personnel. Additionally, the services that they were offering did not fit within our budgetary considerations given the low rate of return on the service. We believe that TrialFacts meets our needs best and will be submitting a revised IRB protocol to UW IRB when we have finalized this new recruitment plan using TrialFacts; once we have UW IRB approval, we will send it to HRPO. It is important to note that TrialFacts will only support national recruitment. Thus, based on suggestions from our PO, we will be widening our recruitment efforts to national recruitment, following adaptation of the intervention materials, and approval from the IRB around this change in methodology. Our study counselor has researched off-post places of worship that may be frequented by service members and their family members; for places that allow us to have our study materials, we will mail them or drop them off in person. The Project Director has been working with the Chaplain in the Warrior Transition Battalion (WTB), which has resulted in team members presenting at the weekly WTB new orientation for service members. We are hoping that this continued work will allow us the opportunity to present to all Chaplains across JBLM at their briefings, to increase knowledge and understanding of our project.

We have created psychoeducation presentations about related topics (e.g., general stress and PTSD) as both a service and as a way to advertise the study. Presentations have been conducted as part of the quarterly JBLM Military Police Training, Warrior Transition Battalion weekly briefings, substance use classes (ASAP PRIME for Life), the ASAP managers annual conference, the Military Family Life Counselors (MFLC) monthly meeting, and at the 1st Sergeants Breakfast at McChord Field.

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 ongoing supervision to the Project Director 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. Previously the study Assessor was also included in this group. 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 and November 2018. 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. At the 2017 Forum she attended a workshop targeting integration of Motivational Interviewing techniques with Cognitive Behavior Therapy. These training opportunities are directly related to this project's Counselor training and supervision.

Dr. Walker and Dr. Bergman attended a Collaborative Assessment and Management of

Suicidality (CAMS) training in June 2018 at UW. CAMS is an evidence-based intervention for evaluating suicidal risk and developing and implementing a suicide-specific treatment plan. This training opportunity is directly related to how staff personnel can provide good clinical care to participants who are at risk for suicide. It becomes an additional option, along with completing our in-house Safety Assessment and ability to connect them with the Veterans Crisis Line, to offer participants who endorse suicidal thoughts and/or behaviors.

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 primary plan for the next reporting period is to use our efforts to expand recruitment nationally. Our methods to expand recruitment include planning to use TrialFacts, submitting an updated IRB protocol to UW IRB and subsequent submission to HRPO that documents this change in recruitment procedures. We plan to continue our in-person recruitment efforts both on- and off-post. Additionally, we plan to continue with the DMDC Reporting System request in order to obtain JBLM .mil email addresses for recruitment purposes.

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

National conference presentations

Bergman, H. E., Dworkin, E. R., DeCou, C., Walton, T. O., Kaysen, D., & Walker, D. (2018, November). Association of psychopathology and post-deployment social support with suicidal ideation among soldiers with untreated alcohol use disorder. Poster presented at the meeting of the International Society for Traumatic Stress Studies, Washington, DC.

Walker, D. (2018, March). *Warrior Check-Up: Attracting substance abusing soldiers to volunteer for intervention*. Invited presentation to the meeting of the Association of Military Osteopathic Physicians and Surgeons, Joint Base Lewis-McChord, WA.

Bergman, H. E., & Kaysen, D. (2018, March). *Overview of posttraumatic stress disorder*. Invited presentation to the meeting of the Association of Military Osteopathic Physicians and Surgeons, Joint Base Lewis-McChord, WA.

Local presentations

Bergman, H. E., Walker, D., & Kaysen, D. (2018, November). *UW Stress Check Project*. Invited speaker to the 1st Sergeants Breakfast meeting, Joint-Base Lewis-McChord, WA.

Bergman, H. E., Walker, D., & Kaysen, D. (2018, July). *Stressed about stress?* Invited presentation to the Dragon Fighter Reset Day with the 42D Military Police Brigade, Joint Base Lewis-McChord, WA.

Bergman, H. E., Walker, D., & Kaysen, D. (2018, July). *Improving voluntary engagement for PTS treatment among service members: UW Stress Check*. ASAP Program Mangers Conference, Joint Base Lewis-McChord, WA.

Bergman, H. E., Walker, D., & Kaysen, D. (2018, April). *Stressed about stress?* Invited presentation to the Dragon Fighter Reset Day with the 170th Military Police Company, Joint Base Lewis-McChord, WA.

Bergman, H. E., Walker, D., & Kaysen, D. (2018, April). *Improving voluntary engagement for PTS treatment among service members*. Nurse Care Managers Meeting, Madigan Army Medical Center, Joint Base Lewis-McChord, WA.

Walker, D., Bergman, H. E., & Kaysen, D. (2018, January). *Improving voluntary engagement for PTS treatment among service members*. Military and Family Life Counselors Meeting, Joint Base Lewis-McChord.

Journal publications

Dworkin, E. R., Bergman, H. E., Walton, T. O., Walker, D. D., & Kaysen, D. L. (in press). Co-occurring PTSD and AUD in U.S. military and veteran populations. *Alcohol Research: Current Reviews*.

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 and was updated for Phase 2 recruitment purposes.

A facebook page (UW Stress Check) was created for the study and for Phase 2 recruitment purposes. It is updated routinely with new posts and study ads.

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?

<i>Name:</i>	Denise Walker, PhD
<i>Project Role:</i>	Co-PI
<i>Researcher Identifier:</i>	orcid.org/0000-0002-3811-5239
<i>Nearest person months worked:</i>	4
<i>Contribution to Project:</i>	<p>Dr. Walker has contributed to the study by:</p> <ul style="list-style-type: none"> • Contributing substantially to the development of the novel intervention – and is lead on the manual development for the Motivational Enhancement Therapy content • Navigating systems at JBLM and building collaboration with JBLM stakeholders • Overseeing hiring and supervision of current staff • Assisting with development of marketing campaign • Finalizing measure selection for informing the intervention

	<ul style="list-style-type: none"> • Gaining necessary approvals from JBLM leadership • IRB and HRPO oversight • Developing procedures for focus groups • Conducting focus groups • Provide supervision and training of project counselors • Coding of MET intervention sessions • Manuscript preparation • Attending weekly study exec meetings
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<i>Name:</i>	Debra Kaysen, PhD
<i>Project Role:</i>	Co-PI
<i>Researcher Identifier:</i>	orcid.org/0000-0001-7961-2787
<i>Nearest person months worked:</i>	5
<i>Contribution to Project:</i>	<p>Dr. Kaysen has contributed to the study by:</p> <ul style="list-style-type: none"> • Contributing substantially to the development of the novel intervention – and is lead on the PTSD treatment content • Building collaboration with JBLM stakeholders • Recruiting for post-doctoral fellow and assessor positions • Assisting with development of marketing campaign • Finalizing measure selection for informing the intervention • Developing procedures for focus groups • Conducting focus groups • Establishing our Data Safety and Monitoring Plan • Provide supervision and training of project counselors • Provide training and supervision to project assessors • Manuscript preparation • Attending weekly study exec meetings

<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>	12
<i>Contribution to Project:</i>	<p>Dr. Bergman has contributed to the study by:</p> <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

	<ul style="list-style-type: none"> • 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 • Conducting assessments with prospective and enrolled participants • Conducting the clinical intervention with participants • Attending weekly clinical supervision meetings • Conducting in-person presentations and briefings at JBLM as part of recruitment efforts • Participating in recruitment activities • Leading weekly exec meetings
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<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>	6
<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 • Conducting assessments with prospective and enrolled participants • Attending weekly assessment fidelity meetings • Participating in recruitment activities • Attending weekly study exec meetings

<i>Name:</i>	Cameron Paine-Thaler, LAICSW
<i>Project Role:</i>	Study Assessor
<i>Researcher Identifier:</i>	
<i>Nearest person months worked:</i>	6
<i>Contribution to Project:</i>	<p>Ms. Paine-Thaler has contributed to the study by:</p> <ul style="list-style-type: none"> • Conducting assessments with prospective and enrolled participants

	<ul style="list-style-type: none"> • Attending weekly assessment fidelity meetings • Participating in recruitment activities
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<i>Name:</i>	Ernest McGarry, LMHC
<i>Project Role:</i>	Study Counselor
<i>Researcher Identifier:</i>	
<i>Nearest person months worked:</i>	6
<i>Contribution to Project:</i>	Mr. McGarry has contributed to the study by: <ul style="list-style-type: none"> • Conducting the clinical intervention with participants • Attending weekly clinical supervision meetings • Participating in recruitment activities

<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>	Ms. Bushnell has contributed to the study by providing: <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 developing a recruitment campaign to elicit participation from service members with PTSD \ who are not otherwise treatment-seeking.



Based on feedback that participants thought they would not be eligible for the study because their trauma was not military-related, the included ad image is updated to clarify all trauma types are eligible for participation.

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)	\$503	\$693	\$714	\$737

Updated: 13 December 2018

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 checked="" 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: \$952,982	
Actual Expenditure: \$912,690	